Received: 30 May 2023 | Revised: 22 February 2024 | Accepted: 11 March 2024

DOI: 10.1111/aas.14414

RESEARCH ARTICLE

acta Anaesthesiologica Scandinavica

Risk stratification-based thromboprophylaxis does not affect mortality after fast-track hip and knee arthroplasty

Annette M. Moisander[1] | Konsta Pamilo[2] | Jukka Huopio[3] | Hannu Kautiainen[4,5] | Anne Kuitunen[6] | Juha Paloneva[7]

[1]Department of Anesthesia and Intensive Care, Hospital Nova, Wellbeing Services County of Central Finland, Jyväskylä, Finland

[2]Coxa Hospital for Joint Replacement, Wellbeing Services County of Pirkanmaa, Tampere, Finland

[3]Department of Orthopaedics and Traumatology, Kuopio University Hospital, Wellbeing Services County of North Savo, Kuopio, Finland

[4]Primary Health Care Unit, University of Eastern Finland, Kuopio, Finland

[5]Finland and Folkhälsan Research Center, Helsinki, Finland

[6]Department of Intensive Care, Tampere University Hospital, Wellbeing Services County of Pirkanmaa, Tampere, Finland

[7]Department of Surgery, Hospital Nova, Wellbeing Services County of Central Finland, Jyväskylä and University of Eastern Finland, Kuopio, Finland

Correspondence
Annette M. Moisander, Anesthesiology and Intensive Care, Hoitajantie 3, 40620 Jyväskylä, Finland.
Email: annette.moisander@hyvaks.fi

Funding information
Finnish Arthroplasty Society; the Finnish Medical Research Foundation

Abstract

Background and Purpose: Use of thromboprophylaxis effectively prevents pulmonary embolism (PE) and deaths after total hip and knee arthroplasty (THA and TKA). The optimum length of thromboprophylaxis is not known and has traditionally been based on the type of operation. Nowadays, a more individualized approach is preferred. This study analyzed if risk stratification-based planning of thromboprophylaxis has an association with the all-cause mortality after fast-track THA and TKA.

Patients and Methods: We compared fast-track THAs and TKAs operated between 2015–2016 and 2020–2021. Between 2015 and 2016, all patients received a routine length of thromboprophylaxis. From 2020 onwards, thromboprophylaxis was planned by risk stratification, and patients at low risk for venous thromboembolism received thromboprophylaxis only during hospitalization. All causes of death within 90 days of surgery were identified and the incidence of mortality was calculated. Mortality rates between the two periods were then compared.

Results: Between 2015 and 2016, 3192 arthroplasties were performed. A total of eight deaths occurred within 90 days of surgery, yielding an incidence of all-cause mortality of 0.3% (95% CI 0.1–0.5). Between 2020 and 2021, a total of 3713 arthroplasties were performed to patients who received risk stratification-based thromboprophylaxis. Thirteen of these patients died within 90 days of surgery, yielding an all-cause mortality incidence of 0.4% (95% CI 0.2–0.6). Cardiovascular diseases were the main cause of death during both study periods. None of the deaths were caused by PEs.

A retrospective register study from Kuopio University Hospital, Kuopio and Hospital Nova, Jyväskylä, on how does risk stratification-based planning of thromboprophylaxis effect all-cause mortality after fast-track primary hip and knee arthroplasty.

Interpretation: Risk stratification-based thromboprophylaxis was not associated with increased all-cause mortality within 90 days of fast-track THA and TKA.

Editorial Comment

This study investigated the safety of adopting the recommendations for thrombosis profylaxis by the European Society of Anaesthesiology and Intensive Care, (ESAIC) after elective hip and knee arthroplasty. By comparing 3192 patients with 10–14 days LMWH treatments to 3713 patients with the risk-based ESAIC algorithm, including only treatment during hospitalization if low risk, the authors found no difference in mortality between groups (0.3% vs. 0.4%, respectively). These findings support the implementation of the novel guidelines.

