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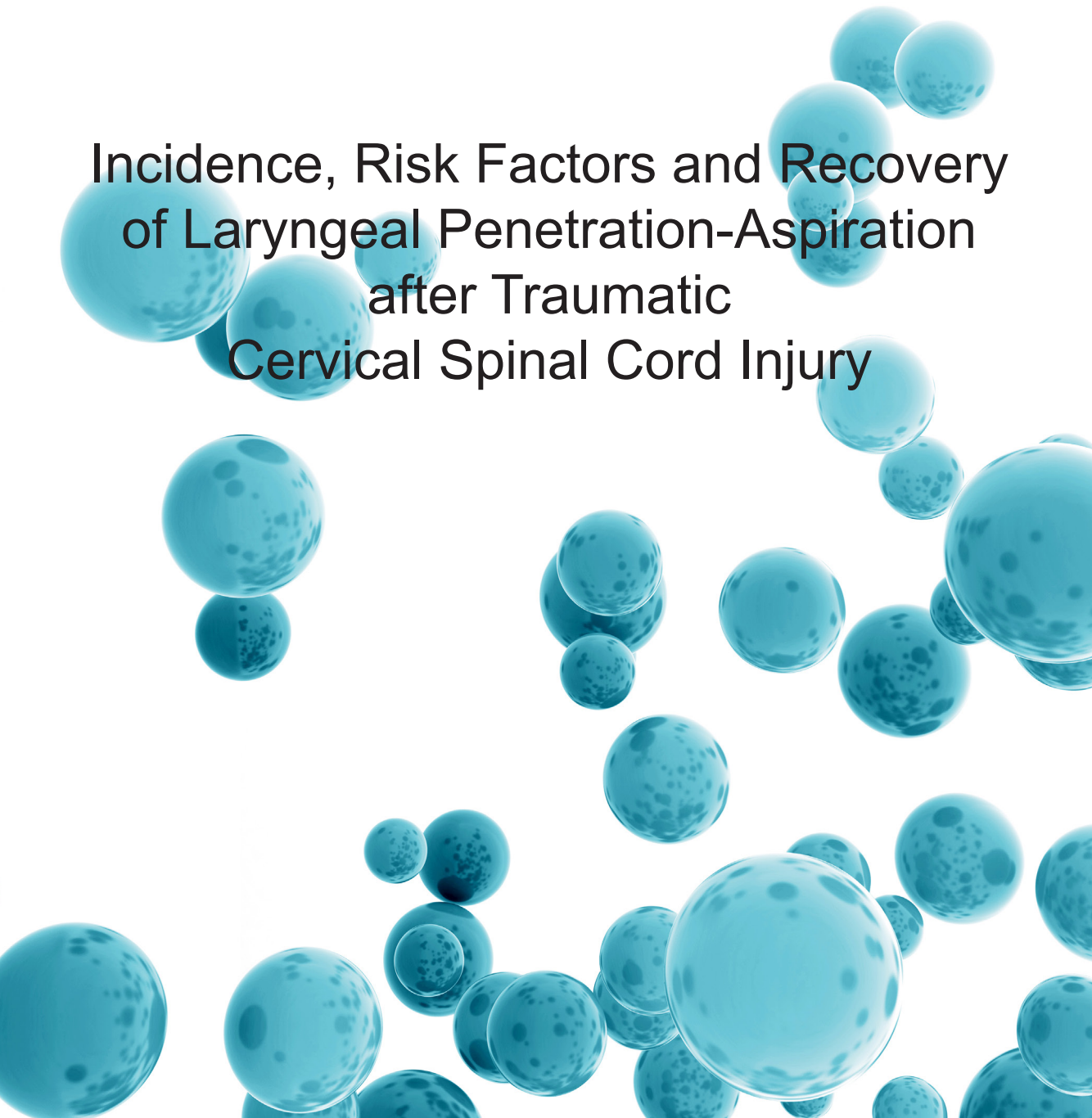
TIINA IHALAINEN

Incidence, Risk Factors and Recovery of Laryngeal Penetration-Aspiration after Traumatic Cervical Spinal Cord Injury



TIINA IHALAINEN

Incidence, Risk Factors and Recovery of Laryngeal Penetration-Aspiration after Traumatic Cervical Spinal Cord Injury

ACADEMIC DISSERTATION
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UNIVERSITY OF TAMPERE

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University of Tampere
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Finland

Supervised by
Professor Anna-Maija Korpijaakko-Huuhka
University of Tampere
Docent Teemu Luoto
University of Tampere
Docent Antti Ronkainen
University of Tampere
Finland

Reviewed by
Professor Jari Arokoski
University of Helsinki
Finland
Docent Per Östberg
Karolinska Institutet
Sweden

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To the patients whom I have had the privilege of treating and learning from over the years

ABSTRACT

Traumatic spinal cord injury (SCI) results in the partial or complete loss of motor and sensory functions below the neurological level of the injury. In tetraplegic patients, the injury is at the level of the cervical segments of the spinal cord, whereas in paraplegia, the lesions involve the thoracic, lumbar, or sacral regions of the spinal cord. In addition, a spinal cord injury affects somatic and autonomic nervous control of the blood vessels, respiratory tract, sweat glands, bowel, urinary bladder, and sex organs. Dysphagia is a relatively common secondary complication encountered in patients with traumatic cervical SCI. Dysphagia is associated with many negative outcomes, such as pneumonia, malnutrition, dehydration, and a reduced quality of life. In general, the pneumonia risk is greatest in those patients experiencing aspiration.

The purpose of this thesis was to determine the incidence and risk factors for laryngeal penetration-aspiration in a cohort of patients with traumatic cervical SCI. In addition, this thesis aimed at describing the recovery of penetration-aspiration and functional oral feeding outcome in these patients. The study sample consisted of a prospective cohort of applicable patients (n=46) with acute traumatic cervical SCI admitted to Tampere University Hospital from February 2013 to April 2015. A videofluoroscopic swallowing study (VFSS) and Rosenbek's penetration-aspiration scale (PAS) were used to determine the incidence of penetration-aspiration. The Functional Oral Intake Scale (FOIS) to determine the functional feeding outcome was used. All the patients received speech therapeutic interventions based on their clinical needs.

Fifteen patients (33%) showed aspiration in the first VFSS and the overall incidence of penetration-aspiration was 48%. Of those patients who aspirated, 73% aspirated silently, i.e. without coughing. The clinical signs and risk factors for predicting penetration-aspiration were coughing, throat clearing, choking and changes in voice quality related to swallowing, lower level (C5-Th1) of anterior cervical operation and a necessity for bronchoscopy. The majority (88%) of the patients had a total oral intake without restrictions at the time of the final follow-up. Only one patient (2%) showed persistent aspiration and was still tube-dependent with consistent oral intake. In conclusion, the incidence of penetration-aspiration

based on VFSS is high (48%) among patients with acute traumatic cervical SCI with the majority of patients exhibiting silent aspiration. These findings highlight the importance of performing a routine evaluation of swallowing before initiating oral feeding.

TIIVISTELMÄ

Traumaattinen eli tapaturmaperäinen selkäydinvamma (SYV) johtaa liikuntakyvyn ja tuntoaistitoimintojen osittaiseen tai täydelliseen menetykseen vammatason alapuolella. Kaularangan tasolla sijaitseva selkäydinvamma johtaa täydelliseen tai osittaiseen neliraajahalvaukseen eli tetraplegiaan. Rintakehän tai lannerangan tasolla sijaitseva selkäydinvamma puolestaan vaikuttaa alaraajojen toimintaan. Lisäksi selkäydinvamman seurauksena tapahtuva autonomisen hermoston toiminnan vaurioituminen aiheuttaa useiden elinjärjestelmien, kuten hengityksen ja verenkierron, toimintahäiriöitä.

Nielemisvaikeus eli dysfagia on suhteellisen yleinen tetraplegiapotilailla. Dysfagiaan liittyy useita mahdollisia haittavaikutuksia, kuten keuhkokuume, aliravitsemus, nestevajaus ja elämänlaadun heikkeneminen. Riski sairastua keuhkokuumeeseen on suurin niillä potilailla, joilla on aspiraatiotaipumus, eli nestettä tai ruokaa pääsee nielemisen aikana äänihuulitason alapuolelle eli henkitorveen ja keuhkoihin. Penetraatiolla tarkoitetaan, että nestettä tai ruokaa pääsee hengitystien yläosaan ja/tai äänihuulien tasolle, mutta ei henkitorveen.

Tämän väitöstutkimuksen tavoitteena oli selvittää traumaperäisten tetraplegiapotilaiden penetraation ja aspiraation esiintyvyys ja riskitekijät. Lisäksi tutkimuksen tavoitteena oli kuvata penetraatiosta ja aspiraatiosta toipumista ja potilaiden kykyä syödä suun kautta turvallisesti. Tutkimusaineisto kerättiin Tampereen yliopistollisessa sairaalassa helmikuun 2013 ja huhtikuun 2015 välisenä aikana. Tutkimusjoukko koostui yhteensä 46 tetraplegiapotilaasta. Penetraatio-aspiraation esiintyvyys tutkittiin nielemisen läpivalaisututkimuksen eli videofluorografian (VFG) avulla. Penetraation ja aspiraation vaikeusasteluokitteluun käytettiin Rosenbekin kahdeksanluokkaista asteikkoa (PAS), jossa luokat 1–2 edustavat normaalia nielemistoimintoa, luokat 3–5 penetraatiota ja luokat 6–8 aspiraatiota. Ravitsemustavan luokitteluun käytettiin seitsemänluokkaista FOIS-asteikkoa, jossa luokat 1–3 tarkoittavat ravitsemusta syöttöletkun kautta kokonaan tai osittain ja luokat 4–7 tarkoittaa ravitsemusta kokonaan suun kautta helposti nieltävillä eli muunnelluilla ruokakoostumuksilla tai tavallisella ruokakoostumuksella. Tutkimuksen aikana kaikki potilaat saivat puheterapiaa kliinisten tarpeidensa perusteella.

Viidellätoista potilaalla (33 %) esiintyi aspiraatiota (PAS 7–8) ensimmäisessä VFG-tutkimuksessa, ja heistä 73 % aspiroi hiljaisesti eli ilman yskimisreaktiota. Penetraatiota ja aspiraatiota (PAS ≥3) esiintyi yhteensä 22 potilaalla (48 %). Penetraation ja aspiraation tilastollisesti merkitsevinä kliinisinä tunnusmerkkeinä olivat yskiminen, kurkunselvittely ja kakominen sekä muutokset puheäänen laadussa nielemisen aikana tai sen jälkeen. Muina riskitekijöinä olivat etukautta tehty kaularankaoperaatio kaularangan alaosaan (C5–Th1) ja akuuttihoidon aikana tehdyt hengitysteiden tähystys eli bronkoskopia. Tutkimuksen päättyessä suurin osa potilaista (88 %) söi suun kautta ilman ruoan koostumuksen rajoituksia. Vain yhdellä potilaalla (2 %) esiintyi yhä aspiraatiota, ja hän oli edelleen riittävän ravitsemuksen turvaamiseksi riippuvainen vatsanpeitteiden läpi mahalaukkuun viedystä syöttöletkusta. Tutkimuksen johtopäätöksenä voidaan todeta, että VFG-tutkimuksella todennetun penetraation ja aspiraation esiintyvyys on suhteellisen suuri (48%) tutkitussa potilasjoukossa. Suurin osa potilaista aspiroi hiljaisesti. Tämä havainto korostaa nielemistoiminnon rutiininomaisen arvioinnin tärkeyttä ennen kuin potilas voi aloittaa syömisen suun kautta.

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LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following three original publications which are referred to in the text using Roman numerals I-III. The original publications have been reprinted with the permission of the copyright holders. In addition, some previously unpublished results are included in the thesis.

I Ihalainen T., Rinta-Kiikka I., Luoto T. M., Koskinen E. A., Korpijaakko-Huuhka A-M., & Ronkainen A. (2017). Traumatic cervical spinal cord injury: a prospective clinical study of laryngeal penetration and aspiration. Spinal Cord, 55(11): 979-984.

II Ihalainen T., Rinta-Kiikka I., Luoto T. M., Thesleff T., Helminen M., Korpijaakko-Huuhka A-M., & Ronkainen A. (2018). Risk factors for laryngeal penetration-aspiration in patients with acute traumatic cervical spinal cord injury. Spine J, 18(1): 81-8.

III Ihalainen T., Luoto T. M., Rinta-Kiikka I., Ronkainen A., & Korpijaakko-Huuhka A-M. (2018). Traumatic cervical spinal cord injury: Recovery of Penetration/Aspiration and Functional Feeding Outcome. Spinal Cord, 56(10): 1000–1007.

ABBREVIATIONS

AIS	ASIA Impairment Scale
ASIA	American Spinal Cord Injury Association
BSE	Bedside Swallow Evaluation
C1	First Cervical Vertebrae/Spinal Nerve
C2	Second Cervical Vertebrae/Spinal Nerve
C3	Third Cervical Vertebrae/Spinal Nerve
C4	Fourth Cervical Vertebrae/Spinal Nerve
C5	Fifth Cervical Vertebrae/Spinal Nerve
C6	Sixth Cervical Vertebrae/Spinal Nerve
C7	Seventh Cervical Vertebrae/Spinal Nerve
C8	Eighth Spinal Nerve
CT	Computed Tomography
FEES	Fiberoptic Endoscopic Evaluation of Swallowing
FOIS	Functional Oral Intake Scale
ISNCSCI	International Standards for Neurological Classification of Spinal Cord Injury
MBS	Modified Barium Swallow
MBSImp	Modified Barium Swallow Impairment Profile
MRI	Magnetic Resonance Imaging
NLI	Neurological Level of the Injury
PAS	Penetration-Aspiration Scale
PEG	Percutaneous Endoscopic Gastrostomy
SCI	Spinal Cord Injury
SD	Standard Deviation
Th1	First Thoracic Vertebrae/Spinal Nerve
VFSS	Videofluoroscopic Swallowing Study
WST	Water Swallowing Test

1 INTRODUCTION

Traumatic cervical spinal cord injury (SCI) is a life-changing incident, as it results in partial or complete loss of motor and sensory function in the arms, trunk, pelvic organs, and legs. Furthermore, damage to the spinal cord evokes changes in autonomic functions such as cardiovascular and respiratory system, urinary bladder, bowel, and sexual organs. Thus, the injury may have devastating consequences for the physical, economical, and psychosocial well-being of patients and their loved ones. In Finland, the incidence of traumatic SCI is 31.8 per million and the vast majority (70%) of these injuries result in tetraplegia (Koskinen et al., 2014). SCI may also be caused by non-traumatic reasons such as spinal stenosis, tumors, ischemia or infection (McKinley, Seel, & Hardman, 1999). The focus of this thesis will be on traumatic cervical SCI.

Dysphagia, difficulty in swallowing, is a common complication in patients with cervical SCI. According to the published literature, the overall incidence of dysphagia in traumatic and non-traumatic cervical SCI patients varies from 16% to 80% (Abel, Ruf, & Spahn, 2004; Brady et al., 2004; Chaw, Shem, Castillo, Wong, & Chang, 2012; Kirshblum, Johnston, Brown, O'Connor, & Jarosz, 1999; Seidl, Nusser-Muller-Busch, Kurzweil, & Niedeggen, 2010; Shem, Castillo, & Naran, 2005; Shem, Castillo, Wong, & Chang, 2011; Shem, Castillo, Wong, Chang, & Kolakowsky-Hayner, 2012b; Shem et al., 2012a; Shin, Yoo, Lee, Goo, & Kim, 2011; Wolf & Meiners, 2003). Dysphagia is associated with many negative clinical short- and long-term outcomes, such as pneumonia, malnutrition, dehydration, and reduced quality of life (Carrión et al., 2015; Garcia-Peris et al., 2007; Leibovitz et al., 2007; Smithard, O'Neill, Parks, & Morris, 1996). Additionally, aspiration, is considered to be a risk factor for pneumonia (Martino et al., 2005; Smithard et al., 1996). Aspiration means that the swallowed material enters into the airways whereas in penetration it enters the laryngeal vestibule but remains above the vocal cords (Rosenbek, Robbins, Roecker, Coyle, & Wood, 1996). Thus, early identification of the patients with an increased risk for aspiration, is critical to ensure safe nutrition and optimal pulmonary function.

The purpose of this thesis was to determine the incidence and risk factors for laryngeal penetration-aspiration in a cohort of patients with traumatic cervical SCI.

In addition, the thesis aimed to provide a description of the recovery of penetration-aspiration and functional oral feeding outcome in these patients. An improved understanding of the incidence rates and risk factors of laryngeal penetration-aspiration in this clinically demanding patient group could help to minimize any possible negative consequences i.e. aspiration pneumonia, dehydration and malnutrition. Furthermore, this knowledge could lower treatment costs and facilitate a better recovery.

2 REVIEW OF THE LITERATURE

2.1 Traumatic Cervical Spinal Cord Injury

2.1.1 Basic Anatomy of the Spinal Cord

A brief overview of the anatomy of the spinal cord is outlined based on the handbooks of Thibodeau and Patton (2003, pp. 413–419) and Tortora and Derrickson (2009, 460–489).

The spinal cord is located within the vertebral canal and it extends from the medulla oblongata through the foramen magnum to the level of the superior border of the second lumbar vertebrae. Thus, the spinal cord is shorter than the vertebral column. The vertebral column consists of 33 vertebrae grouped as follows: 7 cervical, 12 thoracic, 5 lumbar, 5 sacral and, 4 coccygeal. In comparison, the spinal cord is divided into 31 segments and pairs of spinal nerves: 8 cervical, 12 thoracic, 5 lumbar, 5 sacral and, 1 coccygeal. The first seven pairs of cervical spinal nerves (C1–C7) exit the vertebral canal above the same numbered cervical vertebrae. Cervical nerve eight (C8) exits below the seventh cervical vertebrae. The remaining spinal nerves emerge below the same numbered vertebrae. Figure 1 illustrates the vertebrae and the spinal nerves.

The spinal cord and spinal nerves are the pathways allowing sensory input to the brain and motor output from the brain. In addition, the autonomic nervous system pathways travel in the white matter of the spinal cord. Each spinal nerve is attached to the spinal cord by an anterior (i.e. ventral) root and a posterior (i.e. dorsal) root. The anterior root (descending tract) carries motor, both somatic and autonomic, information from the brain through the spinal cord to the skeletal muscles as well as to the smooth muscles and cardiac muscle, and glands. Likewise, the posterior root (ascending tract) carries sensory information from receptors in the skin, skeletal muscles, and organs via the spinal cord to the brain. The anterior and posterior roots unite to form a mixed spinal nerve at the intervertebral foramen.

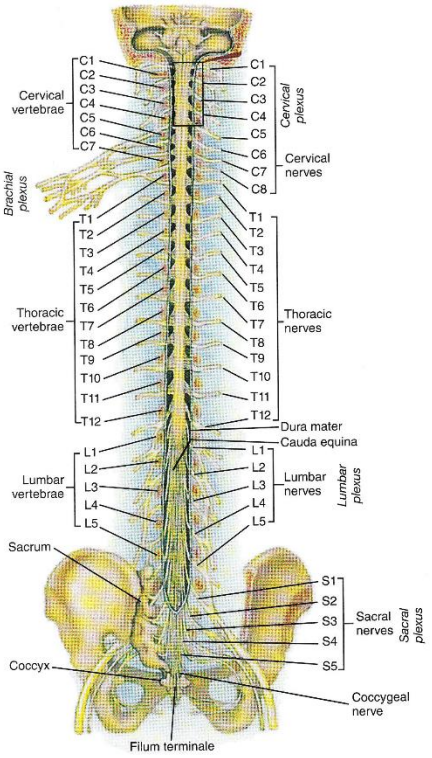

Figure 1. The vertebrae and spinal nerves. Reprinted with permission (Thibodeau & Patton, 2003, p. 414).

2.1.2 Traumatic SCI

In traumatic SCI, the neural elements within the spinal canal are damaged by an external force e.g. a fall, a motor vehicle crash, sporting activity or violence. A traumatic injury to the spinal cord itself can occur with or without fractures or dislocation of the vertebral column. SCI results in the partial or complete loss of motor and sensory functions below the neurological level of the injury (Kirshblum, Burns et al., 2011). In tetraplegic patients, the injury is at the level of the cervical segments (C1–C8) of the spinal cord, whereas in paraplegia, the lesions involve the thoracic, lumbar, or sacral regions of the spinal cord. In addition, a spinal cord injury can affect somatic and autonomic nervous control of the blood vessels, respiratory tract, sweat glands, bowel, urinary bladder, and sex organs (Krassioukov et al., 2012).

The International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) are widely used to evaluate the neurological level of the injury (NLI) and to classify the degree of impairment (Kirshblum et al., 2011; Kirshblum, Waring et al., 2011). The NLI refers to the most caudal segment of the spinal cord with normal motor and sensory function on both sides of the body. The degree of the injury is classified based on the American Spinal Injury Association (ASIA) Impairment Scale (AIS (Kirshblum et al., 2011; Kirshblum, Waring et al., 2011). AIS grade A is the term for a complete injury. AIS B refers to motor complete-sensory incomplete injury. AIS C–D represents incomplete motor and sensory injuries and AIS E designates normal motor and sensory functions. SCI is defined as complete when motor or sensory function is absent at levels 4 and 5 of the sacral segments. For detailed instructions for AIS determinations see the ISNCSCI worksheet in Appendix 1.

According to the review written by Lee and colleagues (2014), the median incidence of traumatic SCI is 40 cases per million in North America and 16 cases per million in Western Europe. A cervical SCI accounts for approximately 50% of all traumatic SCIs in Canada and USA (Chen, He, & DeVivo, 2016; Lenehan et al., 2012). In Iceland and Finland, even higher percentages for traumatic cervical SCI have been reported (57% and 70%, respectively) (Knutsdottir et al., 2012; Koskinen et al., 2014). Currently, the average age of traumatic cervical SCI patients is increasing with older individuals being more likely to sustain an incomplete tetraplegia (Chen et al., 2016; Knutsdottir et al., 2012; Koskinen et al., 2014; Lenehan et al., 2012).

2.1.3 Clinical Consequences and Treatment of Traumatic Cervical SCI

Cervical SCI results in the partial or complete loss of motor and sensory function in the arms, and legs as well as in the trunk, and pelvic organs (Kirshblum et al., 2011). The severity of functional disability varies from a complete need for assistance in activities of daily living (i.e. ablution, dressing, eating, catheterization and bowel management and a permanent need for a wheelchair for mobility) to partial or completely independence in daily activities with minor restrictions in an ability to use the lower and upper extremities. Furthermore, patients with SCI suffer dysfunctions of many organ systems (i.e. cardiovascular and pulmonary system, sweat glands, urinary bladder, bowel, and sexual organs), because the descending spinal voluntary motor and involuntary autonomic pathways are interrupted (Krassioukov et al., 2012). The main goals of the acute care of traumatic SCI are to preserve adequate

breathing and circulation, inhibit hypoxemia, normalize vital signs, maintain spinal stability, and prevent secondary medical complications (Heary, Zouzias, & Campagnolo, 2011). During the early phase after the injury, close monitoring of cardiac, hemodynamic and respiratory functions is often required in an intensive care unit. Cervical vertebrae fractures or dislocations are often associated with traumatic cervical SCI. If the fracture site is unstable, stabilizing spine surgery will be necessary. Surgical interventions to the cervical vertebrae can be classified as either anterior or posterior approaches (Figure 2b and 2c), although in some cases, a combined anterior and posterior approach may be required (Figure 2a). When the fracture is considered as being stable, an external orthosis, a halo vest or a hard collar, may be placed to achieve stabilization.

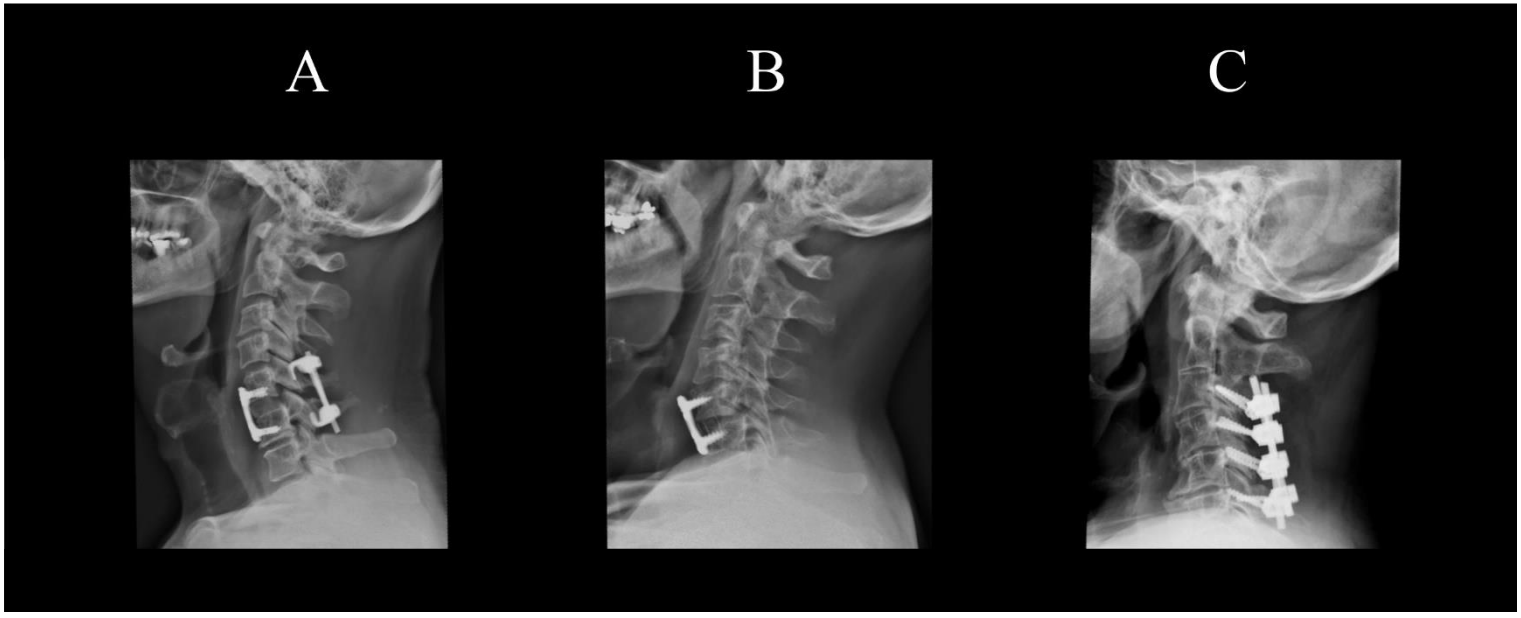

Figure 2. Anterior and posterior fixation of C5-C6 (A), anterior fixation of C5-C6 (B), and posterior fixation of C3-C6 (C). The x-ray images were retrieved from the Picture Archiving and Communication Systems and represent clinical cases treated in the Tampere University Hospital.

From the speech therapist's point of view, the pulmonary and cardiovascular dysfunctions and pain are the most important clinical consequences influencing the clinical evaluation and rehabilitation of these patients. According to the review article of Schilero and colleagues (2009), an injury to the cervical level of the spinal cord disrupts the functionalities of inspiratory and expiratory muscles causing a reduction in lung volume and vital capacity. In addition, patients with cervical SCI have decreased chest wall and lung compliance, increased abdominal wall compliance, and rib cage stiffness with paradoxical chest wall movements. Expiratory muscle function is more compromised than inspiratory muscle function, which results in ineffective coughing and difficulties in clearing secretions which in turn predispose to mucus retention atelectasis, respiratory insufficiency, and pulmonary infections. The higher the level of injury, the more severe will be the pulmonary dysfunction. An injury level of C5 and above often results in the need for intubation or tracheostomy and mechanical ventilation (Claxton, Wong, Chung, & Fehlings, 1998; Como et al., 2005; Harrop, Sharan, Scheid, Vaccaro, & Przybylski, 2004). Successful weaning and decannulation are dependent on the cervical level and the completeness of the injury. The patients with the injury at the level of C5 or below are more often likely to be successfully weaned from tracheostomy (Como et al., 2005; Nakashima et al., 2013).

