Patients with Hip Fracture

Various aspects of patient safety

ANNA-KARIN GUNNARSSON
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Abstract

The overall aim of the thesis was to investigate whether patient safety can be improved for patients with hip fracture by nutritional intervention and by pharmacological treatment with cranberry concentrate. Another aim was to describe the patients’ experience of involvement in their care. The thesis includes results from four studies that include both quantitative and qualitative design. Studies I and II were intervention studies with a quasi-experimental design, with intervention and comparison groups. Study III was a randomised, double-blind, placebo-controlled trial with intervention and control groups. Study IV took a qualitative approach.

Study I showed that when patients with hip fracture received nutritional supplementation according to nutritional guidelines, from admission until five days postoperatively, fewer patients developed pressure ulcers. Study II showed that it is possible to objectively evaluate a short-term nutritional intervention through the nutritional biochemical marker IGF-1, as it was affected by a five-day high-energy regimen. The randomised controlled trial, Study III, showed that a short-term treatment from admission until five days postoperatively with cranberry as capsules does not seem to be useful in preventing positive urine cultures in female patients with hip fracture and a urinary catheter. Finally, Study IV showed that patients with hip fracture reported experiencing very little involvement in their nursing care, to the extent that fundamental aspects of nursing care went unfulfilled. Patients did not feel valued by the nurses and unbearable pain that affected rehabilitation was reported. Positive interactions with nurses, however, did encourage patients to be more active.

It is possible for every nurse to improve patient safety at bedside when caring for patients with hip fracture. Simply by increasing caloric/energy intake, it is possible to prevent pressure ulcers. It is also important to involve patients in nursing care, since the patients have experienced low or almost no involvement in care. Nurses need to see each patient as a whole person with different wishes and needs. However, certain prerequisites have to be in place to give nurses the opportunity to increase patient safety at bedside for patients with hip fracture.

Keywords: Hip fracture, patient safety, nutrition, cranberry, patient involvement, adverse event, elderly

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urn:nbn:se:uu:diva-232825 (http://urn.kb.se/resolve?urn=urn:nbn:se:uu:diva-232825)
To my family
Joel, Klara & Agnes
This thesis is based on the following papers, which are referred to in the text by their Roman numerals.


III Gunnarsson, A-K., Larsson, S., Gunningberg, L., Jonsson KB. Cranberry juice concentrate does not significantly decrease the incidence of hospital-acquired bacteriuria in female hip fracture patients receiving urine catheter: a double blind randomised trial. *Manuscript*


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Abbreviations

AE  Adverse Event
AN  Assistant Nurse
BMI Body Mass Index
CRP C-reactive protein
EQ-5D Euro Qual 5 Dimensions
FoC Fundamentals of Care
IGF-1 Insulin-like Growth Factor 1
ITT Intention To Treat
MNS Modified Norton Scale
PAC Proanthocyanidin
PP Per Protocol
PU Pressure Ulcer
RN Registered Nurse
SALAR Swedish Association of Local Authorities and Regions
SPMSQ Short Portable Mental Status Questionnaire
STC Systematic Text Condensation
UTC Urinary Tract Catheter
UTI Urinary Tract Infection
WHO World Health Organization

Terms used in this thesis
Patient  A person who is a recipient of healthcare
Eighty-year-old Elsa arrives in the emergency department at the hospital on a late afternoon in October. It’s almost dark outside in the afternoon at this time of year, and she had tripped and fallen on the carpet on her way to the kitchen. She wasn’t able to see the carpet because she hadn’t turned on the light. Lying on the floor, she experienced severe pain in her left hip and couldn’t stand up. She managed to reach the phone to call an ambulance.

Now at the emergency department, Elsa tells the doctor about her high blood pressure, her diabetes and that her memory is starting to fail her. The registered nurse (RN) talks to Elsa and is told about her urinary incontinence, that she has lost her appetite and that she has terrible pain both in the hip and on her heels. Elsa has to be fasting, so the RN gives her an IV infusion. She asks Elsa about urination and checks her bladder with a bladder scan to make sure that Elsa doesn’t need a urinary catheter. After an x-ray examination, the doctor tells her that she has a fracture in her left hip, and that surgery is planned for the next day. Elsa has not eaten or drunk anything since lunch. Now she has to fast until surgery the next day. In the orthopedic ward, Elsa meets the RN and the assistant nurse (AN). The RN and AN introduce themselves to Elsa and first of all ask her if she is in pain and needs pain medication. Elsa will be transferred from the stretcher to a comfortable bed as soon as possible.

As a newly graduated RN, I started to work at an orthopedic ward. I soon realized that the largest group of patients in the department represented patients with hip fracture. Early in my career, I knew I wanted to improve nursing care; I wanted to make a difference, not only for the patients I cared for, but for all patients. After a couple of years on the ward, I was asked to develop new nutritional guidelines for the patients with hip fracture. I accepted this challenge immediately; I saw my chance to improve nursing care.
Introduction

Patient with hip fracture

An estimated 1.6 million people worldwide sustained a hip fracture in 2000 (1). This figure is expected to increase to 4 million in 2025 and 6 million in 2050, mainly because osteoporosis will become a truly global problem. The highest global incidence of hip fracture is in northern Europe (2). Every year, 18 000 people in Sweden, a country of 9.5 million inhabitants, suffer a hip fracture (3). The patient sustaining a hip fracture is commonly a woman around 80 years of age (4) and she often has a number of frailty-related characteristics, such as comorbidities, dementia and living in long-term care (4). This has a significant impact on current and future care needs and services (4). The advanced age is related to increased mortality and worsened functional recovery after the hip fracture (5). It is estimated that 1 year after fracture, 42 % of survivors fail to return to their pre-fracture mobility, 35 % are incapable of walking independently, and 20 % are unable to shop independently (6). A considerable number of these patients also have to endure the consequences of hospital-acquired complications, such as pressure ulcers and infections (7, 8).

A large amount of research has been conducted to improve outcomes for this patient group. Much of this research centres on what surgical method to employ and implant to use (9, 10). To improve care for these patients preoperatively, clinical pathways, or fast tracks, have been adopted around the world (11). These clinical pathways shorten the time from admission to hospital to surgery (12). Another way of improving the care is co-management, where a geriatrician is integrated in the orthopaedic ward and cares for geriatric fracture patients (13). In terms of nursing care, different aspects of care have been investigated and improved. These include how to prevent pressure ulcers in these patients (7, 14), and how gender differences influence care and recovery (15). To get patients’ perspective of the care they received, Hommel et al (2012) asked patients with hip fracture for their views. The patients were satisfied with the nursing care provided. However, the patients reported that they had experienced stressful waiting for surgery, more than 24 hours and various issues with pain during their hospital stay (16).
Patient safety and nursing care

Healthcare should be of good quality and safe for the patient. According to the World Health Organization (WHO), patient safety is the prevention of errors and adverse effects to patients associated with health care (17). The discipline of patient safety is the coordination of efforts to prevent harm caused by the process of health care itself, from occurring to patients (17). Preventable harm can be described as an adverse event (AE). An AE is defined by Swedish law as: suffering, physical or psychological injury, illness or death that could have been avoided if necessary interventions had been taken when the patient was in contact with the healthcare system (18). AEs include complications that are deemed as leading to harm but of low preventability (19).

Examples of AEs include urinary tract infection (UTI), pressure ulcer (PU), falls and malnutrition (20). A number of patients endure an adverse event (AE) during their hospital stay. Figures from Australia indicate the rates for AEs among surgical patients to be 17.8% for elective patients and 16.9% for acutely admitted patients. In teaching hospitals, the figure was higher; 24.3% for elective and 19.7% for acutely admitted patients (21). In Sweden, 8.6% of patients experience an AE. Of these patients, 62% are under surgical care. This corresponds to about 65,100 patients that are injured during healthcare each year under surgical care. Of those patients, 1,860 die due to an AE. An AE prolongs the hospital stay on average by six days. For one year in Sweden, that is 390,600 extra days spent in hospital (22).

Among patients with hip fracture who suffer an AE, the percentage of patients ranges from 15% to 72% (7, 23-27). For example, of the hip-fracture patients admitted to one orthopaedic ward and treated with urinary tract catheters (UTC), 52.3% of them had an UTI at discharge from the ward (25). According to the literature, some groups of patients have an increased risk of developing a UTI: women, the elderly, patients with a UTC, patients with diabetes and other chronic diseases, and patients with functional limitations because of illness or age (28). A symptomatic UTI in the elderly requires treatment with antibiotics, which is expensive (29), causes side effects (30) and may result in antibiotic immunity (28). Furthermore, a UTI typically prolongs the hospital stay by one to five days, which is expensive for society and results in suffering for the patient (31).

Upon admission to an orthopaedic ward, 30%–50% of patients are malnourished (32-34). Malnutrition is an AE and can lead to other AEs; e.g., surgical wounds that do not heal as well and might become infected (35). During hospital stay, patients with hip fracture often do not receive the energy and calories they need post surgery (32, 36). As a result, malnourished patients
have a longer length of stay at the hospital (35, 37), and an increased risk of mortality during the first year after the hip fracture (38). Pressure ulcers are developed by 22%-29% of patients with hip fracture (7, 26, 27). For the patient, a PU is also very painful and negatively affects the rehabilitation process (39).

In 2007, the Swedish Association of Local Authorities and Regions (SALAR) launched a national initiative for improved patient safety. The national initiative focuses on eight AEs that are particularly common and serious: urinary tract infection, central line infection, surgical site infection, medication errors, fall injuries, PUs, malnutrition and medication-related problems. These AEs could in many cases be prevented through active, structured risk-reduction measures (20).

The nurses’ role to protect patients from AEs has shown to be significant (40-42). Through nursing assessments and interventions, it is possible to prevent delirium, pain, pressure ulcers, dehydration, malnutrition and constipation (43, 44). If these issues do occur, it is possible to resolve them if they are identified early and the nurse management is timely and appropriate (43, 44).

When performing clinical trials, AE have another definition: any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment (45).