1 | INTRODUCTION

Total hip and knee arthroplasties (THA and TKA) are performed to improve the quality of life of patients with advanced osteoarthritis (OA). The incidences of THA and TKA are currently increasing all over the world[1–4] due to population growth, aging, and obesity, leading to increased prevalence of THA and TKA.[5,6]

Although comorbidities in THA and TKA patients have increased, mortality incidence has decreased.[7,8] No consensus exists on the optimal follow-up period for postoperative mortality. A short follow-up period of 30 days is more likely to demonstrate surgery-related mortality and provide information on the quality of surgery. However, most studies report 90-day mortality despite the increasing effect of other factors when the follow-up period is longer.[9]

The use of thromboprophylaxis has diminished the 90-day incidence of venous thromboembolism (VTE) from 15%–30% to 2%.[10,11] VTEs consist of pulmonary embolism (PE) and deep venous thrombosis (DVT). PE can be lethal and is therefore feared complication after THA and TKA. However, no consensus exists on the best agent to use or the optimal length of thromboprophylaxis.[10,12–14] Recommendations vary from 10 to 14 days after TKA and 4–6 weeks after THA. Recommended agents include unfractionated heparin, low-molecular weight heparins (LMWH), antiplatelets, and direct oral inhibitors of coagulation. Questions have arisen, whether a more VTE risk and care protocol-based approach is needed?[15–17]

Fast-track protocols were designed to improve patient care and recovery.[18] Fast-tracking has been shown to decrease length of stay (LOS) without compromising quality of care.[15,16,19] Fast-tracking combined with thromboprophylaxis used only during hospitalization has not led to an increased mortality after THA and TKA.[17,20–22]

The aim of this study was to analyze the effect of risk stratification-based thromboprophylaxis protocol on all-cause mortality 90 days after fast-track THA and TKA.

2 | METHODS

2.1 | Patients

This retrospective register-based study comprised two separate data collections. The first of these included all the TKAs and THAs performed at Kuopio University Hospital, Kuopio and Hospital Nova, Jyväskylä Finland, from January 1, 2015, to December 31, 2016. These hospitals had implemented a fast-track protocol in early 2010s. The fast-track protocol included standardized information on surgery, postoperative care, and discharge criterions to home, standardized opioid-sparing anesthesia and postoperative pain management, avoidance of drains and urinary catheters, at least one dose of intravenous tranexamic acid to diminish blood lose and early mobilization on the day of the surgery. During the study period, the hospitals administered long thromboprophylaxis with rivaroxaban or enoxaparin after THA and TKA: 10–14 days for TKAs and 4–6 weeks for THAs. Patients with permanent anticoagulation medication returned to their own anticoagulation medicine as soon as possible.

The second data collection comprised all TKAs and THAs performed from January 1, 2020, to December 31, 2021, in the same hospitals. From 2020 onwards, these hospitals changed their thromboprophylaxis protocol based on the European guidelines on perioperative VTE prophylaxis for day surgery and fast-track by the European Society of Anaesthesiology and Intensive Care, ESAIC (previously known as the European Society of Anaesthesiology, ESA).[14] According to this guideline, thromboprophylaxis can be limited to hospital stay in low VTE-risk patients if LOS is 5 days or less. The new risk stratification-based thromboprophylaxis assessment is based on patients' individual minor and major risks for VTE. Major risks are active cancer or cancer in treatment, previous VTE or VTE of a 1st degree family member, a hereditary clotting disorder, and operation time over 120 min. Minor risk are age >60 years, body mass index >40, immobilization (not walking) before surgery and chronic venous insufficiency (Table 1). If a fast-track THA or TKA patient presents no major risks or only one minor risk, thromboprophylaxis can be limited to the period of hospitalization providing the patient is discharged home within 5 days of surgery. For high-risk patients with one major or at least two minor risks, VTE prophylaxis is recommended for 10–14 days after both THA and TKA. For patients with extreme high VTE risk thromboprophylaxis can be extended to last for 4 weeks. The recommended anticoagulants were rivaroxaban and tinzaparin. Patients were to return to their regular anticoagulation as soon as possible after surgery or after termination of postoperative thromboprophylaxis.

TABLE 1 Risks for venous thromboembolism.

Major risk	Minor risk
Active cancer or cancer in treatment	Age >60 years
Previous venous thromboembolism	Body mass index >40
Venous thromboembolism in 1st degree family members	Immobilization before surgery (nonwalking)
Operation time >120 min	Chronic venous insufficiency
Hereditary clotting disorder	

During both data collections, patients using permanent anticoagulation were instructed to suspend their anticoagulation medication before the operation to ensure the safety of spinal anesthesia. The length of suspension was determined by the agent used. If needed, antiplatelet agents were substituted by acetylsalicylic acid products. Bridging was used if patients had a hereditary clotting syndrome or mechanical heart valve. None of the study hospitals had consistent use of compression stockings or mechanical thromboprophylaxis during data collection periods.

