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LAPAROSCOPIC CHOLECYSTECTOMY

Patients' experiences of self-reported
symptoms, perception of health and sense
of coherence in the short and long term
perspective

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ABSTRACT

The aim of **Study I** was to explore patients' experiences related to gallstone disease and to their experiences of postoperative symptoms during the first week following outpatient laparoscopic cholecystectomy (LC). Twelve patients treated in day surgery were interviewed one week after surgery and a qualitative analysis was performed. A number of symptoms were expressed, e.g. preoperative anxiety, postoperative amnesia, experience of pain, need for additional pain medication, feelings of nausea and difficulties having small children at home. In a randomized study (**II**), the aim was to compare the two treatment modalities, outpatient and inpatient LC, the first postoperative week. Seventy three patients answered questionnaires concerning perceptions of pain and other postoperative symptoms, the amount of distress these symptoms caused and the levels of anxiety and general health during the first postoperative week after LC surgery. The result showed no significant differences between the outpatient (n=34) and the inpatient (n=39) groups regarding the occurrence of postoperative symptoms except from a slightly higher frequency of reduced mobility (outpatients day 1) and sleeping disturbances (inpatients day 7). In **Study III** the progress of recovery up to 6 months following LC was investigated, as well as sex differences. The above-mentioned questionnaires were repeatedly answered by the 73 patients up to six months following surgery. Patients' perception of health improved over time, especially depending on increased physical well-being between day 7 and 1 month. Symptom occurrence and symptom distress decreased rapidly during the first postoperative week. However, 30% of the patients reported at least one distressful symptom at 6 months. In **Study IV**, the aim was to investigate predictors of average pain the first postoperative week (VAS-mean) and changes in Health Index (HI) following LC with special reference to Sense of Coherence (SOC). Except for the questionnaires above, the 73 patients also completed the SOC scale preoperatively and at 6 months. By multiple regressions, 29% of the variability in VAS-mean could be explained by the variables age, HI and education. Further, 19% of the variability in HI improvement between day 7 and 1 month could be explained by symptom distress day 1 and the SOC (preoperative value). SOC was found to be a weak but significant predictor of health improvement and pain after LC. Patients scoring low SOC regained health later than patients scoring high SOC.

Key words: Ambulatory surgery, anxiety, controlled trial, day surgery, gallstone disease, health, laparoscopic cholecystectomy, pain, sense of coherence, symptom distress, symptom occurrence

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LIST OF ABBREVIATIONS

ASA	American Society of Anesthesiologists Physical Status Classification
BMI	Body mass index
EWB	Emotional well-being
GIQLI	Gastrointestinal Quality of Life Index
HI	Health Index
HIV	Human immunodeficiency virus
IASP	International Association for the Study of Pain
IPS	Inpatient surgery
ITT	Intention to treat
LC	Laparoscopic Cholecystectomy
NSAID	Non steroidal anti-inflammatory drugs
OPS	Outpatient surgery
POD	Postoperative day
PONV	Postoperative nausea and vomiting
PWB	Physical well-being
RCT	Randomized controlled trial
SCT	Stem-cell transplantation
SF-36	Short Form 36
SFD	Symptom Frequency and Distress Scale
SOC	Sense of Coherence
SRH	Self-related health
STAI	State Trait Anxiety Inventory
VAS	Visual Analogue Scale
WHO	World Health Organization

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1 INTRODUCTION

1.1 Gallstone disease and gallstone symptoms

Gallstone symptoms are frequently experienced in the population. The prevalence of gallstone disease increases with age, and, at 75 years or more, 53% of women and 32% of men either have gallstones or have previously undergone cholecystectomy [1]. Approximately 80% of all gallstones are asymptomatic [2, 3]. Female sex, age and obesity, low serum cholesterol levels are identified as significant risk factors for the development of gallstones [4] and gallstone disease can lead to serious complications like acute cholecystitis, common bile duct stone or acute pancreatitis [5]. The diagnosis of gallstones is based primarily on patients' anamnesis of pain attacks and the presence of gallstones. Since 1980 the presence of gallstones has been diagnosed with ultrasonography [2].

A typical pain pattern for gallstone attacks starts after food intake in the late evening or at night. In 35% of the patients, the pain attacks occur between midnight and 03.00 and the most common duration of these attacks is usually from 30 minutes to 2 to 5 hours [6]. Further, Berhane *et al.* [6] reported that all patients had pain in the right upper quadrant including the upper midline epigastrium. Ninety percent of the patients could define an area of maximal pain. Maximal pain was located under the costal arch in 51% of the patients, in the epigastrium 41%, behind the sternum 3% and in the back 5%.

Although 74% of the patients used analgesics for pain relief such as non-steroidal anti-inflammatory drugs, the pain intensity was reported to be very high, (mean 90 mm VAS, 0-100 mm). Before the pain attacks started, 90% of the patients recognized a pattern of a low grade warning of pain and a need for walk around during the attacks. This was described by 71% of the patients. Other symptoms described by approximately half of the patient group during a gallstone attack were perspiration, constricting pressure under the diaphragm and difficulty in breathing. Dyspepsia and bowel symptoms were mentioned. Intolerance of at least one kind of food was experienced by 66% of the patients and almost half of the patients did not tolerate fatty foods [6].

1.2 Managing daily life with gallstone disease

To live with gallstone disease during the waiting time for surgery, involves a prolonged period of decreased health during which patients' psychological and social life suffers

in some degree. Oudhoff and co-workers [7] investigated patients with gallstones with regard to providing insight to the physical and psychosocial impact of waiting for elective surgery. No association was found between the time the patients had to wait for surgery and the perceptions of general health. During the waiting time, problems concerning one or more dimensions of quality of life were reported by 74% of the patients. Especially pain/discomfort and daily activities were affected during time waiting for surgery. The mean levels of anxiety measured with the STAI instrument were significantly higher during the waiting time than 3 months after surgery, but not higher than the mean score obtained from a sample of the general population. Of wage-earning patients, sick leave was reported by 12%, whilst 39% found their leisure activities were interfered with by the condition. Patients with gallstones reported limitations in going out (39%), inference with hobbies (20%) and with meeting family or friends (22%). Delayed surgery put patients at risk for developing acute complications requiring hospital admission and urgent treatment. Emotional reactions to waiting tended to be less negative when patients received information of the date of surgery. Dimensions of anxiety/depression were significantly improved after surgery than compared to before [7].

1.3 Treatment of gallstones

The main treatment of cholelithiasis is surgery. Earlier, open surgery was the standard approach but decreased surgical trauma with the laparoscopic technique has a clear advantage with a significantly smaller scar, less postoperative pain, shorter hospital stay and faster return to normal daily activities and work [8-10]. Compared to open cholecystectomy, reductions in morbidity, pain and fatigue have been demonstrated with laparoscopic surgery [11]. Moreover, there is also an obvious clinical advantage of LC over open cholecystectomy because of less metabolic stress response [12]. Patients with previous episodes of acute cholecystitis (14%) are more likely to respond a successful operation [12]. LC is more likely to be successful when performed within 3 days of the onset of symptoms [13].

1.4 Laparoscopic cholecystectomy

LC is one of the most common surgical procedures in the western world. Approximately 50,000 cholecystectomy procedures are performed annually in England and 500,000 in the United States [14]. The first LC was performed by Dr. Erich Mühe in Böblingen, Germany 1985 and, at the same time, the two surgeons Philippe Mouret

and Francois Dubois brought the method to clinical acceptance in France. The first video demonstration of LC was performed in Bordeaux by Jacqu Perissat in 1989 and this was the starting point for this procedure throughout Europe. In Scandinavia the first LC was performed in 1990 in Norway [15]. Within a few years, almost all cholecystectomy procedures were performed laparoscopically in the western world [16].

When performing a LC procedure, the patient is placed in a supine position with a steep head-up tilt under general anaesthesia. To get access to the abdominal cavity, four small incisions, working ports (trochars) are made. To get visibility and access for dissection of the gallbladder, the abdomen is inflated with gas (usually CO₂) called pneumoperitoneum. In this procedure, intra-abdominal instruments (approximately 300 mm) are used. The other incisions are used for optics, light, instruments for suction and electrocautery. The gall bladder is removed through one of the working ports [17]. The operating time for LC with the aid of a robotic camera holder is approximately 70 minutes [18].

1.5 Day surgery

There has been a tremendous change over the past two decades in emphasis from inpatient to outpatient surgical care. The concept of day surgery was first developed in the 1950's by providing early discharge, shorter hospital stay for the patients and economic advantages for the health economy. The first surgical procedure performed to reduce the number of patients on waiting lists was a series of herniorrhaphies using local anaesthesia [19] and the move from hospital stay to early ambulation following surgery started. Day surgery has potential advantages both for patients and efficiency and effectiveness in the use of resources [20].

One of the first LC in outpatient surgery was performed in Indianapolis, USA [21]. More advanced surgery, such as laparoscopic fundoplication and adrenalectomy, has been reported in day surgery [22] [23]. To successfully increase the number of day surgery procedures, considerable attention has to be paid to quality and to the patients' acceptance of day surgery [24].

Rapid recovery after laparoscopic procedures, and advances in the anaesthetic technique, has made it possible to perform LC in day surgery [25, 26]. Due to large volumes of patients with gallstone disease, gallstone surgery demands considerable resources, so even small changes in management strategies have a great impact on total costs for society. Day surgery was developed to reduce waiting lists for elective surgery

and for increasing demand of cost savings [27]. Patients undergoing LC in day surgery are discharged within a few hours to recover at home. Approximately ninety percent of patients undergoing LC in day surgery are able to be discharged the same day [28].

1.6 Day surgery versus inpatient surgery

For evaluation of outpatient versus inpatient LC, several studies have been conducted [29-35]. The overall aims of these studies were to determine the feasibility of LC in outpatient surgery and to assess if patients may be discharged within 4 hours after surgery. The number of admissions, readmissions and complications were also considered. Patient satisfaction, quality of life, patients' and carers' experiences in convalescing from LC and the costs following LC were also investigated in some of the studies. A more detailed description of the published studies relating to outpatient versus inpatient LC between the years the 1998-2009 is shown in Table 1. A total of 507 patients were included in six studies comparing outpatient and inpatient LC. The results showed no statistically significant differences between the outpatient and the inpatient groups concerning admissions, readmissions or complications following LC [29, 30, 32-34]. Quality of life, patient satisfaction and resumption of activities were comparable between the investigated groups [29, 30, 32-34]. Moreover, no differences were found between patients' recovery scores [33, 35]. Pain, mobility and elimination displayed the highest mean scores (*i.e.* bad health) for both groups but inpatients experienced more problems with tiredness and eating [35]. Various results regarding costs for outpatient surgery have been reported. Hollington *et al.* [32] found no cost advantages for LC performed in day surgery, but in other studies, costs for LC in day surgery was found to be lower in comparison to inpatient surgery [30, 34, 36].

1.7 Symptoms

The word symptom has a Latin origin, *synthoma* and was first used in the 1600s. In the 1800s the word *sign* was differentiated from symptom. A sign is noticed by other people, defined as alteration by an observer and may be objectively observable. A symptom however, is defined as functional changes in an affected part of a body and is a subjective perception of an individual [37]. Assessment and management of symptoms are vital aspects of patient care through the entire illness trajectory of diagnosis, treatment and recovery from a disease. Symptom experience has been defined as the patients' perception and response to the two specific components,

Table 1. Published randomized controlled trials concerning outpatient versus inpatient laparoscopic cholecystectomy (LC) 1998-2009.

First author year, country	Purpose of the study	Participants and comparison group	Questionnaires	Results/Conclusions
Gurusamy 2008 [31] UK	To assess the advantages and disadvantages of day-case surgery compared with overnight stay in patients undergoing elective LC.	215 patients (day-care) 2:1 to (overnight-stay) were randomized. The trial recruited 49.1 % of patients presenting for cholecystectomy.	Meta analysis	No differences were seen between the groups regarding morbidity, prolongation of hospital stay, readmission rates, pain, QOL, patient satisfaction, return to normal activity and work. 80.5% of the day care patients were discharged on the day of surgery. Day care is safe and effective for symptomatic gallstone surgery.
Johansson 2006 [33] Sweden	To assess complications admissions, readmissions, QOL and health economics.	100 patients were randomized, (90 were included) to day-care procedure or overnight stay.	Hospital Anxiety and Depression scale and Psychological General Well-Being Index. Estimates of direct medical costs of each strategy were based on a reimbursement strategy.	Forty-eight (92%) of the day care patients were discharged 4 -8 h after LC. Forty-two (88%) overnight patients went home the following day. The overall conversion rate was 2%. Two day care patients had complications. No significant differences were found between the groups. The mean direct medical cost was lower for the day-care group.
Dirksen 2001 [30] Netherlands	To compare the effects and costs of an ambulatory treatment versus an overnight stay for LC.	94 patients were randomized, (86 were included) to outpatient or overnight stay.	Operative time, complications, hospital stay and readmissions, pain, nausea, activity, QOL1 and patient satisfaction were assessed after 1 and 6 weeks. Cost analysis was performed from a social perspective.	LC was successfully performed as an ambulatory procedure in 69% of the patients. QOL, patient satisfaction and resumption of activities in both groups were comparable. The ambulatory treatment was less expensive.
Curet 2002 [29] USA	To determine if LC patients may be discharged home after 4 hours with similar outcome as overnight patients.	80 patients were randomized (74 were included) to outpatients (OP) or inpatients (IP).	Patient demographics, degree of postoperative pain, PONV 2 and patient satisfaction, amount of pain and PONV medication taken, number of phone calls, readmissions and complications were investigated with questionnaires 24h, 1 week and 1 month after surgery.	Two OP were converted and 4 required admission. The OP group received more oral pain medication prior to discharge. Patients undergoing LC who are discharged home after 4 h postoperatively will experience the same satisfaction with no increase in complications as patients admitted overnight.

