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Risks of Laparoscopic Surgery

Abstract

Laparoscopic surgery, like any operative intervention carries risks. In gynaecology in particular the patients are largely young fit women and significant complications, although rare, have devastating consequences. We review in short the issues to consider with regards to minimising risks and obtaining informed consent.

Keywords: Women; Laparoscopy; Risks; Surgery; Trocar; Injury

Mini Review

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Introduction

Early reference to a form of endoscopy dates back to the time of Hippocrates. It wasn't, however, until the turn of the last Century that the first experimental laparoscopy was performed. Georg Kelling used a cystoscope to examine the abdomen of a dog after first insufflating it with air [1]. Even though the rudiments of the technique are more than one hundred years old, operative laparoscopy did not gain acceptance until the late 1980's. Kurt Semm, a pioneer of gynaecological laparoscopic surgery, performed the first laparoscopic appendicectomy in 1980. This was deemed unethical by his peers [2]. Eric Muhe faced the same rejection from the German Surgical Society after performing the first laparoscopic cholecystectomy in 1985 [3]. The common theme was the belief that minimal access surgery was inherently risky and therefore flawed. The following account critically evaluates the evidence that laparoscopic surgery carries increased clinical risks to the patient, and increased risks of litigation to the surgeon. A discussion of new technologies in the field is included. An approach to auditing personal practise is outlined, and communication of specific risks to prospective patients undergoing laparoscopic gynaecological surgery is discussed.

The risks of laparoscopic surgery can be divided into risks associated with access and those risks related to the procedure [4,5]. Risks of access are quoted as 0.4 per 1000 incidence of bowel injury and 0.2 per 1000 incidence of major vascular injury [6]. Even if the higher risks from other studies are taken, 1.3 per 1000 [7] or 3 per 1000 [8], the rate of injury is significantly lower than for laparotomy or vaginal surgery; quoted as 8.3 per 1000 and 7.3 per 1000 respectively [9]. In Krebs' study the rate of bowel injury from laparotomy was similar to Richardson's figure of 3 per 1000, but even minor procedures (dilatation and curettage and evacuation of retained products of conception) carried a 1.5 per 1000 incidence of bowel injury. The risk of death from laparoscopic surgery is quoted as 8 per 100, 000 [10]. This is less than half the risk of death from driving, 17 per 100,000 [11], and puts the magnitude of the problem into perspective. Although the absolute risk from laparoscopic surgery is low, the number of laparoscopic procedures performed is large and the low risk rates are translated into a significant number of complications. For laparoscopic tubal occlusion alone there were 19 787 admissions in the United Kingdom in 2004-2005 [12]. This would result in four bowel injuries and two vascular injuries in otherwise presumed healthy young women. The expectations of the patients are of a low risk day case procedure. Consequently any significant misadventure related to such surgery is likely to proceed to litigation [13]. The Physician Insurers Association of America examined 535 laparoscopic cases of which 163 claims were settled out of court [14]. An average settlement figure of over $212000 is quoted. A quarter of claims were related to primary or secondary trocar insertion and 8.2% related to Veress needle injuries. Cautery equipment and instruments such as scissors or scalpels accounted for only 5.4% of claims. Claims for gynaecological cases with the Medical Defence Union have increased from 1 in 1000 in 1978 to 24 in 1000 in 1998 (Cuzner E for MDU Pers Comm 211106). In a review of potential claims notified to the Medical Defence Union from 1990 to 1996: 732 files were opened relating to laparoscopic abdominal procedures of which 74% were for laparoscopic gynaecological procedures [15]. In this respect laparoscopic surgery does carry increased risks of litigation to the surgeon.

In a prospective observational study of 5764 laparoscopic procedures, 57% of complications were caused by laparoscopic access [10]. A number of strategies have been explored to reduce risks of access of laparoscopic surgery. Hasson open laparoscopy is recommended on the grounds that use of the technique should prevent all type 1 injuries and, most importantly, all major vascular injuries of access [16]. The technique requires larger incisions with poorer cosmetic results and does not appear to reduce the risk of type 2 bowel injury [17]. Injuries to major vessels are usually immediately apparent with visible bleeding and shock. If such an injury is suspected insufflation should be immediately stopped to prevent massive carbon dioxide embolus. Immediate midline laparotomy with the Veress needle or trocar in situ may aid identification of the injured vessels. Bleeding should

be controlled with direct pressure accompanied by aggressive resuscitation whilst awaiting the arrival of a vascular surgeon [18].