The occurrence of pneumonia is high among patients with cervical SCI. Jackson and Groomes (1994) reported that the incidence of pneumonia was 63% in a patient group with an injury at the level of C1-C4, and 28% in patients with a C5-C8 level injury. Later, Liebscher and colleagues (2015) reported the occurrence of pneumonia to be 51% in patients with an injury level of C4-C8 and complete motor injury (AIS A and B). Hence, patients with cervical SCI are particularly prone to periods of pulmonary dysfunctions (Vazquez, Sedes, Farina, Marques, & Velasco, 2013; Winslow & Rozovsky, 2003; Zimmer, Nantwi, & Goshgarian, 2007), which remain a major cause of morbidity and mortality (Aarabi et al., 2012; Claxton et al., 1998; DeVivo, Krause, & Lammertse, 1999; Grossman et al., 2012; Jackson & Groomes, 1994; Krause, Cao, DeVivo, & DiPiro, 2016; Sabre, Rekand, Asser, & Kõrv, 2013). Additionally, pulmonary complications increase the length of hospital stay and increase further the cost of hospitalization (Aarabi et al., 2012; Winslow, Bode, Felton, Chen, & Meyer PR Jr, 2002).

Due to the cardiovascular dysfunction after a cervical SCI, patients can experience cardiac arrhythmias (most usually bradycardia), a low resting blood pressure and orthostatic hypotension which may require medical attention (Claydon, Steeves, & Krassioukov, 2006; Claydon & Krassioukov, 2006; Furlan & Fehlings,

2008; Popa et al., 2010). Because orthostatic hypotension leads to blurred vision, dizziness, fatigue, restlessness, and dyspnea, it may have a negative impact upon the patient's ability to participate fully in their clinical assessment and rehabilitation (i.e. it may impair the patient's ability to sit in an upright position in a bed or in a wheelchair) (Claydon et al., 2006; Furlan & Fehlings, 2008).

Pain is a common consequence of SCI. Based on the review article of Dijkers, Bryce and Zanca (2009), the prevalence of pain varies from 26% to 96%. The nature of pain may be nociceptive or neuropathic or a combination of these two. Neuropathic pain following SCI is a consequence of damage to or dysfunction of the nervous system, whereas nociceptive pain is caused by damage to non-neural tissue (e.g. skin, muscles and bones). Spasticity, increased muscle tonus and reflex movements elicited by movement or tactile stimulation, can also be painful. The incidence of spasticity among patients with traumatic cervical SCI has been reported to be as high as 79% (Sköld, Levi, & Seiger, 1999). Both the pain and spasticity may affect the patient's ability to undertake daily activities and participate in his/her rehabilitation.

Other clinical consequences of SCI are dysfunctions in bladder, bowel and sexual functions and disturbances in thermoregulation (Krassioukov et al., 2012). In addition, patients with SCI are prone to pressure ulcers. Prophylactic measures to prevent the development of pressure ulcers should begin immediately after the injury (Heary et al., 2011). Furthermore, Wong and colleagues (Wong et al., 2012) reported that patients with SCI are particularly vulnerable to malnutrition. In particular, tracheostomized patients may require additional attention when devising a nutritional management plan. Reduced serum protein levels associated with malnutrition and hypoproteinaemia have even been noted as significant indicators of mortality in patients with acute cervical SCI (X. Chen, Liu, Sun, Ren, & Wang, 2014). Nutritional support and early enteral nutrition (initiated within 72 hours) are generally recommended (Dhall et al., 2013). Chapter 2.3 will describe in detail the swallowing difficulties experienced by patients with cervical SCI.

2.2 Evaluation of Dysphagia

The term dysphagia refers to difficulties in swallowing. A normal swallow consists of four phases (Chapter 2.2.1), and dysphagia may appear in one or more of them. Penetration and aspiration are the most severe symptoms of dysphagia and may occur before, during, and/or post-swallowing. Penetration means that the swallowed material enters the airways but remains above the vocal folds (Rosenbek et al., 1996). In the case of aspiration, the swallowed material passes below the vocal cords into the trachea. Aspiration can occur with or without a cough reflex, with the latter being referred to as silent aspiration. A bolus residue in the pharynx is also an indicator of dysphagia and a significant predictor of aspiration (Eisenhuber et al., 2002), since the residue may enter the airway after swallowing.

In general, evaluation of swallowing usually begins with a screening and/or bedside examination (Chapter 2.2.2) and it is often followed by an instrumental evaluation with a videofluoroscopic swallowing study (VFSS) and/or fiberoptic endoscopic evaluation of swallowing (FEES) (Chapter 2.2.3). The goals of the swallowing assessment are to determine the optimal nutrition method (oral vs. non-oral) in order to support adequate nutrition and hydration, and to maximize safe swallowing since proper swallowing safety aims to reduce the pulmonary complications associated with penetration-aspiration.

2.2.1 Basic Physiology of Normal Swallowing

To understand deviations in swallowing, it is essential to recognize how normal swallowing occurs. A normal swallow is a complex activity that clears food, liquid and saliva from the oral cavity through the pharynx into the esophagus as well as ensuring adequate airway protection. A swallow is controlled by the brain stem; this is where the motor and sensory nuclei of the following cranial nerves are located; trigeminal, facial, glossopharyngeal, vagus and hypoglossal (Ertekin & Aydogdu, 2003). These cranial nerves innervate the anatomical areas involved in swallowing, i.e. the structures of the oral cavity, pharynx, larynx, and esophagus. Additionally, the ansa cervicalis, a loop of spinal nerves from C1–C3/C4, innervates the infrahyoid muscles of the larynx (Banneheka, 2008). The superior root of the ansa cervicalis travels with the hypoglossal nerve. Next, the basic knowledge about the four normal

phases of swallowing will be surveyed (Dodds, Stewart, & Logemann, 1990; Logemann, 1998, pp. 23-35).

First, in the oral preparatory phase of swallowing (Figure 3a), the food is masticated, if necessary, and mixed with saliva and a suitable bolus is formed prior to swallowing. Secondly, the oral phase of swallowing (Figure 3b) is initiated by the elevation of the tongue tip against the hard palate and then followed by the posterior movement of the tongue that pushes the bolus backward into the pharynx; this phase takes about one second to complete. These two phases of swallowing are voluntary.

Thirdly, the pharyngeal phase of swallowing (Figure 3c) begins when the pharyngeal swallow is triggered and from this point on swallowing is involuntary. In the beginning of the pharyngeal phase, the soft palate seals off the nasopharynx and the base of tongue retracts. Then the pharyngeal constrictor muscles move the bolus through the pharynx, and the larynx and hyoid bone are elevated and moved anteriorly. The downward moving bolus forces the elastic cartilage of the epiglottis to tilt over the trachea, and respiration is temporarily suspended. Simultaneously, the vocal cords and the vestibular cords are tightly adducted to protect the airways. Then the upper esophageal sphincter opens and the bolus passes into the esophagus. After the pharyngeal triggering of the swallow, it takes normally a second or less to move the bolus through the pharynx into the esophagus. It is important to be aware that the pharyngeal phase of swallowing will not occur until the pharyngeal swallow has been triggered. As a result, the bolus may rest in the valleculae or drain down the aryepiglottic fold into the pyriform sinuses or even gain access to the trachea. The entry of food or liquid into the level of vocal cords should normally result in a cough reflex.

The fourth and final phase of the swallowing, the esophageal phase (Figure 3d), begins when the upper esophageal sphincter opens and a peristaltic wave pushes the bolus down through the esophagus. This phase ends when the lower esophageal sphincter opens and the bolus enters into the stomach.

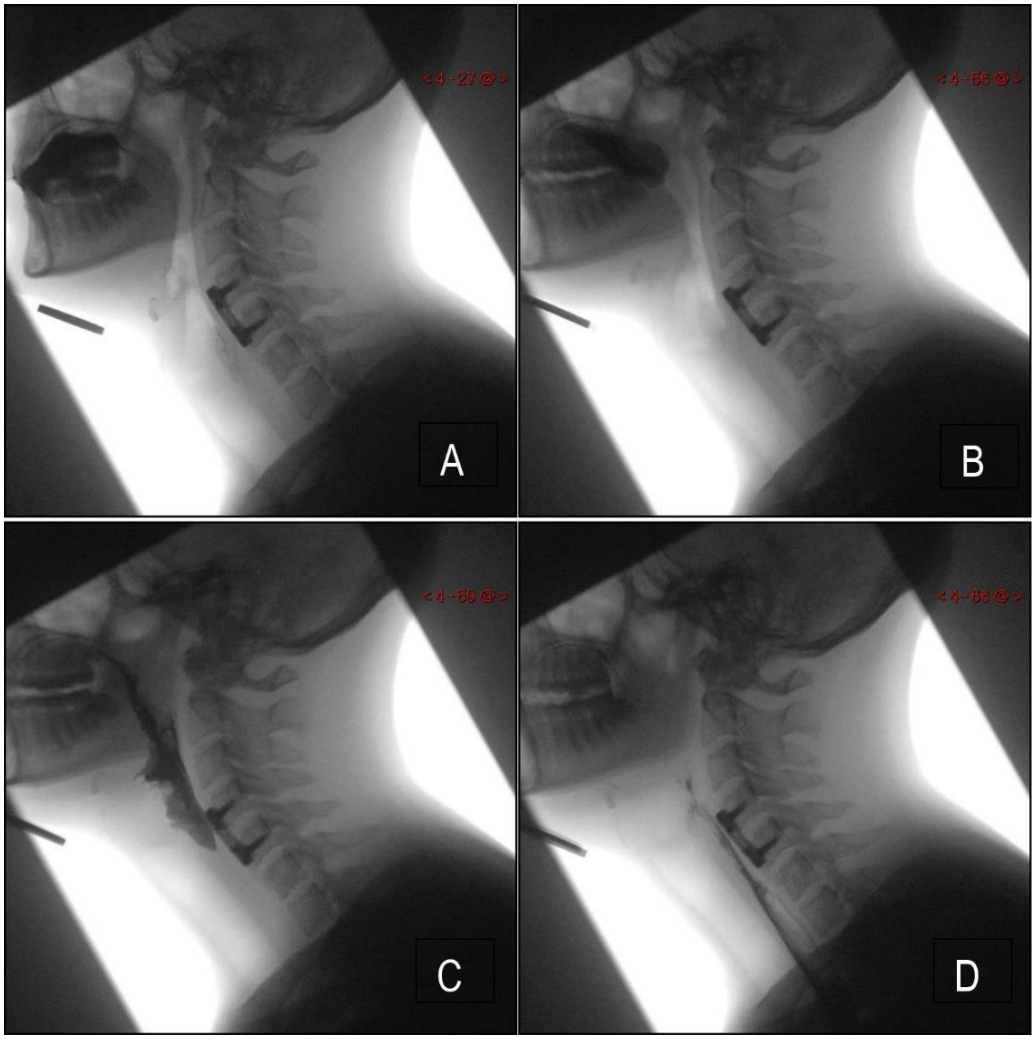

Figure 3. A series of VFSS images showing the normal passage of a contrast agent bolus through the pharynx at different phases: the oral preparatory phase (A), the oral phase (B), the pharyngeal phase (C) and the esophageal phase (D). The swallowed contrast agent appears as black in the images. The x-ray images were retrieved from the Picture Archiving and Communication Systems and represent clinical cases treated in the Tampere University Hospital.

2.2.2 Screening and Bedside Evaluation

According to Logemann (1998, pp. 135-139), a swallowing screening procedure aims to identify the signs and symptoms of aspiration and dysphagia. The screening test should be quick (taking less than 15 minutes), easy, cost-effective, and pose a low risk to the patient. In addition, the screening procedure should have good sensitivity (ability to identify true positives, i.e. patients who are aspirating) and good specificity (ability to identify true negatives, i.e. patients who are not aspirating). Accordingly, the screening test should not produce false negatives or false positives. The screening may be conducted by a nurse (Edmiaston, Connor, Loehr, & Nassief, 2010; Leder, Suiter, Warner, & Kaplan, 2011; Martino et al., 2009; Perry, 2001; Suiter & Leder, 2008), a speech therapist (Logemann, Veis, & Colangelo, 1999; Trapl et al., 2007) or a physician (Antonios et al., 2010).

In comparison with the screening procedure, a bedside examination aims to identify the cause and nature of dysphagia and to devise a management plan (Logemann, 1998, p. 139). As stated by Swigert, Steele and Riquelme (2007), clinicians struggle with the differentiation between screening and a clinical bedside examination. This is also evident in the literature, as the terms screening and bedside examination are used confusingly even in review articles (Bours, Speyer, Lemmens, Limburg, & de Wit, 2009; Daniels, Anderson, & Willson, 2012; Kertscher, Speyer, Palmieri, & Plant, 2014; Romano, Schultz, & Tai, 2012). In the review article published Daniels, Anderson and Wilson (2012) five categories were identified as elementary parts of screening: 1) patient's demographics, 2) medical history, 3) global assessment (i.e. alertness, functional ability), 4) oral mechanism evaluation, and 5) swallowing evaluation. The same elements can be present in a bedside examination but are conducted in a more extensive form (Logemann, 1998, pp. 139-168).

The swallowing evaluation typically includes a swallowing trial. The ways to perform the trial varies between different screening or bedside procedures, but the majority of procedures include some type of water swallowing test (WST) where the amount of water varies from 1 ml to 100 ml (Brodsky et al., 2016). In addition to water, some of the procedures also use other materials with differing consistencies such as thickened liquids, puree, and/or chewable materials (Clave et al., 2008; Logemann et al., 1999; Trapl et al., 2007). In their review article, Romano, Schultz, Tai and White (2012) stated that a bedside examination is a reasonably accurate way to identify aspiration in dysphagic patients, with an overall summary sensitivity of 71% and specificity of 76%. The authors emphasized, however, that these results were based predominantly on adult, acute post stroke patients. When using WST's,

an airway response such as coughing/choking with or without voice changes (e.g. wet voice quality) is monitored to identify aspiration (Brodsky et al., 2016). Brodsky and colleagues (2016) also found that pooled estimates for single sip volumes (1-5 ml) had sensitivity of 71% and specificity of 90%, consecutive sips of 90 to 100 ml trials were 91% sensitive and 53% specific. The authors suggested that using both single sips and consecutive sips from a large volume in a stepwise manner may improve both the sensitivity and specificity of the evaluation.

Aspiration without coughing or choking - silent aspiration – remains, however, difficult to identify with screening procedures. Unfortunately, silent aspiration is frequent as shown in two retrospective studies with large heterogeneous groups of dysphagic patients, (Garon, Sierzant, & Ormiston, 2009; Smith, Logemann, Colangelo, Rademaker, & Pauloski, 1999): the incidence of silent aspiration among patients who aspirated varied from 55% to 59%. Thus, an instrumental evaluation (i.e. VFSS and FEES) is often necessary to detect silent aspiration.

2.2.3 Instrumental Assessment

The most widely used instrumental swallowing assessment techniques are videofluroscopic swallowing study (VFSS), also referred to as the modified barium swallow (MBS), and fiberoptic endoscopic evaluation of swallowing (FEES). VFSS is conducted by a speech therapist and a radiologist. During the VFSS, the speech therapist provides the patient with various consistencies of liquid and food mixed with a water-soluble contrast agent or barium. VFSS allows the real time visualization of the oral preparatory, oral, pharyngeal and esophageal phases of swallowing (Dodds, Logemann, & Stewart, 1990). More specifically, VFSS enables the detection of the presence of post-swallow bolus retention (Rommel et al., 2015) and penetration and/or aspiration (Rosenbek et al., 1996).

Various ways have been described for conducting VFSS (Belafsky & Kuhn, 2014; Logemann, 1998, pp. 120-131; Martin-Harris et al., 2008; Palmer, Kuhlemeier, Tippett, & Lynch, 1993). In the clinical setting, the procedures may differ between facilities, and even between clinicians. Typically, the type, consistency, and volume of contrast agent is defined. For example, in one approach, Belafsky and Kuhn (2014) utilized only two consistencies, a nectar thick barium with gradually increasing volumes from 1 ml up to 60 ml and one 3 ml bolus of barium paste in the lateral fluoroscopic view. In addition, they recommend administering 3 ml and 20 ml

boluses of nectar thick barium and one 13 mm barium tablet in the anterior-posterior view. In contrast, the Modified Barium Swallow Impairment Profile (MBSImp) -protocol recommended by Martin-Harris and colleagues (2008) uses various consistencies and different volumes of barium; two trials of 5 ml and sequential swallows from a cup containing thin liquid, 5 ml and sequential swallows from a cup with nectar-thick liquid, 5 ml of honey-thick liquid, 5 ml of pudding-thick barium and a one-half portion of a cookie coated with 3 ml pudding-thick barium in the lateral view. Additionally, 5 ml of nectar-thick and 5 ml of pudding-thick barium are administered in the anterior-posterior view. The VFSS procedures which have been used in scientific research have varied widely, one example of this has been described in the previous literature concerning dysphagia in patients with cervical SCI as seen in Table 1 on pages 29–30.

The interpretation methodology of VFSS findings also varies. For example, the Rosenbeks´s penetration-aspiration scale (PAS) focuses solely on classifying the degree of penetration and/or aspiration (Rosenbek et al., 1996). The PAS will be explained in more detail in chapter 4.4.3. In comparison, the MBSImp -protocol evaluates a total of 17 different physiologic components of swallowing, beginning with lip closure and ending with esophageal clearance in the upright position (Martin-Harris et al., 2008). In short, the interpretation of VFSS aims to describe any physiological abnormalities in the preoral, oral, pharyngeal and esophageal phases of swallowing (Dodds et al., 1990; Dodds et al., 1990). In addition, the radiologist will be able to identify any anatomical abnormalities.

Moreover, VFSS provides clinically useful information on strategies can that improve both the safety and efficiency of a patient's swallowing and nutrition. These activities can be focused on the use of compensatory strategies to improve swallowing, changes in diet textures, changes in the mode of intake (oral vs. non-oral) and referral to swallowing therapy (Martin-Harris, Logemann, McMahon, Schleicher, & Sandidge, 2000). Similarly, the severity of dysphagia may be defined based on the VFSS (Kim et al., 2014; O'Neil, Purdy, Falk, & Gallo, 1999).

FEES is another widely used instrumental evaluation technique; the first description of the FEES procedure was presented by Langmore, Schatz and Olsen in (1988). FEES may be performed by a speech therapist, an otolaryngologist, a phoniatrician, or a neurologist (Langmore, 2017). FEES does not permit visualization of either the oral or the esophageal phase of swallowing, but it enables the visualization of the pharynx before and after swallowing as during the swallow a light reflects from pharyngeal and laryngeal tissues into the endoscope; this is referred as "white-out". There are several advantages associated with FEES i.e. the

examination can be conducted repeatedly at the patient's bedside without exposing him/her to any radiation. Furthermore, regular liquids and food can be used during the examination, although it is easier to visualize colourful liquids (i.e. milk and water with food dye) (Langmore, 2017). The FEES can also be used to assess current progress and effectiveness of therapy.

2.3 Dysphagia in patients with cervical SCI

2.3.1 Incidence of Dysphagia

Relatively few studies have been published on dysphagia in patients with strictly traumatic cervical SCI (Kirshblum et al., 1999; Shem et al., 2011; Shem et al., 2012b; Shem et al., 2012a). Slightly more attention has been paid to dysphagia in cervical SCI patients with trauma and non-trauma etiologies, but the majority (68.7–97.5%) of the participants in these studies have been trauma patients (Abel et al., 2004; Brady et al., 2004; Chaw et al., 2012; Seidl et al., 2010; Shin et al., 2011; Wolf & Meiners, 2003). A summary of the previous studies on cervical SCI, instrumental evaluation methods and procedures and penetration-aspiration findings is presented in Table1.

In summary, the literature reviewed in Table 1 seems to suggest that dysphagia is a relatively common secondary complication in patients with cervical SCI and that the focus has been on the difficulties they experience in the pharyngeal phase of swallowing. The incidence of aspiration verified by VFSS or FEES varies between 6% and 41% (Abel et al., 2004; Brady et al., 2004; Chaw et al., 2012; Seidl et al., 2010; Shem et al., 2011; Shem et al., 2012b; Shem et al., 2012a; Shin et al., 2011; Wolf & Meiners, 2003). In addition, Wolf and Meiners (Wolf & Meiners, 2003) reported the incidence of laryngeal edema or aspiration to be 39%. The incidence of penetration was reported in only two studies, and it varied from 5% to 24% (Brady et al., 2004; Seidl et al., 2010) and even in those two studies, the degree of penetration was not clearly defined.

Table 1. A summary of the previous studies on cervical SCI, instrumental evaluation methods and procedures and the penetration-aspiration findings.

Reference (Nature of the study)	**Patients, n** (gender; mean age; range/SD)	**Etiology, n**	**AIS / Frankel score**	**Method of instrumental assessment**	**Time frame**[1]	**VFSS/FEES procedure**	**Findings of instrumental assessment**[2] (n; %)
Kirshblum et al., 1999 (Retrospective)	187 M 156, F 31; 44.3; range 15–86	Trauma, 187	AIS A 38%, AIS B–E 62%	VFSS 42/187	Not reported	Not reported	Aspiration or requiring a modified diet (n=31; 16.6%)
Wolf & Meiners, 2003 (Longitudinal study)	51 M 35, F 16; 43.4; range 16–89	Trauma, 46 Non-trauma, 5	AIS A 58.8%, AIS B–E 41.2%	FEES 51/51	Not reported	White yoghurt, methylene blue stained water	Aspiration (n=21; 41.2%) Laryngeal oedema or mild aspiration (n=20; 39.2%)
Brady et al., 2004 (Retrospective)	131 M -, F -; 55.6; range 17–87	Trauma, 90 Non-trauma, 41	Not reported	FEES or VFSS 59/131	Not reported	Not reported	Aspiration (n=23; 17.6%) Laryngeal penetration (n=32; 24.4%)
Abel et al., 2004 (Prospective)	73 M 51, F 22; 42.9; range 0.57–86.8	Trauma, 56 Non-trauma, 17	AIS A 56.2%, AIS B–D 43.8%	VFSS or blue dye test 32/73	Not reported	Not reported	Aspiration (n=11; 15.1%)
Shem et al., 2005 (Retrospective)	68 M -, F -; 33; range 17–83	Not reported.	AIS A 53%, AIS B–D 47%	VFSS 17/68	Not reported	Not reported	Aspiration not reported

Table 1 continues

Reference (Nature of the study)	**Patients, n** (gender; mean age; range/SD)	**Aetiology, n**	**AIS / Frankel score**	**Method of instrumental assessment**	**Time frame**[1]	**VFSS/FEES procedure**	**Findings of instrumental assessment**[2] (n; %)
Seidl et al., 2010 (Retrospective)	175 M 144, F 31; 43.45; range 14–89	Trauma, 147 Non-trauma, 28	TA 58.86%, TB–TE 41.14%	FEES 175/175	Not reported	Der Berlirner Dysphagie Index[3]	Aspiration (n=7; 4.0%) Silent aspiration (n=13; 7.4%) Penetration (n=8; 4.6%)
Shin et al., 2011 (Retrospective)	121 M 105, F 16; 44.93; range 9–78	Trauma, 118 Non-trauma, 3	AIS A 59.5%, AIS B–D 40.5%	VFSS 121/121	Mean 178.35 days post injury, range 12–1062	Liquid and semisolid barium, 10 ml and 50 ml	Aspiration (n=10; 8.3%)
Shem et al., 2011 (Prospective)	29 M 22, F 7; 41	Trauma, 29	Complete 44.8%, Incomplete 55.2%	VFSS 21/29	BSE within 31 days of injury, VFSS within 72 hours of BSE	Food and liquids of different consistencies	Aspiration (n=4; 13.8%)
Shem et al., 2012a (Prospective)	39 M 30, F 9; 41.6; SD 16.63	Trauma, 39	Not reported	VFSS 26/39	BSE avg. 20.6 days of injury, VFSS avg. 1.58 days after BSE	Solids and liquids of different consistencies	Aspiration (n=4; 10.3%)
Shem et al., 2012b (Prospective)	40 M 31, F 9; 41; SD 16.5	Trauma, 40	Complete 42.5%, Incomplete 57.5%	VFSS 27/40	VFSS avg. 1.52 days after BSE	Food and liquids of different consistencies	Aspiration (n=4;10.0%)
Chaw et al., 2012 (Prospective)	68 M 57, F 11; 43; SD 17.2	Trauma, 58 Non-trauma, 4 Other, 6	Complete 41.2%, Incomplete 58.8%	VFSS 33/68	BSE avg. 31.8 days of injury, VFSS avg. 1.39 days after BSE	Not reported	Aspiration (n=4; 5.9%)

[1]Time between the onset of tetraplegia symptoms and instrumental assessment. [2]Incidence of aspiration or penetration if reported in an original article. The incidence percentage is calculated in relation to the whole study population. [3] Seidl RO, Nusser-Muller-Bush R, Westhofen M & Ernst A. Der Berlirner Dysphagie Index- Evaluation und Validierung eines Untersuchungbogens zur endoskopischen Schluckuntersuchun. Forum HNO 2006; 8: 9–16. Abbreviations: AIS = ASIA Impairment Scale; AIS A = complete injury, AIS B–D = incomplete injury; Frankel score = Frankel classification grading system for acute spinal injury; TA = complete injury; TB–TD = incomplete injury, TE = normal motor function; VFSS = videofluoroscopic swallowing study; FEES = fiberoptic endoscopic evaluation of swallowing; BSE = bedside swallow evaluation; M = male; F = female.

2.3.2 Risk Factors for Dysphagia

Previous studies focusing on cervical SCI with trauma and non-trauma etiologies have presented some risk factors for dysphagia. In summary, tracheostomy is the most widely accepted risk factor for dysphagia among cervical SCI patients (Abel et al., 2004; Brady et al., 2004; Chaw et al., 2012; Kirshblum et al., 1999; Seidl et al., 2010; Shem et al., 2005; Shem et al., 2011; Shem et al., 2012b; Shem et al., 2012a; Shin et al., 2011). Mechanical ventilation has also been considered as a risk factor for dysphagia (Chaw et al., 2012; Kirshblum et al., 1999; Shem et al., 2005; Shem et al., 2012b; Shem et al., 2012a), but contradictory results have also been presented (Shem et al., 2011).

The role of age as a risk factor is controversial. Five studies (Kirshblum et al., 1999; Shem et al., 2011; Shem et al., 2012b; Shem et al., 2012a; Shin et al., 2011) have reported age as a risk factor, but this was not confirmed in five other studies (Abel et al., 2004; Brady et al., 2004; Chaw et al., 2012; Seidl et al., 2010; Wolf & Meiners, 2003). Gender does not seem to be a risk factor for dysphagia (Chaw et al., 2012; Kirshblum et al., 1999; Seidl et al., 2010; Shem et al., 2011; Shem et al., 2012b), but it is important to acknowledge that the majority of the patients are males as shown in Table 1.

In addition, the level (Abel et al., 2004; Kirshblum et al., 1999; Seidl et al., 2010; Wolf & Meiners, 2003) and completeness of the cervical SCI (Abel et al., 2004; Shem et al., 2005) have been reported to be risk factors for dysphagia. On the contrary, there are also, some studies that have not found any association between dysphagia and the level or completeness of the injury (Chaw et al., 2012; Shem et al., 2011; Shem et al., 2012b; Shem et al., 2012a; Shin et al., 2011). Furthermore, Kirshblum and colleagues (1999) reported that the cause of the injury (fall, motor vehicle accident, gunshot wound, diving, other) had no association with dysphagia.

The surgical treatment of the cervical SCI may also affect the swallowing function. Kirshblum and colleagues (1999), as well as Brady and colleagues (2004) found that cervical spinal surgery, particularly if an anterior approach had been used, was related to the likelihood of dysphagia. Later, conflicting findings have been reported (Abel et al., 2004; Chaw et al., 2012; Seidl et al., 2010; Shem et al., 2005; Shem et al., 2011; Shem et al., 2012a; Shin et al., 2011). Furthermore, the use of an orthosis, a collar or a halo vest, do not seem to have an association with the likelihood of dysphagia (Chaw et al., 2012; Shem et al., 2005; Shem et al., 2011; Shem

et al., 2012b; Shem et al., 2012a), but Kirshblum and colleagues (1999), reported that patients with a halo vests had a higher occurrence of dysphagia.

In addition, Brady and colleagues (2004) reported, that cervical SCI patients with dysphagia had a statistically significantly higher co-occurrence of traumatic brain injury. However, the severity of the brain injury was not defined. Instead, some studies have found no association between dysphagia and the co-occurrence of a mild traumatic brain injury (Abel et al., 2004; Chaw et al., 2012; Shem et al., 2011; Shem et al., 2012b; Shem et al., 2012a).

As reviewed, the published literature on traumatic cervical SCI-induced dysphagia is inconsistent. Heterogeneity in the diagnostic criteria of dysphagia, study methodologies, and major characteristic differences between study populations are some of the main reasons for this situation. In conclusion, it is difficult to draw firm and generalizable conclusions based on the literature.

