

MAIJU KEKKI

Neonatal Birth Injuries

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ACADEMIC DISSERTATION

To be presented, with the permission of the Faculty of Medicine and Health Technology of Tampere University, for public discussion in the Jarmo Visakorpi auditorium of the Arvo building, Arvo Ylpön katu 34, Tampere, on 18 August 2023, at 12 o'clock.

ACADEMIC DISSERTATION

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Cover design: Roihu Inc.

ISBN 978-952-03-2959-4 (print) ISBN 978-952-03-2960-0 (pdf) ISSN 2489-9860 (print)

ISSN 2490-0028 (pdf)

http://urn.fi/URN:ISBN:978-952-03-2960-0



Carbon dioxide emissions from printing Tampere University dissertations have been compensated.

PunaMusta Oy – Yliopistopaino Joensuu 2023

To Raisa & Tuovi

ACKNOWLEDGEMENTS

This study was conducted at the Department of Obstetrics and Gynecology, Tampere University Hospital, and the Faculty of Medicine and Health Technology, Tampere University. Financial support for this work was received by the Competitive State Research Financing of the Expert Responsibility Area of Tampere, Tampere University Hospital Support Foundation, the Research funding provided by the Tampere University Hospital, and the Finnish Medical Foundation. I appreciate the support I received.

I express my sincere gratitude to my supervisor, Docent Tuomas Huttunen, for providing the idea for my thesis and enabling the work. I thank him for his detailed advice, the kind, and encouraging support, for sharing his experience and knowledge of science, and for his patience throughout the project.

I am incredibly grateful to my supervisor, Docent Kati Tihtonen, for her endless support, dedication, and gentle guidance. I admire her expertise in perceiving what is essential, her intelligence, profound knowledge of obstetrics, sense of humor, and honesty. I feel privileged to have worked with her in our clinic and during the research.

I am deeply grateful to Professor Hannele Laivuori for participating in the study. I admire Hannele's extensive experience in scientific research. I wish to extend my gratitude to Professor Ville Mattila. His support has been crucial to the study, and I respect his positive attitude toward research. Furthermore, I warmly thank Emerita Professor Johanna Mäenpää for encouraging me in scientific work.

I am sincerely thankful to the co-authors for their fundamental contribution. I am deeply grateful for M.D., Ph.D. Anne Salonen, for the initial idea for the study, knowledge in pediatric surgery, positive encouragement, and support during this project. Above all, I am forever thankful for her friendship and kindness. I also warmly thank Professor Mika Gissler for participating in the study. I admire his profound expertise in MBR and research in general. Special thanks to MSc. Topias Koukkula, for statistical analysis and endless patience in clarifying the world of statistics.

I am sincerely grateful to the official pre-examiners, Docent Mervi Väisänen-Tommiska and Docent Kjell Helenius, for their time and effort in reviewing the manuscript. Their valuable comments, the conversations we had, and detailed corrections helped improve the final result. Furthermore, I express my gratitude to Professor Kaarin Mäkikallio for kindly agreeing to be my opponent in the public defense of this thesis.

I sincerely thank the members of the follow-up group, Docent Synnöve Staff and M.D., Ph.D. Anita Virtanen, for their interest in my work and the help and encouragement I received. My gratitude extends to Docent Jukka Uotila for his advice. I admire his extensive knowledge of obstetrics and science. I also thank Peter Heath for carefully reviewing the English Language of original manuscripts and my thesis.

I greatly appreciate that I have had an opportunity to work with skillful gynecologists, midwives, and nurses throughout my career. Thanks to the librarians and staff in the Research services for assistance during my research. Furthermore, I am grateful to my past and present chiefs for enabling me to combine clinical work and research. I also wish to thank my former and current colleagues in the Department of Obstetrics and Gynecology for the friendly and cheerful atmosphere at work. The helpfulness and talent of my co-workers amaze me repeatedly. It has been an honor, and I simply love working with you. Thanks to Elina Ylilehto, Riikka Vuorinen, and Mari Kalamo for helping me numerous times when finalizing this thesis. I owe special thanks to the obstetric team that I have been warmly welcomed to be part of. It has been a privilege to work with you and learn from you. Furthermore, I want to thank Kati Jalkanen for introducing me to Anne and, thus, setting the starting point for this research.

I am deeply grateful for my friends who have filled my life with happiness. My dearest friends since the first grade, Anna-Kaisa, Sonja, Riina, and all other childhood friends – I am thankful for our lifelong friendship. Anna, Jenni, Kaisu, Sari, and all other friends from the field of basketball, thank you for being an essential part of my life. My friends from medical school (Paulat, Linda, Reetta, Kaisa, Maarit, Laurat) and my dearest colleagues during the specialization and beyond (Elinat, Riikat, Eeva, Laura, Johanna) thank you for your support, conversations, and many laughs. Additionally, I want to thank my precious family friends from Tampere, Helsinki, Mikkeli, and Joensuu.

My warmest gratitude belongs to my family. I want to thank my mom and dad, Tuuli and Sakari, for their unconditional love, encouragement, and help throughout my life. Thank you, my brother Samuli, and his family, for the support and love. I am grateful to my parents-in-law, Tarja and Tapio, for their interest in my research, overall enthusiasm, and for helping me in many ways. I also want to thank my

extended family, Terhi, Antti, Jussi, and their spouses and children, for making my life even more enjoyable.

Tuovi, my hilarious, sensitive, wise little rock star. I admire your bravery and sense of justice. Thank you for being what you are. I am extremely proud of you! Finally, I owe my deepest gratitude to the love of my life, my wife, Raisa. Thank you for your advice in research practice and our numerous discussions about art and diverse aspects of life. I am grateful for your encouragement and for seeing and believing in me. My soulmate, without whom I would not be what I am today. Thank you for your love.

May 2023

Maiju Kekki

ABSTRACT

The incidence of birth injury is approximately 2% to 3% of all births, and a severe birth injury occurs in 2 to 5 neonates per 1000 births. In many ways, birth injuries are a burden for neonates and their families. Moreover, the more severe birth injuries, such as intracranial hemorrhage or brachial plexus injury, can be lethal or have a long-term effect on the life of the child. Multiple factors, some of which are not known prenatally, may affect the individual risk for injury. Indeed, various forces acting on the fetus during the normal delivery process and maternal or fetal reasons increasing the need for operative birth predispose to injury. The disproportion between the size of the fetus and maternal pelvis, the presentation of the fetus, maternal diabetes, contraction abnormalities, and fetal characteristics that make them more vulnerable (e.g., bleeding disorders) are associated with an increased risk for injury. In practice, predicting injuries is challenging, as most known risk factors are common, but birth injuries are rare. In addition, injuries often occur in pregnancies without any known risk factor, making the prevention of such injuries even more challenging.

This study aimed to investigate neonatal birth injuries in live-born neonates in Finland between 1997 and 2017. Briefly, the objective was to describe the incidence rates of different birth injuries, the risk factors for injury, and the epidemiological changes related to birth injuries. This dissertation includes four retrospective national studies using the data from Finnish Medical Birth Register (MBR) and the Care Register for Health Care (CRHC) databases maintained by the Finnish Institute for Health and Welfare (THL). In studies II–IV, neonates were born between 2004 and 2017.

The first study included all live-born neonates born between 1997 and 2017 in Finland. A total of 28 551 birth injuries occurred, and clavicle fractures, cephalohematomas, and brachial plexus palsies (BPP) were the most common injury types. During the study period, the incidence of birth injury decreased from 3.4% to 1.7% of all live births, primarily due to the decline in the incidence of clavicle fractures. The incidence of BPP also decreased during the same period.

Clavicle fractures were assessed more thoroughly in singleton neonates with cephalic presentation born vaginally at or after 37⁺⁰ weeks of gestation (6577)

neonates with clavicle fracture). The incidence of many risk factors for clavicle fracture, e.g., gestational diabetes and vacuum-assisted deliveries, increased during the study period. A birth weight of at least 4000 grams was clinically the most crucial risk factor involving 45% of all injuries. The decreased incidence of neonates with high birth weight probably affected the overall decline in fractures. Shoulder dystocia and pregestational diabetes also predisposed neonates to injury. Interestingly, a quarter of the pregnancies with an injured neonate were without risk factors, and the incidence of clavicle fractures in these low-risk pregnancies decreased during the study period.

In the third study, severe birth injuries in the pregnancies of women with diabetes were analyzed and compared to the pregnancies of women without diabetes (1934 neonates with severe birth injury). The study included vaginal deliveries with cephalic presentation at or after 35⁺⁰ weeks of gestation. BPP was the most common injury, and the incidence of injury was highest in the neonates of women with pregestational diabetes. In contrast, the incidence of injury in the neonates of women with gestational diabetes or without diabetes was low. Increasing birth weight had a stronger impact on the injury risk in pregnancies with pregestational diabetes than in the other pregnancies.

In the fourth study, birth injuries were infrequent among breech deliveries, including 4344 vaginal breech deliveries and 16 979 cesarean sections with breech presentation. However, the incidence of severe birth injury was higher in vaginal breech deliveries than in cephalic vaginal deliveries. In vaginal breech deliveries, BPP was the most common injury, followed by clavicle fracture. No clinically relevant risk factors for birth injury in breech deliveries were found.

In conclusion, birth injuries have decreased, even though the rate of many risk factors has increased and the cesarean section rate has remained stable. The most important risk factors for birth injury were high birth weight, pregestational diabetes, vacuum-assisted delivery, and shoulder dystocia. However, injuries can often occur unpredictably among pregnancies without known risk factors.

TIIVISTELMÄ

Vastasyntyneistä 2–3 %:lla todetaan jokin syntymävaurio ja 0,2–0,5 %:lla vakava syntymävaurio. Syntymävaurio voi aiheuttaa vastasyntyneelle esimerkiksi kipua, raajan liikerajoitusta ja pitkittynyttä sairaalaseurantaa. Vakavasta syntymävauriosta, kuten esimerkiksi aivoverenvuodosta tai olkahermopunoksen vauriosta, voi jäädä lapselle pysyvää haittaa. Lisäksi vakava syntymävaurio voi lisätä kuolleisuuden riskiä. Monet asiat vaikuttavat syntyvän lapsen vaurioriskiin, eikä kaikkia myötävaikuttavia tekijöitä välttämättä tiedetä ennen lapsen syntymää. Synnytyksen aikana sikiöön kohdistuu monenlaisia voimia, jotka voivat altistaa syntymävauriolle. Esimerkiksi sikiön ja synnyttäjän synnytyskanavan kokojen epäsuhta, tarjontavirheet ja synnytyksen aikaiset ongelmat, joiden vuoksi lapsen syntymistä joudutaan avustamaan toimenpidesynnytyksellä, lisäävät syntymävaurion riskiä. Tiedetään, että myös esimerkiksi synnyttäjän diabetekseen, kohdun supistuspoikkeavuuksiin ja sikiön verenvuodoille altistaviin sairauksiin liittyy suurentunut syntymävaurioihin. Vaurioriskin luotettava arviointi ja vaurioiden ehkäiseminen on haasteellista sillä syntymävauriot ovat harvinaisia ja vaurioille altistavat riskitekijät ovat yleisiä. Syntymävaurioita todetaan myös ongelmattomien synnytysten jälkeen, vaikka raskauksissa ei ole ollut tiedossa riskitekijöitä.

Väitöskirjatutkimuksen tavoitteena oli tutkia vuosina 1997–2017 Suomessa syntyneiden vastasyntyneiden syntymävaurioita. Retrospektiivinen rekisteritutkimus pyrki arvioimaan syntymävaurioiden esiintyvyyttä, niille altistavia tekijöitä ja sekä vauriomäärissä että riskitekijöissä tapahtuneita epidemiologisia muutoksia. Tutkimuksessa käytettiin Terveyden ja hyvinvoinnin laitoksen (THL) ylläpitämien *Syntyneiden lasten rekisterin* ja *Terveydenhuollon hoitoilmoitusrekisterin* tietoja. Osatöissä II–IV lapset syntyivät ajanjaksolla 2004–2017.

Ensimmäinen osatyö kattoi kaikki tutkimusaikana (1997–2017) Suomessa elävänä syntyneet lapset. Syntymävaurioita todettiin yhteensä 28 551. Yleisimpiä vauriotyyppejä olivat solisluun murtuma, kefaalihematooma ja olkahermopunoksen vaurio. Syntymävaurioiden esiintyvyys väheni 3,4 %:sta 1,7 %:iin. Muutos johtui ennen kaikkea solisluun murtumien vähenemisestä. Myös olkahermopunoksen syntymävauriot vähenivät.

Toisessa osatyössä perehdyttiin raivotarjonnassa raskausviikolla 37⁺⁰ tai myöhemmin syntyneiden vastasyntyneiden solisluun murtumiin. Tutkimusaikana todettiin 6577 syntymään liittyvää solisluun murtumaa yksisikiöisissä raskauksissa alatiesynnytyksen jälkeen. Monien solisluun murtumille altistavien riskitekijöiden, kuten esimerkiksi raskausdiabeteksen ja imukuppisynnytysten, esiintyvyys nousi tutkimusjakson aikana. Iso syntymäpaino oli kliinisesti merkittävin riskitekijä: 45 %:lla solisluun murtuman saaneista lapsista syntymäpaino oli vähintään 4000 grammaa. Syntymäpainoltaan yli 4000 grammaa painaneiden lasten määrällinen väheneminen todennäköisesti selittää ainakin osittain solisluun murtumien määrän vähenemistä. Myös hartiadystokia ja raskautta edeltänyt synnyttäjän diabetes lisäsivät murtumariskiä. Mielenkiintoinen löydös oli se, että neljäsosassa solisluun murtumat vähenivät tutkimusaikana matalan riskin raskauksissa.

Vakavien syntymävaurioiden esiintyvyyttä eri diabetesryhmissä verrattuna eidiabeetikkoraskauksiin tutkittiin raskausviikolla 35⁺⁰ tai myöhemmin raivotarjonnassa alateitse syntyneillä lapsilla. Tässä joukossa oli yhteensä 1934 vakavaa syntymävauriota. Vakavia syntymävaurioita esiintyi eniten lapsilla, joiden synnyttäjällä oli todettu diabetes ennen raskautta. Raskausdiabeetikoiden lapsilla vakavia syntymävaurioita ei todettu juurikaan enempää kuin raskauksissa ilman diabetesta. Olkahermopunoksen vaurio oli yleisin vauriotyyppi. Syntymäpainon nousulla oli suurempi vaikutus vaurioriskin kannalta tyypin 1 ja tyypin 2 diabeetikoiden raskauksissa kuin muissa raskauksissa.

Vastasyntyneiden syntymävauriot olivat satunnaisia perätilasynnytyksissä. Tutkimuksessa oli mukana 4344 perätilan alatiesynnytystä ja 16 979 sektiota, joissa lapsi syntyi perätarjonnassa. Vakavia syntymävaurioita todettiin perätilan alatiesynnytyksissä enemmän kuin niillä lapsilla, jotka syntyivät alateitse raivotarjonnassa. Perätilan alatiesynnytyksissä olkahermopunoksen vaurio oli yleisin ja solisluun murtuma toiseksi yleisin syntymävaurio. Tutkimuksessa ei löydetty riskitekijöitä, jotka altistaisivat syntymävaurioille perätilan alatiesynnytyksessä.

Väitöstyö osoittaa, että vastasyntyneiden syntymävauriot ovat vähentyneet siitä huolimatta, että monien riskitekijöiden esiintyvyys on noussut ja keisarileikkausten määrä on pysynyt vakaana. Syntymävauriolle altistavat lapsen iso syntymäpaino ja raskautta edeltävä synnyttäjän diabetes sekä synnytyksen aikaiset ongelmat, jotka johtavat imukuppisynnytykseen tai hartiadystokiaan. Kuitenkin syntymävaurio todetaan usein myös yllättäen ilman ennalta tiedossa olleita riskitekijöitä.

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ABBREVIATIONS

BMI Body mass index
BPP Brachial plexus palsy

Breech CS Cesarean section with breech presentation

Breech VD Vaginal breech delivery

Cephalic VD Vaginal delivery with cephalic presentation

CI Confidence interval

CRHC The Care Register for Health Care

CS Cesarean section
GDM Gestational diabetes
GW Gestational week

ICD-9, ICD-10 The 9th or 10th Revision of International Statistical

Classification of Diseases and Related Health Problems

ICH Intracranial hemorrhage IRR Incidence rate ratio

LGA Large for gestational age

MBR (the Finnish) Medical Birth Register

OR Odds ratio
OR-ratio Ratio of odds
RD Risk Difference
SCI Spinal cord injury
SD Standard deviation

SGA Small for gestational age SGH Subgaleal hemorrhage

SVD Spontaneous vaginal delivery

THL The Finnish Institute for Health and Welfare

T1D Type 1 diabetes
T2D Type 2 diabetes
VD Vaginal delivery

ORIGINAL PUBLICATIONS

This thesis is based on the following publications referred to in the text by their Roman numerals I–IV.

- I Kekki M, Salonen A, Tihtonen K, Mattila VM, Gissler M, Huttunen TT. The incidence of birth injuries decreased in Finland between 1997 and 2017: A nationwide register study. Acta Paediatr. 2020; 109: 2562-2569.
- II Kekki M, Salonen A, Koukkula T, Laivuori H, Tihtonen K, Huttunen TT. Incidence changes in risk factors associated with the decreasing number of birth-related clavicle fractures in Finland: A nationwide retrospective birth cohort from 2004 to 2017. Birth. 2023; 50: 428-437.
- III Kekki M, Tihtonen K, Salonen A, Koukkula T, Gissler M, Laivuori H, Huttunen TT. Severe birth injuries in neonates and associated risk factors for injury in mothers with different types of diabetes in Finland. Int J Gynecol Obstet. 2022; 159: 195-203.
- IV Kekki M, Koukkula T, Salonen A, Gissler M, Laivuori H, Huttunen TT, Tihtonen K. Birth injury in breech delivery: A nationwide population-based cohort study in Finland. Arch Gynecol Obstet. (2022).

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AUTHOR'S CONTRIBUTION

The original idea to study neonatal birth injuries nationally came from Anne Salonen (AS) and Tuomas Huttunen (TH). TH and AS contributed to the data acquisition from the Finnish Institute for Health and Welfare (THL). The author of this dissertation, Maiju Kekki (MK), planned the study design with her supervisors (Kati Tihtonen [KT], TH) and AS (I–IV). MK formulated the specific aims of the studies and planned the execution with supervisors (I–IV). Statistical analyses were planned by MK, TH, and KT and executed by TH (I) and Topias Koukkula (TK) (II–IV). The author was responsible for interpreting the results with supervisors and TK. MK (I), together with TK (II–IV), prepared all figures and tables for the published studies. MK wrote the first draft of all the manuscripts and revised them according to changes and suggestions made by supervisors and co-authors.

1 INTRODUCTION

The aim of perinatal care is to improve maternal and neonatal health and to reduce morbidity and mortality. In Finland, the quality of perinatal care is considered to be high. According to the European Perinatal Health Report 2019, the rates of neonatal mortality (0.14%), infant birth weight of less than 2500 grams (4.0%), and preterm birth (5.3%) in Finland were among the lowest in Europe (EURO-PERISTAT Project. European Perinatal Health Report, 2019). Furthermore, the Finnish mortality and preterm birth rates are low in global comparison (Australian Institute of Health and Welfare, 2021b; National Center for Health Statistics, 2022; Unicef data, 2021). The tendency in Finland towards fewer and larger delivery hospitals has improved neonatal outcomes, as the risk for early neonatal mortality and birth injuries are reported to be lower in larger delivery units (Pyykönen, 2017; Pyykönen et al., 2014). Moreover, interest in quality of care and patient safety issues has increased during the last decade (Health Care Act, 2010; Potilas- ja asiakasturvallisuusstrategia 2017– 2021 toimeenpanon ja seurannan suunnittelun työryhmä, 2020). Simulation-based training, which aims to improve patient safety in obstetric emergencies and reduce birth injuries, has been arranged since 2014 in Finnish delivery units (Brogaard et al., 2022; Heinonen et al., 2020; Kaijomaa et al., 2022; Wagner et al., 2021; World Health Organization, 2011). Furthermore, this training has become more frequent during the last years (Working group set up by the Finnish Association of Perinatology, 2021).

According to the previous literature, the estimated overall incidence of birth injury reported in national register studies is 3% of neonates (Gupta & Cabacungan, 2021; Sauber-Schatz et al., 2010; Tomashek et al., 2006). The most frequent injuries sustained by neonates are scalp and skeletal injuries (Gupta & Cabacungan, 2021; Sauber-Schatz et al., 2010). Minor birth injuries, which are considered to have a good prognosis, cover most of the reported injuries. In contrast, severe birth injuries (e.g., intracranial hemorrhage, subgaleal hemorrhage, skull fracture, long bone injuries, brachial plexus palsy) are rare but can lead to permanent disability and increased odds of mortality (Gupta & Cabacungan, 2021; Pressler, 2008). However, minor birth injuries can also occasionally be associated with an increased risk for severe

neonatal morbidity (Gupta & Cabacungan, 2021). Neonatal birth injury has been proposed as one of the indicators of the quality of obstetric care (Agency for Healthcare Research and Quality (AHRQ), n.d.).

Well-recognized risk factors for birth injury include high birth weight of the neonate, instrumental vaginal delivery, and a difficult birth or shoulder dystocia (Högberg et al., 2020; Reichard, 2008; van der Looven et al., 2020). Furthermore, obesity, diabetes, breech, and other malpresentation are also associated with increased risk of birth injury (Högberg et al., 2020; Sauber-Schatz et al., 2010; van der Looven et al., 2020). Some injuries are unexpected and are diagnosed in neonates without a known risk factor.

The incidence of the maternal and labor characteristics associated with birth injuries are changing. For example, an increasing prevalence of maternal obesity (EURO-PERISTAT Project. European Perinatal Health Report, 2015; Hales et al., 2020; Poston et al., 2016) and diabetes (Chen, Magliano, D.J., Zimmet, 2012; Ellenberg et al., 2017; Saravanan et al., 2020; Shah et al., 2021) in post-industrial societies, which is associated with high birth weight and increased risk for birth injury, has been reported. In addition, the incidence of type 1 diabetes in Finland is among the highest in the world (Patterson et al., 2019). Further, labor induction is becoming more and more common (Australian Institute of Health and Welfare, 2021a; Finnish Institute of Health and Welfare, 2020; Papalia et al., 2022), and the rate of vacuum-assisted deliveries in Finland has increased from 5.0% in 1995 to 9.6% in 2020 (Finnish Institute of Health and Welfare, 2020).

Cesarean section (CS) can be a life-saving intervention for complications during pregnancy and birth that also reduces the risk for birth-related injury to the neonate (Liston et al., 2008; Sandall et al., 2018). However, when compared with vaginal delivery, CS is associated with an increased risk for immediate and long-term adverse neonatal and maternal outcomes, and a higher risk for adverse outcomes in a subsequent pregnancy (Sandall et al., 2018). The CS rate has risen in many countries in the last decades (Betran et al., 2021). As birth injuries are rare after CS (Alexander et al., 2006), some studies have linked the decreasing incidence of birth injury to the increased rate of CS (Abzug et al., 2019; Gupta & Cabacungan, 2021). In contrast, the CS rate in Finland has remained low and stable. Interestingly, Finland is one of the few European countries where vaginal breech deliveries are still common practice (EURO-PERISTAT Project. European Perinatal Health Report, 2015). The European Perinatal Health Report 2015 concluded that the CS rate in Finland in 2015 was 16%, in the Nordic countries 16% to 22%, and the European median rate was 27% (range, 16% to 57%) (EURO-PERISTAT Project. European Perinatal Health

Report, 2015). In the US, the CS rate has been increasing since 1996, being approximately 32% over the past ten years (Osterman et al., 2022). In Australia, the CS rate has risen from 25% in 2004 to 31% in 2019 (Australian Institute of Health and Welfare, 2021a). A systematic review of CS rates data, covering more than 95% of live births worldwide, showed that 43% (range, 5.4% to 58.1%) of births in Latin America and the Caribbean were estimated to be CS in 2018 (Betran et al., 2021).

The objective of this dissertation was to assess birth injuries in Finland. The study describes the incidences of different birth injuries, the risk factors for injuries, and the epidemiological changes related to birth injuries using high-quality and nationwide register data in Finland between 1997 and 2017.

2 REVIEW OF THE LITERATURE

2.1 Classification and incidence of birth injuries

Birth injury, also referred to as birth trauma, is defined as injury, structural damage, or functional impairment of a neonate related to the labor process (Akangire & Carter, 2016; Sauber-Schatz et al., 2010). Birth injuries can vary from minor skin injuries to life-threatening intracranial hemorrhage. Although with proper care some birth injuries could perhaps be avoided, some are part of the delivery process and, therefore, cannot be prevented (Abzug et al., 2019; Ahn et al., 2015; Akangire & Carter, 2016; Kumar et al., 2015; Sauber-Schatz et al., 2010). Of these, severe birth injuries, in particular, may be associated with seizures, hypoxic-ischemic encephalopathy, respiratory problems, meconium aspiration, hyperbilirubinemia, and death (Gupta & Cabacungan, 2021; Linder et al., 2013).

Birth injuries lack a comprehensive classification. For example, whereas intracranial hemorrhage that occurs due to mechanical forces during delivery is considered a birth injury, organ dysfunction secondary to hypoxic-ischemic encephalopathy is typically not (Kumar et al., 2015). Intracranial injuries, central nervous system injuries, nerve injuries, and fractures are often classified as severe birth injuries. However, in some studies, clavicle fractures are categorized as a minor and others as a major birth injury (G. M. Muraca et al., 2018; Pressler, 2008; Wen et al., 2018). Furthermore, many studies often consider cephalohematoma, chignon, and skin bruises as birth injuries, whereas some researchers think that they should be included as part of natural birth (Kumar et al., 2015). Most studies cover only singleton neonates born at 37⁺⁰ weeks of gestation or later (often referred to as "term pregnancy").

In Finland, pediatricians diagnose birth injuries primarily based on clinical examination. Radiologic imaging may be performed if severe birth injuries such as intracranial hemorrhage are suspected. A physiotherapist and specialized physicians, such as pediatric or hand surgeon, are also consulted when needed.

The total birth injury incidence is approximately 2% to 3% of all births (Table 1). In retrospective national register studies from the US, the overall incidence of neonatal birth injury ranges from 2.6% to 3.1% (Gupta & Cabacungan, 2021;

Moczygemba et al., 2010; Sauber-Schatz et al., 2010; Tomashek et al., 2006). Similarly, retrospective register studies from Canada, including singleton term neonates, have reported a birth injury incidence of 1.9% to 2% (Baskett et al., 2007; Liston et al., 2008). In single center studies using varying inclusion criteria from Israel, Cameroon, Iran, and India, the overall birth injury incidence has varied from 1.5% to 4.1% (Borna et al., 2010; Linder et al., 2013; Mah et al., 2017; Ray et al., 2016).

The incidence rates of severe birth injury are presented in Table 2. The incidence of severe birth injury varies depending on whether clavicle fractures are regarded as severe birth injuries or not. In studies that include clavicle fracture in the severe/major birth injury group, the severe birth injury incidence is estimated to be 0.4% to 0.5% of all births (Gupta & Cabacungan, 2021; Liston et al., 2008; Phuengphaeng et al., 2022; Wen et al., 2018). However, the incidence of severe birth injury without clavicle fractures after 37 weeks of gestation is approximately 0.2% of all singleton live-births (Baskett et al., 2007; G. M. Muraca et al., 2018).

Over time, the overall incidence of birth injury (Gupta & Cabacungan, 2021; Tomashek et al., 2006; Zeck et al., 2007) and severe birth injury (Gupta & Cabacungan, 2021; Hildén et al., 2020; Wen et al., 2018) has declined. The temporal changes in the incidence of birth injury are presented in Tables 1 and 2. It seems possible that study population and delivery mode can affect the changes in the annual incidence of birth injury. For example, Wen et al. reported that the incidence of severe birth injury declined only in the spontaneous vaginal delivery group, whereas, Muraca et al. reported that the incidence of severe birth injury increased among women who underwent operative vaginal delivery (G. M. Muraca et al., 2018; Wen et al., 2018).

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Study	Study design	Study population	Inclusion criteria	Birth injury incidence
Gupta et al., 2021, US	Retrospective register study 2006–2014	n = 35 317 076 NIS database (approximates a 20% stratified random sample of all short-term US community hospitals)	In-hospital births All birth injuries ICD-9-CM: 767.0–767.9	2.5% in 2006 3.1% in 2014
Sauber-Schatz et al., 2010, US	Retrospective register study 2003	n = 890 582 KID database. The data represented a weighted national estimate of 3 920 787 in-hospital birth discharges in 2003	In-hospital births All birth injuries ICD-9-CM: 767.0–767.9	2.9%
Tomashek et al., 2006, US	Retrospective register study 1989–1990, 1999–2000	n = 55 210 in 1989–1990 n = 68 678 in 1999–2000 NHDS database	All neonates All birth injuries ICD-9-CM: 767.0–767.9	3.7% in 1989–1990 2.9% in 1999–2000
Moczygemba et al., 2010 US	Retrospective register study 2004–2005	n = 8 176 523 NIS database	Singleton live-born neonates In-hospital births	2.6% (all birth injuries) 0.2% AHQR PSI birth injuries
Baskett et al., 2007, Canada	Retrospective register study 1988–2001	n = 119 432 Clinical database, Nova Scotia	37+ GW Singleton live-born neonates Cephalic presentation No major anomalies	2%

Liston et al., 2008, Canada	Retrospective register study 1988–2002	n = 142 929 The Nova Scotia Atlee Perinatal Database	36+ GW Singleton live-born neonate No congenital anomalies	1.9%
Linder et al., 2013, Israel	Retrospective single-center case-control study 1986–2009	n = 118 280 Discharge records	37+0-41+6 GW Singleton neonates No chromosomal or major structural anomalies	2.4%
Mah et al., 2017, Cameroon	Retrospective single-center descriptive study 2003–2014	n = 14 284 Hospital medical records	All neonates with birth injury (n=263)	1.8%
Borna et al., 2010, Iran	Prospective, single-center case-control study 2002–2005	n = 3596	Vaginal deliveries Cephalic presentation No major anomalies	4.1%
23 Ray et al., 2016, India	Prospective observational single-center study March 2014–October 2014	n = 4741	Singleton live-born neonates	1.5%

ICD-9-CM codes 767.0: subdural and cerebral hemorrhage, 767.1 injuries to the scalp, 767.2 fracture of the clavicle, 767.3 other injuries to the skeleton, 767.4 injury to the spine and spinal cord, 767.5 facial nerve injury and facial palsy, 767.6 injury to the brachial plexus, 767.7 other cranial and peripheral nerve injuries, 767.8 other specified birth trauma, 767.9 unspecified birth trauma GW, gestational week;

The incidence of severe birth injury.

Table 2. The incidence	dence of severe birth injury.			
Study	Study design	Study population	Inclusion criteria and diagnoses	Birth injury incidence
Gupta et al., 2021, US	Retrospective register study 2006–2014	n = 35 317 076 NIS database (approximates a 20% stratified random sample of all short-term US	ICD-9-CM: 767.0, 767.2–767.9 Includes clavicle fracture Scalp injuries not included	Severe birth injury: 0.54% in 2006 0.47% in 2014
Wen et al. 2018, Washington State US	Retrospective register study 2004–2013	n = 732 818 BERD and CHARS databases, Washington State	20–43 GW, singleton in-hospital live births, cephalic presentation ICD-9-CM: 767.0, 767.11, 767.2 - 767.8 Includes clavicle fractures	Severe birth injury: 0.53% in 2004 0.45% in 2013
Muraca et al., 2018, Canada	Retrospective register study 2004–2014	n = 1 938 913 CHIH database, 4 Canadian provinces	37–41 GW, singleton in-hospital deliveries ICD-10-CA: P10, P11.0–P11.2, P11.4–P11.5 P12.2, P13.0, P13.2, P13.30, P13.38, P14.0, P14.1, P14.3, P15.0, P15.1 Clavicle fractures not induded	Severe birth injury: 0.17% No temporal change in overall incidence
Liston et al., 2008, Canada	Retrospective register study 1988–2002	n =142 929 The Nova Scotia Atlee Perinatal Database	Major injury: Any fracture, facial palsy, phrenic nerve palsy, Erb's palsy, Klumpke's palsy, spinal cord trauma, traumatic intracranial hemorrhage or intraventricular hemorrhage of grade III or IV	Major injury: 0.40%

Baskett et al., 2007, Canada	Retrospective register study 1988–2001	n = 119 432 Clinical database, Nova Scotia	Major trauma: Depressed skull fracture, intracranial hemorrhage (tentorial tear, spinal cord hemorrhage, subgaleal hemorrhage, or other intracranial hemorrhage), or brachial plexus palsy	Major trauma: 0.2%
			Minor trauma: Linear skull fracture, other fractures (davicle, ribs, humerus, femur), facial palsy, or cephalhematoma	Minor trauma: 1.8%
GW, gestational week;	000	7 101		

ICD-10-CA birth injury codes: P10 Intracranial laceration and hemorrhage, P11.0-P11.2 Cerebral edema, other specific and unspecific brain damage, P11.4-P11.5 ICD-9-CM birth injury codes; 767.0 Subdural and cerebral hemorrhage, 767.1 Injuries to the scalp, 767.11 Subgaleal hemorrhage, 767.2 Fracture of the clavide, 767.3 Other injuries to the skeleton, 767.4 Injury to the spine and spinal cord, 767.5 Facial nerve injury and facial palsy, 767.6 Injury to the brachial plexus, 767.7 Cranial nerve, spine or spinal cord injury, P12.2 Subgaleal hemorrhage, P13.0 Skull fracture, P13.2 Femur fracture, P13.30 Other long bone fracture, P13.38 Other Other cranial and peripheral nerve injuries, 767.8 Other specified birth trauma, 767.9 Unspecified birth trauma skeleton injuries, P14.0, P14.1, P14.3 Brachial plexus injury, P15.0 Injury to liver, P15.1 Injury to spleen

2.2 Different types of birth injury

The classification of birth injuries is based on the International Classification of Diseases (ICD-10) developed by the World Health Organization (WHO).

2.2.1 Intracranial hemorrhage or laceration due to birth injury

Intracranial hemorrhage (ICH) includes subdural, subarachnoid, cerebellar, intraparenchymal, and intraventricular hemorrhages (Figure 1). ICH, especially subarachnoid, intraventricular, and cerebellar, is often associated with prematurity. In a retrospective national register study from Israel, the incidence of severe intraventricular hemorrhage in singleton preterm deliveries with a birth weight of 1500 grams or less was 10.4% of all live births (Riskin et al., 2008). In that study, the mode of delivery did not alter the odds for severe intraventricular hemorrhage. In contrast, subdural and intraparenchymal cerebral hemorrhages are seen more often in term neonates (Brouwer et al., 2010; Collins & Popek, 2018; Tavil et al., 2016). Among cases of ICH associated with traumatic birth injury, subdural hemorrhage is the most common type, followed by subarachnoid hemorrhage (Åberg et al., 2019; Hong & Lee, 2018; Towner et al., 1999).

In term neonates, the overall incidence of ICH is reported to be 0.008% to 0.04% (Åberg et al., 2016; Ekéus et al., 2014; Linder et al., 2013; G. M. Muraca et al., 2018; Sauber-Schatz et al., 2010). Further, a retrospective register study also covering preterm neonates reported the incidence of subdural and cerebral hemorrhage to be 0.04% (Gupta & Cabacungan, 2021). The total incidence of ICH reported in retrospective register studies with different delivery modes is presented in Table 3. Although the incidence varies a great deal between studies, the total rate of ICH in all delivery modes is low, with the highest rate of 0.1% to 0.3% reported after attempted operative vaginal birth (Table 4). However, even higher incidence rates have been reported. For example, a single-center study from Israel reported an ICH incidence rate of 0.7% of live births after attempted vacuum delivery on term neonates (Krispin et al., 2017). Furthermore, the incidence of ICH in singleton vaginal breech delivery after 37 weeks of gestation ranges from 0.04% to 0.2% of live births (Azria et al., 2012; Ekéus et al., 2019; Vlemmix et al., 2014).

ICH may be asymptomatic or cause seizures, apnea, hypotonia, neurological findings, and mortality (Åberg et al., 2019; Brouwer et al., 2010; Hong & Lee, 2018; Parker, 2005). The prognoses depend on the severity and extent of the bleeding and can vary from complete recovery to developmental delay and death. The mortality rate and risk for poor outcome increase with concurrent birth asphyxia (Brouwer et al., 2010; Collins & Popek, 2018; Hong & Lee, 2018).

Table 3. The incidence of intracranial hemorrhage in singleton deliveries and different delivery modes. Retrospective register studies.

Study	Study population	ICH	l incidence / 100 l	pirths
		SVD	Operative VD	CS
Muraca et al., 2022, Canada	In-hospital deliveries in Canada, excluding Quebec 2013–2018, n = 1 326 191 >37+0 GW, no previous CS	0.003	Vacuum: 0.08 Forceps: 0.07	
Muraca et al., 2018, Canada	In-hospital deliveries in 4 Canadian provinces 2004–2017, n = 1 938 913 37–41 GW	0.01	Vacuum and Forceps: 0.06	0.01
Åberg et al., 2016, Sweden	Swedish MBR 1999–2012, n = 1 030 755 Live births, > 36 GW, birth weight >3000 g, cephalic presentation, no elective CS or forceps deliveries	0.02 ICD-10: P10, P52	Vacuum: 0.1 ICD-10: P10, P52	0.05 ICD-10: P10, P52
Ekeus et al., 2014, Sweden	Swedish MBR 1999–2010, n = 1 013 713 Live births, >37 GW, cephalic presentation, no elective CS or forceps deliveries	0.004	Vacuum: 0.06	0.008
Towner et al., 1999, US	Hospital-discharge register, includes 98% of all births in California 1992–1994, n = 583 340 Nulliparous women, live births, birth weight 2500–4000 g, cephalic presentation	0.05	Total: 0.1 Vacuum: 0.1 Forceps: 0.2	No-labor: 0.05 In-labor: 0.1 Failed V/F: 0.3

SVD, spontaneous vaginal delivery; Operative VD, operative vaginal birth or attempted operative vaginal birth; CS, cesarean section; GW, gestational week; MBR, Medical Birth Register; Failed V/F, CS after failed vacuum or forceps delivery

ICD-10 codes P10: intracranial laceration and hemorrhage due to birth injury, P52: intracranial non-traumatic hemorrhage of fetus and newborn

 Table 4.
 The incidence of birth injury in different delivery modes.

Study	Injury type	Study design	Injury incidence (%) SVD	Injury incidence (%) Operative / attempted operative vaginal birth (vacuum/forceps)	Injury incidence (%) CS
Muraca et al., 2018, Canada	Severe birth injury	Retrospective national register, 2004–2014 n = 1 938 913 Singleton in-hospital deliveries 37–41 GW	0.1	0.7 (V or F)	0.07
Wen et al., 2018 Washington State US	Severe birth injury, including clavicle fractures	Retrospective register, 2004–2013 n = 732 818 Singleton in-hospital live births, cephalic presentation 20–43 GW	0.5	V: 1.4 F: 2.5	0.2-0.5
Liston et al., 2008, Nova Scotia Canada	Severe birth injury Any birth injury: including severe birth injury and cephalohematoma	Retrospective national register, 1988–2002 n = 142 929 Singleton live-born neonates 36 GW or later	Severe birth injury: 0.3 Any birth injury: 1.4	Severe birth injury: 1.4 Any birth injury: 6.3 (V or F)	Severe birth injury: In-labor CS: 0.2, Elective CS: 0.1 Any birth injury: In-labor CS: 1.3, Elective CS: 0.1
Towner et al., 1999, US	ICH: subdural or cerebral hemorrhage, intraventricular hemorrhage, subarachnoid hemorrhage Brachial plexus injury Facial nerve palsy	Retrospective register, 1992–1994 n = 583 340 Singleton neonates, nulliparous women, cephalic presentation, birth weight 2500 grams–4000 grams	ICH: 0.05 BPP: 0.08 Facial nerve palsy: 0.03	ICH (V): 0.1 ICH (F): 0.2 BPP (V): 0.3 BPP (F): 0.3 Facial nerve palsy (V): 0.05 Facial nerve palsy (F): 0.5	ICH: Emergency CS: 0.1, Elective CS: 0.05 BPP: Emergency CS: 0.02 Elective CS: 0.04 Facial nerve palsy: Emergency CS: 0.03

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Werner et al., 2011, US	Cephalohematoma or scalp laceration Skeletal fracture Facial nerve palsy Brachial plexus injury Intraventricular hemorrhage Subdural hemorrhage	Retrospective register, 1995–2003 n= 414 999 Singleton live-born neonates, cephalic presentation 34 GW or later		Cephalohematoma or scalp laceration (V): 0.3, (F): 0.08, Skeletal fracture (V): 0.8, (F): 0.8 Facial nerve palsy (V): 0.05, (F): 0.6% BPP (V): 0.4, (F): 0.6 IVH (V): 0.07, (F): 0.05 SDH (V): 0.2, (F): 0.1	Cephalohematoma or scalp laceration: 0.07 Skeletal fracture: 0.2 Facial nerve palsy: 0.02 BPP: 0.01 IVH: 0.08 SDH: 0.09
Backe et al., 2008, Norway	Brachial plexus injury	Retrospective single center register, 1991–2000 n= 30 574 Hospital births	0.2	V; 1.8 F: 0.8	0.05
Åberg et al., 2016, Sweden	ICH (ICD-10 P10, P53) Brachial plexus injury	Retrospective national register, 1999–2012 n=1 030 755 Singleton live-born neonates, cephalic presentation, birth weight ≥ 3000 grams 36 GW or later Elective CS and forceps excluded	ICH 0.02 BPP: 0.2	ICH: 0.1 BPP: 0.9	ICH: Emergency CS: 0.05 BPP: 0

GW, gestational week; SVD, Spontaneous vaginal delivery; V, vacuum-assisted delivery, F, forceps delivery; CS, cesarean section; ICH, intracranial hemorrhage; IVH, intracranial hemorrhage; SDH, subdural hemorrhage; BPP, brachial plexus palsy

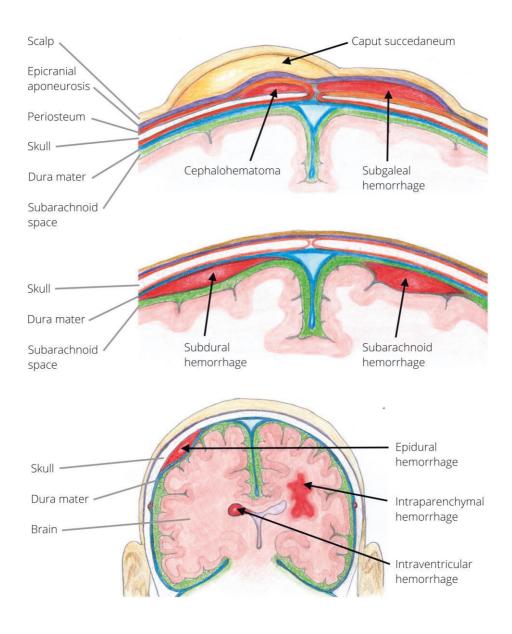


Figure 1. Layers of the scalp. Extracranial and intracranial hemorrhage. Figure created by Raisa Foster.

