Fast-track programs in total hip and knee replacement at Swedish hospitals

Influences on safety, outcome and patients' experiences

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Dedicated to the One who knew this book before it was written…

Psalm 139:16-17

CONTENT

1. ABBREVIATIONS

THR	Total Hip Replacement
TKR	Total Knee Replacement
OA	OsteoArthritis
SHAR	Swedish Hip Arthroplasty Register
SKAR	Swedish Knee Arthroplasty Register
ERAS	Enhanced Recovery After Surgery
ERP	Enhanced Recovery Program
BMI	Body Mass Index
ASA	American Society of Anesthesiologists Classification of physical status
LIA	Local Infiltration Analgesia
LOS	Length Of Stay
PRO	Patient-Reported Outcome
PROM	Patient-Reported Outcome Measure
PREM	Patient-Reported Experience Measure
EQ-5D	EuroQol Group 5 Dimension Instrument for measuring health status
EQ-5D-3L	EQ-5D – 3 levels
EQ-5D-5L	EQ-5D – 5 levels
VAS	Visual Analogue Scale
NRS	Numeric Rating Scale
SF-36	Short Form (36) Health Survey
HHS	Harris Hip Score
HOOS-PS	Hip Disability and Osteoarthritis Outcome Score – Physical Function Short Form
KSS	American Knee Society Score
KOOS	Knee injury and Osteoarthritis Outcome Score
KOOS-PS	Knee injury and Osteoarthritis Outcome Score – Physical Function Short Form
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
AE	Adverse Event
HR	Hazard Ratio
OR	Odds Ratio
RR	Risk Ratio

CI	Confidence Interval
ROM	Range Of Motion
ICD-10	International statistical Classification of Diseases and related health problems 10th revision
NOMESCO	Nordic Medico-Statistical Committee Classification of surgical procedures codes for interventions
GP	General Practitioner
PHC	Primary Health Care
OPD	Out-Patient Department
PJI	Prosthesis Joint Infection
SSI	Surgical Site Infection
NSAID	Non-Steroid Anti-Inflammatory Drug
DR	Democratic Republic (of Congo)
UEA	Université Evangelique en Afrique University in Bukavu, DR Congo
CEPAC	Communauté des Eglises de Pentecôte en Afrique Centrale. Denomination of pentecostal churches in DR Congo
UK	United Kingdom

2. LIST OF PAPERS

PAPER I

No increase in readmissions or adverse events after implementation of fast-track program in total hip and knee replacement at 8 Swedish hospitals: An observational before-and-after study of 14,148 total joint replacements 2011-2015. Berg U, Bülow E, Sundberg M, Rolfson O. Acta Orthop 2018 Oct; 89(5): 522-527.

PAPER II

Influence of fast-track programs on patient-reported outcomes in total hip and knee replacement (THR/TKR) at Swedish hospitals 2011–2015: an observational study including 51,169 THR and 8,393 TKR operations. Berg U, W-Dahl A, Rolfson O, Nauclér E, Sundberg M, Nilsdotter A. Acta Orthop 2020 Feb 28:1-7 (Epub ahead of print)

PAPER III

Influence of fast-track programs in total hip and knee replacement at Swedish hospitals on 2-year risk of revision and mortality. Berg U, W-Dahl A, Nilsdotter A, Nauclér E, Sundberg M, Rolfson O.
In manuscript.

PAPER IV

Fast-track program of elective joint replacement in hip and knee - patients' experiences of the clinical pathway and care process. Berg U, Berg M, Rolfson O, Erichsen Andersson A. J Orthop Surg Res 2019;14(1):186

3. PREFACE

Some of you may be curious and wonder why an orthopaedic surgeon, after almost 40 years of clinical work and just a few years before retirement, would want to start a research project as a doctoral student in medical science. Is it a life crisis based on dissatisfaction when looking back on the past and in the hope of finding new challenges and fulfilling a dream before dying? The reasons may be many, but please allow me to present my background, which ultimately led to this PhD thesis.

I began studying medicine very young, at the age of 18, and got my Medical Doctor Degree when I was 24. From the very outset I was convinced that my mission was to become a physician, and I have never regretted that choice. Early on in life I also felt a calling to make a difference for people in need of medical care. In 1981, at the age of 28, I and my wife and our two small children went for the first time to Zaire (now the Democratic Republic of Congo) for six months. This experience influenced the rest of my life. On my return to Sweden I continued my training and became a specialist in orthopaedics in 1984, and in general surgery in 1987. For a period of 10 years I combined studies and clinical work in Sweden with two further periods working in the Congo, spending a total of five years as doctor in charge at Lemera Hospital in the eastern part of the country. When I first began specializing in orthopaedics, I was involved in a research project in Sweden, but the challenging work in Africa for long periods was a barrier to further research as a doctoral student. However, when I was in the Congo, I started a pilot study to assess the occurrence of malaria resistant to chloroquine, but I was unable to find a scientific supervisor and the study was never published. Consequently, I decided to abandon my research aspirations and continue to focus on clinical work.

After moving back to Sweden with my family (wife and four children) in 1991, I had to adapt to the Swedish context, and I really loved working clinically as a consultant orthopaedic surgeon at Kungälv Hospital. The hospital work, including further training in hand surgery, church activities as a leader at the Smyrna Church in Gothenburg, and looking after my family together with my wife, were more than enough to fill my calendar. I could not see any space for research projects, even if I still had an interest in scientific work and teaching. Nevertheless, I continued to spend short periods in the Congo, and since 2005 I have been invited

each year to run the course in orthopaedics for the medical students at the Evangelical University of Africa (UEA) in Bukavu. The teaching, which is conducted in French, has been challenging but inspiring, and I have also had the opportunity to do some clinical work at Panzi Hospital, which has become well-known worldwide due to the courageous work by Dr Denis Mukwege to treat victims of sexual violence.

In 2012, "Rapid Recovery", a fast-track program focusing joint replacements, was introduced at Kungälv Hospital, and I was appointed process leader. This role gave me new knowledge but also opened my eyes to the need for clinical research in this field. I contacted Ola Rolfson, whom I knew from the time he was a resident in orthopaedic surgery at our department. Ola, who had become an experienced researcher and member of the board at the Swedish Hip Arthroplasty Register, was the perfect collaborator and he responded very enthusiastically, agreeing immediately to be the main supervisor for his colleague, who was 20 years older! And that was how I was encouraged to embark on a PhD project despite being 60+ and holding a position as a consultant orthopaedic surgeon at a hospital outside the academic sphere. Nevertheless, I quickly felt comfortable and inspired in my new position and realized that I could be a role model and encourage other colleagues in a similar situation to have the courage to think anew.

During the past 5-6 years I have combined my clinical work with research but also continued my collaboration with UEA, Panzi Hospital, and other health institutions run by the Congolese church CEPAC. When I met my friend Denis Mukwege, the Director of Panzi Hospital and a professor at UEA, shortly after he was awarded the Nobel Peace Prize in 2018, I asked him: How can I continue to support the work at Panzi Hospital and at the university? His response was unequivocal: "I suggest that you complete your PhD thesis as soon as possible and then come and stay here in Bukavu after you retire. We need you here and your PhD will give you a new platform and new opportunities to train young doctors clinically and scientifically."

I have already been invited to become affiliated to UEA after defending my PhD thesis. If my ambition to work in the Congo was a barrier to doing research when I was young, it is now pushing me to complete my PhD and opening the door to a new role in the Congo following my retirement in Sweden.

4. ABSTRACT

Background
Fast-track is a care concept that aims to enhance recovery after surgery, resulting in shortened perioperative hospital stay. By using evidence-based methods in preparation and perioperative care the clinical pathway and care process is optimized to achieve early discharge from hospital based on functional criteria. The implementation of fast-track care programs at Swedish hospitals that perform total hip and knee replacements (THR and TKR) is explored in this thesis based on 3 observational and 1 qualitative study.

Methods
A questionnaire was sent to Swedish hospitals that performed elective THR and TKR operations during the period 2011-2015 to determine whether a fast-track program had been introduced and if so when. Based on the questionnaire operations performed within a fast-track program were compared with those performed within a non-fast-track care program in 3 observational register-based studies. Data was obtained from the Swedish Hip and Knee Arthroplasty Registers (SHAR and SKAR).

In the first observational study, which covered 8 public hospitals in the western region of Sweden, all readmissions and new contacts with the healthcare system within 3 months were requested from the regional patient register. The risk of readmission and adverse events within 90 days after surgery was calculated using regression analyses.

The second observational study used data from SHAR and SKAR to compare the 1-year Patient-Reported Outcomes (PROs) from the fast-track and non-fast-track groups on a national level. The patient-reported health-related quality of life, pain and satisfaction outcomes were analysed for both THR and TKR operations by using multivariable regression analysis with adjustments. The PROs for TKR also included the knee-specific instrument KOOS.

In the third observational register study the 2-year risk of revision and mortality within the different care programs was compared by using Kaplan-Meier survival analysis and multivariable Cox regression models with adjustments. The risk was expressed by calculating the hazard ratio (HR) with 95% confidence interval (CI).

Finally, in the fourth study a qualitative approach was used to explore patients' experiences of the care process from decision to operate through to follow-up 3 months after surgery. Semi-structured individual interviews were conducted with 24 patients from 3 hospitals with a fast-track care program: 14 women and 10 men, 13 with THR and 11 with TKR. The mean age was 65 years (44-85). An inductive content analysis method was used.

Results

No increase in readmissions or adverse events could be identified within fast-track programs in elective THR and TKR at 8 Swedish hospitals. The implementation of fast-track resulted in a decrease in median length of stay (LOS) from 5 to 3 days in both THR and TKR. The PROs were in favour of fast-track for both THR and TKR. However, the differences were small. The fast-track program was associated with an increased risk of revision within 2 years after THR (HR 1.19, CI 1.03-1.39) but not after TKR (HR 0.91, CI 0.79-1.06). The risk of death within 2 years was lower with fast-track for TKR (HR 0.85, CI 0.74-0.97) but not for THR (HR 0.96, CI 0.85-1.09).

The qualitative study showed that patients' need for information and participation varied a lot. The recovery phase was filled with questions about unfulfilled expectations and need for improved feedback and follow-up after discharge from the hospital. The importance of person-centred care was a pervasive theme in all phases of the fast-track pathway.

Conclusion

Fast-track programs in elective THR and TKR at Swedish hospitals are safe and associated with a patient-reported outcome that is at least as good as with conventional care. An increased risk of revision after THR, due mainly to infections, raises concerns and requires further investigation and analysis. The clinical pathway and care process could be improved by adopting a more person-centred approach.

4.1 SAMMANFATTNING PÅ SVENSKA (Summary in Swedish)

Fast-track vid planerad höft- och knäprotesoperation på svenska sjukhus – inverkan på patientsäkerhet, resultat och patienters upplevelser av vårdprocessen

Bakgrund

Fast-track är ett vårdkoncept, som syftar till att underlätta en snabb återhämtning och förkorta sjukhusvistelsen i samband med planerade kirurgiska ingrepp. Konceptets grundidé är att med hjälp av vetenskapligt välgrundade metoder planera och genomföra vården effektivt men också skonsamt för patienterna genom att både fysisk och mental påfrestning minskas. De senaste 10 åren har fast-track införts som modell för vårdprocessen vid planerade höft- och knäprotesoperationer på de flesta ortopedkliniker i Sverige.

Frågeställningar

Övergripande frågeställningar för avhandlingsarbetet har varit: Vilken inverkan har fast-track på patientsäkerhet och resultat efter höft- och knäprotesoperationer i svensk rutinsjukvård? Hur påverkas risken för komplikationer på kort och medellång sikt? Vilka upplevelser och erfarenheter har patienter av vårdprocessen när fast-track använts som vårdkoncept?

Metodik

Genom en enkät till svenska ortopedkliniker som genomfört planerade höft- och knäprotesoperationer under perioden 2011-2015 har vårdrutinerna vid dessa operationer kartlagts. Syftet med enkäten var att definiera om fast-track införts som vårdkoncept och vid vilken tidpunkt. Med detta som grund har operationer genomförda på sjukhus som tillämpat fast-track jämförts med operationer där fast-track inte införts. Uppgifter från Svenska Höftprotesregistret och Svenska Knäprotesregistret om genomförda operationer under åren 2011-2015 har använts för att genomföra tre observationella registerbaserade studier. Risken för återinläggning och komplikationer inom 3 månader (studie 1), skillnad i patienters rapporterade hälsa, smärta och nöjdhet med operationen efter 1 år (studie 2) samt risken för omoperation och död inom 2 år (studie 3) har beräknats. I den första studien, som belyser införandet av fast-track på 8 sjukhus i Västra Götaland har

data också inhämtats från den regionala vårddatabasen VEGA. De två övriga registerbaserade studierna belyser inverkan av fast-track på sjukhus i hela landet. I en kvalitativ studie har patienters upplevelser av vårdprocessen utforskats, från beslut om operation fram till 3 månader efter operationen. Data har samlats in genom semi-strukturerade intervjuer, vars innehåll har analyserats och lett fram till formulering av övergripande teman (Studie 4).

Resultat

Risken för återinläggning, nya vårdkontakter och oönskade händelser inom 3 månader är likvärdig vid jämförelse mellan vårdprocess enligt fast-track och icke fast-track (studie 1). Patienters rapporterade resultat avseende smärta, hälso-relaterad livskvalitet och nöjdhet med operationen 1 år efter höft- eller knäprotesoperation är generellt bättre där fast-track använts, men skillnaden är liten och den kliniska relevansen tveksam (studie 2). För höftprotesopererade patienter som vårdats enligt fast-track är risken för omoperation inom 2 år ungefär 20% större jämfört med konventionell vårdprocess främst till följd av fler infektioner, men säkerheten i beräkningen är inte hög och orsaken inte fastställd. För knäprotesoperationer ses ingen ökad risk med fast-track. Risken att dö i efterförloppet till höft- eller knäprotesoperation är låg, och när fast-track används är risken för knäopererade patienter att dö inom 2 år lägre än med konventionell vårdprocess. För höftopererade patienter har någon statistiskt signifikant skillnad mellan fast-track och annan vårdprocess inte kunnat påvisas (studie 3).