2.3.3 Recovery of Dysphagia

To date, only a few studies have examined the recovery of dysphagia after cervical SCI with trauma and non-trauma etiologies (Abel et al., 2004; Brady et al., 2004; Seidl et al., 2010; Wolf & Meiners, 2003). In the prospective study of Abel and colleagues (2004), 26 (36%) patients of their study population of 73 patients were reported to have dysphagia. At the time of discharge from hospital, the dysphagia had resolved in nine (35%) patients, whereas seven (27%) patients had persistent dysphagia, but they were able to have sufficient oral intake. Six (23%) patients were discharged with PEG tubes.

Brady and colleagues (2004) reviewed a patient cohort of 131 patients and estimated that 72 (55%) of the patients had dysphagia. The authors described the trend for recovery with ASHA NOMS (American Speech-Language-Hearing Association National Outcomes Measurement System, levels 1-7), and summarized that the mean level for ASHA NOMS at admission was 2.7 whereas at discharge, it has risen to 5.3. A level of 5 indicates that all nutrition and hydration needs are met by mouth with only minimal dietary restrictions.

Another retrospective study conducted by Seidl and colleagues (2010) reported that 28 (16%) out of the 175 patients had dysphagia. Eight (29%) of these patients showed consistent aspiration on repeated FEES and ten (36%) patients were unable to have an adequate oral intake and thus they were discharged with PEG tubes. In

their prospective, Wolf and Meiners (2003) reported that 41 (80%) out of 51 patients had dysphagia. Three (7%) patients showed persistent severe dysphagia with a risk of substantial aspiration based on repeated FEES. The authors stated that eight (20%) patients required a PEG tube at the end of the treatment, although only one (2%) of them was fully tube dependent.

3 AIMS OF THE STUDY

The purpose of this thesis is to reveal the incidence and risk factors for laryngeal penetration-aspiration in a cohort of patients with traumatic cervical SCI. In addition, another study aim is to evaluate the recovery of penetration-aspiration and functional oral feeding outcome of these patients.

More precisely, the aims of this study are:

1) to determine the incidence of laryngeal penetration-aspiration by using VFSS and Rosenbek's penetration-aspiration scale (Study I).

2) to investigate a wide range of potential pre-, peri- and post-injury risk factors of laryngeal penetration-aspiration on VFSS including clinical signs assessed by a speech therapist (Study II).

3) to examine the recovery of laryngeal penetration-aspiration by conducting follow-up VFSS examinations (Study III).

4) to evaluate functional feeding outcome by applying a functional oral intake scale (FOIS) (Study III).

4 SUBJECTS AND METHODS

4.1 Design and Ethical Aspects

This is a prospective cohort study that has evaluated acutely injured cervical SCI patients admitted to the Tampere University Hospital from February 2013 to April 2015. In Finland, the acute care, the subacute rehabilitation, and the lifelong follow-up care of patients with traumatic SCI are centralized to three university hospitals, which are situated in Helsinki, Oulu, and Tampere. Between 2013 and 2015, Tampere University Hospital served a population of 2.8 million from both urban and rural areas. Ethical approval for the study was obtained from the Ethical Committee of Pirkanmaa Hospital District, Finland, in the 2013 (code: R12250). A written informed consent according to the Declaration of Helsinki was obtained from all of the participating subjects prior to commencing the investigations.

4.2 Subjects

The study sample consists of a prospective cohort of applicable patients with acute traumatic cervical SCI admitted to Tampere University Hospital ≤ 3 months' post injury. In total, 94 consecutive patients were screened with 46 of them (48.9%) being included in this study. The patients were included irrespective of the severity or level of the cervical injury. In these included patients, the mean time from the injury to their admission in Tampere University Hospital was 6.09 days (SD=12.3, median=1, min=0, max=54). Possible confounding factors were controlled by applying numerous exclusion criteria. A flowchart demonstrating the study protocol and exclusion criteria is presented in Figure 4. Additionally, in Study II those patients in whom VFSS had been conducted > 28 days post injury were excluded.

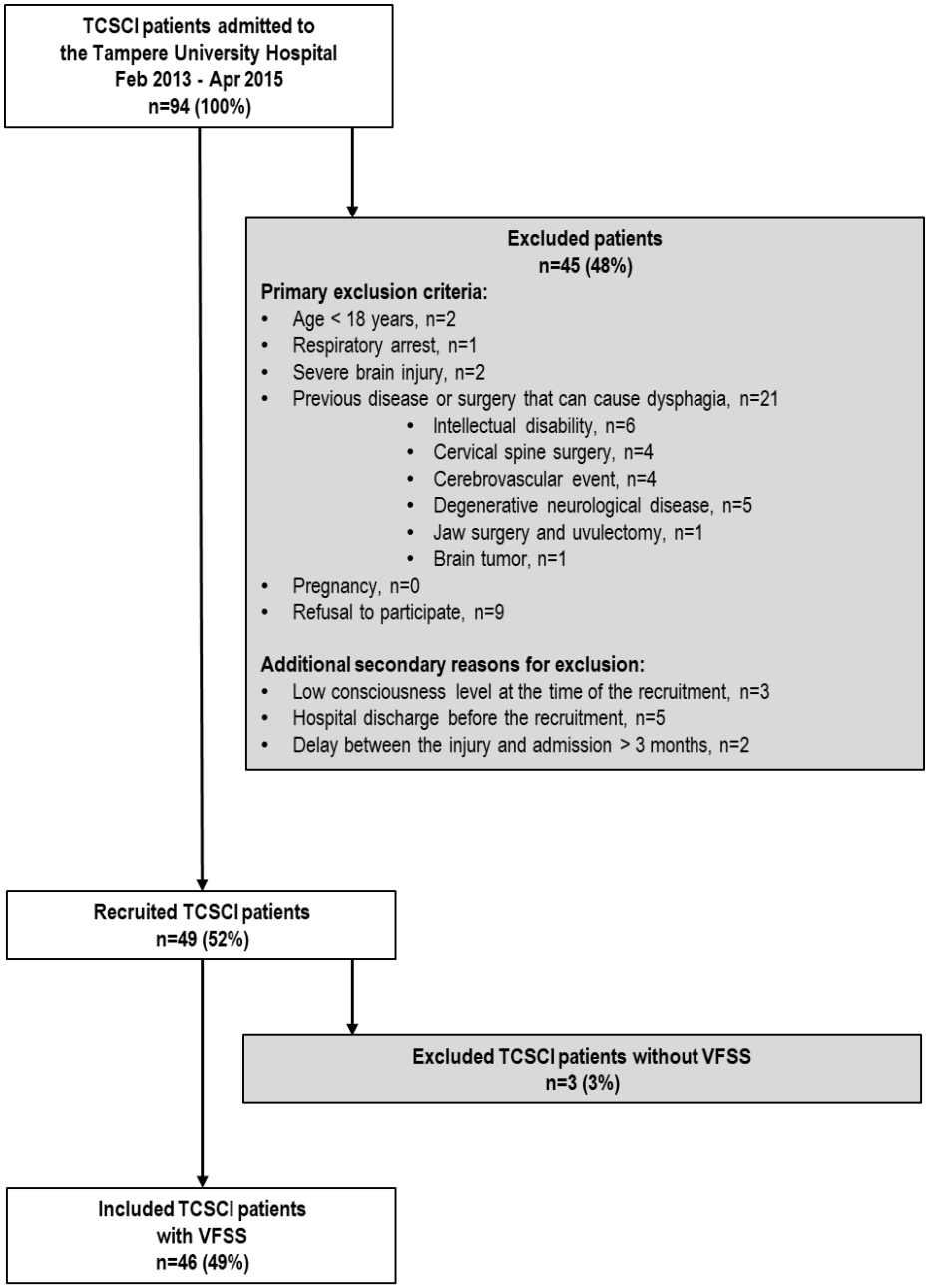

Figure 4. The study flowchart. Reprinted with permission (Study I). Abbreviations: TCSCI= traumatic cervical spinal cord injury; VFSS= videofluoroscopic swallowing study

The vast majority, 85% of the 46 included patients were male. The mean age at the time of the injury was 62.1 years (median 64.1, min.–max. 25.7–91.6). Similarly, the majority of the 48 excluded patients were male (36 patients = 75%). The mean age of the excluded patients was 63.6 years (median 66.1, min.–max. 17.6–94.4). There were no statistically significant differences between the included and excluded patient groups based on age ($p=0.193$, Mann-Whitney U-test) or gender ($p=0.307$, Fisher's Exact Test). The characteristics of patients in studies I, II and, III are presented in Table 2. Study II included only those patients in whom VFSS was conducted ≤ 28 days post injury.

Table 2. The characteristics of patients in studies I, II and, III.

	Studies I and III (n=46)	Study II (n=37)
	n (%)	n (%)
Gender		
Male	39 (84.8)	31 (83.8)
Female	7 (15.2)	6 (16.2)
Age at the time of injury (years)		
Mean (SD)	62.1 (13.3)	61.2 (14.4)
Median (min.–max.)	64.0 (25.7–91.6)	62.7 (25.7–91.6)
Injury mechanism		
Sport	2 (4.3)	2 (5.4)
Assault	0 (0.0)	0 (0.0)
Transport	7 (15.2)	6 (16.2)
Fall	36 (78.3)	28 (75.7)
Unknown	1 (2.2)	1 (2.7)
AIS grade		
Complete	10 (21.7)	8 (21.6)
Incomplete	36 (78.3)	29 (78.4)
AIS impairment scale		
AIS A	10 (21.7)	8 (21.6)
AIS B	4 (8.7)	3 (8.1)
AIS C	6 (13.0)	5 (13.5)
AIS D	26 (56.5)	21 (56.8)
The level of injury		
C1–C4	39 (84.8)	32 (86.5)
C5–C8	6 (13.0)	4 (10.8)
Unknown	1 (2.2)	1 (2.7)
Tracheostomy	7 (15.2)	5 (13.5)
Nasogastric tube	24 (52.2)	21 (56.8)
PEG-tube	7 (15.2)	5 (13.5)
Death ≤ 3 months post injury	3 (6.5)	2 (5.4)
Death 3–12 months post injury	0 (0.0)	0 (0.0)

Abbreviations: AIS = ASIA Impairment Scale; AIS A = complete injury, AIS B–D = incomplete injury; VFSS= videofluoroscopic swallowing study, PEG= Percutaneous Endoscopic Gastrostomy

4.3 Medical and Background Data

The findings in the medical records of each patient were reviewed prior to recruitment to verify the history of neurological diseases and head, neck, or premorbid cervical spine surgeries. In addition, available neck and head computed tomography (CT) and magnetic resonance imaging (MRI) findings were reviewed to exclude those patients with a significant traumatic brain injury. The variables examined in this thesis consisted of demographics, injury- and treatment-related variables, VFSS, and computed tomography (CT) findings, and the observations made by a speech therapist (the author) during a clinical swallowing trial. In detail, the demographic and injury-related variables included gender, age at the time of injury, injury mechanism classified according to the International Spinal Cord Injury Core Data Set (DeVivo et al., 2006), and alcohol intoxication at the time of the injury.

The International Standards for Neurological Classification of Spinal Cord Injury were used to evaluate and classify the neurological consequences of the traumatic cervical SCI (Kirshblum et al., 2011; Kirshblum, Waring et al., 2011). The completeness of the injury was defined according to the American Spinal Injury Association impairment scale (AIS) (Appendix 1). The AIS classification was conducted jointly by a physician and a physiotherapist.

The treatment-related variables consisted of the necessity for bronchoscopy/-ies, necessity for tracheostomy, necessity for nasogastric tube or percutaneous feeding tube, the presence of hard collar at the time of first VFSS, length of stay (LOS) on the rehabilitation ward, and the total number of speech therapy interventions during acute care and rehabilitation. The cervical trauma-related surgery variables were necessity for cervical surgery, including skull traction, prior to the VFSS. We also determined the specific levels and number of cervical levels operated and whether an anterior fixation plate was used or not, and the duration of anesthesia and surgical procedure. In addition, the duration of time between the injury and swallowing evaluations, and the duration of time between the injury and changes in functional eating ability (FOIS) were recorded.

The first available post-traumatic preoperative CT images were evaluated for degenerative signs of cervical vertebrae C1-7, according to Kellgren and Lawrence (1958). We also determined the incidence and size of osteophytes between cervical vertebrae C3 and C6, and also the incidence and level of fracture(s) in the cervical vertebrae. The presence of degenerative signs and the presence and size of the osteophytes were evaluated by a radiologist (Irina Rinta-Kiikka). The incidence and level of cervical fractures were assessed by a neurosurgeon (Tuomo Thesleff).

4.4 Evaluation Procedures and Measures

4.4.1 Bedside Examination

The bedside swallowing examination was performed in all enrolled patients as soon as practically possible after the injury. The mean time from the injury to the bedside examination was 11.7 days (SD=12.7, median=7.5, min.–max. 1–58). First, the symmetry of facial and oral mechanism was evaluated. Secondly, the patient was asked if she/he had either sustained or occasional pain or a globus sensation in the pharynx. Subsequently, the patient was asked to swallow and cough voluntarily and to vocalize a continuous /a/ sound, if possible. Lastly, a swallowing trial was conducted. The trial involved the voluntary swallowing of different consistencies (thin liquid, nectar-thick liquid and puree). The trial was designed to be quick to perform (10 min.) and to pose little risk to the patient while identifying the symptoms of penetration and aspiration. At the end of the trial, a 100 ml WST was performed, if possible (Patterson, McColl, Carding, Kelly, & Wilson, 2009; Patterson et al., 2011; Wu, Chang, Wang, & Lin, 2004). The patient was instructed to drink the water "as quickly as is comfortably possible" with breathing pauses being allowed. In patients with a tracheostomy (n=7), the swallowing trial was conducted with a decuffed cannula, if possible (two patients had an inflated cuff). Fifteen patients (32.6%) had initiated oral feeding on the recommendation of the physician prior to the swallowing trial, and they were tested only with the 100 ml WST. The swallowing trial procedure is presented in Table 3.

Table 3. The swallowing trial procedure step by step.

1.	2.	3.	4.	5.	6.
3 x tsp of water	3 mouthfuls of water with a straw or from a cup	3 x tsp of material with a nectar-thick consistency	3 x mouthfuls of material with nectar-thick consistency with a straw or from a cup	3 x tsp of material with a puree consistency	100 ml WST

Abbreviations: tsp = teaspoon, WST = water swallowing test

During the swallowing trial, the following variables were recorded: (i) coughing, throat clearing, and choking related to swallowing, (ii) changes in voice quality related to swallowing, (iii) delayed pharyngeal swallow, (iv) reduced or inconsistent laryngeal elevation, and (v) multiple (≥ 3) swallows per bolus. This set of variables was adapted from Logemann et al. (1999). The signs of penetration or aspiration were considered to be: 1) coughing, throat clearing or choking during or after swallowing and 2) changes in voice quality after the swallowing (Daniels, Ballo, Mahoney, & Foundas, 2000; Logemann et al., 1999; Mari et al., 1997; McCullough, Wertz, & Rosenbek, 2001). The trial was discontinued if any signs of penetration-aspiration occurred. A stethoscope, held on the side of the larynx, was used to detect every effort to cough, to clear the throat, or if there were signs of choking and also for detecting any changes in voice quality related to swallowing in patients with tracheostomy or reduced ability to cough voluntarily.

The bedside examination involved the following variables: (i) asymmetry in the lower face, (ii) asymmetry of the soft palate, (iii) deviation of the tongue, (iv) a pain sensation in the pharynx, (v) a globus sensation in the pharynx, and (vi) the presence of hematoma in the upper pharynx.

4.4.2 Videofluoroscopic Swallowing Study (VFSS)

The first VFSS (Siemens Axiom Luminos DRF, Erlangen, Germany) was conducted on all 46 patients with a rate of 15 frames per second. The VFSS was carried out with the patient in an upright position to allow a lateral scanning view. A metal coin (diameter 3 cm) was taped to the chin or neck of the patient to allow measurement calibration. The VFSS was conducted by a speech and language therapist (the author) and a radiologist. The VFSS protocol included 5 ml, 10 ml, and 20 ml boluses of a thin, water-soluble contrast agent (Omnipaque 350 mgI/ml, GE Healthcare, Oslo, Norway). The average volume of a single mouthful of thin liquid is 21 ml for adults (Adnerhill, Ekberg, & Groher, 1989). Additionally, the patients were given a 1 ml practice bolus.

The patients were asked to hold the bolus in their mouth until they were instructed to swallow. Furthermore, they were requested to swallow as many times as they needed and also to cough and clear their throat if they felt it necessary. After the primary swallow, the fluoroscopy was continued for at least 6 seconds. All patients did not receive all bolus sizes (5 ml, 10 ml, and 20 ml) since the VFSS

research protocol with thin liquids was discontinued if severe aspiration occurred. For the patients with penetration-aspiration or other signs of dysphagia (i.e. excessive post swallowing retention, pharyngeal regurgitation), the VFSS was continued with nectar-thick liquid and puree as part of the creation of a dysphagia management plan.

In patients with tracheostomy (1st VFSS, n=6; 2nd VFSS, n=1; 3rd VFSS, n=0), the examination was conducted with a decuffed cannula. The follow-up VFSSs were primarily conducted on patients with penetration/aspiration (PAS score ≥3) which had been evident in the previous VFSS. In addition, a follow-up VFSS was conducted on seven non-penetrator/aspirators (PAS score ≤2) based on clinical needs. The second, third, and fourth VFSSs were scheduled according to clinical needs.

4.4.3 Rosenbek's Penetration-Aspiration Scale (PAS)

The PAS was originally developed to quantify penetration and aspiration severity during the VFSS (Rosenbek et al., 1996). It is a validated 8-point scale that ranges from "no material entering the airway" (PAS=1) to "material entering the airway without a cough response" (PAS=8). Penetration is scored as either 2 or 3 if any residue remains above the vocal folds and as 4 or 5 if any residue gains access to the level of the vocal folds. Aspiration is scored as 6, 7, or 8. The original PAS is presented in Table 4 and examples of penetration and aspiration are shown in Figures 5 and 6. Rosenbek and colleagues (Rosenbek et al., 1996) reported the inter-rater reliability for PAS to be 57–75% between judging pairs and overall intrarater reliability to be 74%. Later, Hind and colleagues (2009) reported on overall accuracy of 69–76% between a clinician and an expert with respect to the use of the PAS.

The PAS scoring was conducted jointly by a speech therapist (the author) and a radiologist (Irina Rinta-Kiikka). The first set of VFSSs was analyzed in spring 2015 and the remainder (2nd, 3rd, 4th and 5th) of the VFSSs were analyzed in spring 2017. The patient's worst (i.e. highest) PAS was score was included in the statistical analyses.

In study I, the incidence of penetration-aspiration was reported based on original PAS scores (1–8). In studies II and III, the patients were divided into penetrator/aspirators (PAS score ≥ 3) and non-penetrator/aspirators (PAS score ≤ 2). This division was made based on published studies which have indicated that a PAS score of 2 represent the normal variation in swallowing (Allen, White, Leonard, & Belafsky, 2010; Daggett, Logemann, Rademaker, & Pauloski, 2006; Robbins, Coyle, Rosenbek, Roecker, & Wood, 1999).

Table 4. Final version of the 8-Point Penetration-Aspiration Scale (Rosenbek et al., 1996). Reprinted with permission

Score	Description
PAS 1	Material does not enter the airway.
PAS 2	Material enters the airway, remains above the vocal folds, and is ejected from the airway.
PAS 3	Material enters the airway, remains above the vocal folds, and is not ejected from the airway.
PAS 4	Material enters the airway, contacts the vocal folds, and is ejected from the airway.
PAS 5	Material enters the airway, contacts the vocal folds, and is not ejected from the airway.
PAS 6	Material enters the airway, passes below the vocal folds, and is ejected into the larynx or out of the airway.
PAS 7	Material enters the airway, passes below the vocal folds, and is not ejected from the trachea despite effort.
PAS 8	Material enters the airway, passes below the vocal folds, and no effort is made to eject.

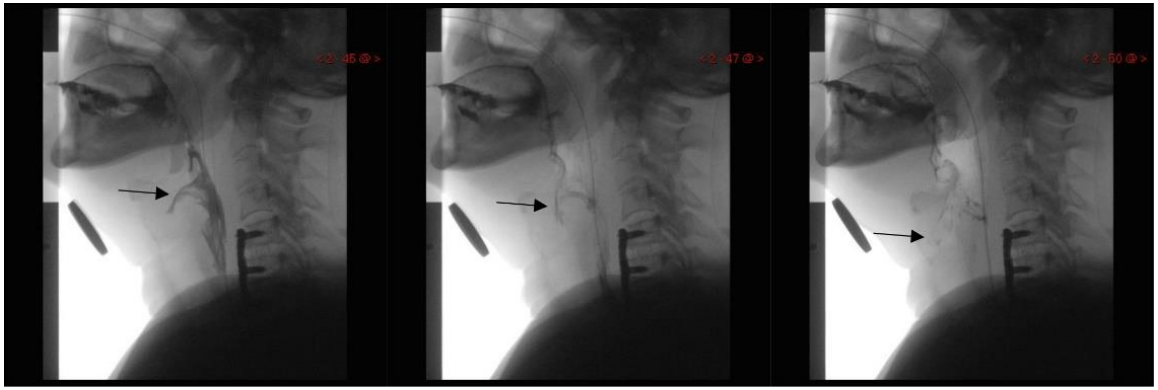

Figure 5. A series of VFSS images showing penetration. Material enters the airway, remains above the vocal folds, and is not ejected from the airway (PAS 3). The x-ray images were retrieved from the Picture Archiving and Communication Systems and represent clinical cases treated in the Tampere University Hospital.

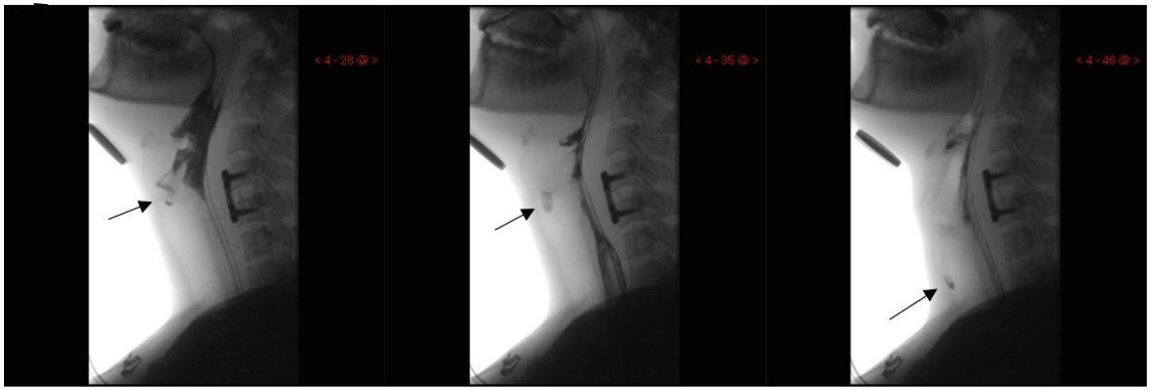

Figure 6. A series of VFSS images showing aspiration. Material enters the airway, passes below the vocal folds, and no effort is made to eject (PAS 8). The x-ray images were retrieved from the Picture Archiving and Communication Systems and represent clinical cases treated in the Tampere University Hospital.

4.4.4 Functional Oral Intake Scale (FOIS)

The FOIS is a validated 7-point tool for estimating and documenting change in functional eating abilities over time (Crary, Mann, & Groher, 2005). Levels 1–3 indicate that the patient is dependent on tube feeding with nothing by mouth (level 1) or with varying degrees of oral feeding (levels 2–3). Levels 4–7 refer to a total oral diet with varying degrees of oral feeding with different food consistencies. The original FOIS is presented in Table 5. FOIS was initially designed for stroke patients, but it has also been widely used with other patient populations, for example, patients with traumatic brain injury (Hansen, Engberg, & Larsen, 2008), and head and neck cancer (van der Molen et al., 2011) and, recently also in patients with cervical SCI (Hayashi et al., 2017).

Crary, Mann and Groher (2005) reported that the interrater agreement of FOIS scoring ranged from 85% to 95%. Additionally, Crary, Mann and Groher cross-validated the FOIS by comparing FOIS scores with two other measures: dichotomized dysphagia and aspiration ratings and categorical dysphagia and aspiration severity ratings derived from VFSS of swallowing function. The FOIS ratings were significantly associated with the presence of aspiration and dysphagia severity but not with aspiration severity. In the current study, the FOIS has been scored by the author based on medical records, a clinical evaluation, and the VFSSs.

Table 5. FOIS scale (Crary et al., 2005). Reprinted with permission.

Level	Description
1	Nothing by mouth.
2	Tube dependent with minimal attempts of food or liquid.
3	Tube dependent with consistent oral intake of food or liquid.
4	Total oral diet of a single consistency.
5	Total oral diet with multiple consistencies but requiring special preparation or compensations.
6	Total oral diet with multiple consistencies without special preparation, but with specific food limitations.
7	Total oral diet with no restrictions.

4.5 Speech Therapeutic Interventions

All 42 patients treated in the Tampere University Hospital's rehabilitation ward received speech therapeutic interventions based on their clinical needs. Each speech therapy session included one or more interventions; a summary of the interventions for both subgroups (penetrator/aspirators vs. non-penetrator/aspirators, based on Study III) is provided in Table 6. These numbers include interventions from the first bedside evaluation to the final follow-up.

Table 6. The summary of speech therapy interventions for penetrator/aspirators and non-penetrator/aspirators.

Speech therapy intervention	Number of interventions for penetrator/aspirators (n=19)	Number of interventions for non-penetrator/aspirators (n=23)
Bedside examination	57	36
VFSS	44	27
FEES	27	3
Supervising the mealtime	37	20
Swallowing exercises without food	214	0
Swallowing exercises with food	241	13
Counseling	9	5
VitalStim®Therapy -trial	4	0
Total number of interventions	633	104

Abbreviations: VFSS= videofluoroscopic swallowing study, FEES= fibreoptic endoscopic evaluation of swallowing

The bedside examination included swallowing trials and/or evaluation of swallowing during a mealtime. Supervising the mealtime consisted of the evaluation combined with guidance on the use of compensatory strategies for improving the patient's ability to swallow and reduce aspiration and/or penetration. These compensatory strategies included limiting the bolus size, effortful swallow (swallowing hard), multiple swallows, slowing the rate of feeding (by a nurse) or eating (by a patient), and alternating the food and/or liquid consistencies. Swallowing exercises without food consisted of thermal and tactile pharyngeal stimulation to elicit swallows as well as pharyngeal strengthening exercises. Swallowing exercises with food included exercises with different bolus sizes, and different food and/or liquid consistencies.

Counseling involved giving information to the patient and his/her loved ones about the patient's swallowing ability, the use of compensation strategies, as well as the means and goals of swallowing rehabilitation. VitalStim® Therapy is a one form of neuromuscular electrical stimulation which can be delivered only by a certified VitalStim® Therapy System provider.

4.6 Statistical Analysis

The Statistical Package for Social Sciences software program (IBM SPSS Statistics for Windows, Version 23.0 (Studies 1 and II) and Version 24.0 (Study III), Armonk, NY, USA) was used to perform all of the statistical analyses. The descriptive statistics [frequency (n), percentage, mean, standard deviation (SD), median, min.-max.] were used to calculate variable and subgroup characteristics. The normality of the variable distributions was tested using the Kolmogorov-Smirnov and Shapiro-Wilk tests.

In Study II, group comparisons were tested with the Fisher's exact test, the Pearson's Chi Square test and the Mann-Whitney U-test. Correlations were tested with the Spearman's rank correlation coefficient. Variables with clinical interest and relevance were placed into three different binary logistic regression models to determine eventual independent risk factors for penetration-aspiration. The regression models included the following variables: age (continuous), AIS grade (complete/incomplete), anterior cervical surgery (yes/no), and coughing and/or changes in voice quality related to swallowing (yes/no). Odds ratios were calculated with 95% confidence intervals. Missing data was not modelled or imputed.

In Study III, group comparisons were tested with the Fisher's exact test and Mann-Whitney U-test. Differences in the FOIS levels for the whole study sample were tested with the Wilcoxon Signed Rank Test. Additional group comparisons presented in the current study were tested with Fisher's exact test and Mann-Whitney U-test. Correlations were tested with the Spearman's rank correlation coefficient.

The statistical significance level was set at 5%. All statistical analyses were performed under the guidance of a statistician (Mika Helminen).

