Urinary catheter policies for short-term bladder drainage in hip surgery patients
To my beloved family

"I am always doing that which I can not do, 
in order that I may learn how to do it"

P. Picasso
To my beloved family

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in order that I may learn how to do it”

P. Picasso

MARIA HÄLLEBERG NYMAN

Urinary catheter policies for short-term bladder drainage in hip surgery patients
Abstract


The overall aim of this thesis was to evaluate methods for urinary catheter handling in patients undergoing hip surgery. The intention was to gain knowledge in order to provide optimal and cost-effective care regarding urinary catheterisation in this group of patients.

In Study I, 45 of the 86 catheterised patients (52%) contracted nosocomial urinary tract infections (UTIs). Diabetes was a risk factor for developing UTI, and cloxacillin as a perioperative antibiotic prophylaxis seemed to offer a certain protection. Study II was a randomised controlled trial on the effect of clamping (n = 55) or not (n = 58) of the indwelling urinary catheter before removal. No significant differences were found between the groups with respect to time to normal bladder function, need for recatheterisation, or length of hospital stay. Study III was a randomised controlled trial among patients with hip fracture and hip arthroplasty, in which the patients were randomised to intermittent (n = 85) or indwelling (n = 85) urinary catheterisation. No significant differences in nosocomial UTIs (9% vs. 12%) or cost-effectiveness were shown. The patients in the intermittent group regained normal bladder function significantly sooner after surgery. Fourteen percent of the patients in the intermittent group did not need any catheterisation. In Study IV, 30 patients were interviewed about their experiences of bladder emptying and urinary catheterisation. The patients’ views were described through the main category ‘An issue but of varying impact’. Both bladder emptying through micturition and bladder emptying through catheterisation were described as convenient, but also as uncomfortable and an intrusion on dignity. The patients were aware of risks and complications of urinary catheterisation.

In conclusion, this thesis indicates that UTI is common in hip surgery patients. Clamping of indwelling catheters seems not necessary. There is no preference for either intermittent or indwelling urinary catheterisation according to the results of this thesis, either for the development of nosocomial UTI or, for cost-effectiveness, or from the patient perspective. Nurses should be aware that catheterisation might make the patients feel exposed, and it is essential that their practice reflect the best available evidence.

Keywords: urinary catheterisation, nosocomial urinary tract infection, hip fracture, hip arthroplasty, nursing, patient experiences, clamping.
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LIST OF PUBLICATIONS

This thesis is based on the following papers, which will be referred to in the text by their Roman numerals:


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### ABBREVIATIONS AND DEFINITIONS

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<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>ASB</td>
<td>Asymptomatic Bacteriuria</td>
</tr>
<tr>
<td>CAMTÖ</td>
<td>Centre for Assessment of Medical Technology Örebro</td>
</tr>
<tr>
<td>CBA</td>
<td>Cost-Benefit Analysis</td>
</tr>
<tr>
<td>CEA</td>
<td>Cost-Effectiveness Analysis</td>
</tr>
<tr>
<td>CFU</td>
<td>Colony-Forming Unit</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
<tr>
<td>CMA</td>
<td>Cost-Minimization analysis</td>
</tr>
<tr>
<td>CUA</td>
<td>Cost-Utility Analysis</td>
</tr>
<tr>
<td>EBM</td>
<td>Evidence-Based Medicine</td>
</tr>
<tr>
<td>EBN</td>
<td>Evidence-Based Nursing</td>
</tr>
<tr>
<td>EQ-5D</td>
<td>EuroQol, five dimensions</td>
</tr>
<tr>
<td>EQ VAS</td>
<td>EuroQol, Visual Analogue Scale</td>
</tr>
<tr>
<td>HRQoL</td>
<td>Health-Related Quality of Life</td>
</tr>
<tr>
<td>M</td>
<td>Mean value</td>
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<tr>
<td>NIC</td>
<td>Nursing Interventions Classification</td>
</tr>
<tr>
<td>OA</td>
<td>Osteoarthritis</td>
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<tr>
<td>POUR</td>
<td>Post-Operative Urinary Retention</td>
</tr>
<tr>
<td>QALY</td>
<td>Quality Adjusted Life Year</td>
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<tr>
<td>QoL</td>
<td>Quality of Life</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
</tr>
<tr>
<td>SAHFE</td>
<td>Standardized Audit of Hip Fractures in Europe</td>
</tr>
<tr>
<td>SD</td>
<td>Standard Deviation</td>
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<tr>
<td>SF-36</td>
<td>The 36-item Short Form health survey</td>
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<tr>
<td>SF-6D</td>
<td>The 6-dimensional health state classification</td>
</tr>
<tr>
<td>SG</td>
<td>Standard gamble</td>
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<tr>
<td>TTO</td>
<td>Time trade-off</td>
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<tr>
<td>UTI</td>
<td>Urinary Tract Infection</td>
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</tbody>
</table>
INTRODUCTION

The intention of this thesis is to improve patient safety associated with urinary catheter management in hip surgery patients. The origin of the project was that some of my nursing colleagues at the orthopaedic surgery department at Örebro University Hospital, Sweden, raised the question of whether urinary catheters were handled safely and in accordance with the evidence. Urinary catheterisations and helping patients with bladder emptying are important parts of perioperative care. The nurses did not know whether the routines at the department regarding urinary catheterisation were in accordance with the best available research evidence.

With support from the Centre for Assessment of Medical Technology, Örebro (CAMTÖ), which aims to promote the development of evidence-based care in Örebro County Council, an evidence-based project was started. I was asked to be facilitator for the project at one of the two orthopaedic wards. We started the project by formulating questions for reviewing the literature on urinary catheterisation. The literature review showed areas where research evidence was available and areas where there was no clear evidence (Bachelor in Nursing, unpublished data). Regarding parts of urinary catheter management, there was a need for further studies to fill gaps in knowledge. These findings were the starting point for this PhD project.
BACKGROUND

Evidence-based nursing
The concept evidence-based nursing (EBN) arises from the concept evidence-based medicine (EBM), and the concepts are similar in many ways. A typical definition of EBM is

The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine requires the integration of individual clinical expertise with the best available external clinical evidence from systematic research and our patient’s unique values and circumstances.\(^1\)

A definition of EBN is

Evidence-based nursing is a process by which nurses make their clinical decisions using best available research evidence, their clinical expertise and patient preferences, in the context of available resources.\(^2\)

EBN is both a matter of attitude and a process. Attitude includes the intention to use best available scientific evidence as the basis for nursing decisions, and process means to systematically compile, scrutinise, value, interpret, and apply research results.\(^3\) Research evidence alone is never sufficient to make a clinical decision. Nursing also needs to include established experience and patients preferences.\(^2,3\) According to Rycroft Malone et al.,\(^4\) the four sources of evidence are: (1) personal knowledge and experience of patients, (2) research, (3) clinical experiences, and (4) information from the local context.

EBN is accused of only considering meta-analyses of randomised controlled trials (RCTs) and RCTs as the basis for the evidence.\(^4,5\) RCT is the most appropriate design for studies evaluating the effectiveness of nursing interventions, provided that the studies are of good quality.\(^2\) However, the choice of research design is depending on the research question, and clinically relevant research should not only be restricted to RCTs and meta-analyses.\(^2\)

When developing evidence-based guidelines, it is stated that patients’ preferences should be taken into consideration.\(^4\) In Sweden this is even legislated. The Swedish Patient Safety Act states that all health care must be conducted in concordance with research and established experience and that care should be developed and performed in consultation with the patients.\(^6\)
In daily praxis evidence-based nursing, in the best of worlds, means that the individual nurse integrates the best available external evidence (research) into practice and together with the patient comes to a decision about various nursing interventions. Besides providing a basis for good care, EBN can support the goal of gaining the greatest health benefit from limited resources. By providing evidence-based nursing instead of ineffective or even dangerous nursing, health care resources can be spent in a cost-effective way.

**Hip surgery**

Hip surgery is common all over the world and is mostly performed for two reasons, either because of hip fracture or because of osteoarthritis (OA). In Sweden every year about 18,000 patients undergo hip surgery due to fracture, and about 14,000 patients due to OA. About 1.6 million hip fractures are estimated to occur worldwide during one year. A study comprising hip arthroplasty registers from 31 countries reports 1.4 million operations in 2007.

Patients with OA undergo elective surgery, and those with fractures undergo acute surgery. OA is a degenerative progressive disorder of the joints caused by gradual loss of cartilage. The symptoms of OA in the hip include joint pain, stiffness, and reduced mobility. Hip replacement surgery is an effective intervention in OA patients. The main indication for hip replacement surgery in OA patients is pain. Hip replacement surgery is shown to be cost-effective and to improve the patients’ quality of life.

Hip fracture is defined as a fracture in the proximal part of the femur. There are two main types of hip fractures: fracture of the femoral neck (intracapsular) and fractures through the muscle insertions distal to the femoral neck (extracapsular). In elderly patients, hip fractures are often caused by a minimal trauma, such as a fall from standing height, most often indoors. The risk of contracting a hip fracture increases exponentially from age 50 years and onwards. Intracapsular fractures are treated either with internal fixation, single or multiple screws or pins, or with hemi- or total hip replacement surgery. Extracapsular hip fractures are treated with internal fixation, either extramedullary implants or intramedullary nails.

The majority of hip surgery patients are women (75%). The mean age of patients with hip fractures is 80 years, and about 70 years for patients with OA. In 2010, the mean hospital stay was 9.4 days for hip fracture patients and 5.6 days for OA patients. The total hospital days for the whole patient group in Sweden was in 2010 over 300,000.
Post-operative urinary problems

Post-operative urinary problems, such as post-operative urinary retention (POUR) and nosocomial urinary tract infection (UTI) are common in patients undergoing hip surgery. Both bladder distension, which is a complication of untreated POUR, and UTI could be considered to be preventable adverse events, according to the definition in the Swedish Patient Safety Act. A preventable adverse event is defined as suffering, bodily or mental injury, or illness and death that could have been avoided if adequate care had been provided.

Post-operative urinary retention

POUR is defined as the sudden inability to pass any urine, despite a full bladder. The cut off limits for defining a full bladder vary from 400 ml to 600 ml in different studies. POUR is associated with a risk for over-distension of the bladder and large retention volume, which can cause the patient prolonged micturition problems. These micturition problems are described as causing constraints to everyday life and suffering in terms of pain, UTI, impaired sex life, and leakage, as well as concerns about the future.

Ultrasound has been used as a diagnostic tool for POUR during the past decade. Bladder-scan ultrasound has shown high agreement with the true urine volume and is deemed suitable for post-operative monitoring of bladder volume.

It is well known that hip surgery patients have an increased risk of urinary retention. The figures on incidence of POUR vary between studies. In hip replacement patients the incidence is reported to be from 12% to 84%, and in hip fracture patients from 18% to 56%. Old age, male sex, surgery in the pelvic area, spinal anaesthesia and opioids, and a history of urinary tract problems are known risk factors for POUR. Smith and Albazzaz found that urinary retention in women with hip fracture was associated with higher fatality.