2.2.2 Other birth injuries to the central nervous system

ICD-10 P11*, other birth injuries to the central nervous system include facial nerve, spine, and spinal cord injuries (SCI).

2.2.2.1 Facial nerve injury

The facial nerve (cranial nerve VII) is most often injured in forceps deliveries or when the face presses against the sacrum. The injury is usually unilateral and causes diminished movement on the affected side of the face. Facial nerve injury is associated with an ipsilateral clavicle fracture, and has a good prognosis. Most injuries heal within days to a couple of months (Collins & Popek, 2018). Cases of facial nerve injury are rare and only occur in approximately three neonates per 10 000 deliveries. Moreover, the total incidence of facial nerve injury ranges from 0.005% to 0.07% of all live births (Baskett et al., 2007; Linder et al., 2013; Rehm et al., 2019; Sauber-Schatz et al., 2010; Towner et al., 1999; Werner et al., 2011). The incidence of facial nerve injury in different delivery modes is presented in Table 4.

2.2.2.2 Spinal cord injury

Spinal cord injuries (SCI) can be caused by hyperextension, excessive longitudinal stretching, and later traction or rotation of the neck associated with difficulties delivering the head or shoulders. Injuries can also occur as a result of ischemia or compression.

SCI are rare with an estimated incidence of 0.001% to 0.009% of live births (Brand, 2006; Linder et al., 2013; Rehan & Seshia, 1993; Sauber-Schatz et al., 2010). Muraca et al. have reported the total incidence of brain damage and central nervous system injury in singleton term neonates to be 0.005% (G. M. Muraca et al., 2018). The incidence of injury in neonates was highest after operative vaginal birth, 0.02% and very low after spontaneous vagina delivery (SVD), 0.003%, and CS, 0.006% (G. M. Muraca et al., 2018). The symptoms of SCI are related to the degree and the level of injury, and the prognosis is often poor. Neonates can have severe respiratory difficulties, hypotonia, and motor function and cognitive disability (MacKinnon et al., 1993; Reichard, 2008).

2.2.3 Birth injury to the scalp

Scalp injuries are one of the most frequent injuries, and the incidence of scalp injuries appears to be increasing (Gupta & Cabacungan, 2021). In addition to superficial lesions and bruises, scalp injuries also include extracranial hemorrhage such as cephalohematoma, and subgaleal hemorrhage (SGH, the term subaponeurotic hemorrhage is also used). An injury can appear within and between different layers of the scalp, Figure 1. Scalp injuries are often benign, and newborns usually recover without treatment. However, scalp injuries are also reported to be associated with increased odds for neonatal morbidities, such as hypoxic-ischemic encephalopathy, seizures, and meconium aspiration (Gupta & Cabacungan, 2021).

The overall incidence of scalp injury is reported to be 1.6% to 2.7% of live births (Gupta & Cabacungan, 2021; Linder et al., 2013; Sauber-Schatz et al., 2010). However, among attempted operative vaginal deliveries, the incidence of scalp injury ranges from 0.2% to 8.4% of live births, being higher in vacuum-assisted deliveries than in forceps deliveries. In CS, the incidence of scalp injury is 0.07% to 0.7% of all CS (Alexander et al., 2006; Ducarme et al., 2015; Werner et al., 2011).

2.2.3.1 Caput succedaneum and cephalohematoma

Caput succedaneum is caused by contractions pressuring the scalp against the uterus and pelvis during SVD or by the squeezing a vacuum device. Edema and swelling can occur under the scalp and above the periosteum crossing the suture lines, and it disappears in a few days (Parker, 2005).

Cephalohematoma is a relatively common condition caused by bleeding between the periosteum and the skull. It is diagnosed in 1.6% to 2.5% of all live births (Baskett et al., 2007; Parker, 2005; Reichard, 2008; Thacker et al., 1987). Furthermore, 2.3% of all singleton neonates born vaginally and up to 16.8% of neonates born with attempted vacuum-delivery after 37 weeks of gestation are reported to have cephalohematoma (Ashwal et al., 2018; Krispin et al., 2017). In many cases, a hemorrhage is detected after birth which increases in size for a few days. The swelling does not, however, cross the suture lines and dissolves within a few weeks to a few months (Parker, 2005). Most cases of cephalohematoma are benign and resolve spontaneously, but some may be associated with skull fracture and ICH (Kim et al., 2014; Parker, 2005). In addition, hyperbilirubinemia, infections, and calcification of the hematoma have all been reported (Blanc et al., 2019; Staudt et al., 2016; Thacker et al., 1987; Ulma et al., 2021).

2.2.3.2 Subgaleal hemorrhage

Subgaleal hemorrhage (SGH) is a rare but potentially fatal scalp injury. It results from bleeding into the subaponeurotic space beneath the epicranial aponeuroses of the scalp and superior to the periosteum. This space is large enough to accumulate the entire blood volume of the neonate. Although SGH can develop spontaneously, 50% to 95% of injuries are associated with vacuum-assisted deliveries in which force targeted to the skull can tear the large emissary veins (Chang et al., 2007; Colditz et al., 2015; Levin et al., 2019; G. M. Muraca et al., 2018; Swanson et al., 2012).

The general incidence of SGH is 0.01% to 0.06% of live births (Chang et al., 2007; G. M. Muraca et al., 2018; Swanson et al., 2012). SGH is most common in attempted vacuum-assisted deliveries, but less so in SVD and CS (Table 5). The reported incidence of injury in SVD is 0.001% to 0.004%, and 0.007% or less in CS (Bailit et al., 2016; G. M. Muraca et al., 2018, 2022). The large variation in the incidence of injury among vacuum deliveries is probably associated with the different study designs used (prospective vs retrospective, multicenter register study vs single center hospital records, inclusion criteria). The hospital's vacuum delivery rate and the practitioners' experience of vacuum extractions may also influence the injury rate. The discrepancy in incidence rates also implies that SGH may occasionally be underdiagnosed.

A subgaleal hemorrhage may be confused with caput succedaneum, as it also crosses suture lines. SGH can be associated with skull fracture, intracranial hemorrhage, and cerebral compression (Collins & Popek, 2018; Parker, 2005). In some cases, neonates may be asymptomatic. The most common symptoms associated with SGH are increasing head circumference, symptoms of hypovolemia and anemia, jaundice, and seizures (Chang et al., 2007; Colditz et al., 2015). The mortality rate of neonates with SGH ranges from 12% to 25% due to extensive blood loss (Chang et al., 2007; Collins & Popek, 2018; Swanson et al., 2012).

Table 5. The incidence of subgaleal hemorrhage (SGH) in operative vaginal birth.

Study	Study design	Incidence (%)
Muraca et al., 2018, Canada	Retrospective register, 4 Canadian provinces, 2004–2014 Operative vaginal deliveries, n = 207 675 Singleton neonates born 37–41 GW Operative vaginal delivery rate: 11 % of all deliveries	(V/F): 0.09
Muraca et al., 2022, Canada	Retrospective national register, excluding Quebec, 2013–2019 Attempted operative vaginal deliveries, n = 149 487 Singleton neonates born 37 GW or later Attempted operative vaginal delivery rate: 11 % of all deliveries	V: 0.2 F: 0.09
Bailit et al., 2016, US	Retrospective cohort, 25 academically affiliated hospitals, 2008–2011 Attempted operative vaginal deliveries, n= 2400 Singleton non-anomalous neonates, cephalic presentation, born 37 GW or later, a fetal station of +2 or below. No prior vaginal birth	V: 0.4 F: 0.1
Boo et al., 2005, Malaysia	Prospective observational, single center, 2/2000–3/2002 Vacuum delivery or attempted vacuum delivery, n = 338 Vacuum delivery rate: 3.4% of all deliveries	V: 21
Krispin et al., 2017, Israel	Retrospective cohort, single center, 2012–2014 Attempted vacuum-assisted deliveries, n = 1779 Singleton neonates born 37–42 GW Vacuum delivery rate: 8 % of all deliveries	V: 1.0
Levin et al., 2019, Israel	Retrospective, case-control, 2009–2018 Attempted vacuum-assisted delivery with SGH n = 350, controls n = 350 Attempted vacuum delivery rate: 8% of all deliveries	V: 4.5
Chang et al., 2007, Taiwan	Retrospective single center register, 1995–2004 Neonates with SGH, n = 42	V: 0.5

GW, gestational week; V, vacuum delivery; F, forceps delivery

2.2.4 Birth injury to the skeleton

Birth injuries to the skeleton consist of different types of fractures. In large retrospective register studies, the overall incidence of skeletal fractures is 0.08% to 0.8% of live births (Baskett et al., 2007; Högberg et al., 2020; Linder et al., 2013; Rehm et al., 2020; Wen et al., 2018). A clavicle fracture is the most common skeletal injury, followed by humerus, femur, and skull fractures.

2.2.4.1 Clavicle fracture

Previous researchers have proposed that clavicle fracture is caused by the pressure of the anterior shoulder against the maternal symphysis pubis or maneuvers used to release the entrapped shoulder (Högberg et al., 2020). A clavicle fracture should be considered in neonates who have decreased upper extremity movement, tenderness, swelling, bruising, and crepitation over the affected shoulder (Ahn et al., 2015). The fracture can be diagnosed during routine clinical examination or based on symptoms, and a clinical diagnosis can be confirmed with radiography. Fractures are also occasionally found incidentally on chest x-rays, or the diagnosis is made after discharge. Although clavicle fractures generally heal well without sequelae, between 2% and 9% of neonates also have brachial plexus palsy (Ahn et al., 2015; Wall et al., 2014).

The reported incidence of clavicle fracture varies between different studies. Table 6 presents a summary of the incidence rates of clavicle fracture in different delivery modes. In national register studies, the incidence of clavicle fracture has been reported to be 0.03% to 0.3% of live births (Gandhi et al., 2019; Gupta & Cabacungan, 2021; Högberg et al., 2020). Often, however, the incidence is somewhat higher in singe center studies (Ahn et al., 2015; Choi et al., 2017; Lam et al., 2002; Linder et al., 2013; Wall et al., 2014). In vaginal deliveries, especially after operative vaginal birth, clavicle fracture is more common and is diagnosed in 0.3% to 1.7% of neonates (Ahn et al., 2015; Bjørstad et al., 2010; Choi et al., 2017; Ducarme et al., 2015; Krispin et al., 2017; Lam et al., 2002). However, clavicle fracture after CS is rare, as it is diagnosed in only 0.03% to 0.05% of neonates born by CS (Ahn et al., 2015; Alexander et al., 2006; Choi et al., 2017; Dolivet et al., 2018). Interestingly, studies from the US have revealed that the incidence of clavicle fracture has decreased during the last couple of decades (Gandhi et al., 2019; Gupta & Cabacungan, 2021; Wen et al., 2018).

 Table 6.
 The frequency and incidence of clavicle fractures.

Study	Study design	Study population	Number of	Incidence (%)
`	,	-	clavicle fractures	
Högberg et al., 2020, Sweden	Retrospective national register, 1997–2014	Infants born in Sweden, n = 1 855 267	4736	0.03
Gupta et al., 2021, US	Retrospective national register, 2006–2014	In-hospital births, n = 35 317 076		0.2
Gandhi et al., 2019, US	Retrospective national register, 1997–2012	Weighted data represents a national estimate of $23.385.597$ births. $n = 5.564.628$	60 803	0.3
Sauber-Schatz et al., 2010. US	Retrospective national register, 2003	Weighted data represented a national estimate of 3 920 787 in-hospital births. n = 890 582	6353	0.2
Bjørstad et al., 2010, Norway.	Retrospective national register, 1999–2005	Vaginal delivery	1220	0.4 (VD)
Aubry et al., 2019, Switzerland	Retrospective national register, 2005–2016	Singleton neonates, n = 324 664	563	0.2
Clinder et al., 2013, Israel	Retrospective case-control, 1986-2009	Singleton neonates, 37^{+0} to 41^{+6} GW, n = 118 280	922	0.8
Wall et al., 2014, US	Retrospective register, 1988–2012	In-hospital births, n = 366 408	3739	1.0
Rehm et al., 2019, UK	Retrospective single center cohort, 2000–2016	Live-births, radiological identification of fractures, n = 87 461	46	0.05
Choi et al., 2017, Korea	Retrospective single center cohort, 2003–2014	In-hospital births, n = 89 367	392 (all) 373 (VD)	0.4 (all) 0.7 (VD) 0.05 (CS)
Kaplan et al.,1998, Israel	Retrospective case-control, 1986-1994	Singleton, term, vaginal delivery, n = 27 386	403	1.7 (VD) 0.2 (CS)
Gudmundsson et al., 2005. Sweden	Retrospective singe center cohort, 1990–1996	Singleton, vaginal delivery, cephalic presentation, n = 14 359	211	1.5 (VD)
Lam et al., 2002, China	Retrospective case-control, 1997-2000	Vaginal delivery, live-births, n = 9540	153	1.6 (VD)

1.5 (VD)	0.4 (all) 0.7 (VD) 0.05 (CS)	0.6 (VD)	0.3 (OVD)	2.3 (OVD)	0.03 (CS)	0.03 (CS)
396	319 (all) 289 (VD)	284	7	41		2
Singleton, term vaginal delivery, BW ≥3500	grams, no diabeuc pregnandes, n = 20 szu Vaginal delivery, n = 77 543	Singleton vaginal delivery, n = 44 092	Singleton, live-births, term neonates, cephalic presentation, attempted operative vaginal delivery, n = 2138	Singleton, 37–42 GW, attempted vacuum-assisted delivery, n = 1779	Cesarean delivery, n = 37 110	Cesarean delivery, singleton, live births, ≥32 GW, n = 6840
Retrospective single center cohort,	1390-2013 Retrospective case-control, 2003-2012	Retrospective single center cohort, 2009–2013	Prospective single center cohort, 2008–2013	Retrospective single center cohort, 2012–2014	Prospective multicenter cohort, 1999–2000	Retrospective case-control, 2003–2015
Ashwal et al., 2018,	Israel Ahn et al., 2015, Korea	Iskender et al., 2014, Turkey	Ducarme et al., 2015, Canada	Krispin et al., 2017, Israel	Alexander et al., 2006, US	Dolivet et al., 2018, France

2.2.4.2 Humerus, femur, and skull fractures

Long-bone injuries other than clavicle fractures are rare, with a total incidence of 0.02% of live births (Basha et al., 2013; G. M. Muraca et al., 2018; Rehm et al., 2020). Humerus fractures occur in 0.006% to 0.01% of all births and femur fractures in 0.002% to 0.02% of all births (Basha et al., 2013; Högberg et al., 2020; Morris et al., 2002; Toker et al., 2009; von Heideken et al., 2020). Long-bone fractures are often treated with immobilization for two to four weeks and have a good prognosis (Basha et al., 2013; Kancherla et al., 2012).

Skull fractures are most often seen after operative vaginal birth or in-delivery cesarean section with the fetal head pushed back to the uterus (Collins & Popek, 2018). The incidence of skull fracture, including all delivery modes, is 0.002% to 0.009% of live births (Baskett et al., 2007; Högberg et al., 2020; G. M. Muraca et al., 2018). In spontaneous vaginal deliveries, 0.001% of neonates sustain a skull fracture (G. M. Muraca et al., 2022), whereas 0.03% to 0.3% of neonates in attempted vacuum-assisted deliveries sustain a skull fracture (Ducarme et al., 2015; Krispin et al., 2017; G. M. Muraca et al., 2022). Skull fractures can be associated with extracranial or intracranial hemorrhage (Parker, 2005). Usually, linear skull fractures heal within two to six months without intervention, but depressed skull fractures ("ping-pong fracture") may need surgical intervention (Collins & Popek, 2018; Parker, 2005).

2.2.5 Birth injury to the peripheral nervous system

Brachial plexus palsy (P14.0 Erb's palsy, P14.1 Klumpke's palsy, P14.2 Phrenic nerve palsy, P14.3 Other injury to brachial plexus) covers most of the birth injuries to the peripheral nervous system. In addition, there are other unspecific injuries in the peripheral nervous system. In the literature, brachial plexus birth palsy (BPP) has been extensively studied. In two recent reviews, the epidemiology, anatomy, risk factors, prevention, diagnoses, and treatment are comprehensively described (Gherman et al., 2014; Grahn-Shahar, 2021). Lateral hyperextension or the downward traction of the head when the shoulder is impacted under the pubic bone in cephalic presentation, or delivering the aftercoming head in vaginal breech delivery, can damage the brachial plexus nerve (Collins & Popek, 2018; Mollberg et al., 2007). Direct shoulder compression against the symphysis pubis can also cause

injury. BPP is a complex event. Forces acting on a fetus during the delivery process and forces applied in the second stage of labor can affect the risk for injury (Gherman et al., 2014).

2.2.5.1 The incidence of brachial plexus palsy

BPP is the most common severe birth injury. In retrospective national studies, the incidence of BPP is reported to range from 0.1% to 0.3% (Abzug et al., 2019; Gupta & Cabacungan, 2021; Hedegaard et al., 2015; Mollberg et al., 2007; G. M. Muraca et al., 2018; van der Looven et al., 2020) (Table 7). However, the incidence of BPP found from the records of single hospitals is more inconsistent (Backe et al., 2008; Chauhan, Rose, et al., 2005; Gurewitsch et al., 2006; Lindqvist et al., 2012; Rehm et al., 2019). The incidence of BPP is generally higher in vaginal deliveries and the highest after operative vaginal birth or attempted operative vaginal birth (Table 4). In a retrospective national study using the Medical Birth Register of Norway between 1999 and 2005, the incidence of BPP in all vaginal deliveries was 0.3% of all births (Bjørstad et al., 2010). For SVD, the incidence ranges from 0.1% to 0.2% of all births and from 0.2% to 0.9% of all births after attempted operative vaginal birth (Åberg et al., 2016; G. M. Muraca et al., 2022; Towner et al., 1999). Overall, the incidence of BPP has declined in recent years (Hedegaard et al., 2015; van der Looven et al., 2020). This decline has been associated with improved obstetric care, increased awareness of BPP, increased labor induction and cesarean section rates, and a decreased incidence of high birth weight neonates (Abzug et al., 2019; Hedegaard et al., 2015; Lalka et al., 2020; van der Looven et al., 2020).

 Table 7.
 The incidence of brachial plexus palsy.

Study	Study design	Study population	Incidence (%)
Van der Looven et al., 2020	Systematic review and meta-analysis publications before 3/2019	22 randomized control trials and observational cohort or case-control studies, n = 29 419 037	0.2 Decreasing incidence over time
Muraca et al., 2018, Canada	Retrospective national register, 2004–2014	Singleton term neonates, n = 1 938 193	0.1
Hedegaard et al., 2015, Denmark	Retrospective national register, 2000–2012	Neonates born ≥ 37 GW, n = 770 926	2000–2012: 0.1 2000–2002: 0.14 2003–2010: 0.1 - 0.11 2011–2012: 0.08
Mollberg et al., 2007, Sweden	Prospective national case-control, 1999–2001	Cephalic vaginal deliveries, n = 38 443	0.3
Gupta et al., 2021, US	Retrospective register, 2006–2014	NIS – database (a 20% stratified random sample of all short-term US community hospitals), n = 982 033	2006–2014: 0.1 2006: 0.11 2014: 0.09
Abzug et al., 2019, US	Retrospective register, 1997–2012	Kids' inpatient database Live births, n = 24 159 426	1997–2012: 0.1 1997: 0.17 ± 0.01 2012: 0.09 ± 0.01
Lalka et al., 2020, US	Retrospective register, 2000–2014	The state hospital discharge, birth claims data, Colorado, n = 966 447	20002014: 0.06 2000: 0.082 2014: 0.055
Rehm et al., 2019, UK	Retrospective register, 2000–2016	A tertiary hospital data, Cambridge, n = 87 461	0.05
Linqvist et al., 2012, Sweden	Retrospective case– control, 1990–2005	Malmö, n = 51 841	0.3 Permanent injury: 0.07
Backe et al., 2008, Norway	Retrospective register, 1991–2000	A tertiary care hospital record, Trondheim, n = 30 574	0.3 Permanent injury: 0.05
Gurewitch et al., 2006, US	Retrospective register, 1993–2004	A single hospital birth record, Baltimore, n = 23 273	0.6 Permanent injury: 0.05
Chauhan et al., 2005, US	Retrospective register, 1980–2002	A university hospital data, Mississippi, n = 98 978	1980–2002: 0.1 1980–1991:0.09 1991–2002: 0.1 Permanent injury: 0.01

GW, gestational week

2.2.5.2 The anatomy of brachial plexus

A brachial plexus injury causes impaired motor function and, less often, diminished or loss of sensory function in the upper limb. The brachial plexus is a network of four cervical nerves (C5–C8) and the first thoracic nerve (T1). In BPP, one or more of the nerves are damaged due to compression or traction that causes the nerves to stretch, rupture, or avulse from the spinal cord (Gherman et al., 2014; Grahn-Shahar, 2021). The severity of the injury varies from local myelin sheath or axon damage to complete peripheral nerve rupture (Buterbaugh & Shah, 2016; Smith et al., 2018). The injury is classified in either three or four groups, based on the anatomical location. Erb palsy (C5-C6, sometimes C7) is the most common type of BPP, accounting for 50% to 80% of cases with an incidence of 0.1% of births (Collins & Popek, 2018; Gherman et al., 2014; Lindqvist et al., 2012; Parker, 2006; L. J.-S. Yang, 2014). It is characterized by limitation of shoulder abduction and lateral rotation, elbow flexion, and forearm supination (Parker, 2006; L. J.-S. Yang, 2014). If the injury extends to the root of C7, it can also affect wrist extension and finger flexion movements. In one-third of injured neonates, nerves from C5 to C7 are damaged (Buterbaugh & Shah, 2016). Injuries involving only lower nerve roots (Klumpke's palsy, C7, C8-T1) are rare (incidence 0.005% of births) and cause a deficit in the flexion of the wrist and fingers and the intrinsic function of the hand (Gherman et al., 2014). The least common type of injury, complete palsy, includes approximately 20% of all injuries and involves nerve roots C5-T1 (Buterbaugh & Shah, 2016). The injury may include the total loss of hand function, Horner's Syndrome (miosis, ptosis and anhidrosis), and phrenic nerve palsy, causing dyspnea and asymmetrical diaphragmatic movements (Collins & Popek, 2018; Parker, 2006; L. J.-S. Yang, 2014). Less than half of neonates with complete paralysis recover without treatment.

2.2.5.3 Permanent injury and prognoses

The diagnosis and evaluation of the severity of injury is generally done by clinical examination (Buterbaugh & Shah, 2016). Diagnoses of milder injuries can be delayed due to only mild impairment of hand function. However, in more extensive injuries, the movement function is indisputably affected (Grahn-Shahar, 2021). As BPP among neonates with permanent injury is often more extensive, covering C7 to T1 nerves, a quite reliable prognosis can be proposed soon after delivery (Backe et al., 2008; Lindqvist et al., 2012). It is reported that 80% to 90% of injuries limited to the

C5–C6 nerves recover spontaneously (Buterbaugh & Shah, 2016; Lindqvist et al., 2012; L. J.-S. Yang, 2014). However, patients with more comprehensive injuries may have permanent or long-lasting functional impairment and pain in the affected arm even after surgical treatment (Johansson et al., 2019; Kirjavainen et al., 2011). Approximately 0.05% of all neonates and 10% to 20% of neonates with BPP have a permanent injury, defined most often as a persistent deficit lasting longer than 12 months (Backe et al., 2008; Buterbaugh & Shah, 2016; Chauhan, Rose, et al., 2005; Gurewitsch et al., 2006; Johansson et al., 2019; Lindqvist et al., 2012; Mollberg et al., 2007). In the Helsinki University Hospital district, the incidence of permanent BPP between 1995 and 2019 was reported to be 0.04% of all births and 0.05% of vaginal births (Grahn-Shahar, 2021). Since 2014, the total incidence has declined to approximately 0.03% of all births (Grahn-Shahar, 2021).

Shoulder dystocia increases the risk for permanent injury (Backe et al., 2008; Gurewitsch et al., 2006). Also, a humerus fracture is more common in neonates with permanent injury than transient (Backe et al., 2008). Approximately 5% to 25 % of neonates with BPP have concurrent clavicle fractures (Gandhi et al., 2019; Gudmundsson et al., 2005; Wall et al., 2014). It has been suggested, however, that the occurrence of clavicle fracture does not correlate with the severity of BPP or it could have a protective effect on more severe BPP (Backe et al., 2008; Gandhi et al., 2019; Leshikar et al., 2018; Wall et al., 2014). A trial of vaginal delivery is generally not recommended for women with a permanent obstetrical BPP in a previous delivery (Pondaag et al., 2011). Further, diabetes and macrosomia increase the risk for a repeat injury.

Most neonates recover spontaneously and treatment depends on the severity and location of the injury (pre- or postganglionic lesion). As immobilization is no longer recommended, conservative treatment includes passive and active movements of the affected arm. Additional imaging is done for more severe injuries. The indications for surgical treatment vary among practitioners. For more extensive injuries and when recovery is insufficient by 3 to 6 months of age, nerve reconstruction is often recommended (Buterbaugh & Shah, 2016; Smith et al., 2018; L. J.-S. Yang, 2014).

2.2.6 Other birth injuries

Other birth injuries, ICD-10 P15, include injuries to the liver, spleen, face, external genitalia, skin, and unspecific birth injuries. Severe intra-abdominal injuries, such as injuries to the liver or spleen, are extremely rare (G. M. Muraca et al., 2018).

2.3 Risk factors for birth injury

2.3.1 High birth weight

High birthweight is associated with an increased risk for birth injuries and other neonatal and maternal adverse events (Barth & Jackson, 2020; Beta, Khan, Fiolna, et al., 2019; Beta, Khan, Khalil, et al., 2019). The risk for birth injuries and obstetric complications, such as prolonged labor and CS, start to increase when birth weight exceeds 4000 grams. However, with birth weights of more than 5000 grams, the risk for infant morbidity and mortality increases markedly (Boulet et al., 2003; X. Zhang et al., 2008). The term "macrosomia" is defined as an absolute birth weight of more than 4000 grams (or 4500 grams), whereas large for gestational age (LGA) implies the birth weight of a fetus or neonate more than 90^{th} – 95^{th} percentile for a given gestational age (Barth & Jackson, 2020).

In Finland, the average birth weight is approximately 3500 grams (Finnish Institute of Health and Welfare, 2020). Moreover, 5% to 20% of neonates are born with a birth weight over 4000 grams (Chauhan, Grobman, et al., 2005; Finnish Institute of Health and Welfare, 2020; Harvey et al., 2021; Salihu et al., 2020). The prevalence of macrosomia has decreased in some countries in the 21st century (Australian Institute of Health and Welfare, 2021b; Chauhan, Grobman, et al., 2005; Harvey et al., 2021; Hedegaard et al., 2015; Hildén et al., 2020; Salihu et al., 2020). This drop in prevalence is speculated to be associated with increased rates of gestational diabetes screening, CS, and labor induction (Chauhan, Grobman, et al., 2005; Hedegaard et al., 2015).

The interaction between macrosomia, risk factors for macrosomia, and related adverse outcomes is complex. Maternal diabetes and obesity increase the risk for fetal macrosomia and are also associated with an increased risk for birth injury (Beta, Khan, Khalil, et al., 2019; Salihu et al., 2020). Moreover, multiparity, high maternal weight gain, maternal age, and gestational age at birth are all risk factors for high birth weight (Bjørstad et al., 2010; Salihu et al., 2020). Furthermore, macrosomia increases the risk for shoulder dystocia and instrumental vaginal delivery, which are also associated with risk for birth injury.

An increasing or high birth weight (>4000 grams, 4500 grams) is a well-known risk factor for clavicle fracture and BPP and also increases the risk for ICH (Åberg et al., 2016; Ahn et al., 2015; Ashwal et al., 2018; Avram et al., 2021; Backe et al., 2008; Beta, Khan, Fiolna, et al., 2019; Beta, Khan, Khalil, et al., 2019; Bjørstad et al.,

2010; Dodd & Lindqvist, 2021; Gudmundsson et al., 2005; Högberg et al., 2020; Mollberg et al., 2005; Narendran et al., 2021; van der Looven et al., 2020). Indeed, a high absolute birth weight is a more critical risk factor for birth injury than LGA (Persson et al., 2012). However, even though increasing birth weight is associated with the severity of BPP (Pondaag et al., 2011), approximately half of the neonates who sustain a clavicle fracture have a birth weight of less than 4000 grams (Högberg et al., 2020).

The effect of birth weight on injury risk has been comprehensively studied. A meta-analysis that compared pregnancies with a birth weight of less than or more than 4000 grams concluded that the odds for fractures were 6.43 (95% CI 3.67-11.28) and for BPP 11.03 (95% CI 7.06–17.23) in pregnancies with a birth weight of more than 4000 grams (Beta, Khan, Khalil, et al., 2019). A retrospective national register study from Norway compared neonates with a birth weight of 2500-3999 grams to neonates with a birth weight of 4000-4499 grams or 4500-4999 grams (Bjørstad et al., 2010). In that study, 22% of vaginally born neonates had a birth weight >4000 grams. Compared to neonates with a birth weight of less than 4000 grams, the odds for BPP among neonates with a birth weight of 4000-4499 grams and 4500–4999 grams were 5.6 (95% CI 4.7–6.7) and 17.2 (14.3–21.0), respectively. Also, the odds for clavicle fracture were 3.4 (95% CI 3.0–3.8) with a birth weight of 4000 to 4499 grams and 7.1 (95% CI 6.1-8.4) with a birth weight of 4500-4999 grams (Bjørstad et al., 2010). A similar trend of increased injury risk with increasing birth weight was seen in a Swedish retrospective national study among women participants in a trial of vaginal delivery. The incidence of BPP and ICH was 0.1% and 0.03% in neonates with a birth weight of 3000-3999 grams, 0.5% and 0.04% with a birth weight of 4000-4500 grams, and 1.4% and 0.06% in neonates with a birth weight of 4500-5000 grams (Åberg et al., 2016). Furthermore, a cohort study from the UK compared neonatal and maternal complications in pregnancies with macrosomia to normal birth weight. The incidence of birth fracture and BPP was higher in neonates with macrosomia, but the absolute number of injuries was negligible and in line with the findings of other studies in all birth weight groups (Beta, Khan, Fiolna, et al., 2019).

2.3.2 Shoulder dystocia

Shoulder dystocia is an unpredictable event where additional maneuvers are needed in vaginal delivery to release an impacted shoulder with the neonate in cephalic presentation. The McRoberts maneuver and suprapubic pressure are commonly used initially if shoulder dystocia is suspected. If these methods are insufficient, other maneuvers, such as posterior arm delivery and Rubin or Woods Screw maneuvers, are used. Shoulder dystocia is associated with an increased risk for birth injuries, especially clavicle and humerus fractures, BPP and spinal cord injuries, perinatal asphyxia, and neonatal mortality (Brand, 2006; Högberg et al., 2020; Sentilhes et al., 2016). BPP is diagnosed in 5% to 22% of shoulder dystocia cases and a long bone fracture in 10% (Backe et al., 2008; Gurewitsch et al., 2006; Habek et al., 2022; Narendran et al., 2021; Volpe et al., 2016). Maternal complications include perineal tears and postpartum hemorrhage.

The incidence of shoulder dystocia is 0.17 % to 0.23% of all births (Gandhi et al., 2019; Grossman et al., 2020; Heinonen et al., 2020) and 0.7% to 1.2% of vaginal births (Bjørstad et al., 2010; Habek et al., 2022; Hedegaard et al., 2015; Narendran et al., 2021; Øverland et al., 2014). The incidence of shoulder dystocia has remained stable in the US, but has increased slightly in Finland and Denmark (Gandhi et al., 2019; Hedegaard et al., 2015; Heinonen et al., 2020). High birth weight or macrosomia and shoulder dystocia in previous births are the main risk factors for shoulder dystocia (Bjørstad et al., 2010; Sentilhes et al., 2016; Volpe et al., 2016). Furthermore, maternal diabetes and obesity are also associated with an increased risk for shoulder dystocia and fetal macrosomia (Bjørstad et al., 2010; Heinonen et al., 2020; Sentilhes et al., 2016; C. Zhang et al., 2018). The risk for shoulder dystocia also increases with the severity of pre-pregnancy obesity (C. Zhang et al., 2018). In addition, gestational age at delivery, high maternal age, prolonged labor, and operative vaginal birth has all been associated with increased odds (Heinonen et al., 2020; Sentilhes et al., 2016). Nevertheless, shoulder dystocia is, in part, still an unpredictable event. Most pregnancies with risk factors do not end up with shoulder dystocia, and two-thirds of shoulder dystocia cases occur without any known risk factors (Sentilhes et al., 2016).

However, shoulder dystocia is a main risk factor for BPP (van der Looven et al., 2020). Overall, only shoulder dystocia has been shown to be a clinically useful predictor of BPP and is related to 19% to 56% of BPP cases (Avram et al., 2021; Backe et al., 2008; Chauhan, Rose, et al., 2005; Gandhi et al., 2019; Gherman et al., 2014; Gurewitsch et al., 2006; Lindqvist et al., 2012). Thus, to protect the brachial plexus, gentle maneuvers should be used to relieve the impacted shoulder instead of vigorous downward traction of the head (Mollberg et al., 2007). The predictive value for injury of shoulder dystocia is, however, limited, because BPP quite often occurs without preceding shoulder dystocia (Backe et al., 2008). It has also been proposed

that physicians might underestimate the force used and as the diagnosis depends on subjective recognition, shoulder dystocia may often be underdiagnosed and underreported (Mollberg et al., 2007).

The mechanism of BPP injury may be different in injuries with or without shoulder dystocia (Gurewitsch et al., 2006). Among neonates with shoulder dystocia, BPP most often occurs in the anterior upper limb, whereas in BPP without shoulder dystocia, the posterior shoulder is more likely to be injured (Gudmundsson et al., 2005; Gurewitsch et al., 2006). Often, neonates with BPP and shoulder dystocia have a higher birth weight and more severe injury than injured neonates without shoulder dystocia (Chauhan, Rose, et al., 2005; Gurewitsch et al., 2006).

2.3.3 Pregestational diabetes, gestational diabetes and obesity

Pregestational and gestational diabetes (GDM) are well-known risk factors for birth injuries and other adverse pregnancy and perinatal outcomes (Billionnet et al., 2017; Hildén et al., 2019; Persson et al., 2009; van der Looven et al., 2020; J. Yang et al., 2006). The risk for adverse outcomes is highest among the pregnancies of women with pregestational diabetes (Billionnet et al., 2017). Obesity is also associated with an increased risk for injury, but to a lesser extent than diabetes (Aubry et al., 2019; Avram et al., 2021; Blomberg, 2013; Freeman et al., 2017; von Heideken et al., 2020).

There is little published research on birth injuries among neonates of women with pregestational diabetes. In a national register study from France, the incidence of birth injury (Erb's palsy or clavicle fracture) was 2.0% among neonates of women with type 1 diabetes (T1D), 1.5% among neonates of women with type 2 diabetes (T2D), and 0.7% of vaginal live births among neonates of women with GDM. In the pregnancies of women without diabetes, the incidence of birth injury was 0.5% of vaginal births (T1D OR 3.7, 95% CI 1.9–6.9, T2D OR 2.7, 95% CI 1.6–4.7, GDM OR 1.3, 95% CI 1.1–1.5) (Billionnet et al., 2017). In the Swedish T1D population, 2.5% of vaginally delivered neonates had Erb's paralysis and 3.4% had clavicle fracture (Persson et al., 2012).

Some previous studies have assessed the risk of birth injuries among women with GDM or unspecified diabetes. In studies from the US, the incidence of BPP in neonates of women with gestational or any maternal diabetes ranged from 0.5% to 0.7% of live births (Freeman et al., 2017; Lalka et al., 2020). High birth weight, shoulder dystocia, instrumental vaginal delivery, and obesity were associated with BPP in pregnancies of women with diabetes (Freeman et al., 2017). Swedish national

register study reported Erb's paralysis to be more common in pregnancies with GDM compared to pregnancies without diabetes (incidence 0.6% vs 0.2% of vaginal deliveries) (Hildén et al., 2019). Maternal overweight and obesity were independent risk factors for Erb's paralysis in the Swedish study. Another national study from Sweden reported an overall incidence of birth injury (including Erb's palsy, spinal cord injury, basal skull fracture, intracranial hemorrhage, and fracture of long bones) to be approximately 3% of births in women with GDM in 1998 and 1.5% in 2012 (Hildén et al., 2020). The decreasing trend per year (0.94, 95% CI 0.91–0.97) in the incidence of birth injury was suggested to be due to a decrease in absolute birth weight and LGA, an increase in the CS rate, and improved obstetrical management. The incidence of birth injury also declined among women without diabetes (Hildén et al., 2020).

Increasing maternal body mass index (BMI) is associated with higher odds of birth injuries. In retrospective case-control study from the US, the incidence of BPP among neonates of obese women was 0.2% of live birth (Freeman et al., 2017). High birth weight, shoulder dystocia, instrumental vaginal delivery, and a prolonged second stage of labor increased the risk for BPP among obese women (Freeman et al., 2017). In a Swedish retrospective national study, the risk for skeletal injury was doubled (0.5% vs 1.2% of live births), and the risk for peripheral nervous system injury was 4-fold (0.2% vs 0.6% of live births) in neonates born to morbidly obese women (BMI >40) compared to women with normal weight. However, the odds for intracranial hemorrhage and central nervous system injury were similar regardless of the women's weight (Blomberg, 2013).

Multiple factors affect the odds of birth injury in women with diabetes or obesity. Increased risk for birth injuries is at least partly linked to high birth weight as pregestational diabetes, GDM, and obesity are associated with increased odds of LGA/macrosomia (Dai et al., 2018; Hildén et al., 2020; Lim & Mahmood, 2014; Persson et al., 2012; Vats et al., 2021; Ye et al., 2022). However, even though the induction of labor is associated with lower risk for macrosomia, evidence is conflicting on whether the induction of labor reduces the odds of BPP or shoulder dystocia among obese women (Lee et al., 2016). Indeed, the association between shoulder dystocia, diabetes, and obesity is inconsistent. In a multicenter study from Germany, obesity was not independently associated with shoulder dystocia, whereas diabetes and high birth weight were (Vetterlein et al., 2021). Nevertheless, some studies have reported an association between obesity and shoulder dystocia (Aubry et al., 2019; Kuitunen et al., 2022). A recent meta-analysis of 156 studies did not find a difference in the odds of shoulder dystocia or instrumental delivery between

women with GDM and women without diabetes (Ye et al., 2022). However, another meta-analysis found a linear association between increasing fasting and post-load glucose concentrations, and adverse perinatal outcomes, including shoulder dystocia (Farrar et al., 2016). Further, a higher rate of shoulder dystocia was found in women with GDM than in women without diabetes in a Swedish national register study (Fadl et al., 2010).

The incidence of obesity (Australian Institute of Health and Welfare, 2021b; Hales et al., 2020; Hildén et al., 2020; Kuitunen et al., 2022; Poston et al., 2016), GDM (Australian Institute of Health and Welfare, 2021b; Ellenberg et al., 2017; Feig et al., 2014; Gregory & Ely, 2022; Hildén et al., 2020; Shah et al., 2021), and pregestational diabetes (Feig et al., 2014; Gortazar et al., 2020; Patterson et al., 2019; Saravanan et al., 2020; Wen et al., 2018) has increased. In Finland, the incidence of T1D is among the highest in the word. Moreover, the incidence of T1D had been increasing until very recently when a plateau in the incidence of T1D among young children was reported (Harjutsalo et al., 2008, 2013). In addition to an increasing rate of obesity, the increase in the incidence of GDM is partly due to a change in GDM screening policy. The screening for GDM differs between countries, and there are no standardized criteria for GDM. Furthermore, direct evidence of the benefits of comprehensive screening is limited (Ellenberg et al., 2017; Hillier et al., 2021; Pillay et al., 2021). However, a gestational high blood glucose levels are associated with increased birth weight and the treatment of GDM is associated with markedly reduced risk for macrosomia and LGA. There is also some evidence that treatment reduces the risk for birth injuries (OR 0.33 95% CI 0.11–0.99) (Billionnet et al., 2017; Group et al., 2008; Koivunen et al., 2020; Pillay et al., 2021).

2.3.4 Other risk factors

Other risk factors for birth injuries occasionally mentioned in studies are primiparity, prolonged or precipitous labor, malpresentation, and hypotonia or hypoxia (Abzug et al., 2019; Collins & Popek, 2018; Sauber-Schatz et al., 2010; Swanson et al., 2012). Bone dysplasia such as osteogenesis imperfecta, increases the risk for fractures (Marini et al., 2017).

ICH is often associated with prematurity. However, in addition to prematurity, ICH can also be due to perinatal or intrapartum hypoxic-ischemic events, infection, vascular abnormalities, or coagulation disorders (Collins & Popek, 2018; Davies & Kadir, 2016; Tan et al., 2018). Furthermore, ICH is a surprisingly common incidental

finding in the magnetic resonance imaging (MRI) of asymptomatic neonates born vaginally after 37 weeks of gestation without difficulties during labor or the need for instrumental assistance (Kumpulainen et al., 2020; Looney et al., 2007; Whitby et al., 2004). A cohort study from Finland that acquired MRI scans 2 to 5 weeks after birth found ICH in 7% of asymptomatic term neonates. All neonates with hemorrhage were born vaginally, one-third by vacuum-assisted delivery, and their neurological assessment was normal (Kumpulainen et al., 2020). Clavicle fracture is also quite often diagnosed in neonates without any predisposing factors for injury (Ahn et al., 2015; Kaplan et al., 1998; Lurie et al., 2011). Furthermore, approximately 10% to 50% of neonates with BPP do not have a known predisposing factor (Abzug et al., 2019; Gurewitsch et al., 2006; Lalka et al., 2020).

2.4 The effect of delivery mode on birth injury risk

2.4.1 Operative vaginal birth

Vaginal delivery, especially instrumental vaginal delivery, is associated with an increased risk for birth injury (Baskett et al., 2007; Linder et al., 2013; Murphy et al., 2003). The incidence of injury in different modes of delivery is presented in Table 4.

There are some differences in the rates of the different birth injury types between vacuum and forceps deliveries. For example, vacuum-assisted delivery is often associated with cephalohematoma, laceration, other superficial scalp injuries, and retinal hemorrhage. Moreover, less common injuries, such as depressed skull fractures, SGH, and intracranial hemorrhage can be directly linked to the use of vacuum extraction (Akangire & Carter, 2016; Collins & Popek, 2018; Ekéus et al., 2014; G. M. Muraca et al., 2022; Murphy et al., 2020; Peaceman, 2020; Thacker et al., 1987; Vayssière et al., 2011). SGH is especially associated with vacuum-assisted deliveries due to force targeted to the skull (Aberg et al., 2014; Chang et al., 2007; Colditz et al., 2015; Levin et al., 2019; G. M. Muraca et al., 2018; Swanson et al., 2012). In addition, primiparity, a prolonged second stage of labor, and a difficult vacuum procedure increase the risk for SGH (Levin et al., 2019, 2020; Swanson et al., 2012). The use of forceps predominantly increases the risk for facial injuries and facial nerve injury, but skull fractures, and intracranial hemorrhage are also known to occur (Akangire & Carter, 2016; Murphy et al., 2020; Peaceman, 2020; Vayssière et al., 2011; Verma et al., 2021). Further, forceps delivery in neonates with a cephalic

presentation is associated with increased risk for spinal cord injury (Brand, 2006; MacKinnon et al., 1993; Reichard, 2008; Vialle et al., 2007).

