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BLADDER DISTENSION
ASPECTS OF A HEALTHCARE-RELATED INJURY

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It may seem a strange principle to enunciate as the very first requirement in a Hospital that it should do the sick no harm.

Notes on hospitals
Florence Nightingale, 1863

ABSTRACT

Lower urinary tract symptoms (LUTS) are common health problems. For the individual, LUTS is troublesome and can greatly affect the health-related quality-of- life (HRQOL). One cause of LUTS is urinary retention (inability to void in the presence of a full bladder); a well-known complication following hospital care. If the bladder volume exceeds 500 ml there is a risk of overdistension of the muscle fibres in the bladder wall; bladder distension. This can result in motility problems with post-void residual volumes, urinary tract infections and an inability to void. If the bladder becomes stretched too far, or for a long period, the bladder may be permanently damaged and lose its ability to contract sufficiently for the rest of the person's life. Bladder damage due to overdistension can be classified as a patient injury; harm caused to a patient as a result of their healthcare, and which could have been avoided. The overall aim of this thesis was to improve patient-safety by providing research evidence for bladder monitoring procedures and increase knowledge and awareness of bladder distension as a healthcare-related injury.

Study I was a prospective observational study of peri-operative bladder volumes among orthopaedic or general surgical patients. Bladder volumes were measured on three occasions; after emptying the bladder before being transported to the operating theatre, and then both immediately before and after surgery. Thirty-three of the included 147 patients (22%) developed bladder distension (>500 ml), eight preoperatively and 25 postoperatively. Orthopaedic patients were more likely to develop both preoperative and postoperative bladder distension than surgical patients and had significantly higher post-void residual volumes Age, gender and time of anaesthesia could not predict bladder distension. **Study II** was a randomised controlled trial testing whether a protocol with frequent pre-operative ultrasound monitoring of bladder volumes starting in the ER could reduce the risk of postoperative bladder distension among acute orthopaedic patients. The result showed that patients in the control group (no pre-operative scanning) were more prone to postoperative bladder distension than patients in the intervention group (OR=1.81, 95% confidence interval 1,02-3,23, p=0.042). This association remained after adjusting for confounding factors; neither gender, age nor volume of peri-operative fluid affected the outcome.

Studies III and IV focused on the impact of bladder distension from the patient's perspective. Study III was a prospective, longitudinal follow-up survey exploring lower urinary tract symptoms and health-related quality of life up to three months after acute orthopaedic surgery. Patients who have had postoperative bladder distension reported more LUTS and lower HRQOL than patients without bladder distension. Study IV used a qualitative design with narrative interviews of 20 patients who had reported a healthcare-related injury to the Swedish Patient Insurance LÖF, and who had had their injury classified as avoidable bladder damage due to over-distension. The result showed that micturition problems after bladder distension affected the everyday life through several practical and social constraints. Suffering from pain and infections, impaired sex life and strong concerns for the future were other findings. Lack of knowledge, insufficient routines, mistrust and poor communication between the staff and the patient were contributing factors leading to the injury.

Conclusions: Bladder distension is a common healthcare-related injury that can cause suffering and practical, emotional and psychosocial problems with a great impact on the life of the person affected, and anxiety for the future. Frequent bladder monitoring starting in the ER can reduce postoperative bladder distension among acute orthopaedic patients. Safe and effective prevention of bladder distension is based on early recognition.

LIST OF PUBLICATIONS

I. **Joelsson-Alm E**, Nyman CR, Lindholm C, Ulfvarson J, Svensen C. Perioperative bladder distension: a prospective study. *Scand J Urol Nephrol. 2009;43(1):58-62.*

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IV. **Joelsson-Alm E**, Nyman CR, Svensén C, Ulfvarson J. Living with micturition problems after bladder distension – experiences of a healthcare-related injury. *Submitted.*

CONTENTS

LIST OF ABBREVIATIONS

AUA	American Urological Association
BPH	Benign Prostate Hyperplasia
CI	Confidence Interval
CIC	Clean Intermittent Catheterisation
CONSORT	Consolidated Standards of Reporting Trials
EQ-5D	EuroQol Group trademark for a standardised instrument for use as a measure of health outcome
ER	Emergency Room
HRQOL	Health-Related Quality Of Life
IC	Intermittent Catheterisation
ICS	International Continence Society
IPSS	International Prostate Symptom Score
ISC	Intermittent Self-Catheterisation
LÖF	Landstingens Ömsesidiga Försäkringsbolag
LUTS	Lower Urinary Tract Symptoms
NRS	Numeric Rating Scale
OR	Odds Ratio
POUR	Postoperative Urinary Retention
QOL	Quality Of Life
RRR	Relative Risk Reduction
SPC	Suprapubic Catheter
SPMSQ	Short Portable Mental Status Questionnaire
UTI	Urinary Tract Infection
WHO	World Health Organization
WMA	World Medical Association

1 INTRODUCTION

In the early 2000s, the most common incident report written at the recovery ward at Södersjukhuset concerned patients with a bladder volume > 500 ml; the staff knew that high post-operative bladder volumes could be dangerous for the patient. Some preventive measures existed, such as encouraging patients to void before transport to the operating theatre as well as bladder scanning every fourth hour after surgery, yet many patients were found with too large bladder volumes. The preventive measures were clearly not sufficient.

A patient safety project was started with the aim of reducing the number of patients with post-operative bladder distension (bladder volume ≥ 500 ml). But how was this to be done? A thorough literature review showed a lack of evidence for new guidelines. We had to produce the evidence ourselves. As I was the quality and patient safety co-ordinator at the recovery ward at this time, I was responsible for the project, which soon grew into a larger research project and the beginning of this thesis.

This project is an example of how important, exciting and fascinating it is to work with research questions originating from clinical observation of patients resulting in improved patient care.

2 BACKGROUND

2.1 ANATOMY OF THE LOWER URINARY TRACT

The lower urinary tract consists of the urinary bladder and the urethra (Figure 1). Urine from the kidneys enters the bladder through the two ureters and exits through the urethra.

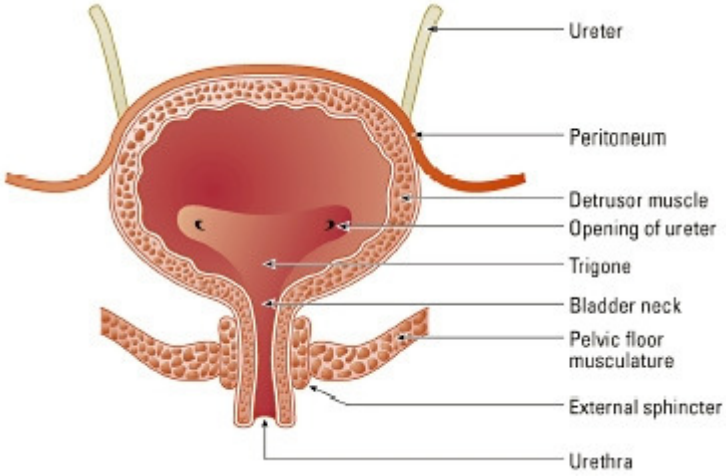

Figure 1. The lower urinary tract

The urinary bladder is a hollow, distensible smooth muscle organ with two important functions; the storage and emptying of urine. The inside of the bladder and urethra is lined with an elastic transitional epithelial tissue layer (urothelium), protecting against the irritating effects of urine. The bladder wall (detrusor muscle) consists of three layers of transversely and longitudinally sectioned smooth muscle bundles in a three dimensional arrangement. The orientation and interaction between the smooth muscle cells are complex and important, as it allows the bladder wall to adapt according to the demands – to relax and elongate during the filling phase, contract and shorten during the micturition phase. The bladder is innervated by both sympathetic and parasympatethetic fibres from the spinal cord and the detrusor contains multiple receptors and signalling pathways[1].

The external urethral sphincter is formed by striated muscle fibres from the pelvic floor and is innervated by the somatic nerve system which allows voluntary control over urination.

2.2 MICTURITION PHYSIOLOGY

The micturition physiology is one of the most complex processes in the body, as it involves both the somatic, sympathetic and parasympathetic nervous systems. Much of the neurogenic regulation of the lower urinary tract is still unknown and needs to be explored.

During **storage**, the urethral sphincter is contracted and the detrusor muscle is relaxed due to sympathetic stimulation. The bladder pressure stays low because of the high compliant bladder nature. When the bladder volume exceeds a certain limit, about l50-300 ml, stretch receptors on the bladder wall start to send signals to the sacral region of the spinal cord[2]. Ascending pathways to the pontine micturition centre in the brainstem are activated and, by connection to the frontal cortex, we become aware of a full bladder and the need to void.

Emptying (voiding) is initiated by parasympathetic stimulation causing relaxation of the pelvic floor and external urethral sphincter. A coordinated contraction of the detrusor muscle is required to empty the bladder. If micturition is not desired or is inconvenient, micturition is prevented by contraction of the sphincter and relaxation of the bladder. This voluntary control of micturition is not fully developed until a few years of age[2].

2.3 LOWER URINARY TRACT SYMPTOMS (LUTS)

Lower urinary tract symptoms (LUTS) are common health problems, highly prevalent among men and women aged > 40 years[3 4]. According to current research, LUTS is a non-sex specific, non-organ-specific group of symptoms that covers all urinary symptoms[5]. LUTS are defined from the individual's perspective, and are according to the International Continence Society (ICS) divided into three groups; storage, voiding and post-micturition symptoms[6]:

Storage symptoms are experienced during the storage phase of the bladder, and include:

- Increased daytime frequency
- Nocturia (the individual has to wake at night one or more times to void)
- Urgency (a sudden compelling desire to pass urine, which is difficult to defer)
- Urinary incontinence

Voiding symptoms are experienced during the voiding phase and include:

- Slow stream
- Spitting or spraying of the urine stream
- Intermittency (intermittent stream with stops and starts during micturition)
- Hesitancy (difficulty in initiating micturition)
- Straining (muscular effort to either initiate, maintain or improve the urinary stream)
- Terminal dribble (a prolonged final part of the micturition)

Post micturition symptoms are experienced immediately after micturition:

- Feelings of incomplete emptying
- Post micturition dribble

There are multiple risk factors and comorbid conditions associated with LUTS, such as increasing age (men only), elevated Body Mass Index, diabetes and vaginal delivery[7].

The incidence of LUTS in the Nordic countries is well studied. Stranne et al. concluded that one third of the male Swedish population over 50 years of age suffers from moderate/severe LUTS while Nørby, Nordling & Mortensen reported that 28% of males and 20 % of females above 50-years in Denmark had moderate/severe LUTS[8 9].

For the individual, LUTS is troublesome and can greatly affect the health-related quality-of- life (HRQOL)[10 11]. Coyne et al. studied 30.000 men and women aged over 40 years in the US, UK and Sweden in a population-representative survey. The authors concluded that a negative effect of LUTS is apparent across several domains of health-related quality of life and that LUTS are associated with high levels of anxiety and depression [10].

2.4 URINARY RETENTION

Urinary retention, also called *ischuria*, is an inability to void in the presence of a full bladder. It can be caused by insufficient bladder contraction, insufficient sphincter relaxation, outlet obstruction (such as benign prostatic hyperplasia (BPH) and urethral strictures) or deficient bladder/sphincter coordination. Acute urinary retention is a serious medical condition, requiring emergent actions to empty the bladder by catheterisation. Acute urinary retention is often due to BPH but is also a well-known complication following hospital care[12]. Age is a risk factor, as the detrusor contractility decreases with advancing age, together with the additional aggravating factor for men that the prostate enlarges with age.

