

Effect of simultaneous morcellation *in situ* on operative time during laparoscopic myomectomy

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BACKGROUND: Laparoscopic myomectomy (LM) is technically difficult and time consuming procedure that requires surgical skill and modifications. The aim of this study was to assess factors which affect operative times in LM. **METHODS:** From March 2003 to June 2007, 174 women, who underwent LM for symptomatic myomas, were enrolled. Standard LM was performed in the first 4 years and simultaneous morcellation *in situ* (SMI) method was applied in the fifth year. **RESULTS:** The mean myoma weight was 213.5 ± 190.4 g and the mean operative time was 117.0 ± 39.6 min. No laparoconversions occurred and there was a 2.3% rate of complications. Total myoma weight increased and operative time declined significantly over time. The surgeon's learning curve and the effect of SMI on operative time were identified by establishing a nonlinear multiple regression model. Model assumptions showed little violation by residual plots. Slopes of the average myoma weight (total myoma weight/number of myoma operated) for describing the operative time declined along with the study year, suggesting that operative experience is a major factor influencing operative time. SMI showed a further 19 min reduction in the predicted operative time. **CONCLUSIONS:** Operative time in LM is dependent on a multitude of factors including surgical experience. Applying SMI during LM is an efficient way to further reduce operative time.

Keywords: laparoscopic myomectomy; operative time; learning curve; modified procedure; nonlinear regression models

Introduction

Uterine leiomyoma is the most common benign tumor of the uterus in women of reproductive age. Laparoscopic myomectomy (LM) is one of the operative procedures used for uterine leiomyoma when fertility preservation is required. This technique is more advantageous than the abdominal myomectomy, with less post-operative pain, a shorter hospital stay and faster convalescence (Mais *et al.*, 1996; Marret *et al.*, 2004). However, LM is technically more difficult than the abdominal myomectomy (Seinera *et al.*, 1997). An initial training period is usually required for the majority of surgeons to become proficient in performing this procedure. Several factors have been used to evaluate surgeon performance and operative outcomes with LM, such as operative time, as well as laparoconversion rate, mortality and morbidity rates, blood transfusion rate, length of hospital stay, re-admission rate and occurrence of uterine rupture in a subsequent pregnancy (Dubuisson *et al.*, 2001; Marret *et al.*, 2006; Sizzi *et al.*, 2007; Rossetti *et al.*, 2007). Operative time, when incorporated to study surgical experience, was interpreted as the learning curve. The learning curve for LM has been rarely studied since operative times for

LM were reported as more variable than other laparoscopic operations such as laparoscopic hysterectomy or laparoscopic colorectal surgeries (Hsu *et al.*, 2007; Rossetti *et al.*, 2007). In addition, as the surgeon becomes more experienced, more difficult cases were subsequently included and modifications in surgical technique might have developed (Rossetti *et al.*, 2007). Interpretation of learning curve in such conditions is difficult. We previously analyzed our first 109 cases of LM and found that operative times in LM depend significantly on the myoma weights and on the number of myoma operated (Hsu *et al.*, 2007). Therefore, the learning curve for LM should be studied by appropriate adjustment using multivariate statistics.

To have a complete analysis on the learning curve, we extended our database to year 2007 so that more than 200 cases of LM were attempted. A new technique, called simultaneous morcellation *in situ* (SMI) (Chang *et al.*, in preparation), was developed in the last year of the study. This method was modified from Sinha's report (Sinha *et al.*, 2005) by doing morcellation directly on the uterine surface without prior enucleation (i.e. simultaneous enucleation and morcellation of the myoma *in situ*). The aim of this study was to use

our database from the first 4 years to provide an exploratory data analysis on the learning curve for LM. We next investigated the efficiency of introducing SMI to LM, by incorporating the learning curve as one of the potential confounding factors in a nonlinear multiple regression model fitted with the 5 years data.

