

Gynaecological laparoscopic injuries: a 10-year retrospective review at a District General Hospital NHS Trust

K. L. Moores¹ · B. Bentick¹

Received: 26 August 2015 / Accepted: 29 February 2016 / Published online: 22 March 2016
© Springer-Verlag Berlin Heidelberg 2016

Abstract Worldwide, increasingly complex surgery is being performed laparoscopically; thus, laparoscopic complication rates may be increasing. Reported risks from all complications of laparoscopic surgery are between 1 and 12.5/1000 cases and serious complications in 1/1000 cases. Accurate complication rates of surgery are difficult to obtain as most data are from retrospective studies and may be incomplete. This paper is a 10-year retrospective review of gynaecological laparoscopic complications from 1 January 2003 to 31 December 2012. Data sources are SEMAHELIX Hospital Database, Gynaecology Complications Register, Clinical Governance Records, Complaints and Legal Cases. Recorded complications were classified as diagnostic, sterilisations and therapeutic laparoscopies. Further classifications are as follows: major complications and type of injury (bowel, urological, vascular, other), minor complications and failed sterilisations. Twenty-nine complications were identified from 5128 laparoscopies; total complication rate is 5.7/1000 procedures. Major complication rates are as follows: diagnostic, 2.2/1000; sterilisations, 3.3/1000; and therapeutic, 3.1/1000, subcategorised into bowel 1.4/1000, urological 0.2/1000 and vascular 1.2/1000. Our total complication rate lies within published national rates. Compared to published standards of major complications, diagnostic laparoscopy and laparoscopic sterilisation rates were comparable. Conversely, our therapeutic laparoscopy complication rate was much lower. The highest complication rate was in the failed sterilisation group; however, this rate is

within published sterilisation failure rates. Bowel and vascular complications were comparable; minor complication rates were low in all groups.

Keywords Gynaecological laparoscopic complications · Diagnostic laparoscopy · Sterilisations · Therapeutic laparoscopy · Laparoscopic bowel injury · Laparoscopic vascular injury · Laparoscopic urological injury

Introduction

Globally, laparoscopic procedures have gained popularity for diagnostic and sterilisation purposes, replacing the traditional laparotomy and their complication rates [1–3]. Furthermore, increasingly complex surgery is being performed laparoscopically, and thus, laparoscopic complication rates may be increasing worldwide [4, 5].

In the UK at present, approximately 250,000 women undergo laparoscopic surgery annually. Reported risks from all complications of laparoscopic surgery are between 1/1000 and 12.5/1000 cases, and serious complications occur in approximately 1/1000 cases [6]. However, in the current climate of advancing complex laparoscopic procedures, as most data are from retrospective studies, the data may be incomplete. There are several well-researched reasons why inadvertent surgical complications are underreported and why these numbers are difficult to obtain. Reasons can be divided into hospital recording system errors, including incorrect coding, human or individual errors and the reporting culture in the workplace environment. Despite governing bodies' encouragement for healthcare professionals to be open and honest with reporting errors, lack of disclosure persists [7]. Fear of medico legal litigation among practitioners is a reason

✉ K. L. Moores
karenshaw@doctors.org.uk

¹ Department of Obstetrics and Gynaecology, Women and Children's Centre, Princess Royal Hospital, Telford TF16TF, UK

of error underreporting [7], although evidence supports that disclosure does not increase litigation risk [8]. This is not solely a surgeon's issue, as there is published recognition that hospitals underreport their adverse events; literature shows that for every disclosed hospital error, 20 incidents were not reported [9]. This study aimed to avoid under-reporting of complications, by obtaining data from four different sources.

Four large independent European studies have evaluated complication rates among gynaecological laparoscopic procedures. The Finnish and Follow-up Finnish studies were retrospective analyses of data reported to the National Patient Insurance Association, which accurately records and investigates all surgical complications for financial compensation without proof of malpractice [10, 11]. The Finnish studied over 70,000 gynaecological laparoscopic procedures; the Follow-up Finnish studied over 32,000 procedures [10, 11]. The Dutch study was a prospective multicentre observational study of major complications in over 25,000 laparoscopic procedures [5]. The French study was a multicentre collaborative study of major complications in over 17,500 procedures with both retrospective and prospective data [12]. Subsequent to this, a French survey on gynaecological laparoscopy was published and revealed that the prevalence of severe complications could be three times the rate published by referral centres for major procedures; advanced laparoscopic complication rates had not yet been fully evaluated [13].