There are several other risk factors that may inhibit voiding in the hospitalised patient[2 13 14].

- **Bed rest** affect voiding negatively, but the reason for this is unclear. Yaminashi et al. showed that voiding in supine and lateral position resulted in decreased urinary flow rate[15].

- **Lack of privacy.** Many people have difficulty voiding where other people are in close proximity, as is often the case in hospitals.

- **Pain, anxiety and stress** increase sympathetic stimulation; relaxing the bladder and contracting the sphincter.

- **Drugs**. Many medications interfere with bladder function. *Opioids* decrease detrusor tone, decrease the bladder sensation (urge to void) and inhibit the voiding reflex. Peripheral mechanism may also play a role in opioid-induced bladder dysfunction[15]. *Anticholinergics* such as atropine block detrusor contractions and cause bladder hypotonia. *Symphathomimetics*, such as epinephrine, relax the bladder and inhibit voiding.

- **Anaesthesia** affects micturition in several ways. *General anaesthetics* cause bladder atony by interfering with the autonomic regulation of detrusor tone. *Sedative-hypnotics* and *volatile anaesthetics* suppress detrusor contraction

and the micturition reflex. *Spinal and epidural local anaesthetics* blocks detrusor contraction and bladder sensation.

- **Intravenous fluids.** Excessive infusion of intravenous fluids can lead to a rapid and large urinary production and subsequent over-distension of the bladder.

Surgical, orthopaedic and obstetrical patients are exposed to many of those factors and are at particularly high risk of urinary retention, but almost all patients admitted to hospital care are at risk. Lack of privacy, anxiety, pain and opiates are examples of risk factors prevalent in both medical and surgical wards. Tubings, drains and intravenous lines prevent mobility and restrict visits to the bathroom. Urinary retention is also common among patients admitted for rehabilitation; Wu & Baguley found an incidence of 21,5% at a general rehabilitation unit[16].

2.4.1 Postoperative urinary retention

When urinary retention occurs after surgery, it is called postoperative urinary retention (POUR). The incidence of POUR reported in different studies varies widely, generally ranging from 4% to 25%, but reports up to 70% [17]. Lack of uniform defining criteria and differences in patient characteristics can explain the varying results. In some studies, 400 ml have been the cut-off limit for defining a full bladder, whilst other studies have used 500 ml resp. 600 ml[17-22]. The length of the postoperative period studied also varies, from a few hours after surgery to several days during the postsurgical hospitalisation period.

Several studies have shown that the risk for POUR increases for patients over 50 years of age[19 23 24]. The impact of gender on POUR is unclear, with conflicting results from studies where either male[24] or female[25] gender has been found to be an independent risk factor, but most studies conclude that gender is not correlated significantly with POUR[17 19 23 26].

Numerous attempts have been made to treat POUR with drugs. However, a Cochrane review published in 2010 concluded that the evidence for drug treatment is weak, and that catheterisation remains the mainstay of management of POUR[27].

2.5 BLADDER DISTENSION

When the bladder exceeds its normal maximum capacity of 400 – 600 ml, micturition becomes more and more difficult. The greater the bladder volume, the greater is the reduction in bladder contractility[28]. For some patients, this will lead to a transient urinary retention requiring one or a few intermittent catheterisation before the bladder regains its capacity. If the bladder becomes stretched too far, or for a long period, the detrusor muscle may be permanently damaged and lose its ability to contract sufficiently for the rest of the person's life.

In this thesis, **bladder distension** is defined as a **bladder volume ≥ 500 ml**.

2.5.1 Patophysiology

Traditionally, bladder over-distension has been thought to simply produce stretch damage of the detrusor muscle, resulting in reduced contractility. Submucosal hemorrhagia, fibrosis, and mucosal necrosis were described in 1987 by Tammela et al.[29]. In 1988, Tammela & Arjamaa found that the reduction of contractility observed during bladder distension was not due to a cellular damage, but rather to changes in the properties of smooth muscles and that stretching for more than 3 hours impaired the bladder function rapidly[30].

During the last years, several studies have pointed out that ischemia/re-perfusion and free radicals play an important role in the patophysiology of bladder distension and are contributing factors leading to prolonged bladder dysfunction[31-34].

2.5.2 Symptoms

The patient can experience discomfort and pain in the lower part of the abdomen, particularly upon palpation. However, the urge to void is often not present, especially not postoperatively. Small voiding volumes may be a clinical sign of over-distension of the bladder with resulting overflow voiding[35].

A large, distended bladder increases the abdominal pressure, which can result in decreased lung compliance, high thoracic pressures, hypotension and tachycardia[36]. Another effect of the increased abdominal pressure is venous obstruction, which can lead to leg oedema and DVT-like symptoms[37-39]. The increased bladder pressure can

also result in impaired drainage of urine from the kidneys, causing hydronephrosis and at worst, kidney failure.

Bladder distension has even been described as causing hyponatremia in a few cases, the possible mechanism for this being inappropriate antidiuretic hormone secretion due to the bladder distension itself or pain related to bladder distension [40].

2.5.3 Diagnosis

In the past, clinical signs like palpation or subjective patient experiences were used, and diagnosis was confirmed by catheterisation. Unfortunately, the clinical signs of bladder distension are unreliable. In a 1999 study by Pavlin et al, 61% of patients with a bladder volume exceeding 600 ml failed to experience discomfort or an urgent desire to void[41]. Bladder palpation is also a very vague method, especially for elderly and obese patients, and can be painful[42]. Currently, non-invasive methods such as portable ultrasound scanning technology can reliably be used to measure bladder volume.

2.5.4 Ultrasound bladder scan

The use of a portable ultrasound scanner to monitor bladder volume makes the clinical assessment easier and more accurate. It is a non-invasive, safe and timesaving method to detect urinary retention and prevent bladder distension. Ultrasonography of the bladder also reduces unnecessary use of catheters and the subsequent risk of trauma and infection[43].

Several studies have addressed the accuracy of portable ultrasound devices and many of them have reported a good correlation between ultrasound scanner estimates of bladder volume and urine volume measured with catheterisation[42-48]. Huang et al found that stationary ultrasonography provided a more accurate estimate of residual bladder volumes than a portable device, but also drew the conclusion that portable ultrasonography is more convenient to use and has an acceptable accuracy for clinical use[45]. In contrast, a study by Byun et al showed that the portable bladder scanner was accurate, reliable and superior to stationary ultrasonography[44]. Marks et al concluded that very little training is required to obtain good-quality scans with portable devices, which is consistent with the results from other studies[48]. The scanning procedure is quick and causes no pain or discomfort for the patient. A complete scanning procedure

takes about 5 minutes, including time to retrieve the device and cleaning it afterwards. This application time is equivalent to that taken to measure other vital signs such as blood pressure or respiratory rate.

2.5.5 Treatment

The gold standard of treatment for bladder distension is catheterisation, as the patient often is experiencing urinary retention and is unable to void. Catheterisation can be either intermittent, where the catheter is removed immediately after urine drainage is complete, or indwelling.

Intermittent catheterisation

Intermittent catheterisation (IC) can be performed either by a care-giver, relative or by the patient him/herself (intermittent self-catheterizing -ISC). Different types of catheter can be used and the inserting technique can be clean or sterile. The most commonly used method, both in hospitals and at home, is clean intermittent catheterisation (CIC) with single use catheters. There is lack of evidence demonstrating the effectiveness of any particular catheter type, technique or strategy[49].

For most patients, the catheterisation is performed on a few occasions in connection with acute urinary retention, but if an irreversible loss of voiding function has occurred, the patient need to be catheterised for the rest of his/hers life.

Urinary tract infection (UTI) is the most frequent complication and increases with longer use of IC, but the prevalence varies widely in different studies[49 50]. Trauma from catheterisation, urethral strictures and false passages can also occur[50].

Indwelling transurethral catheter

An indwelling transurethral catheter, also called Foley catheter, is left in the bladder and is kept in place by a small balloon at the tip, inflated with fluid. It can be used either prophylactically to avoid bladder distension in connection with surgery, childbirth and advanced pain treatment, or to treat bladder distension. Other indications for indwelling catheter treatment are to monitor urine output during surgery or acute illness, and for investigative purposes[51].

If possible, the use of chronic indwelling catheters should be avoided. Complications include UTI, sepsis, trauma, bladder stones and urethral strictures[52 53]. Prophylactic use of an indwelling catheter retained for 24 hours postoperatively after total joint arthroplasty was found not to affect the incidence of UTI, but if the catheter was used for more than 48 hours, there was a higher risk of UTI[54]. In a review of UTI and deep sepsis in patients undergoing total joint arthroplasty, the authors concluded that urinary retention and subsequent bladder over-distension were risk factors for UTI and should be prevented by inserting a bladder catheter immediately preoperatively and removed within 24 hours of surgery[55].

Suprapubic catheter

A suprapubic catheter (SPC) is an alternative to intermittent self-catheterisation when use of an indwelling urethral catheter is contradicted or unsuccessful. The catheter is inserted through the skin just above the pubic bone into the bladder. Insertion of the SPC is often thought of, and referred to, as a simple procedure but Ahluwalia et al. found an intra-operative complication rate of 10% and a 30-day complication rate of 19%. Long-term complications included recurrent UTIs (21%), catheter blockage (25%) resulting in multiple ER attendance (43%)[56]. In a randomised study comparing ISC and SPC in the postoperative care of women following radical hysterectomy, ISC was seen to be more acceptable to patients allowing fewer disturbances at night, greater freedom to lead a normal life during the day and less anxiety/embarrassment compared to SPC[57].

Pharmacological treatment

Several drugs, such as muscarin receptor agonists and α-adrenoreceptor antagonists, have been used with the aim to either increase the detrusor contractile force or to improve decreased sensation, but analyses have shown little beneficial effect and unfavourable side-effects[58].

Alternative treatment

Sacral neuromodulation; electrical stimulation of the sacral root S3 via an electrode connected to an implantable pulse generator, is an alternative treatment for patients where conventional conservative therapy (CIC) has failed. The effect seems to be best for patients with some preserved voiding function [59 60].

For a few patients when intermittent catheterisation via urethra is not possible to perform, and an indwelling catheter is not desirable, a surgical constructed *urinary diversion* might be considered[61].

2.5.6 Psychological impacts

Besides the physical suffering that bladder damage entails for the patient, distress and psychological impacts are common. Patients performing CIS have described feelings of embarrassment and social stigma related to loss of bladder control and a need for discretion and privacy[62]. Cultural taboos and attitudes about excretions are intensely private issues and can impede patients from seeking help from healthcare[63]. For health professionals, there is a need to break the silence with the client about micturition problems.

2.5.7 Prevention

The most important factor for prevention of bladder distension in connection with hospital care is bladder control, which requires the staff's awareness of the problem and the knowledge that many patients in hospitals are at risk of urinary retention. Patients also have decreased sensitivity of the urge to void, so routines should not be based on the patient's capability to tell when the bladder is full.