The odds of clavicle fracture, humerus fracture, and BPP are increased in complicated deliveries ending up with operative vaginal birth (Högberg et al., 2020; Lalka et al., 2020; Mollberg et al., 2005; Sauber-Schatz et al., 2010; van der Looven et al., 2020; von Heideken et al., 2020). These birth injuries are probably associated with complicated delivery and macrosomia per se rather than the specific operative delivery mode used (Akangire & Carter, 2016). Regardless of birth weight, vacuum-assisted delivery is shown to increase the risk for injury, but the risk is multiplied in the vacuum-assisted delivery of neonates with a higher birth weight (Åberg et al., 2016). It has been suggested that complicated labor, regardless of the mode of delivery, increases the risk for ICH (Towner et al., 1999; Walsh et al., 2013). However, other studies have shown that especially prolonged or difficult instrumental vaginal delivery with numerous pulls and cup detachments, mid-pelvic fetal head position, and high birth weight increase the risk for ICH (Åberg et al., 2016, 2019; Krispin et al., 2017).

Severe complications and mortality are relatively rare after operative vaginal births. Thus, instrumental vaginal delivery is considered an acceptable choice in the second stage of labor, at least with a low fetal head station (lowest bony part +2 cm or greater). It is associated with a lower frequency of maternal complications, and the overall rate of neonatal adverse outcomes is not considerably greater than in CS in the second stage of labor (Bailit et al., 2016; Halscott et al., 2015; Peaceman, 2020). There are, however, conflicting results on operative vaginal delivery in mid-pelvic (the lowest bony part at ischial spines to +2 cm) head station. Before operative vaginal birth in a mid-pelvic head station, it is recommended that the risks and benefits in the given clinical circumstances of in-labor CS and operative vaginal birth, in addition to the skills of the practitioner, are evaluated (Murphy et al., 2020). An attempted mid-cavity delivery is associated with higher odds of failure than low or outlet cavity deliveries (Tsakiridis et al., 2020). A retrospective national register study reported an increased risk for birth injury and severe neonatal and maternal morbidity in attempted mid-cavity operative vaginal delivery compared to CS (G. Muraca et al., 2018). However, it is not clear whether mid-cavity operative vaginal birth is associated with a higher risk for injury than low pelvic instrumental delivery (Ducarme et al., 2015). In addition to the mid-pelvic head station, maternal obesity, short stature, occipito-posterior position, high birth weight and head circumference increase the risk for the failure of instrumental vaginal birth (Murphy et al., 2020; Peaceman, 2020; Tsakiridis et al., 2020; Women's Health Committee (RANZCOG), 2020).

The choice of instrument depends on the clinical circumstances and the preferences of the obstetrician (Murphy et al., 2020; Vayssière et al., 2011). It has been suggested, for example, that using forceps makes vaginal delivery more likely achieved than using vacuum extraction (Verma et al., 2021). However, the rate of severe birth injury is similar after a vacuum and forceps delivery (G. M. Muraca et al., 2022). Between different vacuum devices, rigid cups are associated with a higher rate of scalp injury but a lower risk for failure than soft cups (Murphy et al., 2020; Tsakiridis et al., 2020; Verma et al., 2021). Protracted instrumental delivery, use of sequential instrumentation, a failed attempt at instrumental vaginal delivery, and cup detachment all increase the injury risk (Hankins et al., 2006; Krispin et al., 2017; G. M. Muraca et al., 2018; Murphy et al., 2003, 2020; Peaceman, 2020; Tsakiridis et al., 2020). The use of excessive force and multiple instruments might also be associated with the inexperience of the treating physicians (Murphy et al., 2003). Therefore, the safest mode of delivery should be evaluated carefully if an arrest of descent, the head is in the mid-pelvic station, or macrosomia is suspected. The risks should be balanced against the risks of CS, operative vaginal birth, and CS following a failed attempt at operative vaginal birth (Chauhan, Grobman, et al., 2005; Murphy et al., 2020; Sentilhes et al., 2016). Ultrasound assessment prior to instrumental vaginal delivery has not been proven to decrease the rate of birth injury (Mappa et al., 2021). In France, ultrasound is recommended to ensure fetal presentation before operative vaginal birth, whereas the RCOG guideline states that the evidence is insufficient for such a recommendation (Murphy et al., 2020; Vayssière et al., 2011).

2.4.2 Birth injuries in cesarean section

The cesarean section rate has been steadily increasing in many countries (Australian Institute of Health and Welfare, 2021b; Betrán et al., 2016, 2018; Betran et al., 2021; Wen et al., 2018). Therefore, as the procedure is associated with both short- and long-term risks, clinical interventions should be assessed to avoid the overuse of CS (Betrán et al., 2018; Keag et al., 2018; Sandall et al., 2018). It has been suggested that the increase in the CS rate has contributed to the decrease in the birth injury rate (Lalka et al., 2020; Zeck et al., 2007). In contrast, the operative vaginal rate in different populations (Australian Institute of Health and Welfare, 2021b; Gupta & Cabacungan, 2021; G. M. Muraca et al., 2018).

Birth injuries complicate approximately 1% (range 0.8% to 1.7%) of all CSs (Alexander et al., 2006; Dolivet et al., 2018; Liston et al., 2008; Moczygemba et al., 2010). The incidence of injury after an elective CS is, however, lower, affecting approximately 0.1% of deliveries (Liston et al., 2008). Birth injury is often related to the prior clinical circumstances rather than directly to the surgery. For example, a failed attempt at instrumental delivery and an obstetrical emergency demanding the fast delivery of the neonate increase the risk for injury (Alexander et al., 2006). Also, increased injury is related to technically difficult surgeries such as repeat CS and malpresentation (Alexander et al., 2006; Dolivet et al., 2018).

The most common injuries in CS are skin lacerations and cephalohematomas (Alexander et al., 2006; Dolivet et al., 2018). Skull fractures are most often seen after operative vaginal birth or in-delivery cesarean section with the fetal head pushed back to the uterus (Collins & Popek, 2018). In a case-control study from France, pushing the head back through the vagina was associated with an increased risk for cranial fracture (Dolivet et al., 2018). In contrast, in a meta-analysis including three studies (n = 225), reverse breech extraction seemed to be associated with a higher incidence of birth injury than deliveries using the "push method", but the difference was not statistically significant (Jeve et al., 2016). A more recent meta-analysis concluded that the pull technique with reverse breech extraction is safer for neonates than pushing the head upwards (Rada et al., 2022). Femur fractures, and to a lesser extent also humerus fractures, are most often seen after CS and are linked to breech presentation (Basha et al., 2013; Högberg et al., 2020; G. M. Muraca et al., 2018; Toker et al., 2009; von Heideken et al., 2020).

CS can be a lifesaving intervention that prevents severe morbidities such as birth injuries or intrapartum asphyxia. As injuries are rare after CS, the overall incidence of birth injury would probably decrease by increasing the CS rate. However, birth injuries cannot be dismissed simply because CS is the method of delivery. Indeed, cephalohematomas, lacerations, long bone fractures, and BPP are also known to occur in elective CS (Alexander et al., 2006). Furthermore, CS is associated with an increased risk for maternal mortality and severe short-term morbidities, such as infections, hemorrhage, hysterectomy, and thromboembolic complication (Liu et al., 2007; Sandall et al., 2018; Villar et al., 2007). In addition, CS increases the risks for repeat CS and complications in a subsequent pregnancy, including a higher risk for uterine rupture and placenta accreta spectrum (Keag et al., 2018; Sandall et al., 2018). Children born by CS are also at increased risk for short- and long-term adverse

outcomes, such as respiratory distress, altered immune development, allergies, asthma, and obesity (Keag et al., 2018; Kruit, Mertsalmi, et al., 2022; Sandall et al., 2018).

2.4.3 Breech presentation

Approximately 2% to 4% of neonates are in breech presentation, and the prevalence decreases with increasing gestational age (Albrechtsen et al., 1998; Hickok et al., 1992; Macharey, 2018; Vlemmix et al., 2014). Factors that affect fetal movements and rotation into vertex presentation, such as oligo- or polyhydramnios, uterine abnormalities, congenital anomalies, fetal growth restriction, and multiparity, further increase the risk for breech presentation (Macharey, 2018). These antenatal factors that are associated with breech presentation may, in addition to delivery mode, partly explain the adverse events linked to breech deliveries (Macharey, Gissler, et al., 2017).

2.4.3.1 Breech delivery and birth injury

The ideal delivery mode for neonates with breech presentation remains a matter of debate, and attitudes toward vaginal breech delivery are controversial. The Term Breech Trial (Hannah et al., 2000) changed clinical practice worldwide, considerably reducing the rate of vaginal breech delivery (breech VD) in many countries (Sullivan et al., 2009; Vistad et al., 2015; Vlemmix et al., 2014; Wängberg Nordborg et al., 2022). A planned breech VD (trial of breech VD) may be associated with a small increased risk for short-term neonatal morbidity and perinatal mortality compared to planned/elective CS (Bergenhenegouwen et al., 2014; Berhan & Haileamlak, 2016; Bin et al., 2016; Impey et al., 2017; Lyons et al., 2015; Villar et al., 2007; Vlemmix et al., 2014; Wängberg Nordborg et al., 2022; Whyte et al., 2004). However, as most of the studies are retrospective cohort studies, the certainty of the evidence reported remains low (Wängberg Nordborg et al., 2022). Severe adverse outcomes in vaginal breech deliveries are rare, and several studies have shown that with the proper selection of women and skilled obstetric staff, breech VD can be safe in places where vaginal delivery is a common practice (Bjellmo et al., 2017; Goffinet et al., 2006; Kayem et al., 2015; Lorthe et al., 2019; Macharey et al., 2018; Macharey, Ulander, et al., 2017; Mattila et al., 2015; Toivonen et al., 2012, 2018; Vistad et al., 2013). The mode of delivery should be determined based on gestational weeks and the risk

factors associated with a particular pregnancy (A. E. Toijonen et al., 2020). The evidence regarding long-term risks for the mother and child after a planned breech VD compared to a planned CS is scattered (Wängberg Nordborg et al., 2022). Even if CS reduces short-term child morbidity, there is little or no evidence of a difference in child morbidity between delivery modes at long-term follow up (Azria et al., 2016; Macharey et al., 2018; Wängberg Nordborg et al., 2022; Whyte et al., 2004). CS may, however, cause immediate and long-term adversity for the mother, child, and subsequent pregnancies. Therefore, the risks associated with a planned breech VD should be weighed against the risks for complications related to CS (Bjellmo et al., 2017; Impey et al., 2017; Keag et al., 2018; Reddy et al., 2015; A. Toijonen et al., n.d.; Vinkenvleugel et al., 2020; Vlemmix et al., 2014). The lower threshold for urgent CS when the fetus is in breech presentation compared to cephalic presentation should also be considered.

The risk for birth injury is reported to be higher in breech VD than in breech CS but comparable to cephalic VD (Berhan & Haileamlak, 2016; Goffinet et al., 2006), Table 8. In a retrospective national register study from Canada, the overall incidence of birth injury in singleton breech deliveries after 37 weeks of gestation was 0.8% of live births (Lyons et al., 2015). The incidence of birth injury in breech VD, in-labor CS, and planned CS was 3.0%, 1.0%, and 0.6% of live births, respectively (Lyons et al., 2015). The incidence of birth injury in planned breech VD in singleton deliveries after 37 weeks of gestation ranges from 0.4% to 7.4%, whereas in planned CS the incidence ranges from 0.1% to 0.9% (Azria et al., 2012; Berhan & Haileamlak, 2016; Bin et al., 2016; Hannah et al., 2000; Lyons et al., 2015; Vlemmix et al., 2014), Table 8. Following the results of the Term Breech Trial (Hannah et al., 2000), the rate of planned CS in the Netherlands rose from 24% to 60%, and the overall rate of CS in breech presentation was nearly 80% in 2007 (Vlemmix et al., 2014). At the same time, the incidence of birth injury in the breech VD group decreased from 0.6% in 1999 to 0.4% in 2007 (Vlemmix et al., 2014).

Brachial plexus palsy, long bone fractures, and hematomas/contusions are the most common birth injuries among neonates in breech presentation (Azria et al., 2012; Goffinet et al., 2006; Hannah et al., 2000; Jennewein et al., 2018; Lalka et al., 2020; Lyons et al., 2015; van der Looven et al., 2020; Vlemmix et al., 2014), Table 9. Spinal cord injuries are rare, but the risk increases among neonates with breech presentation, especially among preterm neonates after head entrapment (Brand, 2006; MacKinnon et al., 1993; Reichard, 2008; Vialle et al., 2007). Femur fractures are linked to breech presentation and breech CS (Basha et al., 2013; Högberg et al., 2020; Morris et al., 2002; Toker et al., 2009; von Heideken et al., 2020).

Breech VD is associated with an increased risk for BPP (Lalka et al., 2020; van der Looven et al., 2020). The injury may be due to forceful traction during delivery or to difficulties in delivering the head. In a breech presentation, the injury is associated with a higher rate of bilateral injury, concurrent phrenic nerve palsy, avulsion type of injury rather than rupture, fewer total injuries, lower birth weight, and a worse prognosis than injuries among neonates with a cephalic presentation (Al-Qattan, 2003; Al-Qattan et al., 2010; Blaauw et al., 2004; Geutjens et al., 1996). Unnecessary strong traction of both shoulders during a difficult head delivery may explain the higher rate of bilateral injuries (Al-Qattan, 2003). In breech VD, adverse outcomes and birth injuries are more often associated with low birth weight rather than high birth weight (Hinnenberg et al., 2019; Jennewein et al., 2018; Macharey, Ulander, et al., 2017; Vlemmix et al., 2014). However, higher birth weight increases the risk for unplanned CS compared to lower birth weight (Jennewein et al., 2018). It has been suggested that the passive management of breech VD and the choice of positions, such as the upright position requiring fewer maneuvers, may be related to a reduced risk for birth injury (Louwen et al., 2017). However, clinical guidelines do not prefer any particular birth position or maneuver (Morris et al., 2022).

Table 8. The number and incidence of birth injury in singleton breech delivery among neonates born at 37 gestational week or later.

Study	Study design	Included injury types		of injuries ence %)
			Planned VD	Planned CS
Hannah et al. 2000	Randomized multicenter trial, 1997–2000, n = 2083 Planned CS rate: 45% Actual VD rate: 31%	Subdural hematoma, intracerebral or intraventricular hemorrhage, spinal cord injury, basal skull fracture, long bone fracture, peripheral nerve injury, genital injury	14 (1.4)	6 (0.6)
Azria et al. 2012, France, Belgium	Prospective observational, 2001–2002, Planned VD n = 2502 Actual VD rate: 71%	Subdural hematoma, intracerebral or intraventricular hemorrhage, spinal cord injury, basal skull fracture, peripheralnerve injury, genital injury	9 (0.4)	
Berhan et al. 2016	Meta-analysis of 27 observational studies, 1993–2014, n = 258 953	Fracture of clavicle, humerus or femur, intracerebral bleeding, cephalic hematoma, facial nerve paresis, brachial plexus injury, other trauma	421 (0.7)	80 (0.2)
Bin et al. 2016, Australia	Retrospective register, 2009–2012, n = 10 133 Planned CS rate: 76% Actual VD rate: 4.2%	Intracranial laceration, injuries to the central nervous system, scalp or skeleton, brachial plexus birth injury, injury to other parts of the peripheral nervous system, or external genitalia, other birth injury	26 (7.4)	36 (0.9)
Lyons et al. 2015, Canada	Retrospective national register, 2003–2011 n = 52 671 Planned CS rate: 88% Actual VD rate: 3.0%	Intracranial laceration or hemorrhage, other injury to the central nervous system, scalp injury, brachial plexus or phrenic nerve palsy, injury to the skeleton, other parts of the peripheral nervous system or external genitalia, other birth injury	95 (1.5)	276 (0.6)
Vlemmix et al. 2014, Netherland s	Retrospective national register, 1999–2007*, n = 45 937 Planned CS rate: 60% Actual VD rate: 22%	Intracerebral bleeding, cephalic hematoma, facial nerve paresis, brachial plexus palsy, clavicle, humerus or femur fracture, other trauma	76 (0.4)	27 (0.1)

Planned VD, Planned vaginal breech delivery. Neonates delivered vaginally or by urgent cesarean section; Planned CS, Planned/elective cesarean section in breech presentation; VD, vaginal delivery; * years 2000–2007 included

Different types of birth injuries in breech deliveries. Table 9.

				Num	Number of birth injuries (incidence %)	(incidence %				
	Hannah	Hannah et al. 2000	Vlemmix	Vlemmix et al. 2014*	Azria et al. 2012	ä	Ekeus et al. 2017	_	Lyons et	Lyons et al. 2015
	Planned VD	Planned CS	Planned VD	Planned CS	Planned VD	Planned VD	Planned CS	Q	Q	Planned CS
HOI	2 (0.2)		1 (0.04)	1 (0.004)	1 (0.04)	5 (0.06)	2 (0.01)	3 (0.2)		
Spinal cord injury		1 (0.1)								
Other injury to CNS									я	10 (0.02)
Skull fracture	•	1 (0.1)	1 (0.04)		1 (0.04)					
Clavicle or other long	6 (0.6)	1 (0.1)		9 (0.03)					6 (0.4)	83 (0.2)
Brachial plexus injury	5 (0.5)	2 (0.1)	5 (0.2)	6 (0.02)	5 (0.2)	12 (0.1)	5 (0.03)	11 (0.6)	я	9 (0.02)
Genital injury	2 (0.2)	1 (0.1)	2 (0.08)		2 (0.08)					
Other injury				11 (0.04)					34 (2.1)	185 (0.4)

Planned VD, planned vaginal delivery (includes succeeded vaginal deliveries and urgent cesarean sections); Planned CS, Planned/elective cesarean section; VD, vaginal

* Vlemmix: included year 2000–2007;

Ekeus et al: Retrospective national register study from Sweden. The rate of planned CS was 70% of all breech deliveries. The actual vaginal breech delivery rate was 6.4% of breech deliveries.

ICH, Intracerebral or intraventricular hemorrhage; CNS, central nervous system $^{\circ}$, less than five

2.4.3.2 Preterm breech delivery and birth injury

The preferred mode of delivery for preterm neonates with breech presentation also remains controversial (Bergenhenegouwen et al., 2014; Grabovac et al., 2018; Schmidt et al., 2019; Vinkenvleugel et al., 2020). Some studies (Bergenhenegouwen et al., 2014; Grabovac et al., 2018; Källén et al., 2015), but not all (Kayem et al., 2015; Lorthe et al., 2019; Toivonen et al., 2018; Tucker Edmonds et al., 2015; Vinkenvleugel et al., 2020), have reported that CS is associated with reduced neonatal mortality and morbidity when compared to vaginal delivery. However, the methodological differences and heterogeneity, the small number of included neonates, and the variety in obstetric care and CS rates complicate the comparison of different studies (Schmidt et al., 2019).

Birth injuries in preterm breech deliveries are rare but more often seen after vaginal deliveries than after CS. Single-center cohort studies from Australia have reported an increased risk for BPP among preterm neonates with breech VD (Wang et al., 2020), and a reduced risk for bruises and head entrapment between 23 and 27 gestational weeks in CS compared to VD (Hills et al., 2018). A systemic review including neonates between 23 and 27 gestational weeks also reported reduced odds for severe intraventricular hemorrhage after CS (Grabovac et al., 2018). It is reported that macrocephaly, extended fetal neck, narrow maternal pelvis, the prolonged second stage of labor, incompletely dilated cervix, and fast the descent of the fetus are all associated with increased risk for head entrapment (Offringa et al., 2019). Furthermore, head entrapment, with a reported incidence of 0.7% to 7.7% of preterm breech VD, is associated with spinal cord injuries and high mortality (Claire et al., 2022; Hills et al., 2018; Kayem et al., 2015; Lorthe et al., 2019; Vialle et al., 2007). A difficult delivery of the head is also a possible complication in preterm breech CS (Kayem et al., 2015; Robertson et al., 1995, 1996).

2.5 Prevention of birth injuries and clinical practice guidelines

2.5.1 Identification and management of macrosomia

Based on previous studies, the high birth weight of neonates increases the risk for birth injury. However, the rate of adverse outcomes at a given birth weight in clinical trials is probably an overestimate of the frequency of the outcome (Chauhan, Grobman, et al., 2005). The exact birth weight used in most studies is only known postpartum, and the antenatal weight estimation performed by ultrasound or clinical measurement is imprecise (Barth & Jackson, 2020; Chauhan, Grobman, et al., 2005; Khan et al., 2019). The error in sonographic weight estimation is approximately 10% (Scioscia et al., 2008). It is also widely known that the detection accuracy of ultrasound for macrosomia is poor (Chandrasekaran, 2021). For birth weight >4000 grams or >90th percentile for a given gestational age, ultrasound more often underestimates than overestimates the fetal weight (Barth & Jackson, 2020; Malin et al., 2016). The probability of detecting a neonate with a birth weight of more than 4000 grams with ultrasound ranges from 15% to 80% among uncomplicated deliveries and is more than 60% among the pregnancies of women with diabetes (Chauhan, Grobman, et al., 2005). The identification of neonates with birth weight ≥4500 grams is even more imprecise, with an ultrasound prediction rate of 20% to 35% (Barth & Jackson, 2020; Chauhan, Grobman, et al., 2005).

Prenatal identification of macrosomia enables the induction of labor or elective CS for selected pregnancies and, therefore, may reduce the adverse events associated with macrosomia. However, evidence of benefits of these interventions is inconsistent (Barth & Jackson, 2020; Boulvain et al., 2015; Boulvain & Thornton, 2023; Chandrasekaran, 2021; Chauhan, Grobman, et al., 2005). According to clinical guidelines, elective CS is thought to be beneficial in reducing the risk for birth injury and shoulder dystocia when the estimated fetal weight is more than 5000 grams in pregnancies of women without diabetes and more than 4500 grams in pregnancies of women with diabetes (Barth & Jackson, 2020; Crofts et al., n.d.; "Practice Bulletin No 178: Shoulder Dystocia," 2017; Sentilhes et al., 2016).

A randomized control trial (RCT) involving 818 pregnant women from 19 tertiary centers concluded that induction of labor at 37 to 38 weeks of gestation for suspected LGA was associated with a reduced risk for birth fractures and shoulder dystocia, without increasing the risk for CS, operative vaginal delivery, or severe morbidity (Boulvain et al., 2015). There was, however, no difference between the

groups in the risk for rare events such as BPP, ICH, or death (Boulvain et al., 2015). A Cochrane review of four RCTs on induction of labor for suspected macrosomia versus expectant management, which also included the abovementioned RCT, summarized that the risk for fractures and shoulder dystocia decreased in the induction group. However, no difference was found between groups in the risk for BPP (Boulvain & Thornton, 2023). The authors of the Cochrane review concluded that the power of the included studies was limited due to the rarity of BPP. In a retrospective cohort study, no evidence of a difference in the odds for birth injury was seen between the induction of labor for suspected macrosomia (birth weight 4000 grams, 4250 grams, and 4500 grams) at 39, 40, or 41 weeks of gestation and expectant management. However, in a subgroup analysis, neonates with a birth weight of 4000 grams ±125 grams had higher odds for a birth injury in the expectant management group until 42 weeks of gestation than those being induced at 41 weeks of gestation (Cheng et al., 2012). Furthermore, a Cochrane review assessing low-risk pregnancies stated that there is little or no difference in the odds of birth injury (RR 0.97, 95% CI 0.63 to 1.49) between induction of labor after 37 weeks of gestation and expectant management options (Middleton et al., 2020). This review included a total of 34 RCTs, and 5 of these RCTs assessed birth injuries.

At present, there is no consensus on the appropriate gestational age for induction of labor for macrosomia. It has been proposed that the risk for shoulder dystocia may be reduced by induction at 39 weeks of gestation. However, there is probably no justification to induct before 38 gestational weeks (Chandrasekaran, 2021). Interestingly, the American College of Obstetricians and Gynecologists (ACOG) discourages induction of labor solely for suspected macrosomia at any gestational age and delivery before 39 weeks of gestation, unless medically indicated ("Practice Bulletin No 178: Shoulder Dystocia," 2017). However, for prevention of shoulder dystocia, the French guideline recommends induction of labor if macrosomia is suspected and the cervix is favorable after 39 weeks of gestation (Sentilhes et al., 2016).

To conclude, there is inconsistency in the benefits of prenatal awareness of macrosomia. Although prenatally identified macrosomia increases the rates of labor induction and antenatal CS, it does not necessarily reduce the rate of birth injuries, asphyxia-related sequelae, or shoulder dystocia (Dodd & Lindqvist, 2021; Vitner et al., 2019). Moreover, the sensitivity of antenatally suspected macrosomia to predict complications such as shoulder dystocia or birth injuries, is limited (Moraitis et al., 2020). Often, injured neonates have a normal birth weight, and only a few neonates

with a birth weight between 4000 grams and 5000 grams are born with BPP (Backe et al., 2008).

2.5.2 Clinical guidelines for diabetic pregnancies

In Finland, the management of the pregnancies of women with diabetes follows national guidelines (The Medical Advisory Board of the Finnish Diabetes Association et al., 2012; Working group established by the Finnish Medical Society Duodecim, 2013). In pregestational diabetes, delivery is recommended between 38 and 40 weeks of gestation, and the mode of delivery is chosen based on obstetrical indications if the estimated fetal weight measured by antenatal ultrasound is between 4000 and 4250 grams. Furthermore, CS is suggested if the weight estimation is more than 4500 grams (The Medical Advisory Board of the Finnish Diabetes Association et al., 2012). Further, for women with GDM who undergo pharmacological treatment, the guidelines recommend delivery between 38 and 40 gestational weeks and before 41⁺³ gestational weeks for women with GDM who undergo dietary treatment. CS is recommended if fetal weight is estimated to be over 4500 grams in women with GDM who are treated with medication (Working group established by the Finnish Medical Society Duodecim, 2013).

International guidelines on the management of diabetic pregnancies recommend delivery before 39 to 40 weeks of gestation for women with pregestational diabetes and earlier if glucose control is poor or complications occur ("ACOG Practice Bulletin No. 201: Pregestational Diabetes Mellitus," 2018; NICE guideline, 2015; Rudland et al., 2020). For women with GDM, delivery is advised before 41 weeks of gestation (Caughey & Turrentine, 2018; NICE guideline, 2015), and at 39 weeks of gestation for women treated with medication (Caughey & Turrentine, 2018). Induction of labor is an option, although there is a lack of evidence on the benefits of induction ("ACOG Practice Bulletin No. 201: Pregestational Diabetes Mellitus," 2018; NICE guideline, 2015; Rudland et al., 2020). Operative vaginal delivery is also possible but should be considered carefully due to the increased risk for shoulder dystocia. CS is recommended with an estimated fetal weight of 4500 grams or more ("ACOG Practice Bulletin No. 201: Pregestational Diabetes Mellitus," 2018; Caughey & Turrentine, 2018; Rudland et al., 2020; Sentilhes et al., 2016).

2.5.3 Clinical guidelines for operative vaginal birth

Operative vaginal birth is indicated for maternal or fetal reasons. It is commonly used to hasten the delivery when fetal compromise is suspected or the second stage of labor is prolonged or needs to be shortened for the benefit of the mother (Peaceman, 2020; Tsakiridis et al., 2020). For operative vaginal delivery, it is required that the cervix is fully dilated, the head is engaged, the position of the head is determined, and the pelvis is adequate in relation to fetal weight (Murphy et al., 2020; Peaceman, 2020; Women's Health Committee (RANZCOG), 2020). In Finland, the vast majority of operative vaginal births are vacuum-assisted deliveries, and the use of forceps is sporadic (Finnish Institute of Health and Welfare, 2020).

A safe lower limit for gestational age or birth weight in operative vaginal birth has not yet been determined (Peaceman, 2020; Working group set up by the Finnish Medical Society Duodecim and the Finnish Gynaecological Association, 2018). The national guideline directs the management of preterm deliveries in Finland (Working group set up by the Finnish Medical Society Duodecim and the Finnish Gynaecological Association, 2018). According to the guideline, the personal risks and benefits of CS and vacuum delivery should be considered. After 32 weeks of gestation, vacuum-assistance can be used with caution (Working group set up by the Finnish Medical Society Duodecim and the Finnish Gynaecological Association, 2018). Practitioners are advised to be aware of the increased risk for scalp injuries and intra- and extracranial bleeding among preterm neonates (Murphy et al., 2020; Working group set up by the Finnish Medical Society Duodecim and the Finnish Gynaecological Association, 2018). The Royal College of Obstetricians and Gynaecologists (RCOG) recommends caution in operative vaginal births between 32 and 36 gestational weeks. In contrast, The American College of Obstetricians and Gynecologists and The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (ACOG and RANZCOG) discourage operative vaginal birth before 34 gestational weeks (Murphy et al., 2020; Peaceman, 2020; Tsakiridis et al., 2020; Women's Health Committee (RANZCOG), 2020). Operative vaginal birth is contraindicated if a fetal bleeding disorder or bone demineralization disease is suspected due to increased risk for hemorrhage and fractures (Peaceman, 2020; Women's Health Committee (RANZCOG), 2020).

2.5.4 Clinical guidelines for breech delivery

There is no written national guideline for breech presentation Finland. The clinical practices used nationwide for breech pregnancies and deliveries after 37⁺⁰ weeks of gestation follow the recommendations of large international guidelines, such as ACOG and RCOG (an inquiry addressed to the tertiary level obstetrics centers) ("ACOG Committee Opinion No. 745: Mode of Term Singleton Breech Delivery," 2018; Impey et al., 2017). The external cephalic version is offered for women with a fetus in breech presentation between 35 and 37 weeks of gestation. A vaginal breech delivery can be considered if the mother is agreeable to vaginal delivery, the estimated fetal weight is less than 4000 grams, and the fetus is in a frank, complete, or incomplete breech position with the head in a flexed position during the delivery. Frequently, magnetic resonance pelvimetry is used to verify the sufficient measurements of the pelvis. CS is recommended if intrauterine growth restriction is suspected or the fetus is otherwise at high risk for distress during delivery. Cardiotocography monitoring is used during breech labor. Shoulders and arms are often assisted by the Løvset maneuver or the posterior arm is brought down with the classic maneuver. The head is then delivered by the Mauriceau-Smellie-Veit maneuver or Bracht maneuver by a gynecologist. The Løvset and Mauriceau-Smellie-Veit maneuvers are used most often. In complicated deliveries, the head can be delivered with the Prague maneuver or with forceps. Minimally assisted techniques or upright position are not routinely applied, and the management of delivering shoulders and the head is rather active (Macharey, 2018; Macharey, Ulander, et al., 2017; Toivonen et al., 2012; Working group set up by the Finnish Association of Perinatology, 2021). Urgent CS is performed if fetal distress is suspected or the delivery is otherwise complicated. The national guideline for the managing of preterm deliveries recommends CS as a mode of delivery, especially for primiparas and before 32 gestational weeks if the fetus is in breech presentation (Working group set up by the Finnish Medical Society Duodecim and the Finnish Gynaecological Association, 2018). According to the inquiry sent to tertiary-level obstetrics centers, there might be more individual consideration/variation in managing preterm breech deliveries than in term breech deliveries. The mode of delivery in preterm breech pregnancies is chosen by taking into account many clinical aspects such as parity, proportions and weight of the fetus, gestational age (<28 gestational weeks, <32 gestational weeks), and the possible preterm rupture of membranes.

International clinical guidelines for breech deliveries describe antenatal and delivery management in detail ("ACOG Committee Opinion No. 745: Mode of

Term Singleton Breech Delivery," 2018; Impey et al., 2017; Kotaska et al., 2009; Macharey, 2018; Morris et al., 2022; Sentilhes et al., 2020; Vistad et al., 2013). To summarize, the importance of antenatal counseling is highlighted. Adequate maternal pelvis and fetal antenatal and intrapartum well-being must be ensured. Furthermore, a fetus should be in frank or complete breech position, neck flexed, estimated weight between 10th percentile for a given gestational age (or 2500–2800 grams) and 3800–4000 grams, and adequate descent should occur during the passive second stage. In the active second stage, it is suggested that pushing begins when the fetus is engaged as low as possible and traction should be avoided if possible.

Preterm breech delivery is less discussed in clinical guidelines. CNGOF concludes that no recommendation can be given due to insufficient data (Sentilhes et al., 2020). Further, RCOG states that CS is not routinely recommended for preterm breech neonates, and the mode of delivery is determined individually (Impey et al., 2017). However, NICE guidelines recommend considering CS with breech presentation between 26 and 36 weeks of gestation (London: National Institute for Health and Care Excellence, 2015).

2.5.5 Simulation training

The recognition and appropriate management of shoulder dystocia are likely to reduce birth injuries (Brogaard et al., 2022; Crofts et al., 2016; Wagner et al., 2021). International clinical guidelines recommend regular simulation training to improve the management of shoulder dystocia ("Practice Bulletin No 178: Shoulder Dystocia," 2017; Sentilhes et al., 2016). Nevertheless, two recent systematic reviews and meta-analyses on obstetric simulation training concluded that the optimal approach for effective training needs further study. For example, it is still being determined to whom simulation training should be targeted, and how often the training should be arranged (Brogaard et al., 2022; Sollid et al., 2019; Wagner et al., 2021).

A meta-analysis of 16 randomized and non-randomized studies, including 428 552 deliveries, reported that the incidence of BPP after shoulder dystocia was halved after the implementation of shoulder dystocia simulation, and that the overall incidence of BPP decreased from 0.3% to 0.1%. In addition, there was some evidence of a reduction in the incidence of clavicle and humerus fracture concurrent with shoulder dystocia, and the diagnoses of shoulder dystocia increased. Nevertheless, the results on persistent BPP were limited and contradictory, and a

concerning increase in CS rate was seen (Wagner et al., 2021). Another meta-analysis concluded that simulation training may reduce the risk for BPP, but the certainty of the evidence was low (Brogaard et al., 2022). In addition to shoulder dystocia, simulation-based training is also used to improve the management of operative vaginal birth and breech deliveries (Bligard et al., 2019; Walker et al., 2017).

During the last decade, simulation training has become more systematic in Finland. In 2015, regular multi-professional simulation training started at Helsinki University Women's Hospital, and a national simulation training program for obstetric emergencies was launched in 2020 (Kaijomaa et al., 2022; Working group set up by the Finnish Association of Perinatology, 2021). A cohort study conducted at Helsinki University Hospital between 2010 and 2019 reported an apparent reduction in the incidence of permanent BPP after shoulder dystocia (44%-6%) among 113 785 cephalic vaginal deliveries. In absolute numbers, between 2015 and 2019 there was in total 13 persistent BPP cases fewer than between 2010 and 2014. In addition, the overall incidence of permanent BPP decreased (0.05%–0.02%). An increase in the incidence of shoulder dystocia and successful delivery of the posterior arm was seen in the latter part of the study after the beginning of the simulation training (Kaijomaa et al., 2022). Thus, the onset of simulation-based and hands-on training may have improved the safety of breech vaginal deliveries and the management of shoulder dystocia and vacuum deliveries in the last couple of years of our study (Heinonen et al., 2020; Kaijomaa et al., 2022; Working group set up by the Finnish Association of Perinatology, 2021).

3 AIMS OF THE STUDY

The study was conducted to assess national neonatal safety in obstetric care by investigating birth injuries. The main objective was to describe the incidence of different birth injuries, the risk factors for injuries, and the epidemiological changes associated with birth injuries during the last decades. The specific aims of the study were as follows:

- 1. To describe incidence rates and temporal changes of all birth injuries diagnosed during the 21-year study period, between 1997 and 2017, in Finland (Study I).
- 2. To explore risk factors for clavicle fracture and the epidemiological changes in those risk factors occurring between 2004 and 2017 (Study II).
- 3. To examine severe birth injuries among women with different types of diabetes (Study III).
- 4. To determine the incidence of birth injuries among breech deliveries at different gestational weeks and birth weights and to identify the risk factors for severe birth injury in breech delivery (Study IV).

4 SUBJECTS AND METHODS

4.1 Data sources

All four studies were based on retrospective register data. The registers used for these nationwide cohort studies were the Finnish Medical Birth Register (MBR) and the Care Register for Health Care (CRHC). The coverage of these registers is excellent (Gissler et al., 1995; Gissler & Shelley, 2002; Heino et al., 2018; Sund, 2012).

4.1.1 Finnish Medical Birth Register

The Finnish Medical Birth Register (MBR) is a nationwide register established in 1987 and maintained by the Finnish Institute for Health and Welfare (THL). Reforms of the register in 1990, 1996, 2004, and 2017 have increased the amount of collected data and improved its reliability. The MBR includes data on all live or stillborn neonates with a gestational age of at least 22⁺⁰ weeks of gestation or birthweight of at least 500 grams. The MBR includes socio-demographical data, information on maternal age, smoking status, previous pregnancies, diagnoses, and hospitalizations during pregnancy. In addition, interventions during delivery and mode of delivery are also recorded. Further, the MBR includes detailed data on the neonates such as, the place of birth (in- or out-of-hospital) and date, gestational weeks at birth, sex, birth weight, height, head circumference, Apgar score, pH of umbilical blood, diagnoses, and interventions during the first seven days after birth. Data collection is mandatory. The data are prospectively collected from maternal and child welfare clinics and maternity and neonatal wards and linked with the Central Population Register and the Causes-of-Death Register of Statistics Finland (Finnish Institute of Health and Welfare, 2020).

4.1.2 Care Register for Health Care

The Care Register for Health Care (CRHC) is a continuation of the previous Hospital Discharge Register. It has nationwide coverage, and all hospitals in Finland must provide information to the register. The data are reviewed at routine intervals for missing data, and hospitals are mandated to correct any errors when found. The CRHC contains information on the patients' characteristics (e.g., sex, date of birth, place of residence), length of hospital stays, diagnosis (ICD-10 codes), and operations performed during a hospital stay. The CRHC also includes a personal identification number which allows linking the registered data to other data sources, such as the MBR (Finnish Institute for Health and Welfare, 2021).

4.2 Study population

All four studies were conducted using data from the MBR and CRHC. The study population covered all live-born neonates between January 1, 1997, and December 31, 2017, in Finland. A summary of the studies is presented in Table 11.

Study I included all live-born neonates during the whole study period (n = 1 203 434). Studies II–IV covered singleton live-born neonates born in hospital from January 1, 2004, to December 31, 2017 (n = 807 207). These years were selected based on improvements made to the MBR. After 2004, prenatal, delivery, and perinatal characteristics were more extensively registered than in previous years, enabling a more detailed analysis of baseline characteristics and risk factors.

Multiple pregnancies were excluded from studies II—IV due to the unique features and risks associated with them. Furthermore, as the number of forceps deliveries was small and decreasing, they were also excluded from studies II—IV.

Study II covered neonates born at 37⁺⁰ weeks of gestation or thereafter. These gestational weeks were chosen because 99% of skeletal injuries were sustained at 37 weeks of gestation or later in study I. Study III included neonates born between 35⁺⁰ and 42⁺⁶ gestational weeks, as birth injuries were rare before 35 weeks of gestation. Also, complications associated with the pregnancies of women with pregestational diabetes and extremely/very preterm neonates affected the inclusion criteria. In study IV, the gestational age was limited to between 24⁺⁰ and 42⁺⁶ gestational weeks.

In study II, neonates with an osteochondrodysplasia (ICD-10 Q78.00–Q78.9) or spina bifida (ICD-10 Q05.0–Q05.9) were excluded because they could have had a higher risk for clavicle fracture than the other neonates. Initially, 724 552 neonates

born in a cephalic presentation met the inclusion criteria (II). CSs ($n = 95\ 095$) were removed from the risk factor analyses due to the low incidence of clavicle fractures. Consequently, 629 457 neonates were included in the final analysis (564 598 spontaneous vaginal deliveries and 64 859 vacuum-assisted deliveries).

Study III contained vaginally delivered neonates with cephalic presentation (n = 623 649). Among the study population, 1659 parturients had T1D, 548 had T2D, 77 810 had GDM, and 543 632 were women without diabetes. Major congenital anomalies were excluded from this study as they could have affected the neonates' outcome. Major congenital or chromosomal defects were defined as other than minor anomalies defined by the European Surveillance of Congenital Anomalies (EUROCAT) (EUROCAT, 2014).

Study IV covered breech deliveries and the spontaneous or vacuum-assisted deliveries of neonates with cephalic presentation. Neonates who had a birth weight of less than 500 grams, a presentation other than breech or cephalic, and CS with a cephalic presentation were excluded. In addition, major congenital or chromosomal defects, as defined in study III (EUROCAT, 2014), deliveries with placenta previa, placental abruption, or uterine rupture were excluded due to the possible effect on the health of neonates. Finally, there were 650 528 neonates, of which 4344 neonates had vaginal breech delivery (breech VD), 16 979 had a CS with breech presentation (breech CS), and 629 182 had a cephalic vaginal delivery (cephalic VD) (564 928 spontaneous vaginal delivery and 64 254 vacuum-assisted delivery). Breech CS included planned, and unplanned cesarean section.

4.3 Methods

4.3.1 Outcome variables

Birth injuries were defined based on diagnosis codes. Both registers, MBR and CRHC, use the Finnish implementation of the 10th Revision of International Statistical Classification of Diseases and Related Health Problems (ICD-10) for recording diagnoses. In addition to collecting birth injury codes (ICD-10 P10*–P15*) from the MBR, we also included all hospital visits with any birth injury diagnosis recorded into the CRHC during the first year after birth to increase the data coverage concerning birth injuries beyond seven days after birth.

In study I, the main outcomes were the incidence of different birth injuries and changes in the incidence of injury between 1997 and 2017. The following birth injury codes were identified: intracranial laceration or hemorrhage due to birth injury (P10.0–P10.4, P10.8, P10.9), other birth injuries to central nervous system (P11.0–P11.5, P11.9), birth injury to scalp (P12.0–P12.4, P12.8, P12.9), birth injury to skeleton (P13.0–P13.4, P13.8, P13.9), birth injury to peripheral nervous system (P14.0–P14.3, P14.8, P14.9), and other birth injuries (P15.0–P15.6, P15.8, P15.9).

Study II focused on clavicle fractures (P13.4). The main outcomes of the study were the risk factors for clavicle fracture, the temporal change in the risk factors, and the incidence of clavicle fracture between two time periods.

Study III assessed the incidence, and associated risk factors, of severe birth injuries in women diagnosed with pregestational diabetes (T1D or T2D) or GDM and compared the outcomes (birth injuries) with women who were not diagnosed with diabetes. Severe birth injury was defined as one or more of the severe birth injuries presented by Muraca et al. (G. M. Muraca et al., 2018), Table 10. Injuries categorized as severe birth injuries may cause long-term morbidity or require interventions.

Study IV examined the type, rate, and risk factors for birth injuries in the breech VD group, the breech CS group, and the cephalic VD group. The primary outcome variables were severe and mild birth injury (Table 10). Birth injuries other than those included in the severe birth injury group were defined as mild birth injuries. Neonates with both mild and severe birth injury were included in the severe birth injury group only.

Table 10. Mild and severe birth injuries. Severe birth injury as defined by Muraca et al. (G. M. Muraca et al., 2018).