Table 1. Continued

First author year, country	Purpose of the study	Participants and comparison group	Questionnaires	Results/Conclusions
Young 2001 [35] Australia	To determine patients' and carers experiences convalescing from LC at home after discharge within 8 hours or 23 hours post-surgery.	28 patients were randomly assigned (28 patients were included) to 23 h stay or day procedure unit (DPU).	Self administered Postoperative Symptoms Diary measured day 1-4 and telephone interview on day 10 after surgery.	No differences were found concerning the experienced symptoms. Problems with mobility, pain and elimination recorded highest post-surgery mean scores for both groups. Overnight patients also had problems with tiredness and eating. The patients needed assistance from a carer.
Hollington 1999 [32] Australia	To evaluate clinical outcome and costs in patients undergoing LC in day-stay versus overnight-stay LC.	200 patients were randomized, (131 included) to inpatient or outpatient stay.	All patients were reviewed weekly using questionnaires about their recovery and telephone follow-ups. Cost comparisons were made between the groups.	18.3% in both groups required hospital care for PONV or conversion to open surgery. No cost advantages were found for the day-stay group.
Keulemans 1998 [34] Netherlands	To determine the feasibility and desirability of LC in day-care versus LC with clinical observation	80 patients, were randomized, (74 patients were included) to day-care (n=37) or clinical observation (n=37).	Complications, readmissions, consultations of general practitioners or day-care centre within 4 days, use of pain-medication, QOL, convalescence, time off, treatment preference and costs were investigated. Pain was scored 1,6,24,36,48 hours and 6 weeks after surgery.	Effectiveness was equal in both groups. All were satisfied with the treatment. No significant differences were found. Day care was less expensive.

QOL: Quality of life; PONV: Postoperative nausea and vomiting.

symptom occurrence and symptom distress [38]. However, the distinction between the occurrence of a symptom and the emotional response *i.e.* distress, has received limited attention [39].

1.7.1 Symptom occurrence

The most frequently reported symptoms after LC are pain, postoperative nausea and vomiting (PONV), inability to ambulate and fatigue [35, 40, 41]. The International Association for the Study of Pain [42] (IASP 1979 p. 210) defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage”. Pain can also be defined as “the normal predicted physiological response to adverse chemical, thermal or mechanical stimulus associated with surgery, trauma or an acute illness and, thus, characterize it as a sensory response” [43] (p. 2051). Pain can affect emotional, social, familial, occupational and physical functioning.

Postoperative pain after LC is a complicated phenomenon and is different from other laparoscopic procedures due to its three different and clinically separate components: incisional pain (somatic pain), visceral pain (deep intra-abdominal pain) and shoulder pain (presumably referred visceral pain), therefore the treatment of pain should be multimodal [44]. Significant predictors of pain in the early postoperative period are high body mass index, duration of anaesthesia and certain types of surgery among patients in day surgery [45].

Pain is reported to be the most common reported symptom. Following LC pain is most intense for the first 2-3 days with a high inter-individual variability and is dominated by incisional pain rather than other pain components. According to Cason *et al.* [46] approximately 70% of their patients reported abdominal pain with a pain intensity average of 3.5 on a Likert-type scale ranging from 0 (absent or low) to 5 (severe). Further, Talamini *et al.* [41] reported that the morning after LC, 19% of their patients rated pain as 9 or 10 on the VAS scale. When rating distress of pain on the day of surgery, postoperative day 1 and 2, Cason *et al.* [46] found that the patients' experiences exceeded predictions. Further, Cason *et al.* [46] showed that 85% of their patients reported pain the day of LC surgery and somewhat fewer (81%) reported pain the first postoperative day. The relief rate of pain after LC has been reported to be 92% [47].

PONV are also common clinical postoperative symptoms following LC [48]. Incidences of PONV within 24 hours after LC have been reported to occur in 53-72%

[49]. PONV are distressful experiences for patients that may not only delay discharge from hospital but also lead to dehydration, electrolyte imbalance [50], suture dehiscence [51] and oesophageal rupture [52]. Furthermore, patients have an increased risk of haematoma formation and aspiration pneumonitis due to the depression of airway reflexes postoperatively [53] [54]. Cason *et al.* [46] found that nausea was reported by 20% of the patients on postoperative days 2-3 and by 15% as late as postoperative day 7.

Reduced mobility is another common problem following LC surgery. Young & O'Connell [35] reported problems with reduced mobility during the first four postoperative days following LC. Further, Keulemans *et al.* [34], reported that despite no differences being found between inpatient and outpatient groups, reduced mobility was a problem also one week after LC surgery.

Postoperative tiredness or fatigue has been described as one of the most prevalent symptoms related to postoperative recovery after LC [55] and the most important reason for delay in returning to normal activities [56]. Tiredness is a direct consequence of the surgical stress response, psychological and metabolic disturbance, impaired muscle function and impaired nutrition [57]. In a study by Blitzer *et al.* [58], the patient reported outcomes following LC were mainly influenced by the preoperative level of satisfaction, age and self-reported postoperative complaints. However, patients over 50 years were more difficult to discharge from day surgery and this needs to be taken into consideration when planning LC in day surgery [59].

LC is intended to relieve pain and other symptoms of gallstones. Biliary pain, (gallstone pain) disappears in the majority of patients following surgery [2]. However, far from all patients are relieved from their postcholecystectomy symptoms and the onset of new symptoms are commonly reported. Upper abdominal pain persists in 6 to 41% of the patients 6 to 12 months after LC surgery [60]. Twenty five percent of the patients who reported a symptom as most bothersome, still suffered six months following surgery, but only 15% reported a poor outcome [12]. Moreover, 40% of the patients reported at least one persisting symptom at 6-months follow-up after LC [12]. Further post-cholecystectomy symptoms like dyspepsia and diarrhoea have been observed in 3% to 20% of patients 6 months to 10 years following LC [61-65]. Diarrhoea is reported to be persisting in 11%, and new onset of diarrhoea was developed in 11% of the patients [61].

1.7.2 Symptom distress

McCorkle and Young [66] were one of the first to define symptom distress in describing the degree of discomfort reported by patients related to experienced symptoms. They defined symptom distress as “the degree or amount of physical or mental anguish, or suffering experienced from a specific symptom” [37] (p. 243). Further, symptom distress is stated as ‘the degree or amount of physical or mental upset, anguish, or suffering experienced from a symptom’. Factors that determine symptom distress derive from a person’s normal function, sensation, appearance and interpretation of an experience [67].

The distress a specific symptom causes an individual is dependent on the individual’s coping ability [68] which is multifactorial, including personality characteristics, religion and social factors. Leventhal & Johnson explain the relationship between symptom occurrence and distress in their self-regulation theory [38]. This theory suggests that symptom occurrence is the stressor that initiates distress, *i.e.* the emotional response and coping behaviours. Distress makes a patient act, ask for help, and use known coping behaviours to ease the emotional response to the stressor and/or reduce the stressor. A patient with adequate coping behaviours is able to decrease or eliminate distress. However, if the coping strategies are ineffective or absent the distress escalates. [67]. Generally, patients often experience two or more symptoms regardless of diseases or medical conditions. The occurrence of more than one symptom may result in severe symptom distress [67, 69]. Professionals in clinical settings should evaluate symptom intensity and distress to improve patient outcomes.

When evaluating the effectiveness of an intervention, *i.e.* after taking analgesics, the patients may still have pain (intensity), but at the same time be less bothered by that pain (less symptom distress). If the symptom is manageable and the patient is able to cope with a level of discomfort, no additional intervention is necessary. However, if the patient does not believe that the symptom is manageable, experienced distress may remain or worsen, which requires additional intervention [70].

Anxiety corresponds to an emotional distress. It responds to either the constitution of the individual or the situation the individual is in at present [71]. Psychological factors might play an important role in the onset of subjective symptoms. However, few studies have focused on psychological factors related to the symptom outcome after LC. Patients with persisting symptoms following LC have reported being more anxious and depressed, and more often use psychotropic drugs compared with those without such symptoms [62]. Persisting pain 6 to 12 months following cholecystectomy [72],

rasping pain, dyspepsia and introvert personality are independent predictors of pain one year following cholecystectomy [73]. Patients scoring higher levels of pain and those not cured by their treatment were also more neurotic and psychologically vulnerable one year after surgery [73]. Preoperative anxiety is highly correlated with the experience of postoperative pain [74, 75]. There is also an increased risk of developing high-intensity postoperative pain due to unsatisfactory treated postoperative pain [44].

1.8 Postoperative recovery

Postoperative recovery is a dynamic process where patients struggle to regain their preoperative functions and activities [76]. The term ‘postoperative recovery’ is commonly used, however it is a vague and ill-defined concept. Postoperative recovery is a complex process that consists of different turning points in the return to normal activities and wholeness. Allvin *et al.* [77] defined the concept of postoperative recovery:

“Postoperative recovery is an energy-requiring process of returning to normality and wholeness as defined by comparative standards, achieved by regaining control over physical, psychological, social, and habitual functions, which results in returning to preoperative levels of independence/dependence in activities of daily living and an optimum level of psychological well-being” [77] (p. 557).

Today, patients undergoing LC are discharged early *i.e.* the day of surgery or the first postoperative day. Therefore, the patients are forced to manage their postoperative recovery at home without the assistance of health care professionals. The patients’ ability to manage their postoperative recovery at home is therefore of utmost importance for both nurses and carers [78]. Pain and medico-cultural traditions have been defined as factors responsible for prolonged recovery [40, 79]. Nurses need to be aware of the special needs to improve patient information following LC [80].

1.9 Health, illness and disease

Health is a basic concept in nursing care and an important topic in nursing research. It includes health promotion, health maintenance, prevention and treatment of illness as well as rehabilitation and alleviation of suffering [81]. Health is a complicated phenomenon that can be seen from different perspectives [82]. Illness has been defined as a subjective experience because individuals may feel well with or without a disease. Personal perceptions of health, illness and disease depend on factors such as social

class, cultural experiences, sex and age. Further, genetic predisposition, lifestyle and environment play a role for morbidity and mortality. Social capital *i.e.* personal relationships and social networks are contributory factors for perceived health [82]. The World Health Organization (WHO) introduced as early as 1948 a broad definition of health: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" [83]. However this definition has been criticized as utopian [84]. The biomedical model has been the dominant model of disease in the western world, stating that disease is generated by specific etiological agents affecting the body structure and function [84]. This medical approach of the body was inspired by the Cartesian philosophy, viewing the body as a machine, *i.e.* disease as a kind of malfunction that can be repaired and the disease is treated. In the bio-medical model, health is seen as absence of disease.

Another perspective on health is the salutogenesis concept developed by Antonovsky [85]. The term salutogenesis comes from the Latin word *salus*, which means health, and the Greek word *genesis*, which means origin. The term salutogenesis was first used in research in 1979 where Antonovsky studied the influence of a variety of sources of stress on health. The concept focuses on salutary factors, factors that promote health and well-being, rather than on the pathogenic orientation in medicine and social science, that focuses on factors that cause disease and on obstacles and differences. Within medicine today, the pathogenic perspective on health is used. However pathogenesis and salutogenesis should be seen as a complement to each other [86]. Antonovsky [85] stated that during our life time, we are to some degree healthy and we move in a continuum between total ill health, disease, and total health, ease.

Further, Antonovsky [85] found that relatively unstressed individuals had more resistance to illness than people who experienced more stress. He stated that an individual's experience of well-being constitutes a Sense of coherence (SOC) [85, 87]. An individual uses generalized resistance resources when confronting a stressor and an individual with high SOC will be motivated to cope, understand what is needed and will believe that resources to cope are available. Antonovsky's research focused on the question "How do people stay well despite stressful situations and hardships?"

