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TRAINING AND TEACHING

The risks of laparoscopic surgery: II

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Introduction

The use of laparoscopy in gynaecological surgery has expanded considerably over the last 30 years. The main reasons for expansion in laparoscopy are its perceived benefits over traditional open surgery, e.g. less post-operative pain, reduced hospital stay/faster return to work, less scarring and reduced risk of adhesions (0.7 cf. 6.9%) [1]. Along with the increasing use of laparoscopic surgery, so the number of injury claims per annum has also increased, doubling from 750 cases to 1,500 from 1990–1999 [2].

The perceived risks of gynaecological laparoscopy may vary depending on the type of laparoscopic procedure performed and the ability of the surgeon performing it. Thus, the more complicated the laparoscopic surgery, the higher the risk of complications and the more experienced the surgeon, then the lower the risk of complications [3, 4].

As to whether laparoscopic surgery carries increased risks, one must first establish a comparison. The risk of death from laparoscopic surgery approximates the risk of death from home accidents (3/100,000), and even when the higher figure of 8/100,000 is used [5], the risk from driving is still double that (17/100,000) [6]. Conversely, the risk of death from an abdominal hysterectomy is approximately three times higher than that from laparoscopic surgery (25/100,000) [7]. Consequently, it could be argued that laparoscopic surgery does not carry more increased risks than certain traditional abdominal surgery methods in gynaecology, in respect to operative death rates.

When we consider morbidity, Garry describes increased major complication rates of laparoscopic hysterectomy (11.1%) over abdominal hysterectomy (6.2%) [8], which was 10 times (11.1 vs. 1.3%) that quoted by Chaperon et al. in 1999 [9]. This was largely due to the categorisation of major complications being more stringent in the 'evaluate' study compared to Chapron's group.

The risks of laparoscopic surgery can be divided into entry related complications, those that occur during the operation and those occurring post-operatively. New technologies such as the Endo tip device (Karl Storz, Tuttlingen, Germany) allows direct inspection via the laparoscope of the various layers of the anterior abdominal wall, thereby theoretically reducing the risk of type 1 and type 2a injuries [10]. The 'STEP' radially expanding device (Innerdyne, Salt Lake City, Utah USA) also avoids the use of sharp trocars. It is thought that in certain circumstances, some 2a adhesions may be pushed out of the way by the blunt ended dilator rather than penetrated [11]. Alternative approaches have been used with the optical verres system, whereby the use of micro-laparoscopes inserted down the verres needle may theoretically reduce the risk of inadvertent trauma [12]. There are, however, no randomised controlled trials, using any of these trocars, in a large series to prospectively back this new technology up. Even with disposable shielded trocars, the evidence for their use is scanty [13].

Various energy sources are used in laparoscopic surgery to enable both haemostasis and dissection of tissues. These range from mono-polar diathermy, to bi-polar diathermy, to harmonic scalpels and lasers. Theoretically, the thermal energy spread from the CO_2 lasers and harmonic scalpels may result in less risk of thermal damage to surrounding

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viscera, but this theoretical reduction in risk has never been subjected to randomised trials to date.

Robotics in laparoscopic gynaecological surgery are constantly being developed; however, their use in most theatres in the country is limited to all but a very few tertiary centres. Help with holding the laparoscope can either be with a passive holder or using a hand control device as is the case with the 'Lapman' or it can be voice-activated as in the case of the 'Aesop' [14]. Instruments can be manipulated as well with the aid of computer motion such as the 'Zeus' system and the intuitive 'da Vinci' system. Such instrument manipulation enhances surgical dexterity and eliminates tremor and this is ideal for difficult anastomoses, especially with fallopian tubes and ureters. Again the evidence to show that this significantly reduces clinical risks in clinical practice is lacking in the literature to date.