Nosocomial urinary tract infection

Nosocomial UTI can be either symptomatic or asymptomatic. Symptomatic UTI is, according to CDC/NHSN (US Centers for Disease Control/National Healthcare Safety Network), identified through, a positive urine culture, as ≥10^5 colony-forming units (CFU)/ml with at most two different microorganisms and symptoms. Asymptomatic bacteriuria is defined as positive urine culture, ≥10^5 CFU/ml with no more than two different microorganisms and absence of symptoms, obtained within one week from catheterisation. Nosocomial UTI could be caused by either endoge-
nous or exogenous sources. Infections already present at arrival to hospital are not to be considered as nosocomial, unless a change in pathogen or symptoms indicates a new infection.\textsuperscript{50} Urine culture for verifying nosocomial UTI must be obtained either by clean catch technique or catheterisation according to guidelines.\textsuperscript{50}

Urinary catheterisation is the main risk factor for nosocomial UTI,\textsuperscript{51} but there are also other contributing risk factors identified in earlier studies (Table 1). A point-prevalence study in 2008 showed that 11\% of patients in Swedish hospitals had a nosocomial infection, the most common being UTI (26\%).\textsuperscript{52} Surgical wards had the highest prevalence of nosocomial infections.\textsuperscript{52} Subsequently, nosocomial UTI is not unusual in hip surgery patients. Frequency of nosocomial UTI is reported to be 2–16\% in patients that undergo hip surgery due to OA\textsuperscript{39,53-56} and 12–38\% in hip fracture patients\textsuperscript{43,57-64}.

Table 1. Risk factors for nosocomial UTI described in earlier studies

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Reference</th>
</tr>
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<tbody>
<tr>
<td>Dehydration and fasting</td>
<td>Kamel \textsuperscript{62}</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Al-Helali et al., \textsuperscript{65} Johansen, \textsuperscript{66} Maki &amp; Tambyah \textsuperscript{67}</td>
</tr>
<tr>
<td>Duration of catheterisation</td>
<td>Al-Helali et al., \textsuperscript{65} Leone et al., \textsuperscript{68} Wald \textsuperscript{69}</td>
</tr>
<tr>
<td>Faecal incontinence</td>
<td>Leblebicioglu et al., \textsuperscript{70} Tsuchida et al. \textsuperscript{71}</td>
</tr>
<tr>
<td>Female gender</td>
<td>Hedström et al., \textsuperscript{58} Johnstone et al., \textsuperscript{60} Kamel, \textsuperscript{62} Leone et al., \textsuperscript{68} Maki &amp; Tambyah \textsuperscript{67}</td>
</tr>
<tr>
<td>Malignancy</td>
<td>Al-Helali et al., \textsuperscript{65} Johansen \textsuperscript{66}</td>
</tr>
<tr>
<td>Old age</td>
<td>Johansen, \textsuperscript{66} Johnstone et al., \textsuperscript{60} Kamel \textsuperscript{62}</td>
</tr>
<tr>
<td>Poor general state of health</td>
<td>Hedström et al., \textsuperscript{58} Johansen, \textsuperscript{66} Leone et al.\textsuperscript{68}</td>
</tr>
<tr>
<td>Renal failure</td>
<td>Al-Helali et al., \textsuperscript{65} Johansen, \textsuperscript{66} Maki &amp; Tambyah \textsuperscript{67}</td>
</tr>
</tbody>
</table>
Short-term consequences of UTI reported in studies of patients with hip fracture can be acute delirium\textsuperscript{62} and longer hospitalisation\textsuperscript{58-59,62} Nosocomial UTI can affect the quality of life (QoL) and may cause unnecessary suffering in hip surgery patients. Therefore, it is important to investigate causes and also consequences for patients with UTI.\textsuperscript{72} Nosocomial UTI is also reported to be associated with increased mortality rates in different groups of patients.\textsuperscript{73-75} There are to my knowledge no earlier studies investigating long-term consequences of UTI and whether there is an association between increased mortality and UTI among hip surgery patients.

**Urinary catheterisation**

For the patients, hip surgery is associated with pain and difficulties getting out of bed. Spinal anaesthesia, immobilisation, and pain make urination difficult in the post-operative phase.\textsuperscript{48,76} Because of these difficulties the patients usually receive either indwelling or intermittent urinary catheterisation in the perioperative period, in order to monitor urine output and prevent the development of bladder distension.\textsuperscript{45,53,59}

**Urinary catheterisation as a nursing intervention**

A nursing intervention is defined as

\begin{quote}
any treatment, based upon clinical judgement and knowledge, that a nurse performs to enhance patient/client outcomes.\textsuperscript{77}
\end{quote}

Nursing interventions are interventions that nurses do on behalf of patients; these include both independent interventions performed on their own, and collaborative interventions performed together with the patient, other nurses, physicians, or relatives. Nursing interventions can be both direct–‘hands on’– and indirect– performed away from the patient but on behalf of the patient.\textsuperscript{77} Nursing interventions can be nurse initiated, physician initiated, and other-provider initiated. The Nursing Interventions Classification (NIC) has defined and classified 542 nursing interventions. The strengths of the NIC are that it is comprehensive and developed inductively based on existing practice.\textsuperscript{77}

Two of the nursing interventions classified by NIC are Urinary catheterization NIC 0580 and Urinary catheterization: intermittent NIC 0582. Urinary catheterization is defined as ‘insertion of a catheter into the bladder for temporary or permanent drainage of urine’. Urinary catheterization: intermittent is defined as ‘Regular periodic use of a catheter to empty the bladder’.\textsuperscript{77} Although urinary catheterisation is performed on a physician’s order, it is often performed by nurses,\textsuperscript{78} and it is classified as a nurs-
Indwelling urinary catheterisation

The most common method for short-term urinary catheterisation during hospital care is indwelling catheterisation. In indwelling urinary catheterisation the catheter is inserted into the bladder via the urethra and left in place. The indwelling catheter is kept in place by a balloon on the tip of the catheter, inflated with sterile water.

There are guidelines from Sweden and the United States on how to perform urinary catheterisation and how to handle urinary catheters. The guidelines state:

- Perform hand hygiene before and after insertion or any manipulation of the catheter device or site.
- Urinary catheters should only be inserted by properly trained persons.
- Use aseptic technique when inserting catheter in a hospital setting.
- Remove the indwelling catheter as soon as possible.
- Keep the catheter system closed.
- Keep the urine bag below bladder level.

In addition to the above guidelines the Swedish national guidelines also state that time of insertion, indication for insertion, and planned catheterisation time shall be documented in the patient’s medical record. As the risk for UTI is known to increase with time with a urinary catheter, the maintenance of the indwelling catheterisation must also be evaluated every day.

One aspect of handling of the indwelling catheter is whether to clamp the catheter before removal. Clamping the indwelling catheter for bladder conditioning was first recommended in 1936. Clamping the indwelling urinary catheter before its removal is reported to decrease the frequency of urinary retention and shorten the time to return of normal bladder function. It is assumed that clamping stimulates normal bladder filling and emptying by improving bladder tone and sensation. Roe concluded that there is some evidence that catheter clamping minimises post-operative neurogenic dysfunction after short-term catheterisation. However, a Cochrane review on removal of the urinary catheter showed that the evidence is inconclusive as to whether clamping is effective. The review comprised studies published up to 2006. Three trials investigating clamping versus free drainage before removal were included. In two of the trials the
time to first void was shorter after catheter clamping.\textsuperscript{85,88} Two of the three trials had small samples, and they each used different clamping regimens. In the study by Oberst et al.\textsuperscript{88} a six-day clamping programme was performed before the catheter was removed. The catheter was clamped for increasingly longer periods up to a maximum of four hours on the sixth day.\textsuperscript{88} In the study by Williamson\textsuperscript{85} the catheter was clamped three times for three hours each time. In both studies the clamping periods were alternated with five-minute drainage periods.\textsuperscript{85,88} The authors of the Cochrane review called for further randomised controlled trials using large samples to study the effects of clamping before urinary catheter removal.\textsuperscript{86}

**Intermittent urinary catheterisation**

In intermittent urinary catheterisation the catheter is inserted in the bladder via the urethra for the time necessary to empty the bladder and is then removed.\textsuperscript{81,89} Intermittent catheterisation can be performed as a one-time treatment, repeatedly over a short period of time, or long term, depending on the cause of urinary retention.\textsuperscript{89} Guidelines from the US, Europe, and Sweden state that in a hospital setting intermittent urinary catheterisation should be performed using aseptic technique with a sterile catheter, the ‘no-touch technique’.\textsuperscript{83,89-90} But in long-term catheterisation clean intermittent catheterisation is the ‘gold standard’.\textsuperscript{91}

It is suggested that intermittent catheterisation reduces the risk of nosocomial UTI compared to indwelling catheterisation,\textsuperscript{59,92} but other studies have not been able to confirm these results.\textsuperscript{93-94} A Cochrane review has also concluded that there is limited evidence that the use of intermittent catheterisation is associated with a lower risk for UTI than indwelling catheterisation, and therefore, the authors request further randomised controlled studies on surgical patients comparing intermittent and indwelling urinary catheterisation.\textsuperscript{80} They recommend incidence of UTI and, time to normal bladder function as outcome measures.\textsuperscript{80}

**The patients’ view of urinary catheterisation**

To provide good nursing care, it is important to be aware of the patients’ experiences of the provided care. Studies on patients’ experiences of urinary catheterisation have mostly focused on long-term treatment. Persons using long-term intermittent self-catheterisation describe the positive and negative impacts of catheterisation on quality of life.\textsuperscript{95} The positive impact was in terms of improvements in lower urinary tract symptoms, and the negative was due to practical difficulties, worries, and stigma. Other studies showed that long-term intermittent catheterisation was experienced as stressful and could be followed by a reaction of shock and
embarrassment. However, patients also report that they adapt and accept the situation. A study of persons living with long-term indwelling catheterisation showed that living with a catheter could be likened to living with the forces of flowing water. Other studies showed that patients accepted the catheter and wanted to be independent in catheter care. The indwelling catheter was also described as a reminder of mortality.

One study investigating patients’ experiences of short-term urinary catheterisation was found. That study was on patients receiving indwelling urinary catheterisation in connection to abdominal surgery. In this group of patients, men were more dissatisfied with the catheter than women. Moreover, the male patients experienced more pain both at insertion and when the catheter was in situ compared to the female patients.

**Health economics**

In a society where the gap between resources and demands in health care is increasing, health economic evaluations can be helpful in making the most of the resources. The rationale for health economical evaluations is that there are limited financial resources in society for health care, and the existing financial resources cannot cover every need for care. The aim of health economic evaluations is to provide a basis for prioritising spending of resources and at the same time maximising health. According to Drummond et al. health economic evaluations are about determining whether one procedure or intervention is worth doing compared with other procedures or interventions that could be done with the same resources. It is also about deciding whether to go on spending health care resources on the current interventions or medications or whether there are better alternatives which would provide more health for the same or less money.

It is of great importance to perform health economic evaluations of methods used in health care to prevent health damage and to minimise unnecessary suffering for the patients and costs for society. The focus in health economics is on decisions at the group level, for example, in the development of guidelines.

