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A journey to improve treatment outcome of laparoscopic cholecystectomy

Sandra C.Donkervoort



A JOURNEY TO IMPROVE TREATMENT OUTCOME OF LAPAROSCOPIC CHOLECYSTECTOMY

Sandra Carolien Donkervoort

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A journey to improve treatment outcome of laparoscopic cholecystectomy

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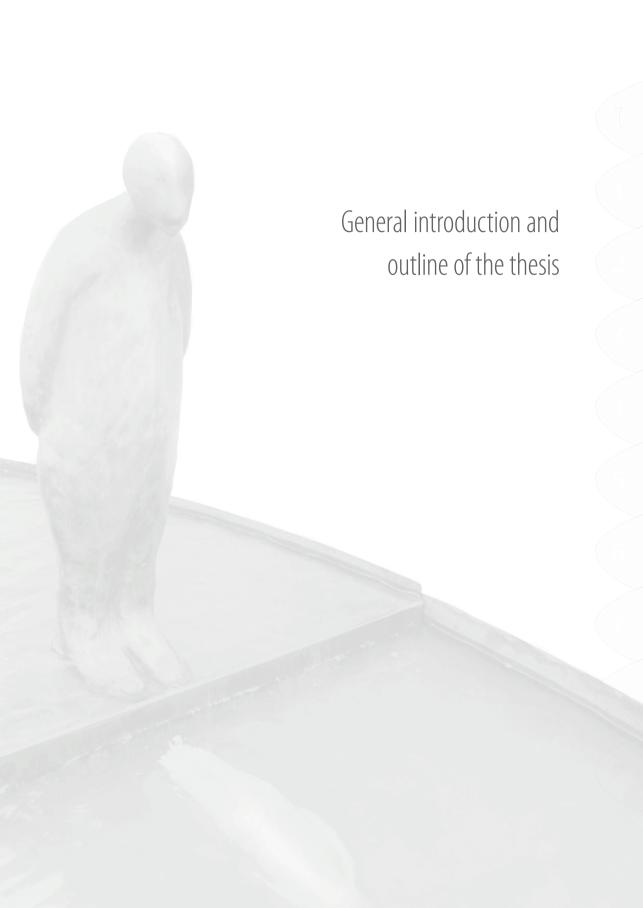
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'Kijken met je hart is geluk zien'

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GENERAL INTRODUCTION

Gallbladder

The gallbladder is a small organ, suspended to the liver, with a bile storage function. (1;2) When stones are formed in the gallbladder due to a disbalance in cholesterol, bilirubin and lecithin, this is called Cholelithiasis, (Greek; *chol*- (bile) + lith- (stone) + iasis- (process). (1-4)

The presence of gallstones in the adult Western population is very common: 10% to 15% is known to have gallstones.(5;6) The incidence of symptomatology is much lower, as the vast majority of patients remain asymptomatic. Still each year, 1% to 4% of these initially asymptomatic patients develop symptomatic cholelithiasis.(7-9)

This mounts to no less than 21,000 cholecystectomies yearly in the Netherlands alone (10) and renders symptomatic gallbladder pathology one of the most frequent diseases to manage. Subsequently, the cholecystectomy is one of the most frequently performed abdominal procedures in daily surgical practice. One out of three patients develops more serious gallstone related disease such as acute cholecystitis, choledocholithiasis and pancreatitis.(11)

For patients with symptomatic gallstone disease standard treatment consists of a cholecystectomy.(12-14) The classical open cholecystectomy was the gold standard for treatment until the late 1980's. A subcostal incision or laparotomy was the route to gallbladder removal. The gallbladder and common bile duct were identified through dissection and digital examination.

In 1987, laparoscopic cholecystectomy (LC) was introduced. This keyhole procedure revolutionized the surgical approach in general, and for the cholecystectomy this minimal invasive technique quickly replaced the open procedure. (4;4;15) For patients, an era began in which cholecystectomy could be performed with less impact. The advantages over the classic open cholecystectomy have become evident (16) with regard to postoperative pain, hospital duration, resumption of activity and cosmetic results. (17) For surgeons an era began in which a three-dimensional field with the possibility of digital and tactile identification changed into a two-dimensional image on a monitor with indirect tactile information.

Conversion

A laparoscopic cholecystectomy can be an unpredictable challenge because of chronic inflammation and fibrosis of the hepatoduodenal area. A surgeon confronted with chronic inflammation and fibrosis will need a high level of skills and knowledge to be able to keep the anatomy of the cystohepatic triangle clear (triangle between the liver, cystic duct and the common bile duct). Intra- and post- operative complications such as vascular- and common bile duct injury can be detrimental.

To prevent misinterpretation of the anatomy it is vital not to perform the procedure laparoscopically at all cost. In worst case, conversion to an open procedure provides the possibility to keep an anatomical overview by antegrade dissection. Digital examination of structures from the inside of an opened gallbladder may be helpful in severe chronic inflamed cases, especially if a Mirizzi syndrome is suspected.(18;19) Conversion thus is a sound decision in selected cases. However, conversion is not without consequences as it is associated with increased postoperative pain, pulmonary complications, longer hospital duration, and a longer recovery to normal activities. (20;21) If conversion can be safely avoided this will improve patient outcome and reduce healthcare cost.

Complication

Even though LC is a low risk procedure, complication rates are around 10-17%(22) (23) and each complication in this high volume surgery is of great medical concern. With about 21,000 cholecystectomies performed in the Netherlands annually we are confronted with postoperative complications in 2000-3000 patients each year. (10) Considering these numbers much can be gained by further improvement of care.