SOC reflects an individual's capacity to respond to stressful situations and the capacity to use the individual resources. An individual's SOC is developed in the individual's social, historical and cultural context. Moreover, the childhood and genetic background are also of importance and the understanding of lived experiences. According to Antonovsky, SOC is fully developed and stabilized around the age of 30

years and thereafter SOC is thought to have considerable stability over time and situations [87, 88].

SOC is a capacity and a combination of peoples' ability to assess and understand the situation they experience and to find a meaning to move in a health promoting direction. SOC is defined as a global orientation to view the life as manageable, meaningful and coherent. It is a personal way of thinking, being, and acts with trust, which leads the individual to use his/her own resources. SOC consists of three elements called comprehensibility, manageability, and meaningfulness. Antonovsky defined SOC as:

“A global orientation that expresses the extent to which one has a pervasive, enduring though dynamic feeling of confidence that (1) the stimuli deriving from one's internal and external environments in the course of living are structured, predictable, and explicable (2) the resources are available to one to meet the demands posed by these stimuli (3) these demands are challenges, worthy of investment and engagement” [87] (p. 19).

1.10 Predictors of postoperative symptoms

It is imperative to identify patients at particular risk of developing unacceptable levels of pain and other postoperative symptoms following LC surgery. Mertens *et al.* [89] conducted a study on 129 patients. They identified risk factors for negative symptomatic outcome 6 weeks following LC and concluded that patients with pre-operative dyspeptic symptoms, especially flatulence, have an increased risk of negative post-cholecystectomy outcomes. A symptom-specific approach should lead to optimalization of the indication of cholecystectomy and extended information of patients.

Weinert *et al.* [12] conducted a study aimed to describe the persistence rate of abdominal symptoms after elective cholecystectomy. Predictors of persistence of a most bothersome symptom were identified as dyspeptic symptoms, worse operative risk, worse self-rated health status, symptom duration > 6 months, and no previous episodes of acute cholecystitis. The major reason why not achieving a very successful outcome (15.2% of patients) was the presence of postoperative abdominal pain. Abdominal bloating and psychiatric medications have been reported to be predictive for persistence of pain after LC [62]. Table 2 shows published studies on predictors of outcome following LC 1991-2009.

1.11 Predictors of health

Few studies have assessed predictors of health and health-related quality of life among patients undergoing cholecystectomy. In a study aimed to determine clinical variables that predict changes in health related quality of life following cholecystectomy, Quintana *et al.* [90], investigated patients in a prospective study in six hospitals. Patients completed the Short Form 36 (SF-36) and the Gastrointestinal Quality of Life Index (GIQLI) before and 3 months after cholecystectomy. Multivariate linear regression models were used to examine factors potentially contributing to changes. They found that patients with asymptomatic cholelithiasis or high surgical risk experienced least improvement in health. In another study [58], the patient reported outcomes of health were mainly influenced by age and self-reported postoperative complaints. In the referred study, the perception of subjective health significantly improved over time especially between one week and one month. This is in line with McMahon [91], however, in their study, no baseline data were measured. Finan *et al.* [92] found improvement in health, but in their final analysis, only 53% of 105 patients undergoing LC were followed up. This makes conclusions about postoperative data uncertain. Contrary, Quintana *et al.* [90] found no improvement in physical health three months after LC.

Table 2. Published studies investigating predictors of outcome following laparoscopic cholecystectomy (LC) 1991-2009.

First author year, country	Purpose of the study	Patients Follow-up	Questionnaires/ analysis	Results/Conclusions
Bitzer 2008 [58] Germany	To assess the feasibility, validity and usefulness of a quality monitoring system of cholecystectomy in short-stay.	n = 205 / 6 months	SF-36, Gallstone symptom checklist	The patient reported outcomes were mainly influenced by the preoperative level, age and self-reported postoperative complaints.
Mertens 2008 [89] Netherlands	To identify and evaluate predictors of negative outcome after six week following LC.	129 / 6 weeks	Self-constructed symptom checklist of biliary-, dyspeptic- and non-specific symptoms.	At 6 weeks post-operatively postoperative biliary symptoms was independently predicted by preoperative dyspeptic symptoms and bad taste. Pre-operative flatulence was an independent predictor of the report of biliary and dyspeptic symptoms and persisting biliary symptoms. Predictors of symptomatic outcome were only not identified in men.
Berger 2000 [2] Netherlands	To evaluate the diagnostic accuracy of abdominal symptoms in gallstones in studies using ultrasonography or oral cholecystography as the reference standard and to assess the extent to which variability in diagnostic accuracy is explained by patient selection and other characteristics of study design.	5 articles	Meta analysis	Although biliary colic was specific for gallstones, 80% of the patients with gallstones reported other abdominal symptoms. There is no current evidence that justifies the use of single abdominal symptoms, other than biliary colic, in the diagnosis of symptomatic gallstones.
Quintana 2003 [90] Spain	To determine clinical variables that predicts changes in health-related quality of life.	887 / 3 months	SF-36, Gastrointestinal quality of life questionnaire	Multivariate linear regression models showed that patients with symptomatic cholelithiasis and low surgical risk experienced the highest HRQoL gains in several SF-36 and GIQLI domains. Patients with asymptomatic cholelithiasis or high surgical risk experienced least improvement.
Bisgaard 2001 [93] Denmark	To characterize postoperative pain intensity and time course. To study preoperative pain responsiveness to cold pressor test, neuroticism and several other pre- and intraoperative factors for their possible influence on pain.	150 / 1 week	Expectation of pain, during the first post- operative week, neuroticism, biliary symptoms and dyspepsia	Preoperative neuroticism, sensitivity to cold pressor induced pain and age were independent risk factors for early postoperative pain.

Table 2. Continued

First author year, country	Purpose of the study	Patients Follow-up	Questionnaires/ analysis	Results/Conclusions
Weinert 2000 [12] USA	To describe the persistence rate of abdominal symptoms and to identify predictors of symptom persistence and operative process to understand which symptoms improve after LC, and to describe important determinants of a successful operation.	2481 / 6 months	SF-36	Predictors of persistence of a most bothersome symptom were dyspeptic symptom, worse operative risk and worse self-rated health status, symptom duration longer than 6 months, and no previous episodes of acute cholecystitis.
Borly 1999 [73] Denmark	To investigate whether pre-operative factors could predict symptomatic outcome after cholecystectomy successful operation.	80 / 1 year	Pain questionnaire symptoms was completed preoperatively and after one year	Patients with pain 1 year after cholecystectomy were characterized by the preoperative presence of a high dyspepsia score, 'irritating' abdominal pain, and an introverted personality and by the absence of 'agonizing' pain. A logistic regression showed that 15 of 18 predicted patients reported postoperative pain.
Gui 1998 [94] UK	To identify which symptom are improved after cholecystectomy and to find a method for selecting patients who would benefit by symptom relief after cholecystectomy.	92 / 31 months	A symptom questionnaire	A logistic regression model failed to predict long-term pain-free outcome after cholecystectomy.
Luman 1996 [62] Scotland	The aim was to assess the effect of the operation on patients' symptoms.	97 / 6 months	Demographics, indication for LC, characteristics of pain, and other associated dyspeptic and colonic symptoms.	Abdominal bloating and psychiatric medications were predictive for persistence of pain after laparoscopic cholecystectomy.
McMahon 1995 [91] UK	To investigate the symptomatic outcome after cholecystectomy and minilaparotomy one year following surgery.	299 / 1 year	Postoperative pain, pulmonary function, hospital stay, returns to normal activity and quality of life.	Patients reporting poor outcome were more likely to have suffered a post operative complication, had lower quality of life scores, higher anxiety and depression.

Table 2. Continued

First author year, country	Purpose of the study	Patients Follow-up	Questionnaires/ analysis	Results/Conclusions
Ure 1995 [95] Germany	To identify patients with excellent results and to find out preoperative predictors of outcome.	468 / 19 months	Self-administered questionnaire, VAS	A logistic regression model failed to predict predictors of postoperative outcome after cholecystectomy.
Scriven 1993 UK [96]	To establish the degree of satisfaction experienced by these patients and to investigate predictors of outcome.	75 / 1 year	Specific symptom questionnaire Specific symptoms	A logistic regression model failed to predict predictors of postoperative outcome after cholecystectomy.
Jørgensen 1991 [72] Denmark	To estimate the outcome after cholecystectomy and to evaluate whether prognostic groups could be identified from self-reported and clinical data readily available under routine circumstances in which the study itself did not influence clinical decision making and surgical procedures.	115 / 12 months	Interviews, vulnerability test	Psychic vulnerability was significantly associated with persisting pain but age, sex, preoperative pain, history of disease, type of surgery, histology and complications did not predict the surgical outcome.
Bates 1991, [97]UK	The aim was to investigate predictors of postoperative outcome after cholecystectomy.	274 / 5 years	A self-assessment questionnaire	Preoperative flatulence together with long duration of attacks of pain is risk factors for postoperative dissatisfaction. The prediction of a poor symptomatic outcome after cholecystectomy from preoperative symptoms or patient characteristics had only limited success and all patients should be warned of this risk.

SF 36: Short Form 36; HRQoL: Health related quality of life; GIQLI: Gastrointestinal Quality of Life Index; VAS: Visual analogue scale for pain assessment 0-100 mm.

2 RATIONALE OF THE THESIS

Day surgery is expanding and progressively more patients are undergoing LC in day surgery. A reduced length of stay at the hospital has shifted much of the postoperative recovery process to the patients' homes where the presence of health care professionals is lacking. Very little research has been conducted to identify patients' own perspectives of having gallstone disease and their own perception of health and symptoms following LC. Studies have reported the occurrence of postoperative symptoms, but the distress related to these symptoms is scarcely investigated. Postoperative symptoms such as pain are subjective in character and difficult to measure. Asking the respondents to share the experiences from their own perspective may give important information about the occurrence and the level of distress of postoperative symptoms and about the benefit of care. Although randomized controlled trials comparing outpatients and inpatients following LC have been performed previously, these studies have not in detail focused on the patients' perceptions of health and symptoms. Furthermore, few clinical trials investigating LC have focused on the progress of perceived health or the degree of symptom distress, in a longitudinal way. Moreover, existence of sex differences in relation to these variables has not been sufficiently investigated. A high SOC score has been associated with less pain in patients suffering from gallstone disease before their treatment, compared with patients scoring low SOC. Thus, these scores seem to play a role in the explanation of health. The connection between SOC and other possible predictors of pain and perceived health in the recovery process after LC has not previously been investigated.

3 AIMS

The aims of the thesis were:

- To explore patients' experiences related to gallstone disease and to the experiences of postoperative symptoms during the first week following outpatient LC (I)
- To compare the treatment modalities outpatient and inpatient LC with regard to patients' perceptions of pain and other postoperative symptoms and to the amount of distress these symptoms cause. Further, to compare the patients preoperative and postoperative levels of anxiety and general health during the first postoperative week (II)
- To investigate the progress of recovery up to 6 months with special reference to patients' perception of their health, symptom occurrence, and degree of distress caused by each symptom. A secondary aim was to examine whether sex differences exist in relation to these variables (III)
- To investigate predictors of average pain the first postoperative week after LC, and predictors of changes in perceived health, with special reference to individual coping resources measured by the SOC scale. Furthermore, a test re-test was performed on the SOC scale to evaluate the stability in the context of LC surgery (IV)

4 METHODS

Characteristics for studies I - IV are presented in Table 3.

Table 3. Characteristics for studies I - IV.

Study	I	II	III	IV
Number of patients	12	34 vs 39	73	73
Design	Interview	Prospective, randomized controlled clinical trial	Prospective longitudinal	Prospective correlational
Observation period	1 week	1 week	6 months	6 months
Data collection	1999-2000	2001-2005	2001-2005	2001-2005
Instruments		Demographics, medical journals SFD-LC ¹ , STAI ² , HI ³ , pain-diary	Demographics, medical journals SFD-LC ¹ , HI ³ pain-diary	Demographics, medical journals, SFD-LC ¹ , STAI ² , HI ³ , SOC ⁴ , pain diary
Data analysis	Qualitative analysis	Descriptive and inferential statistics	Descriptive and inferential statistics	Descriptive and inferential statistics

¹SFD-LC, Symptom Frequency Distress Scale-LC; ² STAI, State Trait Anxiety Inventory; ³ HI, Health Index; ⁴ SOC, Sense of Coherence scale.

4.1 Respondents, data collection and analysis (Study I)

A qualitative approach was used to engender a deeper understanding of patients' experiences of having gallstone problems as well as their experiences of laparoscopic surgery the day of operation and the first postoperative week. The patients were recruited from the day surgery department at a university hospital in Sweden. A total of 12 patients, 10 women and two men were included in the study. Inclusion criteria for participating in the study were being aged 20-70 years, having a good physical status (American Society of Anaesthesiologists Physical Status Classification, System, ASA I-II) and having an adult carer available to accompany the patient at home the first night after discharge. Exclusion criteria for patients undergoing LC in day surgery were immunodeficiency, HIV, previous upper gastrointestinal tract surgery and proven malignancy. The data were collected by the main investigator (CB) between May 1999 and June 2000.