5 RESULTS

5.1 Incidence of Penetration-Aspiration (Study I)

The mean time from injury to the first VFSS was 19.1 days (SD=17.5, median=13.5, min.–max. 2–87). The majority of the patients (80.4%, n=37) were examined no more than 28 days post injury. All patients were alert and able to follow instructions during the VFSS. The highest, meaning the worst, PAS score from each patient was utilized in the statistical analyses. In total, 121 swallows were analyzed. As seen in Figure 7, almost half of the patients (47.8%, n=22) showed penetration-aspiration (PAS score ≥ 3). Fifteen patients (32.6%) exhibited aspiration and 73.3% of them aspirated silently. There was no statistically significant correlation between the PAS scores 1-8 and the time delay between the injury and the first VFSS study (p=0.514, Spearman's rho).

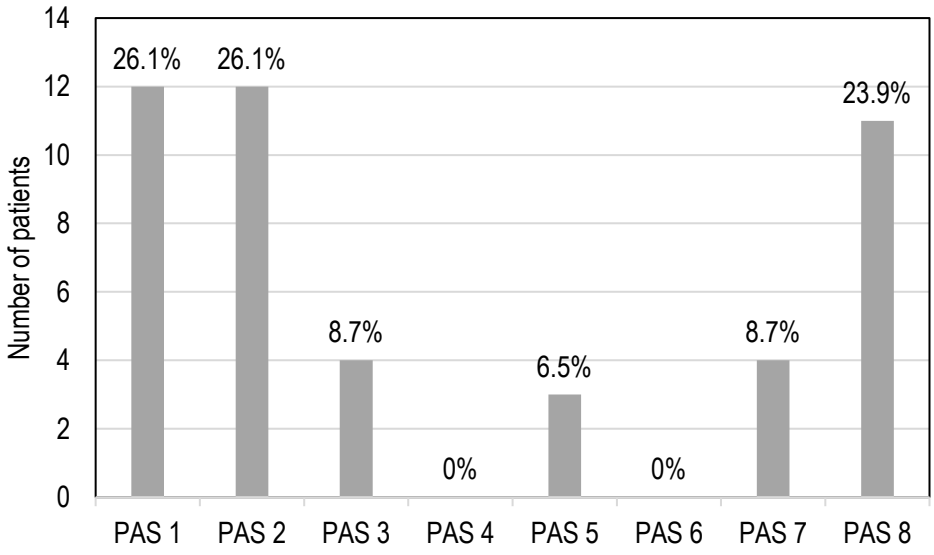

Figure 7. The distribution of the PAS scores (n=46).

5.2 Risk Factors and Clinical Signs for Penetration-Aspiration (Study II)

5.2.1 Risk Factors

In study II, the patients (n=37) were divided into penetrator/aspirators (PAS score ≥ 3) and non-penetrator/aspirators (PAS score ≤ 2). As a result, 51.4% (n=19) of the patients were assessed as penetrator/aspirators and the rest, 48.6% (n=18), were non-penetrator/aspirators (PAS score ≤2). The mean time from the injury to the VFSS was 12.4 days (SD=7.5, median=11.0, min.–max. 2–28). There was no statistically significant difference between the penetrator/aspirators and non-penetrator/aspirators with respect to the time between the injury and VFSS (p=0.704, Mann-Whitney U-test).

Group comparisons between penetrator/aspirators and non-penetrator/aspirators are summarized in Table 7. The penetrator/aspirators required more often bronchoscopies and the necessity of bronchoscopies was the single factor that differed statistically significantly between subgroups (p=0.042, OR=9.9, 95% CI=1.1-91.5). In addition, the penetrator/aspirators also had more often cervical spine fractures and a higher number of fractured vertebrae, but the differences were not statistically significant.

Table 7. Group comparisons between penetrator/aspirators and non-penetrator/aspirators in terms of demographics, injury- and treatment-related and radiological variables.

Variable	Penetrator/aspirators n=19	Non-penetrator/aspirators n=18	p-value
Gender			**.090**
Male	18 (94.7%)	13 (72.2%)	
Female	1 (5.3%)	5 (27.8%)	
Age at the time of injury (years)			**.940**
Mean (SD)	59.3 (15.7)	63.2 (13.1)	
Median (min–max)	64.7 (25.7–87.7)	61.9 (35.1–91.6)	
Injury mechanism			**1.000**
Sport	1 (5.3%)	1 (5.6%)	
Assault	0 (0%)	0 (0%)	
Transport	3 (15.8%)	3 (16.7%)	
Fall	14 (73.7%)	14 (77.8%)	
Unknown	1 (5.3%)	0 (0%)	
Alcohol intoxication at the time of the injury			**1.000**
Yes	8 (42.1%)	8 (44.4%)	
No	11 (57.9%)	10 (55.6%)	
AIS grade			**.447**
Complete	3 (15.8%)	5 (27.8%)	
Incomplete	16 (84.2%)	13 (72.2%)	
AIS impairment scale			**.331**
AIS A	3 (15.8%)	5 (27.8%)	
AIS B	3 (15.8%)	0 (0%)	
AIS C	3 (15.8%)	2 (11.1%)	
AIS D	10 (52.6%)	11 (61.1%)	
The AIS level of injury			**1.000**
Upper (C1–C4)	16 (84.2%)	16 (88.9%)	
Lower (C5–C8)	2 (10.5%)	2 (11.1%)	
Unknown	1 (5.3%)	0 (0%)	
Tracheostomy	4 (21.1%)	1 (5.6%)	**0.340**
Bronchoscopy(ies) ≥ 1	7 (36.8%)	1 (5.6%)	**0.042***
Prevertebral edema at the time of VFSS			
C3 > 7 mm	17 (89.5%)	15 (83.3%)	**0.660**
C6 > 18 mm	3 (15.8%)	2 (11.1%)	**1.000**

*The statistical significance level was set at 5%. Abbreviations: AIS = ASIA Impairment Scale; AIS A = complete injury, AIS B–D = incomplete injury; SD= standard deviation; VFSS= videofluoroscopic swallowing study

Table 7 continues

Variable	Penetrator/aspirators n=19	Non-penetrator/aspirators n=18	p-value
Hard collar at the time of the VFSS	2 (10.5%)	2 (11.1%)	**1.000**
Degenerative changes in cervical spine			**0.660**
No degenerative or minimal changes (Kellgren 0-1)	4 (21.1%)	2 (11.1%)	
Definite to severe changes (Kellgren 2-4)	15 (79.0%)	16 (88.9%)	
Osteophyte size > 10 mm in ≥ 1 vertebrae	5 (26.3%)	3 (16.7%)	**0.693**
Cervical spine fracture	15 (79.0%)	10 (55.6%)	**0.170**
The level of the cervical fracture			
Upper (C0-C2)	2 (10.5%)	1 (5.6%)	**1.000**
Lower (C3-C7)	14 (73.7%)	9 (50.0%)	**0.184**
The number of fractured vertebrae			**0.428**
1 vertebrae	6 (31.6%)	6 (33.3%)	
> 1 vertebrates	9 (47.4%)	4 (22.2%)	

*The statistical significance level was set at 5%. Abbreviations: AIS = ASIA Impairment Scale; AIS A = complete injury, AIS B–D = incomplete injury; SD= standard deviation; VFSS= videofluoroscopic swallowing study

Surgery to the cervical spine had been performed on 28 patients (75.7%) before the VFSS was conducted. The mean time from the injury to the first surgical treatment was 1.9 days (SD=1.3, median=2.0, min.–max. 0–6). Table 8 provides a detailed summary of the surgical procedures. The penetrator/aspirators had more often anterior operations and anterior plate fixations, but the difference was not statistically significant. The only statistically significant difference between these two groups was that lower level anterior operations had been performed more frequently in the penetrator/aspirators as compared to the non-penetrator/aspirators (p=0.050, OR=6.1, 95% CI=1.1-33.2).

Table 8. Group comparisons between operated penetrator/aspirators and non-penetrator/aspirators on surgical details.

Variable	Penetrator/aspirators n=16	Non-penetrator/aspirators n=12	p-value
Cervical spine operation			
Yes	16 (84.2%)	12 (66.7%)	**.269**
No	3 (15.8%)	6 (33.3%)	
Skull traction before operation	2 (12.5%)	1 (8.3%)	**1.000**
The number of operations			**.428**
1	13 (81.3%)	9 (75.0%)	
≥ *2*	3 (18.8%)	3 (25.0%)	
The number of operated levels			**1.000**
≤ *2*	14 (87.5%)	10 (83.3%)	
> *2*	2 (12.5%)	2 (16.7%)	
Operative time, min (1 oper.+2.oper.)			**.981**
Mean (SD)	123.3 (46.9)	120.7 (51.8)	
Median (min.–max.)	111.5 (51.0–217.0)	123.0 (39.0-218.0)	
Anesthesia time, min (1 oper.+2.oper.)			**.552**
Mean (SD)	211.1 (77.6)	187.1 (79.5)	
Median (min.–max.)	193.5 (92.0–373.0)	169.0 (78.0–334.0)	
The number of anterior operations	15 (93.8%)	8 (66.7%)	**.104**
The level of anterior operation			
Upper (C1-C4)	7 (43.8%)	3 (25.0%)	**.434**
Lower (C5-Th1)	13 (81.3%)	5 (41.7%)	**.050***
Anterior fixation plate	14 (87.5%)	7 (58.3%)	**.103**

*The statistical significance level was set at 5%. Abbreviations: SD= standard deviation

5.2.2 Clinical Signs

The mean time from the injury to the bedside examination was 6.9 days (SD=5.7, median=4.0, min.–max. 1–23). Group comparisons between penetrator/aspirators (n=19) and non-penetrator/aspirators (n=18) based on bedside examination variables are presented in Table 9. None of the variables differed statistically significantly between these groups.

Table 9. Group comparisons between penetrator/aspirators and non-penetrator/aspirators on the bedside examination variables.

Variable	Penetrator/aspirators n=19	Non-penetrator/aspirators n=18	p-value
Asymmetry in lower face	4 (21.1%)	1 (5.6%)	**.340**
Asymmetry in soft palate	2 (10.5%)	2 (11.1%)	**1.000**
Unknown	2 (10.5%)	0 (0%)	
Deviation in a tongue	1 (5.3%)	2 (11.1%)	**.604**
Pain sensation in pharynx	5 (26.3%)	3 (16.7%)	**.841**
Unknown	1 (5.3%)	1 (5.6%)	
Globus sensation in pharynx	2 (10.5%)	2 (11.1%)	**1.000**
Unknown	1 (5.3%)	1 (5.6%)	
Hematoma in upper pharynx	1 (5.3%)	3 (16.7%)	**.340**

*The statistical significance level was set at 5%.

Group comparisons between the penetrator/aspirators and non-penetrator/aspirators on the swallowing trial variables are presented in Table 10. Table 10. During the swallowing trial, all of the patients were alert and able to follow instructions. Coughing, throat clearing and choking (p=0.007, OR=9.1, 95% CI=2.0-41.4) and changes in voice quality (p=0.004, OR=13.0, 95% CI=2.2-77.3) in relation to swallowing differed statistically significantly between the groups. These signs were more frequent in penetrator/aspirators than in non-penetrator/aspirators. The incidence of multiple swallows per bolus was also higher in penetrator/aspirators than in non- penetrator/aspirators, although the difference was not quite statistically significant.

Table 10. Group comparisons between penetrator/aspirators and non-penetrator/aspirators on the clinical swallowing trial variables. Reprinted with permission (Study II).

Variable	Penetrator/aspirators n=19	Non-penetrator/aspirators n=18	p-value
Coughing, throat clearing, and choking	14 (73.7%)	5 (27.8%)	**.007****
Unknown (tracheostomy)	1 (5.3%)	0 (0%)	
Changes in voice quality	13 (68.4%)	6 (33.3%)	**.004****
Unknown (tracheostomy)	4 (21.1%)	0 (0%)	
Delayed pharyngeal swallow	0 (0%)	2 (11.1%)	**.230**
Reduced or inconsistent laryngeal elevation	10 (52.6%)	12 (66.7%)	**.737**
Unknown	1 (5.3%)	0 (0%)	
Multiple (≥ 3) swallows per bolus	8 (42.1%)	2 (11.1%)	**.060**
Unknown	1 (5.3%)	0 (0%)	

*The statistical significance level was set at 5%.

5.2.3 Independent Risk Factors and Clinical Signs

In the determination of independent risk factors for penetration-aspiration, the variables of clinical interest and relevance (age, AIS grade, anterior cervical surgery, coughing and changes in voice quality) were placed into three different binary logistic regression model. As shown in Table 11, coughing, throat clearing, and choking, as well as changes in voice quality were independently associated with penetration-aspiration.

Table 11. Three binary regression model summaries assessing risk factors for penetration-aspiration. Reprinted with permission (Study II).

Variable	Bivariate analysis	
	OR (95% CI)	p-value
Model 1.		
Nagelkerke R^2 0.450		
Age (years)	0.99 (0.93-1.05)	**.680**
AIS grade (complete/incomplete)	0.29 (0.03-3.07)	**.306**
Anterior cervical operation	4.73 (0.63-35.46)	**.131**
Coughing	14.20 (2.21-91.22)	**.005***
Model 2.		
Nagelkerke R^2 0.486		
Age (years)	0.97 (0.90-1.05)	**.492**
AIS grade (complete/incomplete)	0.60 (0.06-5.69)	**.659**
Anterior cervical operation	4.01 (0.48-33.80)	**.202**
Changes in voice quality	20.93 (2.53-173.01)	**.005***
Model 3.		
Nagelkerke R^2 0.673		
Age (years)	0.95 (0.86-1.05)	**.329**
AIS grade (complete/incomplete)	2.50 (0.21-29.89)	**.470**
Anterior cervical operation	10.67 (0.59-193.10)	**.109**
Coughing	26.63 (1.48-477.12)	**.026***
Changes in voice quality	47.30 (2.29-975.18)	**.012***

*The statistical significance level was set at 5%. Abbreviations: AIS = ASIA Impairment Scale; CI=confidence interval; OR=odds ratio

5.3 Recovery of Penetration-Aspiration (Study III)

Of the 46 patients, 22 (47.8%) showed penetration-aspiration (PAS score ≥3) in the first VFSS. The second VFSS was performed on 20 patients, of whom 6 patients (30.0%) had penetration-aspiration. The third VFSS was conducted on 9 patients. Of these, only two (22.2%) patients were still penetrator/aspirators and one of them showed persistent penetration-aspiration in the fourth and fifth follow-up VFSS. Based on a telephone interview, the other patient had returned to total oral intake

without restrictions and the percutaneous endoscopic gastrostomy (PEG) tube was removed 264 days post-injury without a follow-up VFSS. Thus, from the 46 patients participating in this study, one patient (2.2%) still suffered from aspiration at the end of the follow-up period (273 days post injury). The flowchart of the VFSS follow-ups and penetration-aspiration results are presented in Figure 8.

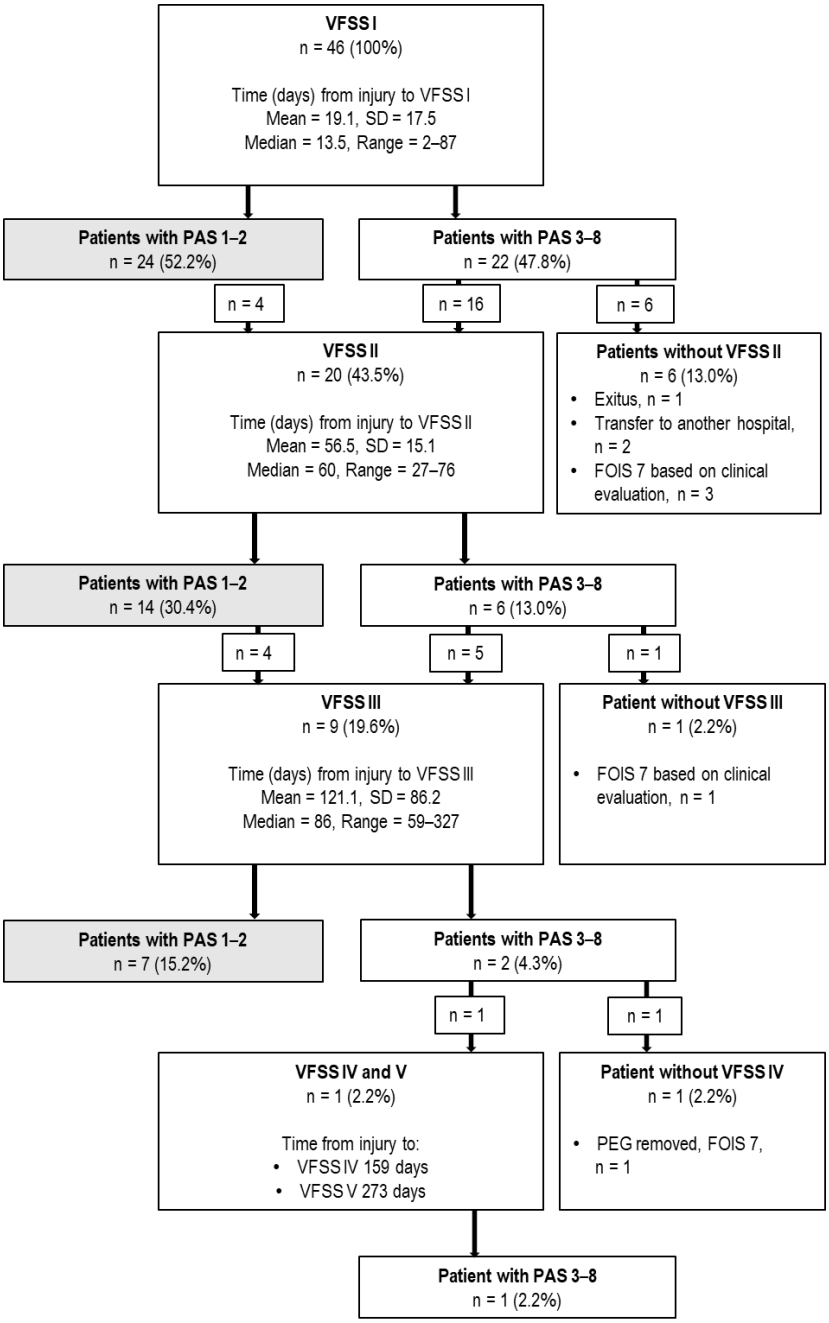

Figure 8. Timing and results of the VFSS follow-ups and penetration/aspiration. Reprinted with permission (Study III). Abbreviations: FOIS = Functional Oral Intake Scale; PAS = Penetration-Aspiration Scale, PEG = percutaneous endoscopic gastrostomy; VFSS =videofluoroscopic swallowing study

5.4 Functional Oral Intake Outcome (Study III)

Forty-two of the 46 patients (91.3%) were treated in the Tampere University Hospital's rehabilitation ward after their acute treatment. In total, 19 patients (45.2%) were penetrator/aspirators and correspondingly the remaining 23 patients (54.8%) were considered as non-penetrator/aspirators. The mean length of the first rehabilitation period was 51.9 days (SD=33.3, median=45.0, min.–max. 7–123).

The FOIS levels of these 42 patients after the first bedside evaluation and VFSS and at the time of the final follow-up are presented in Table 12. The initial FOIS scores for penetrator/aspirators were typically concentrated at the lower end of the scale (levels 1 and 2) while the non-penetrator/aspirators typically scored at the higher FOIS levels (5–7). The differences in initial FOIS scores between the groups were statistically significant (p=0.000). In addition, differences between the FOIS scores in the first clinical evaluation and the final follow-up were found to be statistically significant for the whole sample (p=0.000) and between the subgroups (p=0.000).

Table 12. The FOIS levels (n=42) at the first bedside evaluation, the first VFSS, and at the time of the final follow-up in non-penetrator/aspirators (PAS ≤2, n=23) and penetrator/aspirators (PAS ≥3, n=19). Reprinted with permission (Study III).

FOIS LEVEL	FIRST BEDSIDE EXAMINATION		FIRST VFSS		FINAL FOLLOW-UP	
	PAS ≤2 n (%)	PAS ≥3 n (%)	PAS ≤2 n (%)	PAS ≥3 n (%)	PAS ≤2 n (%)	PAS ≥3 n (%)
FOIS 1	1 (2.4)	10 (23.8)	0 (0)	5 (11.9)	0 (0)	0 (0)
FOIS 2	4 (9.5)	5 (11.9)	2 (4.8)	8 (19.1)	0 (0)	0 (0)
FOIS 3	1 (2.4)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2.4)
FOIS 4	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FOIS 5	5 (11.9)	4 (9.5)	8 (19.1)	6 (14.3)	1 (2.4)	0 (0)
FOIS 6	1 (2.4)	0 (0)	1 (2.4)	0 (0)	2 (4.8)	1 (2.4)
FOIS 7	11 (26.2)	0 (0)	12 (28.6)	0 (0)	20 (47.6)	17 (40.5)

Abbreviations: FOIS= functional oral intake scale; PAS= penetration-aspiration scale; VFSS= videofluoroscopic swallowing study

In summary, in the whole study group of 42 patients, a total of 21 patients (50.0%) required partial or full non-oral nutrition via a nasogastric feeding tube temporarily and, ultimately six patients (14.3%) required PEG tube-feeding for long-term nutritional support (minimum of 77 days post injury). However, by the time of the final follow-up, the majority (88.1%) of patients had achieved on FOIS level 7, indicating that they were on total oral intake without restrictions. Only one (2.4%) patient was still PEG-tube dependent with a consistent oral intake (FOIS 3).

In the group of penetrator/aspirators (n=19), fifteen patients (79.0%) patients required partial or full non-oral nutrition via a nasogastric feeding tube at the time of the first bedside evaluation. However, almost every second patient (47.4%) had achieved total oral intake without restrictions within a maximum of 63 days post injury and by the time of the final follow-up, 17 patients (89.5%) were able to enjoy total oral intake without restrictions. As stated in the previous paragraph, only one patient was still PEG-tube dependent with a consistent oral intake (FOIS 3).

In contrast to the penetrator/aspirators, in the group of non-penetrator/aspirators (n=23), only six patients (26.1%) were partially or totally tube dependent at the time of the first evaluation, and only two patients (8.7%) continued tube feeding with minimal attempts to take food or liquid (FOIS 2) after the first VFSS. Ultimately, these two patients had a special need for speech therapeutic interventions. In one of the patients, an anterior cervical surgical procedure was performed 72 days post injury and pneumonia was diagnosed two days after the surgery. Consequently, this patient required intensive care and the nasogastric tube had to be replaced. The other patient underwent anterior surgery 30 days post injury, and the VFSS, which was conducted two days after the surgery, revealed aspiration. This patient eventually temporarily required PEG-tube feeding.

Additionally, more than half (52.2%) of the non-penetrator aspirators were able to start (n=1) or continue (n=11) to have total oral intake without restrictions based on the first VFSS. By the time of the final follow-up, twenty patients (87.0%) were able to eat by mouth without restrictions. Nevertheless, one patient was still on an oral diet with modified consistencies (FOIS 5), due to fatigue and pulmonary problems; this patient died 46 days post-injury. In addition, two patients were recommended to avoid hard and dry chewable consistencies (FOIS 6) due to a poor dentition and slow mastication speed.

Table 13 shows the time frames between injury and the first bedside evaluation, the first VFSS, and the final follow-up. One patient whose final follow-up was done retrospectively via a phone interview was not included in the final follow-up analysis. The time frames for the final follow-up differed statistically significantly between the

groups, indicating that the penetrator/aspirators required longer periods of speech therapeutic interventions. Furthermore, the number of speech therapy sessions differed statistically significantly (p=0.000) between the penetrator/aspirators and non-penetrator/aspirators. The penetrator/aspirators (n=19) received on average 23 speech therapy sessions (SD=24, median=14, min.–max. 3–97). In contrast, the non-penetrator/aspirators (n=23) received on average 5 speech therapy sessions (SD=6, median=3, min.–max. 2–31). A summary of the speech therapeutic interventions is provided in Table 6 on page 46.

Table 13. Time frames between the injury and the first bedside evaluation, the first VFSS, and at the time of the final follow-up in non-penetrator/aspirators (PAS ≤2, n=23) and penetrator/aspirators (PAS ≥3, n=19).

TIME FRAME (days post injury)	**FIRST BEDSIDE EVALUATION**		**FIRST VFSS**		**FINAL FOLLOW-UP**	
	PAS ≤2	**PAS ≥3**	**PAS ≤2**	**PAS ≥3**	**PAS ≤2**	**PAS ≥3**
Mean	15.2	8.4	22.3	15.0	36.0	85.3
(SD)	(15.6)	(10.0)	(21.5)	(11.3)	(28.0)	(73.2)
Median	9.0	3.0	15.0	12.0	28.0	65.0
(Min.–Max.)	(2–58)	(1–36)	(5–87)	(2–43)	(5–109)	(22–327)
P-value	**.257**		**.337**		**.003***	

*The statistical significance level was set at 5%. Abbreviations: PAS= penetration-aspiration scale; SD= standard deviation; VFSS= videofluoroscopic swallowing study

Finally, four patients (8.7%) out of the 46 recruited in this study were not treated in the rehabilitation ward of Tampere University Hospital's after the acute treatment. Three of them (6.5%) were penetrator/aspirators and one (2.2%) was a non-penetrator/aspirator. One patient performing at FOIS level 1 and scoring 8 on the PAS 8 died during the acute treatment (71 days post injury). Three patients at FOIS levels 5, 2, and 1 and PAS scores 2, 8, and 7, respectively, were transferred to another hospital. Of these, the patient with a FOIS level of 2 and a PAS score of 8 died one day after the transfer to another hospital (32 days post injury).

6 DISCUSSION

6.1 Incidence of Penetration-Aspiration

Almost half of the 46 patients (48%) participating in this study displayed evidence of penetration-aspiration (PAS score ≥ 3) in the first VFSS. Fifteen patients (33%) showed aspiration with 73% of them aspirating silently, in other words, without coughing. Thus, silent aspiration occurred in 24% of the whole study sample. None of the patients who aspirated were able to cough the aspirated material out of the trachea.

It is difficult to make a direct comparison of these penetration-aspiration incidence rates with those reported in the literature due to the methodological heterogeneity between this and previous studies. First, all of the previous studies have primarily focused on bedside and instrumental assessment findings of dysphagia, hence not only on instrumentally achieved penetration-aspiration findings, in patients with cervical SCI including trauma and/or non-trauma etiologies (Abel et al., 2004; Brady et al., 2004; Chaw et al., 2012; Kirshblum et al., 1999; Seidl et al., 2010; Shem et al., 2005; Shem et al., 2011; Shem et al., 2012b; Shem et al., 2012a; Shin et al., 2011; Wolf & Meiners, 2003). Accordingly, the methods to define dysphagia, the severity of penetration and/or aspiration and the manner of reporting the incidence rates have varied significantly. Secondly, in the previous studies, there have also been extensive variations in the manner of reporting patient characteristics and the exact evaluation procedures used in bedside or instrumental examination. Additionally, the mean and range of time frames between the onset of injury and instrumental assessment have been detailed in only one study (Shin et al., 2011). Thirdly, in the majority of published studies, the instrumental assessment (VFFS or FEES) was conducted only on a subgroup of the study participants (Abel et al., 2004; Brady et al., 2004; Chaw et al., 2012; Kirshblum et al., 1999; Shem et al., 2005; Shem et al., 2011; Shem et al., 2012b; Shem et al., 2012a). Thus, all patients with penetration and/or aspiration, and especially patients with silent aspiration, were possibly not identified.

For these reasons, this detailed review will concentrate only on those three studies of dysphagia in patients with cervical SCI that were conducted with an instrumental

examination (VFSS or FEES) in all patients in their study sample. For example, Seidl and colleagues (2010) reported a rather low incidence rate of aspiration (11%) and penetration with coughing (5%) in their study sample of 175 cervical SCI patients who were examined by FEES. Similarly, Shin and colleagues (2011) reported also a low incidence rate of aspiration (8%) based on VFSS in their study sample of 121 patients with cervical SCI.

In contrast, Wolf and Meiners (2003), conducted FEES on 51 consecutively admitted patients and reported that the incidence rate of severe aspiration was much higher, 41% as was the incidence rate of laryngeal edema or mild aspiration i.e. 39%. The current study found the incidence rate for aspiration to be 33%, supporting the finding of Wolf and Meiners (2003) and indicating that patients with traumatic cervical SCI are susceptible to aspiration. Nonetheless, there are some important differences between the patients in the current study and those of Wolf and Meiners (2003). Wolf and Meiners (2003) included only cervical SCI patients with respiratory insufficiency and 59% of the patients had a complete injury (AIS A) and 77% had an injury level of ≥ C4. Furthermore, 90% of their patients had traumatic cervical SCI. In contrast, in the present study, the majority of the patients (78%) had an incomplete injury and 85% had the injury level of ≥ C4 but only 15% of the patients had such severe respiratory insufficiency requiring the temporary use of tracheostomy and ventilator treatment. In addition, the mean age of the patients (62.1 years) in the current study is higher than that described by Wolf and Meiners (2003) (mean age 43.4 years). Thus, the current study suggests that it is not only severely injured patients with respiratory insufficiency who are prone to aspiration.