In order to prevent large bladder volumes, different strategies can be used:

- Tracking the *frequency and time of toilets visits* and *encouraging patients to void* before procedures are unsafe practices as they do not involve control of bladder volumes.
- A *short-term indwelling catheter* protects against bladder distension as long as it is properly located in the bladder, and the outflow is not obstructed. However, after the removal of the catheter there is a clear risk of urinary retention and bladder distension; in a study by Lee et al., 33% of patients treated with indwelling catheter for 3-7 days after surgery failed to pass urine after the withdrawal and were re-catheterised[18].
- *Monitoring bladder volumes* regularly to timely detect large volumes.

The time factor is important, as shown by Pavlin et al in a study of patients undergoing outpatient surgery[22]. Transient over-distension in the range of 500-1000 ml was reported not to be harmful if treated within one to two hours. This is an important fact when designing guidelines; measurements of bladder volume among risk patients must be repeated at least every two hours; for high risk patients in the recovery room preferably every hour.

3 HEALTHCARE-RELATED INJURIES

No patient should be harmed when receiving healthcare. It is a basic principle of all medical activities but nonetheless approximately 100.000 people suffer from avoidable healthcare-related injuries every year in Sweden [64].

3.1 DEFINITIONS

There are several different terms and definitions regarding harmful incidents in healthcare. For example; in a survey 2006, 14 definitions were found for "adverse event", which is the most widely used term [65].

A **patient injury** - a harm caused to a patient as a result of their healthcare and which could have been avoided [66].

Adverse event - an injury related to medical management, in contrast to complications of disease. Adverse events may be preventable or non-preventable [67 68].

Preventable adverse event - an adverse event caused by an error or other type of systems or equipment failure [67].

Sentinel event – serious adverse event [69].

3.2 DIFFERENT TYPES OF ADVERSE EVENTS

Adverse events include both medical errors, such as administration of the wrong drug, and effects of suboptimal care, such as infections, incorrect diagnosis and lack of patient monitoring. The most common adverse events in hospitals are:

- Adverse drug events
- Hospital acquired infections
- Pressure ulcers
- Falls
- Diagnostic errors
- Medical device failures

Medication-related events and invasive procedures including surgical operations are the main causes of adverse events [64 70 71].

3.2.1 Diagnostic errors

Diagnostic errors occur when a diagnosis is unintentionally delayed, wrong or missed. The most common system-related factors involved in diagnostic errors are problems with policies and procedures, inefficient processes, teamwork and communication[72].

3.3 A WORLD-WIDE PROBLEM

Most of the research into adverse events has been carried out in the developed countries, showing that between 3% and 16% of hospitalised patients suffer harm from medical care [70 71]. The report rates vary remarkably, depending on different definitions of adverse events. Studies from the US suggest that approximately 3% - 4% of the patients experience a serious adverse event[73 74], while retrospective medical record review studies from Sweden and the UK, using a less restricted definition, report adverse event rates of 12,3% and 11,7%, respectively [64 75]. In the Swedish study, 70% of the adverse events were preventable.[64] The rates of adverse events from developing and transitional countries are largely unknown, but the existing evidence suggests that adverse events are likely to be at least as frequent, and probably more so, than in developed countries [71].

3.3.1 Under-reporting

When comparing results from retrospective medical record review studies with healthcare provider's adverse events reporting, there are discrepancies suggesting a large under-reporting of adverse events [76 77]. The same conclusion can be drawn when comparing adverse events reports with patient claims. A Swedish study found that only 20% of sentinel events where patients had suffered serious consequences from the injury had been reported by the healthcare provider.[69] Adding the fact that most medical injuries never trigger a complaint gives us a hint of the potentially huge size of the problem with under-reporting [78 79].

3.4 PATIENT EXPECTATIONS OF COMPLAINTS

Once a patient has filed a complaint, there are some common expectations that patients have in health care. Complainants expect to be treated respectfully and with an impartial attitude. They also expect the professionals to admit that a mistake has occurred, to explain how the incident could have occurred and the consequences for

their health[80 81]. Patients prefer this information to be provided for them rather than having to ask numerous questions. For the patient, an explanation seems to be more important than an apology[80].

The most common reason for filing a complaint is to prevent the incident from happening again to other patients. The complainant's sense of justice is disturbed, and they want to restore it by "doing right"; they feel it as a duty to complain and thus prevent further incidents[80]. The possibility of financial compensation does not seem to be a major motive; Bismark et al. concluded that most patients do not seek monetary compensation but instead primarily want better information and corrective measures to be taken [82]. If the patient's expectations are not met, which unfortunately is often the case, dissatisfaction and frustration will occur, and the patient may lose confidence in the healthcare. Friele, Slujs and Legemaate concluded that less than one third of complainants felt that justice had been done through the complaints process, and that they were disappointed in the reactions of and communication with the professionals[83]. To be willing to listen to the patient's story was important for establishing trust.

3.5 BLADDER DISTENSION – A NEGLECTED HEALTHCARE-RELATED INJURY

In many cases, bladder damage due to over-distension has been caused by insufficient monitoring of bladder volumes and could have been avoided. This means that the injury falls under the criteria for diagnostic error - a preventable adverse event. Despite this, bladder distension is not mentioned in any of the published review papers about adverse event incidence and types. When searching the databases MEDLINE, Ovid, Cinahl and Cochrane in December 2011, combining the keyword "bladder distension" together with "patient injury" and "adverse events", no relevant papers were found.

There could be several reasons why bladder distension is so little described in the literature about patient safety and adverse events. First, there are probably a large number of patients who have never reported their micturition problems after bladder distension. It is a well known fact that people with LUTS very seldom seek medical advice [8 9 84 85]. Even among men and women with severe LUTS who are desperate about their voiding situation, less than 50% have visited a physician during the last two

years due to voiding problems [8]. Lack of knowledge of treatment options, feelings of embarrassment over their voiding problems and other health problems with a higher priority might explain this behaviour. A patient who experiences voiding difficulties after surgery is not very likely to mention these problems at a follow-up visit with the surgeon. Secondly, knowledge about bladder distension and its short-term and long-term effects for the patient is low among healthcare personnel. Nurses and physicians have a tendency to believe that voiding problems in connection with hospital care will improve spontaneously and are reluctant to report them. Another reason for the under-reporting is the many obstacles to overcome for a patient if he or she wants to report an injury. It might be difficult for the patient to obtain information about the possibility to claim compensation, and a dilemma to report healthcare staff responsible for the patient's future care.

3.6 COMPENSATION OF PATIENT INJURIES IN SWEDEN

If a patient in Sweden suffers an injury as a result of their healthcare, the patient may in some cases be entitled to financial compensation under the Patient Injury Act, which is administrated by the Patient Insurance LÖF. The patient must report the injury within three years of the incident, and compensation is awarded only for avoidable injuries. Each case is evaluated by experienced specialists at the Patient Insurance LÖF[86 87]. Approximately 10 000 injuries are reported in Sweden every year and about 45% of them are classified as avoidable and therefore compensated[87].

A new Patient Safety Act was introduced in Sweden on 1 January 2011, with the aim of providing safer health care and reducing the number of health care injuries. The intention is also to strengthen the position of patients and increase their influence on health and medical care. In the Act, healthcare providers are obliged to inform the patient promptly that an event has occurred which has resulted in a healthcare-related injury, to advise them how to register complaints with the National Board and to explain the possibility of seeking compensation under the Patient Injury Act[69].

4 AIMS OF THE THESIS

The overall aim of this thesis was to improve patient-safety by providing research evidence for bladder monitoring procedures and increase knowledge and awareness of bladder distension as a healthcare-related injury.

Specific aims were:

Study I To determine the incidence of peri-operative bladder distension in a surgical setting and to identify predisposing factors among patients undergoing common general and orthopaedic procedures.

Study II To explore whether close preoperative ultrasound monitoring could prevent postoperative bladder distension among acute orthopaedic patients.

Study III To explore the impact of postoperative bladder distension on lower urinary tract symptoms and health-related quality of life after acute orthopaedic surgery.

Study IV To explore patient's experiences of micturition problems after bladder distension and the effects of these problems on patients' everyday life, and to explore patients' experiences of having been exposed to a healthcare-related injury.

5 ETHICAL CONSIDERATIONS

Several ethical aspects were taken into consideration in the studies. First, as all research in the project was conducted on humans, the World Medical Association (WMA) Declaration of Helsinki concerning Ethical Principles for Medical Research Involving Human Subjects was applied[88]. This states, among other things, that the well-being of the individual research subject must take precedence over all other interests.

All participants were given written information about the current study before they were asked for informed consent. They were informed that their participation was entirely voluntarily and that they could end the study at any time without a reason and with no consequences for their current or future care. The participants were assured confidentiality for their personal information and that individuals would not be identified. All data from the studies have been handled under the Swedish Personal Data Act.

It can be ethically questionable to include patients in the ER, as in Study II and III. The patients are in a vulnerable position as they are suffering an acute injury, and many of them are affected by pain and anxiety. The researchers took several steps to minimise the impact of the study on the patient's physical, mental and social integrity and to ensure that the participants were fully informed about the study and freely agreed to participate. Patients with cognitive failure, language difficulties or severe medical conditions such as major trauma were excluded before information about the study was handed out. The consent was not gathered until the patients were informed about their diagnosis and care plan.

Ethical approvals for all studies have been obtained from the Institutional Review Board at the Karolinska Institutet, Stockholm, with the following reference numbers: 98/01 (Study I), 2008/1098-31 (Study II and III) and 2010/1095-31 (Study IV).

As Study II was a randomised controlled trial, it was also registered in Karolinska Clinical Trial Registry database (www.kctr.se) with ID CT20100047 and undertaken and reported in line with the CONSORT statement[89].

6 THESIS SUMMARY

6.1 METHODS

Different designs and methods have been used depending on the purpose of the study. An overview of designs and methods is presented in Table I. All studies were conducted with adult patients (> 16 years) and Studies I-III took place at a medium-sized acute care hospital in Stockholm (Södersjukhuset).

Table I. Overview of designs and methods

Study	Design	Inclusion criteria	No of participants	Method of analysis
I	Prospective observational study	Patients scheduled to undergo general or orthopaedic surgical procedures	147	Logistic regression
II	Randomised controlled trial	Patients admitted via the ER to an orthopaedic ward for acute surgery	281	Fisher's exact test, logistic regression
III	Prospective, longitudinal follow-up survey	Same as Paper II	281	Mann-Whitney U-test, Fisher's exact test, Mixed Model analysis
IV	Narrative interviews	Patients with an avoidable bladder injury due to over-distension, classified by the Swedish Patient Insurance LÖF	20	Qualitative content analysis

6.1.1 Study designs

Study I was a prospective observational study of peri-operative bladder volumes conducted during nine weeks in April-June 2003. Bladder volumes were measured on three occasions; after emptying the bladder before being transported to the operating theatre, and then both immediately before and after surgery (Figure 2).

