In Laparoscopic Myomectomy, Does a Caseload of 100 Patients During the Learning Curve Produce a Significant Improvement in Performance Measures?

Savan Shah¹ · Jimi F. Odejinmi² · Nilesh Agarwal³

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About the Author

Savan Shah is a final year medical student at Imperial College London. He received his BSc degree in neuroscience and mental health from Imperial College in 2014. His general research interests include education and training. His current focus is on laparoscopic myomectomy and fibroids. He has published articles in peer-reviewed journals indexed on Pubmed and has conducted poster presentations at national and international conferences including the Royal College of Obstetrics and Gynaecology, UK. His previous work in anaesthesia and psychiatry received research awards from the Royal College of Anaesthetists and the Royal Society of Medicine, respectively.

Savan Shah is a Medical Student in the Faculty of Medicine, Imperial College London, London, UK; Jimi F. Odejinmi is a Consultant Obstetrician and Gynecologist in the Department of Obstetrician and Gynecologist, Whipps Cross University Hospital, London, UK; Nilesh Agarwal is a Consultant Obstetrician and Gynecologist in the Department of Obstetrician and Gynecologist, North West London Hospital NHS Trust, London, UK.

✉ Savan Shah
savan.shah09@imperial.ac.uk

¹ Faculty of medicine, Imperial College London, Imperial College Road, London SW7 2AZ, UK

² Department of Obstetrician and Gynaecologist, Whipps Cross University Hospital, Whipps Cross Road, Leytonstone, London E11 1NR, UK

³ Department of Obstetrician and Gynaecologist, North West London Hospital NHS Trust, Northwick Park Hospital, Watford Road, London HA1 3UJ, UK

Abstract

Purpose Laparoscopic myomectomy (LM) offers considerable advantages over open myomectomy; however, LM is technically complex and associated with a steep learning curve. Few studies have evaluated the effect of the learning curve, and the limitations of most of these studies were the number of women included and the multiplicity of surgeons undertaking the procedure. The aim of this study is to evaluate the effect of a caseload of 100 patients during the learning curve of a single experienced surgeon performing LM.

Methods A prospective comparative analysis of 200 consecutive cases of LM was conducted between December 2004 and March 2013. Outcomes of the first 100 procedures (Group A) were compared with the later 100 (Group B).

Results The mean age of the cohort was 39 years (24–54 years), with a mean BMI of 27 kg/m² (16–46).

Both the groups were very similar with regard to the number, size and weight of myomas removed, the duration of surgery, and blood loss. More women were sent home within 24 h in the second group (27 vs 10.2 %, $p = 0.002$). Group A suffered significantly higher complication rates compared to Group B (11 vs 7, $p < 0.05$). The laparotomy conversion rate was 1.5 % (3 in Group A, none in Group B).

Conclusions After a caseload of 100 patients during the learning curve, there was no difference in outcomes apart from increased confidence to discharge patients after 24 h and reduced complication rates. Thus, mere numbers do not influence the number/size of fibroids removed, operating time, or blood loss but do influence complication rates and post-operative discharge times.

Keywords Fibroid · Myoma · Laparoscopy · Myomectomy · Leiomyoma

Introduction

Uterine myomas are the most common neoplasm affecting the female genital tract [1, 2]. Between 25 and 50 % of women of reproductive age are affected [1, 2]. Uterine myomas are associated with menorrhagia, dysmenorrhea, pelvic pain as well as infertility and recurrent pregnancy loss [3, 4]. Traditionally, hysterectomies were the primary treatment, but since Victor Bonney popularized myomectomy as an alternative uterine conserving surgical method of treatment for fibroids, there has been a shift toward more conservative management of symptomatic myomas [5, 6]. As more women choose to delay childbearing till later years, there is increased demand for conservative treatments such as myomectomies in order to preserve the uterus and as a consequence the reproductive potential [7].

Since Kurt Semm performed the first laparoscopic myomectomy (LM), in selected women, LM has become the gold standard with potential benefits over the traditional open myomectomy (OM) with shorter recovery times and reduced post-operative pain [8–11]. Numerous studies have shown that LM is not only as safe as OM but is also associated with shorter hospitalization, faster recovery, cheaper operative costs, fewer surgical complications and less pain, blood loss, and fever [12]. This was confirmed in a recent meta-analysis by Jin et al. [13]. Furthermore, no significant detrimental differences have been found in long-term outcomes, recurrence rates, and pregnancy rates between LM and OM.

Despite the advantages of LM, its availability has been limited by controversies surrounding selection criteria, the size and number of fibroids and in particular surgeon experience [10, 14]. LM imparts heavy demands on the

surgeon and is associated with a steep learning curve due to its technical difficulty, long operating times, and risk of conversion to laparotomy [14].