Den kvalitativa studien visar att det finns en stor variation när det gäller patienters behov av information och delaktighet. Återkoppling och uppföljning efter utskrivning från sjukhus upplevdes otillräcklig. Resultatet pekar på att den standardiserade vårdprocess som kännetecknar fast-track behöver kompletteras med ett person-centrerat förhållningssätt i hela vårdförloppet (studie 4).

Slutsatser

Fast-track vid planerade höft- och knäprotesoperationer i svensk rutinsjukvård är ett vårdkoncept som är patientsäkert och minst lika bra som konventionell vårdprocess avseende resultat och patientnöjdhet trots kraftigt förkortade vårdtider på sjukhus. Ett observandum är en ökad risk för omoperation efter höftprotesoperation när fast-track använts. Ytterligare studier krävs för att bekräfta en möjlig riskökning och identifiera orsaker till detta.

4.2 RÉSUMÉ EN FRANÇAIS (Summary in French)

Récupération accélérée après une arthroplastie totale de la hanche (PTH) ou du genou (PTG) dans les hôpitaux suédois : influence sur la sécurité, les résultats et les expériences des patients

Introduction

La récupération accélérée après chirurgie (RAAC) est une approche de prise en charge globale, un modèle de soins pour obtenir une récupération rapide réduisant la durée de séjour (DS) à l'hôpital. Les actions à mener commence avant, pendant et après l'opération avec comme objectifs clés d'informer et de former le patient et le personnel soignant à la démarche ; d'anticiper l'organisation des soins dès l'admission du patient jusqu'à sa sortie ; de réduire les conséquences du stress chirurgical, de contrôler la douleur dans toutes les situations ; de favoriser et stimuler l'autonomie des patients. Au cours des dix dernières années la procédure de récupération accélérée a été introduite comme modèle de soins dans les opérations de PTH et PTG dans la plupart des hôpitaux suédois.

Questions de la thèse

Quel est l'impact du programme RAAC chez les patients opérés avec PTH et PTG sur le risque de réadmission et des complications? Quelle est l'influence de RAAC sur les mesures des résultats déclarées par les patients (MRDP) après les opérations de PTH et PTG dans les hôpitaux suédois ? Quelle est l'influence de RAAC sur le risque de révision et mortalité dans les 2 ans après PTH et PTG ? Quelles sont les expériences des malades soignés selon un programme de RAAC ?

Méthodes

Un questionnaire a été envoyé aux hôpitaux suédois en rapport avec opérations électives PTH et PTG 2011-2015. L'enquête visait à définir si un programme de récupération accéléré avait été introduit et quand il a été introduit. Les opérations dans les hôpitaux qui ont répondu au questionnaire ont été divisées en 2 groupes selon que les opérations ont été effectuées dans le cadre d'un programme accéléré ou non. Les données ont été obtenues à partir des registres suédois d'arthroplastie de la hanche et du genou (SHAR et SKAR) ce qui nous a permis de mener trois études observationnelles. Le groupe d'opérations avec programme de RAAC a été comparé au groupe d'opérations où la procédure accélérée n'était pas pratiquée.

Dans la première étude (article I) qui a inclus huit hôpitaux, toutes les réadmissions et nouveaux contacts avec le système de santé dans les 3 mois avec un lien possible avec l'intervention chirurgicale avaient été cherchés grâce à l'interconnexion des bases de données, des registres de ses hôpitaux avec les bases de données de l'autorité régionale de la santé. Le risque de réadmission et de complications dans les 90 jours après la chirurgie a été calculé en utilisant des analyses de régression.

La deuxième étude observationnelle a utilisé les données de SHAR et SKAR pour comparer les résultats entre les groupes RAAC et non-RAAC au niveau national en utilisant les MRDP un an après l'arthroplastie (article II). Les résultats de EQ-5D, la qualité de vie, la satisfaction de l'opération ainsi que l'évaluation de la douleur en utilisant l'échelle visuelle analogique (EVA) avaient été analysés avec un modèle de régression multivariable avec ajustements. Les MRDP pour les PTG comprenaient également le score KOOS. Enfin, le risque de révision et de mortalité dans les deux ans après l'opération a été comparé sur la base des données du registre en utilisant l'analyse de survie de Kaplan-Meier et des modèles de régression cox multivariable avec ajustements (article III).

L'étude qualitative (article IV) avait exploré les expériences des patients depuis la décision de l'opération jusqu'à trois mois de suivi postopératoire. Une méthode d'analyse de contenu inductive a été choisie. Au total, 24 patients de trois hôpitaux avec un programme de RAAC étaient inclus dans l'étude, il s'agissait de 14 femmes et 10 hommes dont l'âge moyen était de 65 ans (extrêmes de 44 – 85 ans) parmi eux 13 avec PTH et 11 avec PTG.

Résultats

Dans les huit hôpitaux suédois, aucune augmentation des réadmissions ou des complications n'a pu être observée avec des programmes RAAC en PTH et PTG. La mise en œuvre de la procédure accélérée a entraîné une diminution de la DS médiane de 5 à 3 jours (Article I).

Les MRDP étaient tous en faveur du programme RAAC pour les PTH ainsi que les PTG, à l'exception de la sous-échelle de KOOS QoL pour les PTG. Cependant, les différences étaient cliniquement non significatives (Article II).

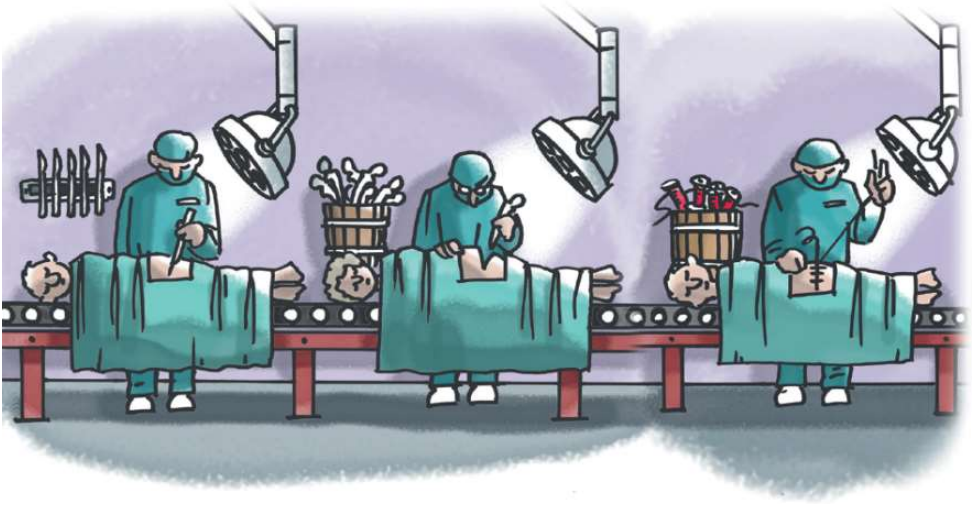
Le programme accéléré (RAAC) était associé à un risque accru de révision dans les 2 ans suivant le PTH avec un Hazard Ratio (HR) de 1.19 avec un intervalle de

confiance (IC*)* à 95% du 1.03 à 1.39 mais pas après les PTG (HR 0,96, IC 0.85-1.09). Le risque de décès <2 ans était plus faible avec la procédure accélérée pour les PTG (HR 0.85, IC 0.74-0.97) mais pas pour les PTH (HR 0.96, IC 0.85-1.09) (Article III).

L'étude qualitative a mis en évidence la diversité des besoins d'informations et d'implication des patients tout au long de la prise en charge et la période de suivi. La phase de récupération après la sortie de l'hôpital était remplie de questions sur les attentes non satisfaites. L'importance des soins centrés sur la personne était un thème omniprésent dans toutes les phases du parcours clinique (Article IV).

Conclusion

Les programmes accélérés (RAAC) des soins de PTH et de PTG dans les hôpitaux suédois sont sûrs et associés à des résultats MRDP au moins aussi bons qu'aux soins conventionnels. Un risque accru de révision après PTH, principalement en raison d'infections, soulève des préoccupations et nécessite des investigations et des analyses supplémentaires. Le cheminement clinique et le processus de soins peuvent être améliorés par une approche davantage centrée sur la personne.



5. INTRODUCTION

5.1 The Swedish context of elective THR and TKR

Sweden has a population of 10.3 million people, according to statistics 2020. The health care is mainly tax-funded aiming to provide equal access to healthcare services for the citizens. The responsibility is decentralized to a regional level, where public hospitals are organized and financed by 21 county councils. Care at private hospitals is less common, but mainly paid by the county councils in accordance with temporary agreements. More than 30 000 THR/TKR are performed annually in Sweden, representing the most common elective surgical interventions in orthopaedics. Patients may be transferred to private hospitals due to capacity problems at public hospitals, and in the period 2011-2015 the private hospitals performed 20-25% of the THR/TKRs.

The main reason for THR/TKR is symptomatic osteoarthritis (OA), if non-operative treatment does not give an acceptable pain relief and the impairment causes considerable functional limitations in daily life. As OA is a degenerative disease and the incidence increases with age, the number of elderly people needing a THR/TKR is high. More than 20% of the population in Sweden has the age of 65 years or more. For patients undergoing THR/TKR the average age is about 68 years and about 57% are females. The proportion of patients younger than 55 years is approximately 10%.

The quality indices of Swedish healthcare are among the best in the world [1] , but the accessibility has been a weak point. In 2005 a health care guarantee was introduced, which means that you will have to wait a maximum of 90 days for an appointment at a specialist clinic or any type of elective surgery, but in some regions the waiting time have sometimes been much longer.

Like in some other countries, patients in Sweden could some decades ago be transferred to units for postoperative rehabilitation and convalescence after discharge from surgery wards at the hospitals. Similar opportunities of further institutional care are no longer available, and patients undergoing elective THR/TKR must be prepared for recovery and rehabilitation at home after hospital discharge. The rehabilitation program is supervised by physiotherapists in the primary health care.

5.2 The Swedish Arthroplasty Registers – a base for evaluation and research

The Swedish Hip Arthroplasty Register (SHAR) is a National Quality Register, which has registered total hip replacement (THR) operations in Sweden since 1979. From the beginning primary and secondary operations (revisions) were reported, but since 2002 patient-reported outcome (PRO) has also be registered in order to have the opinion of the patients and not just the information from the hospitals about operations. The PROMs that are registered are pain relief, satisfaction and gain in health-related quality of life. Since 2005 hemiarthroplasties have also been registered, mainly used in patients who have sustained a femoral neck fracture. The coverage of Swedish hospitals performing THR is 100% as all hospitals report operations and reoperations to the register. In 2018 there were 18,629 THRs reported to SHAR with a data completeness of 98% for primary THR and 92% for revisions of THR (Annual Report 2018). Individual patient data such as age, sex, diagnosis, surgical technique and type of implant used are recorded.

The Swedish Knee Arthroplasty Register (SKAR) was established already 1975 and was the first national arthroplasty register in the world for evaluating outcome and implant survival. Since the beginning of 1990s all Swedish hospitals performing knee replacements participate in the data collection. The data completeness of primary knee replacements is about 97% (Annual report 2019) and more than 90 % of revisions. The PROM registration, which started 2008 as a pilot project, has gained increasing popularity, and in 2018 the number of hospitals reporting PROM data preoperatively and 1 year postoperatively was 27. Both SHAR and SKAR are connected to the Swedish Tax Agency in order to get updated mortality data of patients, who have undergone joint replacement surgery and are reported to the registers. In 2018 the number of knee replacements reported to SKAR was 15,430. Of them 13,885 were TKRs.

The Swedish arthroplasty registries will start a fusion process in 2020 with continued support to Swedish hospitals in the work of quality assurance, aiming to improve outcome after joint replacement and give individual patients the best possible care.

5.3 Total joint replacement in the hip and knee – has the limit of success been reached?

Total joint replacement in the hip and knee is the most commonly performed elective orthopaedic procedure in developed countries [2-4]. Total hip replacement (THR) was described as "the operation of the century" in the Lancet in 2007 [5], referring to the revolutionized treatment of severe OA when THR operations became more widespread in the 1960s. Some 50 years later, THR remains a successful operation in terms of pain relief and improvement in quality of life, even if expectations nowadays are much greater [6]. A similar successful outcome has been reported for TKR [3].

We know from SHAR and SKAR that the long-term results are good with regard to implant survival [7, 8]. Similar implant survival rates of more than 95% for 10-year survival and 85% for 20-year survival in both THR and TKR has been found in a large population-based cohort study from the UK [9]. As patients undergoing primary THR and TKR in Sweden have an average age of around 68 years [7, 8], the implant will last for the rest of their lives, whereas patients younger than 60 years at primary joint replacement, especially males, run a high risk of needing future revision surgery [10, 11].

However, quality should be measured not just in terms of implant survival but also as a low risk of surgery-related complications. Patient satisfaction with function and quality of life as well as a positive experience of care are other quality measures that are of increasing importance. Not all patients are satisfied; 10-30% are dissatisfied with unfulfilled expectations regarding function, pain relief, and quality of life, in particular patients who have undergone TKR [12-14]. The challenge is to find out how quality of care and outcome can be further improved. To achieve a higher rate of patient satisfaction we need to evaluate not only implant design and surgical technique but also explore the entire care process, from decision-making through to the preparation period, surgical care, recovery, and completion of the rehabilitation phase.

5.4 Increased demand for high-quality care with limited resources

The goal of healthcare is to ensure high-quality care and outcome in all respects but also to optimize the use of resources. In Sweden and in many other countries there is a growing number of patients who require joint replacements [4, 15-17] but the healthcare budget is failing to keep pace. The focus has been on the cost of the hospital stay, and in recent decades the number of hospital beds available for elective surgery has been reduced at all Swedish hospitals [18, 19]. For elective joint replacement it is thus economically beneficial if the length of hospital stay (LOS) can be shortened [20], although it is also important to avoid costs arising from complications [21]. In conclusion, we need to carry out more joint replacement procedures more effectively, and with a limited budget [22].

6. Background

6.1 Historical review of clinical pathways in joint replacement

When THR and TKR was popularized worldwide there was a need to adapt a coordinated team approach in the care of patients. A multidisciplinary team needed to develop standardized forms for each discipline in order to improve communication between health professionals during the stay in hospital [23]. The use of clinical pathways began in the 1980s and they were put into practice in elective joint replacement in the 1990s, especially in North America, Europe and Australia, to meet the challenge of reducing costs without jeopardizing safety and outcome [24]. Clinical pathways are logistic guidelines, that define the sequence and timing of actions in the care of patients with a defined diagnosis or who are undergoing a specific surgical intervention. The clinical pathways, sometimes also called care pathways or critical pathways, serve to coordinate the activities of healthcare professionals and may be both hospital-specific and procedure-specific. The aim is to create an optimal regimen of care at the institution and assure cost-effectiveness [25].