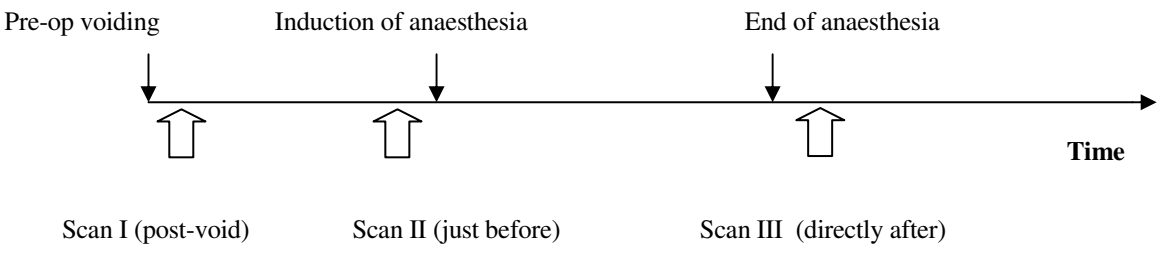

Figure 2. The three scanning events in Study I and their time relation to preoperative voiding and anaesthesia

Study II was a randomised controlled trial testing whether a protocol with frequent ultrasound monitoring of bladder volumes could reduce the risk of postoperative bladder distension. In the intervention group, all patients were scanned in the ER and then regularly on the ward at predefined times until surgery. In the control group, no regular scanning was performed before surgery. The hospital's standard postoperative bladder monitoring procedure was performed for both groups; see Figure 3 for the bladder scanning algorithm. Primary outcome was postoperative bladder distension, defined as a bladder volume ≥ 500 ml, measured by bladder scanner or subsequent voided/catheterised urine volumes according to the hospital protocol. For patients with indwelling Foley catheters, the primary outcome was measured by bladder scanner after withdrawal of the catheter according to hospital protocol. Secondary outcomes were postoperative urinary tract infection (UTI) and hospital length-of-stay. The study was conducted during February 2009 to November 2010.

Study III was a prospective, longitudinal follow-up survey exploring lower urinary tract symptoms and health-related quality of life up to three months after surgery. The participants were asked to complete self-administered questionnaires on three occasions; in the ER, at the day of discharge and three months after surgery. The study started in February 2009 and was completed in March 2011.

Study IV used a qualitative design with narrative interviews which were conducted between October to December 2010.

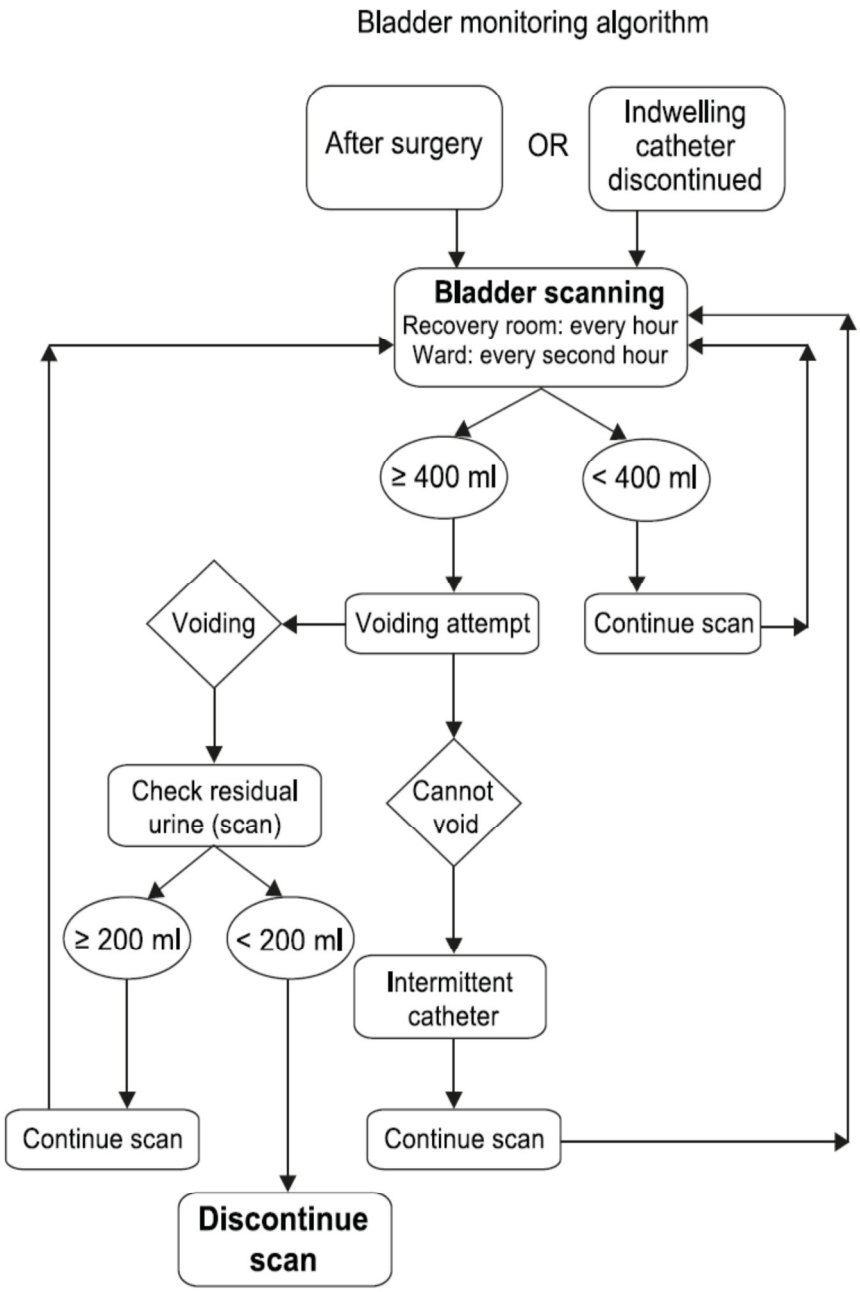

Figure 3. Postoperative bladder scanning algorithm

6.1.2 Participants

In **Study I**, patients at orthopaedic or general surgical wards were included consecutively, in the order they were scheduled for surgery (either acute or planned) and gave their informed consent. Exclusion criteria were surgery requiring a peri-operative indwelling Foley catheter. During the study period, 147 patients were included.

Studies II and III were performed using the same study population and all patients in Study II also participated in Study III. Inclusion criteria were admittance via the ER to an orthopaedic ward for acute surgery. Patients with inability to give informed consent (cognitive failure, language difficulties or severe medical conditions) were excluded. To estimate the required sample size for Study II, a power calculation was performed, showing that 356 patients were needed to detect a statistically significant 50% relative risk reduction (RRR) of postoperative bladder distension, assuming an incidence of 22% in the control group and 11% in the intervention group (power 0.80, significance value 0.05, two-sided). A total of 300 patients were randomised of whom 281 fulfilled Study II and participated in Study III.

The mean age of the study population was 69 years (range 20 – 96 years). The majority (69%) were women and the most common diagnosis was hip fracture (48%), followed by ankle/knee fracture (36%) and arm/shoulder fracture (10%).

Of the 281 patients included in study II, 141 were randomised into the intervention group and 140 into the control group. In the control group, 14 patients did not follow the protocol as the staff in the ER started with bladder scans according to the intervention protocol. The reason for this non-compliance was concern about patients with suspected urinary retention or bladder distension. Adjustments for those 14 patients have been made in the analysis through Per-Protocol and As-Treated analyses (Figure 4).

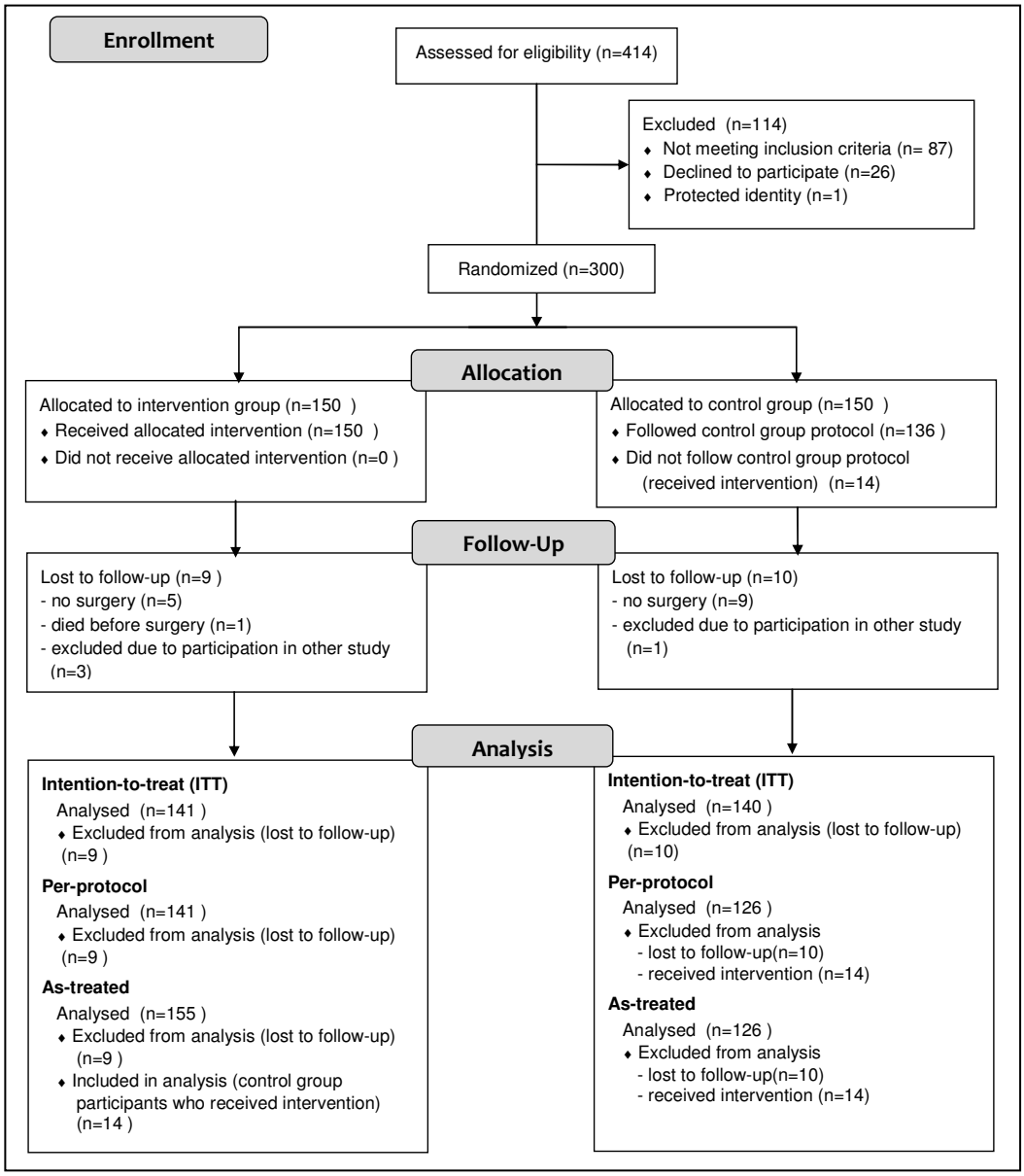

Figure 4. Study II flow diagram according to CONSORT

For **Study IV**, the Swedish Patient Insurance LÖF was used to identify patients from January 2007 to June 2010 who had had their injury classified as avoidable bladder damage due to over-distension. Thirty-two cases were found; of these, interviews with 20 participants (13 women and 7 men) were undertaken, see Figure 5 for participant enrolment flow. The participants were geographically dispersed throughout Sweden and were between 28 and 78 years of age at the time of injury. Of the 20 participants, 14 people were injured during hospital care in connection with surgery, four people were injured during pregnancy or childbirth, one person was injured when hospitalised for a serious infection and one person in connection with treatment for a neurogenic

bladder dysfunction. For several of the participants, the injury was caused or made worse by inadequate bladder monitoring after removal of a Foley catheter. Twelve people had a permanent inability to empty the bladder and were compelled either to perform daily self-catheterisation or to have an indwelling Foley catheter. Seven people had regained some of the bladder function and were able to void, but experienced other persisting micturition problems, such as recurrent urinary tract infections, a reduced ability to feel the urge to void, and the need to use alternative voiding techniques (push-on with the abdominal muscles, double-voiding, etc.). For one of the participants, the micturition problems had disappeared completely. The time between the injury and the interview ranged between one year and ten years, with a median of four years.