Materials and Methods

Patients and indications

Consecutive women, presenting with symptomatic myomas, seeking uterus saving therapy and admitted for LM by Huang SC at the Department of Obstetrics and Gynecology, National Taiwan University Hospital between March 2003 and June 2007, were included. There was no age limitation. Cases initially selected for LM were limited to <8 cm dominant myoma size and no more than two or three myomas as purposed by Dubuisson *et al.* (1996) in the first half year of operation. However, more difficult cases beyond these criteria were gradually included based on the operator's experience. The basic clinical characteristics including age and body mass index (BMI) were recorded at admission. During the operation, the locations and types of the predominant myoma, and the number of myoma operated, were recorded. The operative time, estimated blood loss (EBL), myoma weight after operation, complications and length of hospital stay were recorded before discharge. Complications were categorized as: intraoperative bleeding of >500 ml, visceral organ (including bladder, bowel and ureteral) injury, post-operative ileus that required prolonged hospitalization, post-operative hemorrhage that required treatment, post-operative infection, fistula, thrombosis, embolism, or reoperation within eight weeks, and wound complications. A total of 221 women were enrolled during this study period. Informed consent was obtained from each woman before receiving the operation.

Gonadotrophin-releasing hormones were not used in any of these cases. Cases diagnosed as adenomyosis by pathological examination and cases with more than six myomas removed were excluded. Pedunculated or intraligamentous myoma as predominant myoma were excluded since enucleation is not required in either of these types of myoma (such that the advantage of SMI would not be seen). Standard LM was performed in the first 5 years of the study and the SMI technique was applied in all cases after February 2007 (the fifth year of the study). Data from cases in early 2007 that received the standard LM procedure were grouped into the fourth year for analysis.

Operative procedure

LM was performed by S.-C.H. with the assistance of W.-C.C. (first, second and fourth years of the study), W.-C.H. (first to third years of the study) or S.-Y.C. (last two years of the study). The detailed procedure for a standard LM was described in our previous report (Hsu *et al.*, 2007). Hemorrhage is controlled by subcapsular injection of vasopressin (0.2–0.4 U/ml normal saline) and bipolar coagulation. Women who had a large myoma mass and who desired no further pregnancy received an additional bilateral uterine artery ligation through retrograde umbilical ligament (RUL) tracking (Chang *et al.*, 2005). Such a procedure was documented as an easy-to-learn and quick procedure to control bleeding during laparoscopic-assisted vaginal hysterectomy (Chang *et al.*, 2005). Since higher complications in subsequent pregnancies after uterine artery embolization for fibroids was reported (Goldberg *et al.*, 2006), informed consent was obtained before operation.

The myomas were completely enucleated from the myometrial layers and subsequently subjected to morcellation (Gynecare, Ethicon, Inc.,

Somerville, NJ, USA). The myometrial edge was approximated by interrupted intracorporeal suture in one or two layers. The SMI technique was applied in the last year of the study and the detailed description of this procedure was reported (Chang *et al.*, in preparation). The delineated nature of myoma and the positive pressure of the abdominal cavity under laparoscopic surgery caused the myoma to bulge out spontaneously from its surrounding myometrial junctions while performing morcellation directly on the uterine body. Suturing of the uterine wound after myomectomy by SMI is similar to that done in standard LM.

Operative time was calculated from the first skin incision to the end of skin wound closure. The removed myomas were freshly weighed before fixation in formalin.

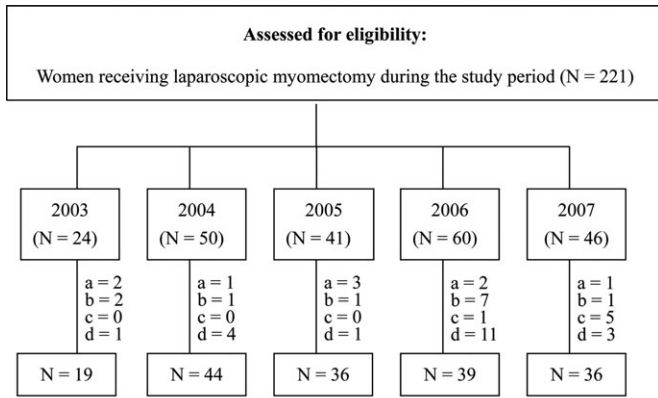
Statistical analysis

Data were expressed as mean \pm SD unless stated otherwise. Differences between each value with year of study were tested by ANOVA for trend using the Statistical Analysis System (SAS) version 8.0 (SAS Institute, Cary, NC, USA). The average myoma weight was calculated as total myoma weight divided by the number of myoma operated. Fitted locally weighted polynomial regression lines were used to compare operative time with the average myoma weight across the years of study. A nonlinear multiple regression test was constructed to model the operative time. The effect of applying the SMI technique to the operation was estimated via an indicator variable in the model. Parameters of this model were determined by nonlinear least-squares estimation. The fit of the model and validity of prediction were assessed by residual plots. A *P*-value of <0.05 was considered statistically significant.