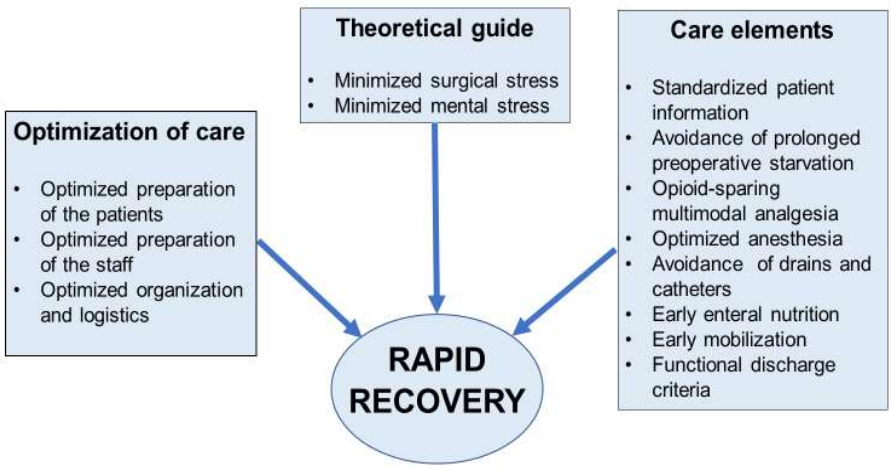
In a literature review from 2003, Kim et al. summarized by stating that clinical pathways in THR and TKR are effective in reducing LOS and hospital costs without compromising patient outcomes. A meta-analysis by Barbieri et al. from 2009 concluded that clinical pathways can reduce LOS and postoperative complications compared with standard care, but the effect on cost-effectiveness is more complex to evaluate. An assumption is that clinical pathways could have an impact on care through the involvement of multidisciplinary teams that critically analyse the organization and are involved in improvement and reorganization of the process [24].

6.2 History of fast-track

The concept of “fast-track surgery” was introduced in the 1990s in abdominal surgery in an effort to address postoperative morbidity and prolonged convalescence related to surgical stress and organ dysfunction [26, 27]. By the early 2000s its use had spread to other types of surgery [28-30], especially elective joint replacement. Beginning in the Netherlands [31] and Denmark [32], followed by other European countries, North America, China, Australia and New Zealand,

orthopaedic departments introduced clinical pathways and care programs, sometimes called “Rapid Recovery” and “Enhanced Recovery”, based on this concept [32-42]. In other types of major surgery the concept was introduced under the name “Enhanced Recovery After Surgery” (ERAS) [43]. Enhanced recovery pathways have spread worldwide, although after 20 years many clinical teams have still not incorporated fast-track principles into clinical practice. A major barrier to ERAS implementation may be the lack of teamwork. Multidisciplinary and multi-professional collaboration with a common goal is a key to success [44].

6.3 What is fast-track?



According to the general meaning of fast-track it is the quickest and most direct route to achieving a goal. In fast-track surgery the clinical pathway, including preparation, hospital stay and rehabilitation, should be a fast yet well-organized track. The focus is not just on the logistics but also on quality of care and outcome and every part of the track should be based on current evidence and best practice. According to evidence-based care principles, the clinical pathway and care process must be organized effectively to achieve rapid recovery and early discharge, thus resulting in a short hospital stay.

A great deal of attention has been put on the length of stay in hospital, which has decreased enormously since the fast-track programs were introduced [20, 45, 46]. A main issue has been knowing why patients need to stay in hospital after surgery. Pain, dizziness and general weakness have been identified as important obstacles to early discharge [36, 47] although organizational and logistical barriers also play a role together with traditions [41, 48]. In fast-track surgery the primary goal is not just to shorten LOS but to achieve earlier recovery by reducing surgery-related morbidity and functional convalescence [48]. Surgical stress and postoperative organ dysfunction need to be minimized [49]. The psychological preparation, with adequate and consistent information from different health professionals in the collaborating multidisciplinary team, is also emphasized. The fast-track concept deals with the underlying factors and how they can be addressed using evidence-based methods [50].

One of the cornerstones in the fast-track program is multimodal pain treatment. The introduction of local infiltration analgesia (LIA) [51, 52] has enabled very early postoperative mobilization and contributed to decreasing the need for systemic opioids, which may cause nausea and dizziness. LIA is effective, especially in TKR, although it has limited additional analgesic value in THA when multimodal analgesia is used. However, the use of wound catheters for prolonged administration has not been shown to improve pain relief when multimodal analgesic treatment is used [53].

Technically, fast-track surgery does not differ from other surgery, although factors that may negatively influence early mobilization are avoided [50]. The presence of drains and catheters [54] and prolonged pre- and postoperative fasting [55] are other factors that may delay mobilization and require attention. Prolonged bed rest [56] and exposure to hospital bacterial flora will increase the risk of complications. The care process as well as anaesthesia and surgical intervention should be optimized to minimize mental and physiological stress. The patient should be well prepared mentally through structured and relevant information, and staff should have a common goal for surgical care and recovery. This could enhance mobilization and recovery and the hospital stay could be shortened without jeopardizing patient safety. According to Professor Henrik Kehlet, who first introduced fast-track programs in joint replacement, the basic idea should be "first better – then faster" [57].

Even if the concept of fast-track surgery is well described in general terms, no definition has been formulated based on specific criteria. It is a coordinated program of perioperative actions aimed at reducing surgical stress and facilitating postoperative recovery [30]. A short LOS is not a main criterion of fast-track but a result of the accelerated care process. In a study of adverse events and readmissions following implementation of fast-track programmes in joint replacement at Swedish hospitals [58], a simplified definition of fast-track was used based on three logistical features: admission on the day of surgery, early mobilization within hours on the same day, and functional discharge criteria in practice. The logistical criteria alone do not define the concept of fast-track surgery, but they indicate that the care principles related to the philosophy of fast-track are put into practice.

6.4 Evolution of clinical pathways and care programs in THR and TKR

Clinical pathways with a structured and standardized care process were introduced before the implementation of fast-track in THR and TKR [24]. However, with the dissemination of new knowledge the methods employed in preparation and perioperative care have changed during the last 20 years, regardless of whether fast-track programs have been implemented or not. The fast-track concept has necessitated the adoption of strategies to improve pain treatment, reduce inflammatory response, and minimize perioperative morbidity. Consequently, all care programs have been developed and to some extent been influenced by the care principles of fast-track.

Although the recommendations formulated by the ERAS Society are widely accepted, the application in clinical practice varies. Based on fast-track principles, an updated consensus statement for perioperative care in total hip and knee replacements was published in 2019 [59]. It summarizes current evidence-based knowledge, but also includes recommendations, where the desired effects clearly outweigh the risks even if scientific support is weak.

In the preparation phase, preoperative information, education, and counselling are the cornerstones and are strongly recommended even if the level of evidence is low [60]. Preoperative optimization through cessation of smoking [61] and use of alcohol [62], as well as treatment for preoperative anaemia, can reduce the risk of complications [63, 64] and should be included in the preoperative protocols.

Obesity is a risk factor for complications following THR [65] and TKR [66] but in the fast-track settings the influence of obesity, smoking, and alcohol use appears to be less pronounced [67, 68]. LIA is strongly recommended in TKR [69] but not in THR [53]. However, the use of LIA in TKR has spread to all hospitals in Sweden and the use of a tourniquet has slowly decreased, regardless of whether a fast-track program has been implemented or not [70]. Based on a large body of evidence, tranexamic acid has been widely used in both THR and TKR for almost 20 years, and a question raised recently is whether oral or topical administration could be as effective as intravenous infusion [71, 72].

The routine use of a urinary catheter is not recommended, but there may be some controversy about the threshold of 800 ml for catheterization [73]. Another controversial area is the use of systemic corticosteroids, and some uncertainty remains about what dose is effective and safe [74]. The duration and type of antithrombotic medication is another subject of discussion as early postoperative mobilization in fast-track programs may reduce the need for prolonged prophylactic treatment [75].

6.5 Differences between THR and TKR in fast-track care programs

Hip prosthesis

Knee prosthesis

The clinical pathways and fast-track care programs in THR and TKR are similar in most respects. The target groups are very similar regarding age, gender and comorbidity, and the medical problems can be addressed in a similar way. According to experience in Sweden and publications from different countries [40, 45, 58] the LOS has been almost the same. Whilst postoperative pain may be a more pronounced problem following TKR [47, 76], the treatment protocols are almost the same with regard to multimodal opioid-sparing pain treatment. However, the use of LIA is standard in TKR but not in THR.

Fast-track has influenced the discharge criteria, especially for knee patients, by focusing on general function and independency and not on a certain ROM of the knee joint, which previously was a common discharge criterion following TKR. For hip patients, movement restrictions to protect the new hip from dislocation, are not emphasized as in the traditional care, and for both categories the functional discharge criteria are the same.

In summary, the clinical pathways and the care processes for THR and TKR are based on the same care principles and have far more similarities than differences.

6.6 What do we know from research into fast-track programs in THR and TKR?

6.6.1 Length of stay

In the 1990s the estimated length of stay (LOS) in hospital after THR and TKR was 10-16 days in Sweden and other countries [4, 20, 77, 78]. The implementation of clinical pathways in the 1990s was aimed at standardizing the care process. It slowly reduced LOS and appeared to be successful [25]. In Denmark, the median LOS decreased from 10 days for THR and 11 days for TKR in 2000 to 4 days for both THR and TKR in 2009, mainly due to fast-track programs [45].

Influenced by experience from Denmark, fast-track was broadly implemented at Swedish hospitals in 2011-2015, resulting in a reduction in LOS to 3 days or less in 2015 [58]. Even if LOS has been reduced in many countries without any documented link to fast-track or enhanced recovery programs [4, 46], a systematic review and meta-analysis based on 25 studies has reported a mean reduction in LOS of 2.03 days following implementation of ERAS programs [79].

According to several studies, the mean LOS in a fast-track setting during the last few years has been 3 days or less [36, 58, 80-82] and both THR and TKR can now be carried out as outpatient arthroplasties in selected patients [57, 83-86]. However, there are concerns about safety [87] and post-discharge complications may eliminate the cost savings [88-90], and even with meticulous patient selection some patients have to stay overnight due to convenience reasons or need of medical observation [91, 92]. Consequently, ambulatory surgical departments will need access to hospital beds for patients not fulfilling the discharge criteria on the day of surgery.

6.6.2 Patient selection

As the fast-track care concept spread throughout the world, questions were raised about patient selection. Can elderly people and patients with risk factors be included in the new care programs? Hospitals with programs aimed at defining a certain LOS have used exclusion criteria [38, 42], whilst other clinics have included all patients in the same program and followed the same care principles [45], but at the same time accepted that some patients need a longer LOS. It has been shown that almost all patients can be included and fast-track care benefits early and enhanced rehabilitation [93-95]. Patients undergoing revision or bilateral simultaneous TKR may also follow the same fast-track protocol as primary operations [96, 97]. However, patients with characteristics that predict a longer period of hospitalization have been excluded from hip and knee replacements in outpatient settings [84].

6.6.3 Readmissions and adverse events

Several studies dealing with short-term safety, including systematic review, have concluded that the readmission rate within 30 and 90 days in fast-track programs do not differ from in conventional care programs [58, 80, 94, 98]. However, one study from Finland has reported a significant increase in the 42-day readmission rate in a fast-track THR program [99], which indicates that the risk of readmissions may vary depending on the context. The reported overall rate of AE has in most studies been lower or shown no significant difference [58, 94, 100] compared to previous programs. Some concerns have been raised about the risk of prosthesis joint infection (PJI) following the introduction of fast-track [100-102], although publications on other AE, such as hip dislocations [103] and cardiovascular complications [75, 104], have not revealed an increased risk of AE after implementation of fast-track.

6.6.4 Patient satisfaction (PREM)

Using a numerical rating scale (NRS) [32, 105, 106], a high degree of patient satisfaction with the care following the introduction of fast-track programs has been reported in comparative studies. The questionnaire was presented to the patient shortly after their stay in hospital. As it reflects satisfaction with the care provided, it is considered to be a patient-reported experience measure (PREM). In a national survey from Denmark there was a significantly higher degree of patient satisfaction with hospital care, with a shorter LOS, in terms of continuity of doctor's rounds and preoperative information [107]. According to a study from the USA, the LOS did not influence the care rating when comparing patients undergoing THR with an LOS of two days and patients with an LOS of more than two days [108]. In a comparative study using a five-point scale to assess patient satisfaction with speed of recovery and pain management, the satisfaction rating among patients in the enhanced recovery program (ERP) group was significantly higher than patients in the standard care group [109].

6.6.5 Patient-reported outcomes (PROs)

Both generic and disease-specific instruments have been used to explore the impact of fast-track programs on PROs following THR and TKR. The follow-up periods varied in length. Only a few of the studies had a control group in another care program [109, 110]. PROs one year after THR or TKR in a fast-track program were reported from Denmark [111, 112], where EQ-5D and SF-36 were used to assess Health-Related Quality of Life (HRQOL) and the Harris Hip Score (HHS) was used to explore the functional outcome for hip patients. The results were compared with PROs from an age- and gender-matched population. The THR patients but not the TKR patients reached the level of the matched population 12 months after surgery. A one-year follow-up from Norway [106] used EQ-5D as an HRQOL instrument in combination with several disease-specific functional scores, including HHS and Hip Disability and Osteoarthritis Outcome Score – Physical Function Short Forms (HOOS–PS) for hip patients. For knee patients the Knee Injury and Osteoarthritis Outcome Score (KOOS–PS) and American Knee Society Score (KSS) were used. The scores were reported after 12 weeks and 1 year for THR and after 8 weeks and 1 year for TKR patients. The PROM scores after 12 months were lower than the matched population level but similar to register-based average gain in general health in THR patients [106]. In the UK, the influence of LOS for THR and TKR patients on WOMAC and SF-36 one year

after surgery was studied. Although the SF-36 scores were slightly higher in the group with a shorter LOS, no significant influence on WOMAC scores could be demonstrated. In summary, the PROs following THR and TKR with fast-track have been considered good, but it has not been proven that fast-track is better than other care programs.