A number of blunt trocars have been developed which are designed to push structures away during insertion rather than cause a laceration e.g. the Endotip® device (Karl Stortz, Tuttlingen, Germany). Alternatively a small bore flexible cannula is inserted and radially expanded with sequentially larger diameter blunt trocars to reduce type 1/2a bowel injuries (STEP® Innerdyne Salt Lake City, Utah, USA). Blunt trocars have also been designed for insertion under direct vision of the abdominal layers through the laparoscope e.g. the Endopath® Bladeless visual obturator trocar (Ethicon Endosurgery, Cincinnati, OH). There is even an optical Veress needle to allow the passage of a micro laparoscope for visualisation prior to in sufflation [19]. Although these new technologies have a logical basis to theoretically reduce the risks of injuries of entry, none have been robustly tested against either standard closed technique or open Hasson laparoscopy.

Less frequently injury may occur as a result of the operative procedure. The risks are directly related to the complexity of the procedure and the experience of the surgeon [4]. In this large multi-centre French study, which included almost 30,000 procedures, the overall complication rate was low (4.64 per 1000). Mortality risk from Chapron's study (3.3 per 100 000) is less than half the rate quoted by the Jansen study and was as a result of one death following a vascular injury which was discovered immediately. Compared to the risk of mortality quoted for abdominal hysterectomy (AH) of 1 in 4000 [20] the mortality rate from all laparoscopies was over eight fold lower. Major laparoscopic surgery carries significantly higher risk of complication at 4.3 per 1000 and advanced laparoscopic surgery higher still at 17.45 per 1000. The study period was divided into two and the complication risks significantly reduced in the later cases, implying increasing surgeons experience led to reduced risks. Surgeons experience has since been confirmed as an important modifying factor for risks [21,22]. Surgical complications are either identified intra-operatively, in the early post operative period or late. Although only 43% of complications arise as a result of the procedure [10] 28.6% remain unrecognised at the index laparoscopy [4]. With regard to bowel injuries alone up to 15% are not detected during surgery [23] and when diagnosis is late, the mortality rate is as high as 20%. A high index of suspicion is necessary for any patient who does not recover quickly from a laparoscopic procedure.

Bladder injury may result from direct perforation during secondary trocar placement or as a result of dissection, e.g. during laparoscopic hysterectomy (LH). If suspected, injury can easily be confirmed by cystoscopy and repaired. In cases of missed diagnosis the patient may present with lower abdominal discomfort due to urine peritonitis and rapidly rising serum creatinine. Injuries to the ureters are less frequently discovered intra-operatively [18] and there may be delayed presentation following thermal injury after several days. Specific imaging of the urinary tract may be diagnostic and urological advice should be sought.

A number of alternative energy sources have been developed to facilitate bloodless dissection in laparoscopic surgery. Carbon dioxide lasers [24] and Harmonic scalpels [25] theoretically reduce the risk of thermal spread and damage to surrounding structures compared to diathermy. These different modalities have not, however, been subjected to a randomised comparison. With very intricate surgery, reduction in surgeon's tremor and improved precision of manipulation is possible with the Da Vinci 'master slave'. The technology is, however, very expensive and the overall benefit is still under evaluation [26]. Simpler automated control devices for the laparoscope and camera have been developed including voice activated camera control, AESOP [27]. They may have a place, particularly in the era of fewer surgical assistants.

Despite potential hazards, the benefits of laparoscopic surgery have been shown to outweigh the risks for a number of common gynaecological procedures. Laparoscopic sterilisation using any method is associated with reduced major morbidity compared to the Pomeroy technique [28]. Laparoscopy is the gold standard for diagnosis in the investigation of chronic pelvic pain [29] and endometriosis [30]. In cases of unruptured ectopic pregnancy the surgical treatment of choice is via laparoscopy [31]. Laparoscopic surgery for benign ovarian tumours is associated with less pain, shorter hospital stay and fewer adverse events [32]. In some areas however the advantages of laparoscopic surgery remain controversial. The place for LH is still debated despite the fact that laparoscopic assisted vaginal hysterectomy (LAVH) was first described in 1989 [33]. Concerns include longer operative time and higher incidence of intra-operative injury, particularly to bladder and ureter, compared to vaginal hysterectomy (VH) or AH [34]. In LAVH there was no significant difference compared to VH regarding urinary tract injury or time for operation. The authors conclude that, where possible, VH should be performed in preference to AH; where VH is not possible a laparoscopic approach may avoid the need for an AH. Laparoscopic uterosacral nerve interruption in the management of dysmenorrhoea has not been shown to be of benefit [35]. Furthermore, the newer vaginal sling procedures appear to offer greater benefits of minimal access surgery than laparoscopic colposuspension in the treatment of urodynamic stress incontinence [36].

Having established that laparoscopic surgery carries some risks it is important for an individual practitioner to attempt to quantify outcome measures in their own surgical practice. The information collected allows easy comparison to established benchmarks and can serve as an alert if observed adverse outcomes are notably higher than those reported in the literature. Critical evaluation of personal practise was a focal point in the report of the public enquiry into children's heart surgery at the Bristol Royal Infirmary, 1984-1995. Clinical audit and reflective practise were highlighted in recommendation 57 [37].