Patient involvement

To improve patient safety, it is important to involve patients throughout the care pathway, from admission to discharge (46). Swedish legislation states that patients should be involved as much as possible in how their care is planned and performed, and all patients should be shown consideration and respect (18). This is not always the case in Sweden, however, a situation that may have a negative impact on both health outcomes and costs (47). In January 2015, a new piece of patient-centered legislation will take effect. This law has the aim of strengthening and clarifying the patients’ position and improving their integrity, self-determination and participation (48). Swedish researchers report that patients receive inadequate information about their treatment and examination results, few opportunities are presented to patients to participate in care decisions, and insufficient information is provided on self-care. It also tends to be worse for acutely admitted patients, who report lower scores for information and pain management than patients with planned admission (49).
When the preferences for involvement in their own care were investigated through interviews of a group of European patients over age 70, their answers were consistent: Older patients do want to be involved. The findings showed that the central issues for involvement include building a trusting relationship, respecting patients, giving patients sufficient time during consultations, and keeping them well informed (50). According to research, including patients on a surgical ward, patients want to be actively involved in their care; they want better communication and participation, not just to be a passive recipient. They want their feelings and opinions to be properly heard and incorporated in the decision-making process (51). The results from these two studies is in line with the international code of ethics for nurses (52). It is also possible to decrease readmissions to hospital by involving patients in the care transition (53).

Patients can play a key role to ensure their safety, even if the responsibility ultimately lies with the health care professionals (46, 54). By involving patients, nurses can empower them to help prevent medication errors or to notify staff when something is wrong, such as an incorrect medication (46). They can also reduce the risk of infection by asking nurses whether they have washed their hands before examinations or treatments (46).

**The nurse-patient relationship**

According to the WHO Safety Strategy, of central importance is to get the basics of care correct to support patient safety and welfare (55). However, lack of good nursing care has been identified as a problem worldwide (56). A framework, Fundamentals of Care (FoC), has recently been developed by an International Learning Collaboration (56). The central part of the FoC is the relationship between the nurse and the patient (57). This relationship is based on a commitment by the nurse to care for the patient and his/her significant others (58). This commitment includes physical dimensions such as keeping the patient warm, clean, hydrated, safe and fed, as well as psychological dimensions such as keeping the patients involved, informed and feeling dignified etc. (58). The commitment also includes a relational dimension wherein the nurse should ensure that goals are set and continuity in care is provided. The nurse should also be empathetic, respectful, compassionate and consistent with and to the patient. At each clinical encounter, the nurse has to be able to see the patient as a whole person, because the needs of the patient will be influenced by his/her illness state. The codependency of the nurse-patient relationship and the wider health care system or context surrounds the framework. This can influence the quality of the nurse-patient relationship through resources, staffing, leadership and broader policy and regulatory issues (58). From the patient’s perspective, the nurse’s commitments to the caring relationship are: be nice to me, keep me safe and help me heal (57).
Nutritional therapy

Research has shown that 30%-50% of the patients admitted to an orthopedic ward suffer from malnutrition (32-34). If hip-fracture patients are malnourished upon admission to the ward, they face a 2.5 times greater risk of developing a surgical site infection, a 5 times greater risk of developing a UTC-associated UTI, and an almost 4 times greater risk of developing a pressure ulcer than do patients without malnutrition (59). Therefore, it is important to identify patients who are at risk for or are malnourished upon admission to hospital in order to provide them with nutritional supplements to prevent postoperative complications (36). Patients with hip fracture are often malnourished upon admission to the hospital because they are elderly and frail (36). According to a Cochrane review, there is some evidence for the effectiveness of oral nutritional supplements in patients with hip fracture (60). A review by Cederholm and Hedström concluded that protein-rich supplements provided to patients with hip fracture may reduce long-term complications and days spent in hospital (61). Stratton and Elia found in their review that oral nutritional supplements (250-600 kcal/day) significantly reduced mortality and postoperative complications in elderly patients and patients in orthopedic care (62). Of note is that it is possible to start nutritional supplementation upon admission to hospital. It has also been reported that providing preoperative carbohydrate supplements to elective patients decreases postoperative insulin resistance (69). By decreasing insulin resistance, the surgical patient is more responsive to postoperative nutrition, which influences the recovery post-surgery (63) as well as shorter length of stay (64) as a result. However, it is not as simple as offering and providing food, fluids and various supplements to these patients. It is also of great importance to educate them about the importance of nutrition in order to help healing and prevent AEs (44).

There are several tools used for nutritional risk screening, including the Mini Nutritional Assessment and Nutritional Risk Screening (65). The purpose of screening is to predict the probability of a better or worse outcome due to nutritional factors (66). Some authors prefer to complement risk-assessment tools with biochemical nutritional markers such as albumin and transthyretin (prealbumin) (67). Research has shown that the biochemical marker Insulin-like Growth Factor 1 (IGF-1) could be useful when assessing nutritional status, especially as it has been shown not to be as affected as albumin in patients with an active infection. S-IGF-1 also has higher diagnostic sensitivity and specificity if the nutritional status improves compared to albumin (68, 69). It has been reported that S-IGF-1 levels increased while albumin levels did not change in patients with hip fracture who had received nutritional supplements for six months (70). The difference between albumin, transthyretin and IFG-1 is that albumin has a half-life time of about 19 days.
(71), while transthyretin has a half-life time of about 1.9 days (72) and IGF-1 has a half-life time of about 15 hours (73). Albumin, transthyretin and IGF-1 are proteins synthesized by the liver (71-73).

Cranberry capsules

UTIs are the most common bacterial infection found in the community and one of the most common hospital-acquired AEs; therefore, UTIs represent a significant healthcare problem (28). UTIs cause about 90% of all UTIs in hospitals (31). Patients with hip fracture often routinely receive a UTC preoperatively to reduce postoperative bladder dysfunction because of anesthesia and analgesia (74). With the placement of a UTC, the risk of UTIs increases. It is therefore important to minimize the duration of use in all patients and especially in patients at risk of UTIs, such as women and the elderly (75).

To prevent UTIs, cranberry (Vaccinium macrocarpon Ait.) in juice or capsule form is the most commonly used naturopathic drug (76, 77). Cranberry contains a substance called proanthocyanidin (PAC) that is believed to prevent bacteria from attaching to the epithelial cells in the urinary bladder (76, 78-83). The blocking of bacterial adhesion by proanthocyanidin in cranberries prevents E. coli and other gram-negative bacteria from colonizing the uroepithelial cells (81, 84). Due to the structural complexities of the molecules and the lack of commercial standards, the absorption and metabolism of cranberry PAC have not been well studied (85). Research has shown that bacterial anti-adhesive compounds from cranberries enter the urine of humans following consumption of cranberry products (78, 80, 86). After intake of 240 ml cranberry juice cocktail containing 83 mg of PAC, the inhibition of bacterial adhesion peaks after four to six hours and persists for at least eight hours. This result suggests potential protection against bacterial attachment in the uroepithelial cells during this period of time (86).

A study from Canada indicated that juice or capsules containing cranberry, along with increased fluid intake, can prevent the occurrence of UTIs in sexually active women with recurrent UTIs by up to 40 % (87). There are also studies showing that it may not be cranberry but the higher fluid intake that prevents the UTIs (88). When evaluating the effect of preventing UTIs with cranberry juice in elderly men and women, no differences was seen between the placebo group and cranberry group (89). In a Cochrane review from 2004 of seven trials, reviewers requested well-designed, randomised placebo-controlled trials to investigate the preventative effect of cranberries on UTIs. Several of the earlier studies had been single blind and/or had small study populations (79). There is also a need for research to determine the optimal dosage of PAC (87).
Patients suffering a hip fracture tend to be elderly and fragile, and often have several comorbidities (4). In addition, the fracture itself is a major trauma for the patient. A significant number of patients with hip fracture also have to endure the consequence of an AE due to their comorbidities and because of the health care process (7, 90). An AE can cause patients a great deal of suffering, as well as longer lengths of stay in hospital and larger expenses for society (91). However, AEs can often be prevented (43, 44, 92). Nutritional supplementation for 12 days is reported to reduce the incidence of PU in patients with hip fracture (93). The incidence of postoperative complications has also been shown to decrease when patients receive nutritional supplements (60, 61). In most of the studies, the treatment period for nutritional supplementation is seven days to one month postoperative (94, 95). It is not clear if a short-term nutritional intervention lasting the duration of the stay on the orthopedic ward affects short-term outcomes for patients with hip fracture. It is also unclear if the nutritional biochemical markers albumin, transthyretin and IGF-1 are affected by the short-term nutritional intervention. Research has also shown, in relatively small studies, that it is possible to prevent UTIs with higher fluid intake (88) or cranberry juice in patients with recurrent UTIs (89, 96). The treatment period with cranberry products has ranged from between 18 days to one year (89, 97). According to Cochrane, larger randomised, placebo-controlled trials are needed in order to investigate the preventative effect of cranberry on UTIs (79). Still, it has not been investigated if cranberries are useful in preventing positive urine cultures in female patients with hip fracture and a urinary catheter during their short stay on an orthopedic ward. Another important consideration in patient safety work is involving patients in their care (48). It is unknown how patients with hip fracture experience their involvement in their care while on an orthopedic ward.

Furthermore, interventional studies are needed in order to evaluate the care of elderly and fragile patients such as patients with hip fracture. In this thesis, two interventions will be evaluated and patients’ views of their involvement in their care will be described.
Overall and specific aims

The overall aim of the thesis was to investigate whether patient safety can be improved for patients with hip fracture by nutritional intervention and by pharmacological treatment with cranberry concentrate. Another aim was to describe the patients’ experience of involvement in their care.

Study I
The aim was to investigate whether there were any differences between patients receiving nutritional intervention both preoperatively and over five days postoperatively and patients who did not regarding: 1. weight loss, confusion, PUs and nosocomial infections; 2. time to recover/return to preoperative ability in activities of daily living; 3. nutrient and fluid intake; 4. length of hospital stay.

Study II
The primary aim was to investigate whether the biochemical markers S-IGF-1, S-Transthyretin and S-Albumin were affected by patients’ energy intake. The secondary aim was to study whether the biochemical markers were useful in predicting postoperative complications.

Study III
The aim was to investigate whether cranberry capsules given pre- and post-operatively are useful in preventing hospital-acquired UTIs in female patients with hip fracture and urinary catheter.