Results

A total of 221 women underwent LM during the study period. Nine patients diagnosed with adenomyosis were excluded. Myoma weights were not recorded in 12 patients and they were excluded from the study. Six cases with more than six myoma removed were also excluded. Twenty patients with intraligamentous and pedunculated myoma as predominant myoma were excluded from the study since both types of myoma could not demonstrate the advantage of SMI (without enucleation). Therefore, 174 patients distributed as 19, 44, 36, 39 and 36 in each year were eligible for analysis (Fig. 1).

The characteristics of these cases are listed on Table I. The average age of patients in the study was 38.9 ± 6.4 years and the average BMI was 21.7 ± 2.8 kg/m². The average number of myoma operated was 1.9 ± 1.2 with an average diameter of the dominant myoma as 7.1 ± 2.4 cm (range 2–18). The mean total myoma weight operated was 213.5 ± 190.4 g, with an operative time of 117.0 ± 39.6 min and an EBL of 82.6 ± 94.5 ml. Fifty patients received bilateral uterine artery ligation by RUL procedure (Chang *et al.*, 2005) before enucleation or morcellation of myomatous nodule during the operation. Despite our stated indications for uterine artery ligation, one patient received uterine artery ligation after morcellation of myoma due to massive bleeding (EBL of 900 ml). Cases with bilateral uterine artery ligation had significantly larger dominant myoma size and greater myoma weights compared with cases without uterine artery ligation. Blood loss during the operation was significantly greater in cases with uterine artery ligation, probably due to the greater operated



Exclusion criteria: a: adenomyosis, b: data incomplete, c: more than 6 myoma removed, d: intraligamentous or pedunculated myoma.

Figure 1: Flow of participants receiving laparoscopic myomectomy through each year. (*N* = number of women).

myoma weight. However, the operative times between these two groups were not significantly different. No laparoconversion and 2.3% rate of complications (one post-operative ileus and three intraoperative bleeding requiring transfusions) occurred. Over time, there was a significant increase in total myoma weight and EBL, and a decrease in operative time (all *P*-value < 0.05 by ANOVA trend test). The increase in total myoma weight was most significant in the last year of the study. By plotting the average myoma weight (calculated as total myoma weight divided by the number of myoma operated) with the operative time according to the study years using the lowest curve estimation, we found an increase in average myoma weight and a decline in operative time with study years (Fig. 2A).

Using exploratory data analysis, four factors were found to be potential predictors of operative time for LM: the BMI, myoma number, total myoma weight and the SMI procedure. Based on the findings from the exploratory analyses, a non-linear regression model was developed to model operative time recorded in the study. Specifically, the model is represented as

$$Y_{ij} = \beta_0 + \beta_1 \times BMI_{ij} + \beta_2 \times Number_{ij} + \beta_3 \times TotalWeight_{ij} + e^{\alpha_0 + \alpha_1 \times (i-1)} \times AveWeight_{ij} + \alpha_2 \times I(i = 5) + \varepsilon_{ij},$$

where Y_{ij} is the recorded operative time for patient j in the i th year; BMI_{ij} , $Number_{ij}$, $TotalWeight_{ij}$ and $AveWeight_{ij}$ represent BMIs, numbers of myoma operated, total myoma weights and average myoma weights, respectively. The indicator variable I was defined as: $I(i = 5) = 1$, when i is the fifth year; and $I(i = 5) = 0$, otherwise. The error term ε_{ij} is assumed to have a normal distribution with mean 0 and a constant variance.

In this model, the slope coefficient of the average myoma weight $e^{\alpha_0 + \alpha_1 \times (i-1)}$ for describing operative time was chosen to represent the positive effects of average myoma weight on operative time change over the study years. The coefficient α_2 represents the effect of SMI on operative time.