6.6.6 Risk of reoperations and revisions

Most studies dealing with safety have focused on the perioperative period and short-term complications. In a systematic review and meta-analysis comparing outpatient and inpatient THR and TKR the overall complication rate was similar, but an increase of reoperations within 90 days was reported, in TKR the difference was statistically significant, in THR it was not [113]. The risk of revision and reoperations within 1-2 years following THR and TKR in fast-track programs compared to other care programs has not been clearly assessed, and knowledge is limited. Some publications have reported an increase in the revision rate following a fast-track THR program [99, 101], but it has been assumed that there could be other reasons for the higher revision rate. In a study from Denmark, which involved a comparison of the reoperation rate at fast-track hospitals and other hospitals, no difference could be demonstrated [100]. From Norway revisions and reoperations within one year were reported at a hospital following implementation of a fast-track program [106], but no comparison was made with a control group or an historical patient cohort without fast-track.

6.6.7 Mortality

Several studies have reported a decrease in the mortality rate within 30 and 90 days [58, 80, 114] following the introduction of fast-track programs for hip and knee replacements, although it has been difficult to draw conclusions. A recent systematic review with a meta-analysis based on 25 studies [79] concluded that the mortality rate was significantly reduced within 30 days with a risk ratio (RR) of 0.48 (95% CI 0.27-0.85), when fast-track programs were used. However, adjustments for confounding factors, such as comorbidity in the different studies, are not clearly defined. The proportion of patients with comorbidity undergoing THR and TKR has increased over the last 20 years, whilst the mortality rate following THR and TKR has declined. Nevertheless, the mortality risk still depends on the comorbidity burden [115]. Consequently, the conclusions regarding the impact of fast-track programs on mortality following THR and TKR should be viewed with caution.

6.6.8 Qualitative studies

The clinical pathway and care process in fast-track programs have also been evaluated in qualitative studies based on interviews with patients, either individually or in focus groups. Certain key factors have been identified, which could influence patients' experiences and outcome. Pain treatment and experience of healthcare [116-118] are two of the main issues, although patient education and information, both preoperatively and at discharge, are also key factors that influence patient satisfaction [119, 120]. The studies indicate that person-centred care may improve satisfaction and recovery. Patient-hospital communication is an issue that could be addressed by developing new communication technologies [121]. Interviews with health professionals working in high-volume, fast-track hospitals reveal residual organizational and logistical dysfunctions and highlight the need for an improved information flow and new communication methods [122].

6.7 Why is there a need for further research into the implementation of fast-track programs in hip and knee replacement and to explore the care process?

- The advantages of fast-track programs in the care of patients undergoing joint replacements have not been proven in a Swedish context, and there is a need for confirmation of the favourable results from other countries

- Previous research from other countries has mainly been conducted at "fast-track units" dedicated to the new concept and does not reflect the broad-based implementation of fast-track in routine care at different hospitals

- With the aid of quality registers, there is an opportunity and a need to confirm patient safety and mid-term outcome in large cohorts with different outcome measures

- It is of vital importance to investigate factors along the entire clinical pathway and care process, that are of particular significance from the patients' perspective, and to identify factors that may influence patient satisfaction and outcome

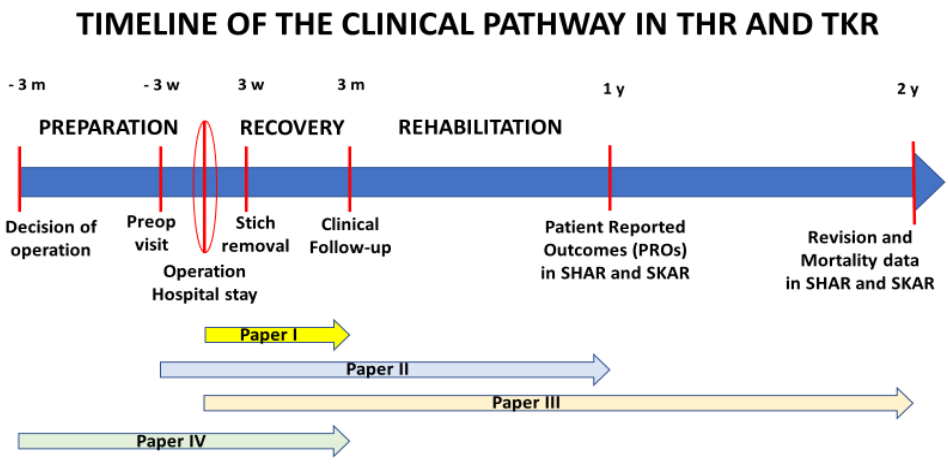
7. AIM

Investigate the influence on safety, outcome and patients' experiences of fast track programs at Swedish hospitals that perform elective total hip and knee replacements.

7.1 Main research questions:

- What is the influence of fast-track on readmissions and adverse events within 30 and 90 days after surgery?
- How are Patient-reported outcomes 1 year after THR and TKR influenced by the implementation of fast-track programs in Sweden?
- What impact has the fast-track programs on the risk of revision and mortality within 2 years after surgery?
- What are the patients' experiences of the clinical pathway and care process in fast track care programs of THR and TKR?

Figure 1.



8. PRESTUDY

The research questions could not be answered without knowing the clinical pathway and care programs at Swedish hospitals performing elective THR and TKR. A national survey with a questionnaire to Swedish orthopaedic departments was a method to identify when and which changes of the care process have been introduced during the last years. The register studies in this thesis are based on the survey, which aims to define when a fast-track program has been implemented during the period 2011-2015.

8.1 Survey of the clinical pathway and care program of elective THR and TKR at Swedish hospitals 2011-2015

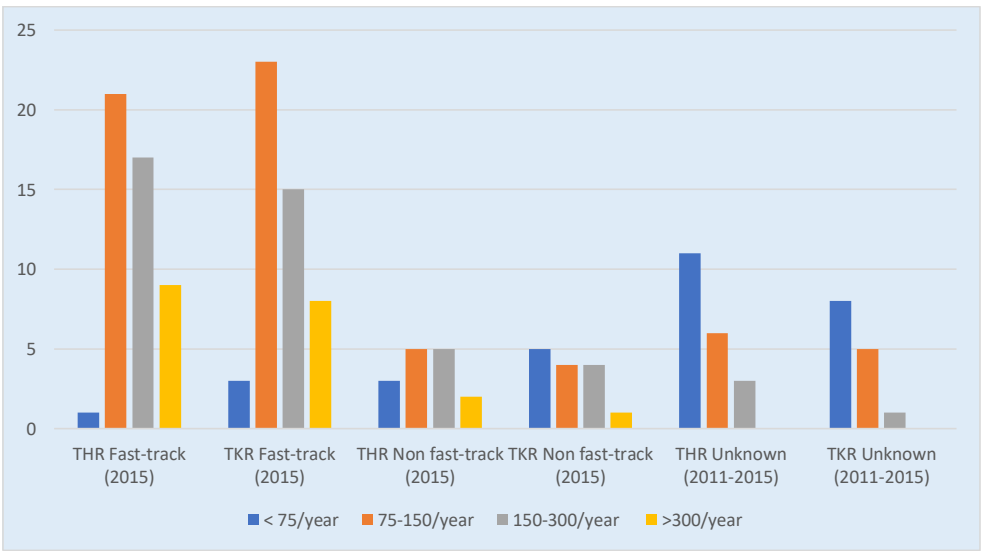
A survey was conducted to evaluate the implementation of fast-track programs at Swedish hospitals that perform elective joint replacements. A questionnaire was prepared in late 2014 and sent to all Swedish orthopaedic departments that performed elective THR and TKR and contained questions about the different parts of the care program. The purpose of the survey was to identify which changes in the care process had been introduced since 2011 and when, with a particular focus on the question of whether a fast-track program had been introduced or not. The questionnaire was completed by the orthopaedic surgeon responsible for the arthroplasty care program at each orthopaedic unit. After a reminder letter, the majority answered with some delay at the beginning of 2015. The departments that had not implemented a fast-track program at the beginning of 2015 were contacted again in 2017 and asked for supplementary information about changes in the care program later in 2015 or in 2016. We received answers from 63 hospitals/departments that had performed elective THR and TKR in Sweden in 2011-2015 (Table 1).

Table 1. Number of Swedish hospitals with fast-track in THR and TKR

	THR			TKR		
Year	**Fast-track**	**Non fast-track**	**Unknown**	**Fast-track**	**Non fast-track**	**Unknown**
< 2011	17	46	20	17	46	14
2011	21	42		20	43	
2012	28	35		28	35	
2013	36	27		35	28	
2014	44	19		44	19	
2015	48	15		49	14	

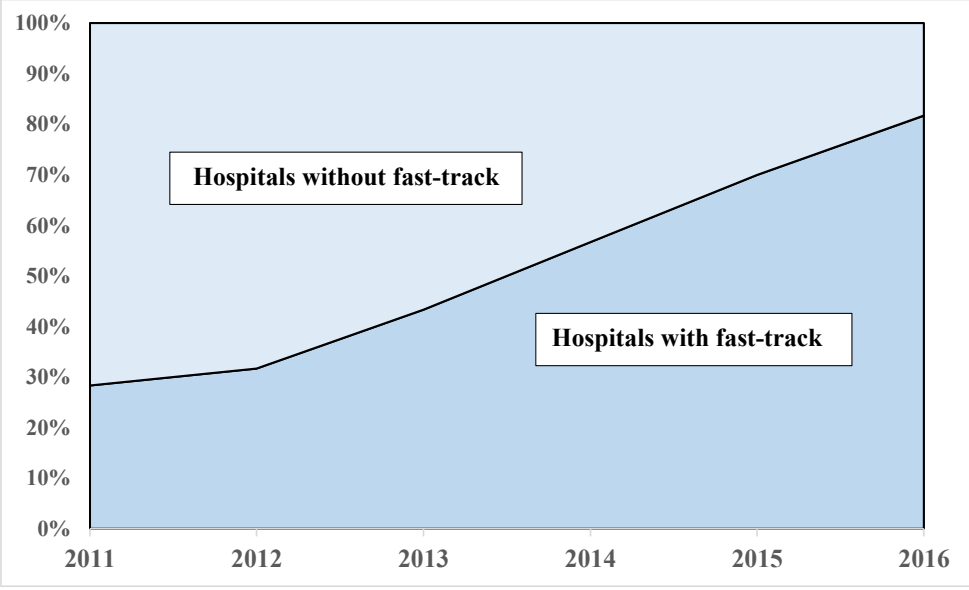
The orthopaedic surgeon who completed the questionnaire was asked if and when a fast-track program had been implemented. We defined fast-track implementation as being the point at which the following criteria for standard of care were met: 1) admission on the day of surgery, 2) mobilization within 3-6 hours after the operation, 3) functional discharge criteria in practice. We also asked for the mean and median LOS to confirm there was no obvious discrepancy in the definition. Within a fast-track care program, LOS did not normally exceed 3-4 days during the period 2011-2015. One hospital answered "yes" to the question of whether fast-track had been implemented but had a median length of stay of 6 days and mobilized the patient for the first time 12-24 hours after surgery. The hospital was excluded from the "fast-track" category and was recategorized as "non-fast-track". The hospitals with a care program defined as "fast-track" or "non-fast-track" had performed more than 90% of the THRs and TKRs in Sweden during the period 2011-2015. The hospitals that failed to respond to the questionnaire had performed less than 10% of the elective THRs and TKRs for OA. Of the hospitals that failed to respond to the questionnaire despite reminders, a total of 20 had performed THR and 14 had performed TKR during the 5-year period. Some of them did not continue with elective joint replacements. The proportion of hospitals with a low annual volume of joint replacements was higher in this category of hospitals with an unknown care program. (Figure 2).

Figure 2. Annual hospital volume of THRs and TKRs with different care programs. Number of hospitals in each category.



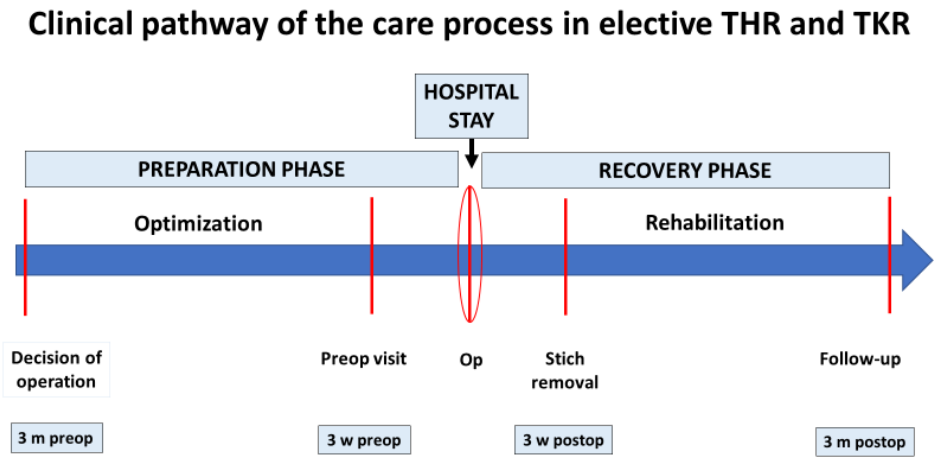
At the beginning of 2011 less than 30% of Swedish hospitals had implemented fast-track in the care of patients undergoing elective THR and TKR. During subsequent years, the number of hospitals introducing the new concept increased and by the end of 2015 almost 80% of hospitals had introduced a fast-track program (Figure 3). At most hospitals, the introduction of a fast-track program took place at the same time for THR and TKR.

Figure 3. Implementation of fast-track program in elective THR and TKR at Swedish hospitals 2011-2015



Fast-track programs were already in place at 17 hospitals/clinics before 2011. Almost half of these were private, even though private hospitals accounted for only 20% of all hospitals that performed joint replacements in Sweden. By the end of 2015 the fast-track concept had been implemented at 49 hospitals. All private clinics that responded to the questionnaire were using fast-track programs in 2015, but all types of public hospitals had also adopted fast-track, both low and high annual volume units (Figure 2). The hospitals that had not yet introduced fast-track at the end of 2015 had a fairly uniform geographical distribution and annual operation volume.