The learning curve is defined as a graphical representation of performance against experience [15]. It plays an important role in deciding when trainees can operate independently, start performing more complex cases in a safe manner, and achieve better patient outcomes. The trainee is assumed to have completed the learning phase when a plateau is reached in performance. While experience is usually quantified by the number of cases performed, performance is assessed by operative parameters such as operating time and blood loss and by patient outcomes such as transfusion requirement, length of stay, morbidity, and mortality rates. Currently, there is no definition for the minimum number of cases required to complete the learning curve nor are there any numerical standards for any of the performance parameters. Previous studies have used arbitrary samples of between 7 and 30 patients as an acceptable number of cases to perform in order to complete the learning curve [16, 17]. In addition, as there are no internationally acceptable standards for the performance measures, they used comparative analysis between the cases performed during the learning curve and an equivalent number of cases performed after the learning curve to identify an improvement in performance measures. Using these methods, if a significant improvement is not seen in a particular performance measure after the learning curve, it is assumed that the number of cases in the learning curve is too small. Reductions have been reported in operating times after learning curves of only 17 and 7 cases in 4-port and 2-port LM, respectively [16, 17]. However, these studies did not show improvements in other operative parameters such as blood loss, conversion to laparotomy rates, and post-operative outcomes such as length of stay, morbidity rates, and transfusion requirement. It is possible that a much larger number of cases are required to achieve improvements in parameters other than operating times. Therefore, the aim of our study was to evaluate the effect of a learning curve of 100 cases performed by a single experienced surgeon on the intra-operative and post-operative outcomes of the subsequent 100 procedures.

Methods

Two hundred consecutive women underwent LM from December 2004 to July 2013. The women were operated on by a single surgeon at Whipps Cross University Hospital, London, UK. All women who provided consent for the procedure and were considered suitable candidates were included. Women with uterine size > 28 weeks were

excluded. The first 100 women operated on were divided into Group A and formed the caseload for the learning curve. The subsequent 100 women were allocated to Group B and formed the post-learning curve caseload.

All women were assessed preoperatively and had preoperative mapping of fibroids either by ultrasound (USS) or magnetic resonance imaging (MRI). Women were counseled preoperatively about their recovery and informed that they would be discharged the next day. They were prescribed antibiotics at induction of anesthesia and appropriate postoperative thromboprophylaxis.

Operating Technique

The LM technique has been described in detail previously [18]. Initial entry was through an intraumbilical port with two 5-mm ancillary lateral ports for operating and suprapubic port. Palmer's point was used for initial entry in cases where the uterine size was more than 14 weeks. For additional hemostasis, 800 µg Misoprostol was administered rectally once the patients were in the Trendelenburg position. VasopressinTM in 1:30 to 1:60 of saline was infiltrated below the capsule as required intraoperatively. The Harmonic scalpel was used for most of the procedure. Bipolar and monopolar energy modalities were used, where extra hemostasis or cutting was required, respectively. A 5-mm myoma screw and grasping forceps were used for traction and counter-traction. The resulting defects were closed in 2 or 3 layers as required, using No. 1 Polyglactin intracorporeal (PolysorbTM, Covidien, UK) sutures, and for the serosa monofilament sutures, we used BiosynTM (Covidien UK). More recently, the V-locTM (Covidien UK) (unidirectional barbed) continuous self-retaining sutures have been used to close the serosa.

In order to minimize post-operative adhesions, site-specific adhesion barriers such as SprayshieldTM were used. Myomas were removed by morcellation through the suprapubic port, routinely weighed, and sent for histology.

Patient characteristics including age, parity, indication for surgery, size of fibroids on scan, associated pathology, number of myomas removed, blood loss during the procedure, length of stay, and intraoperative and postoperative complications were collected in a structured proforma and analyzed.

Data were collected prospectively and stored on a Microsoft Excel spreadsheet according to Caldicott guidelines, and consent was obtained from the patients to contact them regarding fertility outcome. Formal ethics was not required as this was an evaluation of ongoing practice. Data analysis was performed using SPSS. Cases were divided into two groups: the first consecutive 100 cases were labeled Group A and the subsequent 100 cases were labeled Group B. Descriptive analysis was employed

to analyze the data included mean (range), mean $\pm$ standard deviation (SD), or median (range). Boxplots and the Kolmogorov–Smirnov test were utilized to determine the distribution of data. The *t* test was used for the comparison group analysis if data were normally distributed. Otherwise, the Mann–Whitney *U* test was used. Levene's test was used to assess equality of variances, and where unequal variance was identified, the pooled estimate for the error term for the *t* statistic was not utilized and the Welch–Satterthwaite method was utilized to adjust the degrees of freedom. *p* values <0.05 were considered significant.