The reason for variation in aspiration rates in these three published studies and the current study is not clear but it is most probably due to methodological differences in data collection. The rather low incidence rate for aspiration in the study of Seidl and colleagues (2010) may be explained by the retrospective study design which included all patients whose complete data was available during their data reviewing period. Shin and colleagues (2011) conducted VFSS on the patients regardless of the time passed since the injury, thus including also chronic cervical SCI patients. The mean duration between the onset of an injury and VFSS was 178.4 days (range 12–1062 days). Thus, the low incidence rate of aspiration in their study may be explained by recovery. In comparison, the current investigation and that of Wolf and Meiners (2003) were prospective studies focusing on the acute and sub-acute phases of treatment with consecutively admitted patients.

6.2 Risk factors and Clinical Signs for Penetration-Aspiration

A wide range of potential pre-, peri-, and post injury risk factors and clinical signs (in all, a total of 37 different variables) of penetration-aspiration were analyzed in this study. Two clinical signs and two risk factors for penetration-aspiration were identified: 1) coughing, throat clearing, choking, and 2) changes in voice quality during a clinical swallowing trial, 3) the lower level (C5–Th1) of anterior operation and, 4) the necessity of one or more bronchoscopies. Coughing, throat clearing, and, choking as well as changes in voice quality were independently associated with penetration-aspiration based on a further analysis with a binary logistic regression model. However, due to the small sample size, caution is warranted when interpreting these results.

The most important clinically relevant finding emerging from the current study is that coughing, throat clearing, choking and changes in voice quality related to swallowing were statistically significant clinical signs for penetration-aspiration. This is also in agreement with other studies on a wide range of dysphagic patients; coughing, throat clearing, choking and changes in voice quality related to swallowing are well-accepted indicators of aspiration (Daniels et al., 2000; Logemann et al., 1999; Mari et al., 1997; McCullough et al., 2001). This accords with the result of Shem and co-researchers (2012); they determined the diagnostic accuracy of a bedside swallowing evaluation (BSE) compared to VFSS in patients with traumatic cervical SCI. They identified dysphagia if they observed signs of aspiration, such as coughing, choking and wet vocal quality after drinking, and if liquid and/or food was seen in or around tracheostomy stoma during the BSE. Other signs sought for in the BSE were watery eyes, runny nose and limited or uncoordinated laryngeal movement. In contrast, dysphagia in VFSS was identified based on the following findings: pooling of the test material in valleculae and/or pyriform sinuses, decreased laryngeal elevation, lack of epiglottic inversion, and penetration or aspiration of test material into the larynx or trachea. To summarize, they reported that the sensitivity of the BSE in the identification was 100% and the specificity was 93.3%. Thus, some false positives were detected in BSE when compared to the results obtained with VFSS.

In a bedside examination, it is important to bear in mind that patients with cervical SCI often have a reduced ability to cough but an ineffective cough may not be recognized as a clinical sign of aspiration. In the current study, a stethoscope was used to detect every effort to cough, to clear the throat, or to choke and to detect changes in voice quality related to swallowing in patients with a tracheostomy or

reduced ability to cough voluntarily. It is also important to note that aspiration may be silent. In the present study of the 15 patients who aspirated, 73% aspirated silently in VFSS. Therefore, in patients with traumatic cervical SCI, the VFSS verified incidence rate of penetration-aspiration might be higher than suspected if it is based on only the results of the bedside examination.

The present study found that C5 to Th1 level anterior operation increased the risk of penetration-aspiration. Nonetheless, the same association was not statistically evident when all cervical operations were examined in relation to penetration-aspiration. In a review of the published literature as discussed in Chapter 2.3.2 only Kirshblum et al. (1999) and Brady and colleagues (2004) were able to detect a statistically significant association between dysphagia and cervical surgery. Nevertheless, cervical surgery, especially an anterior approach, has been consistently documented as a risk factor for dysphagia in patients with a wide range of cervical spine injuries and diseases (Bazaz, 2002; Kalb et al., 2012; M. J. J. Lee, 2007; Rihn, Kane, Albert, Vaccaro, & Hilibrand, 2011; Riley, Skolasky, Albert, Vaccaro, & Heller, 2005; Riley, Vaccaro, Dettori, & Hashimoto, 2010a; Siska et al., 2011). Dysphagia has also been reported to occur after posterior cervical surgery (Radcliff et al., 2013; Smith-Hammond, 2004).

Postoperative dysphagia may result from a variety of reasons, including peripheral damage of the vagus and hypoglossal nerves due traction or direct pressure on nerves during the operation (Martin, Neary, & Diamant, 1997; Ryu et al., 2012). The anatomic areas involved in the swallowing (oral cavity, pharynx, larynx, and upper third of esophagus) are innervated by the following cranial nerves; trigeminal, facial, glossopharyngeal, vagus and hypoglossal (Ertekin & Aydogdu, 2003). Naturally, any damage to these nerves may impact negatively on the swallowing function.

Postoperative pharyngeal thickness has also been proposed to influence the swallowing function (Leonard & Belafsky, 2011). The reasons why there should be postoperative dysphagia after posterior cervical spine surgery are not clear, but Tian and Yu (2013) proposed that an increase in the C2-C7 angle of the cervical spine would explain the correlation with the increased likelihood of dysphagia after both anterior and posterior surgery. The incidence of dysphagia after cervical surgery seems to be higher during the first postoperative month and it progressively decreases with time (Bazaz, 2002; Riley, Vaccaro, Dettori, & Hashimoto, 2010b; Siska et al., 2011).

The fourth risk for penetration-aspiration in this study was the necessity of bronchoscopy(ies). Previous research has not, however, found any significant difference in the need to undergo bronchoscopy between patients with or without

dysphagia (Chaw et al., 2012; Shem et al., 2011; Shem et al., 2012b). This discrepancy may be related to the differences in the incidence rates of penetration-aspiration. These three prior studies reported considerably lower incidence rates for aspiration (6%–14%), compared to the results of the present study (33%). Nonetheless, it is reasonable to hypothesize that bronchoscopy is required for the therapeutic management of aspiration and excess bronchial secretion as a consequence of penetration-aspiration. However, it is necessary to pose the question if the bronchoscopy is a cause or a consequence of penetration-aspiration. Bronchoscopy is an invasive measure where an endoscopic instrument is inserted into the trachea and lungs, through the nose or the mouth and through the pharynx and passing between the vocal cords. Alternatively, if the patient is a tracheostomized, the bronchoscopy can be performed through the tracheostomy, thus bypassing the pharynx and vocal cords. In the present study, the approach used for performing the bronchoscopy was not specified. Further research will be needed to answer the question if bronchoscopy may evoke changes on swallowing function.

Considering the other medical treatment-related factors that might associate with penetration-aspiration, no association was found in the current study between tracheostomy and penetration-aspiration even though in previous studies, tracheostomy has been the most widely agreed upon risk factor for dysphagia in cervical SCI patients (Abel et al., 2004; Brady et al., 2004; Chaw et al., 2012; Kirshblum et al., 1999; Seidl et al., 2010; Shem et al., 2005; Shem et al., 2011; Shem et al., 2012b; Shem et al., 2012a; Shin et al., 2011). This present result is, however, supported by reports that found no causal relationship between tracheotomy and aspiration status in acute care settings (Leder & Ross, 2000; Leder & Ross, 2010) and in trauma patients (Dietsch, Solomon, Pearson, & Rowley, 2017; Sharma et al., 2007). Further research will be needed to gain a better understanding of the effect of tracheostomy on the swallowing function.

In addition, the present study found no association between the completeness or level of traumatic cervical SCI and penetration-aspiration. This result is in line with many previous studies that have detected no association between dysphagia and the severity of cervical SCI (Chaw et al., 2012; Shem et al., 2011; Shem et al., 2012b; Shem et al., 2012a; Shin et al., 2011). However, there are some reports that the level (Abel et al., 2004; Kirshblum et al., 1999; Seidl et al., 2010; Wolf & Meiners, 2003) and completeness of the cervical SCI (Abel et al., 2004; Shem et al., 2005) are risk factors for dysphagia.

With respect to the demographic background data, the current study was unable to detect any association between age and penetration-aspiration. The relation

between age and increased incidence of dysphagia in general has been well described in the literature (de Lima Alvarenga, Dall'Oglio, Murano, & Abrahão, 2018; Leder, Suiter, Agogo, & Cooney, 2016; Leslie, Drinnan, Ford, & Wilson, 2005; Logemann, Curro, Pauloski, & Gensler, 2013). In addition, the number of cervical injuries is currently rising and the average age of traumatic cervical SCI patients is increasing (Devivo, 2012; Knutsdottir et al., 2012; Koskinen et al., 2014). For these reasons, it would be premature to claim that there is no association between age and penetration-aspiration based on our findings.

Finally, the recent retrospective study conducted by Hayashi and co-researchers (2017) proposed that old age (> 72 years), AIS level A or B, and the presence of tracheostomy were significant risk factors for severe dysphagia in patients with acute cervical SCI. A note of caution is due here since the severity of dysphagia was determined retrospectively purely based on the patients' FOIS scores; patients scoring 1–3 (dependent on tube feeding) were defined as having severe dysphagia and obvious aspiration, in other words the severity of dysphagia was not determined based on any bedside swallowing examination and/or instrumental evaluation (VFSS/FEES).

6.3 Recovery of Penetration-Aspiration and Functional Feeding Outcome

The current study suggests that a propensity for penetration-aspiration is a transient phenomenon in this cohort of patients with traumatic cervical SCI i.e. the majority of the patients achieved safe oral nutrition within the first few months' post injury. Of the 46 patients, 22 (48%) showed penetration-aspiration in the first VFSS. The second VFSS was performed on 20 patients, of whom six patients showed penetration-aspiration. The third VFSS was conducted on nine patients. Of these, only two were still penetrator/aspirators. One of them showed consistent aspiration in the final follow-up. In summary, of the 46 patients followed the incidence of penetration-aspiration decreased from 48% to 2%.

The vast majority i.e. 42 of the 46 participants examined in this study were treated in the rehabilitation ward. A total of 21 (50%) patients required partial or total non-oral nutrition via a nasogastric feeding tube temporarily and six of them required PEG-tube feeding for long term nutritional support. However, by the time of the

final follow-up, the majority of the patients (88%) performed at FOIS level 7, indicative of total oral intake without restrictions. Only one (2%) patient was still PEG-tube dependent with a consistent oral intake (FOIS 3). The differences between the FOIS scores on the first clinical evaluation and the final follow-up were statistically significant for the whole study sample and between the subgroups of penetrator/aspirators and non-penetrator/aspirators.

The generalizability of these results is subject to certain limitations. The patient sample of this study consisted of a consecutive series of adult patients with traumatic cervical SCI recruited with rigorous exclusion criteria. Therefore, similar results may not be obtained in other clinical contexts applying different criteria for patient recruitments. Comparing the results of this study with previous publications is also somewhat problematic as only a few studies have evaluated recovery from dysphagia after cervical SCI (Abel et al., 2004; Brady et al., 2004; Seidl et al., 2010; Wolf & Meiners, 2003), as discussed in chapter 2.3.3. Despite the methodological heterogeneity of the few prior studies and the current one, their findings seem to be in line indicating that the majority of patients will recover from dysphagia.

In addition, the current study demonstrated that the penetrator/aspirators received statistically significantly more speech therapy interventions than the non-penetrator/aspirators. The purpose of this study was not to examine the efficacy of speech therapy in patients with penetration-aspiration, and without a control group not receiving any therapeutic intervention, it is not possible to differentiate the outcome of spontaneous recovery from the treatment results. Furthermore, the time frames for the final follow-up differed statistically significantly between the subgroups, indicating that penetrator/aspirators required a longer period of speech therapeutic interventions. While this finding is only suggestive it has important implications i.e. a VFSS verified penetration-aspiration status may well suffice to indicate an increased and prolonged need for speech therapeutic intervention. In this study, all the treatment decisions were made based on the patients' clinical needs, not only on their penetration-aspiration status. It is important to continue speech therapeutic monitoring of this patient group with a low threshold during the acute phase and rehabilitation, even in those cases where the first VFSS does not reveal any signs of penetration-aspiration.

6.4 Strengths and Limitations

To the best of this author's knowledge this is the first study conducted on patients with traumatic cervical SCI that has used a stringently defined VFSS protocol and a standardized measure (Rosenbek et al., 1996) to determine the severity and recovery of laryngeal penetration-aspiration. Furthermore, the current study is the first that has focused on the clinical signs and the risk factors of laryngeal penetration-aspiration during the acute phase in patients with traumatic SCI. Additionally, a standardized method was used to describe a functional oral feeding outcome of the patients (Crary et al., 2005). The bedside evaluation and swallowing trial were administered to the patients in an established manner as described in Chapter 4.4.1; this was designed to be brief and thus appropriate for patients treated in intensive care settings. In addition, all the patients were evaluated by the same speech therapist and therefore inter-evaluator bias was eliminated. However, intra-evaluator bias was not examined. Furthermore, the exact time frames between the injury and the different assessments points have been presented in detail in contrast to the majority of prior studies as seen in Table 1 on pages 29–30.

In addition, the current study sample consists of a consecutive series of adult patients with traumatic cervical SCI recruited with rigorous exclusion criteria (see Figure 4 on page 36 for details). Premorbid conditions such as previous diseases or surgical procedures that could cause dysphagia were carefully excluded to enhance the validity of the data. The current study sample – even though relatively small – can also be considered as being representative of Finnish patients with traumatic cervical SCI as it examined a consecutive series of patients admitted to one of the three University Hospitals responsible for the care of this patient group in Finland. The distributions of age and gender as well as the injury severity and mechanisms distributions are comparable with those published by Koskinen and co-researchers (Koskinen et al., 2014) who assessed the incidence of traumatic SCI injuries in Finland. Still, it can be argued that the incidence of penetration-aspiration would have been higher if the excluded cases, especially those with premorbid conditions, had been included in the study.

Naturally, this study also has some limitations and methodological issues that need to be discussed. First, the small sample size, restricted the statistical analyses and further limited the generalizability of the results. For example, the small sample size reduced the possibility to perform extensive statistical testing (e.g. multivariable logistic regression) regarding possible factors affecting the recovery of penetration-aspiration and the functional oral intake outcome. As there were not enough cases

in the different subgroups more sophisticated tests would have been underpowered and would have not provided reliable evidence. Second, since no control group was available, it is not possible to differentiate the course of spontaneous recovery from the consequences of treatment. Thus, the speech therapeutic interventions were only described and summarised and no assumptions can be drawn concerning the effectiveness of these interventions. Based on ethical considerations (e.g. not to expose people to radiation unnecessarily), a healthy control group could not be enrolled in this study. This naturally led to the absence of subsequent normative data.

Furthermore, one source of weakness in this study was that our x-ray equipment allowed only a resolution of 15 images per second. In the literature, a frame rate of 30 images per second is recommended in order not to miss any significant pathology (Belafsky & Kuhn, 2014; Martin-Harris & Jones, 2008). For example, Bonilha and colleagues (2013) explored the agreement between PAS ratings at different temporal resolutions; they revealed that one obtained different PAS ratings if one applied a high resolution of 30 images per second as compared to those at lower pulse rates (4, 7.5 and 15) in 80% of the patients studied. However, the difference in PAS ratings between 30 and 15 images per second was not statistically significant. Thus, 15 frames per second can be considered as satisfactory.

Next, the VFSS protocol included only measured boluses (5 ml, 10 ml, and 20 ml) of a thin, liquid consistency in order to reduce the amount of radiation exposure in those patients who did not show signs of dysphagia and penetration-aspiration. A thin liquid was chosen since it is the most sensitive consistency for detecting penetration-aspiration: thicker consistencies are clinically used as compensation strategies for aspiration of thin liquids (Clave et al., 2006; Leonard, White, McKenzie, & Belafsky, 2014; Logemann et al., 2008). Naturally, a systematic use of a wider range of volumes and different consistencies, as for example applied in the MBSImp – protocol (Martin-Harris et al., 2008) in the whole study sample would have enabled a more extensive evaluation of the swallowing function.

The limited approach to determining dysphagia chosen for this study may also be criticized. The present study focused only on penetration-aspiration findings emerging from the bedside examination and VFSS, although dysphagia is a much broader phenomenon including problems in various phases of swallowing (preparatory, oral, pharyngeal and esophageal). However, this choice is defensible as, in acute clinical settings, it is crucial to identify those patients at risk of penetration-aspiration in order to make appropriate decisions on how to administer medication, liquids and nutrition, and to avoid adverse events (i.e. aspiration pneumonia). This is especially important as it is well-known that this patient group is predisposed to

pulmonary complications (Vazquez et al., 2013; Winslow & Rozovsky, 2003; Zimmer et al., 2007).

The decision to include only the patient's worst (i.e. highest) PAS score in the statistical analyses may also be criticized. In comparison, some studies have used the mean of PAS scores as an outcome measure (Langmore et al., 2016; Pearson, Davidoff, Smith, Adams, & Langmore, 2016). Nonetheless, as Steele and Grace-Martin (2017) have emphasized, two individuals may have the same mean score but one of them may still suffer from a clinically more serious condition. For instance, one patient scoring 5,3,3,5,5 and the second scoring 8,5,3,3,2 both have a mean score of 4.2. However, it is apparent that the second patient with silent aspiration (PAS 8) probably needs more speech therapeutic interventions than the first patient. Steele and Grace-Martin (2017) suggested that at least for clinical purposes, the most informative way to represent PAS scores may be to report both the most typical (mode) and the worst score across a set of swallows. Unfortunately, the information provided by Steele and Grace-Martin (2017) was not available when designing the study protocol for the current study. Nonetheless, the decision to emphasize the worst PAS score is defensible especially in acute and intensive care settings, which was the context of this study. It is well established that VFSS verified aspiration is associated with an increased risk of pneumonia in acute and sub-acute settings (Holas, DePippo, & Reding, 1994; Kidd, Lawson, Nesbitt, & MacMahon, 1995; Pikus et al., 2003). In addition, a few studies have reported that the incidence of pneumonia is significantly higher in cervical SCI patients with dysphagia than in those without dysphagia (Abel et al., 2004; Chaw et al., 2012; Shem et al., 2011; Shem et al., 2012b). One important goal in the acute treatment of traumatic cervical SCI is to prevent pulmonary complications.

In addition, the PAS scoring system itself needs to be discussed. Scores 4 and 6 appear to be rarely observed (Kelly, Drinnan, & Leslie, 2007; Martin-Harris et al., 2008; Molfenter & Steele, 2014; Rosenbek et al., 1996) as is also apparent in the current study. This naturally affects the distribution of the scores. Furthermore, Steele and Grace-Martin (2017) have raised the question if the PAS is an linear scale i.e. a scale in which each increasing score is understood to represent greater severity than the previous score. The authors have questioned if PAS scores of 3 and 5 should be considered more severe than scores of 4 and 6 because penetration into the supraglottic space (PAS 3 or 5) does not trigger an immediate swallow response with effective clearance of the penetrated material. Therefore, Steele and Grace-Martin (2017) have proposed a categorical revision of the PAS into four levels of increasing physiological severity. Thus, PAS scores of 1, 2 and 4 would represent a normal

function, and PAS scores of 3, 5 and 6 would refer to abnormal penetration. A PAS score of 7 would reflect a failure of airway protection mechanisms with some residual sensory integrity. Finally, a PAS score of 8 would refer to impaired sensory integrity and ineffective cough responses to aspiration. Further research and expert opinions on this subject are warranted.

6.5 Future Perspectives

Dysphagia following traumatic cervical SCI still seems to be an understudied topic. Thus, more studies investigating the incidence rates and severity of dysphagia are warranted in order to establish a greater degree of certainty on these topics. In addition, future research should concentrate on determining of the numerous factors that may influence the cervical SCI patient's ability to eat by mouth and his/her recovery from dysphagia. It could be most useful to also examine whether there is any association between penetration-aspiration and reduced airflow during a voluntary cough, as has been shown in patients with motor neuron disease and Parkinson's disease (Pitts et al., 2010; Plowman et al., 2016).

Additionally, studies to clarify the association between penetration-aspiration and pulmonary complications in the acute and post-acute settings would be worthwhile in order to develop up treatment-altering clinical protocols. FEES may well be a more suitable method than VFSS for the first acute instrumental evaluation of this patient group since the FEES evaluation can be conducted bedside. Furthermore, a study concentrating on the differences and similarities of dysphagia symptoms and their treatment in patients with traumatic and non-traumatic cervical SCI would be highly worthwhile to assess if these subgroups with different etiologies need different dysphagia evaluations and treatment plans. To the best of this author's knowledge, there are no published studies concerning traumatic cervical SCI patient's own experiences of dysphagia and the quality of life with dysphagia. Studies focusing on this subject would be beneficial.

In addition, further studies are needed to assess the long-term effects of aging and chronic cervical SCI on the swallowing functioning. Age-related changes in swallowing function have been reported in the healthy population (Butler, Stuart, Markley, Feng, & Kritchevsky, 2018; de Lima Alvarenga et al., 2018; Leslie et al., 2005). Swallowing difficulties may predispose individuals to a risk of malnutrition

and lower respiratory tract infection even in independently living elderly people (Serra-Prat et al., 2012). More research is needed to reveal if the swallowing function of elderly chronic cervical SCI patients, for example those over 70 years, should be systematically screened during their life-time follow-up visits in outpatient clinics as a way of preventing pulmonary infections.

Finally, the International Spinal Cord Society (ISCoS) has developed the International Spinal Cord Injury Core Data Set to standardize the collection and reporting of the SCI data (Biering-Sørensen et al., 2006; Biering-Sørensen et al., 2017; DeVivo et al., 2006). The Core Data Set consists of 25 variables, including basic demographic characteristics, cause of injury, presence of vertebral fractures and associated injuries, occurrence of spinal surgery, occurrence of pulmonary complications, and measures of neurological and ventilator status. However, the Core Data Set does not include any variables concerning the evaluation of dysphagia or the severity of the dysphagia symptoms or the functional oral intake ability of patients with SCI. As a way of making data collection more comprehensive in the future, it would be worthwhile considering if the Set should be supplemented with this kind of information, at least with some consideration of whether or not the patient is receiving oral nutrition either completely or partially versus completely non-orally.

7 CONCLUSIONS AND MAIN FINDINGS

The main findings and conclusions of this thesis are summarized as follows:

1) The incidence of penetration-aspiration (PAS score ≥ 3) on the first VFSS was 48%. Fifteen patients (33%) exhibited aspiration and 73% of them aspirated silently, in other words, without coughing, i.e. silent aspiration occurred in 24% of the whole study cohort.
2) The rather high incidence rate of penetration-aspiration indicates that a routine evaluation of swallowing is highly recommendable before initiating oral feeding. An instrumental evaluation of swallowing is recommended to rule out the existence of silent aspiration and to achieve information on safe nutrition consistency.
3) Coughing, throat clearing, choking and changes in voice quality related to swallowing were significant clinical indicators of penetration-aspiration. Thus, a bedside swallowing examination can improve the detection of penetration-aspiration.
4) Post-injury anterior surgery on the lower cervical spine and the necessity for bronchoscopies were marked risk factors for penetration-aspiration. These factors should alert to suspect changes in the swallowing function.
5) The current study suggests that the propensity for penetration-aspiration is a transient phenomenon among patients with traumatic cervical SCI.
6) The majority of traumatic cervical SCI patients (88%) achieve a total oral intake without restrictions within the first few months post injury.

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Tiina Ihalainen

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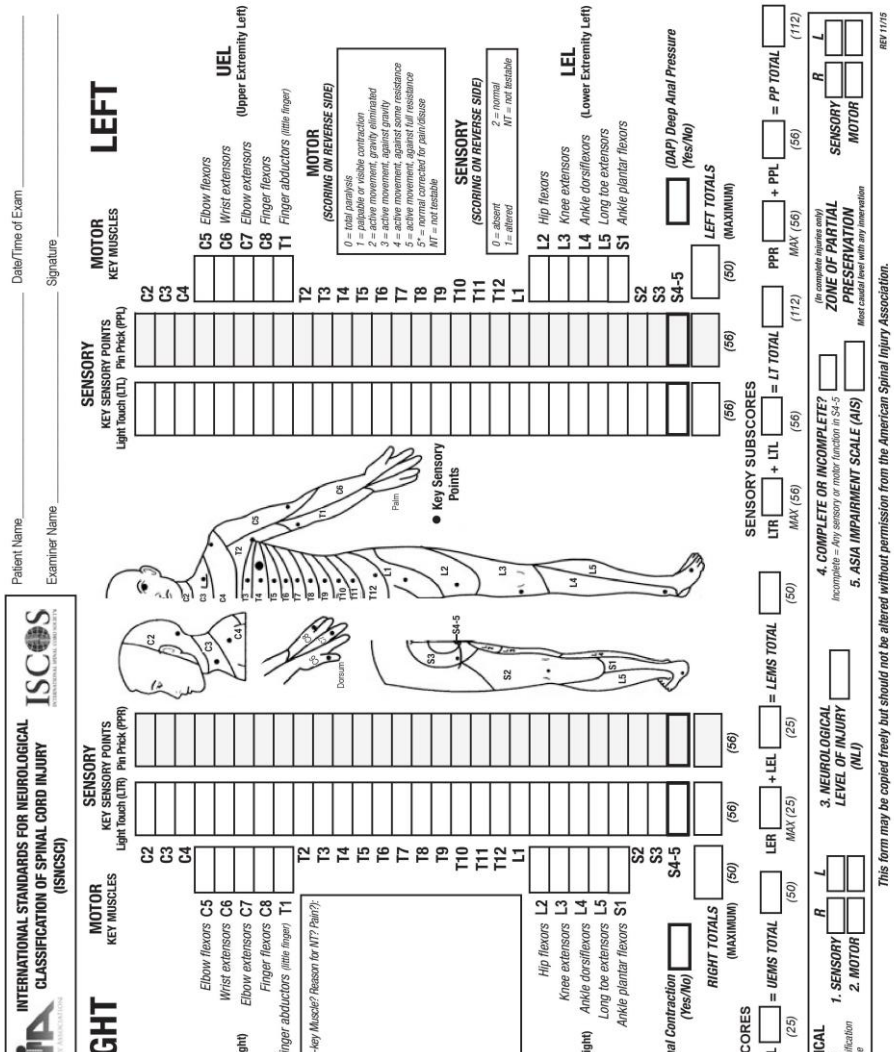
APPENDICES

Appendix 1. The International Standards for Neurological Classification of SCI (ISNCSCI) Worksheet (revised 11/15). Reprinted with permission.



Muscle Function Grading

0 = total paralysis

1 = palpable or visible contraction

2 = active movement, full range of motion (ROM) with gravity eliminated

3 = active movement, full ROM against gravity

4 = active movement, full ROM against gravity and moderate resistance in a muscle specific position

5 = (normal) active movement, full ROM against gravity and full resistance in a functional muscle position expected from an otherwise unimpaired person

5* = (normal) active movement, full ROM against gravity and sufficient resistance to be considered normal if identified inhibiting factors (i.e. pain, disuse) were not present

NT = not testable (i.e. due to immobilization, severe pain such that the patient cannot be graded, amputation of limb, or contracture of > 50% of the normal ROM)

Sensory Grading

0 = Absent

1 = Altered, either decreased/impaired sensation or hypersensitivity

2 = Normal

NT = Not testable

When to Test Non-Key Muscles:

In a patient with an apparent AIS B classification, non-key muscle functions more than 3 levels below the motor level on each side should be tested to most accurately classify the injury (differentiate between AIS B and C).

Movement	Root level
Shoulder: Flexion, extension, abduction, adduction, internal and external rotation **Elbow:** Supination	**C5**
Elbow: Pronation **Wrist:** Flexion	**C6**
Finger: Flexion at proximal joint, extension. **Thumb:** Flexion, extension and abduction in plane of thumb	**C7**
Finger: Flexion at MCP joint **Thumb:** Opposition, adduction and abduction perpendicular to palm	**C8**
Finger: Abduction of the index finger	**T1**
Hip: Adduction	**L2**
Hip: External rotation	**L3**
Hip: Extension, abduction, internal rotation **Knee:** Flexion **Ankle:** Inversion and eversion **Toe:** MP and IP extension	**L4**
Hallux and Toe: DIP and PIP flexion and abduction	**L5**
Hallux: Adduction	**S1**

ASIA Impairment Scale (AIS)

A = Complete. No sensory or motor function is preserved in the sacral segments S4-5.