All THA and TKA patients aged 18 years or older were identified from the Finnish Arthroplasty Registry (FAR) maintained by the National Institute for Health and Welfare for each of the two time periods.[23] Arthroplasties were identified by the Nordic Medico-Statistical Committee (NOMESCO) codes for primary THA and TKA (Appendix A).

This dataset was then combined with data from the Finnish Hospital Discharge Register (FHDR) maintained by National Institute for Health and Welfare. The FHDR data included information about hospital visits, including diagnoses related to these visits, and dates of death reported to the FHDR from the Population Information System maintained by the Population Register Centre. If a death had occurred within 90 days of surgery, both primary and immediate causes were obtained from Statistics Finland.

2.2 | Statistics

Descriptive statistics are presented as means (standard deviation [SD]), medians (interquartile range [IQR]) or counts (%). All-cause mortality incidence was estimated assuming a Poisson distribution with a confidence interval (CI) of 95%. Statistical comparison between the study periods was performed using the Fisher–Freeman–Halton test. Stata 17.1 (StataCorp LP; College Station, TX, USA) was used for all statistical analyses.

2.3 | Ethics

Permissions to perform this study were obtained from the National Institute for Health and Welfare and Statistics Finland. According to Finnish legislation, ethical permission is not required to perform a registry study using only anonymous data.

TABLE 2 Distribution of all causes of death.

	2015–2016	2020–2021
	(*N* = 8), *N* (%); [95% CI]; ICD-10 codes	(*N* = 13), *N* (%); [95% CI]; ICD-10 codes
Cardiovascular	4 (50); [16–84]; I21.9, I25.1, I51.7	7 (54); [25–81]; I25.1, I21.9, I12.0, I11.0, I61.5, I69.3
Neoplasm	0 (0); [0–37][a]	3 (23); [5–54]; C61.0, C80.0
Others	2 (25); [3–65]; M17.0, M17.9	1 (8); [0–36]; M87.8
Digestive system	2 (25); [3–65]; K56.5, K57.2	1 (8); [0–36]; K56.5
Accidental	0 (0); [0–37][a]	1 (8); [0–36]; W20

[a]One-sided, 97.5% confidence interval.
Abbreviation: ICD-10, International Statistical Classification of Diseases and Related Health Problems 10th Revision.

3 | RESULTS

During the 2015–2016 study period, 3192 hip and knee arthroplasties were performed, of which 43% were TKAs and 57% THAs. Mean patient age was 68 years (SD 10), and 60% (1903) of the patients were female and 40% (1289) male. The main indication for surgery was either primary or secondary OA, 2745 (86%). Mean LOS was 4 (SD 1) days.

During the 2015–2016 study period, eight deaths occurred within 90 days of surgery. The incidence of 90-day postoperative all-cause mortality was 0.3% (CI 0.1–0.5), for THA 0.1% (CI 0.0–0.4), for TKA 0.4% (CI 0.2–0.8). Of these eight deaths, 3 (38%) occurred to female patients. Half of the deaths were due to cardiovascular disease followed by gastrointestinal and other reasons (Table 2). There were no deaths due to VTE or bleedings.

During the 2020–2021 study period, 3713 arthroplasties, of which 44% were THAs and 56% TKAs, were performed. Mean patient age was 68 years (SD 10) and 59% (2191) of the patients were females and 41% (1522) were male. The main indication for surgery was the same as in the first study period, that is, primary, or secondary OA, 3304 (89%). Mean LOS was 2 days (SD1).

During the second study period, 13 deaths occurred within 90 days of surgery. The incidence of all-cause mortality was 0.4% (CI 0.2–0.6), 0.6 (CI 0.2–1) for THA and 0.1 (CI 0.0–0.3) for TKA. Of these 13 deaths, only 2 (15%) were female patients. The most common causes of death were cardiovascular disease neoplasms (Table 2). There were no deaths due to PE but there was one death due to intracerebral bleeding.