The estimates and significances of these parameters determined by nonlinear least-squares methods are listed in Table II. We found that operative time was positively correlated with BMI and myoma number, but not significantly. Operative time was found to be significantly positively correlated with total myoma weight, suggesting that longer operative time is required for a myoma with greater weight. The estimates of two coefficients α_0 and α_1 , corresponding to the effect of average myoma weight on operative time, were negative and significant. The five estimated positive slope coefficients shown in Fig. 2B showed a gradual decline over the study years. These results indicated that (i) a longer operative time was required for a larger average myoma weight and (ii) operative time decreased over study years given the same average myoma weight. This finding confirms the hypothesis that surgical experience saved operative time significantly.

The effect of SMI applied in the fifth year was estimated to be -18.9 ± 6.9 min, suggesting that when surgical experience was adjusted, operative time was further shortened by ~ 19 min using SMI. When all the coefficients are included, the model of predicting operative time is denoted as:

$$Y_{ij} = 60.43 + 1.17 \times BMI_{ij} + 2.36 \times Number_{ij} + 0.03 \times TotalWeight_{ij} + e^{-1.37 - 0.5 \times (i-1)} \times AveWeight_{ij} - 18.94 \times I(i = 5).$$

The difference between the expected operative time and the actual operative time (residual) is plotted in Fig. 3 to give a visual representation of the accuracy of prediction based on the year of operation, number of myoma operated, total myoma weight and average myoma weight. These plots indicate that the model was well fitted with little violation of model assumptions.

Figure 4 shows the relationship between the predicted operative time and the average myoma weights according to years of operation given that the average number of myoma is two and average BMI equals 21.7. The decline in predicted operative time over the study years again suggests that greater surgical experience resulted in less operative time. The application of SMI in the fifth year showed a further reduction in operative time ($P < 0.005$).

Discussion

We demonstrated a multidimensional analysis on the learning curve of LM and the efficiency of introducing a new surgical skill to improve LM. Operative time decreased and the operated myoma weight increased with surgical experience and with the introduction of SMI.

The learning curve included an initial steep gradient representing the gaining of ability to complete the surgery followed by a gradually established steady rate. Most previous studies have used simple graphs, split the data arbitrarily into chronological groups and performed univariate statistics to analyze learning curves. Learning curves for studies of laparoscopic hysterectomy (including laparoscopic total hysterectomy, laparoscopic assisted vaginal hysterectomy and laparoscopic supracervical hysterectomy ranging from 15 to 80 cases)

Table I. Demographic characteristics of the study population and the conditions of leiomyoma operated on according to study years ($n = 174$).

	2003 ($n = 19$)	2004 ($n = 44$)	2005 ($n = 36$)	2006 ($n = 39$)	2007 (SMI) ($n = 36$)	<i>P</i> -value
Age (years)	38.2 ± 6.7 (26–47)	38.0 ± 6.7 (24–50)	38.7 ± 5.3 (30–48)	38.6 ± 6.54 (26–50)	40.8 ± 6.5 (29–55)	NS
BMI (kg/m ²)	22.4 ± 3.4 (17.8–30.0)	21.5 ± 2.4 (17.7–27.3)	20.9 ± 2.6 (16.3–27.3)	21.6 ± 3.2 (16.9–29.6)	22.6 ± 2.3 (18.9–28.4)	NS
Total number of myoma operated	35	75	76	72	70	NS
Dominant myoma diameter (cm)	7.2 ± 2.0 (5–12)	6.3 ± 2.0 (2–10)	6.7 ± 2.0 (3–13)	7.5 ± 2.3 (4–12)	8.3 ± 2.9 (3–18)	0.002
Location of dominant myoma (%)						NS
Anterior	26.3	29.6	41.7	20.5	38.9	
Fundus	47.4	31.8	33.3	41.0	25.0	
Posterior	26.3	31.8	25.0	35.9	33.3	
Submucosal	0	6.8	0	2.6	2.8	
Type of dominant myoma (%)						NS
Intramural	47.4	52.3	44.4	64.1	75.0	
Subserosal	52.6	40.9	55.6	33.3	22.2	
Submucosal	0	6.8	0	2.6	2.8	
Total myoma weight (g)	158.6 ± 84.0 (30–355)	146.6 ± 127.9 (10–600)	183.9 ± 148.5 (25–760)	247.5 ± 186.7 (22–660)	317.1 ± 274.2 (25–1260)	<0.001
Operative time (min)	145.5 ± 55.7 (85–280)	117.2 ± 31.1 (70–210)	123.1 ± 42.3 (40–210)	113.5 ± 34.9 (50–185)	99.5 ± 32.1 (60–195)	<0.001
Estimated blood loss (ml)	60.5 ± 35.7 (50–200)	51.4 ± 7.7 (50–100)	66.4 ± 38.9 (50–200)	92.9 ± 81.8 (50–500)	137.5 ± 172.1 (50–900)	<0.001
Complications						
Laparoconversion	0	0	0	0	0	
Excessive blood loss*	0	0	0	1	2	
Post-operative ileus	1	0	0	0	0	
Hospital stay (Days)	3.7 ± 1.6 (2–9)	3.2 ± 0.5 (2–5)	3.3 ± 0.7 (3–6)	3.2 ± 0.6 (2–6)	3.2 ± 0.8 (2–6)	NS