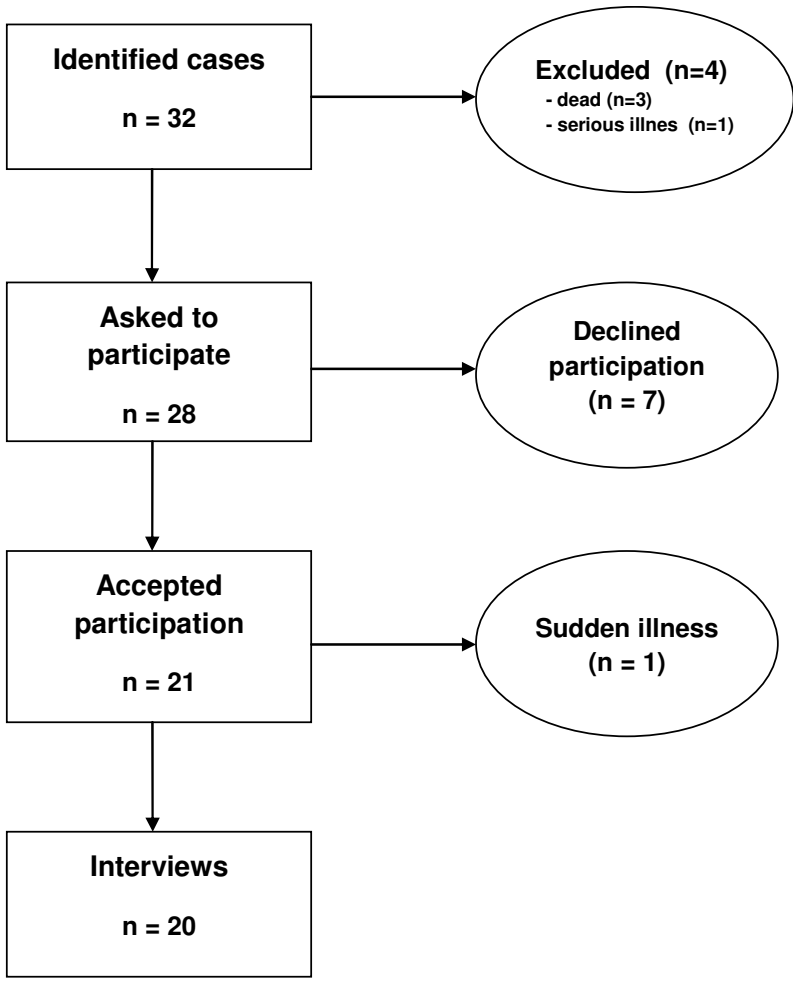

Figure 5. Participant enrolment flow in Study IV

6.1.3 Measures and data collection

Bladder volumes

In **Studies I**, **II** and **III**, bladder volumes were measured by using a portable ultrasound scanner. In Study I, Bladderscan BVI 2000 (Diagnostic Ultrasound Corp, Redmond, WA, USA) was used. In Study II and III a later model was used; Bladderscan BVI 3000 (Verathon, Bothell, WA, USA) and to ensure reliability, the majority (78%) of the scans were performed by two researchers. The two main researchers also made a pilot study of 20 patients at the recovery ward comparing their scanning results with measured urine volume at catheterisation, showing a precision of ±12% with a mean difference between the two researchers of 11 ml (SD 49.6).

Cognitive function

In **Studies II** and **III**, the cognitive status of the participants was measured before inclusion, using the Short Portable Mental Status Questionnaire (SPMSQ) to assess the patient's cognitive function [90]. SPMSQ, also called "Pfeiffer's test" is a brief screening test of organic cognitive impairment. It consists of ten questions, each correct answer gives one score, see Figure 6. Cognitive failure was defined in Study II and III as a SPMSQ score less than six.

1. What is the date today?
2. What day of the week is it?
3. What is the name of this hospital?
4. What is your home address?
5. How old are you?
6. When were you born?
7. Who is Prime Minister of Sweden now?
8. Who was the Prime Minister just before him/her?
9. What was your mother's maiden name?
10. Subtract 3 from 20 and keep subtracting three from each new number all the way down

Figure 6. SPMSQ

Pain

Pain assessment in **Study II** was performed using the Numeric Rating Scale (NRS). The patients were asked to rate their pain on a scale from 0 to 10, where 0 represents "no pain" and 10 represents "worst possible pain".

Urinary tract infection (UTI)

UTI in **Study II** was diagnosed through patient symptoms together with a positive urine culture.

Lower urinary tract symptoms (LUTS)

For measurement of LUTS in **Study III**, the International Prostate Symptom Score (IPSS) was used in the ER, at the day of discharge and three months after surgery. The instrument is identical to American Urological Association (AUA) Symptom Index and has been translated and cross-culturally adapted to Swedish [91]. The questionnaire was originally designed to assess benign prostatic hyperplasia, but has been shown to be reliable for assessing LUTS regardless of origin or gender [4 8 92 93].

	Not at all	Less than 1 time in 5	Less than half the time	About half the time	More than half the time	Almost always
Incomplete emptying How often do you have a sensation of not emptying your bladder completely after you finish urinating?	0	1	2	3	4	5
Intermittency How often have you found you stopped and started again several times when you urinate?	0	1	2	3	4	5
Straining How often do you have to push or strain to begin urination?	0	1	2	3	4	5
Weak stream How often do you have a weak urinary stream?	0	1	2	3	4	5
Urgency How often have you found it difficult to postpone urination?	0	1	2	3	4	5
Frequency How often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5
	None	1 time	2 times	3 times	4 times	5 times or more
Nocturia How many times do you get up to urinate during the night?	0	1	2	3	4	5

Figure 7. IPSS' seven symptom questions

IPSS consists of seven questions covering symptoms (feeling of incomplete emptying, intermittency, hesitancy, weak urinary stream, urgency, frequency and nocturia) where the respondents grade their symptoms using a score from 0 (not at all) to 5 (always), see Figure 7. Symptoms are considered mild for total scores between 0 and 7, moderate between 8 and 19, and severe for total scores between 20 and 35. In Study III,

symptoms were categorised in two groups; mild (total score 0-7) and moderate/severe (total score 8-35).

Health-related quality of life (HRQOL)

Two different instruments were used for measuring HRQOL in **Study III**.

Condition-specific HRQOL was measured at the day of discharge and at three months after surgery by using the additional eighth IPSS question, see Figure 8. The answers were categorised into two groups; "satisfied" and "mostly dissatisfied", where the threshold for "mostly dissatisfied" was a score of ≥4.

	Delighted	Pleased	Mostly satisfied	Neither good nor bad	Mostly dissatisfied	Unhappy	Terrible
If you were to spend the rest of your life with your urinary condition the way it is now, how would you feel about that?	0	1	2	3	4	5	6

Figure 8. IPSS QOL question

Generic HRQOL was measured at three months after surgery by using EQ-5D, a global measure of health status which has been shown to have good validity and reliability in several studies[94-96]. EQ-5D defines health in terms of five dimensions; mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. Each dimension has three levels; no problems, moderate problems, severe problems. Respondents were asked to indicate their health status by marking the most appropriate statement in each of the five dimensions. The result was dichotomised into 'no problems' or 'problems'. The health status was also converted to a single summary index using a formula that attaches weights to each of three levels of severity in each dimension[97].

Interviews

The interviews in **Study IV** took place at a location that was decided in consultation between the researcher and the respondent, mostly in the respondent's home. The form of the interview was narrative, encouraging the respondent to talk freely, with two open-ended questions (domains): "Can you describe your bladder problems and how these have affected your everyday life?" and "Can you tell me about your experiences of being exposed to a healthcare-related injury?" A digital voice recorder was used

during the entire interview and the same researcher conducted all interviews. The recorded interviews lasted between 14 and 90 minutes (median 49 minutes) and were transcribed verbatim.

6.1.4 Methods of analysis

Statistics

All statistical analyses were conducted using SPSS statistical software; in Study I version 15.0, in Studies II and III version 18.0 (SPSS, Chicago, Il, USA). Statistical significance was considered to occur if the two-tailed *p*-value was <0.05.

In **Study I**, *binary logistic regression analysis* was used to explore the probability of bladder distension during the peri-operative period. Age, gender, type of surgery and time of anaesthesia were included as confounding factors. A stepwise forward and backward method was performed, entering relevant variables sequentially and removing non-significant variables.

In **Study II**, *Fisher's Exact Test* was used to compare the proportion of postoperative bladder distension between the intervention group and the control group. To obtain confidence intervals (CIs), a *z-test* based on the normal approximation was performed. Deviations from the allocated protocol were handled by analysing data according to the randomized group (intention-to-treat analysis), completion of the randomised protocol (per-protocol) as well as according to the treatment actually received (as-treated analysis). *Logistic regression analysis* was used to adjust for possible confounders due to imbalances in the baseline characteristics between the two groups; 98/140 (70%) of the participants in the control group were women but only 73/141 (52%) in the intervention group. A stepwise forward and backward method of the analysis was used, as in Study I. Only the intention-to-treat principle was used in the logistic regression analysis.

In **Study III**, *Mann-Whitney U-test* was used to compare nonparametric data (IPSS total score, IPSS QOL-score and EQ-5D Index). *Fisher's Exact Test* was used to compare the proportions of moderate/severe LUTS, mostly dissatisfied condition-specific HRQOL and EQ-5D dimension problems between patients with or without postoperative bladder distension.

Qualitative content analysis

The interviews in **Study IV** were analysed using qualitative content analysis, which is a method of analysing written and verbal communication in a systematic way[98]. Inductive content analysis was performed according to the method described by Elo & Kyngäs [99], which is a preferable method when existing knowledge of the phenomena to be studied is limited [99 100]. The units of analysis were the individual transcripts of the interview and the researcher who had made the interviews became completely familiar with the texts by reading them thoroughly several times. The content of the texts were sorted into two domains corresponding to the two research questions, and each domain was analysed separately. The text was condensed to meaning units, which were labelled by codes. Coding is a crucial step in the process of analysing data from texts, and thus the codes were discussed with two other researchers before going further into the analysis by creating categories and sub-categories within the two domains[101 102]. During the whole analytic process, the codes, categories and sub-categories were compared with the texts, and the authors reached consensus through reflection and discussion about the interpretations.

6.2 RESULTS

6.2.1 Perioperative incidence of bladder distension and pre-disposing factors

In Study I, 33 of the included 147 patients (22%) developed bladder distension (>500 ml), eight preoperatively and 25 postoperatively. The maximum bladder volume was 1000 ml; 9 of the 33 patients had a bladder volume greater than 750 ml. Twenty-eight (85%) of the 33 patients with bladder distension were not able to void spontaneously and were catheterised. A total of 21 patients (14%) had a bladder volume > 300 ml immediately before surgery. Orthopaedic patients were more likely to develop preoperative bladder distension than surgical patients and had significantly higher post-void residual volumes. In the binary logistic regression analysis age, gender and time of anaesthesia could not predict bladder distension. Patients going through orthopaedic surgical procedures, however, were prone to get bladder distension by the odds ratio 6,87 [95% CI: 1,76; 26,79], p=0.006.