**Cost-effectiveness analysis**

In health economics there are four main types of analyses: cost-minimisation analysis (CMA), cost-effectiveness analysis (CEA), cost-utility analysis (CUA), and cost-benefit analysis (CBA). In CMA only costs are measured and no consequences. In CBA both costs and consequences are measured, but the consequences are only valued in monetary terms. CEA is the most commonly used form of health economic analysis. In CEA both costs and consequences of different interventions are taken into considera-
tion. CEA is often used when decision makers have limited resources and must choose from different interventions.\textsuperscript{106} It must be noted that two interventions can be equally cost-effective. In CEA the cost-effectiveness of two or more alternatives is compared, and it is essential to identify which is the central outcome that should be used for comparison of the interventions, for example, years of life gained. CUA is a special case of CEA in which quality-adjusted outcomes are used. In CEA any outcome measure can be used, as long as the outcome measure is the same in all interventions compared, while in CUA usually quality-adjusted life years (QALY) or any similar quality adjusted measure is used. In the literature CEA and CUA are not always distinguished, but considered to be varieties of the same method, especially in literature from the United States.\textsuperscript{106} In this thesis also, CUA is not distinguished from CEA. CEA was chosen because the consequences are measured in patient-related outcomes and not monetary units, as in CBA.

**Quality-adjusted life years**
The concept QALY is based on the theory that the time a person spends in a certain state of health is weighted with a weight corresponding to health-related quality of life (HRQoL) associated with that actual health state.\textsuperscript{106} QALYs can be gained either because of gained life years or improved QoL or a combination of these two. To obtain a QALY weight, either direct or indirect methods can be used. A direct method is to use a rating scale, for example EuroQoL, visual analogue scale (EQ VAS), and an indirect method is to use an HRQoL questionnaire.\textsuperscript{106} When using an HRQoL questionnaire the calculation of QALYs consists of two parts, description and weighting. The description part consists of the patient’s responses to the questionnaire. The weighting part derives from combining the answers into a specific QALY weight, based on preferences for the health states. QALYs make it possible to compare the gained utility in groups of patients receiving different interventions and can be used to support decision making.\textsuperscript{106}
RATIONALE

Hip surgery patients are at risk for urinary retention in the perioperative period. Undetected post-operative urinary retention can result in bladder over-distension which can cause suffering for the affected patient. Therefore, the patients are often catheterised in connection to surgery, with either intermittent or indwelling urinary catheterisation. On the other hand, urinary catheterisation is known to be a major risk factor for nosocomial UTI. In systematic reviews it is highlighted that there are knowledge gaps concerning different methods of handling urinary catheters. The effect of clamping the indwelling catheter is not clear; nor is it clear whether intermittent or indwelling urinary catheterisation is preferable. It is, therefore, from a patient safety perspective, important to investigate urinary tract problems and methods for urinary catheterisation and handling of the urinary catheter. In particular, there is a need for studies that also include health economic evaluations to investigate costs and health effects of importance for both patients and society. EBN makes a strong point of including patients’ preferences when making clinical decisions. The patient perspective on urinary tract problems and urinary catheterisation has not earlier been included, which might produce a more complete basis of knowledge for evidence-based guidelines.
AIMS OF THE THESIS

The overall aim of this thesis was to evaluate methods for handling the urinary catheter in patients undergoing hip surgery. The intention was to gain knowledge in order to provide optimal and cost-effective care regarding urinary catheterisation for hip surgery patients.

Specific aims and objectives of Studies I–IV were as follows

Study I
The aim of the study was to investigate risk factors and consequences of nosocomial UTI in hip fracture patients.
Specific objectives were to
- Investigate differences between patients with and without nosocomial UTI to identify risk factors
- Describe consequences of nosocomial UTI and mortality rate in a one-year perspective

Study II
The aim of the study was to investigate the effect of clamping the urinary catheter before removal in hip fracture patients.
Specific objectives were to determine whether
- Clamping has an effect on the time required to regain normal bladder function
- Clamping has an impact on the need for re-catheterisation
- Clamping has an effect on the length of hospital stay

Study III
The aim of the study was to investigate differences between intermittent and indwelling urinary catheterisation in hip surgery patients with respect to nosocomial urinary tract infection and cost-effectiveness.

Study IV
The aim of the study was to describe patients’ experiences of bladder emptying and urinary catheterisation in connection to hip surgery.
MATERIAL AND METHODS

Different designs, methods, and analyses have been used in the studies, depending on the purposes of the studies. An overview of the four studies is presented in Table 2.

Table 2. Overview of the different studies in the thesis

<table>
<thead>
<tr>
<th>Study</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>Comparative</td>
<td>Experimental /RCT</td>
<td>Experimental /RCT</td>
<td>Descriptive</td>
</tr>
<tr>
<td>Participants</td>
<td>n = 86 Patients with hip fracture</td>
<td>n = 113 Patients with hip fracture</td>
<td>n = 170 Patients undergoing hip surgery</td>
<td>n = 30 Patients undergoing hip surgery</td>
</tr>
<tr>
<td>Data collection</td>
<td>Study protocol, medical records, Rikshöft/SAHFE register</td>
<td>Study protocol, medical records, Rikshöft/SAHFE register</td>
<td>Study protocol, medical records, telephone interviews, SF-36, EQ-5D</td>
<td>Individual interviews</td>
</tr>
<tr>
<td>Data analysis</td>
<td>$\chi^2$ test, Fisher’s exact test, t test, Mann-Whitney U test</td>
<td>$\chi^2$ test, $\chi^2$ test linear by linear, Fisher’s exact test, t test, Mann-Whitney U test</td>
<td>$\chi^2$ test, t test, Mann-Whitney U test, QALY, cost-effectiveness analysis</td>
<td>Inductive qualitative content analysis</td>
</tr>
</tbody>
</table>

Setting

The setting for the studies was the orthopaedic department at a university hospital in Sweden. The primary catchment area of the orthopaedic clinic includes about 172,000 inhabitants. Because it is the only clinic in the catchment area providing care of hip fracture patients, all patients with a hip fracture are admitted to this clinic. Patients with OA in the hip who are about to undergo hip replacement surgery are, according to the health care guarantee, free to choose another hospital if the hospital cannot provide surgery within 90 days. The health care guarantee means that no patient should have to wait more than 90 days, once it has been determined that care is needed. If the time limit expires, patients are offered care elsewhere;
the cost, including any travel costs, is then paid by their own county council. The orthopaedic department at the university hospital consisted at the time of Studies I, II, and IV of two wards providing care for all kinds of orthopaedic patients, including hip surgery patients. During the last inclusion months of Study III, there was a reorganisation at the department, and one of the wards became a ward for old people with multiple illnesses, including all hip fracture patients. The other ward became a ward for elective orthopaedic surgery, including hip replacement surgery.

Sample

Studies I and II
Patients with hip fracture were included consecutively on arrival at the orthopaedic wards between April 2006 and March 2007. Excluded were patients who at the time of admission were under 50 years of age, had a urinary catheter, showed signs of cognitive impairment, or had additional severe physical problems. In this study, cognitive impairment was defined as disorientation in time, place, or room; irrelevant conversation; disorganised thinking; or agitation. These assessments were made by the nurse on duty. The exclusion criterion of being under 50 years of age was used because the Swedish national hip fracture register, part of the Standardised Audit of Hip Fractures in Europe (SAHFE), includes only patients ≥ 50 and because most hip fractures in young people have other causes, such as trauma or pathology.

During the study period 348 patients were assessed for eligibility (Figure 1). Of the 159 patients who fulfilled the study criteria, 14 declined participation and 32 were lost because of organisational factors. Thus, the final sample in Study II consisted of 113 patients.

For Study I nosocomial UTI was the main outcome. Therefore, 11 patients from the sample in Study II were excluded in the analyses, because they had a UTI with the same bacteria at admission and discharge, and another 16 patients were excluded because of missing urine cultures. Thus, the final sample in Study I consisted of 86 patients (Figure 1).
MARIA HÄLLEBERG NYMAN
Urinary catheter policies in hip surgery patients

Figure 1. Flow chart of participants in Studies I and II.
Studies III and IV
The patients were recruited consecutively from the orthopaedic department between September 2009 and May 2011. Inclusion criteria were patients undergoing hip fracture surgery or hip replacement due to OA. Patients younger than 50 years or with an indwelling urinary catheter or cognitive impairment at admission were excluded. During the study period 459 patients fulfilled the study criteria, but 184 declined participation and 93 were lost because of organisational factors (e.g. heavy workload) and were not asked to participate (Figure 2). Altogether, 182 patients were randomised to either intermittent or indwelling urinary catheterisation. Out of these, 2 withdraw their participation; 1 patient deceased during surgery; and 1 patient was included twice, because of two hip fractures during the study period, and was excluded from the study the second time. In 8 patients urine cultures were missing. The final sample included 170 patients (n = 85 in each group).

Patients for Study IV were selected from among the patients in Study III (Figure 2). The patients were selected purposively to achieve variation in characteristics such as gender, age, diagnosis (hip fracture or hip OA), and urinary catheterisation method (indwelling urinary catheterisation or intermittent catheterisation when needed). Thirty-one patients were informed of the purpose of the study and asked to participate, before discharge from the orthopaedic department. One patient declined; therefore, the final sample consisted of 30 patients. Out of these, 16 patients were in the RCT allocated to indwelling urinary catheterisation. They had the catheter for about two days. The remaining 14 were randomised to intermittent urinary catheterisation, and of these, 7 were intermittent catheterised, 5 were able to urinate by themselves during the whole time in hospital, and 2 were first intermittent catheterised but then received an indwelling urinary catheter due to large amount of urine in the bladder.
Figure 2. Flow chart of participants through each step in Studies III and IV.
Procedures

Studies I and II

The patients were informed about the study and invited to participate, at arrival to the orthopaedic ward. All patients participating in the study had an indwelling urinary catheter inserted upon arrival at the orthopaedic ward. Before insertion, the participants underwent pre-operative antiseptic showering. Two registered nurses or nurse assistants on duty inserted the indwelling catheter. A closed catheter system was used. The catheter was removed on day 2 after surgery. This procedure was in accordance with common practice in the orthopaedic department. Participants were assigned to either the clamped catheter group or the free drainage group through a concealed allocation with sealed opaque envelopes. The randomisation was stratified for gender.

Patients randomised to the clamped catheter group had their indwelling catheter clamped at 6 a.m. on post-operative day 2. When a patient in the clamped catheter group needed to urinate, the catheter was removed clamped. The patient urinated in a toilet or in a bedpan. Every fourth hour until normal bladder function was resumed, the patient’s bladder was scanned to assure that urine volume in the bladder did not exceed 450 ml. If the bladder volume exceeded 450 ml after the catheter was removed and the patient was unable to urinate, the patient was re-catheterised. The cut-off limit of 450 ml was chosen because this was the routine at the orthopaedic department.

Patients in the free drainage group had their catheters removed at 6 a.m. on post-operative day 2 without previous clamping. The patients were bladder-scanned every fourth hour until normal bladder function returned. If the bladder volume exceeded 450 ml and the patient was unable to urinate, the patient was re-catheterised.

Studies III and IV

The patients with OA were informed about the study and asked for participation at the pre-operative planning visit, and the hip fracture patients were informed and asked for participation upon arrival at the orthopaedic ward. The participants were assigned to either the intermittent catheterisation group or to the indwelling catheterisation group through a concealed allocation with sealed opaque envelopes. The randomisation code was computer generated and stratified for gender and diagnosis (hip fracture or OA). Block randomisation with various block sizes was used with reduced block size at the end of the study.
Patients randomised to the intermittent catheterisation group urinated in a toilet, a bedpan, or a diaper, when needed. Bladder scans were performed on these patients every fourth hour until normal bladder function was recaptured after the surgery. Normal bladder function was defined as post-micturition residual urine volume of 150 ml or less. If the patient was unable to urinate and bladder scan indicated ≥400 ml urine in the bladder, the patient was intermittent catheterised with a sterile, low-friction hydrophilic catheter. The cut-off limit of 400 ml was chosen because this was the routine in the operating theatre and recovery room. The catheterisation was performed by one registered nurse or nurse assistant on duty.