Given that laparoscopic surgery will have increased risks with a more inexperienced surgeon, the development of virtual-reality simulators to assess the laparoscopic capability of the surgeon have been assessed [15]. The 'mist 2' system evaluated 21 gynaecologists and showed a significant early learning curve for the majority of tasks which plateau by the third session. Whilst such a system is commercially available, more simple, inexpensive home-made laparoscopic trainers can provide training at a fraction of the cost, although a direct comparison of both these types of simulator has not been made to date [16].

Surgical complications

Surgical complications can arise intra-operatively, early post-operatively or late. The sooner a complication is identified, in general terms, the more likely this complication can be managed effectively. Thus, it is important to identify surgical complications as early as possible.

During insertion of a verres needle or indeed a primary trocar, a dramatic drop in blood pressure may signify injury to a major vessel. Blood may or may not exude from the needle. Bradycardia may also occur during creation of a pneumoperitoneum. This can be managed quickly by stopping the flow of gas and administering an anticholinergic agent [17]. Very rarely, a gas embolism may occur where carbon dioxide is introduced into a large vein via the verres needle. This may present with a raised JVP, cyanosis, sudden circulatory collapse, a drop in end tidal carbon-dioxide concentration and a characteristic mill-wheel murmur. It is important that the carbon dioxide and insufflation are stopped immediately and the patient rolled on to the left side and the Trendelenburg position maintained. The patient should be ventilated with 100% oxygen to prevent hypoxaemia and a large catheter inserted into the right atrium through the internal jugular vein to aspirate the gas. Immediate injury to the stomach may manifest itself with bouts of eructations and equivalent damage to the intestine may either result in flatulence or the detection of a faeculent smell. If the damage to the stomach or bowel is only the size of the verres needle, then no further surgical repair is required and antibiotic prophylaxis will usually suffice. If the damaged is of a greater diameter, then surgical repair will usually be required. Damage to the bladder may be apparent at the time of surgery and a small defect may be managed conservatively with the Foley catheter for 2 weeks. A larger defect in the bladder will need suturing. The identification of a ureteric injury can be difficult to assess intra-operatively. Indigo carmine dye injected intravenously to verify the leakage of dye through the ureter can be undertaken.

Patients who have had a laparoscopy should get better quickly and patients who are getting worse should be assessed by a senior clinician at an early stage to avoid fatal complications. Inadvertent injury to the gastro-intestinal system is recognised in only 35% of cases [9]. Hence, it is vital that early signs of abdominal sepsis are recognised and treated appropriately and quickly. Imaging using CT scanning showing 'microbubbles' amongst other more obvious signs has a better sensitivity for diagnosis of bowel injury over ultrasound and X-ray, and a raised serum amylase may also aid diagnosis of bowel injury.

There are many scoring systems that will alert the surgeon to signs of early post-operative complications, e.g. MEWS.(modified early warning system) or ALERT (acute life threatening events by recognition and treatment), that involve pulse rate, respiratory rate, blood pressure and urinary output amongst other factors. Within the first 6 h in abdominal sepsis the respiratory rate will usually be greater than 20. This will result in a reduced arterial carbon-dioxide concentration, usually of less than 4.3 KPa. In the early stages, the blood pressure may be normal or reduced, the pulse rate may be increased >90 and new onset atrial fibrillation may ensue. The white cell count will usually be above 12 (but can be <4) and a reduced mental state and oliguria may be present. Temperature is usually greater than 38°C, but a worsening prognosis would be associated with a body temperature less than 35°C or a respiratory rate less than 4. In such situations, the systemic inflammatory response syndrome (SIRS) will be present and this has a mortality rate of around 30%. A serum lactate may be raised at this very early stage and may provide an early clue to diagnosis.

It is important, at this early stage, that good intravenous access is obtained, blood cultures taken and broad spectrum antibiotics commenced within the first hour. A rapid infusion of intravenous fluid is often required. One should aim to keep the haematocrit >30%, the mixed venous

saturation greater than 70% and a central venous pressure of between 8 and 12 mm Hg. The base excess at this stage may well be negative and this is an early predictor of acidosis along with a reduced serum bicarbonate. Hyperglycaemia may ensue and it is important to keep a steady-state glucose concentration by using a glucose insulin infusion. If blood pressure is not maintained with rapid fluid replacement, then noradrenaline may need to be started (to increase vascular resistance, as sepsis induces massive vasodilatation via nitric oxide) and it is possible that intravenous steroids in the form of hydrocortisone 200 mg/day in divided doses may be useful [18], as may activated protein C in cases of multiorgan failure.