Study IV
The aim was to describe how a group of elderly hip-fracture patients experienced their involvement in the nursing care they received in the orthopaedics ward.
Methods

Design
To answer the overall aim, different study designs were used. Studies I and II were intervention studies with a quasi-experimental design, with intervention and comparison groups. Study III was a randomised, double-blind, placebo-controlled trial with intervention and control groups. Study IV took a qualitative approach. An overview of study designs is presented in Table 1.

Table 1. Overview of studies I-IV.

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample</th>
<th>Data collection</th>
<th>Data analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Quasi-experimental</td>
<td>Patients with hip fracture n=100</td>
<td>Clinical report form</td>
<td>Parametric and non-parametric statistics</td>
</tr>
<tr>
<td>II</td>
<td>Quasi-experimental</td>
<td>Patients with hip fracture n=91</td>
<td>Clinical report form, blood samples</td>
<td>Parametric and non-parametric statistics</td>
</tr>
<tr>
<td>III</td>
<td>Randomised Controlled Trial</td>
<td>Female patients with hip fracture n=215</td>
<td>Clinical report form, urine specimens</td>
<td>Parametric and non-parametric statistics</td>
</tr>
<tr>
<td>IV</td>
<td>Descriptive</td>
<td>Patients with hip fracture n=16</td>
<td>Interview</td>
<td>Systematic text condensation</td>
</tr>
</tbody>
</table>

Setting for studies I-IV
The research studies were performed in the orthopaedic department at a large Swedish university hospital. Data collection for Studies I and II was performed on one trauma orthopaedic ward with 23 beds. For Studies III and IV, patients were included from two orthopaedic trauma wards, with 23 and 17 beds, respectively. Each year, nearly 500 patients with hip-fracture have surgery at the hospital participating in this research.

When patients have sustained a hip fracture, they usually arrive at the emergency department by ambulance. In the ambulance, patients receive pain medication and the affected leg is stabilized with a pillow. At the emergency department, patients are seen by a doctor, who performs an examination and orders pain management measures, often a femoral peripheral nerve block. An RN informs patients about what has happened and what will happen. The
RN also asks patients whether they are in pain, as well as several questions about nutrition and elimination. The RN also scan patients’ bladders to ensure that they do not require intermittent catheterisation. The RN also takes venous blood samples, ensures that patients’ nutritional and elimination needs are fulfilled, inspects patients’ skin and performs an electrocardiogram. The patients’ fractured hip is x-rayed, and from the radiology department, patients are transferred directly to the orthopaedic ward. At the ward, patients are prepared and optimised for surgery by the RN, AN and physician in charge.

The goal is that all patients with hip fracture undergo surgery within 24 hours of admission to hospital. The mobilisation process starts the first postoperative day. The postoperative hospital stay for a patient in an orthopaedic trauma ward is on average eight days, followed by discharge to the patient’s home, to a rehabilitation ward or to a nursing home.

The RN is responsible for the nursing care: assessing, planning, implementing and evaluating the care plan, as well as for medication administration. Important in the nursing process is performing risk assessments, and implementing interventions to prevent common AEs (e.g. PU, malnutrition, falls, infections). The RN should also coordinate the team involved in patient care and ensure that patients receive the best care possible. When caring for patients with hip fracture, teamwork is important. The AN is responsible for tasks such as showering patients upon arrival and ensuring that beds are clean. The orthopaedic surgeon has overall medical responsibility for the patient, e.g. prescribes medications and performs the surgery. The physiotherapist and the occupational therapist focus on patients’ rehabilitation. The physiotherapist focuses on physical training with patients, while the occupational therapist focuses on participation in activities of daily living. Dieticians are consulted when patients support from this competency.

Study I
Participants
The 100 patients with hip fracture in study I were enrolled consecutively from September 2005 until October 2006. The first 50 patients formed the comparison group, while the second 50 made up the intervention group. To achieve a significant and clinically relevant difference, 50 patients in each group were needed, with a significance level of 0,05, power 0,80 and effect size medium large (98). Exclusion criteria comprised patients in need of dialysis, patients with kidney disease requiring protein-reduced food or fluid restrictions, and patients with severe liver disease. Of the patients enrolled in
the study, 71 were women and 29 men; their mean age was 81 years. At admission to the ward, all eligible patients were given oral and written information about the study and were asked to participate.

**Intervention**

The intervention group received nutritional supplements according to new nutritional guidelines (Table 2). The guidelines were developed by a multidisciplinary team consisting of a nurse, a dietician, an anaesthesiologist, and an orthopaedic surgeon with a special interest in and knowledge of nutrition. The guidelines reflected the latest research. The energy need (30 kcal/kg) was calculated for each patient and a specific energy intake goal was set for each day (99, 100). Fluid and energy intake were calculated for five days postoperatively. If the nutritional goal was not reached, additional interventions were performed according to guidelines, including intravenous fluids and tube feeding, if necessary.

The comparison group received regular nutritional support (Table 2), but no written guidelines were followed. After surgery, each patient’s fluid intake was assessed and, if it was found to be inadequate, the patient might or might not receive an infusion (5% glucose 1000 ml), depending on the physician’s or nurse’s knowledge and discretion. No protocol was established for nasogastric tube feeding.

Table 2. *Daily nutritional intake according to hospital standards and the nutritional guidelines. Differences in possible caloric intake between hospital standards and the new nutritional guidelines.*

<table>
<thead>
<tr>
<th></th>
<th>Comparison group, hospital standard Kcal</th>
<th>Intervention group, nutritional guideline Kcal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preoperative</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50 mg/ml glucose infusion (1 x 1000 ml)</td>
<td>200</td>
<td>600</td>
</tr>
<tr>
<td></td>
<td>Preoperative carbohydrate drink (4 x 200 ml)</td>
<td>1000</td>
</tr>
<tr>
<td>Total preoperative</td>
<td>200</td>
<td>Total preoperative 1600</td>
</tr>
<tr>
<td><strong>Postoperative</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breakfast, lunch, dessert and dinner</td>
<td>1090</td>
<td>1090</td>
</tr>
<tr>
<td>Nutritional supplement drink: (2 x 200 ml, 1 x 120 ml)</td>
<td>900</td>
<td></td>
</tr>
<tr>
<td>Total postoperative</td>
<td>1090</td>
<td>Total postoperative 1990</td>
</tr>
</tbody>
</table>
Data collection

The RN and AN working in the ward received 30 minutes of education on how to perform the study assessments. Assessments were performed at admission and five days postoperatively by the author or the RN or AN on the ward (Table 3). From admission until five days postoperatively, each patient’s nutrient and fluid intake were assessed.

Table 3. Assessments, Study I.

<table>
<thead>
<tr>
<th></th>
<th>Admission</th>
<th>Postop day 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of PU</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>PU classification</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Weight</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Infections</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Cognitive ability</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Walking assistance</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Functional ability</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Risk of pressure ulcer

The Modified Norton Scale (MNS) was used to identify patients at risk for developing PUs. The MNS contains subscales on mental condition, activity, mobility, food intake, fluid intake, incontinence and general physical condition on a four-grade scale, whereby 1 indicates complete lack of function and 4 indicates normal function. Patients with a score of \( \leq 20 \) are considered to be at risk for developing PUs (101). The majority of at-risk patients are identified with the MNS (102, 103).

Pressure ulcer classification

Patients’ skin was examined for PUs. The category of a PU was determined using an international classification system:

Category 1. Non-blanchable erythema.

Category 2. Partial thickness skin loss involving epidermis, dermis, or both.

Category 3. Full thickness skin loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed.

Category 4. Full thickness tissue loss with exposed bone, tendon or muscle. Necrotic ulcer was classified as Category 4 (104). The pressure ulcer card was used when categorizing the pressure ulcers (105).

Weight

Weight was measured with the patient sitting, wearing light clothes and shoes, on the morning of the first postoperative day and five days postoperatively, measured in kilograms to one decimal place.
Infections
The medical record was audited for evidence of hospital-acquired infection, i.e., a positive bacterial culture or an x-ray-confirmed pneumonia.

Cognitive ability
Patients’ mental status was assessed using the Short Portable Mental Status Questionnaire (SPMSQ). The SPMSQ contains ten questions. The maximum score is 10, with a low score indicating low cognition (106). The questions include, for example, the Prime Minister’s name, what day it is, and how old the patient is. The SPMSQ gives nurses an objective view of patients’ cognitive ability and is simple and easy to use. The SPMSQ is a validated scale and has good interrater reliability (107, 108).

Walking assistance
Patients were asked about their need for walking assistance prior to the fracture being sustained. The different walking-assistance levels used and assessed included no walking assistance, one crutch, two crutches, a walker, a walking frame or a wheelchair.

Functional ability
The Katz index was used to assess functional ability. Upon arrival to the ward, a nurse asked about patients’ prefracture functional ability. The index includes dressing, bath, toileting, transfer, continence and feeding activities. The index has three different levels, graded 1 to 3. Level 1 means patients needed no help performing the activity, Level 2 means they needed assistance to perform the activity, and Level 3 means they were not able to perform the activity on their own (109). If patients could not say, relatives or nurses were asked. The Katz index was developed to assist with rehabilitation by helping assess whether a patient had progressed (109).

Data analysis
For descriptive purposes, mean values, standard deviations, ranges, medians, interquartile ranges and percentages were used. For comparison between groups, a student’s t-test was used for continuous variables (e.g., weight, ml, kcal, years and length of stay), and a chi-squared test was used for dichotomous variables (e.g., PU yes/no, infection yes/no, fracture type, type of surgery, infections and gender). The Mann-Whitney U-test and Wilcoxon Signed Rank Test were used for non-parametric analysis (e.g., SPMSQ, PU grade, MNS, Katz and walking assistance). For comparison within the groups, a paired sample t-test was used for parametric data (e.g., kg.). A logistic regression was conducted. The outcome measure was the presence of PUs (Category 1-4) five days postoperatively. The presence of PUs at ad-
mission, preoperative length of stay, nutritional intervention and weight at admission were used as covariates in the model. The logistic regression is presented with 95% confidence intervals. Significance level $p < 0.05$ was used. Not all analyses are shown in this document.