Interviews took place 1 week after the operation in an undisturbed environment in a library adjacent to the surgery department and lasted about 45 minutes. Interviews were audio-taped with the consent of the respondents. Each interview started by the interviewer inviting the respondent to answer to the question, “How did you experience having LC at the day surgery department?” After that, respondents could freely describe their experiences of living with gallstone disease before surgery, the day of surgery, and what they experienced during the first postoperative week. The interviewer only asked clarifying questions in response to how the informants described their situation. Data collection was finished after 12 interviews when no new information was obtained and redundancy was achieved [98].

For analysis of the data, qualitative analysis was used [99] [100]. The audio taped interviews were transcribed in their entirety. The transcriptions were read through a number of times and compared with the tapes to verify their correctness. Important phrases and sensory impressions that arose during the interviews and comments were highlighted to define meaning units from the interviews in order to describe specific experiences. Subcategories with the same content were grouped and categories and themes emerged named by their content. Quotations were used to provide additional elucidation [101].

4.2 Respondents, data collection and analysis (Study II - IV)

4.2.1 Patient selection and randomization

Studies II - IV were conducted at the outpatient surgery department at a university hospital in Sweden. The patients were recruited to the study through the hospital's outpatient department. During the period of May 2002 to September 2005 patients who fulfilled the following inclusion criteria were consecutively invited to participate: ultrasonography documented cholelithiasis, scheduled for planned LC, ASA I - II, 20-70 years old, and able to understand and speak Swedish. Moreover, the patient needed support from an adult carer at home for the first night following LC. Exclusion criteria for patients undergoing LC in day surgery were immunodeficiency, HIV, previous upper gastrointestinal tract surgery and proven malignancy.

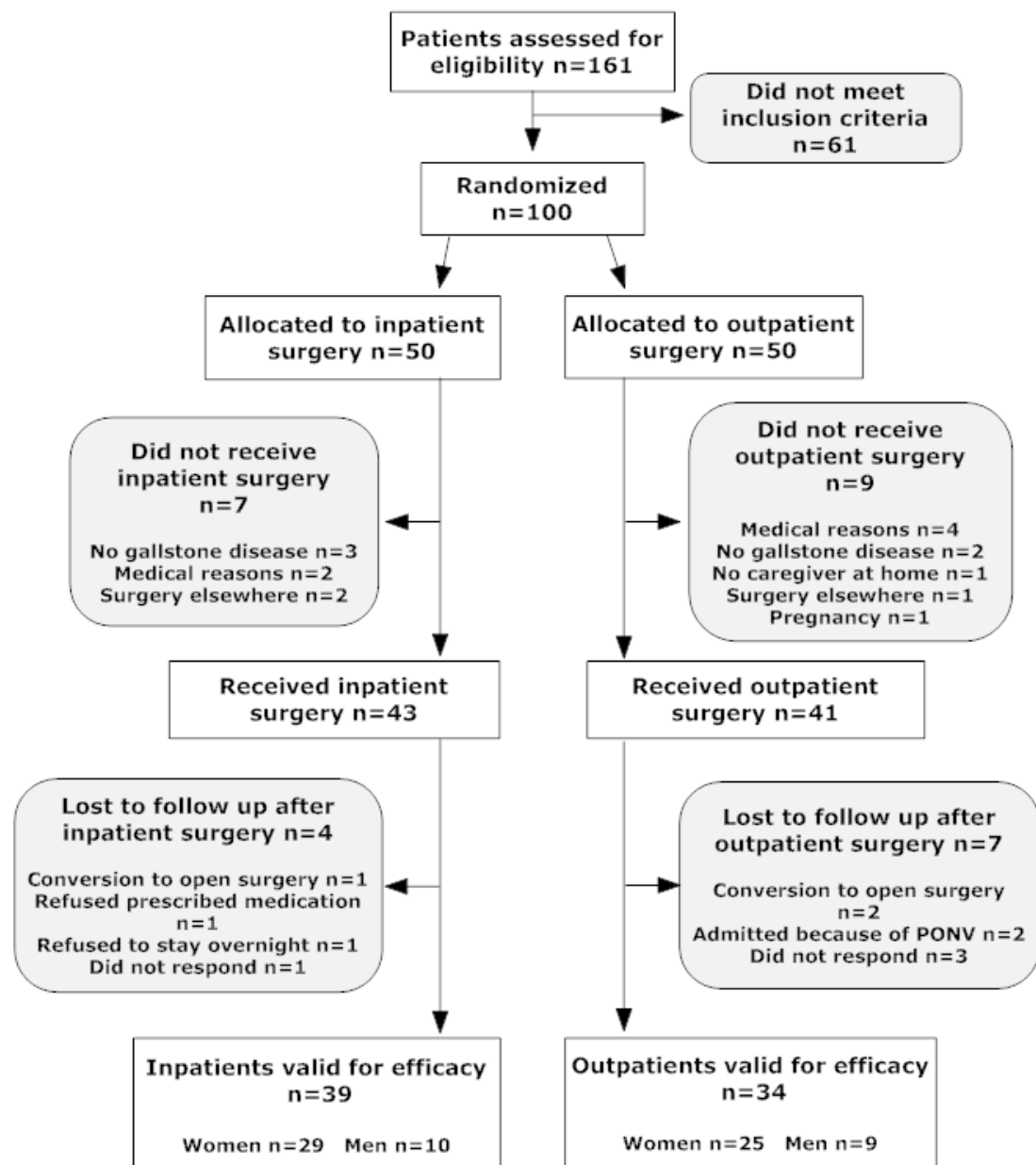


Figure 1. Flow diagram for study II. PONV = post-operative nausea and vomiting

In study II, a randomized controlled trial (RCT), comparisons were made between patients undergoing LC surgery as outpatients and inpatients. In order to recruit sufficient amount of patients for this study, a power analysis was undertaken and it was assumed that the pain difference between the two groups, measured as mm on VAS, would be 10 mm. Pain was chosen as the outcome variable as it is one of the most frequently reported postoperative symptoms following LC. The study was dimensioned in order to detect this difference in pain, with a standard deviation of 14 mm, a significance level of 5% and a power of 80%. With 72 patients these conditions would be met. In order to compensate for included patients not valid for efficacy it was planned to enrol 100 patients. The attrition rate was estimated to about 20%.

The randomization was performed by the surgeon with use of cards in sealed envelopes. One hundred sixty one patients with verified gallstones were assessed for eligibility. Sixty-one patients did not meet the inclusion criteria due to: medical reasons (n=16), no gallstone symptoms (n=14), language problems (n=8), no competent carer at home (n=6), refused day surgery (n = 6), surgery elsewhere (n=6), refused admittance (n=3) and pregnancy (n=2). A total of 73 patients (outpatients n=34 and inpatients n = 39) were valid for efficacy. Figure 1 shows a flow diagram for the patients to either outpatient or inpatient surgery. As only minor differences were found between the outpatient and inpatient groups (II), these are treated as one single group of patients (n=73) in studies III and IV. Sociodemographic data is shown in Table 4.

Table 4. Sociodemographic data of the outpatients, inpatients, and the total sample undergoing laparoscopic cholecystectomy. Values are presented as mean \pm SD or median (range) as appropriate.

	Outpatients n=34	Inpatients n=39	Total %
Women : Men	25 : 9	29 : 10	74 : 26
Age [years]	44 \pm 12	45 \pm 13	–
BMI (body mass index) [kg \cdot m ⁻²]	26 \pm 4	27 \pm 4	–
Marital status Married/cohabiting : Single	27 : 7	32 : 7	81 : 19
Education Elementary school : High school : University	8 : 18 : 8	9 : 13 : 17	23 : 42 : 35
Occupation Working/studying : Sick leave/ pension	28 : 6	35 : 4	86 : 14
History of disease [months]	42 (0.5 - 420)	36 (1 - 360)	–

No statistically significant differences were seen between the groups regarding sociodemographic data.

4.2.2 Surgical procedure, anaesthesia and postoperative recovery

The morning of the day of surgery, the patients in the outpatient group were admitted to the outpatient surgery department and LC was performed before 11 am. The LC procedures in the present study were performed by any of five experienced surgeons. Preoperatively, the patients received postoperative pain prophylaxis: 1 g paracetamol and 50 mg diclofenac. A standard four-trocar technique with carbon dioxide insufflations was used when performing the LC and Intraoperative cholangiography (IOC) was routinely performed. Also a standardized anaesthetic protocol was utilized

and anaesthesia was maintained with remifentanyl, propofol and muscle relaxant with rocuronium. Ketobemidone 0.1 mg/kg and 4 mg ondansetron (PONV prophylaxis) were administered intravenously thirty minutes before emergence from anaesthesia. Before the operation was completed, twenty cc of 0.5% bupivacaine with adrenalin were infiltrated in the trocar puncture sites.

The patient's postoperative recovery was managed at the outpatient surgery department. The same staff at the outpatient surgery department treated and postoperatively observed the outpatient and the inpatient groups until discharge from the hospital or transfer to a hospital ward. The outpatient group was discharged after five to six hours of post-surgical observation. All patients in the outpatient group received a telephone call from the nursing staff at the outpatient surgery department on the evening of the day of surgery and the next morning. Patients were provided with the phone number of the same nurse they had met the day of operation in case of questions arose during the first postoperative night at home.

Patients in the inpatient group underwent the same regimen as the outpatients but after two hours of observation they were transferred to a hospital ward. The inpatients were then discharged from the ward to their homes the next morning.

The discharge criteria for both groups were: adequate pain control *i.e.* VAS < 30, be able to ambulate, able to void and tolerate oral liquids. Patients were provided with a two-day supply of pain medications: diclofenac 50 mg three times a day, paracetamol 1 g four times a day. If severe pain occurred, suppository ketobemidone was prescribed.

4.2.3 Questionnaires

4.2.3.1 Sociodemographic and medical data

A questionnaire designed for this study was used for the collection of background data such as age, sex, marital status and work. Medical data, ASA and body mass index (BMI) were collected from the patient's medical records (II, III, IV).

4.2.3.2 Pain Diary

For measuring pain, a study specific pain diary was used. The patients documented the level of pain they experienced every evening from postoperative day 1 to 7 (II, IV) and after 1 and 6 months (III, IV) using a 100 mm visual analogue scale (VAS) [102]. The patients also recorded their intake of analgesics every evening during the first postoperative week after surgery. In study IV, the dependent variable VAS-mean is

used as an index for each patient, created from the average of all VAS-values postoperative day 1 to 7.

4.2.3.3 *The Symptom, Frequency and Distress Questionnaire (SFD-LC)*

The SFD-LC is a modified version of The Symptom, Frequency, Intensity and Distress Questionnaire (SFID-SCT), developed by Larsen, *et al.* [103] for patients undergoing stem-cell transplantation (SCT). Out of the original 23 symptoms, 18 symptoms were considered as relevant for LC patients and used in this study: nausea, vomiting, pain, shivers, fever, breathing difficulties, coughing, tiredness, sore mouth/throat, loss of appetite, diarrhoea, constipation, sleeping disturbances, reduced mobility, depression, anxiety, concentration difficulties and memory deficiencies. The excluded symptoms (loss of hair, mouth dryness, and changes of taste, skin changes, and changed body image) were specifically intended for SCT and therefore omitted. The 18 symptoms used are considered by the authors to be relevant for LC patients. In this way the validity of the instrument was weighed against scientific and clinical knowledge of postoperative symptoms following LC. For each symptom listed above, the respondents were first asked if they had perceived the symptom during the past postoperative week ('Yes' or 'No'). Thereafter they were asked how distressful they perceived each symptom to be (0 = 'No distress', 1 = 'A little distress', 2 = 'Much distress' and 3 = 'Very much distress'). The original version of the instrument has been used in earlier studies [104] and symptom-specific modified versions of the SFID have been used for other groups of Swedish patients [105, 106]. The questionnaire was answered every evening the first postoperative week (II), and after 1 and 6 months (III, IV) following LC.

4.2.3.4 *State-Trait Anxiety Inventory (STAI)*

The STAI is an established measure of psychological status developed by Spielberger [107]. It distinguishes between dispositional (trait) and transitory (state) types of anxiety. State anxiety can be described as an unpleasant emotional state or condition and trait anxiety as a relatively stable personality trait. State anxiety incorporates feelings of tension, nervousness and worry and describes how patients feel at a particular moment in time. The STAI is a self-report inventory consisting of two 20-item scales formulated as statements answered on a four point Likert-type scale ranging from 'Not at all' to 'Very much'. The score ranges from 20 to 80. The higher the score, the higher the degree of anxiety. In this study the STAI state was used. Internal consistency by means of Cronbach's alfa has varied between 0.91 to 0.95 in different

groups of individuals [108]. The STAI-state test-construction has been shown to have discriminant validity [109]. The questionnaire was responded to preoperatively, postoperative day 1, day 7 (II) and after 1 and 6 months (IV).