Total complication rates were reported between 3.3 and 5.7/1000 cases. The major complication rates of diagnostic laparoscopy were reported between 0.6 and 2.7/1000 cases, and major complication rates among laparoscopic sterilisation were between 0.8 and 4.5/1000 cases. Therapeutic laparoscopic procedures were associated with the highest rates of injury, with rates of major complications reported between 10.1 and 17.9/1000 cases [5, 10–12]. The major complication rates were subdivided into rates of bowel injury, which were between 0.6 and 1.54/1000 cases; urological injury, reported between 0.14 and 2.5/1000 cases; and vascular injury, reported between 0.1 and 1.05/1000 cases [5, 10–12]. Furthermore, rates of conversion to laparotomy of around 3.3/1000 cases were reported [5, 12]. Mortality rates among laparoscopic surgery were low, between 0 and 0.08/1000 cases [5, 10–12]. Minor complication rates were between 0.5 and 2.2/1000; these included minor infections, mild haemorrhage, voiding dysfunction and failed sterilisations.

The objective of our review was to determine the major and minor gynaecological laparoscopic complication rates at Shrewsbury and Telford Hospitals NHS Trust over the last 10-year period and compare our results with the published literature.

Methods

A 10-year retrospective review of all recorded gynaecological laparoscopic complications at the Shrewsbury and Telford Hospitals (SaTH) NHS Trust was conducted between 1 January 2003 and 31 December 2012. The main outcome measure was complication rates in each category of laparoscopy type (diagnostic laparoscopy, laparoscopic sterilisation, therapeutic laparoscopy). Furthermore, complications were further classified into type of major complication (bowel, urological, vascular, and other), minor complications and failed sterilisations; complication rates were recorded. Data sources included SEMAHELIX Hospital Database, Gynaecology Complications Register, Clinical Governance Records, Complaints and Legal Cases. Data were cross-correlated between all sources using patient identification details (namely, the name, date of birth and unit number), clinical coding as per ICD-10 and OPCS (4.6), and the recorded incident date.

Results

A total of 5128 gynaecological laparoscopic procedures were included in the review: 1381 diagnostic laparoscopies, 1206 laparoscopic sterilisations and 2541 therapeutic laparoscopies. Twenty-nine complications were identified; thus, the total complication rate was 5.7/1000 laparoscopic procedures.

The major complication rates per type of laparoscopic procedure were 2.2/1000 diagnostic laparoscopies, 3.3/1000 laparoscopic sterilisations and 3.1/1000 therapeutic laparoscopies. This is shown in Table 1 with comparisons against the four independent European study results. Of the total number of laparoscopies, rates of bowel injury were 1.4/1000 cases, urological injury was 0.2/1000 cases and vascular injury was 1.2/1000 cases. This is shown in Table 2 with comparisons against the four independent European study results. Specifically, in the diagnostic laparoscopy group, there were three major complications: two bowel perforations, one requiring laparotomy and colostomy, and one vascular complication. In the laparoscopic sterilisation group, there were four major complications: two bowel perforations, one requiring ITU admission; one vascular injury to the iliac vein, requiring ITU admission; and one postoperative laparotomy for suspected bowel injury. In the therapeutic laparoscopy group, there were eight major complications: three bowel perforations, one requiring laparotomy and ITU admission and one requiring laparotomy and colostomy; one urological injury (bladder perforation diagnosed during laparotomy for vascular injury); and four vascular injuries, one of which required intraoperative laparotomy.