**Study II**

**Participants**

Study II enrolled 88 of the patients from Study I. Nine patients were lost to follow-up because they left the ward earlier than four days postoperative, or the blood samples were not taken. Because of the short half-life time of the biochemical markers, the blood samples had to be taken on day four or five postoperatively. The comparison group consisted of 46 patients, 31 women and 15 men. The intervention group consisted of 42 patients, 31 women and 11 men. The mean age for both groups was 81 years.

**Intervention**

Intervention was the same as in Study I.

**Data collection**

Venous blood samples were taken at admission to the ward and five days postoperatively by the author or an RN at the ward to measure the levels of S-Albumin, S-Transthyretin and S-IGF-1. S-CRP was also analyzed to elucidate how inflammation affects the nutritional biochemical markers. Biochemical analyses were performed at the Department of Clinical Chemistry at Uppsala University hospital. The samples were kept frozen until analysis by established routine methods at the laboratory.

S-Albumin $<35$ g/L was interpreted as moderate malnutrition and S-Albumin $<30$ g/L was interpreted as severe malnutrition. S-IGF-1 $<55$ µg/L was interpreted as moderate malnutrition. S-Transthyretin $<170$ mg/L was interpreted as moderate malnutrition. S-CRP was used to evaluate the acute-phase response following the fracture event and the surgical procedure.

Each patient’s nutrient and fluid intake was assessed daily from admission until five days postoperatively. PU classification and hospital-acquired infections were assessed as in Study I.
Data analysis

For descriptive statistics, comparisons between groups and non-parametric analysis, see Study I. For comparison within the groups, a paired sample t-test was used for parametric data (e.g., kg, g/l, mg/l and µg/L). Significance level $p < 0.05$ was used.

Study III

Participants

In Study III, 227 consecutive female patients with hip fracture were enrolled. The mean age for the patients was 82.9 years. The enrolment period started in July 2009 and ended in May 2013. Eligible participants were female patients with a hip fracture over 60 years of age who signed an informed consent at admittance to the orthopaedic ward. Exclusion criteria were: presence of a permanent indwelling urinary catheter, warfarin treatment, kidney disease treated with dialysis or protein-reduced food, severe liver disease, high alcohol intake, on-going UTI under treatment, antibiotic treatment upon arrival to the ward, or a general state of health making it unethical to ask for participation. A calculation was performed to estimate the sample size needed in this study. It was based on a pilot study with 23 patients with hip fracture at the orthopaedic ward; five days postoperatively 50% of the patients had a positive urine culture. With 80% probability to detect a 20% reduction in UTIs using a significance level of 0.05, 100 patients in each group were needed. A drop-out rate of 20% was expected; thus, the sample size was increased by 25%, for a total of 250 patients, with 125 in each group. Patients were enrolled from 090701 until 091113, 100316-100623 and from 100906 until 120524. The study was closed for two periods because of summer vacation and organizational changes in the department.

There were some problems with study protocol adherence; as a result, the study population was sought to be expanded. Unfortunately, the study was closed when 227 patients were enrolled, because at that point best-before date of the capsules had passed and it was not possible to obtain an equivalent product. Of the patients who were enrolled, 94 were excluded from the final analysis because they did not adhere to the study protocol.

Intervention

Each patient received two capsules three times a day from admission until five days postoperatively. Each capsule contained 550 mg of cranberry powder (NurtiCran®90) or placebo powder. The cranberry capsule contained 4.2 mg of the active ingredient PAC. The daily dose was 25.2 mg of the active
ingredient. At admission, patients answered the questionnaires and received
the first two capsules, at least 30 minutes before receiving the UTC and the
first urinary specimen was taken. Two days postoperatively, the UTC was
removed. The capsules were prescribed in the electronic health record by a
physician, and the RN administered the capsules to patients and documented
it in the electronic health record.

Endpoint
The primary endpoint in the study was a positive urinary culture at day five
or 14 among patients with sterile urine at admission. A positive urinary cul-
ture was defined as growth of a single organism, urine pathogen (primary or
secondary) of greater than $10^4$ cfu/ml urine specimen (110).

The secondary endpoints were clinical symptoms of UTI (e.g., increased
body temperature, frequency of passing urine, pain when urinating) and
health-related quality of life by measuring health status, mobility, self-care,
usual activities, pain/discomfort and anxiety/depression.

Data collection
Data were collected at arrival to the ward and at days two, five and 14 post-
operatively (Table 4). At all three postoperative assessments, the electronic
health record was audited for AEs. Fluid intake was also measured at admitt-
tance until five days postoperatively. Data were collected by the author, a
study nurse or a nurse at the ward.

Table 4. Data collection, Study III.

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Admittance</th>
<th>Postop day 2</th>
<th>Postop day 5</th>
<th>Postop day 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine culture</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Cognitive ability</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health-related</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>quality of life</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>UTI Symptoms</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>AE</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Urine culture
Urine samples were collected for bacterial analysis -- type of bacteria and
amount. Analyses were performed at the Department of Clinical Microbiol-
ogy at Uppsala University hospital in Sweden.

How bacteriuria is diagnosed depends on the patient, the sampling method
and the bacteria type. In this study, only women were enrolled and the urine
was collected either mid-stream urine or through the catheter if the patient still had a catheter in place.

**Cognitive ability**
Assessed with SPMSQ, as in Study I.

**Health-related quality of life**
EuroQol-5D (EQ-5D) is a standardized instrument for use as a measure of health-related quality of life. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status. It is cognitively simple, taking only a few minutes to complete. The instrument includes questions about mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has three levels: no problems, some problems and extreme problems (111).

**UTI Symptoms**
A study-specific questionnaire was developed to collect and record patients’ UTI symptoms. Patients were asked about increased body temperature, whether they needed to urinate frequently and whether they felt pain when urinating.

**Data analysis**
All data was monitored by an external expert according to Good Clinical Practice (45).

An intention to treat (ITT) analysis was performed including all randomised patients. The effect of the intervention was analysed both for the ITT population and among the per protocol (PP) population; it included patients who had taken more than 80 % of the capsules and had a pre- and at least one postoperative urine culture. The effect was analysed in the ITT population to avoid selection bias. AEs were measured in the ITT population.

Statistical analysis for descriptive purposes was performed as in Study I. The three levels in EQ-5D were divided into a dichotomous variable; problems or no problems (112). For comparison between groups, a student’s $t$-test was used for continuous variables (e.g. ml, age, hours with catheter and length of stay) and a chi-squared test was used for dichotomous variables (e.g., gender, positive urine culture yes/no). A significance level of $p < 0.05$ was used.
Study IV

Participants
The participants in study IV were patients with hip fracture admitted to one of the two selected wards at a university hospital in Sweden. A total of 16 patients were asked to participate between December 2011 and May 2012, and all accepted. The group of interviewed patients with hip fracture consisted of 13 women and 3 men; their mean age was 78 years (range of 65-92 years).

Qualitative interviews
Data were collected through interviews with patients. The interviews were performed approximately 14 days after surgery, a time when patients typically have recovered physically from surgery but still have a clear recollection of what happened during their stay on the ward. The interviews were conducted while patients were still at the orthopaedic ward (n=2), were at the rehabilitation ward (n=11) or were at home (n=3). When interviewing patients at hospital, interviews took place in a conference room outside the ward. An interview guide with open-ended questions was used. First, patients were asked about what happened when they fractured their hip. As the main question, patients were asked to describe their nursing care experience, for example rising from bed the first day after surgery or going to the toilet. Probing questions were used throughout the interviews, which lasted between 20 and 75 minutes. The interviews were recorded and transcribed verbatim.

Data analysis
Systematic Text Condensation (STC) according to Malterud (113) was used to analyse data. The method is inspired by Giorgis phenomenological analysis. STC is a descriptive approach, presenting the experiences of the participants as expressed by them, rather than exploring possible underlying meaning of what was said. STC requires that researchers have sufficiently identified their preconceptions, so that bracketing can be imposed during various steps of the analysis (113).

The analysis was started by the first author (A-KG) reading through all the interviews to identify preliminary themes. Relevant text units from all interviews were sorted under headings representing these themes. For each theme, sub-themes were created, further structuring the text units placed under each heading. The themes and sub-themes were discussed by the authors, and then reformulated and reconstructed until consensus was reached.
The sub-themes were only used as a tool during analysis and were not included in the presentation. To illustrate each theme, quotes from the interviews were chosen. The steps of analysis described so far constitute a process of decontextualisation. The next step was recontextualisation, when all the interview texts were reread with the themes in mind. The themes were then reformulated and, finally, more quotes were added.

The first author and interviewer (A-KG) is an RN with 9 years of experience in the care of orthopaedic patients. However, she had not worked clinically on the orthopaedics ward for three years before the present study. The second author (JL) is a consultant anaesthetist with experience in the area qualitative research. The third author (LG) is a registered nurse and professor in nursing science with expertise in quality improvement. The second and third authors have significant experience in working with patients with hip fracture.

Ethical considerations

All studies were approved by the regional Ethical Review Board in Uppsala (Reg No 2005:150, 2007:287, 2011:346). Study III was also approved by the Medical Products Agency, EudraCT number: 2008-002390-13. The studies were performed in accordance with the Declaration of Helsinki (114). Each patient received verbal and written information about the study and signed an informed consent at the time of study inclusion. If the patients were unable to fully understand the information, a relative was given the information and as a proxy asked about the patient’s participation (except for Study IV). The recommendations for research ethics in Sweden were followed (115). The participants had the right to withdraw from the studies at any time. All data were handled confidentially, and presentation of data has been made in such way that no single participant can be identified. All data were labelled with code numbers to ensure confidentiality.