4.2.3.5 Health Index (HI)

The HI questionnaire comprises 10 items, scored on a 4-graded Likert scale ranging from 'Very poor' to 'Very good'. The instrument is used to assess self-reported health status. The HI consists of items measuring energy, temper, fatigue, loneliness, sleep, vertigo, bowel function, pain, mobility and one item measuring general health. The sum score forms HI ranging from 10 to 40. The instrument consists of two subscales, emotional well-being, EWB (energy, temper, fatigue, loneliness) and physical well-being, PWB (sleep, vertigo, bowel function, pain and mobility). A high value indicates a high level of self-reported health. The HI has been tested for reliability in different patient populations with satisfactory results (Cronbach's alpha 0.77-0.85) [108, 109]. The instrument has also shown to have discriminant validity [109]. The questionnaire was responded to preoperatively (III, IV), on day seven (II, III, IV), and one and six months following LC (III, IV).

4.2.3.6 Sense of Coherence Scale (SOC)

The original SOC scale was developed by Antonovsky [87] and includes 29 items [88] measuring comprehensibility, manageability and meaningfulness. The patients indicate agreement or disagreement with the item on a 7-point scale. In study IV, a shorter format including 13 items was used ranging between 13 and 91. Higher scores indicate a stronger SOC. Extremely high scores according to Antonovsky [87], may indicate rigidity, although no end point is suggested. In studies using the SOC 13 items, Cronbach's alpha range from 0.70 to 0.92. The questionnaire was responded to preoperatively and six months following LC (IV).

4.3 Statistical methods and data management

Statistical methods for paper II to IV are described in Table 5. In order to explore predictions of pain and changes in health (IV), multiple linear regression analysis were performed. The dependent variable pain was measured by means of VAS-mean *i.e.* the average value of VAS (mm) registration of pain postoperative day 1 to 7. Further the dependent variable changes in health were measured by means of changes in the total HI score between day 7 and one month following LC surgery. The independent variables were HI, SOC, STAI (measured preoperatively), Body Mass Index (BMI), age, gender, duration of disease, work status, education, symptom occurrence, symptom distress, and VAS day 1. Significance was accepted at $p < 0.05$, but for data on postoperative symptom occurrence and distress (paper II Table 1 and 2, III Figure 2 and 3), multiple comparisons were made and therefore $p < 0.01$ was considered significant. Fischer's exact test for a 3 x 2 frequency table of changes of SOC over time was computed with the statistical software R 2.8.1 (R Foundation for Statistical Computing, Vienna, Austria). Analyses were conducted using STATISTICA 7.0 (StatSoft Inc., Tulsa, OK) except for Dunn's test where GraphPad Prism 4.02 was used (GraphPad Software Inc., San Diego, CA).

Table 5. Statistical methods used in the studies (II - IV).

Statistical methods	Statistical Test	Study
To describe the basic features of the data in the studies	Descriptive statistics	II, III, IV
Test for normality	Kolmogorov-Smirnov's test	II, III, IV
To test the difference between two independent group means	Student's <i>t</i> -test	II
To test the difference in ranks of scores on two independent groups	Mann-Whitney <i>U</i> -test	II, III, IV
To test the differences among means of three or more related groups	Repeated measurement analysis of variance, ANOVA	II
To test the difference in ranks of three or more related groups	Friedmans test (non-parametric ANOVA)	II, III
Post-hoc test for multiplicity	Dunn's test	
To test proportions of nominal data	Chi-square test, Fisher's Exact Test 3x2 frequency tables	II, III, IV IV
To compare two population proportions that are related to each other	McNemar's test	III
To test the existence of a relationship between two variables	Spearman's rank correlation test or Pearson correlation coefficient	IV IV
To test one dependent and several independent variables	Multiple linear regression	IV

5 ETHICAL CONSIDERATIONS

The studies were approved by The Local Ethical Committee at Karolinska University Hospital, Huddinge, Sweden (Reference numbers 144/99, 434/00).

In studies I - IV, all patients were given both verbal and written information before considering participation in the studies and informed consent was received from all respondents. They were informed that participation was voluntary, could be ended at any time and that confidentiality was guaranteed. To protect the participants' integrity, the results were presented in a way that ensured that it was not possible to identify any of the respondents [110].

For study I, the patients were interviewed one week after the LC surgery by one of the researchers (CB) who also was employed at the day surgery department. Maybe this could have affected the patients' choice to participate in the study if they felt obliged to participate. None of the patients who were asked about participation rejected the interview. The interviewer stated open-ended questions and the respondents had the choice to answer the questions or not. The respondents were provided with the phone number of the researcher (CB) for use if questions arose. Therefore, the ethical dilemma was well thought-out and may be regarded as small.

To randomize to outpatient versus inpatient treatment (II) was an ethical dilemma as the patient was not allowed to decide his/her treatment. The study protocol focused on the patients self-reported symptoms; experiences of anxiety and general state of health both prior to surgery and postoperatively repeatedly investigated up to six months following LC. To repeatedly trouble the patients with questions involves their time and their strength. On the other hand, patients may feel that they receive more attention and that they have access to the day surgery staff which is positive for the individual. In the questionnaire studies (II - IV) the patients had the opportunity to decide if they wanted to answer the questionnaires or not. Identification of self-reported symptoms from the patients' perspective may lead to improvement in postoperative care for LC patients in the future.

6 RESULTS

6.1 Paper I

Patients' Experiences of Laparoscopic Cholecystectomy in Day Surgery

Twelve respondents described different problems in the interviews related to the gallstone disease. They stated their experiences before the operation, the day of surgery, and how they felt at home during the first postoperative week. After coding and categorization of the interview statements, the following four main categories emerged: *Living with gallstone problems*, *Experiences on the day of surgery*, *Experiences the first week after surgery* and *Return to activities of daily life*.

Living with gallstone problems

Living with gallstone problems was described to affect working life. The respondents expressed anxiety and feelings of being socially handicapped because they did not know when the attacks would come.

Experiences on the day of surgery

Meeting the surgeon who would perform the surgery gave feelings of security. Respondents expressed need for tranquilizers and were also worried about the diagnosis and potential malignancies. At discharge from hospital, memory deficit was experienced resulting in not remembering important information given by the surgeon.

Experiences the first week after surgery

The respondents felt tired at home and had a great need of rest. They experienced the operation as a physical and mental trauma. Varying degrees of pain after the operation was expressed. Despite prescribed medication for pain relief, some respondents experienced a relapse of pain on the third day when the 'on demand' medication sent home was finished. New gallstone attacks were reported during the first postoperative week and the respondents described shoulder pain. Questions about their wounds and how they should be cared for were raised. Nausea and vomiting were experienced the evening of the operation and the following morning. One patient was so extremely nauseated that this resulted in dehydration and hospital admission on the third day.

Further, the respondents experienced gastrointestinal symptoms the first few days and they also described having loose bowel movements or diarrhoea. A wish for a longer period of telephone follow-up was expressed by one respondent because of pain.

Return to activities of daily life

The respondents' readiness to go back to work after a week varied to some extent. Some thought that one week was not enough to stay at home and that the staff's attitude toward cholecystectomies performed in day surgery was too casual. Going home to small children without support from a relative felt to be difficult and some respondents would have preferred to remain in hospital the first night after surgery.

6.2 Paper II

Outpatient versus inpatient laparoscopic cholecystectomy. A prospective randomized study of symptom occurrence, symptom distress and general state of health during the first postoperative week

Complications and readmissions

After discharge on postoperative day 2, one patient in the outpatient group, required readmission due to dehydration. No complications or readmissions occurred in the inpatient group. The number of preoperative hospital visits due to gallstone attacks is shown in Table 6.

Table 6. Number of preoperative hospital visits due to gallstone attacks among the outpatients (OPS) and inpatients (IPS) before undergoing laparoscopic cholecystectomy.

Hospital visits	Outpatients (OPS), n=34	Inpatients (IPS), n=39
1	12	16
2	8	6
3	4	2
4	1	4
5	3	1
6	0	1
10	1	0
no response	5	9

Symptom occurrence

Comparisons between the outpatient and the inpatient groups regarding symptom occurrence postoperative days 1 and 7 showed no statistically significant differences between the groups except for a slightly higher frequency of reduced mobility in the outpatient group (postoperative day 1) and sleeping disturbances in the inpatient group (postoperative day 7).

Pain intensity

A statistically significant decrease regarding the perception of pain from postoperative day 1 to 7 was seen in both the outpatient and inpatient groups, but there was with no statistically significant differences between groups at any of the different time points (Figure 2).

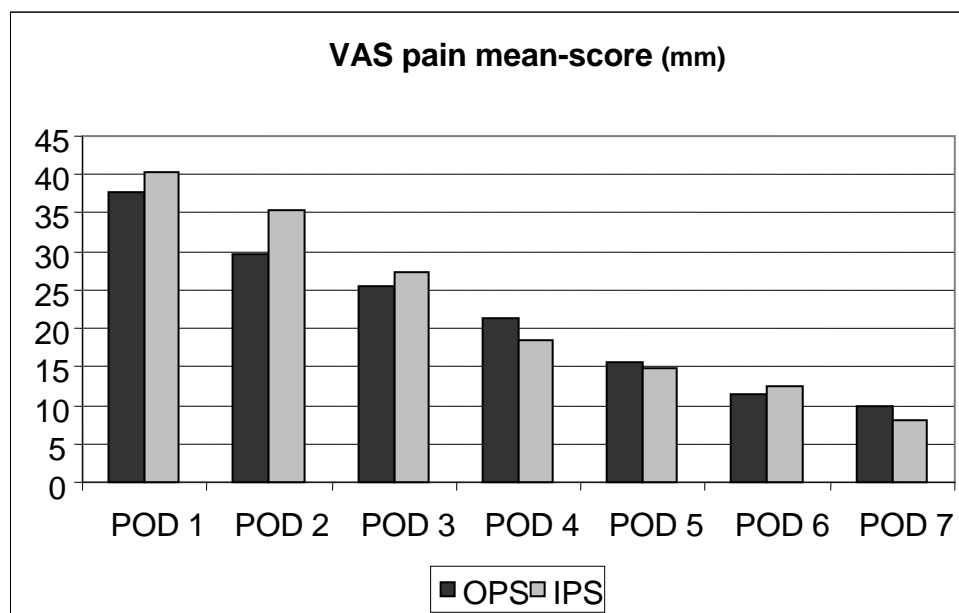


Figure 2. Comparisons between outpatients (OPS) versus inpatients (IPS) who underwent laparoscopic cholecystectomy regarding their perception of pain postoperative day 1 (POD 1) to 7 (POD 7).

Symptom distress

Comparisons between the outpatient and inpatient groups regarding symptom distress reported by the patients as ‘much/very much’ distressing postoperative day 1 and 7 showed no statistically significant differences between the groups.

By postoperative day 1, 41% of the outpatient and 38% of the inpatient group reported pain to be much/very much distressing and almost the same figures were reported for reduced mobility. By postoperative day 7, the number of patients in both groups who reported the symptoms as much/very much distressing, had decreased notably for most of the symptoms.

Anxiety

Comparisons between the outpatient and inpatient groups regarding perceived level of anxiety measured by the STAI preoperatively (median 32 vs 33), on day 1 (34.5 vs 33)

and on day 7 (28.5 vs 27) showed no statistically significant differences at any of the measured time points. Comparisons within groups over time differed significantly. Both groups reported a lower level of anxiety day 7.

General state of health

Comparisons between the outpatient and inpatient groups regarding perceived level of health was measured by the HI preoperatively (mean 31.3 vs 29.9) and day 7 (mean 31.6 vs 30.7). No statistically significant differences were found neither between the groups nor within the groups. Both groups were back to preoperative status by day 7.

6.3 Paper III

Longitudinal Changes in Health and Symptoms following Laparoscopic Cholecystectomy

Perceived health

A significant improvement in HI between day 7 and 1 month ($p<0.001$) was reported for the total score as well as for the PWB subscale score. At one month, the total HI had increased significantly in 42 patients, decreased in 10 patients and remained unchanged in 21 patients. Looking at the HI measured on an item level preoperatively and six months following surgery, a significantly greater proportion of patients reported improvement in relation to pain frequency (43% vs 12%; $p<0.001$) and bowel function (32% vs 14%; $p=0.041$).

Symptom occurrence

A total of 527 symptoms were reported by the 73 patients the first postoperative day. Pain (93%), reduced mobility (91%) and tiredness (91%) were the three most frequently reported symptoms postoperative day 1. These symptoms were also most frequently reported after one week. Fifteen of the 18 symptoms in the SFD-LC questionnaire were significantly less frequently reported after one week compared with the first postoperative day. After one month, pain and loss of appetite were the only symptoms significantly less frequently reported in comparison to day 7 (28% vs 10%; 14% vs 4%). However, difficulties to concentrate were significantly more frequently reported after one month (1% vs 11%). No other symptoms reached a significant change in occurrence between one week and one month following LC.