*Blood loss ≥500 ml.

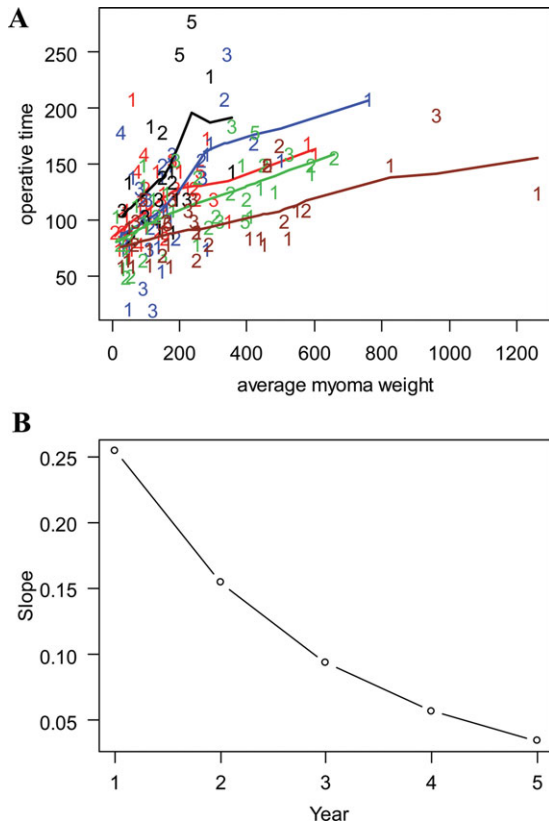


Figure 2: Changes of operative time against average myoma weight over the study years.

(A) Scatter plot of operative time against average myoma weight according to the year of operation (black, first year; red, second year; blue, third year; green, fourth year; brown, fifth year). Numbers in the plot represent the number of myoma operated for each subject. The curves depict the relationship between operative time and average myoma weights using the lowess model (estimated under the variants of BMI, average myoma weight and total operated myoma weight). (B) The model estimated slope coefficients of the average myoma weight for describing the operative time declined with the study year.

have been reported to reduce complication rates or to show a plateau of operative time (Perino *et al.*, 1999; Makinen *et al.*, 2001; Altgassen *et al.*, 2004; Kreiker *et al.*, 2004; Vaisbuch *et al.*, 2006; Ghomi *et al.*, 2007). However, operative time for LM is influenced by multiple parameters that have made the measuring of the learning curve rather difficult. In addition, the basis of measuring the learning curve based on operating time or operative complication has been questioned. Rossetti *et al.* reported an increase in dimension of myoma operated

with experience and a reduction of operative time with the introduction of a new technique such as morcellation in their 332 cases of LM over a 13-year period (Rossetti *et al.*, 2007). The difficulties of procedures undertaken when facing larger myoma size, therefore, represent a potentially confounding variable that may mask a relationship between experience and efficiency. From our previous study, we identified a reliable equation to predict operative time based on our first 109 cases of LM (Hsu *et al.*, 2007). Using the same strategy and on these reported results, we formulated another equation to predict operative time according to the study years. By this non-linear multiple regression model, we evaluated the learning curves as well as the influence of introducing SMI on the last year of study with high validity. Our results demonstrated a significant reduction in operative time over the study years and with the application of SMI.