B = Sensory Incomplete. Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-5 (light touch or pin prick at S4-5 or deep anal pressure) AND no motor function is preserved more than three levels below the motor level on either side of the body.

C = Motor Incomplete. Motor function is preserved at the most caudal sacral segments for voluntary anal contraction (VAC) OR the patient meets the criteria for sensory incomplete status (sensory function preserved at the most caudal sacral segments (S4-S5) by LT, PP or DAP), and has some sparing of motor function more than three levels below the ipsilateral motor level on either side of the body.
(This includes key or non-key muscle functions to determine motor incomplete status.) For AIS C – less than half of key muscle functions below the single NLI have a muscle grade ≥ 3.

D = Motor Incomplete. Motor incomplete status as defined above, with at least half (half or more) of key muscle functions below the single NLI having a muscle grade ≥ 3.

E = Normal. If sensation and motor function as tested with the ISNCSCI are graded as normal in all segments, and the patient had prior deficits, then the AIS grade is E. Someone without an initial SCI does not receive an AIS grade.

Using ND: To document the sensory, motor and NLI levels, the ASIA Impairment Scale grade, and/or the zone of partial preservation (ZPP) when they are unable to be determined based on the examination results.

ASIA
American Spinal Injury Association

INTERNATIONAL STANDARDS FOR NEUROLOGICAL CLASSIFICATION OF SPINAL CORD INJURY

ISCOS
International Spinal Cord Society

Steps in Classification

The following order is recommended for determining the classification of individuals with SCI.

1. Determine sensory levels for right and left sides.
The sensory level is the most caudal, intact dermatome for both pin prick and light touch sensation.

2. Determine motor levels for right and left sides.
Defined by the lowest key muscle function that has a grade of at least 3 (on supine testing), providing the key muscle functions represented by segments above that level are judged to be intact (graded as a 5).
Note: in regions where there is no myotome to test, the motor level is presumed to be the same as the sensory level, if testable motor function above that level is also normal.

3. Determine the neurological level of injury (NLI)
This refers to the most caudal segment of the cord with intact sensation and antigravity (3 or more) muscle function strength, provided that there is normal (intact) sensory and motor function rostrally respectively.
The NLI is the most cephalad of the sensory and motor levels determined in steps 1 and 2.

4. Determine whether the injury is Complete or Incomplete.
(i.e. absence or presence of sacral sparing)
*If voluntary anal contraction = **No** AND all S4-5 sensory scores = **0***
*AND deep anal pressure = **No,** then injury is **Complete.***
*Otherwise, injury is **Incomplete.***

5. Determine ASIA Impairment Scale (AIS) Grade:

Is injury Complete? **If YES, AIS=A** and can record ZPP (lowest dermatome or myotome on each side with some preservation)

NO ↓

Is injury Motor Complete? **If YES, AIS=B**

NO ↓ (No=voluntary anal contraction OR motor function more than three levels below the motor level on a given side, if the patient has sensory incomplete classification)

Are at least half (half or more) of the key muscles below the neurological level of injury graded 3 or better?

NO ↓ **AIS=C** **YES** ↓ **AIS=D**

If sensation and motor function is normal in all segments, AIS=E
Note: AIS E is used in follow-up testing when an individual with a documented SCI has recovered normal function. If at initial testing no deficits are found, the individual is neurologically intact; the ASIA Impairment Scale does not apply.

Full title: Traumatic Cervical Spinal Cord Injury: A Prospective Clinical Study of Laryngeal Penetration and Aspiration

Running title: TCSCI: prospective study of penetration/aspiration

Tiina Ihalainen, MA

Department of Neurosciences and Rehabilitation, Tampere University Hospital, Tampere, Finland

School of Social Sciences, University of Tampere, Tampere Finland

Email: tiina.ihalainen@pshp.fi

Irina Rinta-Kiikka, MD, PhD

Medical Imaging Centre, Department of Radiology, Tampere University Hospital, Tampere, Finland

Email: irina.rinta-kiikka@pshp.fi

Teemu M. Luoto, MD, PhD

Department of Neurosurgery, Tampere University Hospital, Tampere, Finland

Email: teemu.luoto@pshp.fi

Eerika Koskinen, MD, PhD

Department of Neurosciences and Rehabilitation, Tampere University Hospital, Tampere, Finland

Email: eerika.koskinen@pshp.fi

Anna-Maija Korpijaakko-Huuhka, PhD

School of Social Sciences, University of Tampere, Tampere Finland

Email: anna-maija.korpijaakko-huuhka@uta.fi

Antti Ronkainen, MD, PhD

Department of Neurosurgery, Tampere University Hospital, Tampere, Finland

Email: antti.ronkainen@pshp.fi

Corresponding author:

Tiina Ihalainen

Tampere University Hospital P.O. Box 2000 FI-33521 Tampere, Finland

Tel. +358 405679380, +358 331163328

Conflicts of interest

The authors declare no conflict of interest.

ABSTRACT

Study design: Prospective cohort study.

Objectives: Dysphagia is a relatively common secondary complication in patients with traumatic cervical spinal cord injuries (TCSCI). The purpose of this study was to determine the incidence of aspiration and penetration in patients with acute TCSCI.

Setting: Tampere University Hospital, Tampere, Finland.

Methods: A total of 46 patients with TCSCI were evaluated with a videofluoroscopic swallowing study (VFSS). Rosenbek's penetration-aspiration scale (PAS) was used to classify the degree of penetration or aspiration. The medical records of each patient were systematically reviewed.

Results: Of the 46 patients, 85% were male. The mean age at the time of the injury was 62.1 years. Most patients had an incomplete injury (78%), and most of them due to a fall (78%). In the VFSS 19 (41%) patients penetrated and 15 (33%) aspirated. Only twelve (26%) of the patients had a PAS score of 1 indicating that swallowed material did not enter the airway. Of the patients who aspirated, 73% had silent aspiration.

Conclusion: The incidence of penetration or aspiration according to VFSS is high in this cohort of patients with TCSCI. Therefore, the swallowing function of patients with acute TCSCI should be routinely evaluated before initiating oral feeding. VFSS is highly recommended, particularly to rule out the possibility of silent aspiration and to achieve information on safe nutrition consistency.

Keywords: trauma, spinal cord injuries, spinal injuries, dysphagia, deglutition, respiratory aspiration

INTRODUCTION

Traumatic spinal cord injury (SCI) leads to abrupt changes in motor, sensory, and autonomic functions below the level of injury, causing many secondary conditions and increasing the risk for various complications. Especially among cervically injured SCI patients, dysphagia is a relatively common complication.(1-11) Dysphagia is associated with many negative short- and long-term outcomes, such as pneumonia and other respiratory complications as well as malnutrition, dehydration, and reduced quality of life.(12-15) In addition, while SCI in general causes a substantial economic burden, the treatment of respiratory complications further raises hospital costs.(16)

By definition, dysphagia is described as a difficulty in the regular passage of swallowed bolus from the mouth to the stomach.(17) Penetration and aspiration are the most severe subtypes of dysphagia. Penetration means that swallowed material enters the airways, but remains above the vocal folds.(18) In the case of aspiration, the swallowed material passes below the vocal cords.(18) Aspiration can occur with a cough reflex or silently. The videofluoroscopic swallowing study (VFSS) is considered to be the gold standard method for objectively evaluating the degree of dysphagia. Rosenbek's penetration-aspiration scale (PAS) is a widely used method to classify the severity of penetration and aspiration seen on VFSS.(18)

A recent study revealed that the incidence of traumatic SCI in Finland is 31.8 per million and that the vast majority of these injuries are cervical resulting in tetraplegia (70% of all SCIs).(19) Based on the literature the incidence of dysphagia in cervical SCI patients varies from 16% to 80%.(1-11) A summary of the previous studies on cervical SCI and dysphagia is presented in Table 1.

The aim of this study was to determine the incidence of laryngeal penetration/aspiration in patients with acute TCSCI by using VFSS and Rosenbek's PAS.

METHODS

Study Frame and Ethics

This prospective study was conducted at Tampere University Hospital, Tampere, Finland. The study protocol was approved by the Ethics Committee of Pirkanmaa Hospital District, Tampere, Finland (R12250). Written informed consent according to the Declaration of Helsinki was obtained from all the subjects prior to commencing the research. We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research. In Finland, acute care, subacute rehabilitation, and the lifelong follow-up of patients with TSCI is centralized at three university hospitals, which are situated in Helsinki, Oulu, and Tampere. Tampere University Hospital serves a population of 2.8 million from both urban and rural areas. All applicable patients (n=94) with TCSCI admitted to Tampere University Hospital from February 2013 to April 2015 were asked to participate in this study. We included all patients with TCSCI regardless of the severity or cervical level of injury. Possible confounding factors were controlled with numerous exclusion criteria. The medical records of each patient were reviewed to verify the history of neurological diseases and head, neck, or cervical spine surgeries. A flowchart displaying the study process (incl. exclusion criteria) is presented in Figure 1.

Spinal Cord Injury Characteristics

The following variables were recorded for all patients: gender; age at the time of injury; injury mechanism (as per the International SCI Core Data Set;(20)) method of treatment (anterior surgery, posterior surgery, multiple surgeries, no surgery); presence of nasogastric tube, tracheostomy, and/or hard collar at the time of VFSS. The International Standards for Neurological Classification of Spinal Cord Injury was used to evaluate and classify the neurological consequences of the spinal cord injury.(21,22) The completeness of the injury was defined according to the American Spinal

Injury Association impairment scale (AIS): AIS A = motor-sensory complete, AIS B = motor complete-sensory incomplete, or AIS C-D = motor-sensory incomplete.

Videofluoroscopic Swallowing Study and Penetration-Aspiration Scaling

All 46 patients were first assessed for clinical indicators of penetration or aspiration (i.e. coughing, throat clearing, choking, and changes in voice quality) by a speech and language therapist (TI). To confirm the incidence of penetration/aspiration, the patients were subjected to VFSS (Siemens Axiom Luminos DRF, Erlangen, Germany). The frame rate was 15 frames per second. The VFSS was conducted by a speech and language therapist (TI) and a radiologist. The VFSS was carried out with the patient in an upright position from a lateral scanning view. The VFSS protocol included 5 ml, 10 ml, and 20 ml boluses of a thin, water-soluble contrast agent (Omnipaque 350 mgI/ml, GE Healthcare, Oslo, Norway). The patients were asked to hold the bolus in their mouth until they were instructed to swallow. In addition, they were guided to swallow as many times as they needed and to cough and clear their throat if needed. After the primary swallow, the fluoroscopy was continued for at least 6 seconds to clarify if penetration/aspiration occurred after the initial swallow. In patients with a tracheostomy (n=6), the examination was conducted with a decuffed cannula. The VFSS was discontinued if severe aspiration occurred. The Rosenbek's PAS scoring was conducted together by a speech therapist (TI) and a radiologist (IR-K). The timing of penetration or aspiration was classified as (1) pre-, (2) during-, or (3) post swallowing.

Statistical Analysis

The Statistical Package for Social Sciences software program (IBM SPSS Statistics for Windows, Version 23.0, Armonk, NY, USA) was used to perform all the statistical analyses.

RESULTS

Patients

In total, 46 out of 94 patients with TCSCI were included in this prospective study. The characteristics of the study sample are presented in Table 2. Of the 48 excluded patients, 36 (75%) were male and 12 (25%) were female. Mean age was 63.6 years (median 66.1, min.–max. 17.6–94.4).

VFSS

In total, 121 swallows were analysed using VFSS. The mean time from injury to the VFSS was 19.1 days (SD=17.5, median=13.5, min=2, max=87). The highest PAS score from each patient was included in the statistical analyses. Fifteen (33%) patients had aspiration and 19 (41%) patients had penetration on the VFSS. Twelve (26%) patients had a swallowing score of 1, indicating that swallowed material did not enter the airway. The Rosenbek's Penetration-Aspiration Scale scores are presented in table 3. The penetration or aspiration occurred during swallowing in 17 (37%) patients, post-swallowing in 9 (20%) patients, and during and post-swallowing in 7 (15%) patients. Pre-swallowing penetration or aspiration was not detected. In one case (2%) the timing of the silent aspiration was missed because there was a delay in starting the fluoroscopy. Six patients (13%) had severe aspiration and required a percutaneous feeding tube.

DISCUSSION

The main finding of our study was that the incidence of penetration/aspiration based on original PAS scoring was high (74%) in this cohort of patients with TCSCI. Even if we consider PAS scores 1-2 representing normal variation in swallowing (23-25) the incidence of unsafe swallowing is still considerably high (48%). Methodological heterogeneity among earlier studies makes it difficult to compare our results to prior findings. In the earlier studies, the incidence of aspiration varies between 6% and 41% (2-4,6-11), and in some studies, the incidence of aspiration was not reported precisely.(1,2,5) The incidence of penetration was reported in only two studies, and it varied from 5% to 24%.(3,6) Wolf and Meiners (2) reported the incidence of severe aspiration to be 41%, but they included only CSCI patients with respiratory insufficiency. Seidl et al. (6) reported the overall incidence of aspiration to be 11% and they included all patients whose complete data was available. The higher incidence of aspiration in the study of Wolf and Meiners might be explained with the study population of more severely injured patients. Shin et al. (7) performed VFSS to all patients included in their study, but they reported that the mean duration between the onset of spinal cord injury and VFSS was 178.35 days (range 12–1062 days). They concluded that a broad time frame lead to limitations when interpreting the results of VFSS, as dysphagia in CSCI patients tends to be transient and the low prevalence of aspiration may be explained by recovery.

To the best of our knowledge this is the first study conducted on patients with TCSCI that has used the Rosenbek's PAS and a precisely described VFSS protocol in the data collection. The age, gender and injury mechanism distributions of our study sample are comparable with the ones published by Koskinen and colleagues.(19) Our study sample can be considered to be unbiased and representative of Finnish patients with TCSCI as it includes a consecutive series of admitted patients with SCI. We also presented the exact time frame between the injury and VFSS. As shown in Table 1, the time frame between the injury and the instrumental swallowing study is poorly

reported in prior studies. In the majority of prior studies, the instrumental – i.e. VFSS or fiberoptic endoscopic evaluation of swallowing – evaluation was performed only when dysphagia was clinically suspected.(1,3-5) Therefore, all patients who may have been silent aspirators were perhaps not identified. Patients with CSCI have often reduced ability to cough. Weakness in coughing complicates clinical swallowing evaluation and therefore this patient group may have a higher risk for silent aspiration. In our study of the patients who aspirated, 73% had silent aspiration. In two retrospective studies with a large heterogeneous group of dysphagic patients (n=1,101, n=2,000), the incidence of silent aspiration among patients with aspiration varied from 55% to 59%.(26,27) Clinically, a lack of awareness of silent aspiration may lead to a longer period of aspirating food or liquids into the lungs, thereby potentially elevating the risk for pneumonia or pulmonary complications. Besides, coughing is not only a clinical indicator of aspiration, but also a protective reflex against aspiration. In our study, none of the patients who aspirated were able to eject the aspirated material out of the trachea.

Further, preferably multicenter, research is recommended to determine the length and nature of dysphagia symptoms and to elaborate a management plan for TCSCI patients with dysphagia. Earlier studies have presented some risk factors, i.e. age (1,7,8), tracheostomy (1,4,6,7,9,10), the completeness of the injury (1,4), and cervical surgery.(1) Due to the differences in the definition of dysphagia and data collection, future research is nevertheless needed to identify risk factors for dysphagia, including penetration and aspiration.

Limitations of the Study

The limitations of this study are the small sample size and the fact that the VFSS protocol included only measured boluses (5 ml, 10 ml, and 20 ml) of a thin, liquid consistency. Considering the overall incidence of TCSCI in Finland, the number of recruited patients can still be seen as better than satisfactory.

The VFSS protocol used in this study was limited to measured boluses of contrast agent (of a thin, liquid consistency) in order to reduce the amount of radiation exposure to patients who did not penetrate or aspirate. We could have detected even more penetration/aspiration had we included a serial drinking task of involving thin liquid and other consistencies in our VFSS research protocol.

We decided to use rigorous exclusion criteria to reduce or eliminate confounding or ethically questionable variables. It can be argued that the incidence of penetration/aspiration would have been higher if the excluded cases were included in the study. In this study, we also focused only on VFSS findings of penetration/aspiration, although dysphagia is a much broader phenomenon.

Finally, our aim in this prospective study was to conduct the clinical examination and the VFSS as soon as possible post-injury. We did not want to set a too strict time limit since we were aware that especially conducting the VFSS for this patient group is challenging. We accepted the patients to participate in this study if they were admitted to our hospital ≤ 3 months post-injury as did Wolf and Meiners.(2)

CONCLUSIONS

The incidence of penetration/aspiration based on original PAS scoring was high (74%) in this cohort of patients with TCSCI. Of the patients who aspirated, 73% aspirated silently (PAS 8). Therefore, swallowing should be evaluated routinely by an experienced speech therapist before initiating oral feeding. VFSS is highly recommended, particularly to rule out the possibility of silent aspiration and to achieve information on safe nutrition consistency.

Acknowledgements

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TI contributed to the study design, data collection, data analysis, data interpretation, and article preparation. IRK contributed to the data collection and article preparation. TL contributed to the data interpretation and article preparation. EK contributed to the data collection and article preparation. A-MK-H contributed to the article preparation. AR contributed to the study design and article preparation.

The authors declare no conflict of interest.

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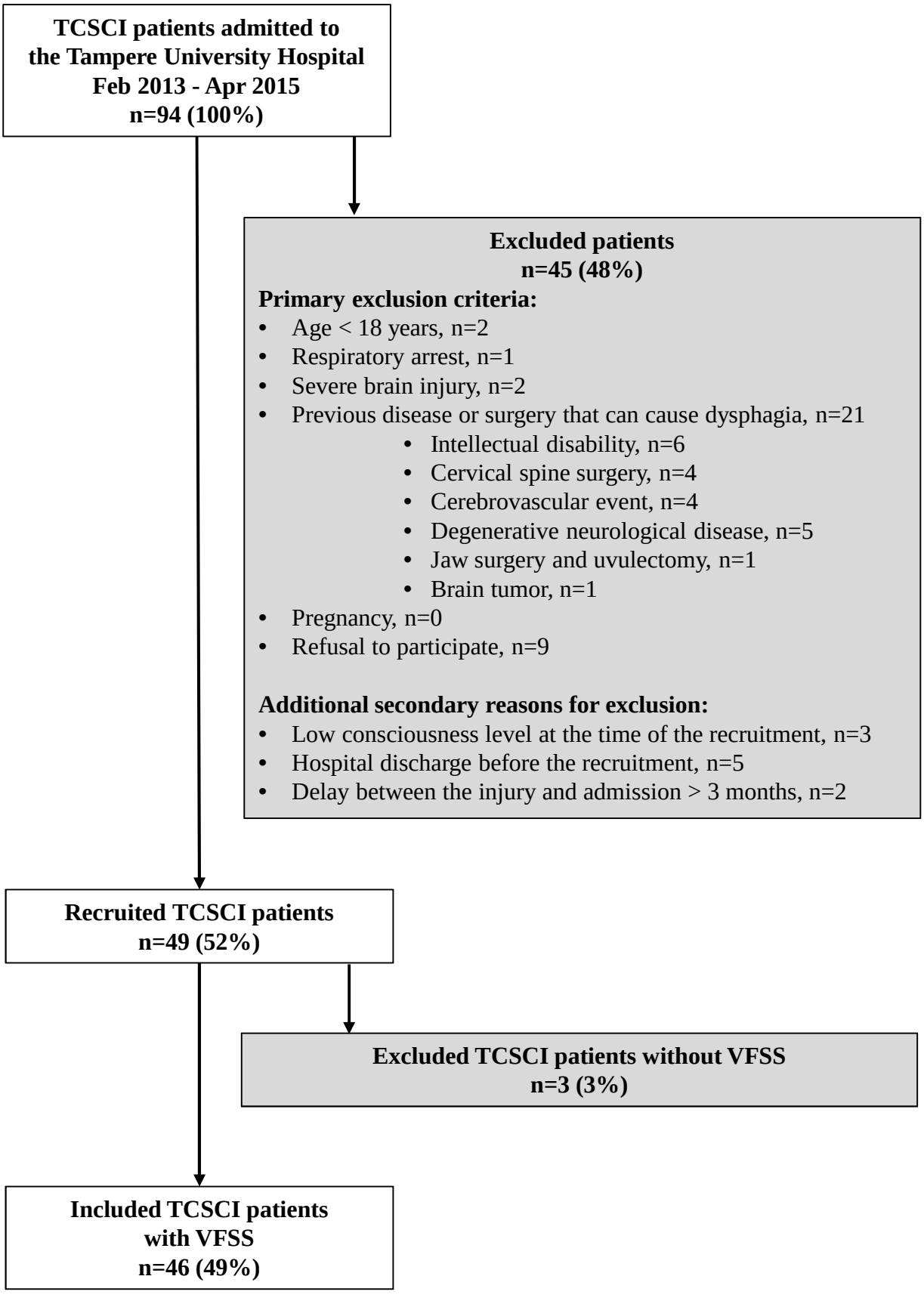
Titles and legends to Figures

Figure 1. The study process.



TCSCI = Traumatic cervical spinal cord injury
VFSS = Videofluoroscopic swallowing study

Table 1 Summary of previous studies that focus on cervical SCI and dysphagia

Reference (Nature of the study)	**Patients, n** (gender; mean age; range/SD)	**Aetiology, n**	**AIS / Frankel score**	**Dysphagia clinically suspected**	**Method of instrumental assessment**	**Time frame**[1]	**Findings of instrumental assessment**[2] (n; %)
Kirshblum et al., 1999(1) (Retrospective)	187 M 156, F 31; 44.3; range 15–86	Trauma, 187	AIS A 38%, AIS B–E 62%	42/187 (23%)	VFSS 42/187	Not reported	Aspiration or requiring a modified diet (n=31; 17%)
Wolf & Meiners, 2003(2) (Longitudinal study)	51 M 35, F 16; 43.4; range 16–89	Trauma, 46 Non-trauma, 5	AIS A 59%, AIS B–E 41%	Not reported.	FEES 51/51	Not reported	Aspiration (n=21; 41%) Laryngeal oedema or mild aspiration (n=20; 39%)
Brady et al., 2004(3) (Retrospective)	131 M -, F -; 55.6; range 17–87	Trauma and non-trauma	Not reported	72/131 (55%)	FEES or VFSS 59/131	Not reported	Aspiration (n=23; 18%) Laryngeal penetration (n=32; 24%)
Abel et al., 2004(4) (Prospective)	73 M 51, F 22; 42.9; range 0.57–86.8	Trauma, 56 Non-trauma, 17	AIS A 56%, AIS B–D 44%	32/73 (44%)	VFSS or blue dye test 32/73	Not reported	Aspiration (n=11; 15%)
Shem et al., 2005(5) (Retrospective)	68 M -, F -; 33; range 17–83	Not reported.	AIS A 53%, AIS B–D 47%	51/68 (75%)	VFSS 17/68	Not reported	Aspiration not reported
Seidl et al., 2010(6) (Retrospective)	175 M 144, F 31; 43.45; range 14–89	Trauma, 147 Non-trauma, 28	TA 59%, TB–TE 41%	Not reported.	FEES 175/175	Not reported	Aspiration (n=7; 4%) Silent aspiration (n=13; 7%) Penetration (n=8; 5%)
Shin et al., 2011(7) (Retrospective)	121 M 105, F 16; 44.93; range 9–78	Trauma, 118 Non-trauma, 3	AIS A 60%, AIS B–D 41%	35/121 (29%)	VFSS 121/121	178.35±161.19 days	Aspiration (n=10; 8%)
Shem et al., 2011(8) (Prospective)	29 M 22, F 7; 41	Trauma, 29	Complete 45%, Incomplete 55%	12/29 (41%)	VFSS 21/29	BSE within 31 days of injury, VFSS within 72 hours of BSE	Aspiration (n=4; 14%)
Shem et al., 2012(9) (Prospective)	40 M 31, F 9; 41; SD 16.5	Trauma, 40	Complete 43%, Incomplete 58%	16/40 (40%)	VFSS 27/40	VFSS avg. 1.52 days after BSE	Aspiration (n=4;10%)
Chaw et al., 2012(10) (Prospective)	68 M 57, F 11; 43; SD 17.2	Trauma and non-trauma	Complete 41%, Incomplete 59%	21/68 (31%)	VFSS 33/68	BSE avg. 31.8 days of injury, VFSS avg. 1.39 days after BSE	Aspiration (n=4; 6%)
Shem et al., 2012(11) (Prospective)	39 M 30, F 9; 41.6; SD 16.63	Trauma, 39	Not reported	15/39 (39%)	VFSS 26/39	BSE avg. 20.6 days of injury, VFSS avg. 1.58 days after BSE	Aspiration (n=4; 10%)

[1]Time between the onset of tetraplegia symptoms and instrumental assessment. [2]Incidence of aspiration or penetration if reported in an original article. The incidence percentage is calculated in relation to the whole study population. Abbreviations: AIS = ASIA Impairment Scale; AIS A = complete injury, AIS B–D = incomplete injury;

Frankel score = Frankel classification grading system for acute spinal injury; TA = complete injury; TB–TD = incomplete injury, TE = normal motor function; VFSS = videofluoroscopic swallowing study; FEES = fiberoptic endoscopic evaluation of swallowing; BSE = bedside swallow evaluation; M = male; F = female.

Table 2 The characteristics of the study sample (n=46)

Gender	
Male	**39 (85%)**
Female	**7 (15%)**
Age at the time of injury (years)	
Mean (SD)	**62.1 (13.3)**
Median (min.–max.)	**64.0 (25.7–91.6)**
Injury mechanism	
Sport	**2 (4%)**
Assault	**0 (0%)**
Transport	**7 (15%)**
Fall	**36 (78%)**
Unknown	**1 (2%)**
Neurological category	
Ventilator dependent	**7 (15%)**
C1–C4 AIS A, B, C	**11 (24%)**
C5–C8 AIS A, B, C	**1 (2%)**
All AIS D	**26 (57%)**
Unknown	**1 (2%)**
Time from injury to AIS classification (days)	
Mean (SD)	**22.4 (28.6)**
Median (min.–max.)	**7 (1–130)**
Method of surgical treatment	
Anterior approach	**24 (52%)**
Posterior approach	**10 (22%)**
Multiple surgeries	**7 (15%)**
No surgery	**5 (11%)**
Tracheostomy at the time of VFSS	**6 (13%)**
Nasogastric tube at the time of VFSS	**21 (46%)**
Hard collar at the time of VFSS	**6 (13%)**

Table 3 Rosenbek's Penetration-Aspiration Scale scores (n=46). The original Rosenbek's PAS is reprinted with permission.

Category	Score	Description	n (%)
	PAS 1	Material does not enter the airway.	12 (26%)
Penetration	PAS 2	Material enters the airway, remains above the vocal folds, and is ejected from the airway.	12 (26%)
	PAS 3	Material enters the airway, remains above the vocal folds, and is not ejected from the airway.	4 (9%)
	PAS 4	Material enters the airway, contacts the vocal folds, and is ejected from the airway.	0 (0%)
	PAS 5	Material enters the airway, contacts the vocal folds, and is not ejected from the airway.	3 (7%)
Aspiration	PAS 6	Material enters the airway, passes below the vocal folds, and is ejected into the larynx or out of the airway.	0 (0%)
	PAS 7	Material enters the airway, passes below the vocal folds, and is not ejected from the trachea despite effort.	4 (9%)
Silent aspiration	PAS 8	Material enters the airway, passes below the vocal folds, and no effort is made to eject.	11 (24%)

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Clinical Study

Risk factors for laryngeal penetration-aspiration in patients with acute traumatic cervical spinal cord injury

Tiina Ihalainen, MA[a,b,*], Irina Rinta-Kiikka, MD, PhD[c], Teemu M. Luoto, MD, PhD[d], Tuomo Thesleff, MD, LicMed[d], Mika Helminen, MSc[e,f], Anna-Maija Korpijaakko-Huuhka, PhD[b], Antti Ronkainen, MD, PhD[d]

[a]*Department of Neurosciences and Rehabilitation, Tampere University Hospital, PO Box 2000, Tampere FI-33521, Finland*
[b]*Faculty of Social Sciences, University of Tampere, Kalevantie 4, Tampere FI-33014, Finland*
[c]*Department of Radiology, Medical Imaging Centre of Pirkanmaa Hospital District, Tampere University Hospital, PO Box 2000, FI-33521 Tampere, Finland*
[d]*Department of Neurosurgery, Tampere University Hospital, PO Box 2000, Tampere FI-33521, Finland*
[e]*Science Center, Tampere University Hospital, PO Box 2000, Tampere FI-33521, Finland*
[f]*Health Sciences, Faculty of Social Sciences, University of Tampere, P.O. Box 100, Tampere FI-33104, Finland*

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Abstract

BACKGROUND CONTEXT: Laryngeal penetration-aspiration, the entry of material into the airways, is considered the most severe subtype of dysphagia and is common among patients with acute cervical spinal cord injury (SCI).