It is always a delicate matter to ask patients to participate in a research study. When involving patients with a hip fracture it is particularly challenging, because patients were to be enrolled in the studies before surgery (Studies I-III). Therefore, the nurse had to ask patients to participate upon their arrival to the ward. Patients thus had to make a decision during a time when they were affected by acute illness and in a very stressful situation. The nurse who asked patients to participate in the study was the same nurse on whom patients would rely to receive good care while at the ward. The nurses were clear to patients that their decision to participate or not would not influence the care given.
Furthermore, patients with cognitive impairment were asked to participate in Studies I-III. About one-third of the patients admitted to hospital for hip fracture have a diagnosis of dementia (116). In a systematic review comprising 72 trials, including patients with hip fracture, only 20% of the trials included patients with dementia or cognitive impairment (117). It is important to include these patients, as they are more sensitive and vulnerable to AEs and constitute a large part of the patient group. In such cases, a relative was informed about the study and asked to give informed consent on the patient’s behalf.

Patients asked to participate in Study III were also informed that if they did not participate in the study, they would get an indwelling UTC according to routine standards at the orthopaedic department.

Patients in Study IV were asked by the author to participate in the interview study about a week after surgery. They were still in hospital when they were asked to participate, and there could be a risk of feeling pressured to participate. However, the author wore non-clinical clothing and presented herself as a doctoral student when talking with patients to mitigate this risk.

The patients who participated in these studies were at no time at risk. However, the research results may improve the care received by patients in the future.
Results

Study I
Two-thirds of the 100 patients included in the study were female. They had a mean age of 81 years, and the time in hospital before surgery was approximately 24 hours. Upon arrival to the ward, no significant differences were observed between the intervention and comparison groups regarding age, gender, preoperative time, cognitive ability, risk for PU, presence of PU, infections, walking ability or walking assistance. The only difference observed was weight; the weight for the intervention group was significantly higher 68.5kg vs. 62.6 kg \((p = 0.048)\). There were no significant differences between the groups regarding the type of surgery performed. During the first three postoperative days, the patients in the intervention group received significantly more calories and fluids than the patients in the comparison group. This shows compliance with the study protocol.

Significantly fewer patients in the intervention group (18.0%) had PUs five days postoperatively compared with those in the comparison group (36.0%) \(\chi^2 = 4.1, \df = 1, p = 0.043\) (Table 5). The patients in the intervention group who had developed PUs had one (mean) ulcer each; in the comparison group, patients with an ulcer had developed 1.4 (mean) ulcers each. The incidence, i.e. the patients who had developed PUs during the hospital stay, was calculated to be 28% (14 of 46) in the control group and 18% (9 of 47) in the intervention group.

Five days postoperatively, 8.7% (n=4) in the intervention group and 18.0% (n=8) of the patients in the comparison group had a hospital-acquired infection, a difference that did not reach a level of significance (Table 5).

In terms of weight, there was still a significant difference observed between the groups five days postoperatively. However, no significant differences were detected statistically within the groups from arrival until five days postoperatively using a paired sample t-test (control group; \(p = 0.286\), intervention group; \(p = 0.077\)).
Table 5. Pressure ulcers and hospital-acquired infections at arrival and five days postoperatively, n=50 in each group.

<table>
<thead>
<tr>
<th></th>
<th>Arrival to the ward</th>
<th>Five days postoperatively</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Comparison group</td>
<td>Intervention group</td>
</tr>
<tr>
<td>Pressure ulcer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category 1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Category 2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Hospital-acquired infections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UTI</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Wound infection</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

Five days postoperatively, no significant differences were found in terms of mental status, risk of PU or nosocomial infections. The risk of PUs decreased equally in both groups and the scores for functional ability and walking assistance increased equally for both groups. No significant differences were found.

The median postoperative length of stay was seven days (IQR 4) in the intervention group and nine days (IQR 8) in the comparison group ($p = 0.137$).

The presence of PUs at admission, preoperative length of stay and not receiving the nutritional intervention were predictors of PU development, according to the results of the logistic regression ($\chi^2 = 24.56$, df = 4, $p < 0.001$). If a patient had PUs at admission, there was an increased risk of 30 times of developing PUs during their hospital stay. The patient’s weight at admission had no effect on the development of PUs.

Study II

The intervention group had significantly higher postoperative energy intake than that in the control group; for example, 1600 kcal versus 841 kcal postoperative day three.

S-IGF-1 decreased significantly ($p<0.001$) between admission and five days postoperatively in the comparison group, while there were no significant differences in the intervention group ($p=0.269$). Within both groups, S-Albumin and S-Transthyretin decreased significantly and S-CRP increased significantly. Non-malnourished and malnourished (moderate and severe) patients identified by the different nutritional biochemical markers are shown in Table 6.
In the comparison group, postoperative complications were found in 21 (46%) patients. Sixteen patients developed PUs, seven patients had hospital-acquired infections, and two patients had both. In the intervention group, postoperative complications were found in 13 (31%) patients, nine patients with PUs and four patients with hospital-acquired infections.

Table 6. Results of the different nutritional biochemical markers at admission and five days postoperatively, divided into non-malnourished and malnourished.

<table>
<thead>
<tr>
<th></th>
<th>Arrival to the ward</th>
<th>Five days postoperatively</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Comparison group</td>
<td>Intervention group</td>
</tr>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Albumin Non-</td>
<td>35 (88)</td>
<td>30 (67)</td>
</tr>
<tr>
<td>malnourished</td>
<td>3 (7)</td>
<td>8 (17)</td>
</tr>
<tr>
<td>Malnourished¹</td>
<td>5 (12)</td>
<td>15 (33)</td>
</tr>
<tr>
<td>Transthyretin Non-</td>
<td>28 (67)</td>
<td>31 (69)</td>
</tr>
<tr>
<td>malnourished</td>
<td>11 (26)</td>
<td>14 (30)</td>
</tr>
<tr>
<td>Malnourished²</td>
<td>14 (33)</td>
<td>14 (31)</td>
</tr>
<tr>
<td>IGF-1 Non-</td>
<td>35 (83)</td>
<td>35 (78)</td>
</tr>
<tr>
<td>malnourished</td>
<td>22 (52)</td>
<td>32 (70)</td>
</tr>
<tr>
<td>Malnourished³</td>
<td>7 (17)</td>
<td>10 (22)</td>
</tr>
</tbody>
</table>

¹<35 g/L ²<170 mg/L ³<55 µg/L

At admission to the ward, there were no significant differences between the group of patients who developed a postoperative complication and the ones who did not in terms of the three nutritional biochemical markers S-Albumin, S-Transthyretin and S-IGF-1. The mean postoperative length of stay was 10.5 days (SD 5.3) in the comparison group and 7.9 days (SD 4.3) in the intervention group, p=0.014.

Study III

A total of 227 female patients with hip fracture were randomised (ITT population). Figure 1 shows the study flow diagram. Included in the per-protocol (PP) analysis were patients who had taken ≥ 80 % of the capsules and had had the preoperative and at least one postoperative urine culture. The PP population included 133 patients, 59 (52% of the randomized patients) in the placebo group and 74 (65% of the randomized patients) in the cranberry group. In total, 94 (41 %) patients out of 227 had not taken ≥80 % of the capsules or submitted a successfully cultured urine sample at follow-up.
Figure 1. Flow diagram, Study III.

Table 7. Baseline characteristics for the ITT population.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>n Placebo group</th>
<th>n Cranberry group</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age; mean (SD)</td>
<td>114 86,2 (8,9)</td>
<td>113 83,1 (8,6)</td>
<td>0,667^a</td>
</tr>
<tr>
<td>BMI, mean (SD)</td>
<td>93 24,4 (4,8)</td>
<td>102 23,1 (4,0)</td>
<td>0,038^a</td>
</tr>
<tr>
<td>SPMSQ, mean (SD)</td>
<td>91 7,59 (3,0)</td>
<td>92 7,26 (3,4)</td>
<td>0,814^b</td>
</tr>
<tr>
<td>UTI last 12 months, n</td>
<td>114 19</td>
<td>113 26</td>
<td>0,382^c</td>
</tr>
<tr>
<td>Positive urine culture at admittance, n</td>
<td>103 31</td>
<td>105 33</td>
<td>0,835^a</td>
</tr>
<tr>
<td>Fracture type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trochanteric fracture, n</td>
<td>58</td>
<td>54</td>
<td>0,739^c</td>
</tr>
<tr>
<td>Cervical fracture, n</td>
<td>51</td>
<td>52</td>
<td></td>
</tr>
<tr>
<td>Symptoms of UTI at admittance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High temperature, n</td>
<td>114 4</td>
<td>113 6</td>
<td>0,586^c</td>
</tr>
<tr>
<td>Urgency, n</td>
<td>114 22</td>
<td>113 21</td>
<td>0,895^c</td>
</tr>
<tr>
<td>Pain when urinating, n</td>
<td>114 4</td>
<td>113 7</td>
<td>0,329^c</td>
</tr>
</tbody>
</table>

^aStudents t-test ^bMann Whitney U test ^cChi square test
The baseline characteristics for the ITT population are shown in Table 7. The baseline characteristics did not differ between the groups in the PP population or between the PP population and the group of patients excluded from the PP analysis (data not shown). The BMI differed between the groups in the ITT population. Regarding UTI symptoms, 49 patients experienced symptoms; 25 patients in the placebo group and 24 in the cranberry group. Of the patients with symptoms, 11 had urgency and pain, and two had urgency, pain and a high temperature.

At baseline, about 30% of the patients in the ITT population had a positive urine culture. The change over time for five and 14 days postoperatively is shown in Table 8. The most common bacterium at baseline was *E. coli*, which colonised 49 of 64 (77%) patients. The same was true at days five and 14, when 70% and 64% were colonised with *E. coli*, respectively.

To evaluate the preventative effect of cranberry capsules only the patients with a hospital-acquired UTI were analysed; patients with a positive urine culture at admission were excluded. There were no differences between the groups in the ITT or the PP populations, Table 8. As antibiotic treatment strongly influences the result of the urinary cultures, an analysis of the PP population excluded all patients who were treated with antibiotics other than as prophylaxis. No differences were seen between the groups at five or 14 days postoperatively, Table 8.