Symptom distress

Sixty eight percent of the patients reported ‘much/very much’ distress of at least one symptom the first postoperative day. The three most commonly reported distressful symptoms the first postoperative day were pain (45%), reduced mobility (40%) and tiredness (36%). In comparison to postoperative day 1, sex of the 18 symptoms reported as ‘much/very much’ distressing were significantly less frequently reported after one week (*i.e.* pain, reduced mobility, tiredness, nausea, loss of appetite, and constipation).

At one month after surgery, tiredness was the symptom most frequently reported as distressful (10%). This was also the case 6 months after surgery (12%). In comparison to one month, no significant differences as regards frequency of distressful symptoms were seen six months after surgery.

When comparing the appearance and disappearance over time of the total number of distressful symptoms, a significant decrease was seen between day 1 and day 7 ($p<0.001$) but this number increased again between one and six months after surgery ($p=0.012$).

Pain intensity and consumed analgesics

The highest VAS scores for pain were reported the first postoperative day (median 41; range 0-98) and a significant decrease was seen between day 1 and day 7 (median 4; range 0-48, $p<0.001$). No differences in pain intensity reached significance in relation to the other time points measured (*i.e.* 1 month and 6 months).

Every evening during the first postoperative week the patients rated their experienced level of pain. They also documented whether or not they consumed analgesics and, if so, which type of analgesics (unpublished data).

To be discharged from the hospital, one criterion was adequate pain control *i.e.* VAS ≤ 30 mm. When the patients assessed their level of pain at home, in the evening of postoperative day 1, 43 patients (59%) rated their pain to be > 30 mm. On day 1, 14% of the patients consumed non-prescribed supplementary paracetamol or Non steroidal anti-inflammatory drugs, NSAIDs and 23% consumed opioids. On postoperative day 3, 55% of the patients consumed supplementary paracetamol or NSAIDs and 19% of the patients consumed opioids in addition to the standard prophylactic analgesic treatment. Figure 3 shows the percentage of patients reporting non-prescribed analgesics, opioid consumption and median VAS scores postoperative day 1 to 7 (unpublished data).

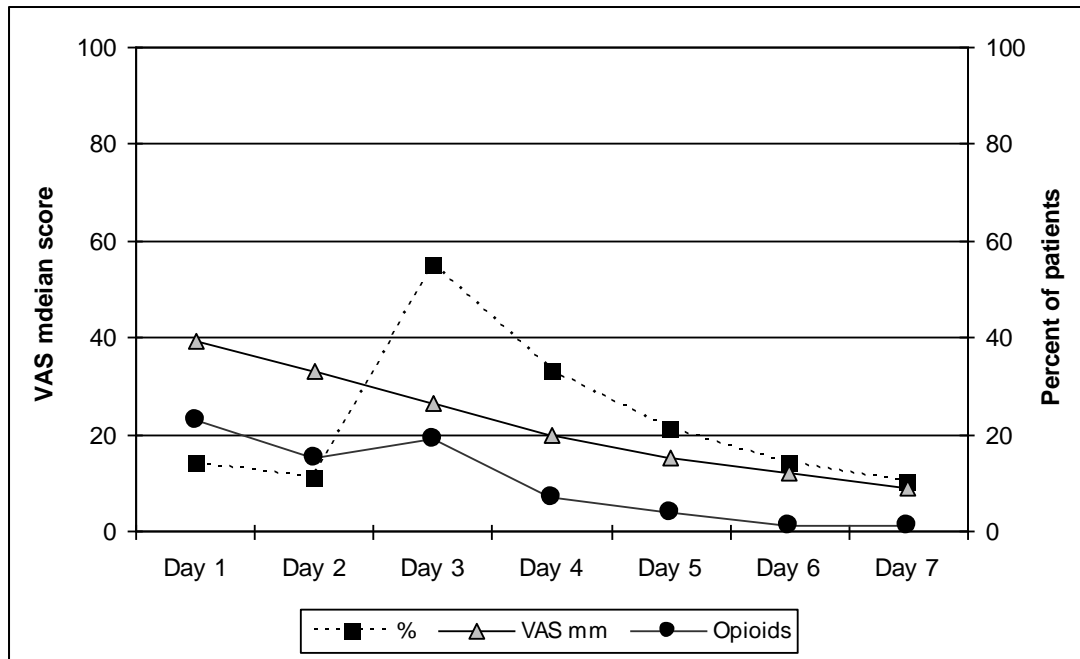


Figure 3. Percentage of patients reporting consumption of non-prescribed analgesics and median VAS scores postoperative day 1 to 7. The consumption of opioids is also given.

Sick leave

A total of 63 patients (86%) were in employment, and 58 of those (92%) could return to work within one week after surgery. Two women needed convalescence for one extra week, and two women and one man had two additional weeks of convalescence.

Sex differences

When investigating sex differences, females reported significantly lower scores on the total HI day 7 (30.7 vs 32.7; $p=0.042$) and on the PWB subscale (15.4 vs 16.5; $p=0.038$). The female group also reported significantly higher frequency of symptoms day 1 (7.7 vs 5.9; $p=0.032$) as well as day 7 (2.4 vs 0.9; $p<0.001$) than did the male group. Further, females also reported a higher proportion of symptoms rated as distressful the first ($p=0.036$) and seventh postoperative days ($p=0.044$) when the sum of 18 symptoms was analyzed (data not shown).

6.4 Paper IV

Sense of Coherence and Other Predictors of Pain and Health following Laparoscopic Cholecystectomy

In order to investigate predictors of pain and changes in perceived health with special reference to individual coping resources measured by means of the SOC scale, multiple regression analysis were performed. Further, a test-retest on SOC to test the stability in the context of LC surgery was also carried out.

Predictors of pain

The average of all VAS-values measured postoperative day 1 to 7 (VAS-mean) was 22 ± 15 mm. When testing the independent variables STAI, SOC and HI for internal correlations, all were inter-correlated with the size of 0.52-0.56. STAI measured preoperatively emerged as the strongest independent variable with r_s 0.48.

In the multiple regression analyses 29% of VAS-mean could be explained by the three variables: age, HI and education. Age turned out to be the strongest predictor and education the weakest due to the high correlations between HI, SOC and STAI. We replaced HI by SOC and HI by STAI respectively in the final regression model. SOC, age and education explained 23% of the variability in VAS-mean. Here, age was the strongest predictor and education the weakest. Further, 24% of VAS-mean was explained when SOC was replaced by STAI. Also in this model age was the strongest variable and education the weakest.

Changes in health

Changes in HI for each measurement interval were used as dependent variable. The mean improvement in HI score between day 7 and 1 month was 1.6 ± 3.3 . We found that 19% of the change in health between day 7 and 1 month could be explained by the two variables symptom distress and SOC.

According to the multiple regression analysis, 19% of the variability in changes in HI between day 7 and 1 month could be explained by the two variables symptom distress day 1 and SOC. When measuring the other two time intervals, preoperatively to day 7, and 1 month to 6 months, respectively, less than 10% of the variability in changes in HI could be explained by multiple regressions.

To illustrate the impact of SOC on health, SOC was dichotomized into one group with low SOC (13-69) and one with high SOC (70-91). The low SOC group showed lower HI scores at all the measured time points. In the low SOC group HI improvement

was significantly greater, than for the high group between postoperative day 7 and 1 month following LC.

Sense of Coherence and health

To test for stability over time, the SOC scale was responded to before and six months following LC. The mean values were 68.9 ± 9.6 and 69.7 ± 11.0 respectively. No statistically significant difference between the groups was seen. The corresponding Cronbach's alpha values were 0.78 and 0.86 respectively. The test re-test of SOC showed a correlation coefficient of 0.55. For 11 patients (15%) their reported SOC score had decreased by -7 or more, (-15 ± 8), and 16 patients (22%) the SOC score had increased by at least 7, (13 ± 6). For the remaining 46 patients their SOC score were stable or within ± 6 , corresponding to approximately $\pm 10\%$. These changes of more than 10% in SOC were not significantly related to the preoperative level of SOC, although there was a tendency that dichotomized low SOC values (< 70) increased more than the high SOC values.

Patients' own comments on short and long term results (unpublished data)

In addition to the questions in the SFD-LC questionnaire, some patients freely commented their own experiences of symptom occurrence and symptom distress. One week after LC, 40 patients (55%) commented on their experiences of symptoms. After six months the corresponding figure was 25 patients (34%). Below, comments on commonly reported symptoms and other experiences are given.

Pain

After 1 week

"Shoulder pain is worse than the pain in the stomach"

"My shoulder pain lasted for 48 hours"

"During the first week I had a new gallstone attack"

"When I experienced pain at day four after surgery, I couldn't take deep breaths"

After 1 month

"I still experience pain at the same sites as before the operation"

"I still have pain on the left side of the stomach after eating and drinking"

"I have severe pain in my stomach, biliary colic; I take painkillers and have had a diet in fourteen days"

Tiredness

After 1 week

“I feel good but I am terribly tired, for me unusually tired”

“It would have been hard for me to work after one week after the operation because I feel very tired”

After 1 month

“I have problems to be spirited and alert after the operation. I feel very tired and have sleeping difficulties”

“After the operation, I have problems to be alert, I have been extremely tired”

Bowel function and the urgency of toilet visits

After 1 month

“I have problems with visits to the toilet. I often suffer from gripe”

“I feel good but my belly doesn’t work normally after the operation. When I eat I get diarrhoea. It’s very tough because I’m driving a car at work”

After six months

“I’m still bothered by a bad stomach, flatulence and several visits to the toilet every day since the operation. I need a toilet right now”

To be discharged on the same day as the operation

After 1 week

“To be discharged on the same day as surgery put a pressure on the carer at home. All people are not familiar with the health care system and I felt that my husband was so tense”

” Day surgery is a perfect model but is built on the strength of the individual”

“To stay in the hospital over the first night was really very good, I felt safe”

(statement from one patient treated in inpatient surgery)

Follow-up

After 1 week

“I request some kind of follow-up to confirm that the wounds are OK. It’s hard to judge by myself if the wounds are OK. I worry for scars and if the wounds will rupture”

“I think that it should be mandatory with a follow-up visit one week after surgery. You feel rather vulnerable and it is easy to get anxious”

Sick leave

After 1 week

“The doctor says that three or five days off from work are enough, but my stomach is so bloated so it’s impossible to zip my trousers. It’s not possible to sit the whole day with a pressure on to the epigastria”

Information

After 1 week

“I would have preferred more information about wound care and about shoulder pain”. “I would have preferred dietary advice at discharge and I would not prefer to be discharged the day of surgery”. “I would have preferred to be informed of what to expect: pain in the wounds, pain in the stomach (where and why) and about digestive problems. I would have felt less anxious if I had known what is normal”

7 DISCUSSION

7.1 Methodological considerations

Study I is a qualitative study. Patients' own experiences of LC in day surgery had not earlier been investigated to a greater extent. Therefore a qualitative design was chosen to increase our knowledge and understanding of living with gallstone problems and postoperative recovery after LC. When analyzing qualitative data, trustworthiness is a central concept and is best expressed by using the terms credibility, dependability and transferability [111]. Credibility has its focus on research referring to confidence in the truth of data. Variation and recognition are central components regarding credibility [98]. In the present study, credibility refers to the respondents' differences in sex and age. Choosing patients with various experiences increases the possibility of shedding light on the research question from a variety of aspects. Choosing the most appropriate method for data collection and the amount of data is also important. As the patients' experiences of LC in day surgery were unknown and could not be captured in a questionnaire, interviews were found to be the most suitable method for gathering data.

Dependability refers to the quality of data and its stability over time and conditions. In this study, dependability was established by using a single interviewer (CB), by performing the interviews in a quiet environment with no interruptions and by having all interviews performed in a relatively short period of time. Transferability refers to the extent of transferring findings to another setting or group. Description of the participants, data collection and analysis, in addition to a rich presentation of findings with appropriate quotations will enhance transferability [112]. Regarding the present study, we judged that transferability can be achieved from our sample to other groups of patients undergoing LC surgery if the same anaesthetic and surgical techniques are used.

In an RCT (II) patients cannot make their own decisions. The patients are individuals with their own desires and it is impossible to ensure their willingness to participate and be available for the study. Another problem is the fact that we are treating ill people and their need for surgery and care must take priority; the research must take second place. When performing a clinical study, there are two different concurring worlds to deal with and many obstacles may occur both organizationally and among the patients delaying the data collection period. The hospital where the study was performed is a large medical centre, where approximately 200 laparoscopic cholecystectomies a year was performed as inpatient LC and only about 50 patients as

day surgery cases at the time of data collection for study II. At the time of start of study II, a considerable organization coalition between two of the largest hospitals in this city was done, so only a small part of all patients available for LC surgery, were able to be allocated to day surgery. It was also difficult to make reservations for beds over the first night for the patients to inpatient surgery.