6.2.2 Preoperative scanning as a preventive measure for postoperative bladder distension

The hypothesis in Study II that frequent preoperative scanning starting at the ER could reduce the risk of postoperative bladder distension for acute orthopaedic patients turned out to be true.

The proportion of patients with postoperative bladder distension was 10.1 percentage points higher in the control group than in the intervention group (27.1% vs 17.0%; p = 0.045, 95% CI 4.9-19.8) using the Intention-To-Treat principle. The difference between the two groups was statistically significant both in the Per-Protocol as well as in the As-Treated analysis (table II).

Table II. Comparison of postoperative bladder distension between the intervention group and the control group

	Intervention Group	Control Group	Two-sided p-value	Difference (95% CI)
	No of patients with postoperative bladder distension/total no. (%)			*percentage points*
Intention-To-Treat	24/141 (17.0%)	38/140 (27.1%)	0.045*	10.1 (4.9-19.8)
Per-Protocol	24/141 (17.0%)	37/126[1] (29.4%)	0.020*	12.3 (2.3-22.4)
As-Treated	25/155[1] (16.1%)	37/126 (29.4%)	0.009*	13.2 (3.4-23.1)

[1] 14 patients in the control group did not follow the protocol. They were scanned at the ER and treated as the intervention group.
* Significant value, p < 0,05

The binary logistic regression analysis showed that according to the Intention-To-Treat principle, patients in the control group were more prone to bladder distension (OR=1.81, 95% confidence interval 1,02-3,23, *p*=0.042). This association remained after adjusting for confounding factors; neither gender, age nor volume of peri-operative fluid affected the outcome. No statistical difference was found between the intervention group and the control group regarding hospital length-of-stay and UTI.

The result also showed that 34 patients (24%) in the intervention group already had bladder distension in the ER. Six of these patients voided spontaneously while 28/34 patients (82%) had urinary retention and were catheterised in the ER. Another 20

patients (14%) in the intervention group were found to have bladder distension at one or more of the preoperative scans at the ward; all of them had urinary retention and were catheterised.

6.2.3 The impact of bladder distension from the patient's perspective

Both Studies III and IV focused on how patients are affected by bladder distension. In Study III, the result showed that patients who have had postoperative bladder distension after acute orthopaedic surgery reported more LUTS and lower HRQOL than patients without bladder distension. At discharge from the hospital, both groups reported more LUTS than at admission. However, at three months after surgery, patients without bladder distension had returned to approximately the same level of LUTS as in the ER, but patients with postoperative bladder distension reported continuing problems. They had both significantly higher mean IPSS scores (Figure 9) and a higher proportion of moderate/severe LUTS compared to patients without bladder distension.

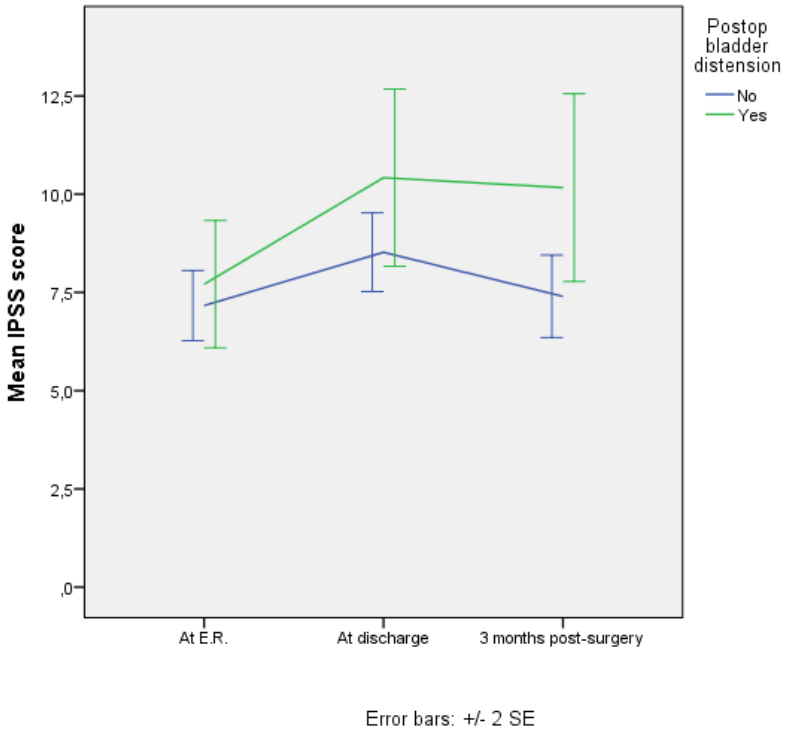

Figure 9. LUTS measured by IPSS for patients with or without postoperative bladder distension.

Patients with postoperative bladder distension rated their condition-specific HRQOL at discharge significantly lower than patients without bladder distension. This was apparent both as higher mean IPSS QOL scores and a higher proportion of "mostly

dissatisfied". Three months after surgery, the condition-specific HRQOL was improved for both groups and the difference was not significant.

The EQ-5D health status profile for both groups is shown in Figure 10. The proportion of patients reporting problems was higher for the bladder distension group in all five domains with the largest differences among the domain "anxiety/depression", which was found statistically significant. Generic HRQOL measured by EQ-5D Index was significantly lower among patients with postoperative bladder distension at three months after surgery.

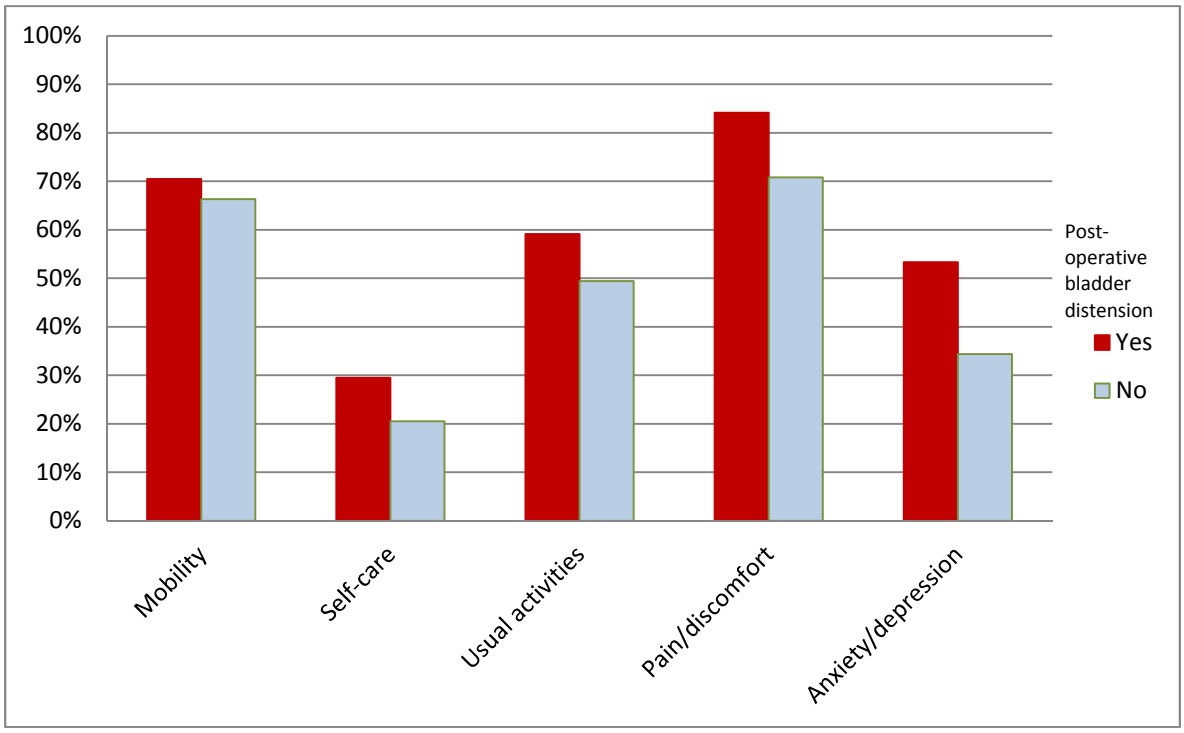

Figure 10. EQ-5D health status profile of the study population (% reporting problems) in Study III.

The response rates for the surveys in Study III were high. In the ER, all 281 patients completed the questionnaire. At the day of discharge 274 patients (98%) answered the questionnaire. Three months after surgery, 207 patients filled in and posted the questionnaire, giving a response rate of74% . Four patients were deceased, all men without postoperative bladder distension, with a mean age of 78 years. The distribution of gender and age among the respondents was similar at all three survey occasions.

If a person suffers from micturition problems after severe bladder distension, it can affect the whole life situation. To actually have been injured when receiving healthcare

is an aggravating circumstance for the affected person. In Study IV, this was described in several categories and sub-categories that emerged from the transcribed interviews. Figure 11 shows an overview of categories and sub-categories within the two domains; "The impact of micturition problems on everyday life" and "Aspects of having been harmed by the healthcare system".

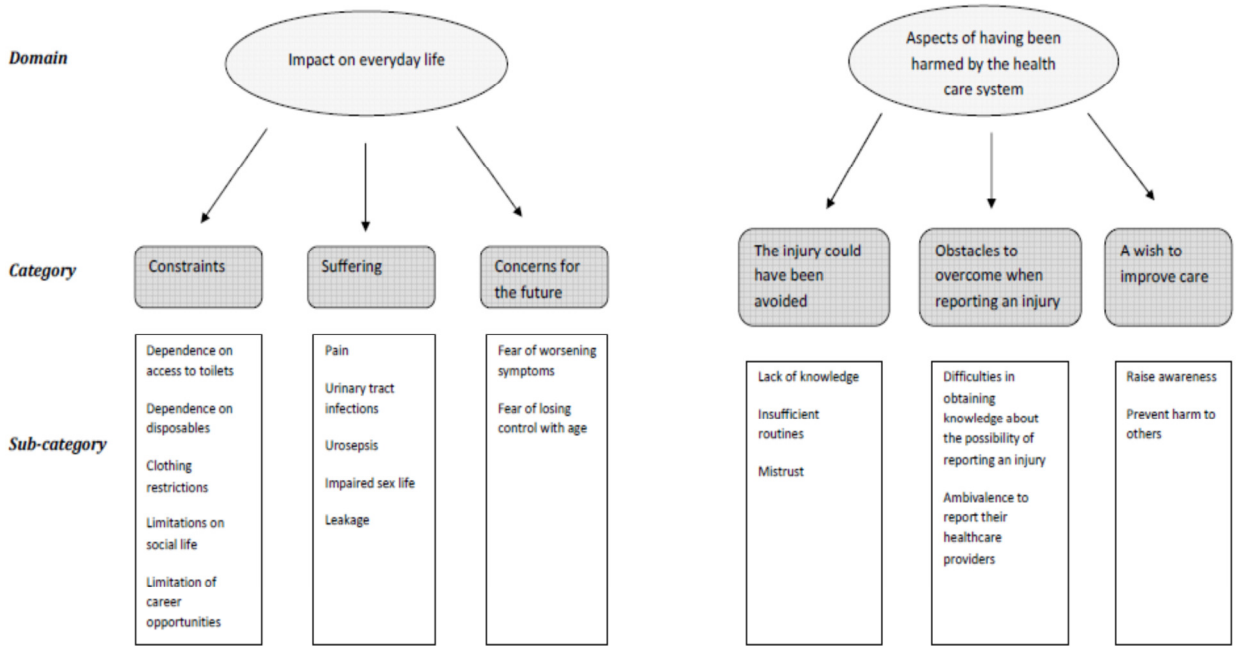

Figure 11. Domains, categories and sub-categories in Study IV.