<table>
<thead>
<tr>
<th>Positive urine culture</th>
<th>Placebo group</th>
<th>Cranberry group</th>
<th>p-value, RR, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admittance to the ward ITT</td>
<td>31 of 103 (30)</td>
<td>33 of 105 (31)</td>
<td>0.835, 1.019, 0.591-1.222</td>
</tr>
<tr>
<td>5 days postop ITT</td>
<td>29 of 72 (40)</td>
<td>32 of 82 (39)</td>
<td>0.874, 0.979, 0.758-1.266</td>
</tr>
<tr>
<td>14 days postoperatively ITT</td>
<td>24 of 70 (34)</td>
<td>25 of 71 (35)</td>
<td>0.908, 1.014, 0.797-1.291</td>
</tr>
<tr>
<td>Hospital acquired UTI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 days postoperatively ITT</td>
<td>15 of 44 (34)</td>
<td>14 of 53 (26)</td>
<td>0.411, 0.896, 0.686-1.170</td>
</tr>
<tr>
<td>14 days postoperatively ITT</td>
<td>10 of 43 (23)</td>
<td>12 of 49 (24)</td>
<td>0.890, 0.969, 0.623-1.506</td>
</tr>
<tr>
<td>Hospital acquired UTI no extra antibiotics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 days postoperatively PP</td>
<td>13 of 34 (38)</td>
<td>11 of 46 (24)</td>
<td>0.167, 0.812, 0.595-1.107</td>
</tr>
<tr>
<td>14 days postoperatively PP</td>
<td>9 of 33 (27)</td>
<td>9 of 37 (24)</td>
<td>0.778, 0.961, 0.728-1.268</td>
</tr>
</tbody>
</table>
| The potential effect of cranberry capsules on the occurrence of any acquired bacteriuria, i.e., the proportion of patients with sterile urine at admittance and a positive culture at either day five or day 14 postoperatively, was investigated. Of the patients in the PP population, 16 of 38 (42%) patients in the placebo group and 18 of 51 (35%) patients in the cranberry group presented
a positive urine culture at either five or 14 days postoperatively ($p=0.513$, RR 0.895, CI 0.638-1.255). Excluding patients who were treated with antibiotics other than perioperative prophylaxis, 14 of 34 patients (41%) in the placebo group and nine of 37 patients (24%) in the cranberry group had a hospital-acquired positive urine culture at either five or 14 days postoperatively ($p=0.130; 0.777; 95\% \text{ CI} 0.556.1.087$).

The patients were asked about clinical UTI symptoms. Five days postoperatively, eight of the 61 patients with a positive culture reported an urgency to urinate; seven of them had received cranberry capsules ($p=0.018$ RR 0.143; 95% CI 0.019-1.057). This was the only statistically significant difference between the groups at any point during the study.

In the ITT analysis, no significant differences between the groups regarding health-related quality of life (EQ5D) were observed at any time point. In the PP population, the only difference between the groups was in the anxiety/depression dimension. At arrival to the ward, 53% (n=31) of patients in the placebo group reported moderate or extreme anxiety/depression compared to 24% (n=17) in the cranberry group ($p=0.001$). At five days postoperatively, there were no differences between the groups. At 14 days postoperatively, 55% (n=29) of patients in the placebo group and 33% (n=21) of patients in the cranberry group reported moderate or extreme anxiety/depression ($p=0.019$).

Analyses were performed to determine whether sustaining a hospital-acquired positive urine culture influenced patients’ health-related quality of life, regardless of treatment group. Among patients in the ITT population who presented a positive urine culture during the study period, 25 of 35 (71%) of them reported moderate or extreme anxiety/depression at postoperative day five, compared to 26 of 65 (40%) of patients with a negative urine culture ($p=0.003$). At 14 days postoperative, there were no differences between the groups.

There was a difference in the registered amount of total fluid intake at the day of surgery, in both the ITT and the PP populations, Table 9. There were no significant differences between the groups regarding time to surgery or the number of hours with UTC in place. No differences were observed between the groups in the type or dose of perioperative antibiotic prophylaxis. Most patients received Cloxacilline. Nor were differences observed between the groups regarding the antibiotics taken from time of surgery until day five and from day six until day 14, all postoperatively. The most common antibiotic prescribed to patients during the study period was Pivmecillinnam for UTI. All results are shown in Table 9.
Table 9. Potential confounding factors for placebo and cranberry groups in both ITT and PP populations.

<table>
<thead>
<tr>
<th></th>
<th>ITT population</th>
<th></th>
<th>PP population</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Placebo group</td>
<td>Cranberry group</td>
<td>p-value</td>
<td>Placebo group</td>
</tr>
<tr>
<td></td>
<td>n=113</td>
<td>n=114</td>
<td></td>
<td>n=59</td>
</tr>
<tr>
<td>Time to surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>hh (SD)</td>
<td>58 (16)</td>
<td>27 (17)</td>
<td>0.663&lt;sup&gt;a&lt;/sup&gt;</td>
<td>29 (18)</td>
</tr>
<tr>
<td>Time with UTC</td>
<td>76 (39)</td>
<td>79 (33)</td>
<td>0.642&lt;sup&gt;a&lt;/sup&gt;</td>
<td>74 (38)</td>
</tr>
<tr>
<td>Perioperative antibiotics</td>
<td>n=110</td>
<td>n=108</td>
<td></td>
<td>n=59</td>
</tr>
<tr>
<td>Cloxacilline 2g</td>
<td>67</td>
<td>78</td>
<td>0.180</td>
<td>40</td>
</tr>
<tr>
<td>Cefuroxime 1,5</td>
<td>39</td>
<td>24</td>
<td></td>
<td>18</td>
</tr>
<tr>
<td>Antibiotics prescribed during the study</td>
<td>n=106</td>
<td>n=105</td>
<td></td>
<td>n=59</td>
</tr>
<tr>
<td>Pivmecillinam 200mg</td>
<td>10</td>
<td>10</td>
<td></td>
<td>8</td>
</tr>
<tr>
<td>Daily total fluid intake, ml</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day of surgery</td>
<td>2156 (1164)</td>
<td>1856 (1083)</td>
<td>0.046&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2542 (827)</td>
</tr>
<tr>
<td>Postop day 1</td>
<td>1498 (970)</td>
<td>1426 (850)</td>
<td>0.552&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1733 (926)</td>
</tr>
</tbody>
</table>

<sup>a</sup> Students t-test

There were no differences between the two groups in the number of detected AEs (51 in the placebo group, 45 in the cranberry group). The most frequent AE reported in the study was the occurrence of UTIs, affecting ten patients in the placebo group and 16 patients in the cranberry group. Renal failure was the second most common AE. Six patients in the placebo group and four in the cranberry group were diagnosed with renal failure. Three patients died during the study, one in the placebo group and two in the cranberry group.

Study IV

The analysis of the interviews resulted in six themes.

**Patients suffer considerable, sometimes unbearable pain, which can hinder rehabilitation.**

According to the patients, they were told by nurses that they had to cope with pain in order to get well. Some patients reported that they did not receive any pain relief. Patients described terrible pain during the first few days after surgery, which made it difficult for them to cooperate with the nurses. Patients were afraid of the pain, but thought they had to accept it, even though they did not know how to cope with it. Patients described not even wanting to go to the bathroom.
Patients are at the mercy of the staff and cannot even decide when to go and relieve themselves.
Patients reported that there was a lot of waiting, especially when they wanted to go to the toilet. First, after ringing for help, they had to wait in bed until someone arrived; then, after they were done in the bathroom, they had to wait again. Sitting there, they found it difficult to know how much time had passed.

Patients feel abandoned in an organisation that seems disorganised. They are often confronted with facts about their care without having been involved in the planning.
Patients feel as if they are pawns in a game. They are transferred to different wards within the hospital and to other units in the county without being informed in advance or taking part in the planning. Patients see a chaotic and poorly functioning organisation on the orthopaedics wards. They experience their healthcare as a mix of highly specialised medical care and ineffective and messy organisation.

Patients often feel that they aren’t valued, and are treated accordingly.
Patients have to fall in line as the staff decides what should be done and how. Staff simply performed their tasks without involving the patient in any way. Should healthcare professionals make a mistake, they did not apologise to the patient. Patients also experienced that when they were in hospital, they had to follow the ward routines, no matter what they may personally have wanted. They had to stand in line and did not necessarily get the time to do things in their own way and at their own pace. This often resulted in more pain for the patients. Patients also felt that they were not wanted on the ward as soon as they were formally discharged, although they had not left yet. Patients stated that the nurses acted like they did not care about them, as if the patients were no one with a right to say anything about anything.

Fellow patients, for better or worse: They interfere with your sleep or disturb your peace and quiet, but they can also make you feel calm and happy.
Patients described how their fellow patients screamed in pain, like children, when healthcare professionals worked with them. In addition, the nurses would disturb patients by moving in a new patient in the middle of the night, or performing bedside nursing care in the room, preventing other patients from sleeping. However, sometimes patients felt sympathy with their fellow patients. Fellow patients made them feel happy and calm and made the hospital stay and rehabilitation easier.
Good interaction between patients and nurses encourages and activates the patients.

When staff are perceived as highly professional, patients dared to be more active. Staff can coach patients to take responsibility for their care. Patients felt that they could ask the nurses at any time if they had questions about something or wanted something. Patients felt that they needed to be pushed by the nurses, because some things they would not do voluntarily.
Discussion

In this thesis, the focus has been on improving patient safety for patients with hip fracture. This thesis has concentrated on the evaluation of two interventions, and additionally, on describing patients’ view of their involvement in care. The result from the nutritional intervention showed that fewer patients developed PUs if they had had a higher nutritional intake. Furthermore, it was possible to objectively evaluate a short-term nutritional intervention using the nutritional biochemical marker IGF-1. The cranberry intervention to prevent UTIs did not seem to have any preventive effect for female patients with hip fracture. Finally, patients had experienced low involvement in care during their stay at the orthopedic ward.

Nutritional intervention

When patients with hip fracture received nutritional supplementation, fewer patients had PUs at five days postoperatively, compared to patients in the comparison group. This is in line with previous results, when development and onset of PUs were delayed (93). However, a systematic review of nutritional supplements for patients with hip fracture showed that while some evidence supports the effectiveness of oral supplements, the overall effectiveness is still weak (118). In earlier research among patients with hip fracture, nutritional supplementation has shown to be favorable for recovery and outcome (62, 118, 119). In the present study, not receiving the nutritional intervention was a predictor for developing a PU. As shown earlier, nutritional supplements decrease postoperative complications in patients with hip fracture (62).