There was an overall correlation between operative time and myoma weight. This probably reflects morcellation time, as there is more tissue to be extracted with larger myoma size. Sinha *et al.* reported on their modification in performing LM by applying morcellation while the myoma is attached to the uterus and found a significantly shorter length of surgery compared with the conventional technique for myoma with similar weight (Sinha *et al.*, 2005). With a further modification by simultaneous enucleation and morcellation of the myoma *in situ*, we named our procedure SMI. By using SMI in our last year of the study, we managed to perform LM in cases with significantly greater total myoma weight and with less operative time compared with the previous years without SMI. By applying a nonlinear multiple regression model to adjust the learning curve as a confounding factor, the efficiency of SMI was calculated to save 19 min of operative time. Co-incidentally, Sinha *et al.* reported ~25 min operative time difference in favor of SM comparing with conventional LM (Sinha *et al.*, 2005). The operated myoma weight reported by Sinha was very much greater than ours, with a minimum myoma weight of 404.1 g, and an average myoma weight of 600.5 g by Sinha’s method; and 584.2 g by the conventional method. In 28 of our cases who had operated myoma weights >400 g (five from the first three years), the average myoma weight was 561.8 ± 190.4 g, with an average operative time of 138.8 ± 34.6 min and an EBL of 178.6 ± 200.2 ml. These 28 cases had longer operative time, but less EBL compared with that reported by Sinha *et al.* It is possible that the excess time that we spent in LM was for bleeding control. Even so, the time saving for SMI compared with the standard LM after adjustment by learning curve is very close to Sinha’s report.

There were several possible reasons why SMI could reduce operative time. The combination of enucleation and morcellation demands less energetic work for the operator, especially when large and multiple myomas are removed. Secondly, morcellating without prior enucleation created more space for a better view and optimum movement of instruments. And thirdly, myoma screws were not required during SMI, and thus reduced unnecessary bleeding and the extra time spent to control bleeding caused by the screws.

The complication rates for LM were reported to be rather low. Rossetti *et al.* reported no blood transfusion and no major

Table II. The estimated coefficients and standard errors in the model.

Parameters	Coefficient	Estimate \pm SEM	P-value
Intercept	$\hat{\beta}_0$	60.43 ± 20.37	0.003
BMI	$\hat{\beta}_1$	1.17 ± 0.91	0.20
Myoma number	$\hat{\beta}_2$	2.36 ± 3.38	0.49
Total myoma weight	$\hat{\beta}_3$	0.027 ± 0.012	0.024
Average myoma weight	$\hat{\alpha}_0$	-1.37 ± 0.17	<0.00001
	$\hat{\alpha}_1$	-0.50 ± 0.14	0.0004
SMI	$\hat{\alpha}_2$	-18.94 ± 6.93	0.007