The minor complication rates for each type of procedure respectively were 2.2/1000 diagnostic laparoscopies, 0.8/1000 laparoscopic sterilisations and 0.8/1000 therapeutic

Table 1 Total complication rates per 1000 cases with literature comparison per type of laparoscopy

Laparoscopy type	SaTH			Finnish	Finnish F/U	Dutch	French
	Total	Major	Minor				
Diagnostic	4.4	2.2	2.2	<0.6	0.6	2.7	1.1
Sterilisation	4.1	3.3	0.8	<0.8	0.5	4.5	
Therapeutic	3.9	3.1	0.8	10.1	12.6	17.9	5.2
Failed sterilisation	6.6	–	–	–	–	–	–
Total complication rate (/1000)	5.7			3.6	4.0	5.7	3.3

laparoscopies. Specifically, these were one perforation of uterus, one voiding difficulty, and one minor wound infection, requiring oral antibiotics in the diagnostic laparoscopy group; one small vaginal bleed in a patient who had undergone a recent LLETZ procedure 5 weeks earlier in the laparoscopic sterilisation group; and two minor wound infections were recorded in the therapeutic laparoscopy group. The rate of failed laparoscopic sterilisation was 6.6/1000 sterilisations; there was one recorded ectopic pregnancy among the eight recorded failed procedures. This is demonstrated in Table 1 with comparisons against the four independent European study results and summarised in Table 2.

Twenty-six complications were identified on the SEMAHELIX Hospital Database; all of these matched the 26 complications identified on the Gynaecology Complications Register. Of the 37 Clinical Governance Records, only 17 described actual surgical laparoscopic complications; 14 of these were cross-correlated with the recorded complication details on the SEMAHELIX Hospital Database; 3 were not recorded on the hospital database. These included two major complications: one conversion to laparotomy for left inferior epigastric vascular injury and one other vascular injury, with a delay in obtaining intraoperative cross-matched packed red-cell blood. The minor complication was a mild postoperative laparoscopic wound infection, requiring oral

antibiotics. Only two out of the total of seven complaints and legal cases described surgical laparoscopic complications; both of these were cross-correlated with the identified complications on the SEMAHELIX Hospital Database.

In total, there were ten recorded intraoperative conversions to laparotomy. These were categorised per type of laparoscopy: one conversion to laparotomy was in the diagnostic laparoscopy group, this identified a bowel injury; two conversions to laparotomy occurred in the laparoscopic sterilisations group, identifying one bowel injury and one vascular injury. Seven conversions to laparotomy were recorded in the therapeutic laparoscopy group; these identified three bowel injuries and four vascular injuries. Furthermore, during one of the conversions to laparotomy for vascular injury, a bladder perforation was also diagnosed. In addition, there was one recorded postoperative laparotomy. This was performed for suspected bowel injury 2 days following a laparoscopic sterilisation; however, no injury was found. Conversion to laparotomy data are summarised in Table 2.

Discussion

Rates of adhesion formation at the umbilicus are reported in 50 % of patients with previous midline laparotomy and 23 %

Table 2 Major and minor complication rates of all laparoscopy types per 1000 cases with literature comparison

Complication	SaTH	Finnish	Finnish F/U	Dutch	French
Bowel	1.4	0.6	0.7	1.13	1.54
Urological	0.2	0.3	2.5	0.14	0.4
Vascular	1.2	0.1	0.1	1.05	0.97
Other	1.9	–	–	3.3	3.25
	Intraop conversion laparotomy			Conversion laparotomy	Conversion laparotomy
	0.2		0.3		
	Laparotomy postop		Incisional hernia		
Deaths/1000 procedures	0	0	0.03	0.08	0.06
Minor	1.0	2.2	–	–	–
Failed sterilisation	1.8	–	–	–	–

of patients following lower transverse abdominal incision [14]. Past surgical history is of vital importance when contemplating future laparoscopic surgery, as laparoscopic entry is a significant time when serious complications can occur [15]. It is difficult to directly compare complications of laparoscopy due to entry technique. Evidence from two large studies have shown that in terms of bowel complications, there were reported rates of 0.6/1000 cases with an open laparoscopic entry technique, compared with 0.4/1000 cases when a closed entry technique was employed [16, 17]. However, no significant difference was demonstrated between open and closed laparoscopic entry techniques in terms of vascular complications [14].

Main findings

Our large review of 1528 procedures has demonstrated a total gynaecological laparoscopic complication rate of 5.7/1000 procedures. This rate not only lies well within published national rates of between 1 and 12.5/1000 cases but also within published rates from four independent large European studies of gynaecological laparoscopic complication rates of between 3.3 and 5.7/1000 cases [5, 10–12].