PURPOSE: The aim of this study was to investigate risk factors for penetration-aspiration in patients with acute traumatic cervical spinal cord injury (TCSCI).

STUDY DESIGN: This is a prospective cohort study.

PATIENT SAMPLE: Thirty-seven patients with TCSCI were included in the study.

OUTCOME MEASURES: The highest Rosenbek penetration-aspiration scale (PAS; range 1–8) score of each patient was the primary outcome measure. The risk factors consisted of patient characteristics, demographics, and clinical signs observed during a clinical swallowing trial.

MATERIALS AND METHODS: A clinical swallowing trial and videofluoroscopic swallowing study (VFSS) was performed on all patients within 28 days post injury. For group comparisons, the patients were divided into two groups: (1) penetrator-aspirators (PAS score ≥3) and (2) non-penetrator-aspirators (PAS score ≤2).

RESULTS: Of the 37 patients, 83.8% were male. The mean age at the time of the injury was 61.2 years. Most patients had an incomplete TCSCI (78.4%) caused by a fall (75.7%). In the VFSS, 51.4% of the patients were penetrator-aspirators, and 71.4% had silent aspiration. The risk factors for predicting penetration-aspiration were (1) necessity of bronchoscopies, (2) lower level of anterior cervical operation, (3) coughing, throat clearing, choking related to swallowing, and (4) changes in voice quality related to swallowing. Binary logistic regression identified coughing, throat clearing, choking, and changes in voice quality related to swallowing as independent risk factors for penetration-aspiration.

CONCLUSIONS: The necessity of bronchoscopies, postinjury lower cervical spine anterior surgery, coughing, throat clearing, choking, and changes in voice quality related to swallowing was a marked

FDA device/drug status: Not applicable.

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* Corresponding author. Department of Neurosciences and Rehabilitation, Tampere University Hospital, PO Box 2000, Tampere FI-33521, Finland. Tel.: +358 331163328.

E-mail address: tiina.ihalainen@pshp.fi (T. Ihalainen)

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risk factor for aspiration and penetration following a cervical SCI. These factors and signs should be used to suspect injury-related pharyngeal dysfunction and to initiate preventive measures to avoid complications. The clinical swallowing evaluation is a relevant adjunct in the management of these patients and can improve the detection of penetration and aspiration.

Keywords: Deglutition; Dysphagia; Respiratory aspiration; Spinal cord injuries; Swallowing disorders; Trauma

Introduction

At the acute phase of a traumatic cervical spinal cord injury (TCSCI), normal swallowing function is often compromised. Early detection of possible dysphagia, especially laryngeal penetration-aspiration, is critical to secure safe nutrition and optimal pulmonary function. In TCSCI, the loss of innervation in respiratory muscles increases the risk of hypoventilation, atelectasis, and poor secretion management caused by the reduced ability to cough [1]. Protection of the lungs is also influenced by the ability to swallow safely and the ability to cough up an aspirated swallow. Generally, aspiration of food, liquids, or saliva is considered to be a risk factor for pneumonia [2,3]. Pneumonia can be a life-threatening complication in the acute phase of a spinal cord injury (SCI) [4,5], and the treatment of respiratory complications is also an economic burden [6]. In the acute phase of TCSCI, one important aspect is to detect and prevent these respiratory complications to optimize rehabilitation.

An improved understanding of the risk factors of laryngeal penetration-aspiration in this clinically demanding patient group could help minimize the possible negative consequences, that is, aspiration pneumonia, dehydration, and malnutrition. Furthermore, these actions could lower treatment costs and facilitate better recovery. The purpose of the present study was to investigate a wide range of potential pre-, peri-, and postinjury risk factors (including clinical signs assessed by a speech therapist) of laryngeal penetration-aspiration on videofluoroscopic swallowing study (VFSS). This generalizable study used a prospective sample of acute TCSCI patients.

Materials and methods

Patients and demographic data

The study population consists of a prospective cohort of 37 applicable patients with acute TCSCI admitted to the Tampere University Hospital from February 2013 to April 2015. Permission to conduct the present study was obtained from the Ethics Committee of Pirkanmaa Hospital District, Tampere, Finland. All patients provided a written informed consent according to the Declaration of Helsinki. A flowchart displaying the study process is presented in Fig. 1.

The variables used in the present study consisted of demographics-, injury-, and treatment-related variables, computed tomography findings, and observations of a speech therapist (TI) during a clinical swallowing trial. The primary outcome variable was the incidence of laryngeal penetration or aspiration as per the validated 8-point Rosenbek penetration-aspiration scale (PAS) [7] assessed during a VFSS. In detail, the demographics- and injury-related variables included gender, age at the time of injury, and injury mechanism (as per the International Spinal Cord Injury Core Data Set [8]). The completeness of the injury was defined according to the American Spinal Injury Association Impairment Scale (AIS) [9]. The mean time from the injury to the first AIS classification was 16.4 days (standard deviation [SD]=23.7, median=5.0, minimum [min]=1, maximum [max]=114).

The treatment-related variables consisted of the necessity of bronchoscopies, the necessity of tracheostomy, acute postinjury surgical procedures before the VFSS, specific levels and number of cervical levels operated, and whether an anterior fixation plate was used or not. The first available posttraumatic preoperative computed tomography images were evaluated for the incidence and level of fractures in the cervical vertebrae (TT).

The clinical swallowing trial

The clinical swallowing trial was performed on all enrolled patients (n=37) by a speech therapist as soon as practically possible after injury. The trial included the voluntary swallowing of different consistencies (thin liquid, thick liquid, and puree). At the beginning of the trial, the boluses were given with a teaspoon, and at the end of the trial, a 100 mL water swallow test was performed if possible. The trial was discontinued if signs of penetration-aspiration occurred. The swallowing trial variable set was adapted from Logemann et al. [10] The mean time from the injury to the clinical swallowing trial was 6.9 days (SD=5.7, median=4.0, min=1, max=23).

VFSS

The VFSS (Siemens Axiom Luminos DRF, Erlangen, Germany) was conducted within 28 days post injury on all 37 patients. The VFSS protocol included 5, 10, and 20 mL boluses of a thin, water-soluble contrast agent (Omnipaque 350 mgI/mL; GE Healthcare, Oslo, Norway). A metal coin (diameter 3 cm) was taped to the chin or the neck of the patient for measurement calibration. The VFSSs were evaluated for the following: the incidence of laryngeal penetration or

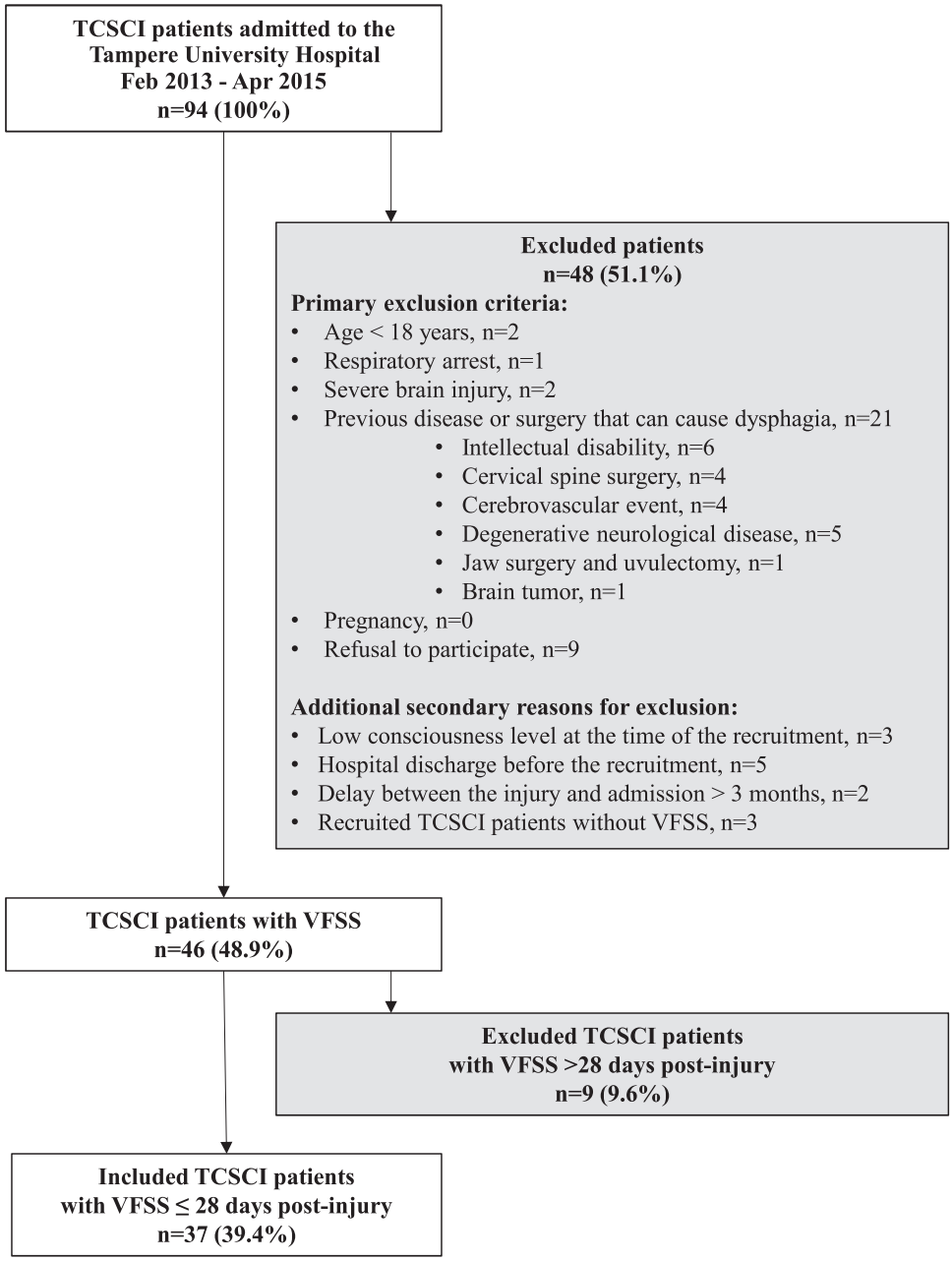

Fig. 1. Study process. TCSCI, traumatic cervical spinal cord injury; VFSS, videofluoroscopic swallowing study.

aspiration as per the validated 8-point Rosenbek PAS (TI and IR-K) and the thickness of the pharyngeal wall at the level of cervical vertebrae 3 and 6 to identify a possible prevertebral edema (IR-K). Given that normal adults are known to score 1–2 on the PAS, patients were considered to be penetrator-aspirators if they scored ≥3 on one or more swallows on the PAS [11–13]. The patient's worst (ie, highest) PAS score was used as the primary outcome measure. In regard to the normal pharyngeal wall thickness, the upper limits were set according to Rojas et al. [14] The mean time from the injury to the VFSS was 12.4 days (SD=7.5, median=11.0, min=2, max=28). The mean time from the clinical swallowing trial to VFSS was 5.5 days (SD=4.4, median=4.0, min=1, max=16).

Statistical analysis

The normality of the variable distributions was tested using the Kolmogorov-Smirnov and the Shapiro-Wilk tests. Group comparisons were tested with the Fisher exact test, the Pearson chi-square test, and the Mann-Whitney *U* test. Correlations were tested with the Spearman rank correlation coefficient. Variables with clinical interest and relevance (age [continuous],

AIS grade [complete or incomplete], anterior cervical surgery [yes or no], and coughing related to swallowing [yes or no]) were placed into a binary logistic regression model to determine eventual independent risk factors for penetration-aspiration. Odds ratios (ORs) were calculated with 95% confidence intervals (CIs). Among some variables there were missing data. We did not model or impute missing data. Statistical significance was set at 5% for all analyses. The Statistical Package for Social Sciences software program (IBM SPSS Statistics for Windows, Version 23.0; Armonk, NY, USA) was used to perform all the statistical analyses.

Results

Patients

In the VFSS, 51.4% of the patients showed laryngeal penetration-aspiration (PAS score ≥3 on one or more swallows) and the rest (48.6%) showed high penetration (PAS score 2) or no penetration-aspiration (PAS score 1). The distribution of the PAS scores is presented in Fig. 2.

As shown in Table 1, the only statistically significant difference between the penetrator-aspirators (n=19) and the non-penetrator-aspirators (n=18 patients) was the necessity for bronchoscopy (p=.042, OR=9.9, 95% CI=1.1–91.5); there were no other significant differences for the other variables. Note that the penetrator-aspirators more often had cervical spine fractures and higher numbers of fractured vertebrates.

Postinjury cervical spine surgery

Surgery was performed on 28 patients (75.7%) before the VFSS: the duration from the injury to the first surgery had a mean of 1.9 days (SD=1.3, median=2.0, min=0, max=6), whereas the duration to the secondary surgery had a mean of 4.3 days (SD=1.7, median=4.5, min=2, max=6). Table 2 shows the detailed summary of the surgical procedures. The lower level of anterior operation was the single factor that differed statistically significantly between these groups (p=.050, OR=6.1, 95% CI=1.1–33.2).

Clinical swallowing trial

As shown in Table 3, coughing (p=.007, OR=9.1, 95% CI=2.0–41.4) and changes in voice quality (p=.004, OR=13.0, 95% CI=2.2–77.3) related to swallowing differed statistically significantly between the groups.

Independent risk factors of penetration-aspiration

To determine independent risk factors for penetration-aspiration, we placed independent variables with clinical interest and relevance (age [continuous], AIS grade [complete or incomplete], anterior cervical surgery [yes or no], coughing and changes in voice quality related to swallowing [yes or no]) into a binary logistic regression model. The results of the three different models are summarized in Table 4. Coughing and changes in voice quality were independently associated with penetration-aspiration.

Discussion

To our knowledge, the current study is the first that focuses on the risk factors and the clinical signs of laryngeal penetration-aspiration at the acute phase in patients with TCSCI. Two risk factors and two clinical signs for penetration-aspiration were identified in our acute TCSCI cohort: the necessity of bronchoscopies and the lower level of anterior operation. The clinical signs were coughing, throat clearing, choking, and changes in voice quality related to swallowing.

Previous studies focusing on SCI have presented some risk factors for dysphagia, for example, age [15–19], tracheostomy

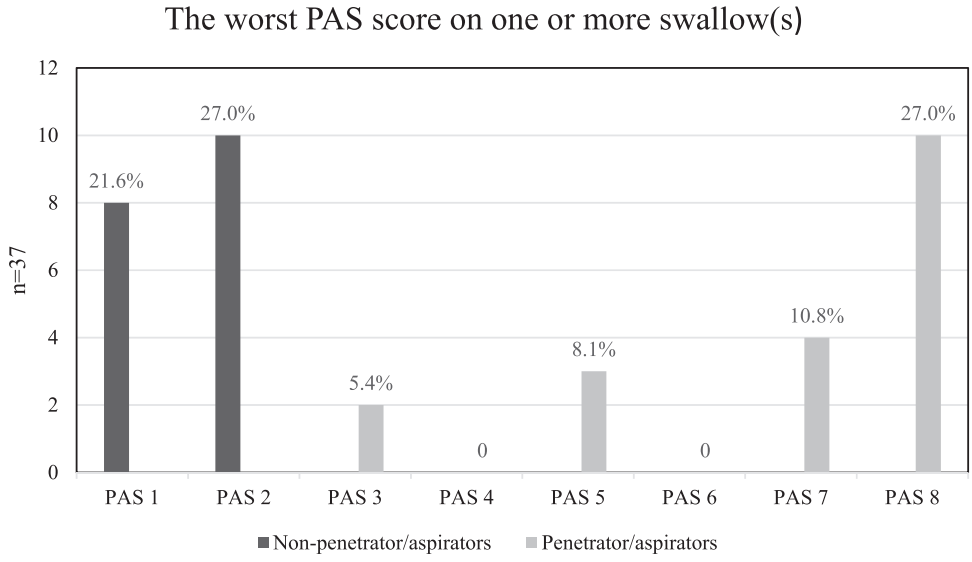

Fig. 2. Distribution of the Rosenbek penetration-aspiration scores. PAS, penetration-aspiration scale.

Table 1
Group comparisons between penetrator-aspirators (n=19) and non-penetrator-aspirators (n=18) on demographics-, injury-, and treatment-related and radiological variables

Variable	Penetrator-aspirators	Non-penetrator-aspirators	p-Value
Patient (n)	19	18	
Gender			.090
Male	18 (94.7%)	13 (72.2%)	
Female	1 (5.3%)	5 (27.8%)	
Age at the time of injury (y)			.940
Mean (SD)	59.3 (15.7)	63.2 (13.1)	
Median (min–max)	64.7 (25.7–87.7)	61.9 (35.1–91.6)	
Injury mechanism			1.000
Sport	1 (5.3%)	1 (5.6%)	
Assault	0 (0%)	0 (0%)	
Transport	3 (15.8%)	3 (16.7%)	
Fall	14 (73.7%)	14 (77.8%)	
Unknown	1 (5.3%)	0 (0%)	
AIS impairment scale			.331
AIS A	3 (15.8%)	5 (27.8%)	
AIS B	3 (15.8%)	0 (0%)	
AIS C	3 (15.8%)	2 (11.1%)	
AIS D	10 (52.6%)	11 (61.1%)	
The AIS level of injury			1.000
Upper (C1–C4)	16 (84.2%)	16 (88.9%)	
Lower (C5–C8)	2 (10.5%)	2 (11.1%)	
Unknown	1 (5.3%)	0 (0%)	
Tracheostomy	4 (21.1%)	1 (5.6%)	.340
Bronchoscopies≥1	7 (36.8%)	1 (5.6%)	.042*
Prevertebral edema at the time of VFSS			
C3>7 mm	17 (89.5%)	15 (83.3%)	.660
C6>18 mm	3 (15.8%)	2 (11.1%)	1.000
Unknown (C6)	1 (5.3%)	1 (5.6%)	
Cervical spine fracture	15 (79.0%)	10 (55.6%)	.170
The level of cervical fracture			
Upper (C0–C2)	2 (10.5%)	1 (5.6%)	1.000
Lower (C3–C7)	14 (73.7%)	9 (50.0%)	.184
The number of fractured vertebrae			.428
1 Vertebra	6 (31.6%)	6 (33.3%)	
>1 Vertebrate	9 (47.4%)	4 (22.2%)	

AIS A, complete injury; AIS B–D, incomplete injury; AIS, American Spinal Injury Association Impairment Scale; VFSS, videofluoroscopic swallowing study.

* Statistically significant, $p < 0.05$.

Table 2
Group comparisons between operated penetrator-aspirators (n=16) and non-penetrator-aspirators (n=12) on surgical details

Variable	Penetrator-aspirators	Non-penetrator-aspirators	p-Value
Cervical spine operation			
Yes	16 (84.2%)	12 (66.7%)	.269
No	3 (15.8%)	6 (33.3%)	
The number of operations			.428
1	13 (81.3%)	9 (75.0%)	
≥2	3 (18.8%)	3 (25.0%)	
The number of operated levels			1.000
≤2	14 (87.5%)	10 (83.3%)	
>2	2 (12.5%)	2 (16.7%)	
The number of anterior operations	15 (93.8%)	8 (66.7%)	.104
The level of anterior operation			
Upper (C1–C4)	7 (43.8%)	3 (25.0%)	.434
Lower (C5–Th1)	13 (81.3%)	5 (41.7%)	.050*
Anterior fixation plate	14 (87.5%)	7 (58.3%)	.103

* Statistically significant, $p < 0.05$.

Table 3
Group comparisons between penetrator-aspirators (n=19) and non-penetrator-aspirators (n=18) on the clinical swallowing trial variables

Variable	Penetrator-aspirators	Non-penetrator-aspirators	p-Value
Patient (n)	19	18	
Coughing, throat clearing, and choking	14 (73.7%)	5 (27.8%)	.007*
Unknown (tracheostomy)	1 (5.3%)	0 (0%)	
Changes in voice quality	13 (68.4%)	6 (33.3%)	.004*
Unknown (tracheostomy)	4 (21.1%)	0 (0%)	
Delayed pharyngeal swallow	0 (0%)	2 (11.1%)	.230
Reduced or inconsistent laryngeal elevation	10 (52.6%)	12 (66.7%)	.737
Unknown	1 (5.3%)	0 (0%)	
Multiple (≥3) swallows per bolus	8 (42.1%)	2 (11.1%)	.060
Unknown	1 (5.3%)	0 (0%)	

* Statistically significant, $p < 0.05$.

[15–24], mechanical ventilation [15,18,19,22,24], the completeness of SCI [15,21], the level of injury [15,21–23,25], and cervical surgery [15,20]. In contrast, some studies found no association between dysphagia and age [20,21,23,25], dysphagia and mechanical ventilation [17], dysphagia and the level of completeness of the injury [16–19,24], and dysphagia and cervical surgery [16,17,19,21–23]. The prior literature is contradictory possibly because of the heterogeneity in diagnostic criteria of dysphagia, the data collection methodology, and the enrolled patient populations. In addition, many studies have focused on only a subgroup of potential risk factors. Therefore, it is difficult to draw firm and generalizable conclusions based on these studies. However, it seems that tracheostomy is the most agreed upon dysphagia risk factor among SCI patients [15–24].

Risk factors

No association between age and penetration-aspiration was found in the present study. Nevertheless, the relation between higher age and increased incidence of swallowing problems in general is well described in the literature [26,27]. Furthermore, cervical injury epidemiology is changing, and currently, both injury rate and age are increasing [28–30]. Thus, it would be premature to exclude an association between age and penetration-aspiration based on our findings.

It is somewhat surprising that we found no association between the completeness or the level of SCI and penetration-aspiration. These results differ from some published studies [15,21,23,25] but are consistent with some others [16–19,24]. These controversies can be at least partly explained by differences in the study design and in the methodology (eg, delays between injury and different assessments, and the method of injury ascertainment).

Table 4
Three binary regression model summaries assessing risk factors for penetration-aspiration

	Bivariate analysis	
Variable	OR (95% CI)	p-Value
Model 1		
Nagelkerke R^2 0.450		
Age (y)	0.99 (0.93–1.05)	.680
AIS grade (complete or incomplete)	0.29 (.03–3.07)	.306
Anterior cervical operation	4.73 (0.63–35.46)	.131
Coughing	14.20 (2.21–91.22)	.005*
Model 2		
Nagelkerke R^2 0.486		
Age (y)	0.97 (0.90–1.05)	.492
AIS grade (complete or incomplete)	0.60 (.06–5.69)	.659
Anterior cervical operation	4.01 (0.48–33.80)	.202
Changes in voice quality	20.93 (2.53–173.01)	.005*
Model 3		
Nagelkerke R^2 0.673		
Age (y)	0.95 (0.86–1.05)	.329
AIS grade (complete or incomplete)	2.50 (0.21–29.89)	.470
Anterior cervical operation	10.67 (0.59–193.10)	.109
Coughing	26.63 (1.48–477.12)	.026*
Changes in voice quality	47.30 (2.29–975.18)	.012*

CI, confidence interval; OR, odds ratio; AIS, American Spinal Injury Association Impairment Scale.

* Statistically significant, $p < 0.05$.

Contrary to earlier studies [15–24], we did not find tracheostomy to be a statistically significant risk factor for penetration-aspiration. Interestingly, we found an association between the necessity of bronchoscopies and penetration-aspiration. However, this finding is not supported by previous literature [17,18,24]. Again, this discrepancy can be related to variability in study methodology. In general, it is reasonable to hypothesize that patients with penetration-aspiration require more often bronchoscopies for the therapeutic management of aspiration and excess bronchial secretion.

Postinjury cervical surgery has been consistently documented as a risk factor for swallowing problems [31–34]. We found that only C5- to Th1-level anterior operation increased the risk of penetration-aspiration. Statistically, the same association was not evident as all cervical operations were examined in relation to penetration-aspiration.

Clinical signs

Coughing, throat clearing, choking, and changes in voice quality related to swallowing were statistically significant clinical signs for penetration-aspiration. Nevertheless, it is important to bear in mind that patients with TCSCI often have a reduced ability to cough. In our study, the clinical swallowing evaluation was performed by one speech therapist (TI) experienced in patients with TCSCI. A cervical auscultation was used to detect every effort to cough, to clear the throat, or to choke and to detect changes in voice quality related to swallowing in patients with a tracheostomy or a reduced ability to cough voluntarily. Some of the clinical signs could have been missed without the cervical auscultation. The association between the clinical signs and penetration-aspiration has not been established in prior studies of this patient group. In general, coughing, throat clearing, choking, and changes in voice quality related to swallowing are well-accepted indicators of penetration-aspiration [10,35,36].

The limitations of the study

The major limitation of the present study is the small sample size. Considering the overall incidence of TCSCI in Finland, the number of recruited patients can still be seen as better than satisfactory. Furthermore, our sample is representative of the Finnish population [30]. The age, gender, and injury mechanism distributions of our study are comparable with the ones published by Koskinen and colleagues [30].

Secondly, the time frame between the clinical swallowing trial and the VFSS was delayed in some cases. As a note for future studies, fiberoptic endoscopic evaluation of swallowing would be a more suitable method for the first acute instrumental evaluation of this patient group.

Conclusions

The necessity of bronchoscopies, postinjury lower cervical spine anterior surgery, coughing, throat clearing, choking, and changes in voice quality related to swallowing is a marked risk factor for aspiration and penetration following a cervical SCI. These factors and signs should be used to suspect injury-related pharyngeal dysfunction and to initiate preventive measures to avoid complications. The clinical swallowing evaluation is a relevant adjunct in the management of these patients and can improve the detection of penetration and aspiration.

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Title: Traumatic Cervical Spinal Cord Injury: Recovery of Penetration/Aspiration and Functional Feeding Outcome

Running title: Recovery of Penetration/Aspiration

Tiina Ihalainen, MA
Department of Neurosciences and Rehabilitation, Tampere University Hospital, Tampere, Finland
Email: tiina.ihalainen@pshp.fi

Teemu M. Luoto, MD, PhD
Department of Neurosurgery, Tampere University Hospital, Tampere, Finland
Email: teemu.luoto@pshp.fi

Irina Rinta-Kiikka, MD, PhD
Medical Imaging Centre, Department of Radiology, Tampere University Hospital, Tampere, Finland
Email: irina.rinta-kiikka@pshp.fi

Antti Ronkainen, MD, PhD
Department of Neurosurgery, Tampere University Hospital, Tampere, Finland
Email: antti.ronkainen@pshp.fi

Anna-Maija Korpijaakko-Huuhka, PhD
Faculty of Social Sciences, University of Tampere, Tampere Finland
Email: anna-maija.korpijaakko-huuhka@uta.fi

Corresponding author:
Tiina Ihalainen
Tampere University Hospital
P.O. Box 2000
FI-33521
Tampere, Finland
Tel. +358 331163328

Keywords: trauma, spinal cord injuries, spinal injuries, dysphagia, deglutition, respiratory aspiration

Conflicts of Interest Statement

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ABSTRACT

Study design: Prospective cohort study.

Objectives: This prospective cohort study aims to evaluate the recovery of penetration/aspiration and functional feeding outcome in patients with acute TCSCI.

Setting: Tampere University Hospital, Tampere, Finland

Methods: Forty-six patients with TCSCI were enrolled. All the patients received speech therapeutic interventions based on their clinical needs and were examined with a videofluoroscopic swallowing study (VFSS) at enrollment. The incidence of VFSS-verified laryngeal penetration/aspiration according to Rosenbek's Penetration-Aspiration Scale (PAS) served as the primary outcome. The secondary outcome was the level of functional oral intake (as per the Functional Oral Intake Scale; FOIS). Based on the PAS results, the patients were divided into two groups: (i) penetrator/aspirators (PAS score ≥3) and (ii) non-penetrator/aspirators (PAS score ≤2). Follow-up VFS studies were primarily conducted on the patients with penetration/aspiration in prior VFS studies. The follow-up VFS studies were scheduled on the basis of clinical demand.