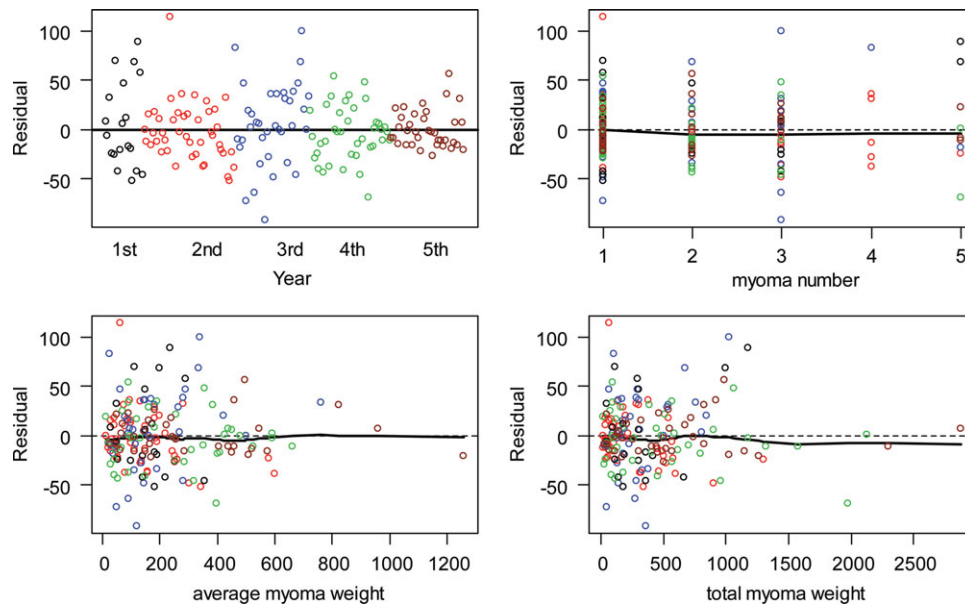


Figure 3: Model diagnostic plots. Scatter plots of residual value (expected operative time minus actual operative time) against the five years of study, the number of myoma operated, the average myoma weight and the total myoma weight according to the years of operation (black, first year; red, second year; blue, third year; green, fourth year; brown, fifth year of the study). The curves depict the relationship of residuals with the number of myoma operated, average myoma weights and total myoma weight using the lowest model.

intraoperative complications in their 332 LM cases (Rossetti *et al.*, 2007). Sizzi *et al.* reported a complication rate of 2.02% in their 2050 cases of LM, and the majority were hemorrhage and post-operative hematomas (Sizzi *et al.*, 2007). The rate of conversion to laparotomy in LM has been reported to be as high as 28% (Marret *et al.*, 2006). In our present study, a complication rate of only 2.3% was found, including one post-operative ileus that required only supportive treatment and three intraoperative bleeding (ranging from 500 to 900 ml) that required blood transfusion. No cases of laparoconversion were found. Therefore, our results agree with most other reports that LM is a safe procedure. The low complication rate for LM highlights that studying the learning curve based on complication rates in LM might not be justified. However, when complications occurred, the learning curve based on operative time should be adjusted accordingly. The zero

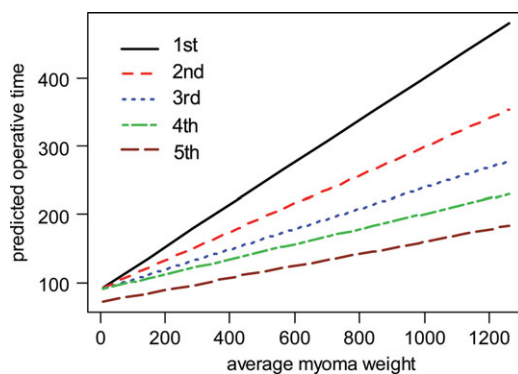


Figure 4: Predicted operative time plotted against average myoma weight according to the year of operation, given that the average number of myoma is two and average BMI equals 21.7 (black, first year; red, second year; blue, third year; green, fourth year; brown, fifth year of the study).

laparoconversion rate and the low rate of complication in our study are possibly due to the surgeon's attitude in patient selection. Easier cases were selected initially, and as the surgeon became more experienced, challenging and high-risk cases were then included. We found that around 70% of the patients who requested myomectomy were treated by LM in the first few years of our study. But in the last year when the SMI procedure was established, >90% of the patients were admitted for LM instead of abdominal myomectomy. This confounding factor of patient selection could be accommodated by regression analysis to incorporate all factors such as total myoma weight, operated myoma number and BMI to have a valid analysis on learning curve. However, the identification of a threshold point on the learning curve in such conditions would be rather difficult. About 100 cases were used liberally in our study as a threshold point with regard to the performance on LM.

The limitation of this study is that it reflects the learning curve of only one surgeon at our institution. This experience may not be reproducible and validated by other surgeons at other institutions, and this therefore strongly reduces the generality of our findings. However, the laparoscopic model described can be used as the basis for performance monitoring between or within surgeons and institutions.

The other limitation is the methodology of our study. The SMI technique was introduced in the last year of the surgery and the analysis of its superiority was performed at the end of the surgeon's learning curve. This result could therefore be biased. Instead, a randomized trial would have been the correct design to study the efficiency of SMI on LM. However, since SMI appeared to be much easier, especially when larger or multiple myomas were encountered, further LM without using SMI seems impractical. Similar situations have usually occurred in clinical studies once a superior

technique is invented and this therefore causes difficulty in carrying out an unbiased randomized study.

In conclusion, the current study suggests that operative time in LM decreased with practice and experience, indicating mastery of LM by the surgeon. An additional 19 min reduction in operative time could be established by the introduction of SMI during LM. Appropriate multidimensional adjustment on factors that affect operative time should be made before any meaningful comparisons on the benefit of introducing new surgical skill to the standard procedure are undertaken.

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