Thus, it is crucial that when surgical complications arise in laparoscopy, that the whole group, from the scrub nurse to the runner in the theatre, can work cohesively early on as a team to prevent intra-operative complications. At an early stage, post-operative complications must be recognised by nursing staff on the ward and junior medical doctors should have early recourse to senior involvement in a multi-disciplinary setting involving anaesthetists, outreach teams and colorectal surgeons.

Informing patients of risk

Women undergoing gynaecological laparoscopic surgery may initially be reluctant to discuss the risks of the procedure in general terms in up to one-third of cases (Moore et al. 2002). When the risks and complications are explained to them, however, almost all feel it is important to be fully informed of the appropriate risk of the procedure. Most risk figures given to patients will be in terms of the simplest basic risk (i.e. the absolute risk). This is the actual risk due to be surgical intervention without placebo.

The RCOG, have issued guidance on how women should be informed of risk in gynaecological surgery [19]. They suggest it better to avoid using verbal descriptors (e.g. high/low risk) or expressions of percentages when discussing risk. They believe it preferable to use natural frequencies and express risk in relative terms (e.g. if 100 people have this procedure, five of them will have this complication). Risks, associated with the woman's own health and medical history, should be explained and recorded on both a consent form and in the case records, and a copy of the consent form given to the patient. Should the patient choose to do so, they should be given the opportunity to discuss their own additional risks with another appropriate medical specialist before consenting to surgery.

Complication rates should be given by an individual surgeon on the basis of their own robust data, given alongside national figures. When risks are explained to patients, it is better if the clinician separates serious risks from frequent risks. Alongside risks of the surgery, the risks of alternative treatments, including no treatment should be explained, as well as explaining the advantages and success rates/benefits of the laparoscopic intervention.

Batt recommends providing the patient with a letter summarising the first consultation and also summarising the pre-operative visit whereby risks and complications and alternative therapies are discussed. He also recommends giving the patient a copy of her operative photographs, operative written report and pathology report at the first post-operative visit [20].

In 1957, medical paternalism was commonplace and generally accepted as exemplified by Bolam [21]. In 1984, the Sidaway judgment argued by Lord Scarman held the belief that it was a doctor's duty to inform a patient fully about a specific procedure [22]. Indeed this judgment was strengthened by the subsequent cases of Bolitho (1997) and Pearce (1999). The courts concluded that a doctor should tell a patient about any significant risk which would affect the judgment of a reasonable patient. Indeed even in very rare complications that may be particular to a specific patient, it is expected that the doctor should inform the patient of any complication that he feels may be appropriate to that patient, however small it may be [23].

Given practical limitations, it is probably impossible to inform a patient about every aspect of a particular procedure fully. It may be helpful to achieve a general standard of information. The Royal College has commissioned the use of guidelines for certain procedures and indeed has recently produced guidance documents on consent for specific gynaecological surgery, for example laparoscopy [5]. It is important, that along with information leaflets in appropriate languages, that doctors are appropriately trained in giving consent, so that patients can understand what they are saying and that an audit of such a consent process is undertaken.

In conclusion, in this essay, I have demonstrated that while gynaecological laparoscopic surgery may entail a higher risk of death than staying at home, the risk is not unacceptably high compared to open surgery. New technological developments may reduce risk of such surgery; however, many of them have not been fully evaluated with proper trials to date. I have highlighted the crucial importance of recognising surgical complications at an early stage by a senior doctor in an expedient manner in order to avoid serious morbidity or mortality. It is becoming increasingly difficult to adequately inform patients fully about all risks of a specific procedure; however, national guidance from the royal college of obstetricians and gynaecologists may help standardise information on risk given to patients in the future.