Results

A total of 200 women underwent LM during the study period and 750 myomas were removed (Table 1). The mean age was 38.9 ± 5.37 years. The mean BMI was 27 (16–46). 65 % of women were Afro-Caribbean, 21 % Caucasian, and 11 % Asian. The modal parity was 0. 49 % of the study population had a previous operation: either operative laparoscopy (37 %) or laparotomy (12 %).

Indications for surgery included subfertility (44 %), bleeding (37 %), and pain and pressure symptoms (19 %). The mean operative time was 115 min (40–240 min). Mean estimated blood loss was 317 ml (50–1500 ml).

The median myoma size was 6.8 cm (2–14 cm). 30 % of women had 1 myoma removed, whereas 70 % had more than 1 myoma removed. 67 % of women had myomas weighing <250 g, 17 % had up to 500 g, and 11 % > 500 g. 72 % of women had concomitant pathology: adhesions (44 %), ovarian cyst (19 %), and endometriosis (22 %).

Table 1 Demographics of Group A and B

	Group A	Group B
Mean age ($\pm$ SD)	39.0 $\pm$ 5.18	36.8 $\pm$ 5.55
Mean BMI (range)	26 (16–39)	27 (20–46)
Ethnicity		
Caucasian	22 %	20 %
Afro-Caribbean	68 %	62 %
Asian	8 %	14 %
Modal parity	0	0
Indications		
Subfertility	23 %	21 %
Bleeding	37 %	37 %
Pain and pressure symptoms	17 %	21 %
Previous operation		
Laparoscopy	35 %	39 %
Laparotomy	16 %	7 %

Table 2 Differences in operative parameters between Group A and B

	Group A	Group B
No. of myomas	3.64 (1–15)	3.47 (1–15)
Weight of myomas (gm)	219 (26–920)	223 (13–1024)
Size of myomas (cm)	7.77 (2–15)	7.62 (4–15)
Duration of surgery (min)	114.3 (40–200)	113.9 (45–240)
Blood loss (ml)	332.26 (50–1200)	306.70 (50–1500)
Discharged within 24 h**	10.2 %	27 %

Mean (range), ** $p < 0.01$

Table 3 Number of complications in Group A and B

Complication	Group A	Group B
Urinary retention	2	0
Blood transfusion	2	1
Mini laparotomy	2	0
Return to theater	1	0
Hysterectomy	0	0
Hernias	4	0

Parameters indicating the complexity of the operations undertaken such as number of myomas, size of myomas, and duration of surgery were higher in Group A compared to Group B (Table 2). However, this difference was not significant. Size of myomas was non-significantly lower in Group B compared to Group A.

Group A lost more blood on average (25.6 ml) than Group B, but this was not significant. Furthermore, Group A patients were approximately 2.5-fold less likely to be discharged early than Group B ($p < 0.01$).

Group A had a significantly higher number of complications than Group B (11 vs 7, $p < 0.05$) (Table 3). No major complications involving the bowel or bladder were encountered. Two patients in Group A were desaturating and required conversion to mini laparotomies. One patient was returned to theater for an exploratory laparotomy. The laparotomy conversion rate for Group A was 3 %, whereas Group B had a rate of 0. No patients in either group required a hysterectomy.

Discussion

LM is an important treatment option in women who want to preserve fertility. However, at the moment, it is only offered to a minority of women. It is a complex procedure with a steep learning curve requiring different skills than open surgery because of a two-dimensional representation of the operative site, limited tactile feedback, difficult suturing techniques, and the need for surgeons to learn different hand-eye coordination skills [13, 19]. Our study

shows that there is no difference in parameters such as blood loss and operation duration after the learning curve is reached. A 13-year longitudinal study by Rossetti et al. showed that these operation parameters do reduce after a learning curve of 4 years [20]. However, a number of confounding factors were present in the study including changes in suturing techniques, laparoscopic equipment, and vasoactive drugs prescribed throughout the study period. Furthermore, cases from all surgeons were pooled together and compared over time instead of comparing cases from individual surgeons over time. Studies assessing the learning curve in individual surgeons found that 7 and 17 cases were sufficient to achieve reductions in operating times in 2- and 4-port LM, respectively [16, 17]. Pandey et al. have shown that procedure-specific skills in general surgery reach a plateau after initial improvement and fail to increase with further operative experience [21]. Generic surgical skills in contrast do improve with increasing operative experience. Therefore, it is feasible that in our study, any initial improvements seen in the operative parameters are diluted because the surgeon rapidly reaches a plateau within the learning curve. However, the overall generic surgical skills of the operator continue to increase as the caseload increases.