Patients in the indwelling catheterisation group with hip fracture got an indwelling catheter at arrival to the orthopaedic ward. The patients with OA got the indwelling catheter in the morning on the day of surgery. In both cases the indwelling catheter was inserted after pre-operative antiseptic showering. Two registered nurses or nurse assistants on duty inserted the indwelling catheter. A closed catheter system was used. The catheter was removed in the morning on day 2 after surgery. The patients were bladder-scanned every fourth hour after catheter removal, until normal bladder function was recaptured. If the bladder volume exceeded 400ml and the patient was unable to urinate, the patient was re-catheterised. The procedure for the patients in the indwelling group was in accordance with common practice in the orthopaedic department.

Outcome measures

Urinary tract infection (Studies I and III)
The primary outcome measure in Studies I and III was hospital-acquired UTI. To identify and confirm hospital-acquired UTI, urine specimens were collected at arrival to hospital and before discharge. In Study III patients with positive urine culture at discharge an additional urine specimen was collected 4 weeks after discharge. In both Study I and Study III, hospital-acquired UTI was defined as a negative urine culture at arrival and a positive urine culture at discharge (≥ 100,000 CFU/ml). In Study III the definition was changed according to Horan et al., and cultures with more than two species of organisms were not considered to be UTIs. Patients with UTI already present at admission were considered not to have nosocomial infections, unless a change of pathogen suggested a new infection.

Normal bladder function (Studies II and III)
In these studies normal bladder function was defined as a post-micturition residual urine volume of 150 ml or less. In Study II time to normal bladder
function was the primary outcome measure, and in Study III it was a secondary outcome measure. In Study II time to normal bladder function was measured in the clamped catheter group from the time the catheter was clamped, and in the free drainage group from the time the catheter was removed. In Study III time to normal bladder function was measured from end of surgery.

Normal bladder function was controlled by bladder scan. The registered nurse or assistant nurse on duty performed the bladder scans. All the nurses had received the same education and training on the bladder scan device before each of the studies started. In Study II a BVI 2500 bladder scan unit (BladderScan Bladder Volume Instrument 2500, Diagnostic Ultrasound, Redmond, WA, USA) was used. In Study III a later model was used, BVI 3000 bladder scan unit (BladderScan Bladder Volume Instrument 3000, Verathon Inc., Bothell, WA, USA). The measurements were made with the patient in supine position and ultrasound transmission gel placed above the symphysis pubis. The measurements were repeated until the bladder was centred in the picture. The largest measured volume was noted in the study protocol. Measurements with the BladderScan BVI 2500 and 3000 have documented high reliability.33,109

Quality of life outcome measures (Study III)

HRQoL was measured before discharge from the orthopaedic department, at 4 weeks after discharge and at 4 months after discharge. Two different questionnaires were used, the Euro QoL(EQ-5D)110-111 and the Short Form-36 Health Survey (SF-36).112 Such scales have been used in Swedish patients with hip fractures and have been found to be valid and reliable.113 These two instruments were selected because they complement each other and can be used for cost-effectiveness analysis.106 The EQ-5D is considered to be blunt, and the SF-36 more complex.

The EQ-5D is a two-part standardised health profile instrument for measuring health outcomes. The two parts are the EQ-5D descriptive system and the EQ VAS. The EQ-5D descriptive system consists of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is measured on a 3-point scale (no problems, some problems and major problems). Responses to these five questions are converted into one of 243 different health state descriptions, the EQ-5D index ranking, between -0.594 and 1.000, where 1.000 indicates full health.110 The QALY weight from EQ-5D can be below 0, as some states of health are considered to be worse than death.114 This utility measure is based on how a general population values the different health states
using the time trade-off (TTO) method. The TTO is based on letting people ‘choose’ between living, for example, ten years in their current health state (worse than full health) or living fewer years (time X) in full health. Time X is varied until the two alternatives are estimated to be equivalent for the individual. In this thesis UK population weights were used to convert to the EQ-5D index. The EQ VAS consists of a 20 cm visual analogue scale graduated between 0 (indicating worst imaginable health state) and 100 (indicating best imaginable health state). The EQ VAS reflects the patients’ valuation of their own health state, and to get a QALY weight, the EQ VAS score is divided by 100.

The SF-36 Health Survey consists of 36 items grouped into eight multi-item dimensions: physical functioning, limitation in physical role functioning, bodily pain, general health, vitality, social functioning, limitation in emotional role functioning, and mental health. At discharge the acute version of SF-36 was used and at the latter occasions the standard version was used. The validity and reliability of SF-36 has been shown to be acceptable in a general Swedish population. For the health economic evaluation data from the SF-36 measurement were transformed to SF-6D using the method proposed by Kharroubi et al. Eleven items from six dimensions (physical functioning, limitation in physical role functioning, bodily pain, mental health, vitality, and limitation in emotional role functioning) in the SF-36 are used to calculate a health score. Full health is scored 1, and the lowest score is 0.2031. As with EQ-5D, SF-6D reflects the general public’s valuation of the state of health described by the patients, but in SF-6D the standard gamble (SG) method is used. The SG valuation of SF-6D is made by a general population in the UK. SG can be explained as representing the following choice: remaining in a specific health state (worse than full health) for ten years or undergoing an operation or treatment that could result in full health for ten years (probability p), but that also carries a specific risk of dying (probability 1-p). The probability p is varied until the two alternatives are estimated to be equivalent for the individual.

The health scores from EQ-5D, EQ VAS, and SF-6D assessed at discharge, 4 weeks, and 4 months were used to calculate QALYs. QALYs describe an individual’s overall health status according to QALY weight and the time spent in the health state. QALY simultaneously captures both quantity and quality, and gains and losses. To calculate QALYs gained, the QALY weight is multiplied with the time spent in that health state. During one year with a health score of 0.8, the gained QALYs are 0.8. During three years spent in a health score of 0.8, the gained QALYs are 2.4, and so on. When calculating QALYs, most often linearity with
respect to duration is assumed. If multiple QoL measurements are made over time the QALYs gained between the measurements are added into a sum. One QALY represents one year lived in full health.

**Measurements of costs (Study III)**

All cost data were collected individually for each patient and captured from the study protocol and medical records.

The material included costs for catheters and material used when inserting catheters. Also, costs for medication due to urinary problems were considered. The labour costs included time for urinary catheterisation, bladder scan, and catheter removal. The time it took to perform these operations were measured several times, and an average of expenditure of time was calculated. This average time was used in the calculations of costs. The cost for nursing time was based on mean wages for registered nurses at the orthopaedic department. Costs on length of hospital stay were also measured. Cost for hospitalisation was estimated at €415 per day (including €95/day in ‘hotel costs’, €50/day in physician costs, and €270/day in costs for nursing). These costs are based on market prices. To avoid double counting of costs, from these costs an average cost for urinary catheterisation (€17.2) was subtracted, and in the calculation of costs for each patient the actual cost for urinary catheterisation and associated costs was added thereto. A catheterisation with indwelling catheter is estimated at €8.9, an intermittent catheterisation at €3.8, a bladder scan control at €1.1, and a nosocomial UTI at €27.2 (including antibiotics and urine culture).

All costs are given at 2011 rates and converted from Swedish crowns (SEK) to Euros (€) using the annual average exchange rate for 2011 (9.03 SEK/€).

**Interviews (Study IV)**

Individual semi-structured interviews with open-ended questions were carried out from October 2009 to March 2010. The interviews took place about two weeks after hip surgery, either in the patient’s own home (n = 25) or in a secluded room at the orthopaedic ward (n = 5). The interviews were audio-recorded. Before the recorder was turned on the patients were once again informed about the purpose of the interview, and informal conversation took place before the interview to build rapport. The interviews started with an open question: ‘What was it like for you being catheterised/not being catheterised, in connection with your hip surgery?’ The interviews also included the question: ‘If you should undergo hip surgery again, or if a friend of yours should undergo hip surgery, which method for
bladder emptying would you say was better?’ Supportive questions were added during the interview. At most, the interviews lasted up to 15 minutes. A professional transcriptionist not involved in the study transcribed the interviews verbatim.

**Demographic and medical variables (Studies I–IV)**

In all studies (Studies I–IV) demographic variables included age, sex, diagnosis, type of anaesthesia, and catheterisation method. In addition, in Studies I–III data were collected regarding ASA (American Society of Anesthesiologists) -class, type of surgery, type of antibiotic prophylaxis, type of analgesics, duration of urinary catheterisation, diabetes, history of urinary tract problems, delirium during the hospital stay, length of stay at the orthopaedic ward, housing, and walking ability. In Study I data regarding cancer, cardiac disease, rheumatoid arthritis, and faecal incontinence were also collected. Data were also collected on blood haemoglobin, plasma albumin, and serum creatinine on arrival. These blood samples are routine for hip fracture patients and can be seen as surrogate measures of general state of health, renal failure, and dehydration. During the hospital stay, data were collected for time elapsed between arrival and surgery, and method of catheter removal.

In Studies I and III data for mortality were collected from the population register, in Study I during the first year after surgery, and in Study III during the first 4 months after surgery.
ANALYSIS

Study I
The patients with nosocomial UTI were compared with those free from UTI at discharge. To analyse differences between the two groups, an independent samples Student’s $t$ test was used for continuous normally distributed data, a Chi-square test for categorical data, Fisher’s exact test for categorical data with small groups, and a Mann-Whitney U test for continuous data with skewed distribution and for ordinal data. The significance level was set to 0.05. Statistical analyses were conducted using the software package SPSS 15.0 for Windows.

Study II
Sample size calculation was performed based on data from medical records ($n = 40$) in the orthopaedic clinic (unpublished data). The standard deviation of the mean time to return of normal bladder function was approximately five hours, irrespective of whether the urinary catheter was clamped or not. A three-hour mean difference in the time for return of normal bladder function between the clamped catheter group and the free drainage group was considered to be of clinical significance. The sample size calculation showed that 50 in each group were required to detect a three-hour difference between the groups (two-tailed, $\alpha = 0.05$, power 85%).

Statistical analyses were conducted to assess differences between patients that participated in the study and the attrition rate. The Chi-square test was used for nominal data, the Chi-square test, linear-by-linear for data ordered in categories, Student’s $t$ test for data normally distributed, and Mann-Whitney U test for skewed continuous data.

Data showing the amount of time required for return to normal bladder function had a positive skewed distribution. The central tendencies in the groups were described with median value and the first and third quartile. The Breslow test was performed to compare the equality of the distributions over time in the clamped catheter group and free drainage group. Kaplan-Meier curves were used to visually illustrate the difference between the two groups, concerning the distribution of time to return to normal bladder function. Differences in the proportion of patients in need of recatheterisation were assessed using the Fisher exact test. Length of hospital stay was analysed with Student’s $t$ test. All patients were analysed in the group they were randomised to, in accordance with the intention-to-treat principle. The level of significance was set at 0.05. Statistical analyses were conducted using the software package SPSS 15.0 for Windows.
Study III

The estimation of sample size was based on reported differences between the catheterisation methods in studies of hip fracture patients^59^ and total joint replacement patients.^92^ In the estimation the results from Study II, where about 50% of the hip fracture patients had UTI, were also considered.^128^ No figures were available for hip replacement patients in the department. Power analysis, considering a reduction of UTI frequency from 35% to 15%, with an alpha of 0.05 and a power of 0.85, showed that at least 83 patients in each catheterisation group should be included in the study.