Figure 4.



8.1.1 Preparation phase

The clinical pathway (Figure 4) starts with the decision to operate when the patient attends as an outpatient to meet the orthopaedic surgeon for assessment and discussion of eligibility for joint replacement. Most patients attend following referral from the GP who conducts the basic investigations, including an X-ray examination. The visit to the orthopaedic outpatient service should be preceded by non-operative treatment, including patient education and training in a self-management program run within the primary healthcare system. Of the hospitals that responded to the questionnaire, around 45% had the patient education self-management program as a requirement before accepting a patient for joint replacement surgery. The visit with the decision to operate took place about 3 months before the operation. Most hospitals (79% for THR and 75% for TKR) gave the patient an information brochure about the operation, the clinical pathway, and the care process during the outpatient visit when the decision to operate was made. An information film about the operation and an information brochure in different languages was available only at four hospitals (7%) that performed THR and five hospitals (8%) that performed TKR.

According to the questionnaire, 92% of the hospitals with a THR care program and 87% with a TKR care program had a preoperative visit as a checkpoint in the clinical pathway, the aim being to further prepare for the operation and the hospital stay. In 62% of the THR programs and 71% of the TKR programs the

visit was planned 1-3 weeks before surgery and included multi-professional participation with information provided individually or in a group. More than 80% the patients met an anaesthesiologist, a physiotherapist, and a nurse. At two-thirds of the orthopaedic departments they also met an orthopaedic surgeon during the same visit. Some hospitals included occupational therapists and assistant nurses in the multi-professional planning team.

8.1.2 Perioperative care

All hospitals except one used cloxacillin as the first choice of prophylactic antibiotic for both hip and knee replacements. The vast majority, 84% of the THR programs and 89% of the TKR programs, administered 3 doses of cloxacillin. Most of them administered the last dose after 6 hours. In all TKR operations LIA had been introduced as part of pain treatment but only in 20% of operations was infiltration combined with a wound catheter to provide supplementary doses. In THR, LIA was used routinely at two-thirds of the hospitals but only 2 hospitals (3%) used a catheter. An indwelling urethral catheter was routinely used perioperatively at 64% of the arthroplasty units performing THR and at 41% of the units performing TKR. Half of the hospitals used a postoperative nasal oxygen catheter, 52% in TKR and 48% in THR. General anaesthesia was the first choice in TKR at 5 hospitals (8%) and in THR at 4 hospitals (6%). All other hospitals recommended spinal anaesthesia, and 80% administered spinal anaesthesia without opioids. Tranexamic acid was used to reduce bleeding at almost all the hospitals and drainage was used at only 2 hospitals that performed TKR.

In postoperative multimodal pain treatment, long-acting opioids (oxycodone) were included routinely at 81% of units performing THR and at 85% of units performing TKR. In the case of severe pain, almost all hospitals used short-acting opioids administered orally, and 44% reported a morphine injection as an option. Non-steroid anti-inflammatory drugs (NSAID) were used as standard at 61% of the hospitals for THR and 78% for TKR. Systemic corticosteroids as standard before commencement of surgery had been implemented at only 18% and 15% of the hospitals respectively for THR and TKR but mainly at fast-track units. At one hospital with a fast-track program was thromboprophylaxis routinely given only during the hospital stay (3-4 days). All other hospitals used thromboprophylaxis for longer periods, in TKR for 7-14 days and in THR for 4 weeks or longer at 87% of the responding hospitals. The choice of antithrombotic drug varied, and for both THR and TKR oral treatment was standard in less than 50%.

8.1.3 After discharge

After discharge there was a follow-up at all hospitals except one, but only at one-third of the hospitals was there a planned follow-up with the surgeon. It was more common for a patient to be seen by a physiotherapist or a nurse. For patients undergoing TKR, the follow-up in most cases occurred 3-6 weeks postoperatively. For THR patients, the follow-up was mostly 7-12 weeks after surgery. In 85% of the hospitals, THR patients were recommended to avoid deep flexion and crossing their legs for at least the first 6 weeks.

8.1.4 Conclusions of the survey

From an analysis of the survey we can conclude that there were considerable similarities in the care programs when comparing fast-track and non-fast-track hospitals. Some of the surgeons who responded to the questionnaires commented that care programs develop over time and new methods are introduced gradually in line with the influx of new knowledge. The differences between fast-track and non-fast-track hospitals in a Swedish context were minor regarding treatment methods. However, the fast-track hospitals differed from other hospitals in terms of logistical routines during admission on the day of surgery, immediate mobilization postoperatively, and functional discharge criteria in practice resulting in a short LOS. The reported median LOS was 2-4 days at hospitals with fast-track and 4-7 days at hospitals without fast-track. The LOS values were not confirmed with data from the healthcare databases, although they do indicate that implementation of fast-track programs was associated with a shorter LOS.

According to information from the questionnaires, all hospitals had a common care program for all patients who underwent surgery at their orthopaedic department. Consequently, patients were not selected to join fast-track or non-fast-track at the same hospital, although there were individual adaptations. If, for example, patients lived far away from the hospital and did not have transport available early in the morning on the day of surgery, admission the day before surgery was accepted at some hospitals. Patients were informed about the intended length of stay, but if they did not fulfil the functional discharge criteria, they needed to stay longer.

The complete results of the questionnaires are reported in the Appendix Table 2 and Table 3.

9. METHODS

9.1 Definition of cohorts

The thesis has 3 prospective observational register studies (Paper I-III) and 1 qualitative study (Paper IV). The register studies were based on the survey of the care programs at Swedish hospitals 2011-2015. A questionnaire was sent to Swedish hospitals performing elective THR and TKR. The survey aimed to define when a fast-track program had been introduced. The operations at hospitals responding to the questionnaire were divided in 2 groups depending on if the operations were made in a fast-track program or not. The criteria that had to be met to de defined as a fast-track program were: 1) admission on the day of surgery 2) mobilization within 3-6 hours after operation, and 3) functional discharge criteria in practice. If the reported median LOS was > 5 days, the care was defined as non-fast-track. A third group with operations at hospitals not responding to the questionnaire, representing less than 10% of the THRs and TKRs, was included in Paper II and III and categorized as a cohort with "unknown care program". The cohort with unknown care program was presented by descriptive statistics to get a complete overview of THR and TKR operations in Sweden but not included in the comparative analysis.

9.2 Source of data

In the observational register studies (Paper I-III) data were obtained from the SHAR and SKAR and included patients with osteoarthritis in hips (M16.0-M16.9) and knees (M17.0-M17.5) operated at Swedish hospitals with primary THR (NFB29, NFB39, NFB49 and NFB62) and TKR (NGB29, NGB39 and NGB49) during the period 2011-2015. In the first study (Paper I) data were also obtained from the regional patient register VEGA.

9.3 Exposure and Outcome

The exposure that was investigated in study I-III were the different care programs (fast-track/non-fast-track) in THR's and TKR's. The outcomes, that were explored consisted of readmissions and adverse events within 30 and 90 days (Study I), patient reported outcomes 1 year after THR and TKR (Study II) and the risk of revision and mortality within 2 years after surgery (Study III).

9.4 Patients and analysis methods in Paper I

In the region Västra Götaland fast-track care programs were implemented at 8 public hospitals between January 2012 and November 2014 at different times. We collected data from SHAR and SKAR and linked them to the regional patient register. In the 8 hospitals 7,774 elective THRs and 6,374 TKRs for OA were performed 2011-2015. Data on readmissions and new contacts within 30 and 90 days after surgery were retrieved from the regional patient register after ethical approval. Both hospital readmissions, new out-patient contacts at the hospital and contacts with the primary health care system were analysed based on the code list for AE (ICD-10 codes for diagnoses and NOMESCO codes for interventions) used by SKAR and SHAR.

Univariable and multivariable logistic regression analyses were used to evaluate the risk of readmissions and adverse events within 30 and 90 days. In the multivariable logistic regression analyses adjustments were made for age, sex, ASA and BMI. Relative risks were approximated by odds ratios (OR) and estimated with a 95% Confidence Interval (CI). The results were considered statistically significant if observed p-values were smaller than 0.05.

9.5 Patients and analysis methods in Paper II

Data from the arthroplasty registries were used to compare PROs of patients operated in a fast-track program with PROs of patients operated in a care program defined as non-fast-track. All Swedish hospitals performing THRs participate in the PROM-program of SHAR and the cohorts of THR operations consisted of patients from 63 Swedish hospitals, where the type of care program was known as fast-track or non-fast-track. Complete PROM data preoperatively and 1-year postoperatively were available in 76% of the patients.

The data from SHAR included THR operations (NFB29, NFB39, NFB49 and NFB62) with OA in the hip (M16.0-M16.9) during the period 2011-2015. Every operation was counted even if patients were operated bilaterally during the observed period. PROM data were collected from SHAR using the generic health status measure EQ-5D [123] with 3 levels of the 5 dimensions mobility, self-care, usual activities, pain/discomfort and anxiety/depression. In addition the visual analogue scale (VAS) [124] with a range from 0 to 100 was used for general health, pain and satisfaction with surgery 1 year after the operation. For general health (EQ VAS) the score 0 represents the worst and 100 the best. For Pain VAS

and Satisfaction VAS the best score is 0 and 100 the worst outcome. Delta values were used to measure improvement by comparing the preoperative values with the values 1 year after surgery. The satisfaction (VAS) score was also categorized into 5 groups; very satisfied (0-20), satisfied (21-40), neither dissatisfied nor satisfied (41-60), dissatisfied (61-80) and very dissatisfied (81-100).

For TKR patients PROM data was collected from SKAR and the cohorts of fast-track and non-fast-track consisted of patients from the 15 hospitals participating in the PROM program of SKAR 2011-2015. Complete PROM data both preoperatively and 1-year postoperatively were available in 71% of the patients. The PROMs used by SKAR was EQ-5D, EQ VAS, Pain VAS and Satisfaction VAS 1 year after surgery as in THR patients. Most hospitals also used the Knee injury and Osteoarthritis Outcome Score (KOOS) [125] with the 5 subscales Pain, Other Symptoms, Activity in Daily Life function (ADL), Sport and recreation function (Sport/Rec) and Knee related Quality of Life (QoL). All subscales have a range from 0 to 100 where the highest scores represent the best outcomes.

The EQ-5D-index [126, 127], EQ VAS, Pain VAS and Satisfaction VAS postoperative scores 1 year after surgery were compared between the non-fast-track and the fast-track groups using multivariable regression analysis. Adjustments were made for patient factors as age, sex, BMI, Charnley category, and the preoperative scores. These factors may influence how patients report their health status 1 year after surgery [128]. Finally, the adjustment also included type of fixation and incision in THR. The significance of each covariate was tested (Wald's test) before being included in the models. The regression coefficients were presented with 95% confidence interval (CI). The effect sizes (standardized mean differences) for the difference between fast-track and non-fast-track as measured by the change from pre to 1-year post operation in PROs were calculated using Cohen's d formula [129].

9.6 Patients and analysis methods in Paper III

The cohorts of THR and TKR operations consisted of patients from 63 Swedish hospitals, where the type of care program was known as fast-track or non-fast-track. Data were obtained from the SHAR and SKAR and included THR operations (NFB29, NFB39, NFB49 and NFB62) and TKR operations (NGB29, NGB39 and NGB49) in patients with OA in the hip (M16.0-M16.9) and the knee (M17.0-M17.5) during the period 2011-2015. The data included demographic and

procedure-specific variables, date and reason for revision and date of death if it occurred within 2 years after surgery. Information of deaths is included in the register data by linkage to the Swedish Tax Agency.

Kaplan-Meier survival analysis was used to analyze revisions and mortality within 2 years for the 2 cohorts with a known care program. The risk of revisions and mortality was compared between non-fast-track and fast-track care program using Cox regression models with restricted follow-up time of 2 years. Both unadjusted univariable models and multivariable models with adjustments were examined. In THRs adjustments were made for age, sex, BMI, ASA class, year of operation, type of fixation and surgical approach. For TKR, age, sex, BMI, ASA class, and year of operation were factors assumed to influence mortality. In the analysis of revision risk after TKR adjustments were also made for the type of fixation (cemented or not cemented) and the use of patella resurfacing or not. The risk of revision and death was estimated by Hazard Ratio (HR) with a 95% confidence interval (CI).

9.7 Patients and methods in Paper IV

To explore patients' experiences of the clinical pathway and care process a qualitative research design was chosen. Data were collected from interviews 3 months after surgery and analysed using an inductive content analysis method according to Elo & Kyngäs. In order to obtain variation and saturation of informative data responding to the research question, we chose a strategic sample of patients, who underwent THR or TKR operations at 3 different hospitals in the western region of Sweden, of both sexes and different ages. All 3 hospitals used a fast-track care program. The exclusion criteria were inability to communicate in the Swedish language or cognitive dysfunction. The patient information and invitation to participate in an interview was given by staff members who were not involved in the study.

In total, 24 patients were included in the study: 8 from a university hospital (A), and 7 and 9 respectively from two district hospitals (B and C); 14 women and 10 men, 13 with THR and 11 with TKR. The mean age was 65 years (range 44-85). 2 patients with THR and 2 with TKR had previously been operated on the contralateral side. Two patients had a LOS of 2-3 days, all other patients were discharged from the hospital the day after surgery.

The patients were contacted by telephone and an interview was planned 3 months after surgery. The interviews were arranged at a mutually convenient time and place. Most patients preferred to be interviewed at home. The interviews were semi-structured and started with open questions. Supplementary open questions were used when necessary in order to cover all phases of the clinical pathway, from surgery decision until the actual situation 3 months after discharge. Special attention was paid to issues pointed out as important by the participants. The interviews lasted on average 50 minutes (range 33-74), were audiotaped and transcribed verbatim.

The first step in the data analysis was to gain familiarization of the content by reading all interviews 2-3 times. Some interviews were read by two other researchers. Next, the text was read again to select analysis units containing informative data. The selected units were confirmed by the other researchers, followed by coding, grouping and categorization. Subcategories were formed and organized in generic categories according to the different phases of the clinical pathway. Finally, the findings were analysed searching for main categories and over-arching themes.