Compared to published rates of major complications of gynaecological laparoscopic surgery, our diagnostic laparoscopy, laparoscopic sterilisation and total major complication rates were comparable: specifically, 2.2/1000 compared with 0.6–2.7/1000, 3.3/1000 compared with 0.8–4.5/1000 and 2.9/1000 compared with 1.4–5.2/1000, respectively [5, 10–12]. Rates of bowel and vascular complications were comparable. Overall rates of conversion to laparotomy were very low; however, the number of cases increased from one in the diagnostic laparoscopy group to two in the laparoscopic sterilisation group and seven in the therapeutic laparoscopy group.

The reported rate of major complications in our therapeutic laparoscopy group was only 3.1/1000 cases; this figure is much lower than similar studies published rates of between 10.1 and 17.9/1000 cases [5, 10–13]; a possible explanation for this low figure may be because the four large European studies included reported complications from all advanced gynaecological laparoscopic procedures, including total laparoscopic hysterectomy (TLH). The first laparoscopic hysterectomy was performed in Finland in 1992 [18]. In the Finnish study, most of the major complications occurred in the TLH group: 64 % in 1993, 61 % in 1994; 94 % of the 18/20 bladder injuries in the therapeutic laparoscopic group and 94 % of the 16/18 urethral injuries in the therapeutic laparoscopic group occurred during TLH. In the Finnish follow-up study, 42 % (3928/9337 cases) of the therapeutic laparoscopies were TLH; 75 % of major complications occurred in this group, including 89 % ureteral injuries, when the injury was sustained during the laparoscopic part of the TLH. In contrast, the Dutch study

reported that of the 49 % (71/145) of major complications that occurred in the therapeutic laparoscopy group, only 16 occurred during TLH, 16 % occurred during laparoscopic oophorectomy and 24 % (17/71) occurred during extensive laparoscopic adhesiolysis. Procedures performed in the therapeutic laparoscopy group in our study included sterilisation (principally Filshie Clips), LAVH, salpingoophorectomy, ovarian cystectomy, excision and diathermy treatment to endometriosis, colposuspension and sacrocolpopexy. TLH was only introduced into our Trust after the study period, which may also explain our very low rate of only one urological injury; the lowest rate among the literature quoted.

Conversely, our highest complication rate of 6.6/1000 procedures was shown in the failed sterilisation group; however, this rate lies within recent published sterilisation failure rates of between 1.1 and 19.3/1000 procedures [19]. The authors believe that this seemingly high figure may be attributable to the relatively static local population in Shropshire, who tend to present back to the same Trust with pregnancy following laparoscopic sterilisation. However, time between the sterilisation procedure and the diagnosis of pregnancy was not evaluated; thus, this may not represent a true laparoscopic sterilisation surgical procedure failure, rather the known problem of recanalisation of the fallopian tube.

Over the last 15 years, practitioners have been aware that complication incidence is far greater in practice than the published literature suggests [20]. Incidents that result in patient harm were most likely to be reported; however, doctors were significantly less likely to report a surgical complication as an incident, as generally they are not perceived as such [21]. In our study, the SEMAHELIX Hospital Database failed to record two major complications. In total, the Hospital Electronic Database recorded only 26 out of 29 complications; 76 procedures were incorrectly recorded as gynaecological laparoscopies and were excluded from the data. The Hospital Electronic Database recorded complications in three gynaecological laparoscopy procedures where there were none. Improvement is therefore required before the Hospital Electronic Database can reliably be used to record gynaecology complication rates. In the current climate of increasing complaints and litigation, hospital Trusts must make every effort to improve and implement their processes of incident recording and reporting to achieve accuracy, thus minimising incorrect information.