An RCT is a preferred scientific method for equalizing groups [112]. RCTs are appropriate where a clear, clinically important choice exists between contrasting alternatives but there are problems with performing this research design. RCT studies are expensive to run. Difficulties about the participants may be that the patients who are stressed or depressed only retain a limited amount of information [113] and may reject RCTs because they do not wish their treatment to be decided by chance [114]. Furthermore, it is important who provides the information, at which point the patients receive it, and how to avoid influencing their decision. If the participation in a study is requested by the patients' doctor, the patient may hesitate to refuse participating in a study. Patients who do not receive the treatment of their choice may have their motivation affected. This, in turn, can influence the outcome and may lead them to drop out of the trial [113].

The revised CONSORT statement for reporting randomized trials: explanation and elaboration [115] is developed in order to improve the quality of reporting of RCTs. It consists of a checklist including 22 items and flow diagram and is a useful tool for authors when planning an RCT. As the planning of the present study (II) took place before the publication of the CONSORT statement, it was not used at this stage. However, we have, where appropriate tried to follow its recommendations when reporting the study. As regards eligibility, a total of 161 patients were assessed. Sixty one of these did not meet the inclusion criteria. According to the performed power analysis a total of 72 patients would be sufficient to allocate. In order to compensate for included patients to cover an attrition rate estimated to 20%, we enrolled 100 patients in the study. In line with the CONSORT statement a flow diagram is presented (Paper II p. 580). Out of the 50 randomized patients in each group (outpatients vs inpatients) almost equal number of patients (9 vs 7) did not receive surgery at all due to factors that were not possible to predict and were out of the patients' control (*i.e.* medical reasons such as breast cancer surgery, no gallstone symptoms, surgery planned elsewhere). Further, out of the 84 patients who received surgery, 11 were lost to follow-up (OPS n=7, IPS n=4) due to for example conversion to open surgery, admitted for PONV, refused hospital stay overnight despite belonging to the inpatient group, not responding

to questionnaires. Thus 73 (34 in the outpatient group and 39 in the inpatient group) were valid for efficacy. According to the CONSORT statement, analysis by ‘intention to treat’ is the most appropriate way to handle ‘protocol violations’ such as when patients do not receive intervention, or the correct intervention. This means that in order to minimize bias, participants should be analyzed according to their original group assignment, regardless of what subsequently occurred. This analysis is based on the initial intent and not on the treatment eventually administered. This is not always straight forward to implement. It would have strengthened this study if an ‘intention-to-treat’ strategy had been implemented. However, all the 73 patients valid for efficacy were successfully followed during the whole six months period.

Study III and IV are prospective longitudinal studies. Such studies take long time, in these cases 3.5 years from start of inclusion to end of the follow-up. They also need a great amount of administration.

For study II, III and IV, data was collected by means of questionnaires and the results of these studies are valued with respect to validity. An instrument/questionnaire is assigned valid after it has been satisfactory tested in the population for which it was designed [84]. The instrument/questionnaires used in these studies are widely used and tested in different population groups with good results. The instruments used (SFD, STAI, HI and SOC) have also been used in several Swedish population studies [104, 108, 109, 116].

There can be several threats to internal validity, one is loss of subjects, attrition. The response rate in studies II, III, IV is 73% which can be considered acceptable to good [84, 98]. To strive for a higher response rate, we used stamped addressed return envelopes and in the absence of no reply, a follow-up phone call was made two weeks after surgery. Another threat of internal validity may occur if the same patients receive the same questions repeatedly and thus get used to the questions. In the present studies questionnaires were answered preoperatively, and postoperatively day 1 and 7 (II, IV) and after one and after six months (III, IV). However, nothing has indicated this type of problem.

The instrument/questionnaires used in study II, III, IV are also tested with regard to reliability [103]. One way of testing reliability is to check the internal consistency. In this thesis, the internal consistency reliability has been measured by means of Chronbach’s alpha, which should be at least above 0.7 [84, 98]. This criterion was fulfilled for the three instruments (STAI, HI, SOC) where this was appropriate to measure.

Another way of testing reliability is by means of test-retest. This is a test of stability of the measure (e.g. reproducibility of the responses to the scale) over a period of time in which it is not expected to change, by making repeated administrations of it [84]. In study IV the SOC scale was administered preoperatively and six months following LC and the Pearson correlation coefficient was used [98]. The correlation coefficient was 0.55 corresponding to an r^2 of 0.31. This means that the variance shared equals 31%.

SOC has been reported to be stabilized by the end of young adulthood and is thereafter only slightly affected of major life events regardless of age, sex, ethnicity, nationality and study design [117]. However, a few studies have indicated some instability of the SOC over time [118-120]. Further, some studies have indicated a change before in comparison to after surgery [121-123]. In our study, a total of 63% were stable in their SOC or within ± 6 (*i.e.* approximately $\pm 10\%$). Also Karlsson *et al.* [122] have reported an unstable SOC and their corresponding figure was 41% *i.e.* SOC had changed more than 10%. A change $> 10\%$ in SOC values over time is considered as clinical relevant [86]. In a study by Eriksson & Lindström [124], 150 articles were investigated in a review. The results from this review showed only minor changes over time. In our study (IV), comparisons of the group means, showed no statistically significant difference. However, when comparing each patient at the two time points (McNemar test), statistically significant differences occurred.

7.2 Discussion of the results

The aims of this thesis were to study patients' experiences of undergoing LC in day surgery and problems associated with the recovery at home. Further, to compare LC performed in outpatient and inpatient care with regard to patients' perceptions of postoperative symptoms, the amount of distress these symptoms cause, levels of anxiety and general health during the first postoperative week. These variables were also investigated in a longitudinal follow-up of one and six months. It was also of interest to study sense of coherence and other predictors of postoperative pain and changes in health as well as the stability of the sense of the SOC scale.

7.2.1 Experiences of laparoscopic cholecystectomy

As studies focusing on patients' own experiences of undergoing LC surgery as an outpatient procedure are rare, it was fundamental to perform a qualitative study (I). The results from this study showed that living with gallstone disease had a great impact on these individuals' daily life before surgery. The respondents experienced various

problems at work and in social life due to the gallstone attacks. Also Menten *et al.* [125] found that gallstone disease had a profoundly negative impact on quality of life especially in symptomatic patients with a history of biliary colic attacks and complication of the disease. Further, the respondents (II) showed a wide range of problem areas such as anxiety the day of surgery, and during the first postoperative week they experienced pain, tiredness, nausea and vomiting, abdominal bloating, diarrhoea, sore throat and questions about wound care. In line with our results, Kleinbeck *et al.* [126] also reported that their patients experienced a wide range of problems and limitation due to soreness and tiredness especially the first postoperative day of recovery.

The descriptive approach in study I gave rise to questions about how frequent and how distressing patients found their postoperative symptoms to be. This was possible to study in a RCT where two groups of LC patients (outpatients and inpatients) were compared with regard to these matters (II) and further also in a longitudinal perspective (III, IV).

7.2.2 Outpatient versus inpatient laparoscopic cholecystectomy

Several studies have compared LC in outpatient versus inpatient care [29, 30, 32-35]. These studies have mainly focused on admissions, readmissions and complications. Further, some of these studies also focused on patient satisfaction, quality of life and costs. However, patients' self-reported postoperative symptoms were not to a greater extent investigated in these studies. In study II, comparisons were made between LC outpatients and inpatients regarding the frequency of postoperative symptoms and symptom distress during the first postoperative week. A high incidence of such symptoms was reported by almost all patients with no significant differences between the two treatment modalities except for a slightly higher rate of reported reduced mobility the first day after discharge (outpatients) and an increased frequency of sleeping disturbances on postoperative day 7 (inpatients). These differences however, are judged not to have an impact on the choice of the treatment modalities, outpatient versus inpatient LC surgery. Earlier, quality of life, patient satisfaction and resumption of activities were comparable between the investigated groups [33]. Various results regarding costs for outpatient surgery have been reported. Hollington *et al.* [32] found no cost advantages for LC performed in day surgery, but in other studies, costs for LC in day surgery was found to be lower [30, 33].

7.2.3 Postoperative symptoms

As there were only minor differences between the outpatient and inpatient groups (II) these groups were treated as one single group of patients in study III, and IV. Before the calculations in study III, a second quality control of the database was performed. This resulted in minor corrections of the frequencies of the symptoms and the amount of distress reported by the patients. However, this did not affect the main conclusion of study II, *i.e.* that outpatients and inpatients recovered equally well and that more LC patients should be offered the outpatient modality. In comparison to most other studies, we measured not only symptom occurrence but also symptom distress and pain intensity.

In the present studies the patients reported a total of 527 symptoms the first postoperative day. Most of these symptoms however, were resolved after six months when a total of only 163 symptoms were reported. In a study by Weinert *et al.* [12] 41% of their patients reported one or two symptoms and 15.5% reported at least three symptoms 6 months following LC. Among our patients 25% reported 1-2 symptoms and 34% reported three or more symptoms after six months. Symptoms occurring *de novo* were reported by our patients which is in line with other studies [65, 94, 95].

The three most frequently reported symptoms by our patients the first postoperative day were pain (93%), reduced mobility (91%), and tiredness (91%), symptoms also reported by other authors [29-35].

Among our patients, pain intensity averaged 40mm (VAS) in the evening of the first postoperative day and 59% of the patients reported VAS > 30 mm. Almost the same amount of patients (55%), consumed supplementary non-prescribed analgesics postoperative day 3 and one fifth (19%) needed opioids in addition to the standard prophylactic analgesic treatment. Other authors have also studied pain intensity. For example Rawal *et al.* [127] who reported an incidence of severe pain in 35% of the patients after day surgery despite analgesic treatment at home. Further, Bisgaard *et al.* [79] reported that 13% of their patients had severe pain throughout the first postoperative week. These results show that our patients as well as others seem to be inadequately provided with pain medication during the first week after LC. To be discharged from our hospital, one criterion is adequate pain control *i.e.* VAS \leq 30 mm, a level that a considerable amount of our patients exceeded the first evening at home. Persistent abdominal pain is the main reason of surgical treatment failure and has been reported to range between 13% to 37% after cholecystectomy [35, 62]. Among our patients, pain was reported by 14% at 6 months following LC. Patients undergoing LC should be

provided with aggressive analgesic treatment to avoid transition to long term pain [44]. Kehlet *et al.* [128] state that 2-10% of their patients postoperatively developed long term pain. This may significantly interfere with the patient's employment status and social life.

Reduced mobility, another common symptom following LC, was reported by almost all of our patients (91%) the first day after surgery (III) as well as by other authors [34, 35]. These authors found that outpatients reported higher mean scores for problems with mobility, probably due to the lack of an available carer at home. This explanation might also be true for our outpatients (II). This result is in contrast to Keulemans [34], who reported reduced mobility in both their outpatient and inpatient groups one week after LC. After one week 23% of our patients reported this symptom, but after 1 and 6 months respectively this figure had decreased to 10% (III).

Tiredness troubled most of our patients (91%) on the first postoperative day (III). This was in contrast to Beauregard *et al.* [129], who reported that 54% of their outpatients (gynaecological laparoscopies, shoulder and hand surgery) experienced tiredness. An explanation for the lower frequency in the referred study might be due to the fact that a LC is a more complicated procedure than the procedures reported by Beauregard *et al.* [129]. Tiredness was significantly less frequently reported postoperative day 7 in comparison to the first postoperative day and further significant improvement in symptom occurrence was noted after one month. The reported frequency of tiredness 6 months after LC (10%) seems to be close to the population baseline in a Swedish normal population, severe tiredness is reported by 10% of the females and 5% of the males [130].

Sleeping disturbances following recovery after uncomplicated LC has been studied by Bisgaard *et al.* [55] who investigated parameters like physical motor activity, sleep duration, night sleep fragmentation, subjective sleep quality pulmonary function, pain and fatigue one week before and one week after LC surgery. They found that levels of physical motor activity, fatigue and pain all returned to normal 2 days after LC. Subjective sleep quality was significantly worsened on the first postoperative night and sleep duration was significantly increased on the first two postoperative nights. About 38% of our patients reported sleeping disturbances the first postoperative night. However, the symptom decreased during the first postoperative week and was much less reported after one and six months respectively.

PONV are other common symptoms after LC. Nausea was reported by approximately half of our patients the first postoperative day while postoperative vomiting was less frequently reported (approximately 20%). PONV among our patients decreased during the first postoperative week where after these symptoms very rarely were reported.