References

1. Audebert AJM (1999) The role of microlaparoscopy for safer wall entry: incidence of umbilical adhesions according to past surgical history. Gynaecol Endosc 8:363–367
2. Physician Insurers Association of America (2000) Physician Insurers Association of America laparoscopic injury study. Physician Insurers Association, Rockville, MD
3. Harkki-Siren P, Sjoberg J, Kurki T (1999) Major complications of laparoscopy: a follow-up Finnish study. Obstet Gynecol 94:94
4. Chapron C, Querlou D, Bruhat M-A et al (1998) Surgical complications of diagnostic and operative gynaecological laparoscopy: a series of 29,966 cases. Hum Reprod 13:867
5. RCOG (2004a) Consent advice 2. Diagnostic laparoscopy, October, RCOG, London
6. Guillebaud J (1984) The pill. Figure 1, Oxford University Press, Oxford
7. RCOG (2004b) Consent advice 4. Abdominal hysterectomy for heavy periods, October, RCOG, London
8. Garry R, Fountain J, Mason S, Hawe J, Napp V, Abbott J, Clayton R, Phillips G, Whittaker M, Lilford R, Bridgman S, Brown J (2004)The eVALuate study: two parallel randomised trials, one comparing laparoscopic with abdominal hysterectomy, the other comparing laparoscopic with vaginal hysterectomy. BMJ 328:129
9. Chapron C, Pierre F, Harchaoui Y (1999) Gastro-intestinal injuries during gynaecological laparoscopies. Hum Reprod 14:333
10. Ternamian AM (1999) A second-generation laparoscopic port system; Endo tip TM. Gynaecol Endosc 8:398–401
11. Turner DJ (1999) Making the case for the radially expanding access system. Gynaecol Endosc 8:391–395
12. Mc Gurgan P, O'Donovan P (1999) Optical verres as an entry technique. Gynaecol Endosc 8:379–382
13. Querleu D, Chapron C (1995) Complications of gynecologic laparoscopic surgery. Curr Opin Obstet Gynecol 7:257–261
14. Mettler L, Ibrahim M, Jonat W (1998) One year of experience working with the aid of a robotic assistant (the voice controlled optic holder Aesop) in gynaecological surgery. Hum Reprod 13:2748–2750
15. Gor M, McCloy R, Stone R, Smith A (2003) Virtual reality laparoscopic simulator for assessment in gynaecology. Br J Obstet Gynaecol 110:181–187
16. Pokorny MR, Mc Laren S (2004) Inexpensive home made laparoscopic trainer and camera. ANZ J Surg 74:691–693
17. Li TC, Saravelos H, Richmond M, Cooke ID (1997) Complications of laparoscopic pelvic surgery: recognition, management and prevention. Hum Reprod Update 3:505–515
18. Annane D, Sebille V, Charpentier C (2002) Effect of treatment with low doses of hydrocortisone and fludrocortisone for on mortality in patients with septic shock. JAMA 288:862–871
19. RCOG (2004c) Clinical Governance Advice No. 6: obtaining valid consent, October, ROCG, London
20. Batt RE, Mc Carthy JV (1999) Communication and documentation before and after laparoscopic surgery. J Am Assoc Gynecol Laparosc 6:379–381
21. Bolam v Friern Hospital Management Committee All ER 118 (1957)
22. Sidaway v Board of Governors of the Bethlehem Royal Hospital and The Maudsley Hospital AO 87(HL) (1985)
23. General Medical Council (1999) Seeking patient's consent: the ethical considerations. General Medical Council, London
24. Garry R (1999) Towards evidence-based laparoscopic entry techniques: clinical problems and dilemmas. Editorial. Gynaecol Endosc 8:315–326
25. Jansen FW, Kapityen K, Trimbos-Kemper T et al (1997) Complications of laparoscopy: a prospective multicentre observational study. Br J Obstet Gynaecol 104:595