Statistical analyses were conducted to investigate differences between patients treated with intermittent catheterisation and indwelling catheterisation. The variables analysed were frequency of UTI, time to normal bladder function, gained QALYs, and costs of material and labour. Chi-square test was used for nominal data, Student’s t test for normally distributed continuous numerical data, and Mann-Whitney U test for skewed continuous numerical data. Cost-effectiveness was investigated by health outcomes expressed as QALYs derived from measurement of quality of life and survival time.\(^\text{106}\) The results of comparisons of gained QALYs in the catheterisation groups were described with 95% confidence intervals (CIs). All patients were analysed in accordance with the intention-to-treat principle.

Statistical analyses were conducted using IBM SPSS Statistics 20 and Microsoft Office Excel 2007.

Study IV

The interviews were analysed through inductive qualitative content analysis.\(^\text{129}\) In the preparation phase, all the transcribed interviews were read through several times to gain a sense of the whole. The audio files were also listened to at the same time as the interviews were read to check the transcription. The texts were organised into meaning units. In the organisation phase meaning units relevant to the aim of the study were extracted and labelled with codes—open coding. After this open coding the codes were compared for similarities and dissimilarities and sorted into sub-categories. The analysis went on with grouping sub-categories into categories in accordance with the aim of the study. Through abstraction the categories were grouped into a main category.\(^\text{129}\) During the whole analysing process, all authors discussed the coding and alternative interpretations, until consensus was reached.
ETHICAL CONSIDERATIONS

The studies were carried out in accordance with the Helsinki Declaration and approved by the Regional Ethical Review Board in Uppsala, Sweden (D. no: 2006/012) (Studies I and II) and (D. no: 2009/075) (Studies III and IV). The four basic ethical principles, autonomy, non-maleficence, beneficence, and justice, were followed. Patients were informed of the study both orally and in writing. All data were handled confidentially, and presentation of the data has been made in such a way that no single participant can be identified. All data were labelled with code numbers to ensure confidentiality. Those who agreed to participate in the studies signed an informed consent form before data collection. The patients were informed of their right to end their participation at any time.

Our intention when planning Studies I and II was to include patients with cognitive impairment, since about one third of hip fracture patients in Sweden have cognitive impairment. But the regional ethics board rejected that request, and therefore, cognitively impaired patients in Studies III and IV also were excluded.

Asking patients to participate in a research study is always a delicate matter. It is a question of when the patient should be asked to participate, how, and by whom. It was, for natural reasons, impossible to ask the hip fracture patients in advance, before the fracture for participation in Studies I, II, and III. They did not have the same time as the OA patients in Study III and the participants in Study IV to think over the decision, as they were asked for participation upon arrival to the orthopaedic ward. The hip fracture patients had to decide whether to participate or not, while they were affected by acute illness, and in a very stressful situation. The patients were invited to participate by the nurses at the orthopaedic wards. The patients had to rely on these nurses to provide good care. The nurses asking the patients to participate were conscious of that situation and sensitive about not pushing patients to make a decision. The OA patients in Study III were asked to participate by a reception nurse at the pre-operative planning visit, about 1 to 2 weeks before planned surgery. They had plenty of time to read the study information and ask questions before they gave their consent to participate. The patients asked to participate in Study III were also informed that if they did not participate in the study they would get an indwelling urinary catheter according to the routine in the orthopaedic department.

All participants in Study IV were asked for participation some days after hip surgery. They were still in hospital when asked, and there could be a
risk of feeling pressured to participate. Therefore, the patients were contacted one more time to make an appointment for the interview, to give them a chance to withdraw their consent.
SUMMARY OF RESULTS

Study I
The study included a total of 86 hip fracture patients treated with an indwelling urinary catheter. Out of the 86 patients in the study, 45 (52.3%) contracted nosocomial UTI in hospital. Thirty-seven (43%) patients had asymptomatic UTI, and eight (9.3%) had symptomatic UTI. The most common bacterial isolates in the urine cultures were *Escherichia coli* (33.3%) and *Enterococcus faecalis* (23.5%). There were no statistical differences between patients with and without nosocomial UTI in terms of age, gender, or ASA class (Table 3). With regard to co-morbidity, only diabetes was identified as a risk factor. The nine patients with diabetes all contracted nosocomial UTIs.

Table 3. Comparisons of demographic and medical characteristics in hip fracture patients with and without nosocomial UTI

<table>
<thead>
<tr>
<th>Variable</th>
<th>UTI  (n = 45)</th>
<th>Without UTI (n = 41)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years mean (SD)</td>
<td>80.2 (11.2)</td>
<td>78.7 (11.2)</td>
<td>0.550*</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
<td>0.607Δ</td>
</tr>
<tr>
<td>Male</td>
<td>12 (26.7)</td>
<td>13 (31.7)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>33 (73.3)</td>
<td>28 (68.3)</td>
<td></td>
</tr>
<tr>
<td>ASA class*</td>
<td></td>
<td></td>
<td>0.318Δ</td>
</tr>
<tr>
<td>ASA I</td>
<td>4 (8.9)</td>
<td>7 (17.1)</td>
<td></td>
</tr>
<tr>
<td>ASA II</td>
<td>27 (60.0)</td>
<td>26 (63.4)</td>
<td></td>
</tr>
<tr>
<td>ASA III</td>
<td>14 (31.1)</td>
<td>8 (19.5)</td>
<td></td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>9 (20.0)</td>
<td>0</td>
<td>0.003†</td>
</tr>
<tr>
<td>Urinary tract problems, n (%)</td>
<td>6 (13.3)</td>
<td>8 (19.5)</td>
<td>0.438Δ</td>
</tr>
</tbody>
</table>

*ASA class (I = normal healthy patient, II = patient with mild systemic disease, III = patient with severe systemic disease, IV = patient with severe systemic disease that is a constant threat to life, V = moribund patient who is not expected to survive without surgery, VI = patient declared brain-dead whose organs are being removed for donor purposes) 125

*Independent Student’s t test

ΔChi-square test

†Fisher’s exact test

Depending on which surgery method was used, the hip fracture patients received different antibiotic prophylaxis to prevent post-surgical wound infection. Cloxacillin (2 g, three doses intravenously (IV)) was administered...
to arthroplasty patients; cefuroxime (1.5g, three doses IV) to patients with single screw, pin, or nail with side plate; and clindamycin (600 mg, three doses IV) to patients with a known allergy to penicillin. Patients treated with one or two pins, screws, or nails did not receive any antibiotic prophylaxis. There was a significant difference between patients with nosocomial UTI and patients without, regarding type of antibiotic prophylaxis \( (p = 0.002) \). Patients, who received cefuroxime, clindamycin, or no antibiotic prophylaxis contracted UTI more often than patients who received cloxacillin. The majority of the patients who received cloxacillin (17/21) belonged to the group without UTI (Table 4).

There was no significant difference between the groups with regard to duration of catheterisation (Table 4), occurrence of delirium during time in hospital, UTI frequencies four months after the fracture, or mortality after one year. Nor was there any difference with respect to whether the catheter was clamped before removal or not.

Table 4. Comparisons of in-hospital variables in patients with hip fractures with and without nosocomial UTI

<table>
<thead>
<tr>
<th>Variable</th>
<th>UTI ( (n = 45) )</th>
<th>Without UTI ( (n = 41) )</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of fracture, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intracapsular</td>
<td>25 (55.6)</td>
<td>28 (68.3)</td>
<td>0.225\textsuperscript{c}</td>
</tr>
<tr>
<td>Extracapsular</td>
<td>20 (44.4)</td>
<td>13 (31.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Type of surgery, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One or two pins, screws, or nails</td>
<td>16 (35.6)</td>
<td>10 (24.4)</td>
<td>0.008\textsuperscript{c}</td>
</tr>
<tr>
<td>Single screw, pin, or nail with side plate</td>
<td>22 (48.9)</td>
<td>12 (29.3)</td>
<td></td>
</tr>
<tr>
<td>Hemiarthroplasty or total hip replacement</td>
<td>7 (15.5)</td>
<td>19 (46.3)</td>
<td></td>
</tr>
<tr>
<td><strong>Antibiotic prophylaxis during surgery, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cefuroxime</td>
<td>24 (53.3)</td>
<td>15 (36.6)</td>
<td>0.002\textsuperscript{c}</td>
</tr>
<tr>
<td>Clindamycin</td>
<td>2 (4.4)</td>
<td>1 (2.4)</td>
<td></td>
</tr>
<tr>
<td>Cloxacillin</td>
<td>4 (8.9)</td>
<td>17 (41.5)</td>
<td></td>
</tr>
<tr>
<td>No antibiotic prophylaxis during surgery</td>
<td>15 (33.3)</td>
<td>8 (19.5)</td>
<td></td>
</tr>
<tr>
<td><strong>Total time with urinary catheter, hours median (quartiles)</strong></td>
<td>66.0 (56.0–84.0)</td>
<td>62.0 (56.5–75.5)</td>
<td>0.546\textsuperscript{i}</td>
</tr>
</tbody>
</table>

\textsuperscript{a}Chi-square test
\textsuperscript{b}Mann-Whitney U test
Study II
Of the 113 patients with hip fractures, 55 were randomised to the clamped catheter group, and 58 to the free drainage group. The mean age was 80 years (SD 11), and 73% were women. Baseline data did not differ between the participants in the clamped catheter group and the free drainage group.

The median time, from 6 a.m. on the second post-operative day when the measurement of time started, until the participants recovered their normal bladder function, was 6 (Q1 4 – Q3 8) hours in the clamped catheter group and 4 (Q1 3- Q3 7.25) hours in the free drainage group (Table 5). The Breslow test showed no significant difference between the time distributions to normal bladder function in the groups ($p = 0.156$) (Figure 3). There was no significant difference between the two groups regarding the frequency of re-catheterisation or mean time in hospital (Table 5).

Figure 3 Kaplan-Meier curves showing the distribution of time required to return to normal bladder function in the clamped catheter group and the free drainage group. The curves show at each time point the probability that the patients had not returned to normal bladder function.
Table 5. Primary and secondary outcomes in the clamped catheter group and the free drainage group

<table>
<thead>
<tr>
<th>Primary and secondary outcomes</th>
<th>Clamped catheter group (n = 55)</th>
<th>Free drainage group (n = 58)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time required to return to normal bladder function, hours, median (quartiles)</td>
<td>6 (4–8)</td>
<td>4 (3–7.25)</td>
<td>0.156*</td>
</tr>
<tr>
<td>Need for re-catheterisation, n (%)</td>
<td>5 (10)</td>
<td>6 (11)</td>
<td>0.904†</td>
</tr>
<tr>
<td>Length of hospital stay, days, mean (SD)</td>
<td>10.9 (6.2)</td>
<td>10.6 (6.5)</td>
<td>0.777‡</td>
</tr>
</tbody>
</table>

*Breslow test  
†Fisher’s exact test  
‡Student’s t test

Study III
Eighty-five patients were randomised to intermittent catheterisation, and 85 to indwelling catheterisation. Neither demographical characteristics nor in-hospital variables differed between the catheterisation groups. Eighteen of the patients in the total sample (n = 170) patients contracted nosocomial urinary tract infections, 8 (9.4%) of the intermittent group and 10 (11.8%) of the indwelling group (Table 6). There were no statistically significant differences between the catheterisation groups (p = 0.618). The most common bacterial isolates were *Escherichia coli* (42.1%) and *Klebsiella species* (15.8%).