Severe birth injury	ICD-10 codes
Intracranial hemorrhage or laceration	P10.0-P10.9
Severe central nervous system injury	P11.0- P11.2, P11.4-P11.5
Subaponeurotic hemorrhage	P12.2
Skull fracture, long bone injury other than clavicle fractures	P13.0, P13.2, P13.3
Brachial plexus injury	P14.0-P14.3
Injury to the liver or spleen	P15.0, P15.1
Mild birth injury	ICD-10 codes
Facial nerve and unspecified central nervous system injury	P11.3, P11.9
Cephalhematoma, chignon, other and unspecified scalp injury	P12.0, P12.1, P12.3-P12.9
Skull injury, clavicle fracture, other and unspecified injury to skeleton	P13.1, P13.4, P13.8, P13.9
Other and unspecified peripheral nervous system injury	P14.8, P14.9
Sternomastoid, eye, face, external genital, other and unspecified birth injury	P15.2-P15.9

Table 11.Summary of studies.

	Study I	Study II	Study III	Study IV
The objective of the study	To describe the rates and trends of birth injuries	To examine risk factors for clavicle fracture, describe temporal changes, and seek explanation for the decreased incidence of clavicle fracture	To compare severe birth injuries among diabetic pregnancies to non-diabetic pregnancies	To identify risk factors for mild and severe birth injuries in breech deliveries, and compare birth injuries in breech deliveries to cephalic VD
Study design Data collection Study period Main outcomes	Retrospective cohort MBR, CRHC Jan 1997–Dec 2017 Birth injury (P10–P15) incidence, temporal changes	Retrospective cohort MBR, CRHC Jan 2004–Dec 2017 Incidence of clavicle fracture, risk factors for clavicle fracture,	Retrospective cohort MBR, CRHC Jan 2004–Dec 2017 Severe birth injury incidence, risk factors for severe birth	Retrospective cohort MBR, CRHC Jan 2004–Dec 2017 Incidence and risk factors for severe and mild birth injury
Live-born neonates	1 203 404	temporal changes of risk factors 629 457	injury 623 649	650 528
Neonates with birth injury	27 179	6577	1934	13817
Inclusion criteria	All live-born neonates	Singleton hospital live births cephalic VD gestational age ≥37 ⁺⁰	Singleton hospital live births cephalic VD gestational age 35 ⁺⁰ to 42 ⁺⁶	Singleton hospital live births breech delivery or cephalic VD gestational age 24 ⁺⁰ to 42 ⁺⁶ birth weight ≥500 grams
Exclusion criteria		Osteochondrodysplasia, spina bifida, forceps delivery	Major congenital or chromosomal defect, forceps delivery	Major chromosomal or congenital defect, forceps delivery, cephalic CS, placenta previa, placental abruption, uterus rupture
CS, cesarean section	CS, cesarean section; VD, vaginal delivery			

CS, cesarean section; VD, vaginal delivery

4.3.2 Maternal, neonatal and delivery characteristics

In study I, neonates were classified into five categories based on gestational age: extremely preterm neonates $(22^{+0} \text{ to } 27^{+6} \text{ gestational weeks})$, very preterm neonates $(28^{+0} \text{ to } 31^{+6} \text{ gestational weeks})$, moderate-to-late preterm neonates $(32^{+0} \text{ to } 36^{+6} \text{ gestational weeks})$, early term to full term neonates $(37^{+0} \text{ to } 40^{+6})$, and late term to post-term neonates $(\ge 41^{+0} \text{ gestational weeks})$.

In studies II–IV, the primary variables were gestational age, mode of delivery, presentation, birth weight, and the type of diabetes. In addition, especially in study II, but also in studies III–IV, numerous variables were analyzed. The variables included in the preliminary analyses are presented in Table 12. A detailed description of the statistics and statistical reports of the MBR can be found on the website (Finnish Institute of Health and Welfare, 2020).

The most accurate estimation of the gestational age, often determined by the last menstruation and confirmed by ultrasound, was collected from the MBR (I–IV). The number of neonates (singleton/multiple) and the mode of delivery were determined by a check-box variable (instead of using ICD-10 codes) (I–IV). Earlier, CS was classified as planned or unplanned, but after 2004 the classification was revised as either elective, urgent, or emergency CS. Since birth injuries were rare in all CS types, planned and unplanned CS were analyzed together in the final analyses (I, II, IV). Recording of a different mode of vaginal delivery remained unchanged during the whole study period (spontaneous vaginal delivery, vaginal breech delivery or breech extraction, forceps delivery, vacuum-assisted delivery) (I–IV). Deliveries defined as "spontaneous vaginal deliveries" also included induced deliveries. Breech presentation at the birth of neonates born by CS was identified by the delivery ICD-10 codes (O32.1, O64.1) (II, IV).

In study II, large for gestational age (LGA) was determined by the ICD-10 code O36.6 used during antenatal care or registered at birth rather than actual LGA diagnosed by birth weight. In studies III and IV, LGA was defined as birth weight of more than +2 standard deviation (SD), and SGA (small for gestational age) less than -2 SD standardized for parity, sex, and gestational age in a Finnish population (Sankilampi et al., 2013).

 Table 12.
 Analyzed variables in studies II, III, and IV.

Variables	Registered by midwife	ICD-10 codes determined by medical doctors
Studies II, III, and IV		•
Age, Height	Х	
Pre-pregnancy BMI	X	
Smoking during pregnancy	X	
Parity, Previous cesarean section	Х	
Administration of antenatal corticosteroids	Х	
Gestational diabetes	Х	O24.4, O24.9
Pregestational diabetes (T1D, T2D)		O24.0, O24.1, E10-E11
Hypertensive disease (chronic or gestational)		010-016
Mode of delivery	Х	080-084
Gestational age	Х	
Labor analgesia (neuraxial, paracervical, pudendal, other)	X	
Use of oxytocin to induct or advance labor	X	
nduction of labor	X	
Shoulder dystocia	X	O66.0
Episiotomy	X	000.0
Birth weight	X	
Neonate length and head circumference	X	
Apgar (1 and 5 min), Umbilical cord Ph (artery, vein)	X	
Early neonatal mortality	X	
Larry neonatal mortality	^	
Study II	<u>-</u>	
Assisted reproduction technology	Х	
Thrombosis prophylaxis during pregnancy (LMWH)	Х	
Anemia during pregnancy	Х	
nsulin treatment started during pregnancy	Х	
Suspicion of SGA (antenatal or labor diagnosis)		O36.5
Suspicion of LGA (antenatal or labor diagnosis)		O36.6
Disproportion or obstructive labor (antenatal or labor diagnosis)		O33, O65
Maternal care for abnormality of pelvic organs (antenatal or labor		O34.0, O34.1, O34.6,
diagnosis)		O34.7
Failed induction of labor		O61
Asphyxia or fetal distress	Χ	O68
nadequate contraction, precipitous labor (evaluated separately)		O62.0-O62.3
Prolonged labor (first and second stage evaluated separately)		O63.0, O63.1
Malpresentation (excluding breech)		064.0, 064.2-064.9
Maternal distress		O75.0
Pyrexia or chorioamnionitis during labor		075.2, 075.3
Vacuum delivery failure		O66.5
Studies II, III, or IV		
GGA (defined by birth weight) (IV)	-	
LGA (defined by birth weight) (III, IV)		
Oligohydramnios (IV)		O41.0
Premature rupture of membranes (IV)		O41.0 O42, O75.6
Neonate admission to intensive care unit (II, IV)	v	O72, O10.0
	X	
Resuscitation, intubation, ventilation (III, IV) Neonate gender (III, IV)	X X	

BMI, Body mass index, reliable data available after 2006; Early neonatal mortality, deaths of live-born neonates during the first week of life; SGA, small for gestational age; LGA, large for gestational age

The diagnosis of pregestational diabetes was based on ICD-10 codes (T1D: O24.0, E10*, and T2D: O24.1, E11*) (II - IV). GDM was described as a pathologic 2-hour 75-grams oral glucose tolerance test and was registered as a check-box variable or by ICD-10 codes 024.4, O24.9 in the MBR (II–IV) (Working group established by the Finnish Medical Society Duodecim, 2013). In 2008, the screening of GDM was revised from the former risk-based screening to more comprehensive screening, resulting in an increased incidence of GDM (Ellenberg et al., 2017; Working group established by the Finnish Medical Society Duodecim, 2013).

Some of the essential variables, for instance, pre-pregnancy body mass index, calculated using self-reported height and weight (BMI, kg/m²) were registered from 2004. Due to missing values from several hospitals in 2004 and 2005, BMI was only included in the analyses after 2005. The registration of shoulder dystocia, pregnancy diagnoses, and delivery diagnoses were also added in the 2004 reform. However, the exact reason for a CS is not registered. In study II, many variables based on ICD-10 codes were analyzed (Table 12). Due to the possibility of variation in diagnosis practices, we used fewer ICD-10 code-based variables in studies III and IV.

In addition, variables describing the health of neonates (Apgar score, etc.) were included in preliminary analyses. As numerous variables, such as gestational age, women's diabetes, and mode of delivery, can affect the outcomes of newborns, and because only birth injury codes were gathered from the CRHC, the main analyses concentrated solely on birth injuries.

4.4 Statistical analysis

Statistical analyses were performed using PASW 19.0 (IBM SPSS) (I), R Statistical Software version 4.0.0 (R Foundation for Statistical Computing, Vienna, Austria) (II), and R Statistical Software version 4.0.3 (R Foundation for Statistical Computing, Vienna, Austria) (III, IV).

The frequency and incidence of different types (I–IV) and a composite of mild and severe birth injuries were calculated (III, IV). Incidences rates were stratified by gestational age in studies I and IV and in different modes of delivery in studies II–IV.

As the MBR contains information on all births in Finland, the incidence rates presented in study I were the precise results for the entire live-born population in

Finland during the study period, rather than cohort-based estimates. As a result, 95% confidence intervals (CIs), essential in cohort or sample-based estimations, were not calculated.

In studies II–IV, categorical background variables were described as proportions, and the groups were compared using chi-squared test (II–IV) and Fisher's exact test (III). Continuous variables were described as means and standard deviations (SDs) or medians with interquartile ranges, and these groups were compared using Welch Two Sample t-test (III, IV) and Mann-Whitney U-test (III, IV). Some of the continuous variables (women's age, women's height, BMI, gestational age, birth weight), which were first analyzed as a continuous variable, were also dichotomized. In addition, the analyses conducted in studies III and IV were calculated using a composite severe/mild birth injury, rather than a single injury as an outcome variable.

In study II, the rate ratio with 95% CI comparing the period 2011–2017 with 2004–2010 was used to describe the temporal change. A rate ratio >1 meant an increased incidence of the calculated variable in 2011–2017. Further, the incidence rate ratio (IRR) with 95% CI was calculated to evaluate the difference in the incidence of clavicle fracture with the most clinically important variables between 2011–2017 and 2006–2010. The variables – shoulder dystocia, T1D, birth weight ≥4000 grams, BMI ≥30 kg/m2, GDM, labor induction, and gestational age ≥41+0 – were chosen based on the risk for clavicle fracture, the temporal change of variables, the accuracy of the registration of the variables, and the clinical interest to evaluate the influence of the timing of the delivery on fracture incidence. Cluster-type analysis of the incidence of clavicle fracture with an increasing number of variables was done to explore the reduced incidence of clavicle fracture. Shoulder dystocia and T1D were excluded from these analyses because of their estimated modest impact on the declining trend of fractures due to their low incidence rates.

An odds ratio (OR) and risk difference (RD), with 95% CI, were calculated (II, III, IV). The odds ratio indicated the odds that injury (clavicle fracture or severe birth injury) will occur within a given exposure group versus an unexposed group. The risk difference indicated the difference between the risk for an injury in an exposed group versus an unexposed group. In study II, relative risk was calculated with 95% CI. A relative risk >1 meant the enhanced impact of a variable on the risk for clavicle fracture in the latter study period (2011-2017). In study III, a ratio of odds (OR-ratio) was used to examine the ratio of odds ratios with 95% CI for a severe birth injury with a given variable in the group of women with diabetes compared to the group of women without diabetes.

Logistic regression analysis was used to assess the effect of primary variables on the risk for injury and to construct risk estimation curves (II–IV). In study IV, a Poisson regression model was used to assess the incidence of birth weight and gestational age by using the number of cases per gestational week/birth weight as an offset term. The model was used separately for mild and severe birth injuries and for different modes of delivery. The statistical significance of the estimates in the regression model was tested using a t-test (IV).

A p-value of <0.05 was considered significant. As the MBR contains information on all births in Finland, the risk for selection bias was estimated to be low.

4.5 Ethical aspects

Under the Act on National Personal Data Registers Kept under the Health Care System (556/1989, section 4), the data stored in the MBR and CRHC are confidential. For scientific research purposes, the National Institute for Health and Welfare (THL) is authorized to allow access this data. Only anonymized data were used. No informed approval of the participants is needed for register-based studies in Finland (the Personal Data Act 1505/2018 section 31, formerly 523/1999, section 14). The data used were preserved in accordance with the THL data security guidelines. This study was approved by the Ethics Committee of Tampere University Hospital 30.5.2017 (reference number R17069). Institutional approval was also obtained from the Finnish Institute for Health and Welfare (reference number THL/1659/5.05.00/2017).

5 RESULTS

5.1 Incidence of birth injury (I–IV)

Between January 1, 1997 and December 31, 2017, there were 1 203 434 live-born neonates, 28 551 birth injuries, and 27 179 injured neonates (2.3%) in Finland (I). Of these, 1372 (5.1%) injured neonates had more than one injury. Skeletal injuries accounted for 48%, scalp injuries 36%, and peripheral nervous system injuries 12% of all injuries. The most common injuries were clavicle fracture, cephalohematoma, and Erb paralysis, with incidence rates of 1.2%, 0.8%, and 0.3% of all live-births, respectively. The frequency and incidence rates of the most common birth injuries are presented in Table 13.

Table 13. Birth injuries between 1997 and 2017 in Finland. The main injury categories and the most common injury types in each subgroup, including 1 203 434 live births and 27 179 injured neonates (I).

ICD-10 codes	Type of birth injury	Injury frequency	Incidence, %
P10	Intracranial laceration and hemorrhage	193	0.02
P10.0	Subdural hemorrhage	97	0.01
P11	Other central nervous system injuries	88	0.01
P11.3	Facial nerve injury	54	0.004
P12	Scalp injuries	10 179	0.8
P12.0	Cephalhematoma	9216	0.8
P13	Skeleton injuries	13 674	1.1
P13.4	Clavicle fracture	13 460	1.1
P14	Peripheral nervous system injuries	3314	0.3
P14.0	Erb's paralysis	3052	0.3
P14.0-P14.3	Brachial plexus injuries	3253	0.3
P15	Other birth injuries	1103	0.1
P15.2	Sternomastoid injury	349	0.03
P10-P15	All birth injuries	28 551	2.4

5.1.1 The incidence of birth injury in different modes of delivery (II–IV)

The frequency and incidence rates of birth injuries in cephalic vaginal delivery and breech delivery are presented in Table 14.

5.1.1.1 Cephalic presentation (II–IV)

The incidence of mild birth injuries in vaginally delivered neonates with cephalic presentation were analyzed in studies II and IV. Between 24^{+0} and 42^{+0} weeks of gestation, the total incidence of injured neonates with a mild birth injury after spontaneous or vacuum-assisted vaginal delivery was 1.9% (11 722/629 182) (IV). Clavicle fracture occurred in 0.9% (6621/724 552) of all neonates born in cephalic presentation at $\geq 37^{+0}$ weeks of gestation (II), and in 1.0% (6380/629 182) of neonates with cephalic VD (IV). The incidence of clavicle fracture among neonates born at $\geq 37^{+0}$ weeks of gestation was 0.9% (5175/564 598) in the spontaneous vaginal delivery (SVD) group, 2.2% (1402/64 859) in the vacuum-assisted delivery group, and 0.05% (44/95 095) in the CS group (II). After clavicle fracture, cephalhematoma was the second most common mild birth injury following cephalic VD (IV). The incidence of cephalohematoma was 0.8% of all live births (4983/629 182).

Study III concentrated on severe birth injuries in singleton neonates with cephalic presentation born between 35⁺⁰ and 42⁺⁶ weeks of gestation. Before excluding unplanned CS from the final analyses, the total incidence of severe birth injury in a SVD was 0.2% (1257/559 552), 1.1% (695/64 097) in a vacuum-assisted delivery, and 0.1% (59/61 296) after an unplanned CS (III). Different types of severe birth injury were 2 to 10 times more common in vacuum-assisted delivery than in SVD. The most evident difference between the vacuum-assisted delivery and SVD groups was in the incidence rates of subaponeurotic hemorrhage and intracranial hemorrhage or laceration, which were 10 and 8 times more frequent in the vacuum-assisted delivery group than in the SVD group (Table 15).

The incidence rates of severe birth injuries after cephalic VD were also evaluated in study IV. In total, 0.3% of live-born neonates had a severe birth injury after vaginal delivery (spontaneous or vacuum-assisted) (III, IV). Brachial plexus palsy covered 86% of the severe birth injuries occurring in vaginal deliveries (an incidence of 0.3% of live births). Intracranial hemorrhage and central nervous system injuries were rare.

Considering the pregnancies of women with diabetes (III), the incidence of severe birth injury in vaginal deliveries was highest in women with T1D (2.5%, 42/1659) and T2D (1.8%, 10/548). However, the incidence of injury in pregnancies of women with GDM was only a little higher than in pregnancies of women without diabetes (0.5%, 415/77 810, and 0.3% 1467/543 632), Table 15.

5.1.1.2 Breech presentation (IV)

In breech VD, a total of 33 neonates had severe birth injury (0.8%, 33/4344) and 63 neonates had mild birth injury (1.5%, 63/4344), Table 14 (IV). The injured neonate often had brachial plexus palsy (P14.0–P14.3), (0.6% of live births, 27/4344), whereas the remaining neonates with severe birth injury had a long bone injury other than clavicle fracture. Clavicle fracture (P13.4), classified into the mild birth injury group, was the second most common injury (0.5% of live births, 23/4344), followed by sternocleidomastoid injury (P15.2) (0.5% of live births, 20/4344). There were no intracranial hemorrhage (P10*) or central nervous system injuries (P11*) in the breech VD group.

The incidence rates of severe and mild birth injuries in breech CS were 0.06% (10/16 979) and 0.2% (35/16 979), respectively.

Table 14. The frequency and incidence of injured neonates in cephalic vaginal delivery, vaginal breech delivery, and cesarean section with breech presentation between 2004 and 2017 (IV).

ICD-10 codes	Type of birth injury	Cephalic VD n = 629 182	Breech VD n = 4344	Breech CS n = 16 979
P10	Intracranial laceration and hemorrhage	78 (0.01)	0 (-)	1 (0.01)
P11	Other central nervous system injuries	33 (0.01)	0 (-)	3 (0.02)
P12	Scalp injuries	5538 (0.9)	6 (0.1)	0 (-)
P13	Skeleton injuries	6460 (1.0)	29 (0.7)	3 (0.02)
P14	Peripheral nervous system injuries	1715 (0.3)	29 (0.7)	8 (0.05)
P15	Other birth injuries	492 (0.1)	34 (0.8)	31 (0.2)
	Severe birth injury	1954 (0.3)	33 (0.8)	10 (0.1)
	Mild birth injury	11 722 (1.9)	63 (1.5)	35 (0.2)
	Any birth injury	13 676 (2.2)	96 (2.2)	45 (0.3)

Severe and mild birth injury as defined in Table 10, also (G. M. Muraca et al., 2018). Cephalic VD, vaginal delivery with cephalic presentation; Breech VD, vaginal breech delivery; Breech CS, cesarean section with breech presentation

In 15. The frequency and incidence of severe birth injury in neonates with cephalic presentation between 35⁺⁰ and 42⁺⁶ weeks of gestation from 2004 to 2017 in Finland (in total, 2011 severe birth injuries, 1952 severe injuries among vaginal delivery) (III). Table 15.

			Number of b	Number of birth injuries (Incidence, % of live births)	., % of live births)		
	Intracranial hemorrhage or laceration	Severe central nervous system injury	Subgaleal hemorrhage	Skull fracture, long bone injury/fracture	Brachial plexus injury	Injury to the liver or spleen	Total number of injuries
	P10-P10.9	P11.0-P11.2, P11.4-P11.5	P12.2	P13.0, P13.2, P13.3	P14.0-P14.3	P15.0, P15.1	
SVD	41 (0.01)	6 (0.001)	66 (0.01)	34 (0.01)	1110 (0.20)	- (0.00)	1257 (0.22)
Vacuum-assisted	37 (0.06)	1 (0.002)	74 (0.12)	23 (0.04)	560 (0.87)	- (0.00)	695 (1.08)
Unplanned CS	11 (0.02)	5 (0.01)	18 (0.03)	12 (0.02)	12 (0.02)	1 (0.002)	59 (0.10)
			Vaginal delive	Vaginal delivery (spontaneous and vacuum-assisted)	vacuum-assisted)		
Type 1 diabetes	1 (0.06)	- (0.00)	2 (0.12)	3 (0.18)	36 (2.17)	- (0.00)	42 (2.53)
Type 2 diabetes	1 (0.18)	- (0.00)	- (0.00)	- (0.00)	9 (1.64)	- (0.00)	10 (1.82)
ВОМ	17 (0.02)	2 (0.003)	19 (0.02)	12 (0.02)	372 (0.48)	- (0.00)	422 (0.54)
No diabetes	59 (0.01)	5 (0.001)	119 (0.02)	42 (0.008)	1253 (0.23)	- (0.00)	1478 (0.27)
SVD, spontaneous vaginal delivery; L	aginal delivery; Unpla	anned CS, includes urg	gent and emergency	cesarean sections; Gl	Juplanned CS, includes urgent and emergency cesarean sections; GDM, gestational diabetes; Clavicle fractures are not included in the	s; Clavicle fractures a	re not included in the

long bone fracture group.

5.1.2 Incidence of birth injury at different gestational ages (I–IV)

The prevalence of different delivery modes was linked to gestational age. A cesarean section was the most frequent delivery mode in preterm deliveries, whereas the rate of spontaneous vaginal deliveries and vacuum-assisted deliveries increased after 32 weeks of gestation (I). Further, the vaginal breech delivery rate fluctuated between 19% and 41% at different gestational ages, Table 16 (IV). The proportion of missing data was low, 0.2% for delivery mode and 0.3% for gestational age, respectively, Table 16 (I).

Table 16. Frequency of live-born neonates and the rate of delivery modes at different gestational weeks (I, IV).

		Ges	tational age in we	eks	
	22+0-27+6	28+0 -31+6	32+0 -36+6	37+0 -40+6	41+0 -
All live-born neonates (n)	3091	6301	58 360	853 707	278 227
SVD (%)	39.3	30.7	54.7	76.0	76.1
Vacuum delivery (%)	0.2	0.8	5.1	6.9	10.5
CS (%)	53.6	66.0	37.5	16.2	13.0
Breech presentation (n)	124	187	1654	18 014	1344
Breech VD (%)	41.1	29.4	30.2	18.5	29.9
Breech CS (%)	58.9	70.6	69.8	81.5	70.1

SVD, Spontaneous vaginal delivery; CS, Cesarean section including elective and unplanned cesarean sections; Breech VD, Vaginal breech delivery

Spontaneous vaginal delivery, vacuum-assisted delivery, and the cesarean section percentages are calculated from the study population I including all live-born neonates from 1997 to 2017 in Finland (n=1 203 434). Breech delivery rates include deliveries between the gestational age 24⁺⁰ and 42⁺⁶, between the years 2004 and 2017 (n=21 323 deliveries with breech presentation), study population IV.

Birth injuries were sporadic among preterm neonates in breech VD and cephalic VD (I, IV). Most injuries (98%) occurred after 37 weeks of gestation, and the total incidence of birth injuries increased with gestational age (Figure 2, Table 17) (I).

For neonates in cephalic presentation, higher gestational age seemed to slightly increase the risk for birth injury (II–IV). Gestational age of ≥41⁺⁰ weeks was a mild risk factor for clavicle fracture (OR 1.31 [95% CI 1.24–1.38], RD 0.003 [0.002–0.004]) (II). In addition, a higher gestational age was associated with a mild increase in risk for injury in pregnancies of women with diabetes (III). Moreover, the

incidence of mild birth injury (1.13 [95% CI 1.11–1.14]) and severe birth injury (1.07 [95% CI 1.04–1.11]) increased along with higher gestational age in the Poisson regression analysis conducted in the cephalic VD group (IV). The influence of gestational age on the injury risk was probably at least partly associated with the higher birth weight.

In the breech VD group, however, the incidence of birth injury remained low and stable, with some infrequent fluctuation after 32 weeks of gestation. Indeed, no association was found in Poisson regression analysis between the incidence of mild birth injury or severe birth injury and gestational weeks. The estimated increase in the incidence of mild birth injury for a gestational week was 0.96 (95% CI 0.88–1.05) and 1.12 (95% CI 0.93–1.35) for severe birth injury. In addition, there was no association found between gestational age and incidence of birth injury in the breech CS group (IV).

Intracranial hemorrhage and other central nervous system injuries (P10, P11) were more common in preterm births than after 37 weeks of gestation (I). In contrast, other birth injury subgroups (P12–P14) were more frequent after 37 gestational weeks (Table 17). Table 17 includes all live-born neonates born between 1997 and 2017. In contrast to the study population of study IV, twin pregnancies and breech extractions are also included.

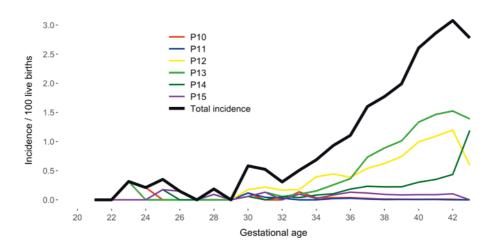


Figure 2. The incidence of birth injuries in different gestational age between 1997 and 2017 (I). P10, Intracranial laceration and hemorrhage; P11, Other birth injuries to central nervous system; P12, Injury to scalp; P13, Injury to skeleton; P14, Injury to peripheral nervous system; P15, Other birth injuries. Figure created by Topias Koukkula

Table 17. The number and incidence of injured neonates in different gestational ages and different delivery modes of all live-born neonates between 1997 and 2017 (I).

		G	estational age in	weeks	
	22+0-27+6	28+0-31+6	32+0-36+6	37+0-40+6	41+0_
	n (%)	n (%)	n (%)	n (%)	n (%)
Live-born neonates	3091	6301	58 360	853 707	278 227
All injured neonates	5 (0.2)	24 (0.4)	525 (0.9)	18 507 (2.2)	8074 (2.9)
Birth injury subgroups					
P10	2 (0.1)	2 (0.03)	25 (0.04)	106 (0.01)	33 (0.01)
P11	0	3 (0.05)	11 (0.02)	58 (0.01)	16 (0.01)
P12	0	8 (0.1)	216 (0.4)	6889 (0.8)	3089 (1.1)
P13	1 (0.03)	4 (0.06)	154 (0.3)	9369 (1.1)	4107 (1.5)
P14	1 (0.03)	2 (0.03)	75 (0.1)	2179 (0.3)	1022 (0.4)
P15	2 (0.1)	5 (0.1)	54 (0.1)	767 (0.1)	254 (0.1)
Delivery modes					
SVD	3 (0.2)	11 (0.6)	335 (1.0)	13 623 (2.1)	5502 (2.6)
VAD	0	1 (2.0)	108 (3.6)	4063 (6.9)	2236 (7.6)
Elective CS	0	1 (0.1)	10 (0.2)	130 (0.2)	10 (0.3)
Unplanned CS	2 (0.1)	8 (0.2)	49 (0.3)	503 (0.8)	269 (0.8)
Breech	0	3 (1.9)	22 (1.4)	145 (2.3)	25 (3.6)

P10, Intracranial laceration and hemorrhage; P11, Other injuries to central nervous system; P12, Injury to scalp; P13, Injury to skeleton; P14, Injury to peripheral nervous system; P15, Other birth injuries; SVD, Spontaneous vaginal delivery; VAD, vacuum-assisted delivery; CS, Cesarean section; Breech, Vaginal breech delivery or breech extraction

5.2 Risk factors for a birth injury in neonates with cephalic presentation (II–IV)

High birth weight/birth weight >4000 grams, shoulder dystocia, pregestational diabetes, and vacuum-assisted delivery had the strongest association with risk for birth injury in neonates in cephalic presentation (II–IV). Odds ratios and risk differences for clavicle fracture and severe birth injury in vaginal delivery with different risk factors are presented in Tables 18–20.

Table 18. Risk factors for severe birth injury in cephalic vaginal delivery (n = 629 182) (IV).

			•	• .	, , ,
	n (%)	Injured neonates of all neonates with risk factor n (%)	OR (95% CI)	p-value	RD (95% CI)
Injured neonates	1954 (0.3)				
LGA	11 196 (1.8)	363 (3.2)	12.74 (11.35–14.30)	<0.001	0.03 (0.03–0.03)
Pregestational diabetes	2191 (0.3)	53 (2.4)	8.0 (6.07–10.54)	<0.001	0.02 (0.02–0.03)
BMI ≥30 kg/m ²	65 809 (10.5)	393 (0.6)	2.18 (1.95–2.44)	<0.001	0.003 (0.003–0.004)
Gestational diabetes	78 671 (12.5)	438 (0.6)	1.98 (1.78–2.21)	<0.001	0.003 (0.002–0.003)
SGA	14 640 (2.3)	12 (0.1)	0.25 (0.14–0.45)	<0.001	-0.002 (-0.003 to -0.002)

OR, Odds ratio; RD, Risk difference represents the difference between the risk for a severe birth injury in the exposed group versus the unexposed group; 95% CI, 95% confidence interval; LGA, large for gestational age (birth weight > +2 SD); SGA, small for gestational age (birth weight < -2 SD); BMI, Body mass index, years 2006 to 2017. Due to missing data, the total frequency of injured neonates used with BMI calculation was 1836.

Risk factors for a clavicle fracture (n = 6577) and the impact of risk factors on the clavicle fracture risk comparing the years 2011–2017 with 2004–2010 in a cephalic vaginal delivery at or after 37⁺⁰ weeks of gestation. N = 629 457 (II). Table 19.

		lle fo setenoen							
		2000	ot all injured						
		neonates with	neonates (%)						
		risk lactor (%)						,	
	2199	13.9	4.6	15.9	14.1–18	12.9	11.5–14.4	0.87	0.71–1.07
	1398	4.6	1.0	4.58	3.56-5.89	3.5	2.6-4.8	0.71	0.43-1.15
Birth weight ≥4000 grams 111	111 840	2.7	45.1	3.89	3.7-4.08	2.0	1.9–2.1	0.59	0.55-0.63
Type 2 diabetes	557	2.0	0.2	1.91	1.05-3.47	6.0	0.6–2.5	9.0	0.18-1.95
BMI $\ge 30 \text{ (kg/m}^2)$ 70	70 473	4.1	14.5	1.52	1.42–1.63	0.5	0.4-0.6	9.0	0.53-0.68
Gestational diabetes 78	78 953	1.4	16.2	1.36	1.27-1.45	4.0	0.3-0.4	0.52	0.46-0.58
8 Induction of labor 125	125 647	1.3	25.1	1.35	1.28–1.43	0.3	0.2-0.4	0.5	0.46-0.55
Gestational age ≥41⁺⁰ (GW) 162	162 123	1.3	31.1	1.31	1.24–1.38	0.3	0.2-0.4	0.56	0.51-0.61
Vacuum-assisted delivery 64	64 859	2.2	21.3	2.39	2.25-2.54	1.3	1.1–1.4	0.62	0.56-0.69
			Vacuun	n-assisted	Vacuum-assisted delivery (n = 64 859)	(658)			
Prolonged II stage of labor 16	16 149	2.6	6.4	1.3	1.16–1.46	9.0	0.3-0.9	89.0	0.56-0.83
Maternal distress 56	5617	2.3	1.9	1.05	0.87-1.26	0.1	-0.3, 0.6	0.53	0.37-0.75
Asphyxia or fetal distress 31	31 243	1.7	8.1	99.0	0.59-0.74	6.0-	-1.2, -0.6	29.0	0.57-0.80
Malpresentation 62	6265	6.0	8.0	0.38	0.29-0.49	4:1-	-1,7, -1.1	0.64	0.38-1.08

OR, Odds ratio; RD, Risk difference represents the difference between the risk for a clavicle fracture in the exposed group versus the unexposed group (*100); RR, Relative risk comparing risk difference between 2011–2017 versus 2004–2010. Relative risk >1 meaning the increased probability of clavicle fracture with exposure in 2011–2017 versus 2014–2010; 95% CI, 95% confidence interval; BMI, body mass index. BMI variables included since 2006–; GW, Gestational week

le 20. Risk factors for severe birth injury by diabetes types in singleton vaginal delivery with cephalic presentation between 35⁺⁰ and 42⁺⁶ gestational weeks (III). Table 20.

				Severe	Severe birth injury			
	T1D		T2D		GDM	Σ	No-diabetes	ites
	=	%	_	%	_	%	_	%
Live births	1659		548		77 810		543 632	
Spontaneous vaginal delivery	1386	83.5	481	87.8	69 496	89.3	488 189	868
Vacuum-assisted delivery	273	16.5	29	12.2	8314	10.7	55 443	10.2
Injured neonates	42		10		415		1467	
Shoulder dystocia	09	3.6	ις	6.0	477	9.0	1617	0.3
Injured neonates of all neonates with risk factor	17	28.3	က	0.09	116	24.3	302	18.7
Injured neonates of all injured neonates	17	40.5	င	30.0	116	28.0	302	20.6
OR (95% CI)	24.89 (12.53–49.46)	-49.46)	114.86 (16.	14.86 (16.53–797.94)	82.79 (65.25–105.03)	5-105.03)	106.62 (92.91–122.35)	-122.35)
6 p-value (OR)	<0.001		<0.001		<0.001		<0.001	
RD (95% CI, %)	26.77 (16.92–39.21)	-39.21)	58.71 (21.76–86.96)	(96.98–92	23.93 (20.30–27.98)	(0-27.98)	18.46 (16.64–20.43)	-20.43)
LGA	421	25.4	55	10.0	2853	3.6	8203	1.5
Injured neonates of all neonates with risk factor	28	2.9	2	3.6	110	3.9	214	5.6
Injured neonates of all injured neonates	28	2.99	2	20.0	110	26.5	214	14.6
OR (95% CI)	6.23 (3.25-11.95)	.11.95)	2.29 (0.4	2.29 (0.47–11.05)	9.88 (7.92–12.33)	:-12.33)	11.42 (9.86–13.22)	-13.22)
p-value (OR)	<0.001		0.303		<0.001		<0.001	
RD (95% CI, %)	5.52 (3.37–8.35)	-8.35)	2.01 (-1.04	2.01 (-1.04 to 10.74)	3.47 (2.82–4.25)	2–4.25)	2.37 (2.05–2.74)	-2.74)
Vacuum-assisted delivery	279	16.5	29	12.2	8314	10.7	55 443	10.2
Injured neonates of all neonates with risk factor	15	5.5	9	9.0	155	1.9	505	6.0
Injured neonates of all injured neonates	15	35.7	9	0.09	155	37.4	202	34.4
OR (95% CI)	2.93 (1.54–5.58)	-2.58)	11.73 (3.22–42.74)	2-42.74)	5.06 (4.14–6.18)	4-6.18)	4.66 (4.18–5.19)	-5.19)
p-value (OR)	0.001		<0.001		<0.001		<0.001	
RD (95% CI, %)	3.55 (1.24–6.97)	-6.97)	8.12 (3.17–17.38)	7–17.38)	1.49 (1.22–1.81)	2–1.81)	0.71 (0.64–0.80)	-0.80)
Primiparity	635	38.3	174	31.8	27 141	34.9	219 207	40.3
Injured neonates of all neonates with risk factor	23	3.62	4	2.3	156	9.0	622	0.3

Injured neonates of all injured neonates	23	54.8	4	40.0	156	37.6	622	42.4
OR (95% CI)	1.99 (1.07–3.68)	.3.68)	1.44 (0.4	1.44 (0.40–5.18)	1.13 (0.92–1.37)	-1.37)	1.09 (0.98–1.21) 0.105	-1.21)
RD (95% CI, %)	1.77 (0.19–3.64)	3.64)	0.69 (-1.62 to 4.25)	2 to 4.25)	0.06 (-0.04 to 0.18)	to 0.18)	0.02 (-0.005 to 0.05)	to 0.05)
Smoking	279	16.8	130	12.2	14 454	18.6	92 028	16.9
Injured neonates of all neonates with risk factor	13	4.7	7	1.5	84	9.0	228	0.3
Injured neonates of all injured neonates	13	31.0	2	20.0	84	20.2	228	15.5
OR (95% CI)	2.28 (1.17-4.43)	4.43)	0.80 (0.1	0.80 (0.17–3.82)	1.11 (0.88–1.42)	-1.42)	0.90 (0.78–1.04)	-1.04)
p-value (OR)	0.016		0.780		0-382		0.160	
RD (95% CI, %)	2.56 (0.44–5.77)	5.77)	-0.38 (-2.51 to 3.63)	1 to 3.63)	0.06 (-0.07 to 0.21)	to 0.21)	-0.03 (-0.06 to 0.01)	to 0.01)
Labor induction	1056	63.7	339	61.9	25 145	32.3	97 826	18.0
Injured neonates of all neonates with risk factor	31	2.9	7	2.1	172	2.0	352	9.0
Injured neonates of all injured neonate	31	73.8	7	70.0	172	41.5	352	24.0
OR (95% CI)	1.63 (0.81–3.26)	3.26)	1.45 (0.3	1.45 (0.37–5.66)	1.49 (1.22–1.81)	-1.81)	1.44 (1.28-	-1.62)
p-value (OR)	0.170		0.595		<0.001		<0.001	
85% CI, %)	1.11 (-0.54 to 2.56)	5 2.56)	0.63 (-2.27 to 2.97)	7 to 2.97)	0.22 (0.11-0.35)	-0.35)	0.11 (0.07–0.15)	-0.15)
Jse	994	6.65	322	58.8	39 509	20.8	239 940	44.1
Injured neonates of all neonates with risk factor	32	3.2	2	1.6	276	2.0	805	0.3
Injured neonates of all injured neonates	32	76.2	2	20	276	66.5	805	54.9
OR (95% CI)	2.18 (1.06-4.46)	4.46)	0.70 (0.2	0.70 (0.20–2.44)	1.93 (1.57–2.37)	-2.37)	1.54 (1.39–1.71)	-1.71)
p-value (OR)	0.033		0.572		<0.001		<0.001	
RD (95% CI, %)	1.72 (0.16–3.18)	3.18)	-0.66 (-3.66 to 1.73)	6 to 1.73)	0.34 (0.23-0.44)	-0.44)	0.12 (0.09–0.15)	-0.15)
Epidural and/or spinal anesthesia	1123	2'. 19	328	65.5	49 229	63.3	325 482	59.9
Injured neonates of all neonates with risk factor	35	3.1	7	1.9	293	9.0	973	0.3
Injured neonates of all injured neonates	35	83.3	7	70.0	293	9.07	973	66.3
OR (95% CI)	2.43 (1.07–5.51)	5.51)	1.23 (0.3	1.23 (0.32–4.82)	1.40 (1.13–1.73)	-1.73)	1.32 (1.19–1.47)	-1.47)
p-value (OR)	0.033		>0.99		0.002		<0.001	
RD (95% CI, %)	1.81 (0.19–3.17)	3.17)	0.36 (-2.78 to 2.64)	8 to 2.64)	0.17 (0.06–0.27)	-0.27)	0.07 (0.04–0.10)	-0.10)
T1D, type 1 diabetes; T2D, type 2 diabetes; GDM, gestational diabetes; LGA, Large for gestational age (birth weight > +2 SD); OR, Odds ratio; RD, Risk difference (*100)	nal diabetes; LG	A, Large for	gestational a	ige (birth weigh	t > +2 SD); OR,	Odds ratio; RI), Risk difference	e (*100)

T1D, type 1 diabetes; T2D, type 2 diabetes; GDM, gestational diabetes; LGA, Large for gestational age (birth weight > +2 SD); OR, Odds ratio; KD, KISK difference ("100)

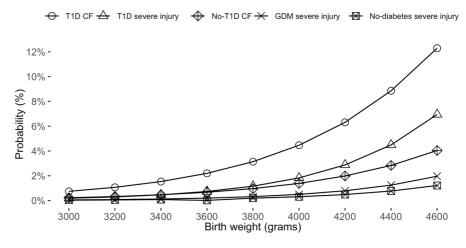
5.2.1 High birth weight

Although 45% of all vaginally delivered neonates with clavicle fracture had a birth weight ≥4000 grams and 10% had a birth weight ≥4500 grams, only 2.7% of neonates with a birth weight of over 4000 grams were diagnosed with clavicle fracture, Table 19 (II). Similarly, 19% of all vaginally delivered neonates with severe birth injury were LGA (birth weight >+2 SD), but the overall incidence of severe birth injury among LGA neonates was only 3.2%, Table 18 (IV). The incidence of severe birth injury among LGA neonates in all vaginal deliveries ranged between 2.6% and 6.7%, being highest in women with T1D and lowest in women without diabetes (III), Table 20.

The probability of clavicle fracture and severe birth injury increased with higher birth weight, and the risk for injury was further strengthened in vacuum-assisted deliveries (Table 21, Figure 3). The probability of birth injury after SVD in pregnancies of women with T1D began to increase with a birth weight of 3500 grams for clavicle fractures and 3900 grams for severe birth injuries (II, III). The probability of these injuries increased more steeply when birth weight was more than 4000 grams and 4300 grams. However, for neonates born by SVD to women without pregestational diabetes, the probability of clavicle fracture and severe birth injury remained low up to a birth weight of 4000 grams and 4500 grams. The effect of high birth weight on the probability of birth injury was clearly seen among neonates born by vacuum-assisted delivery to women with or without diabetes (Table 21, Figure 3).

In study IV, the incidence rates of mild and severe birth injury were studied with regression analysis. The incidence of mild birth injury (1.09, 95% CI 1.09–1.10) and severe birth injury (1.20, 95% CI 1.17–1.22) in neonates with cephalic presentation showed an increasing trend along with higher birth weight (IV). However, considering risk differences, LGA and birth weight of ≥4000 grams moderately increased the risk for clavicle fracture or severe birth injury (II, III). In addition, high birth weight per se was a more important risk factor for severe birth injury than LGA (III).

Spontaneous vaginal delivery



Vacuum-assisted delivery

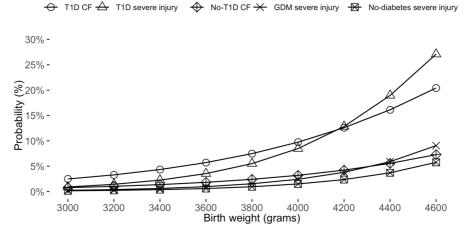


Figure 3. The probability of clavicle fracture and severe birth injury in spontaneous vaginal delivery and vacuum-assisted delivery between 2004 and 2017 (II, III). T1D, type 1 diabetes; CF clavicle fracture, GDM, gestational diabetes; No-T1D, women without type 1 diabetes, No-diabetes, women without any type of diabetes. Figure created by Topias Koukkula.

le 21. The probability of clavicle fracture in neonates of women with type 1 diabetes and women without type 1 diabetes (II). The probability of severe birth injury in neonates of women with different diabetes types and without diabetes (III). Table 21.

