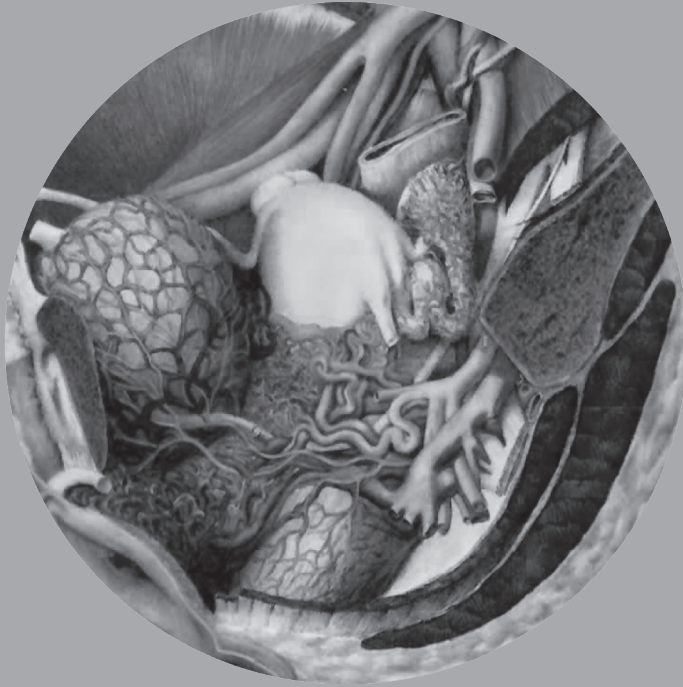


# 1

## INTRODUCTION AND OUTLINE OF THESIS





## INTRODUCTION

Hysterectomy is the most frequently performed major gynaecologic surgical procedure. There are three different approaches: vaginal, abdominal and laparoscopic. The vaginal approach is stated by a Cochrane database review as the preferred route to perform a hysterectomy when compared with the abdominal approach, because of significantly improved outcomes <sup>1</sup>. Comparison between laparoscopic hysterectomy (LH) and abdominal hysterectomy favours the laparoscopic method, because of faster return to normal activities, lower intra-operative blood loss, and shorter hospital stay <sup>1</sup>. The laparoscopic hysterectomy is introduced by Harry Reich in 1989 <sup>2</sup> and is gradually implemented. Besides the advantages of the laparoscopic above the abdominal hysterectomy the risk of major complications, such as haemorrhage and ureteral injuries seems to be increased, in particular during the learning phase.

## HAEMORRHAGE

Haemorrhage is one of the most frequent complications during surgery. Excessive bleeding during laparoscopic surgery increases the risk on complications, since it reduces the visibility of the operation field. Additional haemostatic actions under these conditions may increase the risk on bowel- and ureter related complications and may increase the conversion rate to laparotomy <sup>3</sup>.

In order to reduce haemorrhage related morbidity, adequate haemostatic techniques are essential during surgical procedures. In open procedures, conventional mechanical haemostatic techniques, using sutures or clips, are the most frequently used methods to control bleeding. After the introduction of the laparoscopy, other haemostatic techniques became more important given the difficulties to apply laparoscopic sutures. Different haemostatic techniques and devices have been developed over the time, such as laparoscopic suture ligation with knot tying manoeuvres, application of clips, and different electro- and thermal coagulation techniques using mono- or bipolar coagulation, and ultrasonic or vessel sealing devices.

But which technique is most effective concerning haemostasis? Several comparative studies assessed the efficacy of vessel sealing techniques in comparison to other haemostatic techniques during haemorrhoidectomies. However, comparative studies in open abdominal and laparoscopic surgical procedures are limited. Advancements in surgical technology and improved choice of surgical device have enabled more complex operations to be performed. But what is the evidence so far, which coagulation technique and device is the most (cost)effective during laparoscopic procedures?

## URETERAL INJURIES

It is well known that particularly during the learning curve, the laparoscopic hysterectomy may be associated with more urinary tract injuries such as bladder and ureteral injuries than open abdominal or vaginal approach <sup>1;4;5</sup>. Bladder injuries occur

in 2% (range 0-6%) of laparoscopic hysterectomies and ureteral injuries in 1.2% (range 0.6 -4%)<sup>4,6</sup>. Ureteral injuries are in 70% of cases detected after primary surgery, often resulting in an unintended laparotomy or second laparoscopy<sup>5</sup>. This will diminish the advantage of the initial minimal invasive approach using laparoscopy.

The course of the ureter in the pelvis renders it liable to injury during gynaecological operations, in particular during hysterectomies<sup>7</sup>. The most common location of ureteral injury in pelvic surgery is at the cardinal ligament where the ureter passes inferior to the uterine vessels. The ureter can also be injured at the level of the infundibulopelvic ligament and along the lateral border of the uterosacral ligament or along its course near the anterior vaginal wall<sup>8,9</sup>.