The patients in the intermittent group on average regained normal bladder function 24 hours after surgery, one day and night earlier than patients in the indwelling group (p < 0.001) (Table 6). The median number of bladder scan controls needed before they regained normal bladder function was 6, and the median number of intermittent catheterisations needed was 1 (Q₁ 0 - Q₃ 2). At most, 8 catheterisations were needed before return of normal bladder function. Twelve of the patients (14%) in the intermittent group did not need any catheterisation.

The patients in the indwelling catheterisation group regained normal bladder function a median of 48 hours post-surgery. The median number of bladder scan controls needed before the patients retrieved normal bladder function was 2.

The QALYs gained during the first 4 months after hip surgery did not differ significantly between the catheterisation groups, independent of which instrument was used (Table 7). The patients that did contract nosocomial UTI (n = 18) gained in average statistically significantly fewer QA-
LYs than the other patients, as measured with the EQ-5D measurement ($p = 0.010$). Complete cost data were available for 169 patients (84 intermittent and 85 indwelling). The costs did not differ statistically significantly between the two catheterisation methods. Neither when looking at the direct costs associated with intermittent and indwelling catheterisation (m €18.0, SD13.6, and m €16.6, SD13.1, respectively, $p = 0.455$), nor when including costs for hospitalisation (m €3642, SD1605, and m €3954, SD 1743, respectively, $p = 0.228$), were there any statistically significant differences between the catheterisation groups.

Table 6. Differences between hip surgery patients randomised to either intermittent or indwelling urinary catheterisation concerning bladder function

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intermittent Catheter (n = 85)</th>
<th>Indwelling Catheter (n = 85)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nosocomial UTI, n (%)</td>
<td>8 (9.4)</td>
<td>10 (11.8)</td>
<td>0.618a</td>
</tr>
<tr>
<td>Time to normal bladder function, hours median (quartiles)</td>
<td>24 (13–48)</td>
<td>48 (43–55)</td>
<td>&lt;0.001i</td>
</tr>
<tr>
<td>Number of Intermittent catheterisations, median (quartiles)</td>
<td>1 (0–2)</td>
<td>0 (0–0)</td>
<td>&lt;0.001i</td>
</tr>
<tr>
<td>Number of bladder scans to normal bladder function, median (quartiles)</td>
<td>6 (4–9)</td>
<td>2 (1–3)</td>
<td>&lt;0.001i</td>
</tr>
</tbody>
</table>

a7 patients had intermittent catheterisations after removal of the indwelling catheter
bChi-square test
cMann-Whitney U test

Table 7. Health scores at discharge and at the 4-week and 4-month follow-ups and gained QALYs during 4 months: EQ-5D (n=109), EQ VAS (n=105) and SF-6D (n=90) were used to calculate gained QALYs

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Health score discharge</th>
<th>Health score 4 weeks</th>
<th>Health score 4 month</th>
<th>Gained QALYs</th>
<th>95% CI of difference in gained QALYs</th>
</tr>
</thead>
<tbody>
<tr>
<td>EQ-5D intermittent</td>
<td>0.32</td>
<td>0.56</td>
<td>0.73</td>
<td>0.090</td>
<td>-0.03–0.03</td>
</tr>
<tr>
<td>EQ-5D indwelling</td>
<td>0.32</td>
<td>0.62</td>
<td>0.68</td>
<td>0.093</td>
<td>-0.03–0.03</td>
</tr>
<tr>
<td>EQ VAS intermittent</td>
<td>0.52</td>
<td>0.63</td>
<td>0.69</td>
<td>0.045</td>
<td>-0.02–0.02</td>
</tr>
<tr>
<td>EQ VAS indwelling</td>
<td>0.52</td>
<td>0.65</td>
<td>0.68</td>
<td>0.044</td>
<td>-0.02–0.02</td>
</tr>
<tr>
<td>SF-6D intermittent</td>
<td>0.51</td>
<td>0.58</td>
<td>0.65</td>
<td>0.032</td>
<td>-0.02–0.01</td>
</tr>
<tr>
<td>SF-6D indwelling</td>
<td>0.50</td>
<td>0.60</td>
<td>0.63</td>
<td>0.036</td>
<td>-0.02–0.01</td>
</tr>
</tbody>
</table>
Study IV
The main category ‘An issue but of varying impact’ includes the patients’ experiences of bladder emptying in connection to hip surgery. Under the main category there are five generic categories—ability to urinate, catheter is convenient, bothersome bladder emptying, intrusion upon dignity, and concern about complications—and 10 subcategories (Figure 4). Irrespective of whether the patients were able to urinate or were catheterised, bladder emptying was not as usual. The descriptions of urinary catheterisation varied from experiences of pain and discomfort to descriptions of catheterisation as uncomplicated and convenient. Patients able to urinate by themselves appreciated that ability. Some patients did not want to be catheterised, approving it only reluctantly. There were descriptions of how catheterisation felt like an intrusion upon dignity.

Well, I reacted to the bag at first but it wore off—I mean, everybody had one. If only they could make the bags of another colour, so you couldn’t see how much there was, or how little or...because you’re not used to walking around with a bag of urine. (Patient with indwelling catheter)

There were also descriptions of an awareness of the risks associated with urinary catheterisation. The patients expressed a lot of knowledge about risks and complications associated with urinary catheterisation.

Independent of the method for bladder emptying, most patients in our study would choose the same method next time. They experienced the catheterisation method they had received as the best. This is illustrated by two citations:

It’s very practical having a catheter, it really is. It depends what your operation’s for. If it’s your hip that’s being operated on, I should think it’s an advantage moving as little as possible afterwards. (Patient with indwelling catheter)

It just seems sort of unnecessary— I mean, unless you really need it, it feels unnatural, you might say. Of course, if you’ve got to have it, there’s no choice, is there? But since you’re anyway up and walking so soon after the operation, in a day or so you can just as well go to the toilet... Being without a catheter’s a way of getting going again. So I thought it was nice like that, part of getting better. (Patient who was able to urinate during the whole perioperative period)
Figure 4. Sub-categories, generic categories and main category describing the hip surgery patients’ experiences of bladder emptying and urinary catheterisation in connection to hip surgery.
DISCUSSION

This thesis highlights different aspects of urinary catheterisation and issues associated with urinary catheterisation in connection to hip surgery, to fill in some knowledge gaps through RCTs and with a mixed method approach.

Clamping indwelling catheters

Study II in this thesis is the most recent RCT investigating the effect of clamping short-term indwelling catheters. A Cochrane review on methods for removal of short-term indwelling catheters, comprising studies up to 2006, concluded that the evidence was limited and did not provide a basis for clinical guidelines regarding whether or not to clamp when removing short-term indwelling catheters.\(^86\) In two of the studies in the review the time to first void was shorter after clamping.\(^85,88\) However, these studies had different clamping regimens regarding the time of clamping, and therefore, no meta-analysis could be performed. The clamping regimen in Study II was shorter than in earlier studies, and the catheter was only clamped once until the patient felt urge to urinate. In Study II clamping of the indwelling urinary catheter before removal was not shown to be of any advantage in patients with hip fractures, regarding either time to normal bladder function or need for re-catheterisation. There is also a risk that clamping might cause bladder distension if the clamp is left in place for too long.\(^84\) Because the present results did not show any advantages of clamping or free drainage, other aspects such as workload or costs have to be considered. Clamping is an additional task for the nursing staff in the removal of an indwelling catheter. Even if clamping is not an expensive routine, it involves a higher cost than removal with free drainage. Therefore, it seems that clamping indwelling catheters in patients with hip fractures is not indicated.

Nosocomial urinary tract infection

The prevalence figures of nosocomial UTI in patients with hip surgery varies between studies and also in this thesis.\(^39,43,53-64\) Overall, in Study III the frequency of nosocomial UTI was much lower than in Study I (10.6% vs. 52.3%). A difference of that magnitude was unexpected, even though the sample in the two studies differs. In Study I only patients with hip fractures were included, while Study III included both patients with fractures and patients with OA. Patients with OA are younger than patients with hip fractures and are known to have less morbidity.\(^131-132\) This might not explain the whole difference between the studies. The choice of antibiotic
prophylaxis during surgery seemed to be one explanatory factor. In Study I cloxacillin was found to have a protective influence on the risk for UTI; in Study III half of the patients received cloxacillin, which therefore may reflect the decrease of developed UTIs. The change in antibiotic distribution was due to change of surgery method in intracapsular fractures, which took place between the two studies. In 2006 these patients most often were operated with internal fixation with two screws or pins (i.e. Study I) and did not routinely receive any antibiotic prophylaxis. In 2009 the routines had changed, and these patients were more often operated with hemi- or total hip arthroplasty (i.e. Study III), and for that reason more patients were given cloxacillin. The regimen to give cefuroxime to the patients with extracapsular fractures was unchanged. Another important change that occurred between Study I and Study III was a slight change of the definitions of nosocomial UTI. However, when analysing data from Study I again using the same definition of nosocomial UTI as in Study III, the UTI prevalence was 50%, hence the results remained the same.

Another probable, and perhaps the most important, reason for the great difference in UTI between the two studies was an increased awareness of basic hygiene by campaigns at the hospital where this study took place. In 2006 the nurses wore the same textile gown when caring for all patients in the same room. Before Study III started, in 2009, the textile gowns were replaced with plastic aprons, which were changed between each patient contact. There were also hand hygiene improvements in the form of repeated education with follow-up sessions for the professionals and compliance checks during this time. The hospital has now entered the WHO project Save Lives: Clean Your Hands. Since 2008 national point prevalence measurements of nosocomial infections are performed in Sweden. From 2008 until 2011 the overall prevalence of nosocomial infections has decreased from 11.6% to 9.3%. Diabetes was the only earlier known risk factor for UTI that was confirmed in Study I. All patients with diabetes in that study contracted nosocomial UTI. The lack of other significant risk factors according to previous studies, as presented in Table 1, might depend on several factors. First, not all other studies describing risk factors included patients with hip fractures. Further, the inclusion criteria for Study I might narrow the possibility of identifying the same risk factors. One criterion was that patients 50 years of age and older were included and the mean age was about 80 years. This might have resulted in a sample relatively homogeneous with regard to age, which could explain why old age was not identified as a risk factor. Also, the fact that patients with cognitive impairment were excluded may have resulted in the sample in Study I being healthier than the general hip fracture population, with the
result that poor general state of health did not fall out as a risk factor. Female gender was in earlier studies also found to be a risk factor for UTI among hip fracture patients. The distribution of men and women in Study I was similar to the earlier studies, but female gender did not fall out as a risk factor.