Delivery mode Probability of cl	Proba	bility of clavicle	clavicle fracture		Probab	Probability of severe birth injury	oirth injun					
	No-T1	<u>_</u>	T1D		No-diabetes	betes	GDM		T1D		T2D	
	%	95% CI	%	95% CI	%	95% CI	%	95% CI	%	95% CI	%	95% CI
Birth weight 300	0 g											
SVD	0.22	0.21-0.24	0.74	0.55-1.0	0.03	0.03-0.03	0.05	0.04-0.06	0.18	0.13-0.26	0.19	0.10-0.37
VAD	0.78	0.69-0.87	2.49	1.50-4.10	0.15	0.13-0.17	0.24	0.21-0.29	0.91	0.65-1.27	0.95	0.50-1.80
Birth weight 350	0 g											
SVD	0.56	0.54-0.58	1.83	1.37–2.46	0.10	0.09-0.10	0.16	0.14-0.18	0.58	0.42-0.80	0.61	0.32-1.15
VAD	1.58	1.48-1.69	4.98	3.06-8.02	0.48	0.43 - 0.52	0.77	0.68-0.89	2.83	2.05-3.89	2.95	1.57–5.47
Birth weight 400	0 g											
SVD	1.38	1.35-1.42	4.46	3.35-5.91	0.31	0.29-0.32	0.50	0.45 - 0.55	1.83	1.33–2.50	1.91	1.01-3.56
VAD	3.2	3.03-3.38	9.74	6.11–15.17	1.50	1.39–1.62	2.42	2.22-2.71	8.48	6.29-11.34	8.83	4.85-15.54
Birth weight 4500 g	0 g											
SVD	3.38	3.25-3.52	10.45	7.97-13.59	96.0	0.90-1.04	1.56	1.40–1.74	5.59	4.12–7.55	5.83	3.15-10.52
VAD	6.37	5.84-6.94	18.17	11.77–26.98	4.62	4.23-5.05	7.32	6.53-8.20	22.77	22.77 17.56–28.97	23.55	13.92–36.96
H 471		: 0					-					

T1D, Type 1 diabetes; T2D Type 2 diabetes, GDM, gestational diabetes, SVD, spontaneous vaginal delivery; VAD, vacuum-assisted delivery; g, grams

5.2.2 Shoulder dystocia and diabetes

In addition to high birth weight and vacuum-assisted delivery, shoulder dystocia and pregestational diabetes were associated with the highest risk for birth injury.

GDM was associated with a milder risk for clavicle fracture and severe birth injury than pregestational diabetes, Tables 18, 19 (II, IV). For instance, whereas 4.6% of neonates of women with T1D had a clavicle fracture, only 1.4% of neonates of women with GDM had one.

In total, 20% of neonates experiencing shoulder dystocia had a severe birth injury (III), and 14% of neonates with shoulder dystocia had a clavicle fracture (II). Furthermore, regardless of diabetes type, the strongest risk for severe birth injury was associated with shoulder dystocia (Table 20). A total of 20% of the severe birth injuries in deliveries among women without diabetes and 41% of the severe birth injuries among women in the T1D group also had shoulder dystocia (Table 20). Based on the ratio of Odds Ratios for a severe birth injury in the diabetes group versus the non-diabetic group (OR-ratio, Table 22), shoulder dystocia was a more powerful risk factor for women without diabetes when compared to women with T1D, with a similar tendency being seen in the pregnancies of women with GDM.

5.2.3 Vacuum-assisted delivery

Vacuum-assisted delivery was associated with the highest risk and cesarean section with the lowest risk for birth injury (Tables 19, 20). The risk for clavicle fracture was highest when the procedure was needed due to a prolonged second stage of labor (OR 1.3, 95% CI 1.16–1.46; RD 0.006, 95% CI 0.003–0.009) (II).

The risk for clavicle fracture (II) and severe birth injury (III) in vacuum-assisted deliveries was further increased with higher birth weight and pregestational diabetes, (Figure 3, Table 21). However, as birth injuries were rare in all delivery modes, only 2.2% of vacuum-assisted deliveries ended up with a clavicle fracture (Table 19). Moreover, severe birth injury was diagnosed in 0.9% of neonates after vacuum-assisted deliveries of women without diabetes and in 1.9% of neonates after vacuum-assisted deliveries among women with GDM compared to 5.5% and 9.0% of the vacuum deliveries of women with T1D and T2D, respectively (Table 20). The vacuum-assisted delivery rate varied between diabetes types. Among women with T1D, 16.5% of all vaginal deliveries were vacuum deliveries compared to 10% and

11% of all vaginal deliveries in women with GDM or without diabetes. Considering the risk differences, vacuum-assisted delivery was a moderate risk factor for severe birth injury (Table 20).

5.2.4 Other risk factors

Many of the studied variables were associated with a slightly increased risk for clavicle fracture and severe birth injury (Tables 18–20). For example, obesity was associated with a risk for clavicle fracture and severe birth injury. However, the impact of increasing BMI remained modest and was mostly seen in vacuum-assisted deliveries among women in the pregestational diabetes group.

Some factors, such as induction of labor, use of oxytocin, pain relief during labor, shorter maternal height, older maternal age, and higher birth length of the neonate, had a statistically significant but probably clinically less relevant influence on the birth injury risk.

Interestingly, 25% (1305/5143) of neonates with clavicle fracture between 2006 and 2017 did not have any of the main studied risk factors (shoulder dystocia, T1D, birth weight \geq 4000 grams, GDM, BMI \geq 30kg/m², gestational age \geq 41⁺⁰ weeks of gestation, induction of labor) (II).

The risk for severe birth injury in cephalic vaginal delivery in the group of women with diabetes versus the group of women without diabetes between 35⁺⁰ and 42⁺⁶ gestational weeks (III). Table 22.

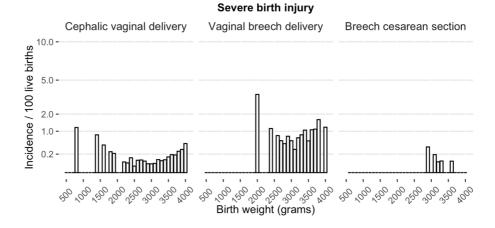
			Severe birth injury	nıy		
	T1D		T2D		GDM	
	OR-ratio (95% CI)	p-value	OR-ratio (95% CI)	p-value	OR-ratio (95% CI)	p-value
Shoulder dystocia	0.23 (0.12-0.47)	<0.001	1.08 (0.15–7.52)	0.940	0.78 (0.59–1.02)	0.071
LGA	0.55 (0.28–1.06)	0.075	0.20 (0.04–0.97)	0.046	0.87 (0.66–1.13)	0.286
Vacuum-assisted delivery	0.63 (0.33–1.21)	0.164	2.52 (0.69–9.22)	0.162	1.09 (0.87–1.36)	0.474
Primiparity	1.82 (0.98–3.41)	0.059	1.32 (0.37–4.77)	0.668	1.03 (0.82–1.29)	0.780
Smoking	2.52 (1.27-4.98)	0.008	0.89 (0.18–4.25)	0.880	1.23 (0.93–1.63)	0.142
Labor induction	1.13 (0.56–2.29)	0.734	1.01 (0.26–3.95)	0.994	1.03 (0.82–1.30)	0.790
Use of oxytodin	1.41 (0.69–2.92)	0.349	0.45 (0.13–1.59)	0.216	1.25 (1.0–1.58)	0.053
Epidural and/or spinal anesthesia 1.84 (0.81–4.20)	1.84 (0.81–4.20)	0.148	0.93 (0.24–3.67)	0.921	1.06 (0.83–1.34)	0.647
OB-ratio the ratio of Odds ratios for a severe high injury in the diabates oroun (110 T20 GDM) versus the non-diabatic oroun within a diabate or an expensive the non-diabatic oroun within a diabate or an expensive the non-diabatic ordinary and the contraction of the contraction	r a severe hirth injury in	the dishetes	MUD (T1D T2D GDM)	presis the no	n-diahatic aroun within	diven rick

OR-ratio, the ratio of Odds ratios for a severe birth injury in the diabetes group (T1D, T2D, GDM) versus the non-diabetic group within a given risk factor. OR-ratio >1 means a higher Odds Ratio in the group of women with diabetes versus a group of non-diabetic women. T1D, type 1 diabetes; T2D, type 2 diabetes; GDM, gestational diabetes; LGA, Lage for gestational age (birth weight >+2 SD)

5.3 Risk factors for a birth injury in neonates with breech presentation (IV)

No risk factors for severe birth injury were found in the breech VD group, and the use of oxytocin was the only risk factor noted in the breech CS group (IV). The variables analyzed in the breech VD group and the breech CS group are presented in Table 23.

The impact of gestational age and birth weight on risk for birth injury was evaluated more thoroughly. In contrast to cephalic VD, there was no association between gestational age or birth weight and mild or severe birth injury in breech delivery. In the breech VD group, 3% of neonates with severe birth injury were LGA and 3% were SGA compared with 19% and 0.6% in the cephalic VD group, respectively (Tables 18, 23). Moreover, no association was found in Poisson regression analysis between birth weight (500 grams to 4000 grams) and the incidence of birth injury. The estimated increase in the incidence of injury for an increase of 100 grams in birth weight was 1.01, 95% CI 0.97–1.06 for mild birth injury, and 1.06, 95% CI 0.98–1.14 for severe birth injury in breech VD. However, in the breech CS group, the incidence of mild birth injury showed a decreasing trend with increasing birth weight (the estimated increase in the incidence of mild birth injury for an increase of 100 grams in birth weight 0.94, 95% CI 0.90–1.0), Figure 4.



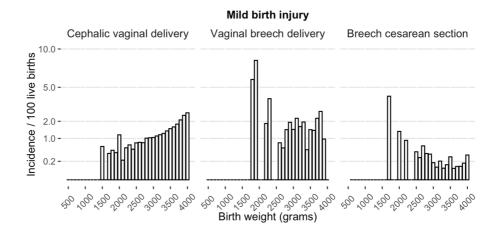


Figure 4. The incidence of severe and mild birth injury in breech deliveries and cephalic vaginal delivery at different birth weight (500 grams–4000 grams). Incidence presented as square root variant (IV). Figure created by Topias Koukkula.

Table 23. Risk factors for a severe birth injury in breech delivery (IV).

	Vaginal breech delivery	Breech CS
Live births	4344	16 979
Injured neonates	33	10
BMI ≥ 30 kg/m ² n (%)	324 (7.5)	1823 (10.7)
Injured neonates of all neonates with risk	5 (1.5)	3 (0.2)
factor n (%)		
OR (95% CI)	2.12 (0.81–5.54)	3.48 (0.90-13.46)
p-value	0.12	0.07
RD (95% CI)	0.008 (-0.001 to 0.03)	0.001 (-2.50 to 0.004)
Multipara n (%)	2086 (48.0)	5663 (33.4)
Injured neonates of all neonates with risk factor n (%)	14 (0.7)	4 (0.1)
OR (95% CI)	0.77 (0.39-1.55)	1.33 (0.37-4.71)
p-value	0.47	0.66
RD (95% CI)	-0.002 (-0.007 to 0.004)	
Gestational diabetes n (%)	450 (10.4)	2258 (13.3)
Injured neonates of all neonates with risk		3 (0.1)
factor n (%)	+ (0.0)	0 (0.1)
OR (95% CI)	1.18 (0.41–3.36)	2.79 (0.72-10.8)
p-value	0.76	0.14
RD (95% CI)	0.001 (-0.005 to 0.02)	
Pregestational diabetes n (%)	11 (0.3)	166 (1.0)
Injured neonates of all neonates with risk		0
factor n (%)	O	0
Use of oxytocin n (%)	2844 (65.5)	505 (3.0)
Injured neonates of all neonates with risk		2 (0.4)
factor n (%)	22 (0.0)	2 (0.1)
OR (95% CI)	1.01 (0.49-2.09)	8.17 (1.73-38.55)
p-value	0.98	0.008
RD (95% CI)	0.0008 (-0.006 to 0.005)	
Induction of labor n (%)	670 (15.4)	322 (1.9)
Injured neonates of all neonates with risk		0
factor n (%)	0 (0.0)	· ·
OR (95% CI)	1.2 (0.49-2.92)	0
p-value	0.69	NA
RD (95% CI)	0.001 (-0.004 to 0.01)	NA
SGA n (%)	199 (4.6)	666 (3.9)
Injured neonates of all neonates with risk		0
factor n (%)	. (6.5)	·
OR (95% CI)	0.64 (0.09-4.7)	0
p-value	0.68	NA
RD (95% CI)	-0.003 (-0.008 to 0.02)	NA
LGA n (%)	23 (0.5)	454 (2.7)
Injured neonates of all neonates with risk		1 (0.2)
factor n (%)	\ -/	V- /
OR (95% CI)	6.0 (0.79-45.89)	4.04 (0.51-31.97)
p-value	0.08	0.19
RD (95% CI)	0.04 (0.000= 0.0)	

BMI, Body mass index; SGA, Small for gestational age (birth weight <-2 SD); LGA, Large for gestational age (birth weight >+2 SD); OR, Odds ratio; RD, Risk difference

5.4 The temporal changes (I, II)

The overall incidence of birth injury decreased from 3.4% in 1997 to 1.7% in 2017, Figure 5. This decrease in incidence of injury was seen in early term to postterm pregnancies (gestational age $>37^{+0}$), whereas before 37 weeks of gestation no apparent temporal trend in the incidence of injury was seen (I).

The incidence of clavicle fracture declined the most, falling from 1.7% to 0.5% of live births. Between 2004 and 2017, the incidence of clavicle fracture decreased by over 60% in both SVD and vacuum-assisted deliveries (II). In SVD, the incidence of clavicle fracture decreased from 1.6% (n = 671) in 2004 to 0.6% (n = 190) in 2017, and in vacuum-assisted delivery from 3.1% (n = 116) to 1.2% (n = 54). In addition, 330 neonates had clavicle fracture and brachial plexus palsy (incidence 0.05%). There were more neonates with both of these injuries in the earlier study period in 2004-2010 (incidence 0.07%) than in 2011-2017 (incidence 0.03%).

The rate of brachial plexus palsy was highest in 2000, 0.4% of live births. However, the incidence decreased to 0.2% by the end of the study period (I). There was, however, some variation in the incidence of scalp injury between years and an upward trend was seen. The incidence of cephalhematoma first decreased from 1.1% in 2004 to 0.6% in 2007. The incidence then started to increase after 2008 and reached the incidence of 0.8% of live births in 2017. Furthermore, the incidence of a chignon or artificial caput succedaneum (P12.1) increased from 0.01% to 0.03% of live births, and subgaleal hemorrhage (P12.2) increased from 0.002% to 0.02% of live births from 1997 to 2017. The incidence of intracranial hemorrhage and other central nervous system injuries (P10, P11) remained low and relatively stable during the whole study period. Instead, the incidence of other birth injuries (P15) declined from 1.1% of live births in 1997 to 0.6% of live births in 2017 (I).

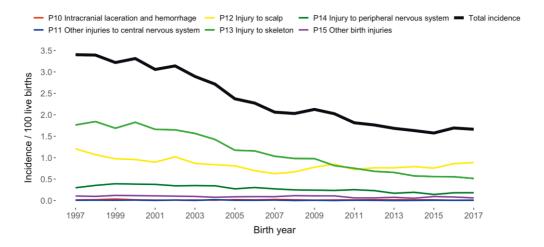


Figure 5. The incidence of birth injury per 100 live births between 1997 and 2017 (I). Figure created by Topias Koukkula.

5.4.1 Temporal change of birth rate and mode of delivery (I)

The annual birth rate varied between 55 000 and 60 000 neonates during the first decade of the study period. However, the rate began to decrease after 2010, and only 50 397 neonates were born in 2017. The spontaneous vaginal delivery rate declined from 77% in 2007 to 73% in 2017. In contrast, the vacuum-assisted delivery rate increased from 5.3% to 9.4%, and the annual caesarean section rate remained stable at around 16% to 17%. The vaginal breech delivery or breech extraction rate declined for a couple of years at the beginning of in the 21th century. Thereafter, the rate remained stable at around 0.8% of all deliveries after 2007.

5.4.2 Temporal change of risk factors (II)

Study II evaluated the risk factors for clavicle fracture and their temporal changes (Table 24). The most noteworthy temporal changes were increased incidences of T2D, GDM, suspicion/diagnosis of LGA in antenatal care, and induction of labor. Furthermore, the incidence of pain relief during labor, the use of oxytocin, and obesity also increased. However, mean birth weight remained stable, and the incidence of birth weight over 4000 grams decreased. In addition, the number of deliveries after 41⁺⁰ gestational weeks decreased, and the incidence of T1D and

shoulder dystocia remained unchanged. The incidence of changes in maternal demographics and delivery characteristics were comparable for SVD, vacuum-assisted deliveries, and CS between the study periods. When considering only vacuum-assisted deliveries, the rate of procedures performed due to a prolonged II stage of labor, a diagnosis associated with slightly increased risk for clavicle fracture, remained stable. However, the rate of vacuum-assisted deliveries due to malpresentation of fetus increased, although these procedures were not associated with an increased risk for clavicle fracture (Table 24).

The impact of risk factors on the risk for clavicle fracture was lower between 2011 and 2017 than between 2004 and 2010 (relative risk, Table 19), with exception of in shoulder dystocia, pregestational diabetes, and insulin treatment started during pregnancy for which the likelihood of fracture remained constant. Furthermore, clavicle fracture was more often linked to shoulder dystocia, GDM, and induction of labor between 2011 and 2017 than between 2006 and 2010 (Table 25). The incidence of clavicle fracture without any of the most important risk factors (shoulder dystocia, T1D, GDM, birth weight \geq 4000 grams, BMI \geq 30 kg/m², gestational age \geq 41⁺⁰ weeks, and labor induction) decreased in 2011–2017 compared to 2006–2010. In the cluster-type analysis of the incidence rates of clavicle fracture with an increasing number of variables, a decrease in the incidence of fracture without any of the risk factors was the only evident temporal change seen (Table 25).

Table 24. Characteristics of the study population II and temporal changes.

	2004–2 n = 321		2011–2 n = 307				
	n	%	n	%	p-value	Rate ratio	95% CI
Maternal characteristics					•		
Multipara	193 717	60.2	188 717	61.3	< 0.001	1.02	1.01-1.03
Age ≥30 years	153 197	47.6	160 069	52	< 0.001	1.09	1.09-1.10
BMI ≥30 (kg /m²)	29 391	12.7	41 082	13.3	< 0.001	1.05	1.04-1.07
Type 1 diabetes	711	0.2	687	0.2	0.85	1.01	0.91-1.12
Type 2 diabetes	186	0.06	371	0.1	< 0.001	2.09	1.75-2.49
Gestational diabetes	32 128	10	46 825	15.2	< 0.001	1.52	1.50-1.55
Insulin treatment	5435	1.7	4778	1.6	< 0.001	0.92	0.88-0.96
LGA	3632	1.1	4758	1.5	<0.001	1.37	1.31–1.43
Delivery characteristics							
Induction of labor	54 904	17.1	70 743	22.3	< 0.001	1.35	1.33-1.36
Gestational age ≥41 ⁺⁰	84 525	26.3	77 598	25.2	< 0.001	0.96	0.95-0.97
Use of oxytocin	134 581	41.8	149 146	48.5	< 0.001	1.16	1.15–1.17
Paracervical and/or pudendal block	67 377	20.9	80 656	26.2	<0.001	1.25	1.24–1.26
Epidural and/or spinal anesthesia	178 799	55.6	201 394	65.4	<0.001	1.18	1.17–1.19
Shoulder dystocia	1120	0.3	1079	0.4	0.87	1.01	0.71-1.07
Birth weight ≥4000 grams	58 170	18.1	53 670	17.4	< 0.001	0.96	0.95-0.98
SVD	290 357	90.3	274 241	89.1	< 0.001	0.99	0.98-0.99
Vacuum-assisted delivery	31 334	9.7	33 525	10.9	<0.001	1.12	1.10–1.14
		Vacuun	n-assisted d	elivery			
	n = 31	334	n = 33	525			
Prolonged II stage of labor	7634	24.4	8515	25.4	0.008	1.04	1.01–1.08
Maternal distress	2558	8.2	3059	9.1	< 0.001	1.12	1.06-1.18
Asphyxia of fetal distress	14 165	45.2	17 078	50.9	<0.001	1.13	1.10-1.15
Malpresentation	2496	8	3769	11.2	< 0.001	1.41	1.34-1.49

P-value calculated from incidence rate ratio (IRR), using Chi-square test; Rate ratio comparing variables' incidence rates between the periods 2011–2017 and 2004–2010. Rate ratio >1 meaning an increased incidence of the calculated variable in 2011–2017 compared to 2004–2010; 95% CI, 95% confidence interval

BMI, Body mass index. BMI included since 2006–; Insulin treatment, insulin treatment started during pregnancy; LGA, antenatal diagnosis of large for gestational age; SVD, spontaneous vaginal delivery

Table 25. Frequency of clavicle fracture with different risk factors and the proportion of fractures with risk factor of all fractures in singleton neonates born vaginally at $\geq 37^{+0}$ weeks of gestation in 2006–2010 (n = 2831) and 2011–2017 (n = 2312) (II).

	2006–2010	2011–2017	p-value	IRR (95% CI)
	n (%)	n (%)		
Shoulder dystocia	118 (4.2)	139 (6.0)	0.003	1.44 (1.13–1.84)
Type 1 diabetes	31 (1.1)	26 (1.1)	0.92	1.03 (0.61-1.73)
Birth weight ≥4000 grams	1263 (44.6)	1044 (45.2)	0.77	1.01 (0.93-1.10)
Gestational diabetes	403 (14.2)	458 (19.8)	< 0.001	1.39 (1.22-1.59)
BMI ≥30 kg/m ²	518 (18.3)	434 (18.8)	0.69	1.03 (0.90-1.17)
Gestational age ≥41 ⁺⁰ weeks	913 (33.3)	694 (30.0)	0.15	0.93 (0.84-1.03)
Induction of labor	670 (23.7)	650 (28.1)	0.002	1.19 (1.07-1.32)
Fracture without any of the risk factors mentioned above	759 (26.8)	546 (23.6)	0.024	0.88 (0.79–0.98)
Number of any of the risk factors*				
0 risk factor	779 (27.5)	564 (24.4)	0.029	0.89 (0.80-0.99)
1 risk factor	914 (32.3)	746 (32.3)	0.99	1.0 (0.91-1.10)
2 risk factors	676 (23.9)	593 (25.7)	0.2	1.07 (0.96–1.20)
3 risk factors	362 (12.8)	297 (12.9)	0.95	1.01 (0.86-1.17)
4 risk factors	85 (3.0)	103 (4.5)	0.007	1.48 (1.11–1.98)
5 risk factors	15 (0.5)	9 (0.4)	0.46	0.73 (0.32-1.68)

^{*}Including: Birth weight ≥4000 grams, gestational diabetes, BMI ≥30, Gestational age ≥41⁺⁰, Induction of labor. 95% CI, 95% confidence interval; *p*-value calculated from Incidence rate ratio (IRR) using Chi-square test; IRR, Incidence rate ratio comparing incidence of clavicle fracture between 2011–2017 versus 2006–2010.

6 DISCUSSION

The aim of the present study was to assess birth-related neonatal injuries, risk factors for injury, and epidemiological changes related to birth injuries. This study has shown that the incidence of birth injury decreased by 50% in Finland during the 21-year study period. The decrease in the incidence of birth injury was mainly due to a decline in the clavicle fracture rate and also probably related to the decrease in high birth weight neonates. However, the incidence of clavicle fractures in neonates without risk factors also decreased. A high birth weight, pregestational diabetes, and complicated delivery, leading to vacuum-assisted delivery or shoulder dystocia, were the main risk factors for injury. Severe birth injuries were, however, rare, and there was a fall in the incidence of BPP, the most common type of severe birth injury. Although birth injuries in breech deliveries were infrequent, the risk for BPP was higher than in cephalic VD.

Birth injuries are complex events, and multiple factors can impact the individual risk for injury. For example, some maternal and fetal characteristics, the disproportion between fetal size and maternal pelvis, malposition or malpresentation of the fetus, various forces acting on the fetus during the whole delivery process, the descent of the fetus, an active second stage of birth, complications during the delivery requiring the birth to be speeded up, all predispose the neonate to injury. In addition, predicting and preventing injuries is challenging, as risk factors are common, but birth injuries are rare, and injuries often occur in pregnancies without any predisposing factors.

6.1 Incidence rates of birth injury and temporal changes (I–IV)

In total, birth injuries occurred in 2.3% of live-born neonates. By the end of the study period, however, birth injuries occurred in only 1.7% of live-born neonates. The prevalence of birth injuries was similar in Canada and lower than reported in the US (Gupta & Cabacungan, 2021; Liston et al., 2008). The incidence of birth injury in Finland halved between 1997 and 2017, meaning approximately 1000 fewer injuries per year at the end of study period than at the beginning. A similar declining

trend is also found in other studies (Gupta & Cabacungan, 2021; Tomashek et al., 2006).

Skeletal injuries, mainly clavicle fractures, accounted for almost half of the injuries, and clavicle fracture was the most common mild birth injury. Birth injuries are classified in various ways, complicating the comparison between studies and leading to inconsistency in the incidence rates of birth injury (Kumar et al., 2015). In the current study, clavicle fractures were classified as mild birth injuries due to their excellent prognosis. A similar classification for severe and mild birth injuries has been used in Canadian retrospective national studies (G. Muraca et al., 2018; G. M. Muraca et al., 2018, 2022). The clavicle fracture incidence of 1/100 live births is evidently higher than in other national register studies. Retrospective national studies from Sweden and the US have reported a clavicle fracture incidence of 0.03% and 0.2% of live births, respectively (Gupta & Cabacungan, 2021; Högberg et al., 2020). The higher clavicle fracture rate compared to the literature could be partly due to the difference in CS rates, as CS is more common in many other countries than in Finland (Betran et al., 2021). However, the CS rate does not explain the difference with Sweden, as the CS rate is similar in the Nordic countries (EURO-PERISTAT Project. European Perinatal Health Report, 2015). The incidence of clavicle fracture was lower than in a cohort study from Israel (Kaplan et al., 1998), but higher among vaginal deliveries than in a retrospective national study from Norway, which also included preterm neonates (Bjørstad et al., 2010).

One possible explanation for the higher incidence of clavicle fracture is that the results of the current study may be more accurate than those of some of the previous ones. The data used in the present study included all live-born neonates in Finland. Moreover, our data also included birth-related injuries diagnosed up to 12 months after birth. This is important because up to 14% of clavicle fractures are diagnosed after discharge (Ahn et al., 2015). Some of the previously reported rates, however, are based on cohorts which have been extrapolated into national incidence rates. Thus, these studies are at risk of bias (Gandhi et al., 2019; Gupta & Cabacungan, 2021; Sauber-Schatz et al., 2010). The differences in diagnostic criteria and study population may also affect the incidence rates of injury. It is essential to remember, therefore, that the incidence of clavicle fracture at the end of the study period (0.5% of live births) was more in line with previously published studies. In 1997, a clavicle fracture was detected in 1026 neonates, whereas only 251 neonates had a clavicle fracture in 2017. The decreasing trend in clavicle fractures is the main reason behind the decrease in Finland's total birth injury rate.

In register studies from the US, scalp injuries have been the most common injury, being far more common than clavicle fractures (Gupta & Cabacungan, 2021; Sauber-Schatz et al., 2010). In Finland, scalp injuries, of which cephalohematoma was the most common, were the second most common injury type. Surprisingly, considering Finland's vaginal delivery and CS rates, the incidence rates of scalp injury and cephalohematoma were lower than in other studies (Baskett et al., 2007; Gupta & Cabacungan, 2021; Reichard, 2008). One explanation for this could be differences in sensitivity to diagnose and register mild scalp injuries. An alarming 10-fold increase in the incidence of subgaleal hemorrhage was seen between 1997 and 2017. This injury is classified as a severe birth injury because it can be fatal or cause severe morbidity. Nevertheless, in 2017 the incidence of subgaleal hemorrhage was still low, with 2 per 10 000 live births, and comparable to that in previous studies, (Chang et al., 2007; G. M. Muraca et al., 2018). The overall increase in scalp injuries and subgaleal hemorrhage is of the utmost importance, as the rate of vacuum-assisted deliveries doubled between 1997 and 2017.

Severe birth injuries were rare in all delivery modes (10 neonates per 1000 vacuum-assisted deliveries, 3 per 1000 cephalic VD, and 8 per 1000 breech VD). The rates in cephalic deliveries were consistent with the literature (Gupta & Cabacungan, 2021; G. M. Muraca et al., 2018; Wen et al., 2018). However, in contrast to the study by Wen et al., our study did not include clavicle fractures in the severe birth injury group. Brachial plexus injury was the most common severe birth injury. The incidence of BPP was at the higher end of what had been previously reported in retrospective national studies (Åberg et al., 2016; Hedegaard et al., 2015; Mollberg et al., 2007; G. M. Muraca et al., 2022). Furthermore, the incidence of ICH in this study was in line with that published previously. The wide range in the incidence of ICH reported in the literature, 0.008%–0.04%, may be related to the rarity of the injury, the discrepancy in diagnostics, and the study populations (Ekéus et al., 2014; G. M. Muraca et al., 2018; Sauber-Schatz et al., 2010). Some birth injury studies have used the P52 (Intracranial nontraumatic hemorrhage of newborn) code in addition to P10 for assessing ICH (Åberg et al., 2016), which intrinsically increases the incidence of injury. In addition, the difference in CS rate and other obstetrical practices may also affect the results.

Comparing the incidence rates of severe birth injury in breech deliveries is difficult due to the different study designs. In contrast to cephalic VD, BPP was the most common injury, more common than clavicle fractures, in breech VD. Indeed, the incidence of BPP was twice as high among breech VD than cephalic VD and was similar to that reported by Ekeus et al. (Ekéus et al., 2019). However, the

incidence of BPP was higher than reported in other studies, most of which reported injury numbers among trials of breech VD, which also included deliveries by urgent CS (Azria et al., 2012; Lyons et al., 2015; Vlemmix et al., 2014). A BPP incidence rate of 0.6% of live births means approximately two cases of BPP in breech VD per year in Finland. Although the absolute number of injuries is low, the BPP in breech deliveries is a clinically relevant issue, as it has been suggested that neonates with BPP have a worse prognosis and a higher rate of bilateral injuries than injured neonates with cephalic presentation (Al-Qattan et al., 2010). There were no ICH or spinal cord injuries in the breech VD group.

An important finding in the present study was that the overall incidence of BPP decreased by 50%. This implies that at the end of study period there were 100 fewer injuries per year compared to the beginning of the period. Moreover, according to a recent study, the incidence of permanent BPP has also decreased recently (Grahn-Shahar, 2021). Permanent BPP is estimated to occur in 3 per 10 000 live births in Finland, which is comparable to the rates reporter in the literature (Backe et al., 2008; Chauhan, Grobman, et al., 2005; Gherman et al., 2014; Grahn-Shahar, 2021). Thus, one-sixth of neonates with BPP have a permanent injury.

Other severe birth injuries, namely spinal cord and other central nervous system injuries, long bone fractures, and internal organ injuries, were rare in all delivery modes, presentations, and gestational ages. No temporal trend could be seen with these injuries. Birth injuries were also infrequent in CS.

6.2 Risk factors in deliveries with cephalic presentation (II–III)

Increasing birth weight, shoulder dystocia, pregestational diabetes, and vacuum delivery were the main risk factors for clavicle fractures and severe birth injuries. The risk factor for severe birth injury mainly reflected the risk factors for BPP.

High birth weight increased the risk for clavicle fractures and severe birth injuries in neonates born in cephalic presentation, especially in the pregnancies of women with pregestational diabetes and in vacuum-assisted deliveries. However, the probability of injury remained moderate in the pregnancies of women without diabetes, even with higher birth weight. The importance of high birth weight as a risk factor for injury is also acknowledged in previous studies (Åberg et al., 2016; Beta, Khan, Fiolna, et al., 2019; Volpe et al., 2016). Macrosomia also has a diverse interplay with other previously known risk factors, such as shoulder dystocia, diabetes, pre-pregnancy obesity, vacuum deliveries, and induction of labor. In the

clavicle fracture study, an LGA was determined by ICD-10 code 036.6 because our aim was to analyze temporal changes in clinical practice (II). It was observed that although the use of LGA diagnoses increased, the rate of neonates with a birth weight over 4000 grams decreased. These changes were probably related to an increased incidence of labor induction and GDM, and a decreased incidence of births after 41 weeks of gestation. In addition, the reduced number of neonates with high birth weight is probably one explanation for the decreased incidence rates of clavicle fracture and BPP. This is supported by the observation that high birth weight was a more potent risk factor for severe injury than "actual" LGA, defined by birth weight above +2SD in given gestational age (III).

In total, 98% of all birth injuries occurred after 37 weeks of gestation. The overall reduction in birth injuries occurred among these neonates, even though the increasing gestational age was associated with higher birth injury and vacuum delivery rates, and a lower CS rate. In preterm deliveries, birth injuries were sporadic. Consistent with the literature, intracranial hemorrhage (P10) and other central nervous system injuries (P11) were more common in preterm than term pregnancies (Riskin et al., 2008). Moreover, higher birth weight in later gestational weeks likely explains the association between birth injuries and gestational age, especially as scalp (P12), skeletal (P13), and peripheral nervous system injuries (P14) were more common with increasing gestational age.

In accordance with the literature, shoulder dystocia was the most potent risk factor for birth injuries, irrespective of the women's diabetes status (Gherman et al., 2014; Gurewitsch et al., 2006; "Practice Bulletin No 178: Shoulder Dystocia," 2017; Sentilhes et al., 2016). After shoulder dystocia, every sixth neonate had a clavicle fracture and every fifth had BPP. The observations of the present study support the importance of shoulder dystocia as an independent risk factor for injury, as the odds of severe birth injury after shoulder dystocia were higher in non-diabetic pregnancies compared to T1D pregnancies, and a clavicle fracture more commonly co-existed with shoulder dystocia between 2006 and 2010 compared to between 2011 and 2017. However, the present study found no evidence of a difference in temporal changes in the incidence of shoulder dystocia, although there was a rising trend. Heinonen et al. and Kaijomaa et al. have reported an increasing incidence of shoulder dystocia in Finland (Heinonen et al., 2020; Kaijomaa et al., 2022). This discrepancy may be due to methodological differences. For example, one study included only deliveries from the Helsinki University Hospital district between 2010 and 2019 (Kaijomaa et al., 2022), whereas the other, based on the MBR, compared incidence of shoulder dystocia between 2004 and 2017, instead of the two time periods (2004-2010 vs 2011–2017) used in the present study (Heinonen et al., 2020). Shoulder dystocia diagnoses have likely risen in Finland. A possible explanation for this finding is the actual increase in the incidence of shoulder dystocia, as the incidence of risk factors for shoulder dystocia, such as GDM, obesity, and vacuum-assisted deliveries, has also increased (Heinonen et al., 2020). Another explanation could be the improved recognition and documentation of shoulder dystocia.

Pregestational diabetes was one of the main risk factors for birth injury. Clavicle fracture occurred in 4.6%, and severe birth injury in 2.5% of the vaginal deliveries of women with T1D compared to 1.0% and 0.3% among women without T1D. The increased odds of clavicle fracture and severe birth injury were highlighted, especially among the pregnancies of women with pregestational diabetes, by rising birth weight and in those deliveries needing vacuum assistance. Our results support previous observations that the clinical circumstances should be carefully considered before an attempt at vacuum delivery with macrosomic neonates, especially in the deliveries of women with diabetes (Gherman et al., 2014; Murphy et al., 2020; Sentilhes et al., 2016). Furthermore, the recommendation of clinical guidelines for CS in pregnancies of women with medically-treated diabetes when a fetal weight estimation is over 4500 grams seems appropriate, as the probability of clavicle fractures and severe birth injuries is also evidently increased among SVD of women with diabetes with a birth weight of 4500 grams ("ACOG Practice Bulletin No. 201: Pregestational Diabetes Mellitus," 2018; Caughey & Turrentine, 2018; NICE guideline, 2015; Working group established by the Finnish Medical Society Duodecim, 2013).

The comprehensive screening for GDM was started in 2008 (Ellenberg et al., 2017; Working group established by the Finnish Medical Society Duodecim, 2013). The change of practice resulted in an increase in the incidence of GDM. The increasing prevalence of GDM was also demonstrated in a higher proportion of clavicle fractures associated with GDM pregnancies in the latter study period (2011–2017) than in the first (2006–2010). The most preferred screening process for GDM is still controversial (Hillier et al., 2021; Pillay et al., 2021). Due to data deficiencies, cases of dietary-treated and medically-treated GDM were analyzed together. The almost identical incidence of birth injury among neonates of women with GDM and neonates of women without diabetes supports the current screening and treatment policy. Our results imply that comprehensive screening may have influenced the birth injury rate. However, more information on the treatment of diabetes (dietary, metformin, insulin), and a separate analysis of diet- and medically-treated women would have been valuable.

In addition to GDM, the incidence rates of T2D and obesity also increased between 2004–2010 and 2011–2017. These demographical changes are probably partly reflected in the increased incidence of labor induction. Obesity and related comorbidities in post-industrial societies are increasing (Poston et al., 2016; Vats et al., 2021). In the present study, obesity was a minor risk factor for clavicle fracture and severe birth injuries. Furthermore, high BMI increased the risk for severe birth injury, mainly in the vacuum-assisted deliveries of women with pregestational diabetes. This finding is consistent with the finding of previous studies (Freeman et al., 2017; Hildén et al., 2019).

There is substantial variation in clinical practice regarding the indications and timing for labor induction (Coates et al., 2020; Papalia et al., 2022). Indeed, the relationship between labor induction and birth injuries is diverse. It can be hypothesized that labor induction could predispose the fetus to unnecessary forces by prolonging the labor. In the current study, labor induction was associated with an overall increased risk for clavicle fractures and an increased risk for severe birth injury in women without pregestational diabetes. Nevertheless, the effect of labor induction on birth injury risk was low. Previous studies have found little evidence of a difference in birth injury risk related to labor induction in term pregnancies compared to expectant management (Grobman & Caughey, 2019; Keulen et al., 2019; Middleton et al., 2020; Wennerholm et al., 2019). Furthermore, it is uncertain whether labor induction due to suspected macrosomia is beneficial when considering birth injuries (Boulvain et al., 2015; Boulvain & Thornton, 2023). The rarity of birth injuries, the uncertainty of antenatal weight estimation, and the heterogeneity of studies complicate the analyses and conclusions about the relationship between birth injuries and labor induction. In other words, even bigger sample sizes would be needed to acquire enough birth injuries (outcomes) in smaller groups. The increased risk for birth injuries with labor induction seen in our study may be related to the indications for induction (e.g., diabetes, macrosomia). Another explanation is that the vast number of neonates in our study population led to a statistically significant association between many variables (labor induction, use of oxytocin, epidural or spinal anesthesia, etc.) and birth injury. However, the clinical impact of a single risk factor on the risk for injury is probably modest and at least partly related to existing clinical circumstances.

Vacuum-assisted delivery was associated with increased odds of clavicle fracture and severe birth injury. This study confirms that the injury risk was related to the indication for the procedure, and injuries were associated with the prolonged second stage of labor (Högberg et al., 2020; G. Muraca et al., 2018). However, perhaps due

to the infrequency of birth injuries, not all previous studies have verified the relationship between birth injuries and different indications for operative vaginal births (Salman et al., 2017). Between 2004 and 2017, nearly half of the vacuum extractions were performed due to suspected fetal distress, the indication which was not associated with increased risk for clavicle fracture. The rate of these fetal distressrelated vacuum deliveries also increased between 2010-2017 and 2004-2009. Therefore, a possible explanation for the decreased incidence rates of clavicle fracture and BPP, regardless of the increased vacuum delivery rate, may be an increase of relatively easy – low or outlet pelvic – vacuum deliveries. The increased injury risk after vacuum-assisted delivery in women with diabetes and among fetal macrosomia has been discussed above. BPP, clavicle and humerus fractures after vacuum deliveries, but also related to shoulder dystocia or macrosomia, are probably due to multiple excessive forces acting on the fetus during complicated or dystocic labor (Akangire & Carter, 2016; Gherman et al., 2014; Högberg et al., 2020; Levin et al., 2021). Thus, the predisposing factors for operative vaginal birth must be considered when assessing the impact of operative delivery on injury risk. Scalp injuries and ICH, although likely to be more directly related to vacuum extraction procedure per se than clavicle fractures, are more common after a difficult operative birth than a rather easy operative delivery (Åberg et al., 2019). The decreased incidence of birth injury despite an increase in the vacuum delivery rate may be due to improved patient selection for vacuum delivery versus CS or an improvement in the technical skills needed to perform vacuum extraction. To conclude, a vacuum delivery is often a reasonable first choice if assistance or the quickening of the second stage of labor are needed. However, if difficulties occur, the attempt should be discontinued and proceed to CS.

Our study confirms that a substantial number of injuries occur in deliveries without any known risk factors (Abzug et al., 2019; Ahn et al., 2015; Högberg et al., 2020; Lalka et al., 2020). Indeed, a quarter of deliveries with clavicle fracture occurred without any known main risk factors. The decline in the incidence of clavicle fracture in this low-risk group between 2006–2010 and 2011–2017 may partly explain the reduced total incidence of clavicle fracture. The majority of clavicle fractures occurred after SVD, and the incidence of fracture more than halved in the SVD group. Thus, regarding absolute injury numbers, the reduced rate of clavicle fractures was mainly due to the decrease in injuries in the SVD group. It could be argued that the reduction of fractures may be due to the generally improved obstetric care. The increasing attention paid to quality of care and patient safety issues, the beginning of simulation training for shoulder dystocia and vacuum deliveries, and the

centralization of the maternity hospitals in Finland may all have influenced the incidence of birth injury (*Health Care Act*, 2010; Kaijomaa et al., 2022; Pyykönen, 2017; Pyykönen et al., 2014). As the use of neuraxial analgesia increased during the study period, it can be hypothesized that the management of delivery may also have become "more gentle" and patient-centered. Diagnoses of GDM also increased due to the implementation of comprehensive screening. As a result, more and more pregnancies were considered high-risk, and the low-risk groups may have been healthier than in the first years of the study.

6.3 Risk factors in breech presentation (IV)

Birth injuries were sporadic in breech deliveries. Perhaps due to the low number of injuries, no clinically relevant risk factors for birth injuries were found in breech deliveries. As 82% of severe birth injuries were BPP, the risk factors analyzed primarily represent the risk factors for BPP.

In contrast to cephalic VD, increasing birth weight or gestational age was not a risk factor for either severe or mild birth injury in breech VD. The finding that birth injuries and other adverse outcomes tend to occur with lower birth weight in breech deliveries is in accordance with the previous literature (Hinnenberg et al., 2019; Jennewein et al., 2018; Vlemmix et al., 2014). It should be remembered, however, that breech VD is not recommended with an estimated fetal weight of over 4000 grams. Thus, the weight distribution differs between breech VD and cephalic VD.