Most complications are minor. They are, however, not irrelevant as complications result in longer hospital stays and subsequent use of healthcare resources have been identified to increase two to five times even with a simple surgical site infection (SSI). (24) In addition, major complications such as bile duct injuries, bowel injuries, postoperative bile leak and haemorrhage are consistently reported as complications with significant consequences. (25) Impact of these severe complications on morbidity and mortality are impressive of which bile duct injury is most feared and known to impair quality of life significantly. (10;26;27)

To make laparoscopic cholecystectomy a safer procedure extensive attention has been given to a critical view of safety (CVS), training and assessment of surgeons performing LCs. Learning curves for residents have been defined. Many interventions have been tried to reduce bile duct injury. Even so, the rate of bile duct injuries (BDI) has remained unchanged over the years. Although bile duct injury rates are low (0.5-1%), they are still significantly higher than BDI rates in the open cholecystectomy era. Compared to the common bile duct injury rates less attention has been given to the more frequent cystic duct leakage and/or Luska leakage rates (1-2%), type A BDI according to the Amsterdam criteria. (28) Although less severe, these complications deserve focus for improvement as morbidity is high and can lead to a potential life threating situation. (29)

To improve LC outcome an additional focus to intra-operative safety, 'critical view of safety' (CVS) may be needed. If preoperative identification of patients at risk for a difficult cholecystectomy is possible and the fibrosis is no more unexpected, finding targeted management strategies accordingly will lead to reduced conversion and complications rates and improve LC outcome.

Quality of care

With quality standards being a topic of great interest in today's healthcare system, the importance of excellent care in high volume procedures cannot be overlooked. Strategies to reduce postoperative complications and conversion rates are of great value and result in health gain and reduction of costs.

Clinical auditing has been introduced in the field of more complex surgical procedures as a tool for quality assessment. Registration providing feedback on delivered care has been shown to lead to more awareness on outcome. (30-32) For gallbladder surgery no registry has been introduced in The Netherlands yet.

When confronted with an undesirable outcome in a registry, however, a journey to understand how outcome can be improved begins. Knowledge of which factors are most predictive for adverse outcome is needed. An epidemiologic assessment of a predefined specific adverse outcome measures is indispensable. Only then strategies to improve care can effectively be implemented.

Aim of this thesis

This thesis arises from information obtained from daily practice and sets out to improve treatment outcome of LC from a clinical perspective. We focus on identification of patients at risk for adverse outcome, optimal timing of surgery, the selection of the surgeon most qualified for the job, and individualized tailor made management for patients. Patients at risk of a specific complication are identified in order to select the optimal surgical technique to improve safety of surgery. Throughout this thesis post-operative complications and conversions were chosen as outcome measure as they are of value in validity.(33) Postoperative deaths and severe bile duct injuries are less applicable outcome measures because of the low incidence of these events.

The topics assessed in this thesis aim to improve 4 out of the 5 quality dimensions according to Donabedian (33), making LC safer, more effective, more efficient and more patient centred by individualizing care. The fifth dimension is accessibility.

OUTLINE OF THIS THESIS

In the **first part** of the thesis we aim to identify patient- and surgeon related factors that are predictive for adverse outcome of LC. When identified we weigh them for their contribution to an adverse outcome to determine their value in pre-operative management strategies in order to optimize care of patients with biliary disease. In the second part the focus is on surgical strategies and techniques with the goal to reduce complication rates and improve complication outcome.

The first two chapters of the thesis focus on insight into the potential pitfall of a difficult cholecystectomy. The question asked is whether the time interval between ERC and LC is of influence on the course of the LC as a reflection of the degree of fibrosis and scarring of the hepatoduodenal ligament. In **Chapter 1** outcome is conversion. In **Chapter 2** a broader scope is chosen in a larger patient population. Besides the time interval between ERC and LC, a larger set of potential risk factors are tested with both complication and conversion as outcome.

With the increasing insight into the relation between case load, specialization, centralisation and outcome for high complex-low volume surgery, the question arises whether outcome may be improved by assigning low complex high-volume procedures such as LC to specialized surgeons. The laparoscopic expertise of a gastrointestinal (GI) surgeon is more extensive than of a general surgeon with experience in LC. Does this expertise influence outcome of care for patients undergoing LC? This theme is addressed in **Chapter 3 and 4**. In chapter 3 the focus lies on surgeon selection in relation to conversion outcome, and in chapter 4 the influence of surgeon's volume on complication outcome is investigated.

Optimizing patient selection and pre-operative management is an important determinant in quality of care. **Chapter 5** addresses the search for individual risk factors associated with a specific complication. To improve individual outcome, knowledge on who is prone for which specific complication is indispensable. Defining individual pre-operative risk profiles can lead to improved care by awareness, individual decision making and individual prevention plans.

In the second part of this thesis we aim to identify the pitfalls in surgical techniques such as cystic duct occlusion and the subtotal cholecystectomy.

In **Chapter 6** a systematic review is performed to identify the different methods of cystic duct closure during LC and to find a superior technique by determining the associated leakage rates of the cystic stump. The consistent post-operative complications of cystic stump leakage are associated with significant perioperative morbidity and an increased risk of sepsis. With a meticulous cystic closure technique this complication

seems preventable, as bile leakage mainly results from failure of a correctly occluded cystic duct.

Chapter 7 addresses the effect of looped cystic duct closure on bile leakage rates compared to the conventional clipped cystic duct closure.

Chapter 8 addresses the subtotal cholecystectomy (STC) as an alternative laparoscopic option to end the procedure laparoscopically. In patients with severe fibrosis of the hepatoduodenal ligament it can be hazardous to obtain a critical view of safety with risk of severe bile duct lesions.

To investigate whether this procedure is safe (with an acceptable outcome of short and long term morbidity and quality of life) reconstituting and fenestrating STCs were analyzed.