Results: Of the 46 patients, 48% had penetration/aspiration in the first VFSS. The second VFSS was conducted on 20 patients, of whom 6 patients (30%) had penetration/aspiration. The third VFSS was conducted on 9 patients. Of these, only two (22%) patients were still penetrator/aspirators. The majority (n=37, 88%) of the patients presented a total oral intake without restrictions at the time of the final follow-up. Only one patient (2%) was still tube-dependent with consistent oral intake.

Conclusion: Swallowing physiology in patients with TCSCI greatly improved during the first months after injury, and the number of penetrator/aspirators decreased progressively.

Keywords: trauma, spinal cord injuries, spinal injuries, dysphagia, deglutition, respiratory aspiration

INTRODUCTION

Dysphagia is a relatively common secondary complication in patients with a cervical spinal cord injury (CSCI). In previous studies, the incidence of dysphagia in CSCI has varied from 16% to 80% [1-11], and the incidence of aspiration verified by VFSS or fiberoptic endoscopic evaluation of swallowing (FEES) varied between 6% and 41% [2-4,6-11]. Studies focusing on CSCI have presented some risk factors for dysphagia, e.g., age [1,7-9,11], tracheostomy [1,3-11], mechanical ventilation [1,5,9-11], the completeness of the spinal cord injury (SCI)[1,4], the level of injury [1,2,4-6], and cervical surgery [1,3]. By contrast, some studies found no association between dysphagia and age [2-4,6], dysphagia and mechanical ventilation [8], dysphagia and the level or completeness of the injury [7,8,10], and dysphagia and cervical surgery [4-8,11]. Longitudinal reports on the rate and extent of recovery from swallowing dysfunction in patients with TCSCI are limited [2-4,6].

In this prospective study we aim to examine the temporal recovery of penetration/aspiration and functional feeding outcome in cohort of 46 patients with TCSCI. In addition, we report the summary of speech therapy interventions for the patients during the follow-up. Data for this study was collected as a part of routine multidisciplinary care at a university hospital that is focused on treating traumatic SCI patients. This current study is the third part of our research project that aims to improve knowledge on the incidence, risk factors and recovery trajectory of laryngeal penetration/aspiration of with patients with TCSCI in Finland. In our first study with the same cohort of patients as used in this current study, we reported the incidence of aspiration with PAS scores 7–8 to be 33 % and the incidence of penetration with PAS scores 2–5 to be 41% [12]. In our second study we reported the following risk factors for predicting penetration-aspiration in patients with TCSCI: (i) necessity of bronchoscopies; (ii) a lower level of anterior cervical operation; (iii) coughing, throat clearing, and choking related to swallowing; and (iv) changes in voice quality related to swallowing [13]. For the purposes of the second study, the patient cohort comprised of 37 out of 46 patients with VFSS conducted in 28 days post-injury.

METHODS

This study was performed with the approval of the Ethics Committee of Pirkanmaa Hospital District, Tampere, Finland. All patients provided written informed consent according to the Declaration of Helsinki. We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

Patients and Demographic Data

The study population consists of a prospective cohort of applicable patients with acute TCSCI admitted to the Tampere University Hospital from February 2013 to April 2015. In total, 94 consecutive patients were screened, and 46 (48.9%) patients were included in this study. The primary exclusion criteria included: (1) age <18 years; (2) respiratory arrest; (3) severe brain injury; (4) a prior medical condition causing dysphagia; (5) pregnancy; and (6) refusal to participate. Secondary reasons for exclusion were: (1) a low level of consciousness at enrollment; (2) discharge before recruitment; (3) a delay of three months or more between the injury and admission to the study hospital; and (4) a videofluoroscopic swallowing study (VFSS) not being performed. The study process is described in detail in our previous publication [12].

The following variables were recorded for all patients: gender; age at the time of injury; injury mechanism (as per the International Spinal Cord Injury Core Data Set [14]); length of stay (LOS) on the rehabilitation ward, a total number of speech therapy interventions during acute care and rehabilitation and timeframes between the injury and swallowing evaluations. The International Standards for Neurological Classification of Spinal Cord Injury was used to evaluate and classify the neurological consequences of the spinal cord injury [15,16]. The completeness of the injury was defined according to the American Spinal Injury Association Impairment Scale (AIS): AIS A = motor-sensory complete, AIS B = motor complete-sensory incomplete, or AIS C–D = motor-sensory incomplete.

VFSS

The first VFSS (Siemens Axiom Luminos DRF, Erlangen, Germany) was conducted on all 46 patients as soon as practically possible post-injury. Based on the Rosenbek's Penetration-Aspiration Scale (PAS) results, the patients were divided into two groups: (i) penetrator/aspirators (PAS score ≥3) and (ii) non-penetrator/aspirators (PAS score ≤2). Scores of 1 and 2 are considered functionally normal [17-19]. The follow-up VFS studies were primarily conducted on patients with penetration/aspiration (PAS score ≥3) evident in the prior VFSS. Additionally, a follow-up VFSS was conducted on seven non-penetrator/aspirators (PAS score ≤2) based on clinical needs. The second, third, and fourth VFS studies were scheduled based on clinical needs. The VFSS protocol included 5 ml, 10 ml, and 20 ml boluses of a thin, water-soluble contrast agent (Omnipaque 350 mgI/ml, GE Healthcare, Oslo, Norway). If severe aspiration occurred during the VFSS protocol with thin liquids, the research protocol was discontinued. For the patients who penetrated/aspirated, the VFSS was continued with thick liquid and puree to elaborate a dysphagia management plan. The VFSS protocol is described in our previous publication [12].

PAS

The primary outcome variable was the incidence of laryngeal penetration/aspiration on the VFSS as graded by the PAS [20]. The PAS is a validated 8-point scale that captures the depth of airway invasion and the patient's response to swallowing (± ejection of penetrated/aspirated material). The scale ranges from "no material entering the airway" (PAS=1) to "material entering the airway without a cough response" (PAS=8). The PAS scoring was conducted jointly by a speech therapist (TI) and a radiologist (IR-K).

FOIS

The secondary outcome variable was the level of functional oral intake as per the Functional Oral Intake Scale (FOIS) [21]. The FOIS is a validated 7-point tool for estimating and documenting change in functional eating abilities over time. The scale ranges from nothing by mouth (level 1) to total oral intake without

restrictions (level 7). The FOIS was initially designed for stroke patients, but it has also been widely used with other patient populations, e.g., traumatic brain injury, and head and neck cancer [22,23]. The FOIS was assessed by the first author based on medical records, a clinical evaluation, and the VFS studies.

Statistical Analysis

The Statistical Package for Social Sciences software program (IBM SPSS Statistics for Windows, Version 24.0, Armonk, NY, USA) was used to perform all the statistical analyses. Descriptive statistics [frequency (n), percentage, mean, standard deviation (SD), median, min/max] were used to calculate variable and subgroup characteristics. The normality of the variable distributions was tested using the Shapiro-Wilk test. Group comparisons were tested with the Fisher's exact test and Mann-Whitney U-test. Differences in the FOIS levels for the whole study sample were tested with the Wilcoxon Signed Rank Test. The statistical significance level was set at 5%. All statistical analyses were performed with the guidance of a statistician.

RESULTS

The Patients

In total, 46 out of 94 patients with TCSCI were included in this prospective study. Of the 46 patients, 85% were male. The mean age at the time of the injury was 62.1 years (median 64.0, min.–max. 25.7–91.6). Most patient had incomplete injury (78%). Details of the patients' demographic and injury characteristics are published in our previous study [12]. There were no statistically significant differences between the non-penetrator/aspirators and penetrator/aspirators in age (p=0.891, Mann-Whitney U-test), gender (p=0.418, Fisher's Exact Test), type of injury (complete vs. incomplete, p=1.000, Fisher's Exact Test), and time between injury and the first VFSS study (p=0.691, Mann-Whitney U-test).

The Incidence of Penetration/Aspiration

Of the 46 patients, 22 (48%) had penetration/aspiration (PAS score ≥3) in the first VFSS. The second VFSS was conducted on 20 patients, of whom 6 patients (30%) had penetration/aspiration. The third VFSS was conducted on 9 patients. Of these, only two (22%) patients were still penetrator/aspirators. One of them showed consistent penetration/aspiration in the fourth and fifth follow-up VFSS at 159 and 273 days post-injury. Based on a telephone interview, the other patient with prolonged aspiration/penetration returned to total oral intake without restrictions and the percutaneous endoscopic gastrostomy (PEG) tube was removed 264 days post-injury without a follow-up VFSS. The flowchart of the VFSS follow-ups and penetration/aspiration results are presented in Figure 1.

The FOIS Outcomes

Forty-two (91%) of the 46 patients were treated at the Tampere University Hospital's rehabilitation ward after the acute treatment. The mean duration of the first rehabilitation was 51.9 days (SD=33.3, median=45.0, min=7, max=123). The FOIS levels of these 42 patients after the first clinical evaluation and VFSS and at the time of the final follow-up are presented in Table 1. Differences in initial FOIS scores between the penetrator/aspirators and non-penetrator/aspirators were statistically significant (p=0.000, Mann-Whitney U-test). In addition, differences between the FOIS scores in the first clinical evaluation and the final follow-up were statistically significant for the whole sample (p=0.000, Wilcoxon Signed Ranks Test) and between subgroups (penetrator/aspirators vs. non-penetrator/aspirators) (p=0.000, Mann-Whitney U-test). The majority (n=37, 88%) of the patients had total oral intake without restrictions at the time of the final follow-up. Only one patient (2%) was still tube-dependent with consistent oral intake.

Of the 46 patients, four (9%) were not treated at Tampere University Hospital's rehabilitation ward after the acute treatment. One patient (2%) with a FOIS score of 1 died during the acute treatment and three patients (7%) with FOIS scores of 5, 2, and 1 were transferred to another hospital.

Detailed FOIS Results in Relation to Aspiration/Penetration Status

In total, 19 (86%) patients with penetration/aspiration in the first VFSS were treated at the rehabilitation ward and their detailed FOIS outcomes are presented in Table 2. After 63 days post-injury, half of the patients achieved a FOIS score of 7 indicating the return to an unrestricted diet.

Respectively, 23 (96%) non-penetrator/aspirators were treated at the rehabilitation ward. Twelve of them (52%) were able to start total oral intake without restrictions based on the first VFSS. However, two of them required follow-up VFS studies. One of them had laryngeal regurgitation and the other a right-sided recurrent laryngeal nerve paralysis and laryngeal retention. Despite these problems, both were able to return to total oral intake without restrictions.

Eleven (48%) of the non-penetrator/aspirators required some diet modification for a short period of time. The detailed FOIS outcomes for these 11 patients are presented in Table 3. As seen in Table 3, two patients (Cases 2 and 4) had a prolonged need for tube feeding and a modified diet. Both were able to start oral intake with a modified diet after the first VFSS and the nasogastric tubes were removed. Case 2 had anterior cervical surgery 72 days post-injury and was diagnosed with pneumonia two days post-surgery. Because of the pneumonia, Case 2 required intensive care and the nasogastric tube had to be replaced. Case 4 had anterior surgery 30 days post-injury, and a VFSS conducted two days post-surgery revealed aspiration. Case 4 eventually required a PEG.

Speech therapy interventions

All patients received speech therapeutic interventions based on their clinical needs. A post hoc analysis revealed that the difference in the number of speech therapy sessions between the penetrator/aspirators and non-penetrator/aspirators was statistically significant ($p=0.000$, Mann-Whitney U-test). The penetrator/aspirators ($n=19$) received on average 23 speech therapy sessions (SD=24, median=14, min=3, max=97). Each speech therapy session included one or more different interventions including (total number of interventions): (i) clinical evaluation (57 evaluations), (ii) VFSS (44 studies), (iii) FEES (27 evaluations), (iv) supervising the mealtime (37 sessions), (v) swallowing exercises without food (214 sessions), (vi)

swallowing exercises with food (241 sessions), (vii) counseling (9 sessions), and (viii) VitalStim®Therapy - trial (4 sessions).

Respectively, the non-penetrator/aspirators (n=23) received on average 5 speech therapy sessions (SD=6, median=3, min=2, max=31). Speech therapy interventions included (total number of interventions): (i) clinical evaluation (36 evaluations), (ii) VFSS (27 studies), (iii) FEES (3 evaluations), (iv) supervising the mealtime (20 sessions), (v) swallowing exercises with food (13 sessions), (vi) counseling (5 sessions), and (vii) voice therapy counseling (4 sessions).

DISCUSSION

The purpose of the current study was to evaluate the recovery of penetration/aspiration and functional feeding outcome in patients with acute TCSCI. The findings of this study suggest that the prognosis to recovery from a propensity for penetrating/aspirating is good in this cohort of patients with TCSCI as the majority of them achieved safe oral nutrition within the first few months post-injury. The generalizability of these results is, naturally, subject to certain limitations. Thus, similar results may not be gained in other clinical contexts. However, our study sample and results are considered to be representative of Finnish patients with acute TCSCI as they are based on a consecutive series of admitted patients with acute TCSCI.

In the existing literature, only a few studies have evaluated recovery from dysphagia after CSCI [2-4,6]. The methodological heterogeneity, however, makes it difficult to compare our results to prior findings. Our study sample consists of a consecutive series of adult patients with TCSCI recruited with rigorous exclusion criteria. Additionally, the mean age of the patients (62.1 years) in our study sample is higher than in former studies. For example, Wolf and Meiners [2] carried out a study of 51 patients (mean age 43.4 years) with heterogeneous CSCI etiologies. They reported that eight (16%) patients had a PEG tube at the end of the treatment, but only one of them was fully tube-dependent. In the course of their study, 27 out of 51 patients (53%) were followed by repeated fiberoptic endoscopic evaluation of swallowing (FEES). They reported that only three (6%) patients showed consistent severe dysphagia with danger of substantial aspiration based on

246 FEES. Respectively, Abel and colleagues [4] reported that six (8%) patients of their study population of 73
247 patients (children and adults, mean age 42.9 years) with heterogeneous CSCI etiologies had persistent
248 dysphagia and were discharged with PEG tubes. A retrospective study by Seidl and colleagues [6] reported
249 that ten (6%) of their study population (n=175, mean age 43.5 years) of patients with heterogeneous CSCI
250 etiologies were discharged with PEG tubes. They followed up 17 patients with repeated FEES. The third
251 FEES revealed that eight of them showed consistent aspiration. Another retrospective study by Brady and
252 colleagues [3] with 72 patients (mean age 55.5 years) reported that the mean level for ASHA NOMS
253 (American Speech-Language-Hearing Association National Outcomes Measurement System, levels 1-7) at
254 admission was 2.7 and at discharge 5.3. The level 5 indicates that all nutrition and hydration needs are met
255 by mouth with minimal diet restrictions.
256
257 Our findings highlight that the majority (88%) of our study patients had total oral intake without restrictions
258 at the time of the final follow-up. The differences between the FOIS scores in the first clinical evaluation and
259 the final follow-up were statistically significant for the whole study sample and between the subgroups
260 (aspirators/penetrator vs. non- aspirators/penetrator). Only one patient (2%) showed consistent severe
261 aspiration and was still tube-dependent with a consistent oral intake. Despite the methodological
262 heterogeneity, our findings seem to be in line with previous research. Nevertheless, it is important to note
263 that there are marked differences in patient selection and follow-up time points between these studies. Wolf
264 and Meiners [2], and Seidl and colleagues [6] did not report the length of stay in hospital or any time frames
265 for the follow-ups. Abel and colleagues [4] reported that their patients spent a median of 200 days in a
266 facility following the initial care. For our study patients, the mean duration of the first rehabilitation period
267 was 51.9 days.
268
269 A post hoc analysis revealed that the difference in the number of speech therapy sessions between the
270 penetrator/aspirators and non-penetrator/aspirators was statistically significant. It is reasonable to
271 hypothesize that patients with penetration/aspiration require more speech therapeutic interventions than
272 patients without penetration/aspiration. However, it is important to bear in mind that dysphagia is a broader
273 phenomenon. In our study sample nearly half (48%) of the non-penetrator/aspirators required some diet

modification at the beginning of oral intake. Two of them had a special need for speech therapeutic follow-ups. Based on these findings, we consider it's important to continue speech therapeutic monitoring of this patient group at a low threshold during the acute phase and rehabilitation, even if the first VFSS does not indicate any penetration/aspiration.

Future research should concentrate on the investigation of the numerous factors that can influence ~~on~~ the recovery of penetration/aspiration and functional oral intake outcome in this patient group. Additionally, further studies regarding the role of penetration/aspiration in the incidence of pneumonia in the acute and post-acute settings would be worthwhile. Further, a future study investigating dysphagia in patients with non-traumatic CSCI would be highly worthwhile.

Limitations of the Study

The limitations of this study are the small sample size and the fact that the VFSS research protocol included only measured boluses (5 ml, 10 ml, and 20 ml) of a thin, liquid consistency. The small sample size restricts the statistical analyses and further limits the generalizability of the results. Secondly, we decided to focus on only VFSS findings of penetration/aspiration, although dysphagia is a much broader phenomenon. Finally, we were unable to implement VFSS monitoring in accordance with a predetermined schedule for patients participating in the study. Data for this study was collected prospectively during acute hospital care and rehabilitation.

CONCLUSIONS

This study suggests that the prognosis to recovery from a propensity for penetrating/aspirating is good in this cohort of patients with TCSCI, and majority of them will achieve safe oral nutrition within the first few months post-injury.

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

TI has received research grants from Maire Taponen säätiö, The Finnish Dysphagia Rehabilitation Association, and Finnish Association of Speech Therapists. TML declares that he has no conflict of interest. IR-K declares that she has no conflict of interest. AR declares that he has no conflict of interest. A-MK-H declares that she has no conflict of interest.

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AUTHOR CONTRIBUTIONS

TI contributed to the study design, data collection, data analysis, data interpretation, and article preparation. TML contributed to the data interpretation and article preparation. IRK contributed to the data collection and article preparation. A-MK-H contributed to the article preparation. AR contributed to the study design and article preparation.

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Figure legends

Figure 1. Timing and results of the VFSS follow-ups and penetration/aspiration.

Abbreviations: VFSS= videofluoroscopic swallowing study, PAS= Rosenbek's Penetration-Aspiration Scale, FOIS= Functional Oral Intake Scale, PEG= percutaneous endoscopic gastrostomy

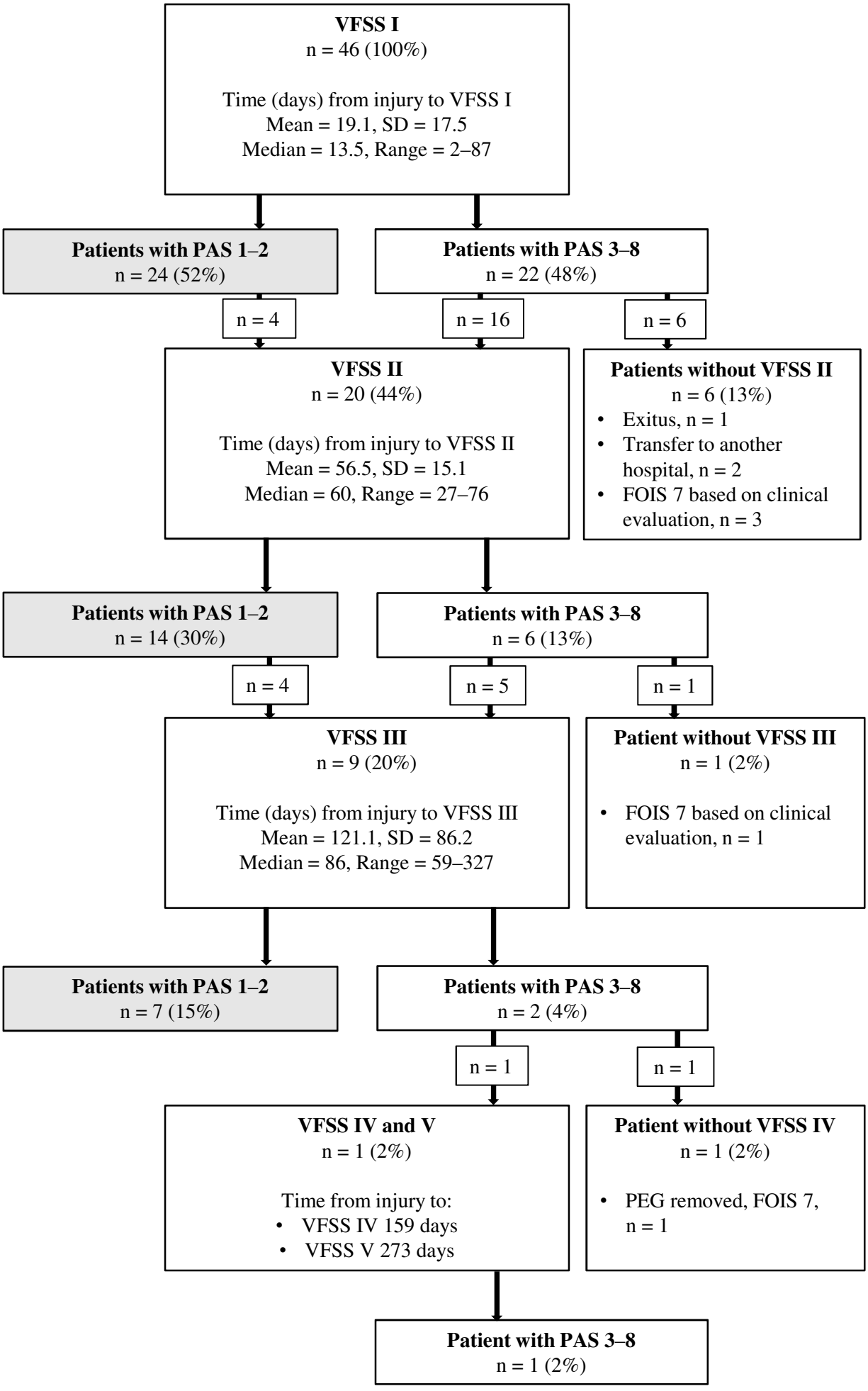
VFSS I
n = 46 (100%)
Time (days) from injury to VFSS I
Mean = 19.1, SD = 17.5
Median = 13.5, Range = 2–87
Patients with PAS 1–2
n = 24 (52%)
Patients with PAS 3–8
n = 22 (48%)
n = 4
n = 16
n = 6
VFSS II
n = 20 (44%)
Time (days) from injury to VFSS II
Mean = 56.5, SD = 15.1
Median = 60, Range = 27–76
Patients without VFSS II
n = 6 (13%)
• Exitus, n = 1
• Transfer to another hospital, n = 2
• FOIS 7 based on clinical evaluation, n = 3
Patients with PAS 1–2
n = 14 (30%)
Patients with PAS 3–8
n = 6 (13%)
n = 4
n = 5
n = 1
VFSS III
n = 9 (20%)
Time (days) from injury to VFSS III
Mean = 121.1, SD = 86.2
Median = 86, Range = 59–327
Patient without VFSS III
n = 1 (2%)
• FOIS 7 based on clinical evaluation, n = 1
Patients with PAS 1–2
n = 7 (15%)
Patients with PAS 3–8
n = 2 (4%)
n = 1
n = 1
VFSS IV and V
n = 1 (2%)
Time from injury to:
• VFSS IV 159 days
• VFSS V 273 days
Patient without VFSS IV
n = 1 (2%)
• PEG removed, FOIS 7, n = 1
Patient with PAS 3–8
n = 1 (2%)

Table 1. The FOIS levels (n=42) at the first clinical evaluation, the first VFSS, and at the time of the final follow-up in non-penetrator/aspirators (PAS scores 1-2) and penetrator/aspirators (PAS scores 3-8).

FOIS Level	First Clinical Evaluation		First VFSS		Final Follow-Up	
	PAS 1-2	PAS 3-8	PAS 1-2	PAS 3-8	PAS 1-2	PAS 3-8
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
FOIS 1	1 (2)	10 (24)	0 (0)	5 (12)	0 (0)	0 (0)
FOIS 2	4 (10)	5 (12)	2 (5)	8 (19)	0 (0)	0 (0)
FOIS 3	1 (2)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
FOIS 4	0	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
FOIS 5	5 (12)	4 (10)	8 (19)	6 (14)	1 (2)	0 (0)
FOIS 6	1 (2)	0 (0)	1 (2)	0 (0)	2 (5)	1 (2)
FOIS 7	11 (26)	0 (0)	12 (29)	0 (0)	20 (48)	17 (41)

Table 2. FOIS outcomes in detail for 19 patients with penetration/aspiration in the first VFSS and treated at the rehabilitation ward.

Case	Type of injury	Age (years)	Max PAS scores on VFSS			Decannulation (days post-injury)	Onset of FOIS 2 (days)	Onset of FOIS 3 (days)	Onset of FOIS 5-6 (days)	Onset of FOIS 7 (days)	Total number of speech therapy interventions
			I	II	III						
Case 1	incomplete	26	8	2	n/a	n/a	5	15	35	53	14
Case 2	incomplete	26	8	1	1	n/a	9	n/a	32	52	17
Case 3	incomplete	35	8	1	n/a	31	26	57	62	76	12
Case 4	complete	53	3	n/a	n/a	n/a	11	n/a	14	33	3
Case 5	incomplete	54	3	2	n/a	n/a	n/a	n/a	3	22	6
Case 6	incomplete	55	5	n/a	n/a	n/a	3	17	19	23	3
Case 7	incomplete	57	8	1	n/a	n/a	n/a	n/a	2	29	5
Case 8	incomplete	61	8	5	2	51	57	66	95	99	52
Case 9[a]	incomplete	65	7	2	7	n/a	19	47	n/a	264	26
Case 10	incomplete	65	5	1	n/a	n/a	12	31	33	69	27
Case 11	incomplete	67	8	n/a	n/a	n/a	2	9	12	45	10
Case 12	complete	68	3	3	n/a	71	36	94	112	137	23
Case 13[b]	complete	68	8	8	8	41	54	147	n/a	n/a	97
Case 14[c]	incomplete	69	7	5	n/a	23	28	88	116	327	56
Case 15	incomplete	70	5	1	n/a	n/a	n/a	n/a	1	29	5
Case 16	incomplete	70	7	5	2	n/a	20	57	59	121	50
Case 17[d]	incomplete	71	8	1	n/a	n/a	n/a	n/a	10	63	8
Case 18	incomplete	73	3	1	n/a	n/a	17	n/a	40	68	10
Case 19	incomplete	88	8	2	2	n/a	n/a	4	8	n/a	18

[a] Case 9: Final follow-up was done retrospectively via phone interview with the patient.

[b] Case 13: Patient showed consistent penetration/aspiration also in the fourth and fifth follow-up VFSS.

[c] Case 14: The final FOIS scores were assessed at a separate outpatient clinic visit afterwards.

[d] Case 17: Patient started with FOIS 7 post-injury. The anterior cervical operation was performed 6 days post-injury and after the operation, the patient showed aspiration in VFSS and needed diet modification. The final FOIS scores were assessed at a separate outpatient clinic visit afterwards.

Table 3. FOIS outcomes in detail for 11 patients with non-penetration/aspiration in the first VFSS and treated at the rehabilitation ward.

Case	Type of injury	Age (years)	Max PAS scores on VFSS			Decannulation (days post-injury)	Onset of FOIS 2 (days)	Onset of FOIS 3 (days)	Onset of FOIS 5-6 (days)	Onset of FOIS 7 (days)	Total number of speech therapy interventions
			I	II	III						
Case 1	incomplete	35	2	2	n/a	n/a	n/a	n/a	2	22	6
Case 2	complete	54	2	n/a	n/a	43	21	n/a	37 and 85	109	9
Case 3	incomplete	60	2	n/a	n/a	n/a	n/a	n/a	3	31	3
Case 4	complete	61	2	7	1	n/a	14 and 36	50	n/a	77	31
Case 5[a]	incomplete	61	1	n/a	n/a	n/a	n/a	n/a	3	n/a	2
Case 6	complete	63	1	n/a	n/a	n/a	n/a	n/a	5	21	4
Case 7	incomplete	65	1	n/a	n/a	n/a	6	n/a	9	13	4
Case 8	complete	69	1	n/a	n/a	n/a	n/a	n/a	3	10	3
Case 9	incomplete	77	1	n/a	n/a	n/a	2	5	7	12	3
Case 10	incomplete	85	2	n/a	n/a	n/a	n/a	n/a	2	n/a	4
Case 11[b]	incomplete	92	2	n/a	n/a	n/a	n/a	4	5	n/a	5

[a] Case 5: Poor dentition, therefore recommended FOIS 6.

[b] Case 11: Fatigue and pulmonary problems, exitus 46 days post-injury.