10. ETHICAL CONSIDERATIONS

Ethical approval was given for all studies by the Regional Ethical Review Board in Gothenburg. The register studies (study I-III) including linking to regional patient register (study I) did not need individual written patient consent according to the Patient Data Act in Sweden. The studies were observational studies with aggregated data without any supplementary patient intervention. There were for the first study remarks from the Ethical Board on the free text box in the prestudy questionnaire, which was addressed to the orthopaedic surgeon in charge of the care program at each hospital. The responses were given without individual written consents. However, the free text box was used just for communication purpose and not to get research data from individuals. After a dialogue with the Ethical Board the prestudy questionnaire was accepted to be used.

For the first study we had also to introduce a supplementary application for approval of access to data from the primary health care units in the regional patient register. The ethical board approved the demand without any further remarks.

In the qualitative interview study individual written patient consent was obtained from all patients prior to study inclusion. Patient data were anonymized. The ethical board approved the study without remarks.

Study I: Approved by the Regional Ethical Review Board in Gothenburg (Dnr 388-15, 2015-06-01 and 2015-07-17, T 1107-16, 2016-12-15).

Study II and III: Approved by the Regional Ethical Review Board in Gothenburg (Dnr 2019-00559/1095-18, 2019-01-10).

Study IV: Approved by the Regional Ethical Review Board in Gothenburg (Dnr 062-17, 2017-02-20).

11. RESULTS

Paper I

Implementation of fast-track programs resulted in a decrease of median hospital length of stay (LOS) from 5 to 3 days in both THR and TKR at 8 public hospitals (Table 2). The mean LOS for THRs decreased from 5.8 days to 3.7 and for TKRs from 5.4 to 3.3 days.

The total readmission rate < 90 days for THR was 7.2% with fast-track compared to 6.7% in the previous care program, and for TKR 8.4% in both groups.

Almost half of the readmissions occurred without any AE identified. Most AE were identified at the hospital, either when the patient was readmitted and hospitalized or at a visit in the Out-Patient Department (OPD), but 10-15 % of the new contacts occurred at a primary health centre outside the hospital (Figure 5).

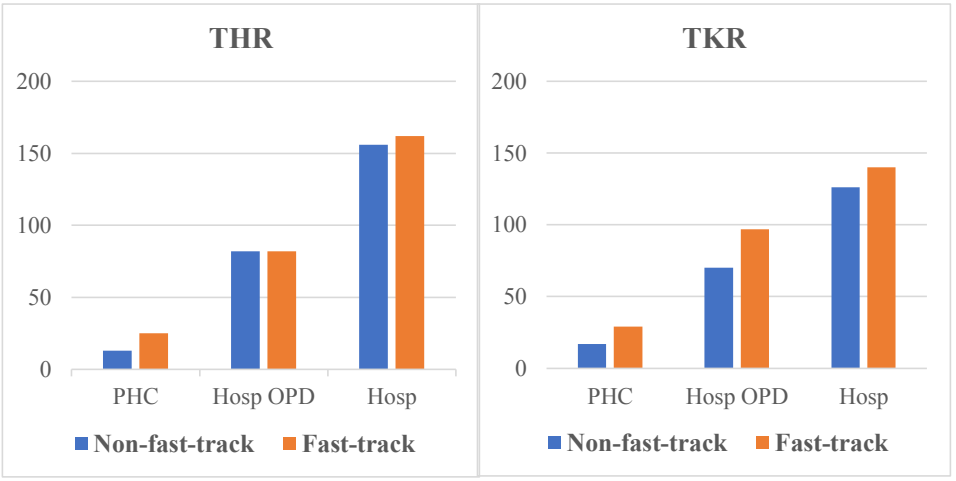
Table 2. Implementation of fast-track in THR and TKR at 8 hospitals. Summary of results.

	Variable, Definition	Non fast-track program	Fast-track program
THR	Operations, n	3,859	3,915
	LOS, median (days)	5	3
	LOS mean (days)	5.8	3.7
	Readmissions < 90 days, n (%)	260 (6.7)	281 (7.2)
	Patients with AE < 90 days, n (%)	308 (8.0)	317 (8.1)
TKR	Operations, n	2,944	3,430
	LOS, median (days)	5	3
	LOS mean (days)	5.4	3.3
	Readmissions < 90 days, n (%)	246 (8.4)	288 (8.4)
	Patients with AE < 90 days, n (%)	276 (9.4)	344 (10.0)

THR: Total hip replacement, TKR: Total knee replacement, LOS: length of stay, n: number
AE: Adverse events

The definition of AE was based on ICD-10 diagnosis codes and NOMESCO intervention codes according to code lists elaborated by SKAR and SHAR. The code list is divided into 5 categories (Figure 6 and 7).

Figure 5. First care contact for AE within 30 days after THR and TKR



AE: Adverse Event; THR: Total Hip Replacement; TKR: Total Knee Replacement; PHC: Primary Health Care; Hosp OPD: Hospital Out-Patient Department; Hosp: Hospitalization

Figure 6. Adverse events (%) within 90 days after THR according to categories of ICD-10 and NOMESCO codes

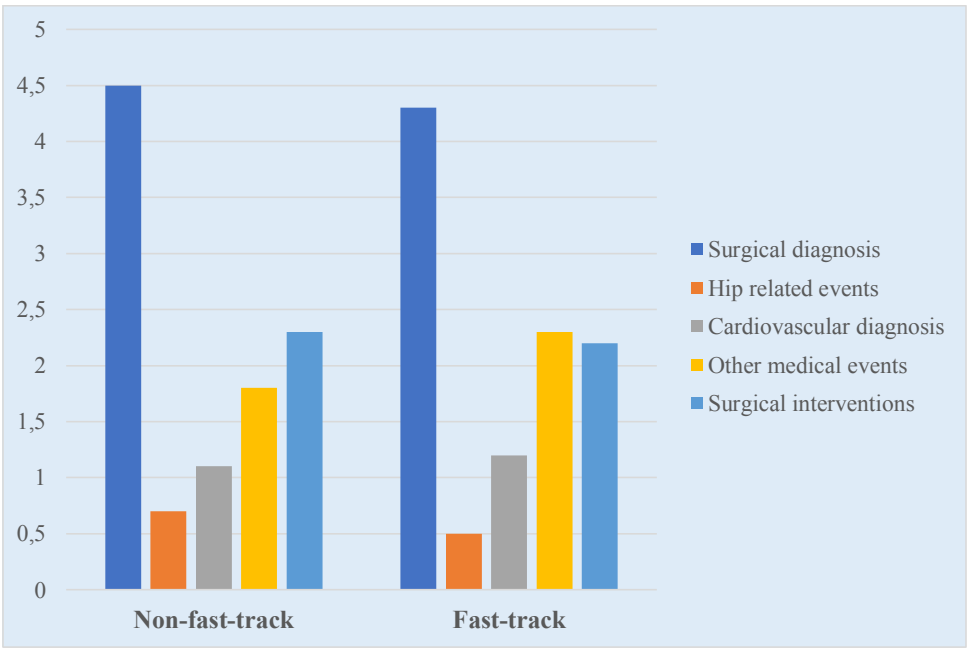
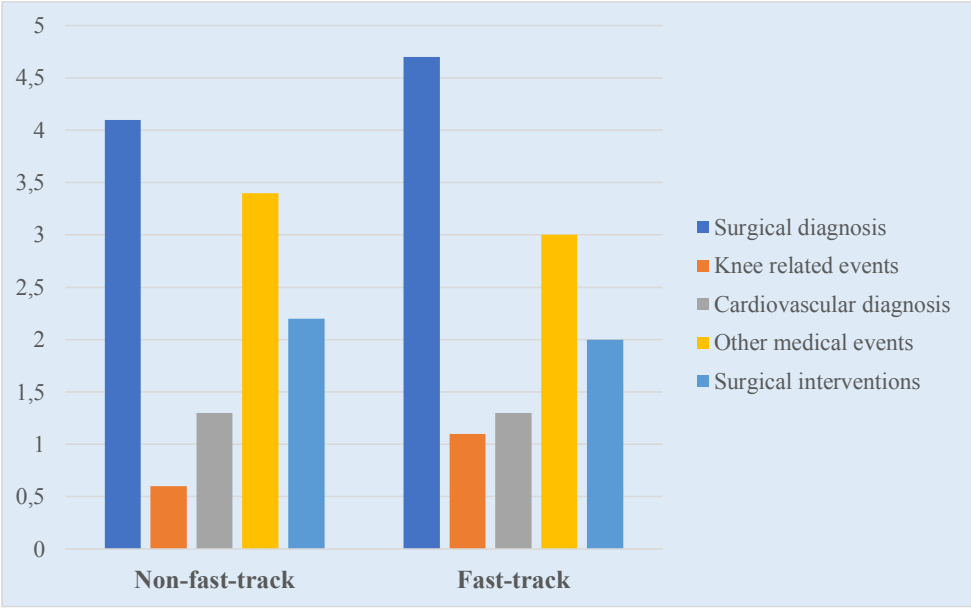


Figure 7. Adverse events (%) within 90 days after TKR according to categories of ICD-10 and NOMESCO codes



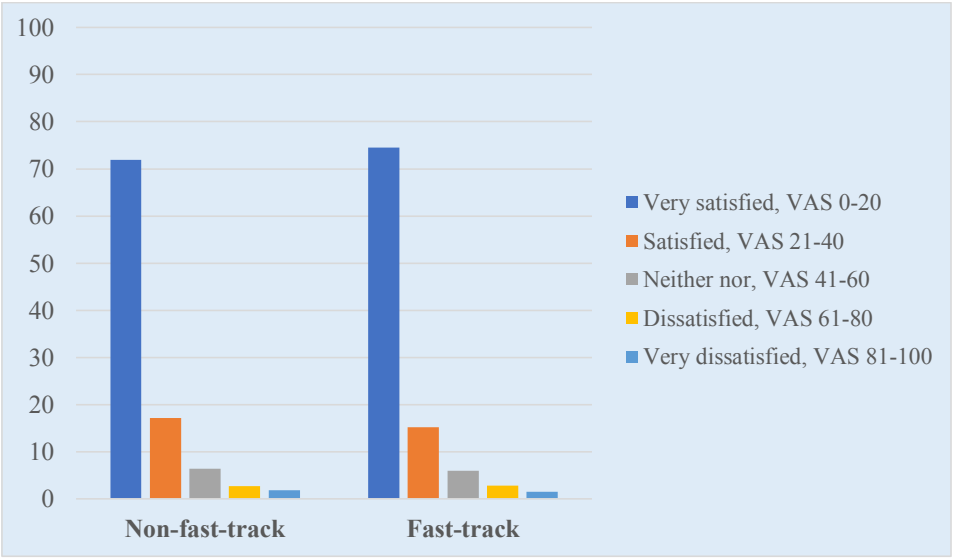
The multivariable logistic regression could not demonstrate a statistically significant influence of fast-track on readmission or adverse events (AE). The estimated risk using Odds Ratio (OR) of readmission after THR in the fast-track group was 1.17 (CI: 0.94-1.45) within 30 days and 1.10 (CI:0.92-1.32) within 90 days. The OR of AE within 30 days in the fast-track group was 1.10 (CI:0.92-1.33) and 1.06 (0.90-1.24) within 90 days. For TKR the OR of readmission in the fast-track program was 1.09 (CI: 0.88-1.35) within 30 days and 1.05 (CI:0.88-1.25) within 90 days. The OR of AE after TKR was estimated to 1.09 (CI: 0.91-1.32) within 30 days and 1.15 (0.98-1.36) within 90 days. When analysing the postoperative complications, we noticed that the number of patients with urinary retention was higher in the fast-track group, and about 30% of them were treated at the health centres outside the hospitals. However, the overall complication rate was similar regardless if the fast-track program was applied or not both for the major local and general complications.

For more details of the results, see the publication of Paper I.

Paper II

The differences of EQ-5D, EQ VAS, Pain VAS and Satisfaction VAS 1 year after surgery were small but all in favour of fast-track compared to non-fast-track for both THR and TKR, also in subscales of KOOS for TKR except KOOS QoL. The proportion of patients, who were satisfied and very satisfied (VAS 0-40) with their operation 1 year after THR were similar, 90% with fast-track and 89% with non-fast-track. However, focusing the category of very satisfied patients (VAS 0-20) the difference was slightly larger, 75% in the fast-track group compared to 72% without fast-track (Figure 8).

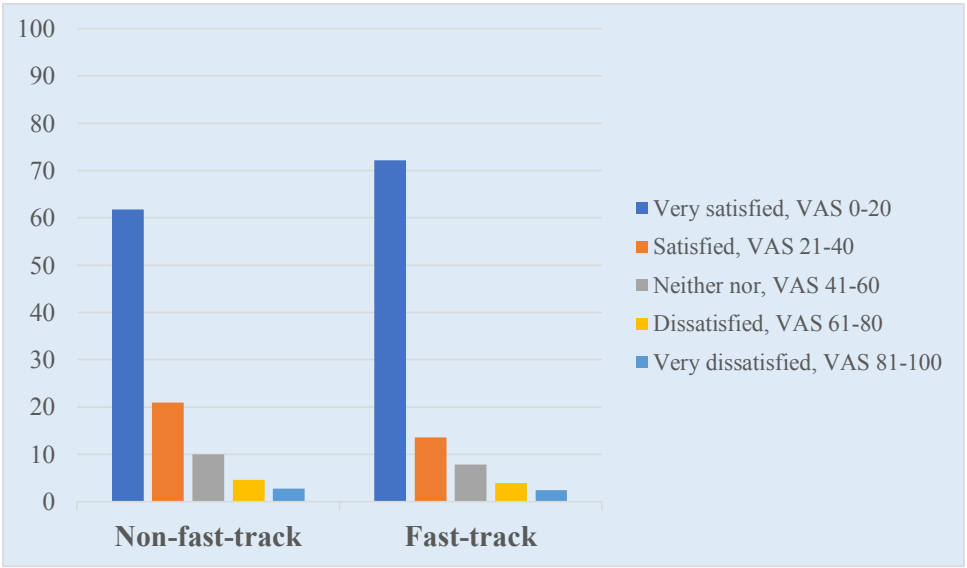
Figure 8. Satisfaction categories 1 year after THR operation (%)



In the regression analyses with adjustments for all variables the deviations in favour of fast-track were small, < 2 on the scale from 0 to 100 for PROMs assessed by the VAS scale.