The stricter antenatal selection of women for a trial of breech VD, a higher elective CS rate, and a lower threshold for intrapartum CS than in cephalic presentation may explain these results. Forceps deliveries were excluded because we did not have data on the presentation of neonates in forceps deliveries. Thus, the most complicated breech deliveries may also have been excluded. Furthermore, information about head entrapments would have been valuable in assessing preterm breech deliveries. However, spinal cord injuries, which are most often associated with head entrapments, were not found (Brand, 2006; Reichard, 2008). Additionally, as breech VD is suggested to be associated with an increased risk for mortality and short-term neonatal morbidity (Wängberg Nordborg et al., 2022) data on asphyxia-related outcomes and the long-term morbidity of neonates with birth injury after breech delivery would have been clinically valuable. With more comprehensive data, the results would have been even more useful for clinical work and for balancing the risks of CS and vaginal delivery.

6.4 Strengths and limitations

This study was conducted using register data of the Finnish MBR, which included all live births in Finland. This extensive data with nationwide coverage over a long study period enabled us to study events as rare as birth injuries. Extending the collection of data on diagnosed birth injuries beyond discharge up to 12 months after birth further increased the coverage of birth injury data, resulting in more accurate results than in most previous register studies. Also, contrary to some of the registers from the US where data is released every third year (e.g., The Kids' Inpatient Database), we were able to analyze annual changes. In Finland, reporting to the MBR and CRHC is mandatory. Moreover, the medical treatment of pregnancies is homogenous and maternity services are free and cover most of the pregnant population. The accuracy and coverage of the MBR and CRHC are reported to be good (Gissler et al., 1995; Sund, 2012). Therefore, the reporting and selection bias was low. The reform of the MBR in 2004 further improved its reliability. It could be argued, therefore, that if there had been an alteration in registration or diagnostic practices, the accuracy would have improved over the years rather than weakened. However, we could not rule out the possibility of variation and potential incorrect coding practices. For example, assessing the ease of delivering the shoulders is subjective. Thus, milder cases of shoulder dystocia may have gone undiagnosed and unregistered. The diagnostic criteria for gestational diabetes also changed during the study period, influencing the prevalence of GDM (Ellenberg et al., 2017).

The main limitation of this study is the retrospective nature of the data. Due to data deficiencies, we could not analyze deliveries in more detail. Therefore, the actual interplay of different factors taking place behind the observed changes remain in part unclear. For example, we did not have data on the maneuvers used in breech VD or shoulder dystocia, the indications for labor induction or CS, the intended mode of delivery, the duration of labor, or the level of experience of the practitioners. We also lacked specific details about vacuum delivery, such as the number of pulls and the position of the head. Further, we did not have data on neonatal adverse outcomes other than birth injuries or maternal adverse outcomes. Surprisingly, even with the large sample size, the number of some of the injuries remained modest, preterm breech deliveries were sporadic, and the low number of T2D pregnancies limited the statistical power of the results. It was not, therefore, possible to draw a conclusion on some of the injuries and their risk factors. As, BPP was more common than other severe birth injuries, the risk factors presented in studies III and IV mainly represented risk factors for BPP. Furthermore, data on the

number of persistent or bilateral injuries would have been beneficial to achieve a more comprehensive view. Because, as only study I included multiple gestations, birth injuries in twin births still require further study.

6.5 Clinical implications and future aspects

Birth injuries are rare events. For every 1000 live births, there are two cases of BPP and five clavicle fractures. In addition, ICH occurs in 2 out of every 10 000 live births. The prediction and prevention of rare and partly unexpected events is challenging. This study has shown that the number of birth injuries can be reduced with a low and stable CS rate. However, as the occurrence of birth injuries is still somewhat higher in Finland than in some other countries, long-term consequences are possible, and having identified the evident risk factors for injury, actions to prevent birth injuries should be sought.

The risk factors for shoulder dystocia are well known, and efforts have been made to provide risk evaluation tools to predict shoulder dystocia (Heinonen et al., 2020; Palatnik et al., 2016). Reliable prediction of shoulder dystocia would ease the decision-making process between operative vaginal birth and urgent CS at full dilatation. According to the ACOG and French clinical guidelines, the risk for shoulder dystocia and associated BPP could be influenced by favoring CS as a mode of delivery in three specific cases: 1) In pregnancies with suspected fetal weight exceeding 5000 grams in women without diabetes or 4500 grams in women with diabetes; 2) Among parturients with prior shoulder dystocia, especially if a severe birth injury had complicated the incident; 3) In mid-pelvic operative vaginal birth with birth weight more than 4000 grams (Gherman et al., 2014; Sentilhes et al., 2016). However, even in these high-risk circumstances, the incidence of BPP is relatively low. The fact that the actual birth weight is not known during the delivery and the imprecision of antenatal identification of neonates with a high birth weight further complicates the assessment (Khan et al., 2019). Operative vaginal delivery is often a recommendable choice when the cervix is fully dilatated, and the fetal head is engaged in the maternal pelvis (Thierens et al., 2023). In addition, the notable risk of adverse outcomes associated with CS should be considered in clinical practice (Häger 2004, Liu et al., 2007; Sandal et al., 2018; Thierens et al., 2023). The induction of labor after 39 weeks of gestation with suspected macrosomia may help to prevent shoulder dystocia and its comorbidities (Sentilhes et al., 2016). However, the evidence of the benefits of labor induction for suspected macrosomia is still

insufficient and requires further study (Boulvain & Thornton, 2023; Ewington et al., 2022).

In addition to the induction of labor with suspected macrosomia, it is probable that actions that reduce fetal macrosomia, such as preventing obesity and excess maternal weight gain during pregnancy, and good blood glucose control of women with diabetes, might reduce the occurrence of birth injuries. Mainly pregestational, but also gestational diabetes, was a risk factor for birth injuries. Maintaining and improving the quality of care for pregnancies with diabetes is essential when considering birth injuries and the comprehensive well-being of neonates and parturients.

Some injuries might be avoided by promoting spontaneous vaginal delivery and reducing the number of operative vaginal births. The optimal use of oxytocin, delayed pushing with epidural analgesia, and the continuous support of the parturient are associated with a reduced number of operative vaginal births. The effect of epidural analgesia on the delivery mode is complex, but it most likely does not reduce the SVD rate (Murphy et al., 2020; Vayssière et al., 2011). In future studies, more detailed information on the management of deliveries ending in spontaneous or operative vaginal birth, might increase our understanding of birth injuries and the related risk factors.

The rate of severe birth injuries, namely BPP, was reasonably high, and even higher in breech VD than in cephalic VD. The management of breech deliveries is standardized and quite similar throughout the country. It has been suggested that an upright position and minimal use of maneuvers would be preferable in managing breech deliveries (Habek, 2022; Louwen et al., 2017). In the future, the national practice in managing breech deliveries should be reviewed and considered if the clinical practice of the active management of the second stage of birth should shift toward minimally assisted techniques.

Promising results have been gained from simulation training on the management of shoulder dystocia (Crofts et al., 2016; Kaijomaa et al., 2022; Sollid et al., 2019). Regular annual training may reduce the occurrence of BPP (Brogaard et al., 2022). Simulation training is also reported to be cost-saving, although cost-effectiveness depends on how the training is arranged (van de Ven et al., 2017; Yau et al., 2021). To date, simulation training has been unsystematic and has differed between Finnish maternal hospitals (Working group set up by the Finnish association of Perinatology, 2021). It will be interesting to see the results of the national training program on obstetric emergencies launched in 2021. The program recommends multiprofessional, standardized, and regular (1-4 times per month or a couple of days per

year) training sessions led by a specialist in simulation instructor training. In addition to technical skills, communication, leadership, and other non-technical skills should also be practiced. Not only shoulder dystocia but also practice in the management of breech deliveries, vacuum-assisted deliveries, emergency CS, and twin births are recommended, to name but a few. The simulation training should be mandatory for all staff who are involved in managing deliveries (Working group set up by the Finnish association of Perinatology, 2021). To be able to evaluate the effects of the simulation training program on patient safety issues, including birth injuries, and to improve the training program if needed, documentation, collaboration between maternal units and research are essential. As there are no national guidelines for shoulder dystocia, breech deliveries, or operative vaginal birth in Finland, international guidelines are adapted into practice. Perhaps the simulation training program will serve to make national clinical practice more uniform and help improve safety in obstetrics. Expertise in technical and non-technical obstetric skills and regular training allows for a more comprehensive assessment of each clinical situation, the ability to choose the appropriate mode of delivery, and enables the avoidance of excessive use of force. Along with this, the number of birth injuries could be reduced.

The findings of this study support the thought that the quality of obstetric care is high in Finland. Birth injuries are rare, and the incidence of birth injuries has decreased. As birth injuries are infrequent and quite often unexpected, all injuries cannot be prevented.

7 SUMMARY AND CONCLUSIONS

The main findings and conclusion of this study are as follows:

- 1. Birth injuries are relatively rare and clavicle fractures, cephalohematoma, and BPP are the most common injury types. The total incidence of birth injury in Finland halved between 1997 and 2017, mainly due to a decreased incidence of clavicle fracture. The incidence of BPP also declined. During the study period, the rate of CS remained low and stable, whereas the rate of vacuum-assisted delivery increased.
- 2. High birth weight, shoulder dystocia, pregestational diabetes, and vacuum-assisted deliveries are risk factors for clavicle fractures. The decline in the incidence of clavicle fracture was associated with a decrease in the number of neonates with a birth weight over 4000 grams and a reduction in the incidence of injury among low-risk pregnancies.
- 3. The risk for severe birth injury is highest among the neonates of women with pregestational diabetes. However, the injury risk is only slightly higher in the pregnancies of women with GDM compared to pregnancies of women without diabetes. Increasing birth weight, shoulder dystocia, and vacuum delivery are the main risk factors for severe birth injury in pregnancies of women with diabetes.
- 4. Severe birth injuries are sporadic in breech deliveries. However, BPP is more common in breech VD than in cephalic VD. In contrast to cephalic VD, no risk factors or evidence of a difference in the injury risk with different birth weight or gestational age was found in breech VD.

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9 PUBLICATIONS

PUBLICATION I

The incidence of birth injuries decreased in Finland between 1997 and 2017:
A nationwide register study

Kekki, M., Salonen, A., Tihtonen, K., Mattila, V.M., Gissler, M., Huttunen, T.T.

Acta Paediatrica. 2020; 109: 2562-2569. https://doi.org/10.1111/apa.15267

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REGULAR ARTICLE



The incidence of birth injuries decreased in Finland between 1997 and 2017: A nationwide register study

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Abstract

Aim: Birth injuries are rare complications that can have a significant impact on neonates and their families. This population-based study describes the rates and trends of all birth injuries in Finland over a 21-year period.

Methods: The study is based on a national Medical Birth Register that includes all live-born neonates of more than 22 gestational weeks or 500 g who were born in Finland between 1997 and 2017. The ICD-10 codes of the birth injuries were obtained from the Finnish Medical Birth Register and the Care Register for Health Care. The incidence of birth injury, changes over time and incidence at different gestational ages were determined.

Results: A total of 28 551 birth injuries were diagnosed, and the total incidence decreased from 34.0 to 16.6 per 1000 live births. The incidence of clavicle fracture, cephalohaematoma, and Erb paralysis decreased while the incidence of chignon and epicranial subaponeurotic haemorrhage increased.

Conclusion: The incidence of birth injury halved during the 20-year study period. This was mainly due to a decrease in the number of clavicle fractures. The incidence of birth injury increased with gestational age, and most injuries occurred after 37 weeks of gestation.

KEYWORDS

birth injury, clavicle fracture, epidemiology, Erb paralysis, gestation age

1 | INTRODUCTION

A birth injury is a trauma suffered by neonates during labour. There have only been a few population-based studies concerning the incidence of birth injuries. Moreover, the reported incidences vary widely ranging from 0.2 to 37 per 1000 births, depending on the

birth injury and study population.¹⁻⁴ Birth injuries may vary from minor soft-tissue injuries to potentially life-threatening intracranial haemorrhages. In previous studies, the most common reported birth injuries are injury to the scalp and cephalohaematoma with an incidence of up to 20.4 per 1000 births. This is followed by clavicle fractures with a varying incidence of 2.4-15 per 1000 births.^{1,5}

Abbreviations: ICD-10, the international classification of diseases 10th revision; MBR, medical birth register; P10, intracranial laceration and haemorrhage due to birth injury; P11, other birth injuries to central nervous system; P12, birth injury to scalp; P13, birth injury to skeleton; P14, birth injury to peripheral nervous system; P15, other birth injuries.

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Acta Paediatrica. 2020;00:1–8. wileyonlinelibrary.com/journal/apa | 1

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These injuries usually heal without residual deformity, and longterm prognosis is good.⁶⁻⁸ Meanwhile, the incidence of more serious and potentially long-term sequelae of trauma, such as brachial plexus injury, has been reported to vary from 1 to 3.5 per 1000 live births. 9-13 Intracranial haemorrhages are rare with reported incidence varying from 0.1 to 1.4 per 1000 live births. 1,14,15 The mode of delivery and birthweight are associated with birth injuries. 1,13,16 In Finland, several of the risk factors associated with birth injuries have changed. For example, the number of neonates with a birthweight of over 4000 g has declined, ¹⁷ but pregnant women tend to be older, more obese, and the incidence of gestational diabetes and induced delivery has increased.¹⁷ Considering these demographic changes, we hypothesised that the incidence of overall birth injuries may have increased over the study period. This study aimed to assess the population-based incidences of birth injuries and to detect whether there have been changes in the incidence of all birth injuries in Finland between 1997 and 2017. Furthermore, the study aimed to describe the distribution of birth injuries in different gestational weeks.

2 | PATIENTS AND METHODS

2.1 | Study population and data collection

This study covered all live-born deliveries in Finland for a period of 21 years from January 1, 1997, to December 31, 2017. In total, 1 203 434 live-born neonates were included in the study. The codes for birth injuries were in accordance with the 10th Revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10), and the number of annual births was obtained from the statutory, computer-based national Medical Birth Register (MBR). The MBR was founded in Finland in 1987 and contains data on all live births and stillbirths with a birthweight of at least 500 g or a gestation age of at least 22 + 0 weeks. The data of the MBR cover all infants born in or out of hospital. According to the standard procedure, data are collected twice during the first week of life-first after delivery by a midwife and second by a paediatrician before discharge. The data collected contain demographic features, maternal characteristics, reproductive history, adverse outcomes during pregnancy and delivery, delivery statistics, neonatal data, infant health outcomes and infant diagnosis up to the age of 7 days or at discharge if earlier. The data of the MBR are complemented by information from the Central Population Register and Causes of death data from Statistics Finland. The validity of the MBR is excellent regarding both the coverage and accuracy of the database. 18 To increase the coverage of our data beyond 7 days after birth, we also included all hospital visits with any birth injury diagnosis (either inpatient or outpatient) that were recorded into the Care Register for Health Care during the first year after birth. The Care Register for Health Care (a continuation of the previous Hospital Discharge Register) is also a statutory computer-based administrative register that contains patient

Key notes

- From 1997 to 2017, a total of 28 551 birth injuries were diagnosed, and the annual injury rate decreased by 51%.
- Clavicle fractures, cephalohaematomas and Erb paralysis accounted for 90% of injuries.
- Birth injuries were rare in premature deliveries, with most injuries occurring after 37 weeks of gestation.

characteristics, such as age, sex, primary and secondary diagnosis, and all operations performed during the hospital stay. The coverage and accuracy of the Care Register for Health Care has been shown to be good. 19,20

After delivery, the birth injury diagnosis is made by clinical examination in most cases. However, if there is suspicion of long-bone (except clavicle) fractures or serious extracranial or intracranial haemorrhage, radiologic evaluation is performed. With suspected Erb paralysis, a newborn is examined by a hand surgeon or by a paediatric surgeon in cases of suspected long-bone fracture. The following birth injury codes (ICD-10) were identified at birth, during the first 7 days of life, or up to the first year of life: intracranial laceration and haemorrhage due to birth injury (P10), other birth injuries to central nervous system (P11), birth injury to scalp (P12), birth injury to skeleton (P13), birth injury to peripheral nervous system (P14) and other birth injuries (P15).

2.2 | Statistical analysis

The incidence of birth injuries was calculated based on the MBR data of the annual neonate population, and the ICD-10 codes P10-15 obtained from the MBR and the Care Register for Health Care. For further analysis, neonates were classified into five categories based on gestation age: 22 + 0 to 27 + 6 (extremely preterm), 28 + 0 to 31 + 6 (very preterm), 32 + 0 to 36 + 6 (moderate-to-late preterm), 37 + 0 to 40 + 6 (early term to full term) and 41 + 0 or after (late term to post-term). The number of injured neonates, rather than the number of different injuries, was used to calculate the injury incidences in the different gestation age categories. The rate of instrumental vaginal deliveries (including vacuum-assisted deliveries and forceps deliveries) and Caesarean sections (including elective and emergency sections) was calculated from all live births, including healthy and injured neonates. Most of the instrumental vaginal deliveries were vacuum extractions. Statistical analysis was performed using PASW 19.0 (IBM SPSS). As the MBR contains all births in Finland, the resulting incidence figures were the true results of the entire live-born population in Finland during the study period, rather than cohortbased estimates, and therefore, the probability estimates or 95% confidence intervals intrinsically needed in cohort or sample-based estimations were not calculated.

Only anonymised data were used in the study. Hence, no informed approval of the registered persons is needed for register-based studies in Finland. This study was approved by the Ethics committee of Tampere University Hospital 30.5.2017. The reference number for this research is R17069. THL/1659/5.05.00/2017.

3 | RESULTS

3.1 | Incidence of birth injury

Overall, 1 203 434 neonates were born in Finland between January 1, 1997, and December 31, 2017. In total, 27 179 neonates suffered 28 551 birth injuries. Of these, 1372 (5%) neonates suffered more than one injury. The overall incidence of birth injuries was 23.7 per 1000 live births. The absolute numbers and incidences of birth injuries and the most common injuries in each ICD-10 group are presented in Table 1. The most common injuries concerned the skeleton (ICD-10 P13), and a clavicle fracture (P13.4) was the most prevalent injury with an incidence of 11.2 per 1000 live births. The second most common birth injuries were related to the scalp (P12), a cephalohaematoma (P12.0) being the most frequent. Erb paralysis (P14.0) was the most dominant peripheral nervous system injury (P14; Table 1).

TABLE 1 The most common birth injury numbers and incidences by the main injury category and the most frequent subcategory in Finland from 1997 to 2017

Type of birth injury ICD-10 codes	Number of live births	Incidence/1000 live births
All births	1 203 434	
All birth injuries	28 551	23.7
P10 Intracranial laceration and haemorrhage	193	0.2
P10.0 Subdural haemorrhage	97	0.1
P11 Other injuries to central nervous system	88	0.1
P11.3 Facial nerve injury	54	0.04
P12 Injury to scalp	10 179	8.5
P12.0 Cephalohaematoma	9216	7.7
P13 Injury to skeleton	13 674	11.4
P13.4 Fracture of clavicle	13 460	11.2
P14 Injury to peripheral nervous system	3314	2.8
P14.0 Erb paralysis	3052	2.5
P15 Other birth injuries	1103	0.9
P15.2 Sternomastoid injury	349	0.3

3.2 | Temporal changes

The number of annual births varied between 55 000 and 60 000 neonates during the first decade of the study, but this number decreased after 2010. After 2015, the decline increased and 50 397 neonates were born in 2017. The overall incidence of birth injuries has declined by 51%, from 34.0 per 1000 live births in 1997 to 16.6 per 1000 live births in 2017 (Figure 1). This decline was mostly due to the injuries concerning clavicle fracture, the incidence of which decreased from 17.4 to 5.0 per 1000 live births. There was also a decrease in the incidence of injuries to the peripheral nervous system and scalp. The rate of Erb paralysis was highest in 2000, 3.7 per 1000 live births, and the lowest in 2015, 1.3 per 1000 live births. The incidence of brachial plexus injuries (P14.0-14.3) decreased from 3.8 per 1000 live births in 1999 to 1.4 per 1000 live births in 2015. The incidence of Erb paralysis and plexus brachialis injury in 2017 was 1.6 and 1.8 per 1000 live births, respectively. The total scalp injury rate, such as the cephalohaematoma rate, varied during the study period. Indeed, the cephalohaematoma incidence rate decreased from 10.7 per 1000 live births in 1997 to 5.6 per 1000 live births in 2007. After 2008, however, the incidence rate increased to 8.0 per 1000 live births in 2017. Other scalp injuries apart from cephalohaematoma were rare. The total incidence rate of a chignon, or artificial caput succedaneum, (P12.1) and epicranial subaponeurotic haemorrhage (P12.2) was 0.2 and 0.1 per 1000 live births, respectively. Although there was some variation between years, an overall upward trend was seen. The incidence of chignon was five times, and the incidence of epicranial subaponeurotic haemorrhage was ten times greater at the end of the study period compared with the beginning. The rate of instrumental vaginal delivery (vacuumassisted and forcens delivery) increased from 5.4% in 1997 to 9.4% in 2017. The annual Caesarean section percentage remained rather stable at around 16 to 17% (Figure 1). The mode of the delivery data was missing from 856 deliveries (1997-2017). Between 1997 and 2001, the mode of the delivery was not recorded in 0.3% of deliveries. After 2001, however, the data were missing in <0.01% of deliveries

3.3 | Gestation age

The total birth injury incidence increased with gestational age. The incidence was lowest in extremely preterm pregnancies and highest in late term and post-term pregnancies (Table 2, Figure 2). The majority of injured neonates (98%) were born after the gestational age of 37 + 0 weeks. The Caesarean section rate was more prominent in preterm compared with deliveries at or after 37 weeks, whereas most of the operative vaginal deliveries took place after 32 gestational weeks (Table 2). The incidence of birth injuries, the number of injured neonates and the rate of operative deliveries in different gestational weeks are presented in Table 2. The incidence of skeletal injury rose markedly after 37 weeks of gestation. Also, the scalp and peripheral nervous system injury rates increased in term

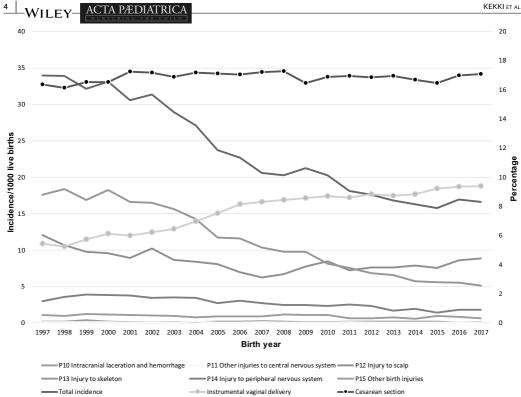


FIGURE 1 Trends in birth injury incidences per 1000 live births and operative delivery rates in percentages between 1997 and 2017

pregnancies. Moreover, 98% of all scalp and peripheral nervous system injuries and 99% of skeletal injuries took place at 37 weeks of gestation or later. The trend of decreased total birth injury incidence during the study period was seen in early term to post-term pregnancies. In moderate-to-late preterm pregnancies, the incidence remained rather stable, whereas in extremely and very preterm births the incidence remained low with sporadic fluctuation (Figure 3). In 44 neonates (0.16%) with birth trauma, the data on gestational age were missing.

4 | DISCUSSION

This study determined the incidences and temporal trends of birth injuries in Finland between 1997 and 2017. The main finding of the present study was that the total incidence of birth injuries in live births halved from 34.0 to 16.6 per 1000 live births during the 21year study period. This decrease was mainly due to the decline in clavicle fractures. The overall incidence of birth injuries was 23.7 per 1000 live births. The most common injuries were clavicle fracture, cephalohaematoma and Erb paralysis. The highest injury rates were found in term pregnancies.

There have only been a few population-based studies concerning the incidence of birth injuries. In this study, the total birth injury rate was similar to that reported in previous studies-approximately 29 per 1000 births. 1,2 Furthermore, other studies have reported that the incidence of severe and total birth injury rate has decreased or remained unchanged.^{2,3,12} This study included all reported birth injuries, including minor ones. The decrease in total birth injuries (51%) seen in our study was more prominent compared with that of an earlier study by Tomaschek et al who reported a decrease of 21% and a lowest incidence of 29 per 1000 live births.²

Most of the decline in birth injuries was due to a decreasing incidence of clavicle fractures. The rate decreased from 17.4 to 5.0 per 1000 live births during the study period. In earlier studies, the incidence has varied from 2.0 to 18 per 1000 births. 1,5,6,21 The decline in the number of clavicle fractures was accompanied by a decrease in the rate of Erb paralysis. The incidence of brachial plexus injury and Erb paralysis approximately halved during the study period, with an incidence of 1.8 and 1.6 per 1000 live births in 2017, respectively. The brachial plexus injury rate was consistent with that reported in previous studies.^{1,9-13,16,22} Plexus injuries are especially associated with shoulder dystocia and are accompanied with clavicle fracture. $^{5,9-11,13,16,22}$ The reduced rate of clavicle fractures and

TABLE 2 Injured neonates, number of injuries, injury incidences at different gestational ages and operative delivery percentage of all live-born neonates at different gestational ages

	Gestational age in weeks				
	22 + 0 - 27 + 6	28 + 0 - 31 + 6	32 + 0 - 36 + 6	37 + 0 - 40 + 6	41 + 0-
Live-born neonates	3091	6301	58 360	853 707	278 227
Number of injured neonates					
All injured neonates	5	24	525	18 507	8074
P10 Intracranial laceration and haemorrhage	2	2	25	106	33
P11 Other injuries to central nervous system	-	3	11	58	16
P12 Injury to scalp	-	8	216	6889	3089
P13 Injury to skeleton	1	4	154	9369	4107
P14 Injury to peripheral nervous system	1	2	75	2179	1022
P15 Other birth injuries	2	5	54	767	254
Incidence/1000 live births					
Total incidence	1.6	3.8	9.0	21.7	29.0
P10 Intracranial laceration and haemorrhage	0.7	0.3	0.4	0.1	0.1
P11 Other injuries to central nervous system	0.0	0.5	0.2	0.1	0.1
P12 Injury to scalp	0.0	1.3	3.7	8.1	11.1
P13 Injury to skeleton	0.3	0.6	2.6	11.0	14.8
P14 Injury to peripheral nervous system	0.3	0.3	1.3	2.6	3.7
P15 Other birth injuries	0.7	0.8	0.9	0.9	0.9
Delivery mode, percentage					
Instrumental vaginal delivery	0.2	0.8	5.1	7.0	10.6
Caesarean section	53.6	66.0	37.5	16.2	13.0

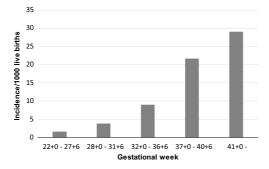


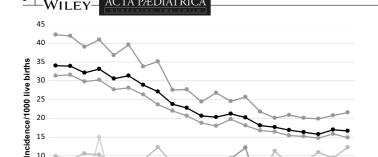
FIGURE 2 Incidence of birth injuries in different gestational weeks

plexus injuries implies that either the incidence of shoulder dystocia is decreasing or that their management has improved over the years.

High birthweight is associated with complicated childbirth and increased risk of birth injury.^{1,13,16,22,23} Thus, high birthweight

is considered to be one of the main risk factors for clavicle fractures and Erb paralysis. Morbidity expands with increasing birthweight. ^{23,24} In Finland, the number of neonates with a birthweight of over 4000 grams decreased from 20.1% in 1995 to 16.7% in 2017 and the number of neonates with a birthweight of more than 4500 g has decreased from 3.6% in 1995 to 2.4% in 2017. ¹⁷ The decrease in the number of macrosomic neonates may partly explain the decreasing incidence of birth injuries, especially clavicle fractures and plexus injuries. The incidence of birth injury increased with gestational age. This finding is comparable to other studies, ²² and it may be linked to the higher birthweight in advancing gestational weeks, since the most common birth injuries were clavicle fractures and Erb paralysis.

It has been proposed that Caesarean section, especially elective ones, protects the neonate against birth injury, whereas instrumental vaginal delivery exposes the neonate to injury. ^{3,13,25} Birth injury incidence has been reported to be 1.2-2.5 per 1000 live births among elective Caesarean section and 4.9 to 13.3 per 1000 live births in Caesarean section during labour. ^{3,25} Furthermore, it has been suggested that dysfunctional labour itself may have a more significant influence on birth injury than the type of operative delivery. ¹ The



1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017

Birth year

→ Total incidence → 22+0 - 27+6 → 28+0 - 31+6 → 32+0 - 36+6 → 37+0 - 40+6 → 41+0 -

FIGURE 3 The incidence of birth injuries in different gestational weeks from 1997 to 2017

global Caesarean section rate differs widely. In Europe, for example, the Caesarean section rate varies from 15% to 52%, whereas in the United States, 32% of all births take place by Caesarean section. 26,27 In Finland, the Caesarean section rate remained at a steady level of 16%-17% during the 20-year study period. Most birth injuries occurred at 37 weeks of gestation or later when the Caesarean section rate was lowest. However, the trend of declining birth injuries was also most prominent from 37 weeks of gestation despite the stable and rather low Caesarean section rate. Therefore, based on the findings of this study, the decreased incidence of birth injuries was achieved without any major changes in the Caesarean section rate. This implies that there are factors other than the Caesarean section rate that affect the birth injury rate.

10 5 0

Furthermore, instrumental vaginal deliveries are thought to be associated with an increased risk of birth injuries. 1,6,13,14,16,28 This was indirectly observed in this study. The rate of operative vaginal deliveries, as well as the incidence of birth injuries, increased with gestational age. The rate of severe birth injury has been reported to vary from 1.1 to 4.7 per 1000 births for spontaneous vaginal deliveries and from 6.5 to 14.2 per 1000 for operative vaginal deliveries. 3,12 When taking into account all, also minor, birth injuries, the birth injury rate after operative vaginal delivery can be as high as 62.5 per 1000 births. 25 In Europe, instrumental vaginal delivery accounts for approximately 7.5% of all births.²⁶ In the United States, the rate of vacuum deliveries has declined from 9% in 1990 to 3.1% in 2015.²⁷ However, in Finland, the number of instrumental vaginal deliveries, most of which being vacuum-assisted deliveries, increased from 5.4% in 1997 to 9.4% in 2017. Based on the findings of this study, after 1997, the rise in vacuum delivery rate was reflected in a slight (30%) increased trend in scalp injuries, especially the increasing trend of artificial caput succedaneum and epicranial subaponeurotic haemorrhages found in our study. Even though the incidence of cephalohaematomas was lower at the end of the study period compared with the beginning, the incidence of scalp injury was lower than previously reported. Earlier, Sauber-Schatz et al had estimated the rate to be 20.1 per 1000 births. One possible explanation for the decline in the scalp injury rate could be attributed to the better management of instrumental vaginal deliveries over the study period. Time-related change of scalp injuries was linked to the temporal trends of cephalohaematoma because the rate of cephalohaematoma dominated in this subgroup.

Severe intracranial head injuries are rare. The incidence of intracranial haemorrhage is reported to vary from 0.1 to 1.4 per 1000 births. 1.12.14.15 In this study, the incidence of intracranial lacerations and haemorrhages was equal to earlier published findings, namely 0.2 per 1000 live births. Contrary to other birth injuries, the incidence of intracranial haemorrhage and other central nervous system injuries was highest in preterm pregnancies and remained stable from early term to post-term pregnancy. Furthermore, there was no temporal change seen within these injuries. Intracranial haemorrhage may therefore be connected to the prematurity of preterm neonates. 29 Other birth injuries were rather uncommon during the premature period. This could be due to the smaller birth size, but also to the fact that operative vaginal deliveries are rare, and the Caesarean section rate is high in preterm births.

There have only been a small number of population-based studies concerning the incidence of birth injuries. To the best of our knowledge, this present study is one of the few studies that provides national estimates of all birth injuries. Since some of the birth injuries are rare, register-based studies with a large population have the advantage that the incidences and trends in birth injuries can be estimated. A strength of this study is the statutory Finnish Medical Birth Registry which contains data on all live-born neonates in the entire nation. We further extended our study beyond the discharge date of the newborn by including information from the Care Register for Health Care that includes data on birth injuries diagnosed after discharge. The accuracy and coverage of the data are reported to be good. 18-20 Even if there was some variation in injury rates between the years, the trends persisted in a logical manner. Moreover, we assume that if there had been changes in registration or diagnostic practices, the accuracy would have improved over the years rather than weakened. Furthermore, in Finland, maternity services are free and cover most of the pregnant population, which reduces social differences in antenatal and labour care. The limitation of this study is the retrospective nature of the data. Taking into account the long time period and the nationwide study population, there is a risk of variation among coding practices and the possible use of incorrect ICD-10 codes. The results of this study can be mostly applied to countries with similar clinical practices and healthcare systems. Additional research is necessary to investigate birth injury risk factors to achieve a better understanding of the causes behind the injuries and to identify ways to further reduce the birth injury rate.

5 | CONCLUSION

Based on the findings of this study, between 1997 and 2017 the overall incidence of birth injuries decreased by 51% from 34.0 per 1000 live births to 16.6 per 1000 live births. The most common injuries were clavicle fracture, cephalohaematoma and Erb paralysis. Moreover, 98% of the injuries occurred to full-term neonates. The Caesarean section rate remained rather stable, but operative vaginal deliveries increased during the study period, suggesting that there are factors other than mode of delivery alone that affect the incidence of birth injury. However, the causes of the decrease in birth injury require further study.

CONFLICT OF INTEREST

Authors do not have any economical or intellectual conflict of interest.

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How to cite this article: Kekki M, Salonen A, Tihtonen K, Mattila VM, Gissler M, Huttunen TT. The incidence of birth injuries decreased in Finland between 1997 and 2017: A nationwide register study. Acta Paediatr. 2020;00:1–8. https://doi.org/10.1111/apa.15267

PUBLICATION II

Incidence changes in risk factors associated with the decreasing number of birth-related clavicle fractures in Finland: A nationwide retrospective birth cohort from 2004 to 2017

Kekki, M., Salonen, A., Koukkula, T., Laivuori, H., Tihtonen, K., Huttunen T.T.

Birth. 2023; 50: 428-437. https://doi.org/10.1111/birt.12662

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ORIGINAL ARTICLE



Incidence changes in risk factors associated with the decreasing number of birth-related clavicle fractures in Finland: A nationwide retrospective birth cohort from 2004 to 2017

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Funding information

The study was financially supported by the Tampere University Hospital Support Foundation

Abstract

Background: A clavicle fracture is one of the most common birth injuries. The objective of this study was to examine whether the decreased incidence of birth-related clavicle fractures in Finland is because of temporal changes in their predisposing factors.

Methods: For this nationwide population-based study, we used the Finnish Medical Birth Register and the Care Register for Health Care databases. The study population included all singleton, live-born newborn born spontaneously or by vacuum-assisted delivery, in cephalic presentation $\geq 37^{+0}$ weeks of gestation. The incidences of clavicle fractures, pregnancy characteristics, and risk assessments for fracture were calculated and compared between two time periods: 2004-2010 and 2011-2017.

Results: A total of 629 457 newborn were born vaginally between 2004 and 2017. The clavicle fracture incidence decreased from 17.6/1000 to 6.2/1000 live births. Shoulder dystocia, diabetes, and birthweight \geq 4000 g were the strongest predisposing factors. The incidence of birthweight \geq 4000 g decreased, meanwhile type 1 diabetes and shoulder dystocia remained stable and gestational diabetes, type 2 diabetes, and maternal obesity increased in the later study period. The incidence of clavicle fractures without known predisposing factors declined. Simultaneously, the cesarean birth rate remained stable (13.2%–13.1%), although the rate of vacuum-assisted deliveries increased (8.5%–9.5%).

Discussion: The incidence of clavicle fractures decreased, even though the incidence of most risk factors remained stable or increased, and the cesarean birth rate remained stable. This decline may be related to the reduction of fracture incidence among deliveries without known risk factors, and the decrease in birthweight \geq 4000 g.

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KEYWORDS

birth injury, birthweight, clavicle fracture, risk factors, vaginal delivery

1 | INTRODUCTION

A clavicle fracture is one of the most common birth injuries occurring in newborns. ^{1,2} The prognosis is usually good, but a birth injury may be cause for concern in subsequent pregnancies and may influence attitudes toward a particular mode of delivery. Over the past two decades, the incidence of clavicle fracture has decreased in several countries, and now ranges from 0.5 to 11.2/1000 live births. ^{1–8}

Several predisposing factors with variable predictive values for clavicle fracture have been identified. The most common risk factor is increased birthweight. Indeed, it has been reported that approximately 20%-50% of injured newborns have a birthweight of over 4000 g.5-10 A difficult birth has been found to be strongly associated with a clavicle fracture, although only 4% of injuries are associated with shoulder dystocia.8 Other identified risk factors are advanced maternal age, short stature, obesity, malpresentation, type 1 diabetes (T1D), gestational diabetes, the use of oxytocin, and pain relief during labor. 4-8,11,12 However, often, there are only a few clinically important differences between injured and uninjured newborns. 5,11,13 The incidence of a clavicle fracture is also dependent on the mode of delivery, and it is mainly associated with spontaneous and instrumental vaginal delivery, even though some controversies exist.4,5,7,8,11

A previous study on birth injuries in Finland showed that the incidence of clavicle fractures in live-born newborns delivered in hospitals (including preterm newborns, multiple gestations, and breech deliveries) decreased by 70%, from 17.4/1000 live births in 1997 to 5.0/1000 live births in 2017.2 Most of the clavicle fractures occurred after 37⁺⁰ weeks of gestation, and the incidence decreased among those born after 37⁺⁰ weeks of gestation.² However, the incidence of known clinical risk factors-such as gestational diabetes, advanced maternal age, and high body mass index (BMI)—have increased globally. 14-17 Here, we aimed to identify the pregnancy- and newborn-related predisposing factors for clavicle fracture, and to describe temporal changes in frequency and risk factors for injury between two time periods (2004-2010 and 2011-2017) in newborns born vaginally with cephalic presentations and gestational age≥37⁺⁰ weeks. The study period was determined based on the changes in the Medical Birth Register (MBR). In the selected time ranges, the prenatal, delivery, and perinatal characteristics were more comprehensively registered than in previous years.

2 | METHODS

Birth data were obtained from the statutory, computerbased national MBR. The MBR is maintained by the National Institute for Health and Welfare and contains data on all live-born births and stillbirths with a birthweight ≥500 g or a gestational age of at least 22⁺⁰ weeks. The MBR includes demographic data, patient prenatal characteristics, delivery characteristics, perinatal outcomes, and infant diagnosis up to the age of 7 days or at discharge if earlier. The data are prospectively gathered during antenatal care and from the delivery units and supplemented by data from the Central Population Register and Causes-of-death registration at Statistics Finland. The validity of the MBR has been established; data quality and completeness are excellent. 18 All hospital visits with any birth-related clavicle fracture diagnosis (ICD-10 P13.4) recorded into the Care Register for Health Care during the first year after birth were included to increase data coverage beyond 7 days after birth. The Care Register for Health Care (a continuation of the previous Hospital Discharge Register) is a statutory, computer-based administrative register that contains patient characteristics, diagnoses, and operations performed during the hospital stay. The coverage and accuracy of the Care Register for Health Care have been evaluated as excellent.19

This study included all live-born newborns $(n=807\,207)$ in Finland from January 1, 2004 to December 31, 2017. Preterm newborns, newborns born in breech presentation, multiple gestations, and newborns with osteochondrodysplasia (ICD-10 Q78.00-Q78.9) or spina bifida (ICD-10 Q05.0-Q05.9) were excluded from the study. Singleton newborns $(n=724\,807)$ born in a cephalic presentation, $\geq 37^{+0}$ weeks of gestation in a hospital were included in a preliminary analysis. Forceps deliveries were excluded from further analysis because of a low number of procedures; cesarean births were also excluded because of the low incidence of clavicle fractures in this group (Figure 1).

The outcome variables in the present study were the number of birth-related clavicle fractures coded with the ICD-10 code P13.4 and variables associated with increased risk for fracture and their temporal alterations. ICD10-codes P14.0–14.3 were used for co-existing brachial plexus palsy. The pediatricians diagnosed a clavicle fracture based on the best clinical practice at the time. Numerous variables concerning demographics and delivery characteristics were analyzed (Table S1). Most of the variables were collected and

FIGURE 1 Study population

629 457 neonates born by vaginal delivery (including spontaneous vaginal and vacuumassisted deliveries)

registered by a midwife. Some of the variables were formed from the Finnish implementation of the 10th Revision of International Statistical Classification of Diseases and Related Health Problems (ICD-10 codes) determined by an obstetrician/gynecologist. The variables included in further analyses are listed in Table 1. Spontaneous vaginal deliveries (SVDs) included spontaneous and induced deliveries as opposed to operative vaginal deliveries (vacuum-assisted deliveries). Large-for-gestational-age (LGA) diagnosis (ICD-10 O36.6) was used if LGA was suspected during antenatal care (estimated weight >2 SD based on ultrasound) or registered as a birth diagnosis (birthweight >2 SD or intervention was needed because of suspicion of birthweight >2 SD). Oxytocin was registered if it was used to either induce or augment labor. To evaluate the temporal change, the study was divided into two time periods-from 2004 to 2010 and from 2011 to 2017. Data concerning prepregnancy BMI were added after 2006, as a considerable number of values were missing in the years 2004 and 2005. Subsequently, part of the temporal change analyses started in 2006. For further analyses, some variables (age, height, BMI, weeks of gestation, and birthweight) first analyzed as a continuous variables were dichotomized.

2.1 | Statistical analysis

The incidences of birth-related clavicle fractures by a different mode of delivery were calculated. The incidences of demographics and delivery characteristics with each categorized variable were calculated, and the temporal change was analyzed by rate ratio with 95% confidence intervals, comparing the years 2011-2017 with 2004-2010. A rate ratio >1 indicated an increased incidence of the calculated variable in 2011-2017. The relative risk was used to estimate the probability of clavicle fracture between the two time periods, with 95% confidence intervals and a relative risk >1 indicating the enhanced impact of a variable on the clavicle fracture risk in the study period 2011-2017. Odds ratios and risk differences, with 95% confidence intervals, were used to evaluate the risk of a clavicle fracture. The odds ratio presents the odds that clavicle fracture will occur within a given exposure group versus an unexposed group; the risk difference represents the difference between the risk for a clavicle fracture in an exposed group versus an unexposed group. The difference in fracture incidence with the most clinically important variables was calculated by comparing the years 2011-2017 with 2006-2010 (incidence rate ratio [IRR], with 95% confidence intervals). Shoulder dystocia, T1D, birthweight ≥4000 g, BMI≥30 kg/m² (obese), and gestational diabetes were included in the analysis and referred to as the main predisposing factors. They were chosen based on the risk for clavicle fracture, the temporal change of variables, and the unambiguousness of the variables' registration. Furthermore, birthweight ≥4500 g, birthweight \geq 5000 g, labor induction, and gestational age \geq 41⁺⁰ were included. The inclusion of these variables was based on the high risk for clavicle fracture associated with elevated birthweight, increasing trend of labor inductions, the decreasing incidence of labor after 41 gestational weeks, and clinical interest in evaluating the influence of the timing of the delivery on fracture incidence. Cluster-type analysis of clavicle fracture incidences with an increasing number of variables was done to explore the reduced incidence of clavicle fracture. Shoulder dystocia and T1D were excluded from these analyses because of their estimated modest impact on the declining trend of fractures because of their low incidences. Logistic regression analysis was used to assess the effect of the primary outcomes on the clavicle fracture risk and to construct risk estimation curves. Statistical analyses were performed using R 4.0.0. Only pseudonymized data were used in the study.