Improvements were seen in postoperative parameters in Group B, suggesting that a caseload of 100 patients during the learning curve does improve post-operative outcomes. Over twice as many patients were discharged within 24 h in Group B compared to Group A. In addition, t tests revealed that Group B suffered significantly less complications. 3 % of patients in Group A required a laparotomy conversion, whereas no patients in Group B required it. As there were no significant differences in the case selection between Group A and B (Table 2), the reduction in complications suggests that the number of cases has either improved the surgeon's operative skills or ability to select patients with a higher likelihood of good post-operative outcomes. Marret et al. have shown that senior surgeons are 2.5-fold less likely to perform laparotomy conversion rates than junior surgeons [22]. However, in contrast to our study, they suggest it is not due to numbers as only one surgeon within their study had performed an LM more than 10 times. Instead they attribute reduced complication rates to other factors such as myoma diameter, fundal location, and generic surgical skills. In our study, factors such as myoma diameter remained the same between Group A and B, suggesting that the reduction in complications may be due to an increase in generic surgical skills, which could be attributed to the size of the caseload during learning curve.

The selection of cases also has an impact on the learning curve and possibly on the improvements achieved in intra- and postoperative parameters. There are no standard criteria for assessing technical difficulty of cases to select

suitable candidates for surgery. Various studies emphasize selecting cases which avoid blood loss, prolonged operating times, and conversion to laparotomy [13]. In addition, LM should not be performed on more than 4 myomas or myomas >8–10 cm in diameter [2, 7, 11]. Furthermore, it is not indicated in a uterus >14 weeks or in myomas near vessel walls or ostia or with deep penetration into the myometrium [13, 23]. With increasing experience, it is expected that surgeons become better at selecting appropriate cases [13]. Although there is no change in number or size of myomas operated on, the low rate of complications in Group B compared to Group A suggests that the patient selection has stayed the same with better post-operative outcomes, possibly suggesting increasing surgical skill. Conversely, it is possible that there is better patient selection but other criteria such as comorbidities are being used rather than number or size of myomas. In other specialties such as cardiothoracic surgery, a significant improvement has been shown in outcome measures when patient selection criteria based on experience and knowledge gained during the learning curve are instituted [24]. Therefore, it is highly possible that in LM, the improvements in outcome measures seen after the learning curve are largely due to better patient selection as a result of informal selection criteria developed by the surgeon through experience during the learning curve. If this is indeed true, the development of formal patient selection criteria for use in training may aid in reducing the length of learning curve.

Based on other laparoscopic procedures, it is also expected that the surgeons transition from simple cases to performing simple and technically complex cases [25]. Indicators of technical difficulty of cases such as number, size, and weight of myomas did not change between Group A and Group B, suggesting that the complexity of cases undertaken did not change over time. However, it could be argued that technical difficulty of cases selected is limited at both the learning curve and afterwards by the criteria established by the local surgical department.

This study was limited by the utilization of cases from only one surgeon. Individual learning abilities, technical skills, general surgical experience, and teaching support available may influence the learning curve for the individual surgeon and provide potential confounders for the data.

Conclusion

LM is a complex minimal access surgical procedure associated with a steep learning curve. It is clear that caseloads of 100 patients during the learning curve reduce complication rates and increase confidence in discharging

patients within 24 h. These improvements can be indirectly attributed to improvements in surgical skills as no significant differences were found in patient and operative parameters during and after the learning curve. Despite the effect of a large caseload on post-operative parameters, no improvement was seen in intra-operative parameters. Data from previous studies have shown that a caseload of 30 patients during the learning curve is sufficient to achieve improvements in operative times but not other intra-operative parameters [16, 17]. Studies involving larger caseloads during the learning curve are needed to identify how large the caseload needs to be to achieve improvements in intra-operative parameters such as blood loss as well evaluating if further improvements can be achieved in post-operative parameters by increasing the learning curve caseload beyond 100 patients. Finally, future studies must involve comparing learning curves in multiple surgeons from different institutions so that robust national or international standards can be set for performance measures and an optimal learning curve caseload number can be identified for training programs.

Compliance with Ethical Standards

Conflict of interest Savan Shah, Nilesh Agarwal, and Jimi Funlayo Odejinmi declare that they have no conflicts of interest.

Ethical approval The study did not require any formal ethics approval as it was a review of ongoing practice. However, informal approval was sought from the appropriate institutional research ethics committee and has been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Informed consent For this type of study, formal consent from patients is not required.

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