During the 2015–2016 study period, most common causes of death were cardiovascular diseases, including atherosclerotic heart disease, myocardial infarction, and cardiopathy. These were followed by two cases of intestinal perforations and knee arthrosis. The immediate causes of death for the two cases of knee arthrosis were pneumonia. Five years later, atherosclerotic heart disease remained the

leading cause of cardiovascular deaths, followed by arterial hypertension and myocardial infarction. There was one death due to intracerebral bleeding. The most frequent cause of death related to the digestive system was intestinal perforation. The most prevalent cause of death from neoplasms was prostate cancer. Additionally, there was one accidental death and one death due to osteonecrosis, with pneumonia being the immediate cause of death in the osteonecrosis case. There was no statistically significant difference in the distribution of all causes of death between the study periods ($p = .34$).

4 | DISCUSSION

This study showed that all-cause mortality within 90 days of surgery is low among Finnish fast-track THA and TKA patients even when thromboprophylaxis is based on VTE risk stratification No deaths occurred due to PE or VTE, meaning that the length of thromboprophylaxis can safely be as short as the LOS if not more than one minor risk factor exists. Neoplasms and cardiovascular diseases were the most common causes of death.

Our finding of an all-cause mortality incidence of 0.4% 90 days after fast-track hip and knee arthroplasty when risk stratification-based thromboprophylaxis is used after fast-track THA and TKA is at the same level than that reported by Jørgensen et al.[22] They analyzed 13,775 arthroplasties performed in eight fast-track centers in Denmark during 2010–2013 to patients without permanent anticoagulation and reported an all-cause mortality incidence of 0.3% (CI 0.2–0.4). The fast-track protocol used in their study was like ours but, thromboprophylaxis was administered only during hospitalization if LOS was 5 days or less. If LOS was longer than 5 days, thromboprophylaxis was extended to last at least 10–14 days.

Large meta-analyses and reviews of nonfast-track THA and TKA patients receiving thromboprophylaxis based on operation type have reported similar findings. Berstock et al.,[24] who analyzed 32 studies published between 2003 and 2013, reported mortality results following hip replacements. These studies, comprising a total of 1,129,330 THAs, found a pooled 90-day mortality incidence of 0.7% for THA. Four years later, Berstock et al.[25] published a meta-analysis of 37 studies of knee replacements, comprising a total of 1,753,449 TKAs, in which the pooled 90-day mortality incidence was 0.4%.

Our study found little change in the incidence of 90-day all-cause mortality between the two study periods even after the thromboprophylaxis planning protocol changed to risk stratification-based treatment and the length of thromboprophylaxis was shortened for low VTE-risk patients. For these patients thromboprophylaxis was limited to the period of hospitalization providing their LOS was 5 days or less. Thus, the length of thromboprophylaxis for low VTE-risk patients was significantly shorter in the later than earlier study period when all THA patients received thromboprophylaxis at least for 4 weeks and TKA patients for 10 days. This reduction may also affect bleeding complications. Among Finnish fast-track THA and TKA patients receiving longer thromboprophylaxis after THA and TKA 1% of patients suffered from bleeding complications.[26] While most bleeding complications occur at the operative site and are not fatal, they cause discomfort and pain and delay healing and rehabilitation after surgery.

A larger register study of more than 360,000 THA and TKA patients has shown that the incidence of PEs has decreased, especially after TKAs over the years.[27] This decrease of PE incidence potentially explains the missing fatal PEs in our study. Other explanations might be better awareness of medical personnel and patients of PE symptoms, leading to earlier diagnosis and treatment of PE. Easier and earlier diagnosis of DVT has been facilitated due to increased availability of Doppler ultrasonography at point of care.[28,29]

The common cause of mortality during both study periods was cardiovascular disease, accounting for at least 50% the deaths.[30] There were no deaths due to neoplasms during the first study period; however, in the second study period neoplasms accounted for 23% of deaths. According to Statistics Finland, cardiovascular diseases and neoplasms were the main causes of death in the general population during both study periods.[30] Similar findings have been reported from the National Joint Registry for England, Northern Ireland, and the Isle of Man by Hunt et al.[31]

There was a difference in distribution of causes of death between study periods. However, the confidence intervals overlapped, indicating no statistical difference in the distribution of all causes of death between the study periods.