The impact of micturition problems on everyday life

All participants described ***constraints*** on everyday life, leading to practical difficulties and restrictions on their lifestyle. To depend on access to a toilet was seen as a major constraint, especially during travel. Many participants described frequent and time-consuming problems finding toilets that were clean enough. For those who needed to perform self-catheterisation, carrying the necessary disposables (catheters, cleaning equipment, alcohol-based hand rub) was seen as a particular problem. The practical difficulties with toilets and disposables, but also feelings of embarrassment and fatigue, led to limitations on social life. For some participants, the micturition problems had also led to limitations of career opportunities. Another constraint described by the participants was clothing restrictions due to genital irritation or fear of stains.

The micturition problems caused ***suffering***, both in terms of pain, urinary tract infections, urosepsis, impaired sex life and leakage. Most patients had lost the sense of urge, and many of them instead recognised the need to void from increasing pain in the bladder region. Urinary tract infections had affected 18 of the 20 participants, and nine of them had recurrent infections every year. For four participants, the urinary tract infection had led to urosepsis. The infections led to increased pain (especially when catheterising/voiding), more frequent visits to the toilet, disturbed sleep and negative side effects of antibiotics.

Concerns for the future were described in the majority of the interviews. The participants were aware that their injury was chronic and that they had little chance of improvement. Fear of worsening symptoms, especially infections, and fear of losing control of their micturition with age were linked to strong feelings of anxiety.

Aspects of having been harmed by the healthcare system

The participants were well aware that their **injury could have been avoided** if the staff had monitored the bladder volume and taken the correct actions when the bladder volume was high. They were surprised by the lack of knowledge among staff about urinary retention and bladder distension, and the insufficient routines to prevent large bladder volumes at the care unit. “If only they had listened to me” was a common remark, indicating mistrust and deficiencies in communication.

A major **obstacle to overcome when reporting an injury** was difficulty in obtaining knowledge about the possibility of reporting an injury and applying for financial compensation. Only one respondent had been informed by the responsible caregiver; instead, it was friends, relatives and other healthcare personnel who had informed and encouraged them to report their injury. Some of the participants expressed ambivalence towards filing a report about their healthcare provider. Reasons for this were fear of reprisals or reluctance to report staff that had been friendly and otherwise done a good job.

A common motive for agreeing to participate in the study was **a wish to improve care** and prevent harm to others by highlighting and raise awareness of the consequences of bladder distension.

7 DISCUSSION

7.1 METHODOLOGICAL CONSIDERATIONS

Study I had a descriptive design which limits the possibilities to draw conclusions. However, the study provided new information about peri-operative bladder distension and generated new research questions.

An ethical and methodological dilemma in **Study II** was the decision to terminate the study when only 84% of the calculated sample size was achieved. The main reason for this was an increasing tendency of the staff in the ER to violate the study protocol by implementing bladder scans according to the intervention protocol in all patients. Since the staff members were responsible for catheterisations, the knowledge about frequent findings of large bladder volumes and urinary retention in the intervention group resulted in growing awareness and concerns for the patients in the control group. The researchers found it unethical to prevent the staff from performing scans in the control group, and a decision was made to end the study prematurely. This is in line with the intentions in the Helsinki Declaration, which states the well-being of the research subject as the most important interest[88]. In the analysis, the problem with deviation from the study protocol was handled by performing Intention-to-treat and Per-protocol as well as As-treated analysis. The difference between the intervention and control group was found significant in all three analyses, with the highest significance level achieved when performing the As-treated analysis, which strengthens the efficacy of the protocol.

The principle of intention-to-treat can be interpreted in various ways[103]. The strictest definition is that all randomised patients should be included in the analysis. Another definition introduced by Chan et al is that no data should be excluded for reasons other than loss to follow-up[104]. In our study 19 patients (6%) were lost to follow up. The frequency was the same in both study groups and with an equivalent distribution of age, gender and diagnosis. Since the reasons for losses to follow-up were independent from the study intervention and beyond the control of the researchers and, as no data could be gathered about the primary outcome in these patients, they were accordingly excluded from the intention-to-treat analysis as shown in Figure 8.

Precautions to ensure validity and reliability in Study II were taken by having the majority of scans (78%) be performed by two researchers who validated their scanning results in a pilot study. There were no signs of abnormal, unexpected or unusual values in the remaining scans performed by the ward staff. The portable bladder scanner device was familiar to all staff at the orthopaedic department and was also regularly used for all postoperative patients according to the hospital protocol.

In **Study III**, the population size was decided according to power calculations for Study II, and the study might have been underpowered to detect statistical significance between the two groups for certain variables, such as the condition-specific HRQOL three months after surgery.

Another methodological issue in Study III was the relatively short follow-up period; three months. Some patients still experiencing bladder problems after three months may be recovering during the following months, and may have less problems one year after surgery. However, we believe that persisting LUTS three months after surgery is an undesirable complication with implications for the patient's well-being. We also chose the follow-up time based on the probability of getting high response rates, which are likely to decrease the longer the time elapses after discharge. A time period of three months was decided as an appropriate follow-up time, as according to a Cochrane review, there is no evidence of effect on response rates when sending out questionnaires sooner than 9-14 weeks after discharge from hospital[105].

In **Study IV**, the qualitative approach with open-ended interviews yielded very rich and extensive data that provided new insights into what it means to be injured by healthcare and how micturition problems due to bladder distension affect the patient's everyday life. However, publication limitations meant that the authors had to choose what to present. Other researchers may have made other choices and focused on other parts of the data. Another methodological aspect with the study was that by using the Patient Insurance LÖF to identify potential participants, the study population was limited to people who had managed to overcome the obstacles to reporting their injury and had received medical care for their micturition problems. This is not very common among patients who have suffered bladder damage after hospital care. It would have been

interesting to interview patients who had not reported their injury, although finding such patients would present great difficulties.

7.2 GENERAL DISCUSSION

The four studies in this thesis have highlighted different aspects of bladder distension and contributed to increased knowledge of the problem. The studies have shown that bladder distension is common in connection with surgery, that preventive measures should start early in the ER for acute orthopaedic patients and that bladder distension can lead to long-term suffering for the individual patient.

Decreasing the risk for over-distension of the bladder is an important patient safety issue. Bladder damage is to a large extent an avoidable health-care related injury caused by inadequate bladder monitoring routines. The consequences for the patient even if the damage is reversible include suffering from micturition problems, prolonged hospital stay and increased costs both for the patient and society. Irreversible bladder damage greatly affects the patient's health-care related quality-of-life and can imply life-long inability to void, the need for daily intermittent self-catheterisation and a subsequent risk of chronic UTI. Monitoring bladder volumes regularly is a simple and quick method to prevent chronic bladder damage caused by over-distension.

7.2.1 Preoperative bladder distension and orthopaedic patients

To our knowledge, Study I is the first study showing that bladder distension can occur even before surgery starts. Eight of the 33 patients (24%) with bladder distension were discovered preoperatively, and 14% of all patients had a bladder volume more than 300 ml immediately before the start of anaesthesia. If the patient starts surgery with an almost full bladder there is a great risk that over-distension will occur either intra- or postoperatively. The conventional method of encouraging patients to void at the ward before transport to the operating theatre is clearly not sufficient to guarantee an empty bladder at the start of the operation.

Study I also showed that orthopaedic patients undergoing surgical intervention were more prone to bladder distension peri-operatively than were patients subjected to general surgery. Multiple causes might explain this. The majority of the orthopaedic

patients were admitted for acute surgical repair of a fracture; they were in pain and had been treated with opiates which increase the risk for urinary retention. Immobilising and a supine position are other contributing risk factors that can affect the acute orthopaedic patient. The high post-void residual volumes can also be a sign of already acquainted bladder damage, maybe caused by longer waiting for an ambulance or delay in the ER. The patients in the general surgical setting were more likely scheduled for an elective operation and thus were more optimised and pain free. This implied that for orthopaedic surgical patients mandatory scanning should already be undertaken in the ER and pre-surgical scanning and emptying of the bladder should improve the care of these patients.

In Study II, the conclusion from Study I was tested and a protocol with preoperative bladder monitoring by ultrasound starting in the ER resulted in a statistically significant reduction in postoperative bladder distension among acute orthopaedic patients. The finding in Study I that preoperative bladder distension is highly prevalent was confirmed. The majority of the patients (58%) in the intervention group with postoperative bladder distension were diagnosed with bladder distension either in the ER or preoperatively at the ward. The bladder volumes at these preoperative time points were all above 700 ml. The incidence of preoperative bladder distension in the control group is unknown as no regular scanning was performed according to the study protocol.

The relatively high incidence of bladder distension and urinary retention in the ER found in Study II is not surprising. The acute orthopaedic patient is exposed to many risk factors for urinary retention, such as pain, opiates and immobilisation. In the study, the highest pain scores during hospital stay were obtained in the ER, leading to a high risk for urinary retention. The mean time between admission and the first scan in the ER was also quite long; 2 h 46 min. This was due to the fact that inclusion of patients in the study was dependent on the surgeon's decision to admit the patient for surgery. In order to reduce preoperative bladder distension, future clinical applications of the scanning protocol should start scans earlier than in this study, preferably as close to the admission to the ER as possible. Starting bladder monitoring early in the ER seems to be a logical and simple way to increase the safety and well-being of acute orthopaedic patients.

7.2.2 Preoperative scanning and cost-benefit

The lack of difference regarding UTI and hospital length-of-stay between the intervention group and the control group in Study II can lead to a questioning the benefit of preoperative scanning in relation to costs. We believe that the study does not provide sufficient basis for a cost/benefit analysis for several reasons. First, the hospital length-of-stay was relatively short for both study groups and determined largely by the patient's medical condition, the availability of orthopaedic resources (e.g. access to the operating theatre) and the need for postoperative rehabilitation. Second, all hip fracture patients, who were 48% of the study population, were discharged to another health care facility as soon as there was availability, either at a rehabilitation centre or a nursing home, with a median hospital length-of-stay of five days. The decision to transfer was taken if the medical treatment of the orthopaedic injury was considered completed, regardless of any existing urinary tract symptoms, UTI or indwelling catheter. As the current study ended when discharge from the hospital occurred, we do not know how many patients who may have suffered from UTI in the following days or weeks. In a recent study from Hälleberg Nyman et al., 52,3% of hip fracture patients had UTI when diagnosed at a median of 9 days from admission[106]. Further studies with longer follow-up time are needed to evaluate the impact of preoperative bladder scanning on UTI.

7.2.3 Consequences for the patient

I'm not ill, just damaged. That's how it feels: I'm damaged for the rest of my life.