Strengths and limitations

This is a large retrospective review of gynaecological laparoscopic complications, including a total of 5128 laparoscopic procedures over a 10-year period. Complication rates were categorised into laparoscopy type (diagnostic laparoscopy, laparoscopic sterilisation, therapeutic laparoscopy) and further classified into type of major complication (bowel, urological, vascular, and other), minor complications and failed

sterilisations. These complications were collated using several data sources including the SEMAHELIX Hospital Database, the Gynaecology Complications Register, Clinical Governance Records, and Complaints and Legal Cases. Subsequently, data were cross-correlated between all sources using patient identification details, clinical coding as per ICD-10 and OPCS (4.6), and the recorded incident date. Limitations in data cross-correlation occurred due to incomplete recording of complications on the SEMAHELIX Hospital Database and inadequacy in the systems for maintaining the Gynaecology Complications Register and Clinical Governance Records and recording all the Complaints and Legal Cases.

Interpretation (in light of other evidence)

Our total complication rate among gynaecological laparoscopic procedures lies within published national rates. Major complications in patients undergoing diagnostic laparoscopy and laparoscopic sterilisation were comparable to those in the literature. However, major complications in patients undergoing therapeutic laparoscopy were much lower. This may be a representation of the types of procedures being performed; during our study period, TLH procedures were not being performed in the Trust. Thus, hospitals performing increasingly advanced operative laparoscopic procedures are potentially more likely to have a higher complication rate.

Conclusion

Our total gynaecological laparoscopic complication rate of 5.7/1000 is within the published national rates of between 1 and 12.5/1000 cases. Compared to published standards of major complications, our diagnostic laparoscopy, laparoscopic sterilisation and total major complication rates are comparable. Our highest complication rate was in the failed sterilisation group of 6.6/1000 procedures; however, this rate lies within recent published sterilisation failure rates of between 1.1 and 19.3/1000 procedures. Conversely, our therapeutic laparoscopy complication rate of 3.1/1000 cases was much lower than the reported rates of between 10.1 and 17.9/1000 cases in the literature. Our rates of bowel and vascular complications were comparable to published rates of major complications of gynaecological laparoscopy. Total complication rates were comparable to literature rates; only one urological injury was reported; the lowest rate among the literature; no deaths were reported, and our overall rates of conversion to laparotomy were very low. Furthermore, the minor complication rates were low in all laparoscopy groups.

As regulatory bodies (Care Quality Commission), national bodies (Royal College Of Obstetricians & Gynaecologists), local bodies (Care Commissioning Groups, Trust Clinical Governance Bodies and Medical Directors), the media and patients all scrutinise the efficacy and risks of surgical procedures, it is important that the statistics are accurate and that organisations have comprehensive mechanisms to improve patient care and safety.

There are significant patient costs of surgical complications, including distress, delay in recovery, occasional loss of function or impaired lifestyle and impaired confidence in clinical care. For the Trust/organisation, complications result in the expenditure of significant time and resources to identify and address the issues to achieve resolution of the problem for the particular patient affected, improve patient care and to reduce complication rates, where possible. For the NHS and funding organisations, complication rates may be used as a measure of quality of care and result in increased costs of a service. Thus, any measures taken to reduce the incidence or impact of surgical complications are valuable. No attempt was made to calculate the cost of complications to the Trust, but this would be a useful exercise in the future, as it has been shown that implementing a programme of full disclosure of medical errors with compensation can be achieved without increasing total claims and liability costs [22].

In view of the imperfect Hospital Electronic Database in accurately recording gynaecological laparoscopic complications, our recommendations are to prospectively record data on all laparoscopic complications and to further evaluate our process of coding for gynaecological complications on the Hospital Electronic Database, using this to produce a dashboard of our local complications. The Clinical Governance Processes in the organisation should be used to validate the hospital electronic recording of surgical complications. These processes can potentially be extended to cover other endoscopy procedures, particularly hysteroscopic complications. Furthermore, in order to accurately document and inform patients of complication rates of increasingly complex laparoscopic surgery, such as TLH, we plan to conduct a prospective review for our Trust and again compare these results with current literature.

This 10-year review aims to raise readers' awareness of the current methods of recording laparoscopic complications and may encourage gynaecological departments to accurately record surgical complications rates and improve reporting compliance, to enable the Clinical Governance Processes to address these complications (particularly using root cause analysis). The overall objectives should be to publish accurate complication rates and reduce risk of complications, aid patient decisions regarding surgery, improve patient safety and to enable benchmarking for comparison.

Acknowledgments The authors would like to thank our Patient Experience Midwife and Patient Safety Advisor for their contributions in the review.