The strength of our study is that it was real-life population-based and there was no patient selection in the study hospitals. All patients aged 18 years or older who were operated during the periods studied were included. Thus, this study includes patients on permanent anticoagulation and patients with bleeding disorders. Patients with bleeding disorders might have received mechanical thromboprophylaxis after operation. This can be questioned because we cannot present results separately for high and low VTE risk patients. However, this kind of register-based study protocol makes it difficult to do an adequate exclusion of permanent anticoagulation users and patients with bleedings disorders because FAR does not record use of mechanical prophylaxis in own category nor does it record use of permanent anticoagulation before surgery. Thus, patients continuing their own anticoagulation medication are recorded in the same category as anticoagulation naïve patients. Also, risk stratification-based evaluation to high and low VTE risk patients would have been impossible using FHDR. Thus, presenting results of the whole population gives us real-life results of all-cause mortality.

This study has its limitations. The FAR does not, unfortunately, record the length of thromboprophylaxis, only the agent used. This lack of information on the exact proportion of patients who only received thromboprophylaxis only during hospitalization is the major limitation of this study. According to the FAR, enoxaparin, tinzaparin, or rivaroxaban were the most used antithrombotic medicines used and 1%–2% of patients during both study periods did not receive thromboprophylaxis after THA or TKA.[23,32] This group of patients also includes patients with permanent anticoagulation as continuation of previous anticoagulation medication might not be regarded as thromboprophylaxis. The adoption of this new protocol has been good in the study hospitals. In 2022, the Finnish Arthroplasty Association

updated its recommendations on thromboprophylaxis after fast-track THA and TKA. In the new recommendation thromboprophylaxis only during hospitalization is recommended to low VTE risk fast-track THA and TKA patients if LOS is under 5 ays.[33]

Another issue to consider is the quality of the registers used. All hospitals must report arthroplasties performed in Finland to the Finnish Arthroplasty Register (FAR). The completeness rate of the FAR for primary arthroplasties was over 95% during the two study periods.[32] The completeness rate of the FHDR is also good, with more than 95% of all discharges reported.[34] The cross-validation of arthroplasties between these two registers is also high.[35] Causes of death were obtained from Statistics Finland, which has a completeness rate of around 99%.[36] Because autopsies are not required of all deceased, some of the patients who died of neoplasm might have had PE. However, the process of death certification practices in Finland has been evaluated by Lahti et al.[37] In this study, the Finnish system was found to serve the coding of causes of death for mortality statistics appropriately.

This study found no deaths due to VTEs and very low incidences of 90-day all-cause mortality after fast-track THAs and TKAs. The all-cause mortality incidence remained at the same level even though the length of thromboprophylaxis was based on risk stratification for VTE. Our results indicate that a risk stratification-based approach to thromboprophylaxis does not increase mortality after fast-track THA and TKA.

AUTHOR CONTRIBUTIONS

All authors contributed to the design of the study. The data analyses were made by HK and AMM. AMM was the main author of article. KP, JH, AK, and JP contributed to critical analyses of the data, interpretation of the findings and critical revision of the article.

FUNDING INFORMATION

AM received personal grants to conduct this study from the Finnish Medical Research Foundation and Finnish Arthroplasty Society.

CONFLICT OF INTEREST STATEMENT

None of the authors has conflict of interest regarding this study.

DATA AVAILABILITY STATEMENT

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

ORCID

Annette M. Moisander https://orcid.org/0000-0002-3058-6343

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How to cite this article: Moisander AM, Pamilo K, Huopio J, Kautiainen H, Kuitunen A, Paloneva J. Risk stratification-based thromboprophylaxis does not affect mortality after fast-track hip and knee arthroplasty. *Acta Anaesthesiol Scand*. 2024;1-6. doi:10.1111/aas.14414

APPENDIX A

NOMESCO codes: Finnish version.

NFB40 Primary total prosthetic replacement of hip joint using hybrid technique.

NFB50 Primary total prosthetic replacement of hip joint using cement.

NFB60 Demanding prosthetic replacement of hip joint.

NFB99 Other primary prosthetic replacement of hip joint.

NGB20 Primary total prosthetic replacement of knee joint without patellar part – sliding prosthesis.

NGB30 Primary total prosthetic replacement of knee joint without patellar part – connected prosthesis.

NGB40 Primary total prosthetic replacement of knee joint with patellar part – sliding prosthesis.

NGB50 Primary total prosthetic replacement of knee joint with patellar part – connected prosthesis.