To decrease the levels of PONV among patients undergoing LC, identification of those who are at increased risk is crucial. A high incidence of PONV have been reported in women, individuals with a history of motion sickness or previous PONV, non-smokers and in association with the use of opioids [50, 131]. Recommendations for PONV prophylaxis and treatment are given with regard to the patients' risk for PONV, potential adverse events associated with various antiemetics and efficacy of antiemetics. Patients at low risk are unlikely to benefit from prophylaxis and could be exposed to potential side-effects of antiemetics [50].

Experiences of gastrointestinal symptoms such as bloating and diarrhoea were expressed in the qualitative study (I) and approximately 12% of the patients (III) reported diarrhoea the first postoperative day and the frequency remained unchanged over time. However, when measuring bowel function by means of HI preoperatively and after six months, a significantly greater proportion of patients reported improvement after six months (III). Giurgiu *et al.* [61], have reported on gastrointestinal problems and the vast majority of their patients who reported persisting diarrhoea were women. Men reported no change in bowel function. Further, unresolved pain is shown to be correlated with preoperative bloating and constipation [132].

Sore throat was also experienced as a problem among our respondents the first week following LC. The frequency of patients reporting this symptom decreased after one week where after only a few patients reported this symptom. Chung [133] reported an incidence of sore throat in 28.6%. This was found to be surprising since 70% of these patients were not intubated and did not have an oropharyngeal airway.

Another issue that concerned our patients were questions about wound care (I). Also Young & O'Connell [78] reported that their patients were concerned about whether to bathe the wound or not and about re-dressing the wounds. Further, Leeder *et al.* [48] found that patients felt dissatisfied because of inadequate advice given regarding suture management. Some of their patients visited their general practitioners due to wound problems. To reduce this problem, patients should be provided with better instructions on how to care for their wounds. In the event of skin discoloration and bruising, nurses

should provide the patients with information to help them understand and cope with such conditions.

7.2.4 Symptom distress

Symptom distress is initiated by the occurrence of a symptom and is the emotional response to a stressor [38]. Distress makes the patients actively manage a symptom, ask for help, and use their own strategies to reduce the stressor. However, the distress escalates if the patient's ability to manage useful strategies is ineffective or absent [67]. The occurrence of more than one symptom may result in severe symptom distress [67, 69]. Management of symptom distress following surgical procedures has become increasingly important to enhance patients in their recovery. Forty percent of our patients reported that they were much/very much distressed by pain on the first postoperative day (III). This was also in line with the results reported by Cason *et al.* [46]. They reported that the umbilicus was the site of the most distressing incisional pain. This type of pain is described to be the most dominating pain component following LC [79]. Another pain element, shoulder pain, presumably referred visceral pain [44] was described as distressing by respondents (I, II). According to Cason *et al.* [46] shoulder pain, reported by 31% of their patients, was found to be most intense and most distressing on day 1. Finan *et al.* [92] investigated patients as regards sixteen gastrointestinal symptoms following cholecystectomy. Their result showed that the distress of diarrhoea was rated to 1.3 out of 4, not significantly different from preoperative scores and the most persistent distressing symptom throughout the study period was tiredness, reported to be 'much/very much' distressing by approximately 10% of our patients (II, III). Studies assessing the distress of symptoms in a longitudinal perspective following LC are scarce. In study III, 30% of our patients reported at least one 'much' distressing symptom 6 months following LC which calls for further investigation.

7.2.5 Sense of Coherence and health

Patients ability of managing stressful situations has been studied by Antonovsky [87] using his salutogenic model of health, where sense of coherence (SOC) is the central concept. Antonovsky [87] states that experiences of health are related to an individual's SOC, meaning whether the stressors in life are experienced as comprehensible, manageable and meaningful. Studies have shown that people with high SOC seem to be more flexible under stressing circumstances than people with low SOC. A relation

between SOC and good perceived health has been confirmed. The stronger the SOC the lower the amount of subjective complaints and symptoms of illness [134-143]. SOC has been found to be strongly related to especially mental health, [141, 143] and may also predict health. Moreover, SOC is reported to be an important contributor for the development and maintenance of people's health. However, SOC together with other factors like age, social support and education may predict health [116].

In study IV, SOC was investigated preoperatively and six months after LC surgery in order to define predictors of changes in HI. Our multiple regression models showed that 19% of changes in HI between day 7 and 1 month following LC could be explained by high symptom distress score postoperative day 1 and a low SOC score. One explanation of this finding might be that patients with low SOC who perceive severe early postoperative symptom distress have a prolonged recovery after surgery. Further, our patients were healthy except for gallstones, which might have caused a 'ceiling effect' because for patients reporting a HI score close the highest possible value before surgery, any improvement is unlikely to be recognized postoperatively. Quintana *et al.* [90] also investigated predictors of health related to LC. In their study, health was reported to improve three months following LC in symptomatic patients with low surgical risk after one year as well as after 17 months [92].

7.2.6 Predictors of pain

Predictors of early pain the first postoperative week were investigated in a multiple regression model (IV). Twenty-nine percent of postoperative pain measured as VAS-mean could be explained by the three independent variables age, HI and education. Bisgaard *et al.* [93] reported that less than 10% of variability of pain the first postoperative week was explained by preoperative neuroticism, sensitivity to preoperative cold pressor-induced pain, and age. In our multiple regression models, age was the strongest predictor. On the contrary, in a study by Jørgensen *et al.* [72], age failed to predict pain.

Pain and psychological symptoms have earlier been stated to relate with poor postoperative outcome following LC [144]. Bisgaard *et al.* [93] stated that preoperative neuroticism was a predictor of pain but only one-half of their patients complaining of intense postoperative pain, were considered as neurotic. In study IV, SOC was investigated as a predictor of postoperative pain following LC. SOC has not earlier been investigated as regards LC patients. Svebak *et al.* [145] found that low SOC correlated with higher pain scores in gallstone disease before surgery. Further, they

reported that patients with persisting pain were more neurotic and they found a strong association between pain and psychic vulnerability. Our results showed that low SOC score was a significant though weak predictor of postoperative pain the first week.

7.2.7 Sex differences

Few studies have focused on sex differences in the recovery after LC despite the fact that LC is relatively common also among men. In the present study (III), females reported significantly more symptoms day 1 and day 7. Moreover, women scored significantly higher overall level of distress the first postoperative day. Women also perceived poorer health and worse physical well-being one week after surgery compared to the male group. This is in line with Stefaniak *et al.* [146], reporting that women perceive more postoperative complaints, indicating that they might recover differently from men. Further, women have been found to report more anxiety than men [147-149]. Generally, women seek medical advice more often than men at the time of symptom onset and men wait for undergoing surgery until a more advanced stage [150].

8 SUMMARY AND CONCLUSIONS

- A great number of symptoms and problem areas were expressed by the patients during the first postoperative week. All these issues need to be considered in planning and delivering future nursing care.
- Pain was one of the most common and distressful postoperative symptom the first week after LC surgery and the pain medication provided did not seem to be sufficient. Thus patients should be provided with a prescription on analgesics preferably at the preoperative visit.
- LC patients in outpatient and inpatient care recover almost equally well, indicating that a greater proportion of LC patients should be offered the outpatient modality.
- Symptom occurrence and symptom distress decreased rapidly during the first postoperative week and patients' perception of their health mainly improved between one week and one month after LC. After six months, however, 30% of the patients reported at least one distressful symptom. Females reported more postoperative symptoms suggesting a different recovery after surgery. Future research focusing on distress management may lead to a more effective management of symptoms.
- SOC was found to be a significant but weak predictor of pain intensity the first week after LC. Patients scoring low SOC values experienced a delay in their health improvement during the first month. Patients with low preoperative SOC values might benefit from an individualized support programme. SOC was more unstable over time than previously suggested.

9 CLINICAL IMPLICATIONS AND FUTURE RESEARCH

The knowledge gained has shown a number of important clinical aspects of undergoing LC and the patients' experiences of symptoms after LC surgery. Nurses play a key role in improving patients' well-being in the recovery and it is imperative that nurses employ a holistic approach in relation to symptom management. Nursing care for patients undergoing LC involves early identifying of anxious and vulnerable patients to provide extended information about the operation and the recovery process. Patient information is a key factor for optimal management of postoperative symptoms after surgery for the patient and the carer as well. Consistent information about the surgical procedure, anticipated sensory experiences and analgesics treatment may promote the recovery and make the patient to feel safe and comfortable at home. Support and necessary advice should not end with discharge from hospital. Future research from a nursing perspective is important and should focus on the following questionings:

- What do LC patients consider as good postoperative care?
- What impact does patient information and nursing support have on vulnerable LC patients?
- Is SOC a clinically useful measure to identify vulnerable LC patients?
- Do LC patients benefit from individualized pain medication, information and nursing care?
- Do women and men request the same type of information as regards the recovery following LC?
- Do women and men differ as regards distressful symptoms following LC?

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11 SWEDISH SUMMARY

Syftet med **Studie I** var att undersöka patienters upplevelser i samband med gallstenssjukdom samt hur den första postoperativa veckan upplevdes efter laparoskopisk galloperation i dagkirurgi. Tolv patienter intervjuades en vecka efter operationen och data analyserades med kvalitativ metod. Resultatet visade försämrad livskvalitet på grund av plötsligt uppkomna gallstensattacker samt att respondenterna kände sig socialt handikappade. Inför operationen upplevdes oro och lugnande läkemedel efterfrågades samt önskemål om att få träffa ansvarig kirurg. I samband med utskrivning från sjukhuset, upplevdes amnesi och man mindes inte viktig information. Smärtupplevelsen varierade i hög grad den första postoperativa veckan och smärtåterfall förekom på tredje dagen då de medskickade smärtstillande läkemedlen var slut. Behov av ytterligare smärtstillande medel uttalades. Uppkördhet, illamående och kräkningar upplevdes och frågor om skötsel av operationssåren ställdes. Att som nyopererad komma hem till småbarn upplevdes som svårt. Syftet med **Studie II** var att jämföra de två behandlingsalternativen LC utförd i dagkirurgi respektive korttidsvård samt att undersöka patienters självrapporterade förekomst av symtom, besvär av dessa symtom, oro/ångest samt upplevelsen av allmänt hälsotillstånd under den första veckan efter LC. Av 100 randomiserade patienter besvarade 73 patienter utskickade frågeformulär (dagkirurgi n=34, korttidsvård n=39). Resultatet visade inga signifikanta skillnader mellan grupperna avseende postoperativa symptom, förutom en viss ökad frekvens av rörelsesvårigheter dag 1 (dagkirurgi) och sömnsvårigheter dag 7 (korttidsvård). Cirka 90 % av patienterna i båda grupperna rapporterade smärta, svårigheter att röra sig och trötthet postoperativ dag 1. Illamående och aptitlöshet rapporterades av hälften av patienterna. Beträffande symtombesvär, sågs inga skillnader mellan grupperna. Cirka 40% rapporterade 'en hel del/mycket' besvär av smärta, svårighet att röra sig och trötthet dag 1 och 20% rapporterade illamående. Trots minskad symtomförekomst postoperativ dag 7, rapporterade en tredjedel av patienterna i båda grupperna smärta, men endast en patient var besvärad av symtomet. Under första postoperativa veckan minskade graden av oro/ångest signifikant i båda grupperna och upplevt hälsotillstånd hade efter en vecka (båda grupperna) återgått till utgångsvärdet. I **Studie III** undersöktes patienternas upplevelse av hälsoförbättring, symtomförekomst och besvär av symtom upp till sex månader efter galloperationen. Efter en månad rapporterades en signifikant hälsoförbättring samt fysiskt välmående jämfört med en vecka efter operationen. Hälsan förbättrades hos 42 patienter, 10 försämrades och 21 upplevde ingen förändring av sin hälsa. De vanligaste symtomen var smärta (93%), nedsatt rörelseförmåga (91%) och trötthet (91%). Totalt sex av 18 symtom rapporterades mindre besvärande dag 7 jämfört med den första postoperativa dagen. Mellan 1 och 6 månader sågs inga signifikanta skillnader avseende hälsoförbättring och symtomförekomst. Efter 6 månader rapporterade 30% av patienterna minst ett mycket besvärande symtom. Syftet med **Studie IV** var att undersöka prediktorer för postoperativ smärta och upplevd hälsa efter laparoskopisk galloperation. Sjuttiotre patienter, besvarade frågeformulär avseende känsla av sammanhang, självupplevd hälsa, symtomförekomst samt hur besvärande symtomen upplevts upp till sex månader efter operation. En multipel regressionsanalys visade att 29% av smärtintensiteten kunde förklaras av parametrarna ålder, preoperativt hälsotillstånd samt utbildning. Vidare kunde 19% av hälsoförbättringen förklaras av de två variablerna 'besvär av symtom dag 1' och 'känsla av sammanhang'. Reliabilitetstest av instrumentet KASAM mätt preoperativt samt efter sex månader visade en korrelation på $r = 0,55$.

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