The role of a learning curve has been postulated in a cohort study, in which significantly more urinary tract injuries were seen when the first and more recent years of experience were compared in terms of complications of total laparoscopic hysterectomy; 2.3% versus 0.9% urinary tract injuries and 0.6% versus 0.2% ureteral injuries<sup>10</sup>. This was also underlined in 2001 after the analysis of a large Finnish database, including all 10.110 hysterectomies performed because of a benign indication in 1996. The incidence of ureteral injury decreased significantly from 2.2 to 0.5% in case the surgeons had performed more than 30 LHs compared to those who did perform 30 or less laparoscopic hysterectomies<sup>6</sup>. Ten years later a substantially lower incidence of ureteral injuries was reported during LH in the same database, which resembled the reported incidence during abdominal hysterectomy (0.3%)<sup>11</sup>. Nevertheless, ureteral injuries also occur in the hands of experienced gynaecologists, as the indication for LH is expanding and the difficulty of the operation is increasing<sup>12</sup>. However, despite the fact that LH is one of the most common performed major laparoscopic procedures in gynaecology, evidence based (peri)operative recommendations for optimal surgical techniques in terms of reduction of bleeding and prevention of ureteral injuries during LH are lacking. Most recommendations are authority or experienced based.

## OUTLINE OF THE THESIS

PART I: The first part (Chapter 2-4) of this thesis considers the effect of various haemostatic devices in laparoscopy on operation time, blood loss and complications.

PART II: The second part (Chapter 5-7) of this thesis considers predisposing factors for ureteral injuries during laparoscopic hysterectomy and recommendations to prevent them.

### *Part I - haemostatic devices used during laparoscopy to prevent bleeding and related complications*

Vessel sealing devices have been developed in order to improve efficacy of haemostatic action and reduction of lateral thermal damage injuries such as ureteral injuries. Based on these positive qualities, we tested the hypothesis that vessel sealing devices were in favour of other haemostatic techniques for its use during laparoscopic procedures, in particular during gynaecological procedures in terms of reduction of haemorrhage and related complications. Given the lack of randomized controlled trials on the use of vessel sealing devices in comparison to other haemostatic devices during laparoscopy in gynaecology on haemorrhage and complications we conducted two randomized controlled trials to study the most optimal device to be used during laparoscopic removal of adnexa and uteri and performed a systematic review.

In Chapter 2 we described a randomized controlled trial (RCT) to compare the effect of Ligasure (using the 5 mm vessel sealing device with pointed tip: LS1500 v) versus the conventional bipolar technique on operating time and blood loss during laparoscopic salpingo-oophorectomy.

In Chapter 3 the same Ligasure device was compared versus the conventional bipolar technique in a RCT on operating time and blood loss during laparoscopic hysterectomy.

The objective of the review in Chapter 4 was to report the available literature in a systematic way with respect to the efficacy and costeffectiveness of vessel sealing techniques in comparison to electro thermal or ultrasonic techniques in abdominal surgical procedures.

### *Part II - recommendations to prevent ureteral injuries during laparoscopic hysterectomy based on predisposing factors*

As the laparoscopic hysterectomy still has to be implemented in several clinics and countries, many gynaecologists have to complete their learning curve. In the second part of this thesis we tried to identify predisposing factors for the occurrence of ureteral injuries and tried to develop evidence based recommendations for gynaecologist performing LH in order to reduce its incidence and to improve the early detection of these complications to reduce undesired outcome of LHs.

In order to acquire all evidenced based information on the effect of specific surgical techniques applied or equipment used during laparoscopic hysterectomy on the incidence of ureteral injuries, we systematically reviewed all available literature on this topic (Chapter 5).

To develop also uniform international recommendations on the prevention of urinary tract injuries during LH, we performed a structured consensus procedure (Delphi method) among international experts in LH (**Chapter 6**). The Delphi technique is a method for structuring a group communication process in order to make the process more effective in allowing a group of individuals, as a whole, to deal with a complex problem<sup>13</sup>. The object of this study was to achieve consensus on required education, learning curve, equipment, surgical techniques, and on the application of diagnostic tools in early detection of urinary tract injuries.

Given the low incidence and the high clinical impact of ureteral injuries, much can be learned from each individual case. In order to identify predisposing factors for ureteral injuries and delayed recognition, we tried to identify all ureteral injuries that had occurred during LH in the Netherlands during the first 20 years after the introduction of this procedure in the Netherlands. In **Chapter 7** we describe the outcome of a survey among all LH-performing gynaecologists. All identified cases with an ureteral injury were analysed in a structured way. We aimed to identify patient- and surgeon-related risk factors for ureteral injuries during laparoscopic hysterectomy and related them to the previous recommendations as formulated in Chapter 5.

The main findings of this thesis, its shortcomings, the interpretation of the findings and its clinical and societal impact and the required future research are discussed in the general discussion of this thesis (**Chapter 8**). A summary of the main findings of included chapters are presented in both English and in Dutch (**Chapter 9**).

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