In an audit of personal surgical practice I would review a surgical procedure which I perform regularly and, for the purposes of this assignment, hysterectomy for benign gynaecological pathology is the chosen example. A useful standard is set in the meta-analysis by Johnson et al. [34]. The review looks at randomised control trials comparing AH and VH with LH subdivided into LAVH, LH (a) with uterine artery secured laparoscopically and Total(T) LH [34]. The data provides some interesting benchmarks with regards to operating time, intraoperative injury to the urinary tract, estimated blood loss, transfusion rates, incidence of pelvic haematoma, infection rates and length of hospital stay. The pilot

audit of hysterectomy would involve a retrospective analysis of operating lists for a designated period (initially 12 months which may be extended if required to achieve power). A simple proforma would be devised to collect data in the categories pertaining to the outcomes listed above. Data would be entered on an Excel spreadsheet with type of operation as separate rows and each of the outcome measures in separate columns. The pilot would allow simple comparison of outcome measures between the five methods of hysterectomy commonly employed (VH, AH, LAVH, LH(a) and TLH). The outcome measures could then be compared to the benchmark data tabulated in the Johnson meta-analysis. The use of a pivot table would allow comparison of any one outcome measure and the alternative methods of hysterectomy. In my own practice there has been a reduction in overall numbers of hysterectomy for benign disease as well as a shift towards VH or LH from AH. A common criticism of retrospective audit is limitation of data to that which is easily collectable rather than that which is most clinically relevant. For example, in an audit of a surgical technique, operative time is most clinically relevant but the total time from entering the anaesthetic room until discharge to the recovery area is what is usually recorded. This can be addressed by collecting clinically relevant data prospectively. Following the retrospective pilot study I would continue to collect clinically relevant data prospectively to allow continuous assessment of outcomes. The prospective audit should inform me of any trends in complication rates. Another major criticism of audits of personal series are the small numbers of patients involved and the relatively lengthy period of time required to show any meaningful trends. I would propose that a mechanism be developed to pool data along the lines of the National Database for Surgical treatment of Urinary Incontinence in Norway [38]. Such a database would allow comparison between surgical procedures, surgeons and departments and is in keeping with the philosophy of informed choice for patients.

Effective communication of risk is fundamental to allowing the patient informed choice before consenting to any procedure. Consent is a process involving discussion between the patient considering treatment and the doctor offering the treatment. The discussion should include potential consequences both of undergoing the proposed treatment and of avoiding treatment altogether [39].

An interview based qualitative study has shown that women undergoing laparoscopy for chronic pelvic pain wished to receive full and accurate information about the complication risks [40]. However, the study had limited power. Even when patients are deemed to have given informed consent, many fail to understand what they have been told. Most patients fail to understand the risks and benefits associated with carotid endarterectomy [41]. The perception of risk can either be grossly under estimated or over estimated in an un-systematic way. This degree of confusion is alarming as the onus is on the doctor to provide accurate information in a manner that is accessible to patients. No one method of describing risk suits all patients. Some prefer descriptive terminology but such descriptors do not have standardised meaning [42]. Natural frequencies are a less confusing way of conveying the message [43]. However, the most reliable approach involves a combination of tools including use of a consistent denominator, discussion of both positive and negative outcomes, and use of absolute numbers; possibly with pictorial representation [44]. The Royal College of Obstetricians and Gynaecologists have produced a number of guidelines for consent for common procedures, including hysteroscopy [45], laparoscopy [46], laparoscopic tubal occlusion [47], and hysterectomy [20]. The published advice reiterates the advantages of discussing absolute risks and natural frequencies. Any absolute risks should be qualified according to the woman's personal circumstances, e.g. obesity, previous surgery and co-morbidities. In an ideal scenario personal complication rates of the individual surgeon may be available. Patients should be given a written summary of the risks divided into frequently occurring risks and rare but serious risks [48]. What is required for informed consent has changed dramatically over the last fifty years. In 1957 it was deemed acceptable for the doctor to withhold information regarding serious risks if this would be the usual practice of a body of opinion [49]. Across the Atlantic however, in Canterbury versus Spence [50], the concept of material risk was deemed mandatory for disclosure. The definition of material risk remains confusing, being a risk that a reasonable person would be likely to attach significance to. In this context reasonable has not been defined.

Summary

In summary laparoscopic surgery carries some risks but in general these are less than risks associated with open surgery. Poor outcomes and medical negligence claims can be minimised by adopting safe methods of laparoscopic entry and maintaining vigilance for early identification of missed intraoperative injury.

Practise should be subjected to continuous critical evaluation and adaptation where necessary. The standard determining how much should be told to the patient should be patient centred, preferably to the particular patient in question [51,52]. It is likely that in the future every risk, however infrequent is likely to require discussion supplemented with accompanying literature in the quest for truly informed consent.

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