The quotation is from a young woman exposed to bladder distension after gynaecologic surgery, now facing lifelong clean intermittent catheterisation. For professionals in healthcare, it is extremely important to find out the patient's own subjective experience of their health and the care they have received. This was the focus of Studies III and IV; exploring the patient's own perception of LUTS, HRQOL and micturition problems after a healthcare-related injury.

In Study III, postoperative bladder distension affected the patient's well-being several weeks after acute orthopaedic surgery. Patients with postoperative bladder distension had persisting micturition problems three months after surgery with almost 55% experiencing moderate/severe LUTS. The HRQOL measured by EQ-5D was also lower three months after surgery among patients with postoperative bladder distension

and they reported more problems with anxiety/depression than patients without bladder distension. This is in accordance with findings from Coyne et al.; men and women with LUTS reported the lowest levels of HRQOL and highest levels of anxiety and depression[10]. Interestingly, the condition-specific HRQOL measured by IPSS three months after surgery had improved from discharge for patients both with or without bladder distension. The rationale for this might be that they have become accustomed to their urinary tract disorders and may not feel as uncomfortable, but are still worried about the future. Further studies are needed to explore the patients' experiences of micturition problems after bladder distension.

Study IV shows that micturition problems after bladder distension have a large negative impact on the affected person's life and can cause suffering and practical, emotional and psychosocial problems. Persistent micturition problems and deep concern for the future, such as a fear of infection and a fear of losing control, were common sources of anxiety. Problems related to access to clean toilets were brought up in all interviews. This has previously been described in studies of intermittent self-catheterisation[62 107], but we have shown that the problem also affects people with other micturition problems and alternative voiding techniques. Infections, leakage and limitations to social life are other persistent problems regardless of micturition status.

Anxiety was a prominent finding in both Studies III and IV. The deeper understanding of what underlies the anxiety described by the participants in Study IV helps to explain the levels of anxiety/depression reported by patients with postoperative bladder distension in Study III. Notably, concerns about the future seem to be a particular cause of anxiety. Society's view of urinary tract disorders as something embarrassing together with lack of treatment options can make the future look bleak.

Some of the participants in Study IV described negative experiences with suprapubic catheters, in particular during the insertion. This may be due to insufficient preparation and information from staff, as other studies [108 109] have found, but the intensity of the traumatic and painful experiences of insertion that respondents described was surprising. This area needs to be studied further.

All participants in Study IV had felt that healthcare workers displayed significant gaps in knowledge about bladder distension and that preventive routines were insufficient. Mistrust and poor communication led to a failure to notice and remedy the participant's symptoms in time. This points to a severe lack of care, as the risk of permanent bladder damage increases if the overfilled bladder is not treated within one to two hours [22]. It is well-known that poor communication contributes to medical errors, but the focus in most studies has been on poor communication between staff [110-112], not communication with the patient. A recurring theme in many of the interviews in Study IV was that the participants felt that the failure by staff to listen to them was the main cause of their injury.

The obstacles that must be overcome when reporting an injury need to be discussed. It was remarkable that only one of 20 participants in Study IV had been informed by the responsible healthcare provider about the possibility of filing a report and obtaining financial compensation. An ambivalence towards reporting a healthcare provider may be explained by the fact that patients are in a vulnerable position, they have been harmed by the people in whom they placed trust and on whom they depend for future care [113]. The healthcare system must address these issues in order to decrease the huge number of unreported cases.

7.3 IMPLICATIONS FOR CLINICAL PRACTICE

The findings in this thesis implicates that the healthcare must improve preventive measures to avoid bladder distension. This is prominent for, but not limited to, patients in connection with surgery. If bladder damage due to over-distension occurs, very few treatment options exist and the patient might need to perform self-catheterisation for the rest of his/her life. Given the substantial negative impact on the affected person's life and the large number of patients who undergo hospital care and surgery every day, the increased burden of LUTS related to bladder distension affects the health status of the population and healthcare economics negatively.

Consequently, there is a need for more accurate protocols for bladder monitoring in relation to hospital care in general, and surgery in particular. Safe and effective prevention of bladder distension and management of urinary retention can be based on early recognition. Since many patients also have a decreased sensitivity of the urge to

void, routines should not be based on the patient's capability to tell when the bladder is full. If the patient is unable to void when bladder volumes exceed a critical limit, 400-500 ml, actions to empty the bladder must be initiated promptly. For the acute patient, the protocol should preferably start already in the ER. The protocol should also include bladder monitoring after removal of an indwelling urinary catheter.

As knowledge of the subject is low among healthcare staff, it is important for healthcare management to raise awareness about the risk of urinary retention and bladder distension, and to improve patient safety by implementing evidence-based bladder monitoring guidelines. Healthcare management also need to take action to make it easier for patients to report an injury.

7.4 FUTURE RESEARCH

During work on this thesis, several ideas for future research have emerged:

- The preoperative bladder monitoring protocol used in Study II could be tested with other groups of patients, such as acute general surgery patients.
- A study of acute medical patients admitted to hospital care to explore if they would benefit from bladder scanning in the ER. Many of them suffer from pain, anxiety and deteriorated condition. Possible risk groups are patients with acute myocardial infarction, stroke or severe infections.
- The negative experiences with the insertion of suprapubic catheters need to be addressed. How can the insertion procedure be more tolerable from the patient's perspective?
- Bladder distension in the peri-partum period needs to be further explored, with a special focus on assessment and prevention. Bladder assessment of a pregnant woman is difficult and the conventional bladder scanner may not be reliable.
- A retrospective study of all bladder distension cases at the Swedish Patient Insurance LÖF during the last ten years could reveal information about causes and possible differences over time. The register could also be used to identify groups of patients, where qualitative studies could improve the knowledge of how patients' lives are affected after other healthcare-related injuries.

8 CONCLUSIONS

- Bladder distension is a healthcare-related injury that can cause suffering and practical, emotional and psychosocial problems with a great impact on the life of the person affected, and anxiety for the future.

- In surgical cases, bladder distension can be a problem even before surgery starts.

- Frequent bladder monitoring starting in the ER can reduce postoperative bladder distension among acute orthopaedic patients.

- A preoperative bladder monitoring protocol should be implemented early in the ER for all patients admitted for acute orthopaedic procedures.

- The conventional method of encouraging patients to void at the ward before transport to the operating theatre does not imply an empty bladder at the start of the operation

- Orthopaedic patients are more prone to peri-operative bladder distension than surgical patients.

- Postoperative bladder distension can result in increased lower urinary tract symptoms and decreased healthcare-related quality of life up to three months after acute orthopaedic surgery.

- Mistrust and poor communication between staff and the patient can lead to a failure to notice and remedy the patients' symptoms in time.

- Safe and effective prevention of bladder distension and management of urinary retention is based on early recognition.

9 SAMMANFATTNING (SUMMARY IN SWEDISH)

Bakgrund

Urinretention (oförmåga att tömma urinblåsan) är en vanlig komplikation till sjukhusvård. Vid ca 300 ml är urinblåsans förmåga till tömning optimal, därefter minskar tömningsförmågan då blåsans muskelfibrer tänjs för kraftigt och förlorar förmågan att dra ihop sig. Vid *blåsövertänjning* (≥ 500 ml) blir det allt svårare att tömma blåsan och risken ökar för kroniska skador med urintömningsbesvär, infektioner och i svåra fall livslångt behov av kateterbehandling.

Det finns flera faktorer i samband med sjukhusvård som bidrar till ökad risk för blåsövertänjning och urinretention. Många läkemedel påverkar urinblåsans funktion, t ex morfinpreparat. Smärta, ryggläge, integritetsproblem, oro och stress kan försvåra blåstömning. Flera av dessa faktorer gör att risken för urinretention och blåsövertänjning ökar redan vid ankomsten till sjukhuset, vilket speciellt gäller patienter med akuta och smärtsamma tillstånd. Patienterna har ofta svårt att själva känna om de behöver kissa och det är därför vårdpersonalens ansvar att hjälpa patienterna att övervaka blåsvolymen. Som hjälpmedel finns portabla ultraljudsapparater som är lätta att använda för vårdpersonalen och som ger ett tillförligt mått på urinblåsans volym.

Orsak till blåsövertänjning på sjukhus är oftast bristande övervakning av urinblåsans volym, och en övertänjningsskada kan därför klassas som en vårdskada, d v s en undvikbar skada som orsakats av hälso- och sjukvårdens bristande rutiner. Om patienten får en bestående blåsmuskelskada på grund av övertänjning, finns idag ingen medicinsk eller kirurgisk åtgärd som kan återställa urinblåsans funktion. För sjukvården är det därför av stor vikt att förebygga blåsmuskelskador genom att undvika överfyllnad.

Syfte

Det övergripande syfte var att förbättra patientsäkerheten genom att ta fram vetenskapliga underlag till riktlinjer för att förebygga blåsövertänjning, samt att öka kunskaperna om patientens självupplevda urinvägsbesvär efter en blåsövertänjning och hur dessa besvär påverkar patientens hela livssituation.

Studie I var en prospektiv observationsstudie med syfte att undersöka incidens av blåsövertänjning i samband med operation samt att finna riskfaktorer. I studien deltog 147 vuxna patienter som skulle opereras på ortopedisk eller kirurgisk klinik. Resultatet visade att 22% av patienterna hade en övertänjd urinblåsa vid operationstillfället, och att ortopedpatienter hade en större risk att drabbas jämfört med kirurgpatienter. Studien visade också att många patienter hade problem med stora blåsvolymer redan innan operationen startade.

Studie II var en randomiserad studie av 281 akuta ortopedpatienter med syfte att undersöka om blåsövertänjning kan förebyggas med hjälp av regelbundna preoperativa ultraljudsundersökningar (scanningar) av blåsvolymen. Resultatet visade att patienter som scannades på akutmottagningen och därefter regelbundet fram till operationen hade mindre risk att drabbas av postoperativ blåsövertänjning än patienter där preoperativ scanning inte utfördes.

Studie III och IV undersökte följder av blåsövertänjning från patientens perspektiv. Studie III var en enkätstudie där 281 akuta ortopedpatienter själva fick skatta sina urinvägsbesvär och hälsorelaterade livskvalitet på akutmottagningen, vid utskrivning från sjukhuset samt tre månader efter operation. Resultatet visade att postoperativ blåsövertänjning medförde mer urinvägsbesvär och lägre hälsorelaterad livskvalitet tre månader efter operation. Studie IV var en intervjustudie med 20 patienter med en konstaterad övertänjningsskada av urinblåsan, bedömd som undvikbar vårdskada av Patientförsäkringen LÖF. Resultatet visade att urinvägsbesvär efter blåsövertänjning innebär både praktiska och sociala begränsningar av vardagslivet, lidande och en stark oro för framtiden. Kunskapsbrister hos personalen, bristande rutiner, misstro och dålig kommunikation mellan patient och vårdpersonal var bidragande orsaker till att vårdskadan uppkommit.

Slutsatser

Blåsövertänjning är en vanlig vårdskada som kan orsaka långvariga urinvägsbesvär, nedsatt hälsorelaterad livskvalitet och lidande för patienten. Regelbunden övervakning av blåsvolymer med start redan på akutmottagningen minskar risken för blåsövertänjning hos akuta ortopedpatienter. Tidig upptäckt och behandling av stora blåsvolymer kan leda till färre vårdskador.

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