In TKR patients the differences of postoperative mean scores between the cohorts were small, slightly better in the fast-track group. The proportions of very satisfied and satisfied (VAS 0-40) were 86% in the fast-track group and 83% in the group without fast-track. The difference was larger in the category of very satisfied patients (VAS 0-20), 72% with fast-track compared to 62% with a care program defined as non-fast-track (Figure 9).

Figure 9. Satisfaction categories 1 year after TKR operation (%)



The improvement of KOOS scores preoperatively to 1 year postoperatively was considerable in all subscales of KOOS in both cohorts. However, the differences between the groups were small (1-2 points) both pre- and 1 year postoperatively. The adjusted regression estimate of the effect of care process was in favour of fast-track in all subscales except for the subscale KOOS QoL, but the effect sizes as measured by Cohens' d formula were < 0.2 for all PROs in TKR as well as in THR indicating a small effect of the care program.

For more information of the results, see Paper II.

Paper III

The proportion of patients with a revision within 2 years after primary THR was low, 1.6% in the fast-track cohort and 1.3% in the cohort with THR operations without fast-track. The cox regression analysis with adjustments for age, sex, BMI, ASA class, year of operation, type of fixation and surgical approach indicates that the risk of revision within 2 years after THR was almost 20% higher with fast-track programs. The HR was 1.19 (CI 1.03-1.39). However, ASA class and type of fixation were stronger predictors of increased risk of revision than the care program.

In TKR there were 1.4% revisions in the fast-track group and 1.8% in the non-fast-track. The estimated risk of revision within 2 years after TKR using cox regression analysis with adjustments for age, sex, BMI, ASA class, year of operation, type of fixation and patella resurfacing was similar in the different care programs. The HR for the fast-track group was 0.91 (CI 0.79-1.06). Prosthetic joint infection (PJI) was the most common reason of revision in TKR as well as in THR (Table 3).

Table 3. Revision within 2 years after THR and TKR in different care programs

	Variable, Definition	Non-fast-track program	Fast-track program	Unknown care program
THR	Operations, n	25,520	35,867	6,526
	Revisions all, n (%)	335 (1.3)	565 (1.6)	137 (2.1)
	Revisions due to PJI, n (%)	174 (0.7)	300 (0.8)	67 (1.0)
TKR	Operations, n	23,036	31,686	4,546
	Revisions all, n (%)	405 (1.8)	434 (1.4)	56 (1.2)
	Revisions due to PJI, n (%)	217 (0.9)	221 (0.7)	36 (0.8)

THR: Total Hip Replacement; TKR: Total Knee Replacement; PJI: Prosthesis Joint Infection

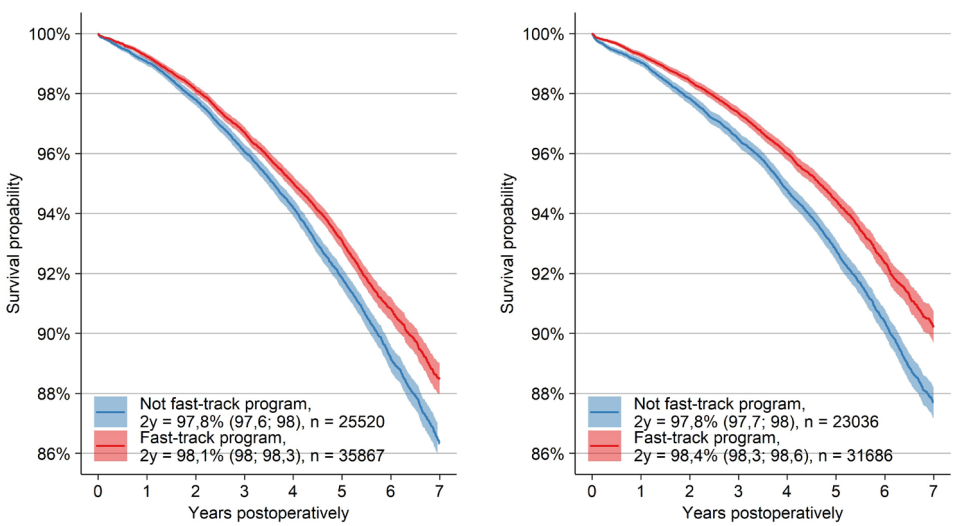
The mortality within 2 years after primary THR was 1.9% in the fast-track program compared to 2.2% without fast-track. After adjustments in the multivariable cox regression analysis no significant difference between the care programs could be demonstrated concerning the risk for death within 2 years after THR. The HR was 0.96 (CI 0.85-1.09) for the fast-track program. In the fast-track cohort of TKR the mortality within 2 years was 1.4% compared to 1.9% in the cohort of non-fast-track. After adjustments in the multivariable cox regression analysis the risk for death was significantly lower in the fast-track program with

a HR of 0.87 (CI 0.74-0.97). The 30-day and 90-day mortality was also explored for both THRs and TKRs, but the figures were low (Table 4), and we could not demonstrate a statistically significant difference in the estimated risk of death between the care programs. The survival probability for patients operated with THR and TKR in 2011-2015 is presented with Kaplan-Meier curves (Figure 10).

Table 4. Mortality within 30 days, 90 days and 2 years after THR and TKR

	Variable, Definition	Non-fast-track program	Fast-track program	Unknown care program
THR	Operations, n	25,520	35,867	6,526
	Deaths < 30 days, n (%)	34 (0.1)	37 (0.1)	4 (0.1)
	Deaths < 90 days, n (%)	66 (0.3)	64 (0.2)	11 (0.2)
	Deaths < 2 years, n (%)	564 (2.2)	674 (1.9)	122 (1.9)
TKR	Operations, n	23,036	31,686	4,546
	Deaths < 30 days, n (%)	25 (0.1)	18 (0.1)	3 (0.1)
	Deaths < 90 days, n (%)	53 (0.2)	42 (0.1)	9 (0.2)
	Deaths < 2 years, n (%)	442 (1.9)	453 (1.4)	78 (1.7)

Figure 10. Survival probability after THR **Survival probability after TKR**



More details of the results with tables and figures are presented in Paper III.

In a sub-analysis of revisions due to PJI at hospitals, where a non-fast-track program had been replaced by fast-track during the observed period, we explored the PJI rate before and after implementation of fast-track. At 11 hospitals with at least 300 THRs in both types of programs there was an increased PJI rate at 6 hospitals, a decreased rate in 3 hospitals and unchanged PJI rate at 2 hospitals after the implementation of fast-track. The overall revision rate due to PJI was 0.9% without fast-track and 1.1% with fast-track. However, the range of PJI rate at the 11 hospitals was 0.2-1.9% without fast-track and 0.3-2.9% with fast-track.

Paper IV

The interview study exploring patients' experiences in fast-track programs of THR and TKR identified the importance of information and patient involvement in all phases of the clinical pathway.

The generic categories that were identified in the preparation phase were:

- Confirmation that surgery was needed
- Planning the date of surgery
- Planning the anaesthesia
- Information about the care and expected outcome

The generic categories of the hospital stay focused on the experience of:

- Admission on the day of surgery
- Early mobilization after surgery
- Early discharge

In the phase after discharge from the hospital the issues of importance were:

- Managing daily life
- Rehab program and recovery
- Feedback and follow-up

However, the diversity in needs was striking. Although the hospital stay was very short, in most patients just one night, there were mainly positive experiences regarding admission, pain treatment, mobilization and early discharge. The rehabilitation phase was often filled with feelings of uncertainty about the progress, and patients expressed a need for improved feedback and follow-up. Regardless of the different phases, we found the importance of a person-centred care to be an over-arching theme.

A summary of patients' experiences is presented in Table 2 of Paper IV.

12. DISCUSSION

Fast-track programs have had a tremendous impact on Swedish hospitals by substantially shortening the perioperative hospital stay for patients undergoing elective hip and knee replacement. As the number of hospital beds has decreased considerably during the last decade due to budget limitations, the fast-track programs have been a success for the hospitals as they allow the number of hospital beds to be reduced but still maintaining elective surgery capacity. Nevertheless, a well-founded question needs to be asked: Is it also good for the patients? The thesis addresses this overall question and attempts to eliminate some of the doubts and uncertainties.

When fast-track programs were introduced in hip and knee replacements at pioneer clinics in Europe and the message of rapid recovery began to spread, it was received almost as if it was a universal solution for the care at arthroplasty units. Not only was LOS reduced significantly, but quality of care and satisfaction also seemed to improve in most respects. However, a number of crucial questions came to the fore: If patients are discharged very quickly, is there not a risk of increased readmissions? Is there not a risk that more complications will appear after discharge and may not be handled properly? Do patients need to visit primary healthcare centres and GPs, who do not have the competence to identify and handle potentially serious complications? These concerns were the reasons behind our first observational study on readmissions and adverse events following THR and TKR.

Our results indicate there is no increased risk of readmissions and adverse events within 30 and 90 days after surgery, even if the number of new healthcare contacts following discharge from hospital was slightly higher following the introduction of fast-track. The difference compared to conventional care programs was small and not significant. As far as we know, our study is unique in that it includes the primary healthcare contacts, and our conclusion is that even if certain postoperative adverse events are identified by GPs, almost all serious complications are identified and treated at the hospital. The fear that adequate treatment of complications could be delayed was not confirmed. Patients were also informed at discharge that wound problems during the first few weeks after surgery should always be examined by the orthopaedic professionals at the hospital and not by the GPs.

The second observational study explored the PROs reported to the national arthroplasty registers 1 year after THR and TKR. In the case of hip patients, the study was nationwide and included 63 hospitals. The PROs of fast-track programs could therefore be compared with the PROs of care programs defined as non-fast-track using cohorts that included the vast majority of THR operations in Sweden for five years. Even if data completeness was less than 80% it provides a very solid view of the influence of fast-track programs in a Swedish context. Our conclusion is that fast-track is at least as good as conventional care with regard to PROs 1 year after surgery. In fact, the results consistently supported the use of fast-track, even if the differences were small.

For TKR, PROM data was reported to SKAR from 15 hospitals representing 5 of the 21 county councils in Sweden. The demographics were similar to the demographics at hospitals that did not participate. In TKR, the difference in favour of fast-track was even larger, especially regarding satisfaction with the operation, improvement in Pain VAS, and improvement in the KOOS symptom subscales. However, the differences were far below the level of perceptible clinical improvement in an individual.

The third observational register study examined the risk of revision and mortality. For both THR and TKR more than 90% of the elective THRs and TKRs in Sweden in 2011-2015 were defined as fast-track or non-fast-track and could be included in the two main cohorts. The statistical analysis revealed an increased risk of revision in fast-track programs within 2 years after primary THR. The Hazard Ratio was 1.19, which indicated an increased revision risk of approximately 20% with fast-track. If a difference exists between the care programs, the increased number of revisions is estimated to be 2-3 per 1000 primary THRs, when the calculation is made on a revision rate of 1-2% We should also consider that, even if the cohorts are large with more than 35,000 operations in the fast-track group, the confidence interval in the risk calculation is wide (1.03-1.39), and some uncertainty remains. Nevertheless, the finding of increased risk raises concerns, but we must be cautious in drawing conclusions. The main reason for revision was confirmed or suspected PJI, although other reasons for revision as recurrent hip dislocation were also slightly more frequent in the fast-track cohort compared to the non-fast-track cohort.

In the analysis of revisions due to infection we explored data from hospitals with both types of programs during the review period. At some hospitals, the revision rate due to infection increased while at others it decreased. The PJI rate between hospitals varied considerably for both programs, indicating that increased PJI rates may be associated more with local conditions at certain hospitals than with the care program.

Another conceivable explanation for the increased revision rate with fast-track programs is the fact that broad-based implementation of fast-track coincided timewise with a change in attitude, with early intervention in the case of suspected surgical site infections (SSI) but not yet confirmed PJI. A Swedish patient safety project called "PRISS" (Prosthesis Related Infections are Stopped) with the aim to reduce the real infection rate of implant operations lasted 2009-2013. Almost all orthopaedic clinics participated in the project, which resulted in a recommendation of early intervention including debridement, antibiotics and implant retaining (DAIR procedure) in case of SSI or suspected PJI. As the DAIR procedure often includes exchange of modular implant parts, it is consequently classified as revision. However, it is difficult to explain why fast-track in our study was associated with an increase of revisions in THR and not TKR.

Our results indicate that mortality after THR and TKR in fast-track programs within 30 and 90 days as well as within 2 years may be lower compared to the non-fast-track programs. In our first study on the regional level, which explored readmissions and AEs within 90 days, the number of deaths was lower in the fast-track group. However, fatal events shortly after surgery are so few that conclusions cannot be reached with statistical certainty. In the nationwide study using register data, the cohorts were larger and the observation period longer. When exploring the risk of death within 2 years using Cox regression analysis with adjustments, we could demonstrate a small yet statistically significant reduction in mortality in the fast-track group of TKRs. In THR there was a trend towards lower mortality, although this was not proven statistically.

The reduction in mortality within 90 days with fast-track may be even greater, but as the mortality rates within 30 and 90 days after THR and TKR are very low regardless of the care programs, we need very large cohorts to statistically confirm this hypothesis. The care principles behind fast-track, which include minimizing surgical stress, early mobilization, and rapid recovery, may reduce the risk of

cardiovascular and thromboembolic events in the postoperative period, but this must be proven. If recovery is faster and functional outcome better after THR and TKR in fast-track programs, it may also have favourable effects on mortality from a more long-term perspective.

The qualitative interview study exploring patients' experiences of the care provided was highly informative. The patients were allowed to speak freely about their experiences and highlight their fears and disappointments, but also share when their expectations in the clinical pathway and care process were exceeded. One main issue was how information and patient involvement were perceived. There was considerable variation between patients in terms of the need for information. Both oral and written information are used by the healthcare professionals, but sometimes the volume of information exceeds the capacity to receive and assimilate. A key to improving the information in all phases may be to ask the patients what they want to know and invite them to engage in a dialogue instead of providing extensive standardized information.

An overarching theme in the content analysis was the need for a person-centred approach in all phases of the clinical pathway. It could be a challenge to secure acceptance of a very short hospital stay, but most patients tolerated the rapid process very well and accepted early discharge without objections if they felt safe and knew what was going to happen.