2.2 | Missing data and sensitivity analysis

The proportion of overall missing data was low (<1%), except for length 1.7% and BMI 4.3%. Thus, any methods for managing missing values were not applied. As the MBR contains all births in Finland, the study population covered all live births with the cephalic presentation, born beyond 37 gestational weeks during the study period. Therefore, the risk for selection bias was estimated to be low (Figure 1).

3 | RESULTS

The final study population included 629457 newborns born in cephalic presentation, ≥37⁺⁰ weeks of gestation, spontaneously or by vacuum extraction (Figure 1). The total incidence of clavicle fracture was 10.4/1000 live births (n = 6577) including all vaginal deliveries, 9.2/1000 live births in SVD (n = 5175), and 21.6/1000 live births in vacuum-assisted deliveries (n = 1402). The clavicle fracture incidence in SVD decreased by 66% from 16.4/1000 live births (n = 671) in 2004 to 5.5/1000 live births (n = 190) in 2017, and by 61%in vacuum-assisted delivery from 31.1/1000 live births (n = 116) to 12.1/1000 live births (n = 54), respectively. In addition, 44 fractures were recorded after cesarean birth (incidence 0.46/1000 live births) during the whole study period. The 66% of fractures among the cesarean group were after unplanned cesarean births. Since injuries after cesarean remained infrequent and stable, they were excluded from the

TABLE 1 Maternal demographics, delivery characteristics, associated risk for clavicle fracture and temporal changes among singleton term vaginal deliveries with newborns born in cephalic presentation, Finland, 2004–2017

Maternal and delivery characteristics	2004-2010 (n = 321691) Frequency $(\%)^a$	2011–2017 (n = 307766) Frequency $(\%)^a$	P-value	Rate ratio (95% CI)	Relative risk (95% CI)	Odds ratio (95% CI)	Risk difference (95% CI)
Shoulder dystocia	1120 (0.3)	1079 (0.4)	0.87	1.01 (0.93, 1.09)	0.87 (0.71, 1.07)	15.9 (14.1, 18)	12.9 (11.5, 14.4)
Type 1 diabetes	711 (0.2)	687 (0.2)	0.85	1.01 (0.91, 1.12)	0.71 (0.43, 1.15)	4.58 (3.56, 5.89)	3.5 (2.6, 4.8)
Birthweight ≥4000 (g)	58 170 (18.1)	53 670 (17.4)	<0.001	0.96 (0.95, 0.98)	0.59 (0.55, 0.63)	3.89 (3.7, 4.08)	2.0 (1.9, 2.1)
Birthweight ≥4500 (g)	8235 (2.6)	7024 (2.3)	<0.001	0.89 (0.86, 0.92)	0.62 (0.53, 0.72)	4.85 (4.47, 5.25)	3.52 (3.21, 3.86)
Birthweight ≥5000 (g)	537 (0.2)	412 (0.1)	<0.001	0.8 (0.71, 0.91)	0.67 (0.41, 1.08)	7.38 (5.76, 9.45)	6.1 (4.7, 8.0)
Large-for-gestational-age	3632 (1.1)	4758 (1.5)	<0.001	1.37 (1.31, 1.43)	0.6 (0.48, 0.76)	3.45 (3.06, 3.89)	2.4 (2.0, 2,8)
Type 2 diabetes	186 (0.06)	371 (0.1)	<0.001	2.09 (1.75, 2.49)	0.6 (0.18, 1.95)	1.91 (1.05, 3.47)	0.9 (0.6, 2.5)
Use of oxytocin	134 581 (41.8)	149146 (48.5)	<0.001	1.16 (1.15, 1.17)	0.56 (0.52, 0.6)	1.55 (1.47, 1.63)	0.4 (0.4, 0.5)
BMI $\ge 30 \text{ (kg/m}^2)^b$	29 391 (12.7)	41 082 (13.3)	<0.001	1.05 (1.04, 1.07)	0.6 (0.53, 0.68)	1.52 (1.42, 1.63)	0.5 (0.4, 0.6)
Insulin treatment ^c	5435 (1.7)	4778 (1.6)	<0.001	0.92 (0.88, 0.96)	0.85 (0.62, 1.16)	1.49 (1.27, 1.75)	0.5 (0.3, 0.8)
Gestational diabetes	32 128 (10)	46 825 (15.2)	<0.001	1.52 (1.50, 1.55)	0.52 (0.46, 0.58)	1.36 (1.27, 1.45)	0.4 (0.3, 0.4)
Induction of labor	54 904 (17.1)	70 743 (22.3)	<0.001	1.35 (1.33, 1.36)	0.5 (0.46, 0.55)	1.35 (1.28, 1.43)	0.3 (0.2, 0.4)
Gestational age≥41 ⁺⁰ (weeks)	84 525 (26.3)	77 598 (25.2)	<0.001	0.96 (0.95, 0.97)	0.56(0.51, 0.61)	1.31 (1.24, 1.38)	0.3 (0.2, 0.4)
Paracervical and/or pudendal block	67 377 (20.9)	80 656 (26.2)	<0.001	1.25 (1.24, 1.26)	0.59 (0.54, 0.65)	1.2 (1.13, 1.27)	0.2 (0.1, 0.3)
Epidural and/or spinal anesthesia	178 799 (55.6)	201 394 (65.4)	<0.001	1.18 (1.17, 1.19)	0.6 (0.56, 0.63)	1.18 (1.23, 1.24)	0.2 (0.1, 0.2)
Multipara	193 717 (60.2)	188 717 (61.3)	<0.001	1.02 (1.01, 1.03)	0.61 (0.56, 0.66)	0.99 (0.95, 1.05)	0(-0.1, 0.01)
Age≥30 (years)	153 197 (47.6)	160 069 (52)	<0.001	1.09(1.09, 1.10)	0.54 (0.50, 0.58)	0.95(0.91, 0.10)	-0.1(-0.1,0)
Height≥165 (cm)	184 443 (59)	176 127 (57.4)	0.57	1.00 (0.99, 1.01)	0.56 (0.53, 0.6)	0.84 (0.80, 0.89)	-0.2(-0.2, -0.1)
Spontaneous vaginal delivery	290 357 (90.3)	274 241 (89.1)	<0.001	0.99 (0.98, 0.99)			
Vacuum-assisted delivery	31 334 (9.7)	33 525 (10.9)	<0.001	1.12 (1.10, 1.14)	0.62 (0.56, 0.69)	2.39 (2.25, 2.54)	1.3 (1.1, 1.4)
Vacuum-assisted delivery							
Prolonged II stage of labor ^d	7634 (24.4)	8515 (25.4)	0.008	1.04 (1.01, 1.08)	0.68 (0.56, 0.83)	1.3 (1.16, 1.46)	0.6(0.3, 0.9)
Maternal distress ^d	2558 (8.2)	3059 (9.1)	<0.001	1.12 (1.06, 1.18)	0.53 (0.37, 0.75)	1.05 (0.87, 1.26)	0.1(-0.3, 0.6)
Asphyxia or fetal distress ^d	14 165 (45.2)	17 078 (50.9)	<0.001	1.13 (1.10, 1.15)	0.67 (0.57, 0.80)	0.66 (0.59, 0.74)	-0.9(-1.2, -0.6)
Malpresentation ^d	2496 (8)	3769 (11.2)	<0.001	1.41 (1.34, 1.49)	0.64 (0.38, 1.08)	0.38 (0.29, 0.49)	-1.4(-1.7, -1.1)

incidence of the calculated variable in 2011–2017 compared with 2004–2010. Relative risk comparing risk difference between 2011 and 2017 versus 2004 and 2010. Relative risk > meaning the increased probability of clavicle fracture with exposure in 2011–2017 versus 2004–2010. Odds ratio represents the odds that clavicle fracture will occur within a given exposure in 2011–2017 versus 2004–2010. Odds ratio represents the odds that clavicle fracture will occur within a given exposure in 2011–2017 versus 2004–2010. Odds ratio represents the Note: P-value calculated from Incidence rate ratio (IRR), using Chi-square test. Rate ratio comparing variables' incidences between periods 2011 and 2017 versus 2004 and 2010. Rate ratio >1 meaning an increased difference between the risk for a clavicle fracture in the exposed group versus the unexposed group (*100).

Since 2006.

Abbreviation: 95% CI, 95% confidence interval.

^aFrequency of variable and a percentage of total frequency.

^cInsulin treatment started during pregnancy.

^dVariables concerning only vacuum-assisted deliveries.

final study population and subsequent analysis. The overall cesarean birth rate remained stable at 13.2% from 2004 to 2010 and 13.1% from 2011 to 2017, whereas the vacuum-assisted delivery rate increased from 8.5% to 9.5% during the same time period. The annual clavicle fracture incidences with different delivery modes are presented in Figure 2. In addition to clavicle fracture, 330 newborns also had a brachial plexus injury (incidence 0.5/1000). The coexistence of these two injuries was rarer in the latter study period (2004–2010 incidence 0.7/1000, 2011–2017 incidence 0.3/1000). Fifty-nine newborns had clavicle fracture, brachial plexus injury, and shoulder dystocia.

Maternal demographics and delivery characteristics in vaginal deliveries are shown in Table 1. The most notable changes were an increase in the incidence of type 2 diabetes (T2D), gestational diabetes, and induction of labor. In addition, the incidence of LGA, pain relief during labor, oxytocin use, and obesity increased, whereas the incidence of birthweight $\geq 4000 \,\mathrm{g}$ and delivery $\geq 41^{+0}$ gestational weeks decreased. Mean birthweight, mean gestational age, and the incidences of T1D and shoulder dystocia remained stable. When vacuum-assisted deliveries were considered separately, the incidence of malpresentation increased most, and approximately half of the procedures were performed because of asphyxia or fetal distress during the latter study period. The incidence of the most important clinical variables in different delivery modes between 2004-2010 and 2011-2017 are shown in Table S2. The rate ratios of risk factors were comparable among cesarean births, SVDs, and vacuum-assisted deliveries during the study periods.

Shoulder dystocia, T1D, and elevated birthweight were associated with the highest risk for clavicle fracture based

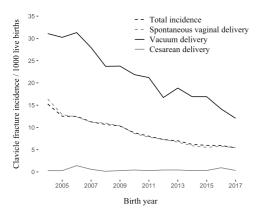


FIGURE 2 Clavicle fracture incidence by mode of delivery among term singleton births with newborn born in cephalic presentation, Finland, 2004–2017

on odds ratios and risk differences (Table 1). The impact of variables on the risk for clavicle fracture was lower between 2011 and 2017 than between 2004 and 2010, except in birthweight ≥5000 g, T1D and T2D, insulin treatment started during pregnancy, and shoulder dystocia of which the likelihood of fracture remained unchanged during the study period (Table 1, relative risk).

The fracture risk was higher in vacuum-assisted deliveries compared with SVDs, and it was highest if vacuumassisted delivery was required because of a prolonged second stage of labor. Furthermore, the risk for clavicle fracture increased with increasing birthweight. For example, the probability of clavicle fracture in newborns born by vacuum-assisted delivery was 1.6% (95% CI 1.5, 1.7) with a birthweight of 3500 g, 3.2% (95% CI 3.0, 3.4) with a birthweight of 4000 g, and 6.4% (95% CI 5.8, 6.9) with a birthweight of 4500 g (Figure 3). The impact of birthweight was highlighted in women with T1D; in vacuum-assisted deliveries, the probability of injury with a birthweight of 3500 and 4000 g was 5.0% (95% CI 3.1, 8.0) and 9.7% (95% CI 6.1, 15.2), respectively. The relationship among birthweight, mode of vaginal delivery, and probability of injury in the whole study population and patients with T1D are presented in Figure 3.

The proportion of clavicle fractures with a risk factor for all clavicle fractures (fracture incidence with different variables/1000 fractures) was compared between the two study periods (Table 2). Only 1.1% of deliveries with clavicle fractures were associated with T1D and 5.0% with shoulder dystocia. Meanwhile, 44.9% of injured newborns had a birthweight of ≥4000 g, thus making high birthweight the most frequent risk factor. In total, 39.7% of deliveries with clavicle fractures were not related to any of the main predisposing factors (shoulder dystocia, T1D, birthweight ≥4000 g, BMI≥30, kg/m², or gestational diabetes). A fracture incidence without any of the clinically important risk factors (also including gestational age≥41⁺⁰ weeks and labor induction) was lower in 2011-2017 than in 2006-2010. Furthermore, fractures were more often associated with shoulder dystocia, gestational diabetes, and induced delivery during 2011-2017 (Table 2). Based on the cluster-type analysis, a decrease in fracture incidence without any of the risk factors was observed in 2011–2017, IRR 0.89 (95% CI 0.80, 0.99). Otherwise, no clear trend in changes in the associated factors was seen. The increased rate of fractures along with the four risk factors could be explained by sporadic fluctuation (Table 2).

4 | DISCUSSION

In Finland, the incidence of birth-related clavicle fractures in newborns born vaginally decreased by more than 60% between 2004 and 2017, despite the increased incidence of most risk factors in this study population, and the stable cesarean birth rate. Shoulder dystocia, high

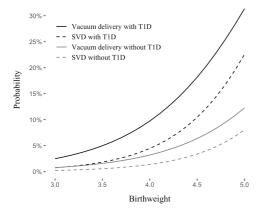


FIGURE 3 The probability of clavicle fracture in relationship to birthweight, mode of vaginal delivery, and type 1 diabetes (T1D)

birthweight, and T1D had the strongest association with the injury. Low-risk patients, without any notable risk factors, accounted for a quarter of the fractures in this study. The incidence of clavicle fractures significantly decreased in these low-risk pregnancies. Furthermore, the decreased injury incidence may be related to the increase in the general incidence of labor induction accompanied by the decrease of high birthweight newborns.

4.1 | Strengths and limitations

The strengths of the present study are the statutory Finnish MBR and the Care Register for Health Care with national coverage and a long study period. The precision and completeness of the data have been reported to be high. ^{18,19} The large sample size enabled us to investigate a relatively rare outcome such as clavicle fracture. Considering Finland's stable and low cesarean rate, this study contributes knowledge on birth-related clavicle fractures in vaginal deliveries. A limitation of the study was that we were unable to analyze deliveries in more

 TABLE 2
 Birth-related clavicle fractures with different risk factors in vaginal deliveries, 2006–2010 and 2011–2017

	2006-2010 (n = 2831)	2011-2017 (n = 2312)		
Risk factors	Frequency ^a (incidence/1000)	Frequency ^a (incidence/1000)	P-value	IRR (95% CI) ^b
Shoulder dystocia (A)	118 (41.7)	139 (60.1)	0.003	1.44 (1.13, 1.84)
Type 1 diabetes (B)	31 (11)	26 (11.2)	0.92	1.03 (0.61, 1.73)
Birthweight \geq 4000 (g) (C)	1263 (446.1)	1044 (451.6)	0.77	1.01 (0.93, 1.10)
Birthweight ≥4500	295 (104.2)	236 (102.1)	0.81	0.98 (0.83, 1.16)
Birthweight ≥5000	29 (10.2)	23 (9.95)	0.91	0.97 (0.56, 1.68)
Gestational diabetes (D)	403 (142.4)	458 (198.1)	< 0.001	1.39 (1.22, 1.59)
BMI \geq 30 (kg/m ²) (E)	518 (183)	434 (187.7)	0.69	1.03 (0.90, 1.17)
Gestational age≥41 ⁺⁰ (weeks) (F)	913 (332.5)	694 (300.2)	0.15	0.93 (0.84, 1.03)
Induction of labor (G)	670 (236.7)	650 (281.1)	0.002	1.19 (1.07, 1.32)
Fracture without A-E ^c	1161 (410.1)	883 (381.9)	0.11	0.93 (0.85, 1.02)
Fracture without A-G	759 (268.1)	546 (236.2)	0.024	0.88 (0.79, 0.98)
Number of any of the risk fac	ctors (C-G)			
0 risk factor	779 (275.2)	564 (243.9)	0.029	0.89 (0.80, 0.99)
1 risk factor	914 (322.9)	746 (322.7)	0.99	1.0 (0.91, 1.10)
2 risk factors	676 (238.8)	593 (256.5)	0.2	1.07 (0.96, 1.20)
3 risk factors	362 (127.9)	297 (128.5)	0.95	1.01 (0.86, 1.17)
4 risk factors	85 (30)	103 (44.6)	0.007	1.48 (1.11, 1.98)
5 risk factors	15 (5.3)	9 (3.9)	0.46	0.73 (0.32, 1.68)

Note: P-value calculated from Incidence rate ratio (IRR), using Chi-square test.

Abbreviation: 95% CI: 95% confidence interval.

^aFrequency of clavicle fractures and incidence/1000 fractures.

^bIRR; Incidence rate ratio comparing clavicle fracture incidence between 2011 and 2017 versus 2006 and 2010.

^cReferred as the main predisposing factors in the Results and Discussion.

detail because of the retrospective nature of the study and the restrictions on data use. For instance, the data on the exact duration of labor could not be used because of the imprecision of the coding, and the experience of health care professionals could not be evaluated. Furthermore, the diagnostic criteria for gestational diabetes changed during the study period, ¹⁵ and we cannot rule out the impact of some variation in diagnosing practices. Thus, for example, the impact of LGA diagnosis should be evaluated with caution. The large sample size and our focus on the most accurately collected data reduce potential biases.

4.2 | Interpretation

A clavicle fracture was rare in all delivery modes. Indeed, it was diagnosed in only 2.2% of vacuum-assisted deliveries and 0.9% of SVDs. The total incidence of clavicle fracture in newborns born vaginally is comparable to that reported in other studies. 5,6,10,20 Clinically, high birthweight was the most important risk factor and was involved in 45% of fractures throughout the study period. The relevance of increased birthweight is explicitly visualized in a regression curve (Figure 3). Elevated birthweight has also been recognized as a risk factor for clavicle fracture in other studies.^{5,7–10} In addition, high birthweight is an important feature linked to many of the observed risk factors, such as pre-pregnancy obesity, diabetes, induction of labor, vacuum-assisted delivery, and shoulder dystocia. 12,14,21-27 Furthermore, high birthweight may increase the likelihood of serious co-existing injury, such as brachial plexus injury, along with clavicle fracture.27 The incidence of birthweight ≥4000 g decreased across the study population, which may have had an impact on our finding of decreased incidence of clavicle fractures.

Global trends in increasing rates of obesity, gestational diabetes, T2D, and labor induction were also seen in this study. 14,17,28 Nonetheless, even as the incidence of gestational diabetes and T2D increased, the rate of newborns with birthweight ≥4000 g decreased. Further, the increased use of oxytocin, pain relief during labor, and LGA diagnosis may mark a change in antenatal and obstetric practices when caring for people with pregnancies deemed high-risk. Cross-culturally, clinical guidelines for labor induction vary substantially.^{28–30} The increased incidence of high-risk pregnancies may partly explain the increased induction rate, and the decreased incidence of prolonged pregnancies and high birthweight. Moreover, the increased induction rate could partly explain the finding of decreased impact of most risk factors on clavicle fractures in the latter study period, especially since the cesarean rate and the incidence of birthweight ≥4000 g among newborns born by cesarean, remained unchanged (Table S2).

The incidence of clavicle fractures decreased by nearly two-thirds in vacuum-assisted deliveries, despite the increased rate of operative vaginal deliveries. During the latter study period, approximately 60% of vacuum deliveries were performed because of maternal distress or suspected fetal asphyxia or distress, and procedures related to these indications increased. This may reflect a lower threshold for intervention and could concurrently increase the rate of relatively easy—low or outlet station—vacuum deliveries. In addition, the technical skills needed to perform vacuum-assisted delivery may have improved. The increased risk for clavicle fractures among vacuum-assisted deliveries was associated with a prolonged second stage of labor, possibly indicating labor dystocia. Nevertheless, almost 80% of clavicle fractures were diagnosed after SVDs, and thus the changes in fracture incidence in vacuumassisted deliveries have only had a modest effect on the total clavicle fracture incidence.

Clavicle fracture has a strong association with shoulder dystocia and T1D. The risk for fracture with T1D was related to increasing birthweight and was intensified if vacuum-assisted delivery was needed. A similar association with birthweight has been reported by Persson et al. ³¹ The incidence of shoulder dystocia and T1D increased or remained unchanged in the latter study period in cases with clavicle fracture. Although T1D and shoulder dystocia were essential risk factors, they could not explain the declining trend of clavicle fractures based on their low and stable incidences.

Numerous variables, such as obesity, gestational diabetes, induction of labor, and gestational age of \geq 41⁺⁰ weeks, were associated with a mildly increased risk for injury. According to the results of this study and from a practical point of view, the influence of these variables on fracture risk is probably modest and at least partly because of birthweight and the large sample size. Even though the incidence of many associated factors increased over time, the risk factors did not accumulate to result in deliveries with a fracture. This discrepancy may be related to the minor impact of single risk factors on the absolute fracture risk.

The centralization of maternal hospitals, increasing interest in quality of care and patient safety issues, and the onset of simulation-based and hands-on training for shoulder dystocia during the latter study period may partly have influenced the clavicle fracture incidence. 32–35 In addition to the deliveries with major risk factors, a clavicle fracture may occur with few or non-existent prior risk factors during regular SVD. These low-risk patients, without any notable risk factors, accounted for a quarter of the fractures in this study. The phenomenon of fracture incidents after regular delivery without risk factors has also been recognized by

others. 5,8,11 According to our findings, the incidence of clavicle fractures significantly decreased in these low-risk pregnancies. The reasons for this decline remain, however, unclear and require further research.

Approximately 45% of the newborns with clavicle fracture had a birthweight ≥4000 g, thus the prevention of high birthweight might appear to be a tempting solution to reduce fracture incidence. However, the probability of fracture in deliveries with a birthweight of approximately 4000 g (without T1D) was low, and the prediction of birthweight or LGA-newborn by ultrasound or clinical measures is unreliable. Amoreover, there is no clear consensus on management with suspected macrosomia or whether labor induction can reduce the birth fracture risk. As a substantial number of injuries were not related to known risk factors, the fundamental reason for the decline in the incidence of clavicle fractures remains unclear.

5 | CONCLUSION

The incidence of clavicle fractures decreased by two-thirds between 2004 and 2017, despite an increasing incidence of pregnancies deemed at risk. This decreased incidence may be a consequence of a decline of injuries in a group of women without risk factors and a decrease in the incidence of high birthweight newborns.

ACKNOWLEDGMENTS

We would like to express our gratitude to Peter Heath for revising the language. Open access funding enabled and organized by ProjektDEAL.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICAL APPROVAL

This study was approved by the Ethics Committee of Tampere University Hospital (reference number R17069) and by the National Institute for Health and Welfare (reference number THL/1659/5.05.00/2017).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Kekki M, Salonen A, Koukkula T, Laivuori H, Tihtonen K, Huttunen TT. Incidence changes in risk factors associated with the decreasing number of birth-related clavicle fractures in Finland: A nationwide retrospective birth cohort from 2004 to 2017. *Birth*. 2023;50:428-437. doi: 10.1111/birt.12662

PUBLICATION III

Severe birth injuries in neonates and associated risk factors for injury in mothers with different types of diabetes in Finland

Kekki, M., Tihtonen, K., Salonen, A., Koukkula, T., Gissler, M., Laivuori, H., Huttunen, T.T.

International Journal of Gynecology & Obstetrics. 2022; 159: 195-203 https://doi.org/10.1002/ijgo.14073

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DOI: 10.1002/ijgo.14073

CLINICAL ARTICLE



Severe birth injuries in neonates and associated risk factors for injury in mothers with different types of diabetes in Finland

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Abstract

Objective: To examine severe birth-related injuries in neonates among mothers with different types of diabetes.

Methods: Retrospective cohort study based on Finnish Medical Birth Register data from 2004 to 2017. The study included singleton neonates born vaginally with cephalic presentation (n = 623 649) after 35^{+0} weeks of gestation. The primary outcome variable was severe birth injury. Incidences, crude and adjusted odds ratios, and probabilities in regression analysis were calculated for different types of diabetes.

Results: There were 1952/623 649 (0.3%) severe birth injuries of which brachial plexus injury occurred most frequently. The injury incidence was highest in neonates of women with type 1 or type 2 diabetes, 42/1659 (2.5%) and 10/548 (1.8%), respectively. For gestational diabetes, the injury incidence was comparable to non-diabetic women: 422/77 810 (0.5%) and 1478/543 632 (0.3%), respectively. Shoulder dystocia, high birthweight, and vacuum-assisted delivery were associated with the highest probability for injury. Birthweight and obesity had a stronger impact on injury risk in women with pregestational diabetes compared to other pregnancies.

Conclusion: Neonates of women with pregestational diabetes have a higher risk for severe birth injury than other neonates. The injury risk in neonates delivered by women with gestational diabetes or non-diabetic women is generally low.

KEYWORDS

brachial plexus injury, gestational diabetes, pregestational diabetes, severe birth injury, vaginal delivery

INTRODUCTION

In Finland, approximately 1.7% of live-born neonates are diagnosed with a birth injury. Most of the injuries are transient, but severe injuries can cause permanent disability and have lifelong consequences. The incidence of severe birth injury, including cranial hemorrhage, central nervous system injury, skeletal or visceral injury, and brachial plexus palsy (BPP), is reported to be between 0.2% and 0.5% in live births, and is mainly associated with vaginal deliveries. ^{2,3} Since the incidence of birth injuries is low and a remarkable number of cases in

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wileyonlinelibrary.com/journal/ijgo 1 Int J Gynecol Obstet. 2022;00:1-9.

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TABLE 1 The frequency and incidence of individual types of severe birth injury associated with different types of diabetes among singleton vaginal deliveries with cephalic presentation between 35^{+0} and 42^{+6} gestational weeks from 2004 to 2017 in Finland

Type of birth injury	ICD-10 codes	T1D (n = 1659)	T2D (n = 548)	GDM (n = 77 810)	No diabetes (n = 543 632)	Total (n = 623 649)
Intracranial hemorrhage or laceration	P10-P10.9	1 (0.06)	1 (0.18)	17 (0.02)	59 (0.01)	78 (0.01)
Severe central nervous system injury	P11.0-P11.2, P11.4-P11.5	- (0.00)	- (0.00)	2 (0.003)	5 (0.001)	7 (0.001)
Subaponeurotic hemorrhage	P12.2	2 (0.12)	- (0.00)	19 (0.02)	119 (0.02)	140 (0.02)
Skull fracture, long bone injury / fracture ^a	P13.0, P13.2, P13.3	3 (0.18)	- (0.00)	12 (0.02)	42 (0.008)	57 (0.009)
Brachial plexus injury	P14.0-P14.3	36 (2.17)	9 (1.64)	372 (0.48)	1253 (0.23)	1670 (0.27)
Injury to the liver or spleen	P15.0, P15.1	- (0.00)	- (0.00)	- (0.00)	- (0.00)	- (0.00)
Severe birth injury ^b		42 (2.53)	10 (1.82)	415 (0.53)	1467 (0.27)	1934 (0.31)
Total		42 (2.53)	10 (1.82)	422 (0.54)	1478 (0.27)	1952 (0.31)

Note: Data presented as number (% of live births).

Abbreviations: GDM, gestational diabetes; T1D, Type 1 diabetes; T2D, Type 2 diabetes.

the general population are unpredictable, it is important to explore the risk factors and incidences associated with high-risk pregnancies.

Maternal diabetes is a risk factor for adverse perinatal outcomes. ³⁻⁷ It increases the risk for macrosomia ^{4,8} and shoulder dystocia (ShD), ^{6,8-10} which are both known risk factors for birth injury. ^{6,11} Maternal obesity, especially associated with gestational diabetes mellitus (GDM) and type 2 diabetes (T2D), is another risk factor for birth-related injuries. ^{7,12} In Finland, the incidence of type 1 diabetes (T1D) is among the highest in the world, ¹³ and the global incidence of T2D and GDM is increasing. ^{3,12,14,15} Furthermore, after the implementation of comprehensive screening, which replaced the former risk-based screening in 2008, the prevalence of GDM in Finland has also increased. ¹⁶ In addition, risk factors associated with birth injuries, such as obesity, ShD, and vacuum-assisted deliveries (VAD), have increased among women with diabetes. ^{9,16}

This study addresses severe birth injuries in vaginal deliveries after 35⁺⁰ weeks of gestation in women diagnosed with T1D, T2D, or GDM and compares the results to non-diabetic pregnancies. The study aims to describe the type of injuries, calculate the incidence rates, and determine the risk factors for severe injuries in a nation-wide birth cohort study.

2 | MATERIALS AND METHODS

This nationwide population-based cohort study was conducted using data from the Finnish Medical Birth Register (MBR) and the Care Register for Health Care (CRHC), which are maintained by the Finnish Institute for Health and Welfare. The MBR includes data on all deliveries in Finland. The MBR comprises information on the health of the mothers and neonates, interventions needed during pregnancy, delivery, and the first 7 days after birth. The data are

completed by information obtained from the Central Population Register and the Cause-of-Death Register. The CRHC contains information on patient characteristics, diagnoses, and operations performed during the hospital stay. The coverage and accuracy of these registers have been shown to be excellent.^{17,18}

The study was based on register data from the years 2004 to 2017. Gestational age was limited to between 35^{+0} and 42^{+6} , as birth injuries were infrequent before 35 weeks of gestation. After excluding those neonates delivered by forceps ($n=273,\,0.03\%$) or those with major congenital anomalies ($n=18\,854,\,2.4\%$), 623 649 singleton live born neonates born vaginally with cephalic presentation were included. The outcome variables were severe birth-related injuries coded with the Finnish implementation of the 10th Revision of International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes. The ICD-10 codes for birth injuries detected at 0–6 days, information on the type of mothers' diabetes, mode of delivery, and baseline characteristics were collected from the MBR. Moreover, hospital visits related to any severe birth injury diagnosis recorded in the CRHC during the first year after birth were included to increase the coverage.

Diagnosis of T1D and T2D were based on ICD-10 codes gathered from the MBR (O24.0, E10*, and O24.1, E11*), and GDM was defined as pathologic 2-h 75-g oral glucose tolerance test with at least one elevated plasma glucose value determined as \geq 5.3 mmol/L (95.4 mg/dl) (fasting), \geq 10.0 mmol/L (180.0 mg/dl) (1 h), and \geq 8.6 mmol/L (154.8 mg/dl) (2 h) (marked as a check-box variable or by ICD-10 codes O24.4, O24.9). Severe birth injuries were defined according to Muraca et al. (2018), Table 1). A composite outcome of any severe birth injury was defined as one or more of the injuries described above and was referred to as "severe birth injury". Data concerning pre-pregnancy body mass index (BMI, kg/m²) were included after 2006, as values from several hospitals were missing for the

^aNot including clavicle fractures.

^bComposite outcome, one or more injuries described above.

years 2004 and 2005. Birthweights above +2 standard deviation (SD) were defined as large for gestational age (LGA) standardized for parity, sex and gestational age in a Finnish population.²⁰ The use of oxytocin was registered if it was used to induce and/or augment labor. Spontaneous vaginal deliveries (SVDs) included spontaneous and induced deliveries as opposed to VAD.

Management of diabetic pregnancies are based on national guidelines 19,21 and is uniform throughout the country. Women with pregestational diabetes or GDM needing pharmacological treatment for glycemic control are regularly guided by physicians and midwifes specialized to treat diabetic pregnant women. According to guidelines delivery is recommended between 38 and 40 weeks of gestation for women with pregestational diabetes or GDM with pharmacological treatment, and before 41+3 for dietary treated GDM. The decision of the mode of delivery is based on the obstetrical indications if the estimated fetal weight by antenatal ultrasound is between 4000 and 4250 g in pregestational diabetes and up to 4500 g in medication treated GDM. Furthermore, an elective cesarean section is recommended if the estimated fetal weight is >4500 g in pregnancies with T1D, T2D and medication treated GDM. 19,21 Mediolateral episiotomy is performed only when deemed necessary. Birth injuries are primarily diagnosed by pediatric clinical examination. Radiologic evaluation is performed when severe birth injury is suspected and a specialized physician such as a pediatric surgeon is consulted.

2.1 | Statistical analysis

The incidences of composite severe birth injury as well as individual types of injuries were calculated. Baseline characteristics were described as proportions for categorical variables and as means and SDs or medians with inter-quartile ranges for continuous variables. The background characteristics in different diabetes categories were compared using chi squared-test and Fisher's exact test for categorical variables and Welch Two Sample t-test and Mann-Whitney U-test for continuous variables. The risk factor analysis was calculated using a composite severe birth injury as an outcome variable. The results are presented as odds ratios (ORs), risk differences (RDs), and ratio of odds ratios (OR-ratios: the ratio of odds ratios for a severe birth injury with a given risk factor in diabetic groups versus non-diabetic group), with 95% confidence intervals (CIs). A logistic regression analysis was performed for the variables associated with the highest risk for injury. P-value of <0.05 was considered significant. Statistical analysis was performed using R Statistical Software version 4.0.3 (R Foundation for Statistical Computing, Vienna, Austria).

2.2 | Ethical approval

Only pseudonymized data were used. This study was approved by the Ethics committee of Tampere University Hospital (reference number R17069). Institutional approval was also obtained from the Finnish Institute for Health and Welfare (reference number THL/1659/5.05.00/2017).

3 | RESULTS

The study population consisted of 623 649 neonates with 1952 severe birth injuries in 1934 neonates. The total incidence of injuries was 1952/623 649 (0.3%) of live births in vaginal deliveries (Table 1). The injury incidence was highest in women with T1D and T2D: 42/1659 (2.5%) and 10/548 (1.8%) of live births, respectively. BPP was the most frequent injury (n = 1670), accounting for 85.6% of all severe injuries. Other severe birth injuries were infrequent.

In diabetic pregnancies, labors were induced, oxytocin was used more often, and neonates were born earlier compared to non-diabetic pregnancies. In pregnancies with T1D ShD, LGA, and VAD occurred most often, whereas the incidences of VAD and ShD were similar between women with GDM and non-diabetic women (Table 2).

The strongest risk factors for severe birth injury were ShD, LGA, and VAD in all study groups (Table 3). The highest risk for injury was associated with ShD in all women. (T1D: OR 24.89, 95% CI 12.53-49.46, T2D: OR 114.86, 95% CI 16.53-797.94, GDM: OR 82.79, 95% CI 65.25-105.03, non-diabetic: OR 106.62, 95% CI 92.91-122.35). One-third of all neonates who experienced ShD had a severe birth injury. Based on OR-ratio, ShD was a more powerful risk factor for non-diabetic women compared to women with T1D, and a similar tendency was observed in pregnancies with GDM. The incidence of injuries among LGA newborns ranged between 214/8203 (2.6%) and 28/421 (6.7%), being highest in women with T1D. In total, from 505/55 443 (0.9%) to 6/67 (9.0%) of VADs resulted in injury, with the highest incidences in the T1D and T2D groups. Considering RDs, LGA and VAD only moderately increased the risk for injury. Primiparity and smoking were moderate risk factors for injury in women with T1D. Labor induction, use of oxytocin, and epidural or spinal anesthesia were associated with an increased risk for injury in women with GDM and non-diabetic women. Based on the RD, the increased probability of injury associated with these factors was, however, quite low (0.07%-0.34%, 95% CI 0.04-0.10% and 0.23-0.44%).

The probability of injury after SVD in pregnancies with T1D or T2D began to increase with a birthweight of more than 3900 g and more steeply with a birthweight of more than 4300 g. The risk was further increased in VAD (Figure 1, Table 4). However, for neonates born by SVD to women with GDM or non-diabetic women, the probability of injury remained low up to a birthweight of 4500 g. The effect of high birthweight on injury probability was clearly seen among neonates born by VAD to women with GDM or to non-diabetic women with a birthweight of more than 4300 g. High birthweight per se was a more important risk factor for injury than LGA (LGA's regression curve not shown).

A high BMI was associated with a risk for birth injury, but BMI had a lower impact than birthweight. Obesity was associated with



TABLE 2 Maternal and delivery characteristics by diabetes type in singleton vaginal delivery with cephalic presentation between 35^{+0} and 42^{+6} gestational weeks

	T1D	T2D	GDM	No diabetes
Live births	1659	548	77 810	543 632
Spontaneous vaginal delivery	1386 (83.5)	481 (87.8)	69 496 (89.3)	488 189 (89.8)
Vacuum-assisted delivery	273 (16.5)	67 (12.2)	8314 (10.7)	55 443 (10.2)
Age (years)	29.7 ± 5.47	32.6 ± 5.68	31.0 ± 5.40	29.3 ± 5.26
BMI (kg/m ²)	25.9 ± 5.87	31.8 ± 7.50	28.0 ± 6.00	23.6 ± 4.20
Smoking	279 (16.8)	130 (23.7)	14 454 (18.6)	92 028 (16.9)
Primiparity	635 (38.3)	174 (31.8)	27 141 (34.9)	219 207 (40.3)
Previous cesarean section	193 (11.6)	66 (12.0)	7147 (9.2)	36 180 (6.7)
Induction of labor	1056 (63.7)	339 (61.9)	25 145 (32.3)	97 826 (18.0)
Use of oxytocin	994 (59.9)	322 (58.8)	39 509 (50.8)	239 940 (44.1)
Epidural and/or spinal anesthesia	1123 (67.7)	359 (65.5)	49 229 (63.3)	325 482 (59.9)
Paracervical and/or pudendal block	409 (24.7)	141 (25.7)	19 982 (25.7)	126 000 (23.2)
Shoulder dystocia	60 (3.6)	5 (0.9)	477 (0.6)	1617 (0.3)
Episiotomy	499 (30.1)	93 (17.0)	17 783 (22.9)	134 882 (24.8)
LGA	421 (25.4)	55 (10.0)	2835 (3.6)	8203 (1.5)
Birthweight (grams)	3709.8 ± 494.52	3599.4 ± 471.04	3634.6 ± 479.86	3552.4 ± 463.86
Gestational age (weeks ^{+days})	38 ⁺¹ (37 ⁺¹ -39 ⁺⁰)	38 ⁺⁶ (38 ⁺¹ -39 ⁺⁶)	39 ⁺⁶ (39 ⁺⁰ -40 ⁺⁴)	40 ⁺¹ (39 ⁺² -41 ⁺⁰)
Infant sex (boys)	775 (46.7)	289 (52.7)	39 839 (51.2)	274 259 (50.5)

Note: Data presented n (% of vaginal live births), mean \pm SD or median with inter-quartile range.

Abbreviations: BMI, body mass index; GDM, gestational diabetes; LGA, large for gestational age; T1D, Type 1 diabetes; T2D, type 2 diabetes.

the risk for injury in VAD in women with pregestational diabetes, but the probability of injury remained low in SVD in women with GDM and non-diabetic women, even in those with severe obesity (Figures 1 and 2). In logistic regression analysis, shorter maternal height, older maternal age, neonate's higher birth length, and higher gestational age were independently associated with increased risk for injury in all groups studied, but the impact of above-mentioned risk factors was not clinically relevant (data not shown).

4 | DISCUSSION

In this population-based study, the incidence of severe birth injury was highest in pregnancies complicated by T1D and T2D. Severe birth injuries, other than BPP, were infrequent. Risk factors were similar in diabetic and non-diabetic women, but high birthweight and obesity had a stronger impact on severe birth injuries in women with pregestational diabetes compared to GDM and non-diabetic pregnancies. This impact was further increased by vacuum extraction. The risk for injury in neonates delivered by women with GDM or non-diabetic women was generally low when labors complicated by ShD and the VAD of high birthweight neonates were excluded.

The distribution of severe birth injury, other than BPP, by different types of maternal diabetes has not previously been reported. The incidence of BPP among the neonates of diabetic women was similar (T1D: 2.2% of vaginal live births, GDM: 0.6% of vaginal live births), ^{7.11} and the total incidence of BPP was higher

than previously described in the literature (0.11% to 0.16% of vaginal births).^{2,23} ShD was the strongest risk factor associated with injury in all neonates irrespective of the diabetes status of the parturient, which is in line with the findings of previous studies.^{6,22} Furthermore, the incidence of ShD was similar to that previously reported. 9,22 Regarding BPP, however, the rates of injured neonates after ShD were higher than those reported in previous studies.²² The high comorbidity in the present study may be due to diverse diagnostic criteria or the broad coverage of the data, as we included all severe birth-related injuries diagnosed during the first year after birth. Moreover, we cannot rule out the possibility of underdiagnosing the milder forms of ShD without birth injury. The overall incidence of severe birth injury and the incidences of subaponeurotic hemorrhage and intracranial hemorrhage were comparable to those reported in previous studies (0.2%, 0.01%, and 0.02% of vaginal births, respectively).2

Baseline characteristics differed considerably between the types of diabetes, as reported earlier by others. 4.5.8 T1D pregnancies had the highest incidences of the main risk factors, namely LGA, ShD, and VAD, explaining the high injury rate. Women with T2D and GDM had a higher BMI, and neonates were more often LGA compared with the neonates of non-diabetic women. Obesity, along with GDM and maternal pregestational diabetes, have been suggested to be independent risk factors for BPP.6.7 In this study, high BMI increased the risk for injury in neonates born by VAD in women with pregestational diabetes, but it was a less important risk factor in women with GDM and in non-diabetic women.