Author contributions The manuscript was written by the corresponding author (Dr KL Moores) with contribution from the co-author (Mr B Bentick). The authors were directly involved in the data collection, analysis and literature review.

Compliance with ethical standards

Funding Funding was not required for the review.

Conflict of interest The authors declare that they have no conflicts of interests.

Human and animal rights This article does not contain any studies with human participants or animals performed by any of the authors.

References

1. Rock JA, Warshaw JR (1994) The history and future of operative laparoscopy. *Am J Obstet Gynaecol* 170:7–11
2. Hulka J, Peterson H, Phillips J, Surrey M (1995) Operative laparoscopy: American Association of Gynaecologic Laparoscopists' 1993 membership survey. *J AM Assoc Gynaecol Laparosc* 2: 133–136
3. Grimes DA (1992) Frontiers of operative laparoscopy: a review and critique of the evidence. *Am J Obstet Gynaecol* 166:1062–1071
4. Querleu D, Chapron C (1995) Complications of gynaecological laparoscopic surgery. *Curr Opin Obstet Gynaecol* 7:257–261
5. Jansen FW, Kapitayn K, Trimbos-Kemper T, Herman J, Trimbos JB (1997) Complications of laparoscopy: a prospective multi-center observational study. *Br J Obstet Gynaecol* 104:595–600
6. RCOG Green-top Guideline No. 49. Preventing entry-related gynaecological laparoscopic injuries. May 2008. RCOG, London.
7. Munro MG (2002) Laparoscopic access: complications, technologies and techniques. *Curr Opin Obstet Gynaecol* 14(4):365–374
8. Leape LL, Berwick DM (2005) Five years after to err is human what have we learned? *JAMA* 293(19):2384–2390
9. Etchells E, O'Neill BM (2003) Patient safety in surgery: error detection and prevention. *World J Surg* 27(8):936–941
10. Harkki-Siren P, Kurki TA (1997) A nationwide analysis of laparoscopic complications. *Obstet Gynaecol* 89(1):108–112
11. Harkki-Siren P, Sjoberg J, Kurki T (1999) Major complications of laparoscopy: a follow-up Finnish study. *Obstet Gynaecol* 94(1):94–98
12. Querleu D, Chapron C, Chevallier L, Bruhat MA (1993) Complications of gynaecological laparoscopic surgery. A French multicentre collaborative study. *N Engl J Med* 328: 1355
13. Pierre F, Chapron CA (1998) French survey on gynaecological laparoscopy. *Hum Reprod* 13(7):1761–1763
14. La Chapelle CF, Bemelman WA, Rademaker BMP, Van Barneveld TA, Jansen FW (2012) A multidisciplinary evidence-based guideline for minimally invasive surgery. Part 1: entry techniques and the pneumoperitoneum. *Gynaecol Surg* 9:271–282
15. Hill DJ (1994) Complications of the laparoscopic approach. *Baillieres Clin Obstet Gynaecol* 8:865–879
16. Penfield AJ (1985) How to prevent complications of open laparoscopy. *J Repro Med* 30:660–663
17. Garry R (1999) Towards evidence-based laparoscopic entry techniques: clinical problems and dilemmas. *Gynaecol Endosc* 8:315–326
18. Mäkinen J, Sjöberg J (1994) First experiences from laparoscopically-assisted hysterectomy in Finland 1994. *Ann Chir Gynaecol* 83:59–61
19. Varma R, Gupta JK (2004) Failed sterilisation: evidence-based review and medico-legal ramifications. *BJOG: an International Journal of Obstetrics and Gynaecology* 111:11322–11332. doi:10.1111/j.1471-0528.2004.00281.x
20. Feste JR, Winkel CA (2009) Is the standard of care what we think it is? *JSLs* 3(4):331–334
21. Kreckler S, Catchpole K, McCulloch P, Handa A (2009) Factors influencing incident reporting in surgical care. *Qual Saf Health Care* 18:116–120
22. Kachalia A, Kaufman SR, Boothman R, Anderson S, Welch K, Saint S, Rogers MAM (2010) Liability claims and costs before and after implementation of a medical error disclosure program. *Ann Intern Med* 153(4):213–221