The nutritional intervention with nutritional supplements pre- and postoperatively increased the calorie intake of patients. This result is in line with previous research including nutritional supplements for patients with hip fracture (34). Nutritional supplements between meals are recommended for patients not meeting their energy intake goal (120). Still, patients do not typically receive the energy intake/calories they need after surgery (32, 36). Therefore, it is favorable to start the supplementation already at admission to the ward, preoperatively (63). Introduction of nutritional guidelines has been found to reduce barriers to providing nutritional support (121). Through a
rather modest bedside nursing intervention, giving the patients nutritional supplements, it is possible to increase the patient’s calorie intake and prevent AEs.

The patients received the nutritional intervention from admission to the ward until five days postoperatively. Previously, the length of intervention differed from 10 to 28 days (34, 94, 122). Although the intervention period was short, it was possible to get an objective measurement of the patients’ nutrient intake through the nutritional biochemical markers. This is in line with previous results, which stated that nutritional intake is important for levels of circulating IGF-1 (32, 123-125). It is also shown earlier that the levels of circulating IGF-1 changed with only one week of supplementation (126). However, IGF-1 is a test that so far is more reliable at the population level than the individual patient level (69). In the present study, there were no differences in albumin and transthyretin at five days postoperatively. This was in contrast to another study with a ten-day nutritional intervention, where differences in both albumin and transthyretin were seen (127). However, since IGF-1 is still not reliable for measurements in individual patients, more research is needed before it is useful in clinical practice.

Cranberry intervention

Another way to increase patient safety for those with hip fracture is to prevent them from having to endure the consequences of a UTI. The present study was the first study investigating the preventative effect of cranberry capsules in female patients with hip fracture and UTC. This is a group of patients predisposed to developing UTIs (75).

A five-to-eight day course of treatment with cranberry capsules for female patients with hip fracture and indwelling urinary catheter, however, did not seem to have any preventative effect on the occurrence of positive urine cultures. This is in line with the results of the latest Cochrane review (2012) on the topic, which found that there is no evidence to support that cranberry juice can prevent UTIs. Cranberry capsules do not appear to be any more effective (128). Previously, the prevention of UTIs was ascribed to a higher fluid intake, rather than cranberry capsules or juice (88). Surprisingly, patients in the control group had a significantly higher fluid intake at the first day after surgery. This difference was observed on only one day and it was the first postoperative day.

In the previous study, the amount of PAC was analysed and found to be a daily dose of 25.2 mg. However, in most of the studies with cranberry capsules, the amount of PAC in the capsules is not reported (128). A year after
the study was initiated, the ideal dose was found to be 36 mg of PAC (129). The daily dose of 25.2 mg PAC in the capsules corresponds to about 200 ml of cranberry juice (129). The amount of cranberry juice/juice cocktail used in other studies varies from 30 ml to 750 ml a day, with the percent of PAC unknown (87, 130). It might be possible that a higher dose would have been effective in preventing UTIs for this group of patients. Before introducing new treatments in clinical practice, it is of great importance that the treatment is evidence-based, for example, in the dose and length of treatment.

Patient involvement

The qualitative study showed that patients with hip fracture often experience low or almost no involvement in their care. When patients are involved in their own care, patient safety is increased (46). It is often healthcare professionals who want patients to be passive recipients of care (131). Patients’ preferences for their involvement in care are also complex, and health professionals need to identify each patient’s individual preferences and capabilities for participation (132). Preferences for involvement may change from day to day for patients in a surgical setting, whose health status may change over time (133). Research has shown that patients want to be actively involved in their care and for example, want better communication and to build a trusting relationship (50, 51).

In general, patients reported severe pain that made it impossible to rest, mobilise or be comfortable. Experiences of pain and insufficient pain management have been reported earlier (16, 134) despite the existence of evidence-based assessments and guidelines (43, 135). This is a remarkable finding, since an important responsibility of the RN is to assess patients’ pain, administer analgesics (when patient need them) or perform other nursing interventions to ease pain and evaluate the effect of the treatment. There are evidence-based guidelines and well-known analgesics, but still the patients reported severe pain.

Some patients did experience a good relationship with their nurses, and those who did so dared to do more and were more active. Earlier mobilization can prevent a number of potential AEs, constipation, PUs and malnutrition (43, 44). Patients who are involved in their care also know that they can and should tell the RN when anything feels wrong, such a new sense of pain or a wet dressing. Patient can also help prevent medication errors (46). However, even though patients can play a key role, it is important to remember that the responsibility ultimately lies with the health care professionals (46, 54).
Study patients felt they weren’t valued by the nurses and were treated accordingly. In order to be able to involve patients in their nursing care, RNs need to establish a relationship with their patients. This relationship is built on a commitment from the nurse to care for the patient (58). This commitment means that RNs are nice to patients, keep them safe and help them heal (58). A relationship can be caring or uncaring. A caring relationship can improve health, while an uncaring relationship may lead to a decreased feeling of health and discouragement (136). The aim of the caring relationship is to improve patients’ health status (137). One focus in the relationship is to keep patients calm, informed and involved (58).

The results can be applied to the model by Wilde et al (1993). According to this model, patients have two kinds of desires regarding their care: human and rational. Humanity includes patients’ desire for respect for their unique situation, a beneficial socio-cultural atmosphere (physical-administrative qualities) and a care organization featuring health care professionals with an identity-oriented approach (person-related qualities). Rationality includes patients’ desire for predictability and order in their care. Health care organisations should provide medically-technically competent staff (person-related qualities) as well as the physical-technical conditions that patients need (physical-administrative qualities)(138).

**Prerequisite for the nurse in bedside patient safety work**

It is possible for every RN to increase patient safety by rather modest bedside nursing care intervention. However, patients with hip fracture still do not receive the bedside nursing care that they need (139). The care that these elderly and fragile patients need is complex, and RNs need certain knowledge and skills (139). Patients’ needs are physical, psychosocial and relational, as examined/described in this thesis. Patients need nutrition to avoid PUs; they need to be respected and involved. Nurses need to be empathetic and set goals with patients (58). The RN needs to see the whole patient and her/his needs in a culture of “thinking and linking.” In this culture, the RN establishes a caring relationship with patients, and is nice to patients, keeps them safe and helps them heal (58). The opposite culture is of “time and task,” where care is depersonalized and RNs perform nursing interventions as if they checking items off a list to demonstrate they have done their duty (58).

To attain a culture of “thinking and liking”, different factors come into play. First, the individual nurse, her level of education, and her level of experience may have some influence. Whether a nurse involves patients in care does not necessarily have to do with their years in practice (140). However, at the
department where these studies took place, there had been a high turn-over among the nurses. This might explain the results in this thesis, since having only a half-year of experience as an RN might influence the way someone performs and delivers nursing care to the patients, operating more as in a culture of time and task. The existing culture at the ward itself may also influence whether it is possible to reach a state of “thinking and linking”. If there is a culture of working safely, it could be considered easier to reach the “thinking and linking” culture (141). At the hospital were the studies were performed, the healthcare professionals describe a culture where they do not experience support from top management in their patient safety work. In addition, there is a low compliance of reporting AEs (142).

Patients’ experience of their care involvement in this study differs from how patients in a different study Hommel et al (2012) described their view of nursing care. In that study, patients felt secure and healthcare professionals showed interest in and empathy for patients (16). In the county council where the Hommel study was performed, there is ongoing, systematic patient safety work to involve patients in their care. This is the kind of initiative that is lacking where the current study was performed (143), showing that the context might be of great value. The culture and the context need to be improved to fulfill patients’ wishes for humanity and rationality in care (138). One possible approach to come closer to a culture of “thinking and linking” may be hourly rounding, whereby each patient is proactively visited every hour by a nurse and their needs are met accordingly, for example, alleviation of pain, thirst or need to go to the bathroom (144).

Methodological considerations

This thesis includes both quantitative and qualitative research designs, a strong combination. The quantitative studies capture measurable factors and statistical significances. The qualitative approach gives a deeper understanding of the phenomena under study. There are some strengths and weaknesses that will be further discussed. First, a reflection on the fact that clinical studies require the effort of a number of health care professionals. In the intervention studies, nurses on the wards enrolled patients and made study-specific assessments. At busy times on the ward, other nursing interventions have been prioritised due to enrolling patients or performing study-specific assessments, as shown in earlier studies (145).

Studies I and II

One strength of this study is that the intervention is performed during the short period of time when the patient is on the ward. The impact of the inter-
vention is evaluated at five days postoperatively, when the patient usually is discharged from the ward. We evaluated what difference the intervention made for patients during their short stay on the orthopedic ward. Another strength is that patients with dementia or cognitive impairment were included in Studies I-III. Since they are one third of the group of patients a very important group of the patient had been lost if we had excluded them (117). All instruments used to collect data are well known, often used in research including patients with hip fracture and are validated.

Randomising patients to different treatment groups would have been the best study design; an alternative would have been to randomise wards. However, randomising patients on the same ward would be ethically wrong, since two patients in different groups could share a room, where one receives the intervention and the other does not. This could present a difficult situation for both patients and nurses. Randomising two wards would have been a good alternative, but it is difficult to find two wards with identical routines.

A long-term follow-up to see the effects of the intervention over time would have been a positive addition. However, in this study only the short-term effect was investigated. It would also have been positive to ask patients about their experiences from the intervention, to get their view. The sample size was estimated with the significance level of 0.05, the power to 80 and the effect size as medium-large (98).

The biochemical analyses used in Study II are standardized and reliable and performed at a certified laboratory. There are no universally accepted cut-off levels for IGF-1, transthyretin or albumin in regard to malnutrition assessments; the cut-off value for every biochemical marker is a compromise between specificity and sensitivity. When evaluating concentration changes during a dietary intervention, as in our study, this is not of major concern.

Study III
This study was a randomised controlled trial. The randomisation was performed by an external company; they randomised the numbers on the plastic containers in which the capsules were pre-packed. The treatment group was blinded for patients, health care professionals and study staff, since the capsules was identical in appearance. Since the patients were randomised, the groups should be about equal in size. The ITT groups were, in fact, alike in size (113/114); however, the PP groups differed (59/74). It is expected that the groups would be alike since they were randomised, even when it came to withdrawals; they too should be equal. The questionnaires Eq-5D and SPMSQ used in this study are validated. The questions about UTI symptoms
are not validated, but the questions are used in practice to ask about clinical symptoms of UTI.