TABLE 3 Risk factors for neonatal severe birth injury by diabetes type in singleton vaginal delivery with cephalic presentation between 35⁺⁰ and 42⁺⁶ gestational weeks

	T1D	T2D	GDM	No diabetes
Number of live births	1659	548	77 810	543 632
Injured neonates (n)	42	10	415	1467
Shoulder dystocia (n)	60	5	477	1617
Injured neonates of total no. of neonates with risk factor ^a	17 (28.3)	3 (60.0)	116 (24.3)	302 (18.7)
Injured neonates with risk factor of all injured neonates ^a	17 (40.5)	3 (30.0)	116 (28.0)	302 (20.6)
OR (95% CI) ^b	24.89 (12.53-49.46)	114.86 (16.53-797.94)	82.79 (65.25-105.03)	106.62 (92.91-122.35)
P ^c	<0.001	<0.001	<0.001	<0.001
RD (95% CI) ^d	26.77 (16.92-39.21)	58.71 (21.76-86.96)	23.93 (20.30-27.98)	18.46 (16.64-20.43)
OR-ratio (95% CI) ^e	0.23 (0.12-0.47)	1.08 (0.15-7.52)	0.78 (0.59-1.02)	
P (OR) ^f	<0.001	0.940	0.071	
LGA (n)	421	55	2853	8203
Injured neonates of total no. of neonates with risk factor ^a	28 (6.7)	2 (3.6)	110 (3.9)	214 (2.6)
Injured neonates with risk factor of all injured neonates ^a	28 (66.7)	2 (20.0)	110 (26.5)	214 (14.6)
OR (95% CI) ^b	6.23 (3.25-11.95)	2.29 (0.47-11.05)	9.88 (7.92-12.33)	11.42 (9.86-13.22)
P ^c	<0.001	0.303	<0.001	<0.001
RD (95% CI) ^d	5.52 (3.37-8.35)	2.01 (-1.04 to 10.74)	3.47 (2.82-4.25)	2.37 (2.05-2.74)
OR-ratio (95% CI) ^e	0.55 (0.28-1.06)	0.20 (0.04-0.97)	0.87 (0.66-1.13)	
P (OR) ^f	0.075	0.046	0.286	
Vacuum-assisted delivery (n)	279	67	8314	55 443
Injured neonates of total no. of neonates with risk factor ^a	15 (5.5)	6 (9.0)	155 (1.9)	505 (0.9)
Injured neonates with risk factor of all injured neonates ^a	15 (35.7)	6 (60.0)	155 (37.4)	505 (34.4)
OR (95% CI) ^b	2.93 (1.54-5.58)	11.73 (3.22-42.74)	5.06 (4.14-6.18)	4.66 (4.18-5.19)
P ^c	0.001	<0.001	<0.001	<0.001
RD (95% CI) ^d	3.55 (1.24-6.97)	8.12 (3.17-17.38)	1.49 (1.22-1.81)	0.71 (0.64-0.80)
OR-ratio (95% CI) ^e	0.63 (0.33-1.21)	2.52 (0.69-9.22)	1.09 (0.87-1.36)	
P (OR) ^f	0.164	0.162	0.474	
Primiparity (n)	635	174	27 141	219 207
Injured neonates of total no. of neonates with risk factor ^a	23 (3.62)	4 (2.3)	156 (0.6)	622 (0.3)
Injured neonates with risk factor of all injured neonates ^a	23 (54.8)	4 (40.0)	156 (37.6)	622 (42.4)
OR (95% CI) ^b	1.99 (1.07-3.68)	1.44 (0.40-5.18)	1.13 (0.92-1.37)	1.09 (0.98-1.21)
P ^c	0.029	0.733	0.256	0.105
RD (95% CI) ^d	1.77 (0.19-3.64)	0.69 (-1.62 to 4.26)	0.06 (-0.04 to 0.18)	0.02 (-0.005 to 0.05)
OR-ratio (95% CI) ^e	1.82 (0.98-3.41)	1.32 (0.37-4.77)	1.03 (0.82-1.29)	
P (OR) ^f	0.059	0.668	0.780	
Smoking (n)	279	130	14 454	92 028
Injured neonates of total no. of neonates with risk factor ^a	13 (4.7)	2 (1.5)	84 (0.6)	228 (0.3)
Injured neonates with risk factor of all injured neonates ^a	13 (31.0)	2 (20.0)	84 (20.2)	228 (15.5)

(Continues)



TABLE 3 (Continued)

TABLE 3 (Continued)				
	T1D	T2D	GDM	No diabetes
OR (95% CI) ^b	2.28 (1.17-4.43)	0.80 (0.17-3.82)	1.11 (0.88-1.42)	0.90 (0.78-1.04)
P ^c	0.016	0.780	0.382	0.160
RD (95% CI) ^d	2.56 (0.44-5.77)	-0.38 (-2.51 to 3.63)	0.06 (-0.07 to 0.21)	-0.03 (-0.06 to 0.01)
OR-ratio (95% CI) ^e	2.52 (1.27-4.98)	0.89 (0.18-4.25)	1.23 (0.93-1.63)	
P (OR) ^f	0.008	0.880	0.142	
Labor induction (n)	1056	339	25 145	97 826
Injured neonates of total no. of neonates with risk factor ^a	31 (2.9)	7 (2.1)	172 (0.7)	352 (0.4)
Injured neonates with risk factor of all injured neonates ^a	31 (73.8)	7 (70.0)	172 (41.5)	352 (24.0)
OR (95% CI) ^b	1.63 (0.81-3.26)	1.45 (0.37-5.66)	1.49 (1.22-1.81)	1.44 (1.28-1.62)
Pc	0.170	0.595	<0.001	<0.001
RD (95% CI) ^d	1.11 (-0.54 to 2.56)	0.63 (-2.27 to 2.97)	0.22 (0.11-0.35)	0.11 (0.07-0.15)
OR-ratio (95% CI) ^e	1.13 (0.56-2.29)	1.01 (0.26-3.95)	1.03 (0.82-1.30)	
P (OR) ^f	0.734	0.994	0.790	
Use of oxytocin (n)	994	322	39 509	239 940
Injured neonates of total no. of neonates with risk factor ^a	32 (3.2)	5 (1.6)	276 (0.7)	805 (0.3)
Injured neonates with risk factor of all injured neonates ^a	32 (76.2)	5 (50)	276 (66.5)	805 (54.9)
OR (95% CI) ^b	2.18 (1.06-4.46)	0.70 (0.20-2.44)	1.93 (1.57-2.37)	1.54 (1.39-1.71)
P ^c	0.033	0.572	<0.001	<0.001
RD (95% CI) ^d	1.72 (0.16-3.18)	-0.66 (-3.66 to 1.73)	0.34 (0.23-0.44)	0.12 (0.09-0.15)
OR-ratio (95% CI) ^e	1.41 (0.69-2.92)	0.45 (0.13-1.59)	1.25 (1.0-1.58)	
P (OR) ^f	0.349	0.216	0.053	
Epidural and/or spinal anesthesia (n)	1123	359	49 229	325 482
Injured neonates of total no. of neonates with risk factor ^a	35 (3.1)	7 (1.9)	293 (0.6)	973 (0.3)
Injured neonates with risk factor of all injured neonates ^a	35 (83.3)	7 (70.0)	293 (70.6)	973 (66.3)
OR (95% CI) ^b	2.43 (1.07-5.51)	1.23 (0.32-4.82)	1.40 (1.13-1.73)	1.32 (1.19-1.47)
P ^c	0.033	>0.99	0.002	<0.001
RD (95% CI) ^d	1.81 (0.19-3.17)	0.36 (-2.78 to 2.64)	0.17 (0.06-0.27)	0.07 (0.04-0.10)
OR-ratio (95% CI) ^e	1.84 (0.81-4.20)	0.93 (0.24-3.67)	1.06 (0.83-1.34)	
P (OR) ^f	0.148	0.921	0.647	

^aValues are given as number (percentage).

High birthweight was the most important risk factor for birth injury. Although ShD is unpredictable, it is often associated with high birthweight, and high birthweight is suggested to be an

independent risk factor for birth injury among neonates with ShD.^{6,10,11} In line with a previous publication,¹¹ the birthweight per se was a more important risk factor for injury than LGA. The

^bOR; Odds ratio representing the odds for a severe birth injury in the T1D, T2D, GDM, or non-diabetes groups with a given risk factor versus women without a risk factor.

^cP-value calculated from incidence rate ratio, using Chi-square and Fisher's exact test.

 $^{^{}d}$ RD; Risk difference representing the difference between the risk for a severe birth injury in the group exposed to risk factor versus the group unexposed to risk factor. Values are presented as absolute numbers \times 100.

^eOR-ratio; The ratio of Odds Ratios for a severe birth injury in the diabetes group (T1D, T2D or GDM) versus the non-diabetic group within a given risk factor. OR-ratio >1 meaning a higher Odds Ratio in the group of women with diabetes versus a group of non-diabetic women.

^fP (OR); P-value from OR-ratio, based on calculated log-OR difference, standard error, and Wald test statistic (Z score).



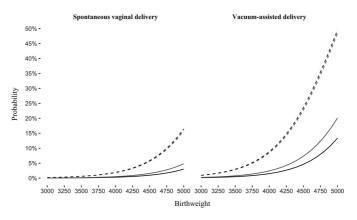


FIGURE 1 The probability of severe birth injury in relation to birthweight, diabetes type, and mode of delivery

TABLE 4 The probability of neonatal severe birth injury by diabetes type in singleton vaginal delivery with cephalic presentation between 35^{+0} and 42^{+6} gestational weeks

	Probability of severe birth injury in vaginal delivery % (95% CI)					
	T1D	T2D	GDM	No-diabetes		
Birthweight 3000 g						
SVD	0.18 (0.13-0.26)	0.19 (0.10-0.37)	0.05 (0.04-0.06)	0.03 (0.03-0.03)		
VAD	0.91 (0.65-1.27)	0.95 (0.50-1.80)	0.24 (0.21-0.29)	0.15 (0.13-0.17)		
Birthweight 3500 g						
SVD	0.58 (0.42-0.80)	0.61 (0.32-1.15)	0.16 (0.14-0.18)	0.10 (0.09-0.10)		
VAD	2.83 (2.05-3.89)	2.95 (1.57-5.47)	0.77 (0.68-0.89)	0.48 (0.43-0.52)		
Birthweight 4000 g						
SVD	1.83 (1.33-2.50)	1.91 (1.01-3.56)	0.50 (0.45-0.55)	0.31 (0.29-0.32)		
VAD	8.48 (6.29-11.34)	8.83 (4.85-15.54)	2.42 (2.22–2.71)	1.50 (1.39-1.62)		
Birthweight 4500 g						
SVD	5.59 (4.12-7.55)	5.83 (3.15-10.52)	1.56 (1.40-1.74)	0.96 (0.90-1.04)		
VAD	22.77 (17.56-28.97)	23.55 (13.92-36.96)	7.32 (6.53-8.20)	4.62 (4.23-5.05)		
Birthweight 5000 g						
SVD	15.86 (11.94-20.75)	16.45 (9.35-27.32)	4.81 (4.24-5.44)	3.01 (2.71-3.34)		
VAD	48.40 (40.20-56.69)	49.49 (33.86-65.23)	20.09 (17.86-22.51)	13.36 (12.0-14.56)		

Abbreviations: GDM, gestational diabetes; SVD, spontaneous vaginal delivery; T1D, Type 1 diabetes; T2D, Type 2 diabetes; VAD, vacuum-assisted delivery.

importance of birthweight as a risk factor for birth injury was most clearly seen in T1D and T2D pregnancies and further strengthened by VAD. On the other hand, the probability of injury was almost the same when comparing the pregnancies of women with GDM and non-diabetic women and remained rather low with higher birthweights among SVD. Nevertheless, the probability of injury also began to rise with birthweights above 4000 g in the neonates of women with GDM, if VAD was required. This increased risk for injury in neonates born by VAD, especially those with high birthweight, is in concordance with previous reports. 6.22 Approximately

one-third of the injured neonates were born by vacuum extraction. Thus, promoting SVD may be one way to reduce the rate of birth injuries. The predictability of the risk of injury based on birthweight was less consistent in the neonates of women with GDM or in non-diabetic women than it was in women with pregestational diabetes. Perhaps because of the low incidences of ShD and LGA, the injuries among the neonates of non-diabetic women occurred less often concomitant with ShD or LGA than injuries associated with maternal diabetes. A similar relationship was also reported by Johnson et al.²³



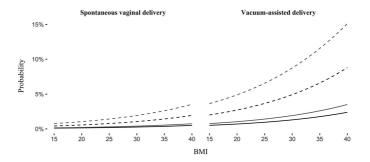


FIGURE 2 The probability of severe birth injury in relation to BMI, diabetes type, and mode of delivery

There is no standardized screening system or criteria for GDM. Indeed, it has been recently questioned whether the comprehensive screening of GDM and the treatment of mild hyperglycemia are worthwhile, and is the current system only increasing the number of women with GDM without improvement in outcomes. 16.24 Nevertheless, it has been shown that there is a linear association between hyperglycemia and adverse pregnancy outcomes, and an association between mild untreated hyperglycemia and higher birthweight. Moreover, the treatment of GDM at least decreases the risk for ShD and high birthweight. 4.25 In this study, the incidence of birth injury was comparable in the neonates of women with GDM and in non-diabetic women, suggesting that without screening and treatment the incidence may well have been higher.

The strengths of the present study are the statutory Finnish MBR and CRHC data with national coverage ruling out selection bias and increasing generalizability. The precision and completeness of the data have been reported to be good. ^{17,18} In Finland, maternal and child welfare clinics are free of charge, ensuring equal opportunity for care and attendance by the entire pregnant population. The limitation of the study is the retrospective nature of the data. Moreover, the diagnostic criteria for GDM changed during the study period. Even with a large sample size, the number of T2D pregnancies remained modest, limiting the statistical power of the results. BPP, as the most common injury, influenced the results, and therefore the risk factors represent primarily risk factors for BPP.

5 | CONCLUSION

The neonates of women with pregestational diabetes have a higher risk for severe birth injury than other neonates. The risk is strongly associated with ShD, higher birthweight and further strengthened by VAD. The incidence of injury in pregnancies with GDM is comparable with pregnancies without diabetes. Moreover, the impact of high birthweight and obesity on the risk for injury in GDM and non-diabetic pregnancies is less important than in women with pregestational diabetes.

ACKNOWLEDGMENTS

The study was financially supported by Tampere University Hospital Support Foundation, Tampere University Hospital.

CONFLICTS OF INTEREST

The authors have no conflicts of interest.

AUTHOR CONTRIBUTIONS

MK, TH, KT, HL, and AS designed the study. TH, AS, and MG contributed to the acquisition of the data. MK, TH, and TK were responsible for data analysis. All authors contributed to the interpretation of the data. MK was a major contributor in the writing of the manuscript. All authors participated in drafting and revising the manuscript. All authors read and approved the final manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author.

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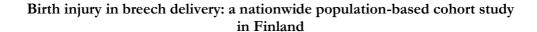
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How to cite this article: Kekki M, Tihtonen K, Salonen A, et al. Severe birth injuries in neonates and associated risk factors for injury in mothers with different types of diabetes in Finland. *Int J Gynecol Obstet*. 2022;00:1–9. doi:10.1002/jigo.14073

PUBLICATION IV



Kekki, M., Koukkula, T., Salonen, A., Gissler, M., Laivuori, H., Huttunen, T.T., Tihtonen, K.

Archives of Gynecology and Obstetrics. 2022 https://doi.org/10.1007/s00404-022-06772-1

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MATERNAL-FETAL MEDICINE



Birth injury in breech delivery: a nationwide population-based cohort study in Finland

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Received: 8 March 2022 / Accepted: 25 August 2022 © The Author(s) 2022

Abstract

Purpose Previous studies have examined the optimal mode of breech delivery extensively, but there is a scarcity of publications focusing on the birth injuries of neonates born in breech presentation. This study aimed to examine birth injury in breech deliveries

Methods In this retrospective register-based nationwide cohort study, data on birth injuries in vaginal breech deliveries with singleton live births were compared to cesarean section with breech presentation and cephalic vaginal delivery between 2004 and 2017 in Finland. The data were retrieved from the National Medical Birth Register. Primary outcome variables were severe and mild birth injury. Incidences of birth injuries in different gestational ages and birthweights were calculated in different modes of delivery. Crude odds ratios of risk factors for severe birth injury were analyzed.

Results In vaginal breech delivery (n=4344), there were 0.8% of neonates with severe birth injury and 1.5% of neonates with mild birth injury compared to 0.06% and 0.2% in breech cesarean section (n=16,979) and 0.3% and 1.9% in cephalic vaginal delivery (n=629,182). Brachial plexus palsy was the most common type of injury in vaginal breech delivery. Increasing gestational age and birthweight had a stronger effect on the risk for injury among cephalic vaginal deliveries than among vaginal breech deliveries.

Conclusion Birth injuries were rare in vaginal breech deliveries. The incidence of severe birth injury was two times higher in vaginal breech delivery compared to cephalic vaginal delivery. Brachial plexus palsy was the most common type of injury in vaginal breech delivery.

 $\textbf{Keywords} \ \ Vaginal \ breech \ delivery \cdot Birth \ injury \cdot Brachial \ plexus \ palsy \cdot Birthweight \cdot Epidemiology \cdot Population-based \ study$

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Published online: 08 September 2022

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What does this study add to the clinical work

In vaginal breech delivery, birth injuries are rare, but brachial plexus palsy is more common than in cephalic vaginal delivery.

Introduction

Approximately two to three percent of neonates diagnosed with birth injury [1, 2] are also at increased risk for other morbidities, such as hypoxic-ischemic encephalopathy, seizures, and death [1]. Concern has been raised about the risks for neonates in breech presentation, especially in vaginal delivery (VD), and the risks for the mother and subsequent pregnancies associated with cesarean section (CS) in term [3] and preterm delivery [4–6].

The risk for birth injury in breech presentation is considered comparable to that of cephalic vaginal delivery (cephalic VD) [7, 8], as the reported incidence of birth injury in singleton vaginal breech delivery at term varies from 0.3% to 7.4% [7–11]. In addition, the incidence of birth injury in breech CS has been reported to be between 0.2% and 0.9% [7, 8, 10, 11].

The incidence of morbidity and mortality of neonates after 37⁺⁰ weeks of gestation with breech presentation was higher after an attempt of VD than after planned CS in two large population-based studies [8, 10] and a randomized multicenter trial (the Term Breech Trial) [11]. Similarly, a systematic review and meta-analysis of non-randomized studies of preterm neonates concluded, and a retrospective cohort study of extremely preterm neonates observed that CS was associated with reduced neonatal mortality [4, 12]. Nevertheless, there is observational evidence showing that VD can be safe with the proper selection of women for both term [13, 14] and preterm neonates with breech presentation [15–17].

A considerable amount of literature has been published on morbidity and mortality rates, whereas only a few studies have focused on birth injuries among neonates born in breech presentation. Since the incidence of birth injuries has been described to be relatively low, a large nationwide register was chosen as a study cohort. This study aims to examine the type and rate of birth injuries in vaginal breech deliveries (breech VD) compared to CS with breech presentation (breech CS) and cephalic vaginal deliveries (cephalic VD) in Finland, where breech VD in selected women is still a common practice. We also aim to describe the incidence of

birth injuries in different gestational weeks and explore the risk factors involved, especially those associated with severe birth injury in different types of delivery.

Materials and methods

This nationwide population-based cohort study was conducted using data from the Finnish Medical Birth Register (MBR) and the Care Register for Health Care. Both registers are maintained by the Finnish Institute for Health and Welfare. All Finnish hospitals are required to report clinical data to these national registries. The MBR includes data on pregnancies, deliveries, and information on the health of neonates. The data are completed by information obtained from the Central Population Register and the Cause-of-Death Register. The Care Register for Health Care contains information on patient diagnoses and operations performed during the hospital stay. The coverage and accuracy of these registers have been shown to be excellent [18, 19].

The study period was from 2004 to 2017, and it focused on singleton breech deliveries that resulted in a live birth. Breech VD and breech CS were studied separately. Planned and unplanned CS were analyzed together (breech CS) since birth injuries were infrequent after CS. Neonates with cephalic presentation born by spontaneous vaginal delivery or vacuum-assisted delivery formed a cephalic VD group, which was used for comparison. Forceps deliveries were excluded as they were rare (254/650,528 neonates), and the presentation of the neonate could not be reliably defined in all cases. Figure 1 presents a flowchart of the study population.

In Finland, five universities with medical faculties offer the education of medical doctors and trainees in gynecology and obstetrics. The management of breech delivery is included in the curriculum of gynecology and obstetrics. There are no national guidelines for term breech pregnancies. However, according to an inquiry addressed to the tertiary level obstetrics centers in Finland, there are common well-established clinical practices for managing breech pregnancies and deliveries after 37⁺⁰ weeks of gestation: Breech VD is an option if the mother is motivated to vaginal delivery, the estimated fetal weight is < 4000 g, and the fetus is in a frank, complete, or incomplete breech position with the head in a flexed position during the delivery. Often, adequate measurements of the maternal pelvis are confirmed by magnetic resonance pelvimetry. CS is preferred if intrauterine growth restriction is suspected, or the fetus is otherwise at high risk for distress during delivery. According to national guidelines for preterm deliveries, CS may lower



the risk for morbidity in primiparas before 32 gestational weeks [20]. However, the mode of preterm delivery is individually selected based on obstetric indications. All breech deliveries are guided by experienced gynecologists, and CS is performed if distress of the fetus is suspected or when difficulties occur during delivery.

The two primary outcome variables were severe and mild birth injury. Birth injuries detected during the early neonatal period (0 to 6 days) were coded with the Finnish implementation of the 10th Revision of International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes and retrieved from the MBR. In addition, hospital visits linked to any birth injury diagnosis recorded in the Care Register for Health Care during the first year after birth were included to increase the coverage. Severe birth injury was defined according to Muraca et al. [21] and included intracranial hemorrhage and laceration, severe injury to the central nervous system, subaponeurotic hemorrhage, skull fracture, long bone injury other than clavicle fracture, brachial plexus palsy (BPP), and injury to the liver or spleen. Mild birth injury included all birth injuries other than severe birth injuries. Outcomes were defined as one or more of the injuries described above. Neonates with both severe and mild birth injuries were included in the severe birth injury group. Outcomes for mild and severe birth injuries with ICD-10 codes are listed in Supplementary information, Table S1.

Tables 2 and 3 present the variables included in the final analysis. Diagnosis of type 1 and type 2 diabetes was based on ICD-10 codes retrieved from the MBR (O24.0, E10*, and O24.1, E11*), and gestational diabetes was defined as pathologic 2 h 75 g oral glucose tolerance test (also O24.4, O24.9). Data concerning prepregnancy body mass index (kg/m²) were included after 2006, as values from several hospitals were missing for the years 2004 and 2005. Birthweight above + 2 standard deviations (SD) or below - 2 SDs were defined as large for gestational age and small for gestational age standardized for parity, sex, and gestational age in a Finnish population [22]. The use of oxytocin was registered if it was used to induce and/or augment labor.

Statistical analyses

The incidences of severe and mild birth injury were calculated and stratified by gestational age. Variables were described as frequencies and proportions for categorical variables, and as means and standard deviations or medians and interquartile ranges for continuous variables. Welch two sample *t*-test and Mann–Whitney *U*-test were used for comparisons of continuous variables. The risk factors for severe birth injury were calculated. The results are presented as odds ratios and risk differences with 95% confidence intervals (CI). Poisson regression model was used to assess the incidences of birthweight and gestational age using the number of cases per gestational weeks/birthweight as an offset term. The model was used separately for mild and severe birth injuries and in different modes of delivery. Regression analysis was limited to birthweight < 4000 g, as the clinical practice in Finland mainly recommend breech VD when the estimated fetal weight is < 4000 g. Statistical analysis was performed using R Statistical Software version 4.0.3.

Results

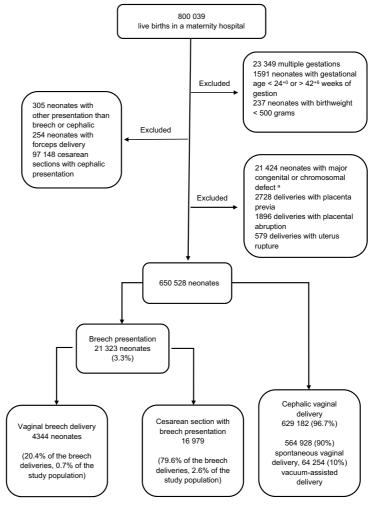
In total, 650,528 neonates were included. Of these, 4344 neonates (0.7%) had breech VD, 16,979 neonates (2.6%) had breech CS, and 629,182 neonates (96.7%) had cephalic VD, either spontaneous (90%) or vacuum-assisted (10%) (Fig. 1).

The incidences and frequencies of injured neonates with different birth injuries are presented in Table 1. The incidence of severe birth injury was highest in the breech VD group, whereas mild birth injury was more common in the cephalic VD group. BPP and clavicle fracture were the most frequent injuries after breech VD. In the breech VD group, 28% of injured neonates had BPP (0.6% of live births) and 24% had clavicle fracture (0.5% of live births). After cephalic VD, clavicle fracture (47% of injured neonates, 1.0% of live births) and cephalhematoma (35% of injured neonates, 0.8% of live births) were the most frequent injuries, followed by BPP (12% of injured neonates, 0.3% of live births). BPP accounted for 82% of the severe birth injuries in the breech VD group and 86% of the severe birth injuries in the cephalic VD group. None of the neonates with breech presentation had both clavicle fracture and BPP, whereas 323 neonates in the cephalic VD group had both. There were no intracranial hemorrhage or central nervous system injuries in the breech VD group and very few in the cephalic VD group. Both severe and mild birth injuries were infrequent in breech CS.

The birthweight of neonates with severe birth injury was 3320 g (SD 483) in the breech VD group and 4071 g (SD 518) in the cephalic VD group. Gestational ages were similar in both groups, 40^{+0} (interquartile range 38^{+5} – 40^{+4}) and 40^{+2} (interquartile range 39^{+2} – 41^{+1}), respectively (Table 2). We found no statistically significant risk factors for severe birth injury in breech VD (Table 3). For neonates in the cephalic VD group, the most important risk factors for



Fig. 1 Flowchart of the study population



^a Other Q-diagnosis than minor anomalies were excluded. The minor anomalies defined as: https://eu-rd-platform.jrc.ec.europa.eu/sites/default/files/Section%203.2-%2027_Oct2016.pdf

severe birth injury were pregestational diabetes and large for gestational age. In the breech VD group, 3% of neonates with severe birth injury were large for gestational age compared with 19% in the cephalic VD group. Conversely, 3% of injured neonates in the breech VD group were small for gestational age in contrast to 0.6% in the cephalic VD group.

The use of oxytocin was the only risk factor found for severe birth injury in the breech CS group.

Between gestational weeks 24^{+0} and 27^{+6} 41% (51/124), 28^{+0} and 31^{+6} 29% (55/187), 32^{+0} and 36^{+6} 30% (500/1654), 37^{+0} and 40^{+6} 19% (3336/18,014), and 41^{+0} and 42^{+6} 30% (402/1344) of fetuses with breech presentation had VD. There were no severe birth injuries, and three neonates (at



Table 1 Frequencies and incidences of neonates with severe birth injury, mild birth injury, and different types of birth injury in vaginal breech delivery, cesarean section with breech presentation, and cephalic vaginal delivery

	Vaginal breech delivery n=4344	Cesarean section with breech presentation $n = 16,979$	Cephalic vaginal delivery n=629,182
Frequency of injured neonates (Incidence/100 liv	e births)		
Severe birth injury	33 (0.76)	10 (0.059)	1954 (0.31)
Mild birth injury	63 (1.45)	35 (0.21)	11,722 (1.86)
Any birth injury	96 (2.21)	45 (0.27)	13,676 (2.17)
ICD-10 codes			
P10: Intracranial hemorrhage or laceration	0	1 (0.0059)	78 (0.012)
P11: Other injuries to central nervous system	0	3 (0.018)	33 (0.052)
P12: Injury to scalp	6 (0.14)	0	5538 (0.88)
P13: Injury to skeleton	29 (0.67)	3 (0.018)	6460 (1.03)
P14: Injury to peripheral nervous system	29 (0.67)	8 (0.047)	1715 (0.27)
P15: Other birth injuries	34 (0.78)	31 (0.18)	492 (0.078)

31 weeks of gestation) in the breech VD group had a mild birth injury between 24⁺⁰ and 31⁺⁶ weeks of gestation. In the cephalic VD group, there was a similar finding of single injuries. After 32 weeks of gestation, the incidence of injury remained stable with some sporadic fluctuation up to 42 weeks of gestation among the breech VD group (Fig. 2). Between gestational weeks 32⁺⁰ and 36⁺⁶ 8 mild and 4 severe birth injuries, 37⁺⁰ and 40⁺⁶ 48 mild and 24 severe, and 41⁺⁰ and 42⁺⁶ 4 mild and 5 severe birth injuries were diagnosed among the breech VD group. Also, in the breech VD group, no association was found in Poisson regression analysis between the incidence of mild birth injury and gestational weeks (estimated increase to incidence of injury for 1 gestational week was 0.96, 95% CI 0.88–1.05) or the incidence of severe birth injury and gestational weeks (1.12, 95% CI 0.93-1.35). In contrast, the incidence of birth injury showed an increasing trend with higher gestational age in the cephalic VD group (mild birth injury: 1.13, 95% CI 1.11–1.14, severe birth injury: 1.07, 95% CI 1.04–1.11), Fig. 2. There was no association between gestational age and incidence of birth injury in breech CS.

Furthermore, no association was found in Poisson regression between birthweight (500 g to 4000 g) and incidence of mild birth injury (the estimated increase in incidence of injury for an increase of 100 g in birthweight was 1.01, 95% CI 0.97–1.06) or between birthweight and severe birth injury (1.06, 95% CI 0.98–1.14) in breech VD. In the cephalic VD group, the incidence of mild birth injury (1.09, 95% CI 1.09–1.10) and the incidence of severe birth injury (1.20, 95% CI 1.17–1.22) showed an increasing trend along with higher birthweight. In the breech CS group, however, the incidence of mild birth injury seemed to show a decreasing trend with increasing birthweight (0.94, 95% CI 0.90–1.0)

(Fig. 3). There were only three neonates with severe birth injury (incidence 1.63%) and no neonates with mild birth injury and birthweight over 4000 g in the breech VD group (total of 184 neonates) (Fig. 4).

Discussion

In this population-based study, the incidence of severe birth injury was higher in the vaginal breech delivery group than in the cesarean section with breech presentation group and the cephalic vaginal delivery group. However, the incidence remained low in all groups. A brachial plexus palsy was the most frequent injury in vaginal breech delivery. Perhaps because of the more rigorous selection of women for vaginal delivery, high birthweight did not seem to be as important a risk factor for birth injury in vaginal breech delivery as in cephalic vaginal delivery.

The total incidence of birth injury in breech VD was similar to that previously reported [8, 9, 11]. Surprisingly, there were no intracranial hemorrhage or central nervous system injuries after breech VD. In breech VD, a BPP was the most common injury followed by clavicle fractures. Although breech presentation is a risk factor for BPP [23], few studies have exclusively focused on BPP among neonates in breech presentation [24]. Moreover, it has been suggested that neonates born in breech presentation with BPP have a worse prognosis, a higher rate of bilateral plexus injuries, and a higher rate of concurrent phrenic nerve palsies than neonates born with an injury in cephalic presentation [24]. In our study, no concurrent clavicle fractures were found, and the birthweight of the injured neonates was lower in the breech VD group than in the cephalic VD group. These



Table 2 Background characteristics of women and neonates with severe birth injury and without severe birth injury in vaginal breech delivery, cesarean section with breech presentation, and cephalic vaginal delivery

	Vaginal breech delivery	P-value	Cesarean section with breech presentation	P-value	Cephalic vaginal delivery	P-value
Number of live births	4344		16,979		629,182	
Number of neonates with severe birth injury	33		10		1954	
Age, years (mean, SD)						
Severe birth injury	30.4 (5.13)	0.64	31.6 (6.13)	0.52	30.0 (5.46)	< 0.001
Without severe birth injury	29.9 (4.97)		30.3 (5.25)		29.5 (5.32)	
BMI, kg/m ² (mean, SD)						
Severe birth injury	25.9 (5.76)	0.02	27.2 (9.48)	0.37	26.3 (5.46)	< 0.001
Without severe birth injury	23.4 (4.23)		24.2 (4.74)		24.2 (4.71)	
Height, cm (mean, SD)						
Severe birth injury	165.1 (0.08)	0.08	166.9 (5.11)	0.34	164.4 (5.77)	< 0.001
Without severe birth injury	167.0 (0.08)		165.3 (6.14)		165.8 (5.97)	
Gestational age, weeks+ days (n	nedian, interquartile range)					
Severe birth injury	40^{+0}	0.11	38 ⁺⁴	0.41	40 ⁺²	< 0.001
	$(38^{+5} - 40^{+4})$		$(37^{+4} - 39^{+4})$		$(39^{+2}-41^{+1})$	
Without severe birth injury	$39^{+3} (38^{+1} - 40^{+2})$		39+1 (38+4-39+4)		$40^{+1} (39^{+2} - 40^{+6})$	
Birthweight, grams (mean, SD	0)					
Severe birth injury	3319.8 (482.92)	0.05	3335.3 (513.51)	0.90	4070.7 (518.26)	< 0.001
Without severe birth injury	3146.1 (564.97)		3314.6 (563.37)		3544.8 (484.98)	

Pregnancies with severe birth injury compared to pregnancies without severe birth injury

BMI Body mass index, years 2006 to 2017

SD standard deviation

P-value calculated using Mann-Whitney U-test

findings may suggest that BPP in breech VD may be due to unnecessary traction of the shoulders during delivery or difficulties in delivering an entrapped head. However, based on the findings of this study, we are unable to draw a definitive conclusion on this. In addition, we do not know whether the BPP identified in our study population were bilateral or persistent. Spinal cord injuries, of which none were found in our data, have been reported after a difficult head delivery [25]. In Finland, Løyset and Mauriceau maneuvers are most often used to deliver shoulders and head. However, due to the retrospective study design, we do not know which maneuvers if any, were used. International clinical practice guidelines recommend avoiding traction in the active second stage of vaginal delivery, but any specific maneuver is not favored [26]. In future studies, BPP in breech deliveries and difficulties with delivering the head should be specifically assessed.

Risk factors for severe birth injury, mostly representing the risk factors for BPP, found in cephalic VD were comparable to the risk factors reported for BPP in previous studies that mainly concerned neonates in cephalic presentation (fetal macrosomia, maternal diabetes, instrumental vaginal delivery, and shoulder dystocia) [23]. In the present study, we found no risk factors for severe birth injuries in breech VD. This finding may be due to the low number of injuries in the breech VD group. Another possible explanation might be the stricter selection of women for vaginal delivery and the lower threshold for antepartum and intrapartum CS when the fetus is in the breech presentation compared to pregnancies with the fetus in the cephalic presentation. The observed increase in the risk for severe birth injury with the use of oxytocin in the breech CS group is probably attributed to the attempted vaginal delivery.

The incidence of birth injury was low in all gestational ages in neonates with breech presentation, and no evidence was found of an association between gestational age and birth injury. It has been suggested that CS reduces perinatal morbidity and mortality in preterm breech neonates [4, 12, 27], but the improvement in neonatal outcomes is not



Table 3 Risk factors for severe birth injury

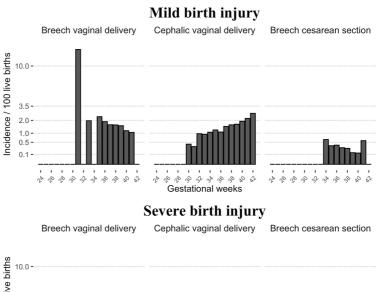
	Vaginal breech delivery	Cesarean section with breech presentation	Cephalic vaginal delivery
Number of live births	4344	16,979	629,182
Injured neonates (freq.)	33	10	1954
BMI \geq 30 kg/m ^{2 a} (freq.)	324	1823	65,809
Rate of injured neonates (%)	15.2	30	21.4
OR (95% CI)	2.12 (0.81-5.54)	3.48 (0.90-13.46)	2.18 (1.95-2.44)
P-value (OR)	0.12	0.07	< 0.001
RD (95% CI)	0.008 (- 0.001-0.03)	0.001 (- 2.50-0.004)	0.003 (0.003-0.004)
Multipara (freq.)	2086	5663	373,376
Rate of injured neonates (%)	42.4	40	58.1
OR (95% CI)	0.77 (0.39-1.55)	1.33 (0.37-4.71)	0.91 (0.83-0.99)
P-value (OR)	0.47	0.66	0.03
RD (95% CI)	- 0.002 (- 0.007-0.004)	0.0002 (- 0.0006-0.001)	- 0.0003 (- 0.0006 to - 2.89
Previous cesarean section (freq.)	177	2224	43,822
Rate of injured neonates (%)	9.1	10	10.2
OR (95% CI)	2.34 (0.71-7.75)	0.74 (0.09-5.81)	1.49 (1.29-1.73)
P-value (OR)	0.16	0.77	< 0.001
RD (95% CI)	0.01 (- 0.002-0.04)	- 0.0002 (- 0.0008-0.002)	0.002 (0.0009-0.002)
Gestational diabetes (freq.)	450	2258	78.671
Rate of injured neonates (%)	12.1	30	22.4
OR (95% CI)	1.18 (0.41-3.36)	2.79 (0.72–10.8)	1.98 (1.78-2.21)
P-value (OR)	0.76	0.14	< 0.001
RD (95% CI)	0.001 (- 0.005-0.02)	0.0009 (- 0.0002-0.003)	0.003 (0.002-0.003)
Type 1 or Type 2 diabetes (freq.)	11	166	2191
Rate of injured neonates (%)	0	0	2.7
OR (95% CI)	0	0	8.0 (6.07–10.54)
P-value (OR)	NA	NA	< 0.001
RD (95% CI)	- 0.008 (- 0.01-0.25)	- 0.0006 (- 0.001-0.02)	0.02 (0.02-0.03)
Use of oxytocin (freq.)	2844	505	276,546
Rate of injured neonates (%)	66.7	20	57.5
OR (95% CI)	1.01 (0.49-2.09)	8.17 (1.73–38.55)	1.67 (1.53-1.83)
P-value (OR)	0.98	0.008	< 0.001
RD (95% CI)	0.0008 (- 0.006-0.005)	0.003 (0.0006-0.01)	0.002 (0.001-0.002)
Induction of labor (freq.)	670	322	12,846
Rate of injured neonates (%)	18.2	0	29.1
OR (95% CI)	1.2 (0.49-2.92)	0	1.65 (1.5-1.82)
P-value (OR)	0.69	NA	< 0.001
RD (95% CI)	0.001 (- 0.004-0.01)	- 0.0006 (- 0.001-0.01)	0.002 (0.001-0.002)
SGA (freq.)	199	666	14,640
Rate of injured neonates (%)	3.0	0	0.6
OR (95% CI)	0.64 (0.09–4.7)	0	0.25 (0.14–0.45)
P-value (OR)	0.68	NA	< 0.001
RD (95% CI)	- 0.003 (- 0.008-0.02)	- 0.0006 (- 0.001-0.005)	- 0.002 (- 0.003 to- 0.002)
LGA (freq.)	23	454	11,196
Rate of injured neonates (%)	3.0	10	18.6
OR (95% CI)	6.0 (0.79–45.89)	4.04 (0.51–31.97)	12.74 (11.35–14.30)
P-value (OR)	0.08	0.19	< 0.001
RD (95% CI)	0.04 (0.0007-0.2)	0.002 (- 0.0002-0.01)	0.03 (0.03-0.03)

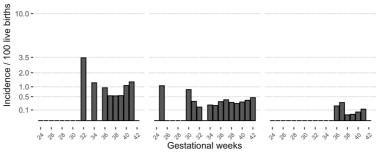
Rate of injured neonates with risk factor of all injured neonates (%). Crude odds ratios (OR) and risk differences (RD) with 95% confidence interval (CI) presented. Neonates with severe birth injury compared to neonates without severe birth injury.

BMI Body mass index, years 2006 to 2017. Due to missing data, the total frequency of injured neonates used with BMI calculation was 1836 in cephalic vaginal delivery, SGA small for gestational age, LGA large for gestational age, OR odds ratio, RD risk difference, CI confidence interval, freq frequency



Fig. 2 The incidence of mild birth injury (%) and severe birth injury (%) in different gestational weeks in vaginal breech delivery (n = 4344), cephalic vaginal delivery (n = 629,182), and cesarean section with breech presentation (n = 16,979) between 2004 and 2017 in Finland. Incidence presented as square root variant





supported by all researchers [15–17]. The Finnish guideline for preterm deliveries concludes that CS may reduce morbidity and mortality for neonates in breech presentation at < 32 weeks of gestation [20]. Although the low number of injuries in breech deliveries reduces the predictability and accuracy of the regression analysis results, our results suggest that the current clinical policy in Finland to manage preterm vaginal breech deliveries in selected women is acceptable, considering the low risk for birth injuries. Unfortunately, head entrapments are not registered in the MBR, and therefore the number of this rare and feared complication that is associated with preterm breech VD is unknown [15, 16].

Furthermore, the significance of high birthweight remains unclear. The guidelines recommend preferring CS when the estimated birthweight is > 3800 to 4000 g [28–30], but high birthweight has not been clearly shown to be associated with

adverse outcomes [14, 31]. In Finland, there are no national guidelines for managing breech deliveries, although an estimated fetal weight of <4000 g is a widely used criterion for attempted vaginal delivery. In the present study, we could not find an association between increasing birthweight or large for gestational age and birth injury in breech VD; however, they were risk factors for severe birth injury in cephalic VD. As previously mentioned, these results regarding breech VD and birthweight may have been affected by the rigorous selection of women and the surveillance of labor in addition to a low number of cases. To summarize, our results suggest that the current Finnish policy of managing breech pregnancies and breech VD up to a birthweight of 4000 g is acceptable, especially concerning birth injuries.

This study provides valuable information on the risks associated with breech deliveries. The strength of this study was the nationwide study population and the long study



Fig. 3 The incidence of mild birth injury (%) and severe birth injury (%) in different birthweight (500–4000 g) in vaginal breech delivery (n=4344), cephalic vaginal delivery (n=629,182), and cesarean section with breech presentation (n=16,979) between 2004 and 2017 in Finland. Incidence presented as square root variant



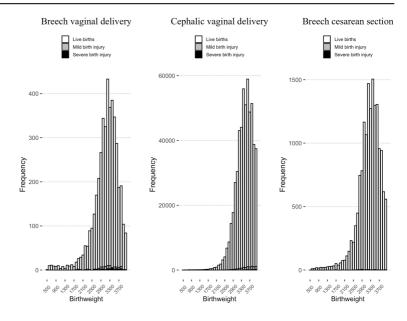
period that enabled us to study rare incidents such as birth injuries. In Finland, reporting to the registers is mandatory, the medical treatment of pregnancies is homogenous even without national guidelines for breech pregnancies, and the rate of breech VD has remained stable during the twenty-first century [32]. Thus, register data have good national coverage, and the reporting and selection biases are low [18, 19]. Our results were, however, restricted by the retrospective study design in which we are unable to study the intended mode of delivery, and rule out the possibility of variation among coding practices. Some of the most difficult deliveries, with failure to deliver head by traditional maneuvers, may have been excluded due to exclusion of forceps deliveries. Furthermore, even with a large sample size, the number of birth injuries remained modest, and thus limited the statistical power of the results. The simulation-based training of breech deliveries started at the end of the study period in delivery units, and a specific program of simulation training was launched in 2021 [33]. Hopefully, the implementation of the simulation training program improves the training and safety of breech deliveries in the future.

Conclusion

Our study confirmed that risk for birth injury is low in breech VD and breech CS. Nevertheless, the risk for severe birth injury, specifically BPP, was higher among breech VD than breech CS or cephalic VD. Birth injuries in neonates with breech presentation were sporadic, and no clinically relevant risk factors were found. These findings suggest that careful selection of women is required to ensure safe vaginal breech delivery.



Fig. 4 Frequency of live births, mild birth injuries, and severe birth injuries in different birth-weight (500–4000 g) in vaginal breech delivery (n=4344), cephalic vaginal delivery (n=629,182), and cesarean section with breech presentation (n=16,979) between 2004 and 2017 in Finland



Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00404-022-06772-1.

Acknowledgements We would like to thank the following individuals for their expertise and assistance in reviewing the management of breech deliveries in Finland: Leena Rahkonen (Helsinki University Hospital), Maija-Riitta Orden (Kuopio University Hospital), and Kristiina Tertti (Turku University Hospital).

Author contributions MK: project development, data management and analysis, manuscript writing. TK: data management and analysis, manuscript editing. AS: project development, data management and analysis, manuscript editing. MG: data management and analysis, manuscript editing. HL: project development, data analysis, manuscript editing. KT: project development, data management and analysis, manuscript editing. KT: project development, data management and analysis, manuscript writing. All authors contributed to the design of the study. TH, AS, and MG contributed to the acquisition of the data. MK, TK, KT, and TH were responsible for data analysis. All authors contributed to the interpretation of the data. MK was a major contributor in the writing of the manuscript. All authors participated in the drafting and revising of the manuscript. All authors read and approved the final manuscript.

Funding The competitive State Research Financing of the Expert Responsibility area of Tampere University Hospital partly supported this study financially.

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This study was approved by the Ethics committee of Tampere University Hospital (reference number R17069). Institutional approval was also obtained from the Finnish Institute for Health and Welfare (reference number THL/1659/5.05.00/2017).

Consent to participate In accordance with Finnish regulations, and due to the retrospective register-based study design, no informed written consent was required. Only pseudonymized data were used.

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