Regarding the consequences of nosocomial UTI, our studies could not confirm any of those pointed out in earlier studies: longer hospital stay, mortality, and delirium. An earlier population-based cross-sectional study of old women describes women with UTI as more delirious than women without UTI, though in a general population of old women. In hip fractures there are other possible risk factors for delirium during hospital stay, such as cognitive impairment, depression, and undertreated pain. This might explain why delirium was as frequent in patients with as those without UTI in Study I. Regarding mortality and length of hospital stay, no differences were found between patients with and without UTI. It is doubtful whether length of stay is an appropriate outcome measure in these patient groups, as earlier studies have shown that length of stay could be biased by many different causes, for example, waiting time for surgery and the length of time it takes to arrange home care. One alternative to length of hospital stay as a measure, used in earlier research on orthopaedic patients, is ‘home readiness’. Home readiness means that a number of discharge criteria are predefined, and when these are fulfilled the patient is considered to be home ready. This might be a more appropriate measure in these groups of patients because home readiness focuses on the patient’s abilities instead rather than on organisational factors.

**Intermittent or indwelling urinary catheterisation**

In Study III no differences in frequency of UTI or cost-effectiveness were found between patients in the intermittent and indwelling catheterisation groups. These results contribute to the latest Cochrane review in the area of short-term catheterisation. In this review three studies were compared, two on orthopaedic patients and one on gynaecological patients. Since then, three RCTs have been performed that compare indwelling and intermittent short-term catheterisation. However, all were performed in patients with obstetric or gynaecological conditions. In two of the studies in the Cochrane review and two of the later studies the UTI rate was higher in the indwelling catheterisation group. In the third of these recent studies, though including patients with obstetric conditions, the UTI rate was, as in Study III, similar in the intermittent and indwelling catheterisation groups. The difference in UTI rate between the catheteri-
sation methods still remains uncertain. The authors of the Cochrane review also suggested that future RCTs should include time to normal bladder function as an outcome measure.\textsuperscript{80} It is suggested that time to normal bladder function could vary, depending on which method is used for urinary catheterisation. In Study III the difference between the time to return of normal bladder function was one day shorter for the patients with intermittent catheterisation than for those with indwelling catheterisation.

Cost-effectiveness did not differ between intermittent and indwelling catheterisation in this study, in contrast to other studies indicating that intermittent catheterisation was more expensive than indwelling catheterisation.\textsuperscript{92,93} However, in an economic comparison, none of those studies\textsuperscript{92,93} used QALYs or any other measure of effect besides costs, such as UTI or length of hospital stay. Therefore, one can conclude that they did not perform a full cost-effectiveness analysis.\textsuperscript{106} Furthermore, it is worth noting that in these studies no bladder scan controls were performed.\textsuperscript{92-93} Instead, intermittent catheterisations were performed every sixth hour. Since the late 1990s bladder scans have become more common to identify urinary retention and for determining when a patient should be catheterised.\textsuperscript{145} In the present Study III the patients were bladder-scanned before the intermittent catheterisation, and no catheterisations were made unless the bladder volume was at least 400 ml. This might be the reason why the patients who were intermittent catheterised required fewer catheterisations compared to the patients in the study by Knight and Pellegrini.\textsuperscript{93}

No studies before this study have taken the hip surgery patients’ preferences on urinary catheterisation into consideration. In the interviews in Study IV most patients answered that they would choose the same method for urinary catheterisation if they should undergo hip surgery again, independent of which method they were randomised to. This is in concordance with the findings in an RCT on women undergoing gynaecological surgery.\textsuperscript{143} The patients in Study IV described both concerns and advantages of urinary catheterisation, irrespective of whether they had intermittent or indwelling catheterisation. The advantage of intermittent catheterisation was that it gave an opportunity to urinate, which promoted their rehabilitation. The advantage of indwelling urinary catheterisation was that it was convenient; the urine just flowed into the urine bag without giving them any bother. This is also shown in a study of people living with long-term indwelling urinary catheters.\textsuperscript{103} Some of the patients with indwelling catheters in this thesis described how they felt exposed, not only during insertion, but also when walking around with the urine bag hanging visible on the walking frame. This could be followed by feelings of embarrassment and intrusion on dignity. Wilde\textsuperscript{101} also described how persons...
living with an indwelling urinary catheter described not wanting to display the urine bag, and how they tried to hide the urine bag when they went out. As the patients in Study IV were aware of risk and complications associated with urinary catheterisation, one can speculate on whether the patients should be given an option to make their own decisions about which method for urinary catheterisation they prefer. Health care professionals should support patient participation by recognising the patient as a person who has information and knowledge that needs attention.\textsuperscript{146} This approach is in accordance with the Swedish Patient Safety Act,\textsuperscript{6} but must be considered in the context of many patients still wanting the professionals to decide.\textsuperscript{147} Hence, patient participation is not synonymous with patients making all the decisions regarding care and treatment; rather, it is about patients being informed and taking part in decision making.\textsuperscript{146}

**Methodological considerations**

One limitation regarding the sample in all four studies in this thesis was the exclusion of patients with cognitive impairment. The ethics board did not approve including patients with cognitive impairment, but this recommendation resulted in another ethical dilemma. Not including the cognitively impaired patients means this group of patients remains uninvestigated. Exclusion of cognitively impaired patients also decreased the external validity of the studies in this thesis.\textsuperscript{148} About one third of patients with hip fractures in Sweden are known to be cognitively impaired,\textsuperscript{130} and cognitive impairment is generally a risk factor for UTI.\textsuperscript{136} Subsequently, the results of this thesis cannot be generalised to the total population of hip surgery patients.

Another limitation was that patients were lost to the studies due to their not being asked to participate. The participants in Studies I–III were asked to participate and included by the nurses on duty at the orthopaedic department. In Studies I and II 32 patients were not asked to participate and in Study III 103 patients were apparently not asked, although all nurses (n = 40) at the orthopaedic wards were involved in inviting the patients to participate. The reason for this is not systematically recorded, but when asked, the nurses at the wards reported that the most probable reasons were heavy workload and a failure to document in the medical record a patient’s decision to decline. An earlier study has described how nurses might act as gatekeepers by excluding patients according to their own subjective view of the patients’ suitability of the intervention.\textsuperscript{149} One cannot exclude the possibility that some patients were assessed as too old or too sick to be asked for participation by the nurses, which might reflect a gate-
keeper bias. However, analysis comparing the patients lost to the study with the included patients showed that in Study I and II they did not differ regarding age, gender, ASA class, mobility, or length of hospital stay. In Study III the patients lost to the study were older, and more were females, compared to the patients included in the study. Nevertheless, since the study was an RCT it is concluded that this is not of major threat to the study regarding the comparison between the intermittent and the indwelling catheterisation groups.

A strength of Studies II and III was the rigorous randomisation procedure. Simple randomisation is sufficiently good in samples consisting of several hundred persons.\textsuperscript{150} As the samples of Studies II and III were power calculated to be smaller, additional efforts were made to get similar distribution in the study groups. The randomisation was stratified, which has been shown to increase the power of small randomised trials.\textsuperscript{127} In Study II the stratification was for gender, and in Study III the stratification was for gender and diagnosis. There are, of course, other characteristics that could influence the outcome, but these two were considered the two most important. It is not recommended that a study should be stratified for many different factors, as this might lead to small numbers of subjects within each strata.\textsuperscript{150}

One limitation in Study III was the attrition in completion of the QoL questionnaires, for which there could be different reasons. One explanation worthy of consideration is the choice of QoL instruments. The largest attrition rate occurred in SF-36. Both SF-36 and EuroQol are stated to be useful with old people, but in Study III some patients had problems in answering, especially for SF-36 and EQ VAS. Other researchers have also found it hard for old people to complete SF-36.\textsuperscript{151} However, the response rate in our study is in parity with earlier research in older patients.\textsuperscript{152} A Cochrane review comprising methods to increase response to postal and electronic questionnaires states that offering monetary incentives and sending reminders to those who do not return the questionnaires are actions that could increase the response rate.\textsuperscript{153} This was not done in Study III; instead, the patients were called when the questionnaires were sent out. They were asked if they had any urinary tract problems, and also were encouraged to fill in and return the questionnaires. In addition, the addresses on the envelopes sent to the participants were handwritten. These are actions also known to increase the response rate.\textsuperscript{153} The main concern regarding missing data is that it can result in bias, and outcomes may not reflect the true situation.\textsuperscript{154} However, the attrition was equal in the two randomisation groups and probably did not affect the result.
Sample size calculations are necessary to know how many participants are needed to achieve statistical conclusion validity. The sample sizes in Studies II and III were set after making power calculations. In Study II the basis for the calculation was an unpublished study on medical records (n = 40). In Study III the power calculation was based on earlier research, but in patients with hip fractures, there were only observational studies and no RCTs. This might have resulted in overoptimistic sample-size calculations with an increased risk for type II error. The question is whether the power calculation was appropriate to detect a true difference in the population. However, samples of thousands would have been required to detect such small differences, which show that the difference was probably of no clinical significance.

The study limitations should be taken into consideration when interpreting the results, but the RCT design of Studies II and III strengthens the results and thereby contributes to the research of the short-term urinary catheterisation area in patients undergoing hip surgery.

**Trustworthiness (Study IV)**

By also using qualitative methods within a clinical intervention trial, the study can be enhanced in terms of situating the interventions in the real world of patients. The qualitative design in Study IV was chosen as a complement to the RCT design in Study III. To achieve trustworthiness, the criteria credibility, transferability, dependability, and confirmability were taken into consideration.

To assure credibility, a well-recognised research method was used, and participants with different characteristics were selected. The main researcher (MHN) had a pre-understanding from her clinical experience in caring for patients undergoing hip surgery. During the interviews and analysis this pre-understanding was kept in mind. The co-researchers (A-KI, A L-E, & MG) had many years of experience of research in different fields and also of nursing in different settings. A detailed description of the setting, selection, and characteristics of the patients was made to enhance transferability. To increase dependability the same interview questions were used in all interviews, and the analysing steps were thoroughly described. To strengthen confirmability all four authors critically reviewed each step in the analysing process.

A possible limitation of Study IV might be how short the interviews were, but even those who replied briefly contributed valuable information. The purpose of the study was to capture the patients’ subjective experiences of urination and urinary catheterisation, but not in the light of their
relationship to patient’s life world. Although it is impossible to know whether all dimensions of urinary catheterisation and bladder emptying were captured in the interviews, it is clear that there were both differences and similarities in the interviews, and at the end, similar areas were raised by the patients. It could have been beneficial to do repeated interviews. An advantage of repeated interviews is that it can improve performance by facilitating recall and reducing forgetting. Multiple interviews also can lead to a fuller story. And, by using multiple interviews, the interviewer and the interviewee are given a chance to get to know each other, which might facilitate talking about sensitive topics. However, efforts were made to build rapport by engaging in a general, introductory conversation before the recorder was turned on.

**Clinical implications in the light of evidence-based nursing**

The intention of this thesis was to provide research to form the basis for evidence-based guidelines regarding urinary catheterisation in hip surgery patients, but results from the studies in this thesis cannot be implemented straight on. The results from one single study are not enough to make changes in practice. The studies in this thesis should be valued and considered together with other studies, personal knowledge, and patients’ experiences, clinical experiences, and information from the local context to provide a basis for evidence-based guidelines.