However, the interviews revealed a weak point in the care process at the 3 hospitals where the operations had taken place. The recovery phase with rehabilitation and follow-up was not optimized. The patients were referred to different physiotherapists outside the hospitals, and according to the patients the care and rehabilitation program varied a great deal and was not person-centred and adapted to the needs of the individual. Another disappointment was the lack of feedback from certain surgeons, and the absence of a follow-up to check if recovery progress was normal or not. The patients' experiences provide important input for further improvement in care.

13. STRENGTHS

The overall aim of the project and the main research questions are extremely relevant as they highlight care in conjunction with the most common orthopaedic operations, which consume a significant proportion of the orthopaedic care budget. The concept of fast-track has influenced the vast majority of Swedish hospitals performing THR and TKR. It is very important following implementation of fast-track to confirm good results using different outcome measures, to assure patient safety when LOS is very short, to avoid quality deficiency costs, and to maintain the capacity for planned surgery when the hospital budget is limited.

We used a simplified definition of fast-track with 3 main logistical criteria. In addition, we asked the responsible orthopaedic surgeon whether the hospital had implemented fast-track and, if so, when (month and year) the fast-track program was introduced. Although LOS was not used as a main criterion, all hospitals defined as fast-track reported a median LOS of 2-4 days.

Data collection using the national quality registers with high validity of data, high coverage and completeness enables a comparison to be made between large cohorts and reflects routine care at Swedish orthopaedic departments.

The survey (prestudy) exploring the care program at Swedish hospitals in 2011-2015 was the key element in the research project and a prerequisite for conducting the observational register studies (I-III). The high response rate, with more than 90% of all elective THRs and TKRs during a 5-year period included in the studies on a national level (Studies II and III), ensures a solid overview of the outcomes in a Swedish context.

By adding a qualitative study, the implementation of fast-track is explored from the patients' perspective. The interview study identifies weaknesses and strengths in the clinical pathway and reveals areas that may further improve quality of care and outcome of joint replacement in hips and knees.

14. LIMITATIONS

One of the most crucial questions is how to define fast-track, as there is no international consensus with clearly defined criteria. The care principles behind fast-track aim to accelerate the care process and enhance recovery, yet the same methods of preparation and surgical care may influence other care programs, and the distinction between fast-track and non-fast-track becomes less clear.

Another weakness is the difficulty controlling all the confounding factors in the clinical pathway and care program. The process from decision-making through to recovery of function is complex and within the groups defined as fast-track and non-fast-track there are variations between hospitals.

The questionnaire used in the survey of care programs at Swedish hospitals is completed by one person (the orthopaedic surgeon responsible for the care program) at a specific point in time and the responses are not validated. The questions cover a 5-year period.

Adverse events are based on the coding at the health institutions, and we know that coding is not always accurate. As we cannot confirm the accuracy of ICD-10 and NOMESCO codes using medical records, a degree of uncertainty remains concerning the correct incidence of specific complications.

In the SHAR and SKAR registers the reporting of minor reoperations other than revisions is incomplete. Thus, reoperations without revision have not been analysed using register data. However, reoperations without revision constitute a minor part of all reoperations.

The PROM program in SKAR is different and the response rate is lower than in SHAR. However, the completeness of PROM responses both preoperatively and 1 year postoperatively is over 70% for the participating hospitals in both registers, which we consider to be quite good for large national registers.

A limitation in the qualitative study is that it is difficult to explore in depth every aspect of the care process in just one interview, which aims to cover a period of more than 6 months and a multitude of experiences. Some nuances may also be lost, when the quotations from the interviews are translated to English.

15. CONCLUSIONS

- Implementation of fast-track programs in elective THR and TKR at Swedish hospitals has resulted in a shorter perioperative hospital stay, but with a retained level of patient safety
- Fast-track is not associated with an increased risk of readmissions and adverse events within 90 days after THR and TKR
- Adverse events within 90 days after THR and TKR are handled mainly at hospitals, but 10-15% of adverse events related to the surgery are identified in the primary health care
- Patient-reported outcomes 1 year after THR and TKR with fast-track programs are at least as good as with non-fast-track
- Fast-track programs at Swedish hospitals in 2011-2015 are associated with an increased risk of revision within 2 years after THR but not after TKR
- The mortality is low within 30 and 90 days after THR and TKR. However, differences in the mortality risk between care programs are not confirmed.
- Mortality risk within 2 years after TKR is lower with fast-track compared to non-fast-track. For THR the decrease in mortality is not significant.
- A greater focus on the period after discharge from hospital may improve patient satisfaction and outcome
- A person-centred approach from the decision to operate through to recovery is a key element in optimizing care

16. FUTURE PERSPECTIVES

The increased risk of revision due to infections in association with fast-track raise concerns, but in all other aspects of safety, patient satisfaction and outcome fast-track programs are equal or better than conventional care programs. Our studies have not included the economic aspects, but other studies support a cost-effectiveness of fast-track, which is superior to previous care programs. Consequently, fast-track programs will be the standard care program in elective joint replacement at all Swedish hospitals with hospital discharge on the day of surgery in an increasing proportion of patients.

However, fast-track programs are dynamic needing continuous reconsideration regarding the different parts in the clinical pathway and care process in order to follow updated evidence-based knowledge. The qualitative study highlights areas in the care process to be addressed in order to improve patient satisfaction and recovery of function.

More attention to the variety of patients' needs based on a person-centred approach from the decision of surgery until accomplished rehabilitation may reduce the number of dissatisfied patients. The standardized care protocol in fast-track settings must be combined with an awareness of the need to identify individual deviations from the standard. The synergy of a process-oriented care program and a person-oriented approach may be the key to an optimized care. Hopefully, our research efforts will lead to an "OSCAR" (Optimized Surgical Care And Recovery) in hip and knee replacement. However, the ultimate goal with the operation is not just an optimized care, but the best possible outcome, with a long-term sustainable impact on the quality of daily life for all patients undergoing hip and knee replacements. The goal is not yet reached, but the knowledge acquired will stimulate research aimed at bringing about further improvement.

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18. APPENDIX.

Tables from survey of care programs at Swedish hospitals performing THR and TKR 2011-2105

Table 1. Summary of Care programs in THR

Questionnaire of THR	N (%)
Hospitals/Clinics responding the questionnaire	63 (77)
Hospitals/Clinics with THR 2011-2015 not responding the questionnaire	20 (23)
Public hospitals responding the questionnaire	51
Private hospitals/clinics responding the questionnaire	12
Public hospitals not responding the questionnaire	12
Private hospitals/clinics not responding the questionnaire	8
Non-responders, no longer performing elective THR 2015	7
THRs for OA at Swedish hospitals 2011-2015	67,913
THRs for OA in hospitals responding the questionnaire	61,387 (90)
THRs for OA in hospitals with unknown care program	6,526 (10)

PREPARATION PHASE THR	Percentage
Multi-professional planning team?	63
Preop patient education self-management program obligatory?	45
Stop smoking before surgery obligatory?	61
Limit of BMI to be accepted for surgery?	44
Checklist in the preparation before surgery?	70
Written information (brochure)?	97
Written information used at decision of surgery?	79
Written information available in other languages?	7
Patient information video in practice?	7
Preoperative visit (PV) before surgery	
Preoperative visit in practice routinely?	92
Timing of preoperative visit 1-3 weeks before surgery?	62
Does the patient meet the orthopaedic surgeon at the PV?	62
Does the patient meet an anesthetic nurse at the PV?	7
Does the patient meet an anesthesiologist at the PV?	81
Does the patient meet an occupational therapist at the PV?	51
Does the patient meet a physiotherapist at the PV?	85
Does the patient meet a nurse assistant at the PV?	32
Does the patient meet a nurse at the PV?	97
Is a checklist used when the oral information is given?	44

HOSPITAL STAY THR	Percentage
Admission on the day of surgery?	83
Is a checklist used at the hospital admission?	91
Perioperative routines	
Perioperative indwelling urethral catheter used routinely?	64
Cloxacillin as first choice of antibiotic prophylaxis?	98
3 doses of cloxacillin given routinely?	84
Last dose of cloxacillin given after 6 h according to ”PRISS”	69
Local infiltration analgesia (LIA) in practice?	67
LIA with postoperative catheter for supplementary doses?	3
Spinal anaesthesia without opioids routinely used?	84
Spinal anaesthesia with opioids routinely used?	16
General anaesthesia routinely used?	6
Tranexamic acid routinely used?	92
Drainage routinely used?	0
Postoperative routines	
Postoperative nasal oxygen catheter as routine?	48
Mobilization, standing/walking, starts < 3 h after surgery?	9
Mobilization, standing/walking, starts < 6 h after surgery?	45
Mobilization, standing/walking, starts 6-12 h after surgery?	36
Mobilization, standing/walking, starts 12-24 h after surgery?	9
The first mobilization attempt assisted by a physiotherapist?	32
Paracetamol routinely used?	100
Short-acting opioids routinely used?	95
Long-acting opioids routinely used?	81
Intravenous opioids routinely used?	44
Glucocorticoids routinely used?	18
NSAIDs or Coxibs routinely used?	61
Gabapentin routinely used?	18
PPIs (proton pump inhibitors) routinely used?	32
Antiemetics routinely used?	66
Fragmin (dalteparin) used as antithrombotic drug	32
Innohep (tinzaparin) used as antithrombotic drug	24
Pradaxa (dabigatran) used as antithrombotic drug	12
Klexane (enoxaparin) used as antithrombotic drug	10
Xarelto (rivaroxaban) used as antithrombotic drug	10
Eliquis (apixaban) used as antithrombotic drug	12
Antithrombotic medication $\geq$ 28 d?	87
Postop X-ray, the day after surgery?	56
Postop X-ray, after hospital discharge?	2
Functional discharge criteria in practice?	80
Discharge information effectuated by the surgeon?	48
Discharge information effectuated by another colleague?	52

RECOVERY PHASE THR	Percentage
Follow-up by the surgeon?	32
Follow-up by a physiotherapist?	48
Follow-up by a nurse?	54
No follow-up?	2
Follow-up in 1-3 weeks after surgery?	20
Follow-up 3-6 weeks after surgery?	20
Follow-up 7-12 weeks after surgery?	46

Restrictions after THR surgery	Percentage
Restriction – avoid hip flexion >90°?	83
Restriction – avoid crossed legs?	85
Restriction – toilet seat elevated?	62
Restriction – seat cushion used?	54

Table 2. Summary of Care programs in TKR

Questionnaire of TKR	N (%)
Hospitals/Clinics responding the questionnaire	63 (82)
Non-responders with TKR 2011-2015	14 (18)
Public hospitals responding to the questionnaire	52
Private hospitals/clinics responding to the questionnaire	11
Public hospitals not responding to the questionnaire	8
Private hospitals/clinics not responding to the questionnaire	6
Non-responders, no longer performing elective TKR 2015	3
TKRs for OA at Swedish hospitals 2011-2015	59,268
TKRs for OA in hospitals with known care program	54,722 (92)
TKRs for OA in hospitals with unknown care program	4,546 (8)

PREPARATION PHASE TKR	Percentage
Multi-professional planning team?	60
Preop patient education self-management program obligatory?	44
Stop smoking before surgery obligatory?	57
Limit of BMI to be accepted for surgery?	36
Checklist in the preparation before surgery?	53
Written information (brochure)?	98
Written information used at decision of surgery?	75
Written information available in other languages?	8
Patient information video in practice?	8

Preoperative visit (PV) before surgery	**Percentage**
Preoperative visit in practice routinely?	87
Timing of preoperative visit 1-3 weeks before surgery?	71
Does the patient meet the orthopaedic surgeon at the PV?	63
Does the patient meet an anesthetic nurse at the PV?	7
Does the patient meet an anesthesiologist at the PV?	82
Does the patient meet an occupational therapist at the PV?	28
Does the patient meet a physiotherapist at the PV?	82
Does the patient meet a nurse assistant at the PV?	28
Does the patient meet a nurse at the PV?	95
Is a checklist used when the oral information is given?	47

HOSPITAL STAY TKR	**Percentage**
Admission on the day of surgery?	80
Is a checklist used at the hospital admission?	85

Perioperative routines	**Percentage**
Perioperative indwelling urethral catheter used routinely?	41
Cloxacillin as first choice of antibiotic prophylaxis?	98
3 doses of cloxacillin given routinely?	89
Last dose of cloxacillin given after 6 h according to ”PRISS”	80
Local infiltration analgesia (LIA) in practice?	100
LIA with postoperative catheter for supplementary doses?	20
Spinal anaesthesia without opioids routinely used?	77
Spinal anaesthesia with opioids routinely used?	21
General anaesthesia routinely used?	8
Tranexamic acid routinely used?	97
Tourniquet routinely used?	65
Drainage routinely used?	3

Postoperative routines	**Percentage**
Postoperative nasal oxygen catheter as routine?	52
Mobilization, standing/walking, starts < 3 h after surgery?	12
Mobilization, standing/walking, starts < 6 h after surgery?	46
Mobilization, standing/walking, starts 6-12 h after surgery?	34
Mobilization, standing/walking, starts 12-24 h after surgery?	8
The first mobilization attempt assisted by a physiotherapist?	36
Paracetamol routinely used ?	100
Short-acting opioids routinely used?	98
Long-acting opioids routinely used?	85
Intravenous opioids routinely used?	44
Glucocorticoids routinely used?	15

	Percentage
NSAIDs or Coxibs routinely used?	78
Gabapentin routinely used?	23
PPIs (proton pump inhibitors) routinely used?	30
Antiemetics routinely used?	65
Fragmin (dalteparin) used as antithrombotic drug	28
Innohep (tinzaparin) used as antithrombotic drug	29
Pradaxa (dabigatran) used as antithrombotic drug	10
Klexane (enoxaparin) used as antithrombotic drug	12
Xarelto (rivaroxaban) used as antithrombotic drug	6
Eliquis (apixaban) used as antithrombotic drug	16
Antithrombotic medication 7-14 days?	97
Postop X-ray, the day after surgery?	43
Postop X-ray, after hospital discharge?	8
Functional discharge criteria in practice?	82
Discharge information effectuated by the surgeon?	50

RECOVERY PHASE TKR	**Percentage**
Follow-up by the surgeon?	33
Follow-up by a physiotherapist?	48
Follow-up by a nurse?	62
No follow-up?	2
Follow-up in 1-3 weeks after surgery	22
Follow-up 3-6 weeks after surgery	36
Follow-up 7-12 weeks after surgery	29

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