One-third of patients had a positive urine culture upon admission to the ward, which was unexpectedly high. It takes a few days to receive the results of a urine culture, making it impossible to enroll patients upon receiving the result, since treatment with cranberry capsules was to begin upon admission to the ward. There was a difference in BMI between the groups even though the patients were randomised. It is unknown whether body weight affects whether a patient presents a positive urine culture.

As the study progressed, there was a large number of patients who did not adhere to the protocol. It was impossible to expand the study population because the capsules’ best-before date had been reached, and it was impossible to obtain an equivalent product. Of the 227 randomised patients, 41% were excluded from the PP analysis; these patients were elderly, fragile and acutely admitted to hospital with a hip fracture. They often had several comorbidities that made them frail and at risk of AEs. Their frailty and AEs might affect their ability to take treatment capsules and be mobilised enough to provide a urine sample. Some patients were excluded by the responsible physician during the study because the patients were too ill to continue.

Other patients were lost to follow-up due to administrative problems. For example, the physician in charge may not have prescribed the capsules in the electronic health record. The complexity of this patient population led to difficulties in maintaining the power of the study. However, from a statistical point of view, the fact that the results from the PP analysis were consistent with the results from the ITT analysis increased the study’s reliability. On the other hand, the groups in the PP population were inadequate, and no significant differences between the groups were found. Nonetheless, in several of our subgroup analyses, we saw a directional trend towards a decreased number of hospital-acquired UTIs in cranberry-treated patients, suggesting that the treatment may have some clinical effect. Thus in order to determine whether this treatment is of value for this patient population, more research is needed.

Study IV

The strength of Study IV is that it provides valuable insight into how patients with hip fracture experience involvement in their care while in hospital. However, some limitations need to be discussed. The fact that the patients were selected from one hospital is one limitation. It would be of value to sample a group of patients from another hospital or region. However, due to economic reasons, this was not possible. The lack of gender balance is an-
other limitation. Only three of the 16 patients enrolled in the study were men, although only about 30% of the patients sustaining a hip fracture are men.

To retain dependability (reliability), an interview guide with open-ended questions was used, and the author conducted all interviews. Probing questions were used during the interviews to increase the richness of the data. Patients described different situations experienced on the ward and were encouraged to speak freely. All interviews were transcribed. The author has limited experience performing qualitative interviews. To assure credibility (internal validity), two co-authors, both of them experienced qualitative researchers, were involved in the analysis of the data. The themes and sub-themes were discussed among the authors until consensus was reached. The themes were verified with quotations from the interviews, which strengthens the confirmability (113). The reader of the study will decide whether the results are relevant in other situations, demonstrating transferability (external validity) (146).

The authors clinical experience as a nurse at an orthopedic ward raised considerations about taking things for granted during the interviews. She paid attention to this and tried to keep this in mind during the interviews, and asked for clarifications and examples about their own experiences. Before starting to interview patients, the author wrote down her preconceptions and all her thought about the study.
Conclusions

This thesis investigated whether it was possible to improve safety for patients with hip fracture through a nutritional intervention and cranberry capsules, and described the patients’ experience of involvement in their own care. The conclusions:

- Nutritional supplements to patients with hip fracture increased patient safety by decreasing pressure ulcers (Study I).

- S-IGF-1 can be used as a short-term nutritional biochemical marker, as it was affected by a five-day high-energy regimen (Study II).

- Cranberry capsules do not seem to influence patient safety for female patients with hip fracture and indwelling urinary catheter in preventing positive urine culture (Study III).

- Patients with hip-fracture reported experiencing very little involvement in their nursing care, to the extent that fundamental aspects of nursing care went unfulfilled (Study IV).
Clinical implications and future research

Elsa, the woman described in the preface, needed excellent nursing care due to her hip fracture and comorbidities. The nurses caring for Elsa can definitely make a difference for her in bedside nursing by involving her in her nursing care, preventing AEs and improving patient safety. According to the results described in this thesis, the optimal outcome is for nurses to:

- Provide all patients with hip fracture with nutritional supplements pre- and postoperatively to increase their nutritional intake and to prevent AEs.

- It is important to build trusting relationships with patients, keep them informed and treat them with respect, in accordance with what older patients perceive as care involvement.

- Use a pain-assessment scale to assess patient’s pain, perform the pain-management interventions needed and evaluate the pain relief intervention.

To further increase patient safety for patients with hip fracture improved nursing care is one core aspect. It could be of interest to find out if any of the following ideas could influence the care given and the safety for the patient.

- An intervention study to evaluate the effect of hourly rounding, where nurses works proactive with the patients.

- Examining how patients with hip fracture want and should be involved in care, followed by intervention studies to involve them and, of course, to evaluate the effect of that involvement.

- Investigate the impact of a multiprofessional team on the nutritional treatment for patients with hip fracture and identify the optimal nutritional supplement.
Svensk sammanfattning


rutinmässigt en urinvägskateter. En UVI behandlas med antibiotika. Antibiotikabehandling kan leda till antibiotikaresistens och är kostsam för samhället. För att förebygga UVI har man sedan länge använt tranbär, i form av juice eller kapsel. Det är dock oklart om en kort tids behandling med tranbär kan förebygga UVI hos äldre kvinnor som har urinkateter i samband med operation för höftfraktur. En annan viktig del för att förbättra patientsäkerheten är att patienten medverkar i vården. Till exempel att patienterna är så välinformerade att de vet att de ska säga till om det är något som är fel eller de inte förstår, som att deras smärta förändras eller de får fel läkemedel. Trots att det finns en svensk lag om patientmedverkan som påpekar detta är medverkan låg och det är negativt både för utfallet av vården och även för kostnaderna. Patienter med höftfraktur har inte tidigare blivit frågade hur de upplever medverkan i vården.

Det övergripande syftet med denna avhandling är att undersöka om det är möjligt att förbättra patientsäkerheten för patienter med höftfraktur genom en nutritionsskötsel, där en av handlingen består av fyra studier där både kvantitativa och kvalitativa metoder används. Delarbete I och II är interventionsstudier med kvasiexperimenterell design. Delarbete III är en randomiserad dubbelblind läkemedelsprövning. Studie IV är en beskrivande studie där kvalitativa intervjuer användes.

I delarbete I var syftet att undersöka om det fanns någon skillnad i resultatet gällande postoperativa komplikationer, rehabilitering, vårdtid, mat och vätskeregistrering från ankomst till sjukhus till fem dagar efter operation mellan patienter som fick nutrition enligt nya riktlinjer (n=50) och de patienter som fick nutrition enligt sedvanlig rutin (n=50). De nya riktlinjerna innebar att patienten fick näringsdryck som mellan målet tre gånger per dag, fick dricka kohydratuppladdningsdrick inför operationen och erhöll en större mängd dropp före operationen och nutritionsdropp om patientens operation blev uppskjuten till nästa dag. Undersökningar gjordes, dels när patienten kom till avdelningen och dels fem dagar efter operationen för att utvärdera riktlinjerna. Resultaten visade att det var färre patienter som utvecklade trycksår om de erhöll nutrition enligt de nya rutinerna. Kalori- och vätskeintaget var högre hos de patienter som erhöll nutrition enligt de nya riktlinjerna.

För att undersöka hur olika nutritionssmarkörer i blodet påverkas av ett ökat energiintag under en kort tid togs blodprover när patienterna kom till avdelningen och fem dagar efter operationen, delarbete II. Det var 46 patienter i gruppen som fick nutrition enligt de nya riktlinjerna och 42 patienter som fick enligt sedvanlig rutin som analyserades. Resultaten visade att det traditionella blodprovet för att mäta nutritionsstatus (albumin) inte påverkades, medan det nya blodprovet (IGF-1) påverkades av det ökade energiintaget.
IGF-1 verkar vara bättre för att objektivt utvärdera effekten av en kort tids ökat nutritionsintag. Dock behövs mer forskning kring IGF-1 innan det kan börja användas kliniskt.

I delarbete III undersöktes om tranbär i form av kapslar kan förebygga att kvinnliga patienter med höftfraktur som har en urinvägskateter i samband med operation får en sjukhusförvärvad urinvägsinfektion. För att se en skillnad som finns behövdes det 100 utvärderbara patienter i varje grupp. Patienterna lottades till att tillhöra antingen den grupp som fick kapslar innehållande tranbär (n=113) eller den grupp som fick placebo (n=114). Patienterna erhöll kapslar tre gånger per dag från att de kom till avdelningen till fem dagar efter operationen. Patienterna lämnade urinodlingar vid ankomst till avdelningen, fem och fjorton dagar efter operationen för att utvärdera effekten av tranbär. När de patienter som saknade ankomst- eller uppföljande urinodling och de som tagit mindre än 80% av kapslarna tagits bort återstod 59 patienter i placebogruppen och 74 i tranbärsgruppen. Resultaten för dessa patienter visade att tranbär inte hade någon effekt för just den här patientgruppen. Resultaten var lika när alla patienter som lottats till en av grupperna var med i beräkningarna. Resultatet är svårvärd erat eftersom grupperna inte var så stora som de behövde vara.

Avslutningsvis i delarbete IV undersöks hur patienter med höftfraktur upplever medverkan i vården på en ortopedisk vårdavdelning. Tre män och tretton kvinnor med höftfraktur intervjuades och materialet analyserades med hjälp av systematisk textkondensering. Resultatet visade att patienterna inte upplever att de får medverka i vården, inte ens så pass att fundamentala delar av omvårdnaden uppfylldes. Patienterna upplevde att de var längst ner i hierarkin och blev behandlade därefter. Många patienter beskrev outhärdlig smärta under tiden de vårdades på ortopedavdelningen, trots att det finns evidensbaserade riktlinjer för smärtbehandling. Men var det ett bra samspel mellan patient och personal så vågar patienten mer, blev mer aktiv och gjorde mer än hon annars skulle gjort.

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