The next step is to move from evidence to action in terms of implementation of the guidelines. There are different models describing the implementation process of evidence-based practice. One of these is Promoting Action on Research Implementation in Health Services (PARIHS). The PARIHS framework declares that innovations and implementation of new knowledge are supported by evidence, context, and facilitation. Evidence means concordant results from well conceived and conducted research. Context means the environment where the change is to be implemented. The context should be an environment open to changes. Facilitation means a process of enabling the implementation of evidence into practice. Implementation seems to be most successful when there is evidence that matches professionals’ demands and patients’ needs, a context with a willingness to change, and in the presence of facilitators.

Considering data from Study II and a Cochrane review regarding removal of short-term catheters, it is suggested that clamping of indwelling catheters should be carefully considered, and not be recommended as routine without reflection after short-term catheterisation. Regarding Study III and a Cochrane review on short-term catheterisation, there is no evidence of intermittent or indwelling urinary catheterisation being preferable
with regard to cost-effectiveness or risk for UTI. Both methods are possible as routine treatment in hip surgery patients. Indwelling catheterisation requires fewer bladder scans, fewer catheterisations, and the risk of bladder over-distension is limited. Intermittent catheterisation is associated with more bladder scans and catheterisations than indwelling catheterisations. What speaks for intermittent catheterisation is the fact that patients who never develop POUR are given the opportunity to urinate by themselves, and an unnecessary catheterisation is avoided. If intermittent catheterisation is used, it is extremely important that rigorous bladder-scan controls are performed, and that they start before surgery. If duration of surgery is expected to be protracted, indwelling catheterisation might be a more appropriate choice. The findings in Study IV reveal that urinary catheterisation is mostly experienced as a minor issue, but some patients experienced it as exposing with respect to privacy and as an intrusion upon dignity. These experiences should be taken seriously and should not be ignored. By asking every patient about earlier experiences of urinary catheterisation and listening to the description, the patient’s dignity can be preserved. Small actions such as hiding the catheter and urine bag when the patient is among other people or waiting long enough for the anaesthetic gel to work before the catheter is inserted can decrease the unpleasant experiences of urinary catheterisation.

The origin of the present research project came from the nurses and nurse assistants at the orthopaedic department where this project took place, and during the project they received an increased awareness of risks and issues regarding urinary catheterisation. There was a willingness to change the routines, and nurses and nurse assistants were involved in the studies by inviting patients, performing the interventions, and filling out study protocols. After the results from Study II were presented, the routines at the department were changed, and now the indwelling catheters are not clamped before removal. When the results from Study I were presented, the nursing staff became aware that over 50% of the fracture patients got nosocomial UTIs. About the same time the basic hygiene campaign started at the hospital. The nursing staff were motivated to make changes that could decrease the frequency of nosocomial UTI. To sum up, this project is an example of how clinical research contributes to improving quality of care in the context of catheterisation of patients undergoing hip surgery. Nurses play an extensive role in the insertion and management of urinary catheters; therefore, it is essential that their practice reflect the best available evidence.
Implications for future research

The studies in this thesis contribute to the knowledge, but also render new research questions to investigate. As the patients in Study III in the intermittent catheterisation group regained normal bladder function on average 24 hours after surgery, this raises the question as to how long an indwelling catheter should be kept in place in connection to hip surgery. A randomised controlled trial comparing indwelling catheterisation with the catheter removed at arrival to the recovery room, and intermittent catheterisation, might answer that question. Relevant outcome measures would be UTI, time to return of normal bladder function, POUR, and ‘home readiness’. As the frequency of nosocomial UTI differed so much between Studies I and III, it would be interesting to perform studies evaluating the effect of basic hygiene campaigns with regards to nosocomial UTI. Also of interest would be large studies investigating the effects that different types of antibiotic prophylaxis used to prevent wound infections have on UTI. Further, there is a need for qualitative studies investigating patients’ experiences of urinary catheterisation in connection to other types of surgery, and also on other groups of patients receiving short-term urinary catheterisation. There is a dearth of research currently available in this area. Studies investigating patients’ preferences of urinary catheterisation would also be interesting. By informing patients about intermittent and indwelling catheterisation, letting them choose one of the methods, and then following them over time with two or three interviews, new insights into patients’ preferences could be revealed.
CONCLUSIONS

- Nosocomial UTI is common in hip surgery patients as a consequence of catheterisation.

- Frequency of nosocomial UTI differs, depending on which antibiotic prophylaxis is used in patients undergoing hip surgery.

- Patients with hip fracture who also had diabetes had an increased risk of contracting nosocomial UTI.

- Intermittent and indwelling urinary catheterisation were associated with similar risk for nosocomial UTI and seemed to be equally cost-effective. However, intermittent catheterisation was associated with a faster return of normal bladder function than indwelling catheterisation. With intermittent catheterisation, patients were given an opportunity to urinate on their own accord.

- This thesis indicates that there were no advantages in clamping the indwelling urinary catheter before removal, with respect to either time to normal bladder function or need for re-catheterisation. Therefore, it is suggested to not clamp indwelling catheters in patients undergoing hip surgery.

- The patients experienced problems regarding both urination and urinary catheterisation, but these were mostly described as being of minor concern. Some however, experienced that catheterisation led to feeling that their dignity had been violated.
SAMMANFATTNING PÅ SVENSKA

“Urinkateterisering i samband med höftkirurgi”

Årligen opereras ca 18000 patienter i Sverige på grund av höftfraktur och 14000 på grund av höftledsartros. Ryggbedövning, immobilisering samt smärta försvårar urinrörelsen i det postoperativa skedet vilket kan leda till urinretention. På grund av detta får patienterna vanligen en kvarliggande urinkateter (KAD) innan operationen. Urinkatetern avlägsnas någon dag efter operationen. Urinvägsinfektion (UVI) är en vanlig komplikation av KAD. Evidensbaserad omvårdnad innebär att fatta beslut som grundar sig på bästa tillgängliga forskningsresultat, klinisk erfarenhet samt patientens förutsättningar och preferenser. Det saknas evidens för vilken av metoderna, KAD och intermittent urinkateterisering, som är förenad med minst risk för UVI. Vidare saknas evidens för om avstängning av KAD innan avlägsnandet leder till att patienten snabbare återtar normal urinrörelse vid korttidsanvändning av KAD. Studier av patienters upplevelser av urinkateterisering i samband med höftkirurgi saknas också.

Avhandlingens övergripande syfte var att utvärdera metoder för hantering av urinkateter hos patienter som genomgår höftkirurgi. Intentionen var att inhämta kunskap för att kunna ge en säker och kostnadseffektiv vård till patienterna avseende urinkateterisering.

I Studie I, som var en beskrivande och jämförande studie, inkluderades patienter med höftfraktur (n=86). Samtliga patienter behandlades med KAD i samband med höftfraktur. Syftet med studien var att undersöka riskfaktorer för och konsekvenser av vårdrelaterad UVI bland patienter med höftfraktur. Totalt fick 52.3 % av patienterna vårdrelaterad UVI. Den vanligast förekommande bakterien var *Escherichia coli* (33.3%). Diabetes var en riskfaktor för UVI. Cloxacillin som givits i samband med operation, som profylax mot sårinfektion, tycktes ha en skyddande effekt mot UVI. Inga signifikanta skillnader kunde påvisas mellan de patienter som fått UVI och de som inte fått UVI beträffande tid med KAD, förekomst av delirium under vårdtiden, UVI 4 månader efter operationen eller mortalitet upp till 1 år efter operationen.

I Studie II, som var en randomiserad kontrollerad studie, inkluderades patienter med höftfraktur (n=113). Samtliga patienter behandlades med KAD i samband med höftfraktur. Syftet med studien var att undersöka effekten av avstängning av KADn innan avlägsnandet hos patienter med höftfraktur. Patienterna randomiserades till att antingen få urinkatetern avstängd innan den avlägsnades (n=55) eller till att få den borttagen utan
föregående avstängning (n=58). För de patienter som fått urinkatetern avstängd tog det 6 timmar tills de återfick normal urinintäktningsfunktion. För de patienter som fått urinkatetern borttagen utan föregående avstängning tog det 4 timmar. Skillnaden var inte statistiskt signifikant. Inte heller beträffande förekomst av omkateterisering eller vårdtid fanns statistiskt signifikanta skillnader mellan grupperna.

I Studie III, som var en randomiserad kontrollerad studie, inkluderades både höftfrakturpatienter och patienter som skulle genomgå planerad höftplastikoperation på grund av artros (n=170). Syftet med studien var att undersöka skillnader mellan intermitturinkateterisering och KAD med hänsyn till vårdrelaterad UVI och kostnadseffektivitet. Patienterna randomiserades antingen till att få KAD (n=85) eller till intermittet urinkateterisering (n=85). Totalt fick 10.6% av patienterna vårdrelaterad UVI. Den vanligast förekommande bakterien var *Escherichia coli* (42.1%). Studien visade att det inte förelåg någon signifikant skillnad mellan de två kateteriseringsgrupperna med hänsyn till UVI eller kostnadseffektivitet. De patienter som randomiserats till intermittet urinkateterisering återfick normal blåsfunktion i snitt 24 timmar efter operationen vilket var ett dygn tidigare än patienterna i KAD gruppen. Av patienterna i gruppen med intermittet kateterisering kunde 14% av patienterna kissa under hela den perioperativa perioden och behövde följaktligen ej kateteriseras.

I Studie IV, som var en deskriptiv studie, intervjuades 30 av patienterna som deltog i Studie III. Syftet med studien var att beskriva patienternas upplevelser av blästömning och urinkateterisering i samband med höftoperationen. Patienternas upplevelser sammanfattas i huvudkategori "Ett problem, men av varierande dignitet". Under huvudkategori framkom 5 kategorier; förmåga att urinera, kateter är bekvämt, bekymmersam blästömning, intrång på integriteten samt oro för komplikationer. Vissa, som behandlades med intermittet kateterisering, upplevde det positivt att få möjlighet att urinera själva medan andra upplevde det bekymmersfritt att få KAD. KAD kunde även upplevas som exponerande, både vid insättandet men även när den var på plats. Patienterna beskrev obehag både av kateterisering och att urinera på bäcken. Flera av patienterna var medvetna om de risker som urinkateterisering innebar. Oberoende av om patienterna behandlats med KAD eller intermittet urinkateterisering uppgav de flesta att de skulle välja samma metod igen om de skulle genomgå en ny höftoperation.

Sammanfattningsvis visade avhandlingen att vårdrelaterad UVI är vanligt förekommande i samband med höftkirurgi och att risken är ökad om patienten har diabetes. Utifrån resultaten i denna avhandling rekommenderas inte avstängning av KAD innan borttagandet. Risken för UVI och kost-
nadseffektiviteten tycks vara likvärdig för intermittent urinkateterisering och KAD och båda metoderna är möjliga alternativ i samband med höftkri-rurgi. Emellertid, genom att inte rutinmässigt sätta KAD i samband med höftkirurgi ges patienterna möjlighet att urinera själva samt att snabbare efter operationen återfå normal blåsfunktion. Patientens preferenser och erfarenheter bör också vägas in i valet av metod för urinkateterisering. Även om de flesta patienterna upplevde att bli kateteriserade inte var ett stort problem utan en nödvändighet så kan de ändå känna sig blottade. Det är väsentligt att kateterhanteringen inte bara utförs i enlighet med bästa tillgängliga evidens utan också med hänsyn tagen till patientens värdighet.
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