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Original Research Article

Comparison of Intra and Post-Operative Outcomes between Laparoscopic and open Myomectomy for Uterine Fibroids

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ABSTRACT

Background
Myomas or fibroids are commonly encountered in clinical practice and are present in more than 50% of the reproductive aged women. According to the Global Burden of Disease (2019) data, the global incident cases of uterine myomas has increased. The choice of treatment for reproductive aged women with symptoms needing to preserve their fertility is still myomectomy.
There are two main approaches of performing myomectomy i.e., abdominal/open and laparoscopic. There have been recent evidence indicating that laparoscopic myomectomy is associated with shorter recovery time, lower risk of post-operative complications and overall similar clinical outcomes when compared to open myomectomy

Objective
To compare the intra-operative and post-operative clinical outcomes among women undergoing open and laparoscopic myomectomy

Methods
This is a retrospective study done in a tertiary care hospital in Odisha, India. Data from women who undergone either of the two surgical approaches between February 2016 to December 2018 were utilized. The outcomes of interest were estimated blood loss, duration of surgery, need for blood transfusion, duration of hospitalization, indicators of recovery and post-operative complications. Regression analysis was done to document the association of surgery type with the outcomes. Effect sizes were reported either as mean difference (MD) or odds ratio (OR) with 95% confidence intervals (CI).

Results
A total of 140 subjects were included in this study (laparoscopic group (LM)=60 and open myomectomy group (OM)=80). Those undergoing LM had lower blood loss (in ml) (MD -21.0; 95% CI: -37.5 to -4.47) and a higher surgical time (in min) (MD 13.0; 95% CI : 3.0 to 23.1), compared to OM. The duration of hospitalization (in days) was comparatively lower in those undergoing LM (MD -2.42; 95% CI: -2.47 to -2.37). The women undergoing LM had higher odds of being free from analgesic at 2nd post-operative day (OR 5.90 ; 95% CI :2.82 to 12.3) and discharged by 3rd to 5th post-operative day (OR 4.74 ; 95%

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CI :2.27 to 9.91). The risk of need for blood transfusion and post-operative complications were similar in both the groups.

Conclusions

The findings suggest that laparoscopic myomectomy offers clear advantage in terms of improved clinical outcomes when compared to conventional open myomectomy.

Keywords: Fibroid, myomectomy, laparoscopic myomectomy, benign tumor of uterus, uterine myoma, open myomectomy.

INTRODUCTION

Myomas or fibroids are commonly encountered in clinical practice and are present in more than 50% of the reproductive aged women [1,2]. According to the Global Burden of Disease (2019) data, the global incident cases of uterine myomas has increased from around 58 lakh in 1990 to nearly 96 lakh in 2017 i.e., 65% increase [2]. These are fibromuscular benign tumours that are hormone sensitive and originate from smooth muscle cells of the uterus [3]. The prominent symptoms include abnormal uterine bleeding, pelvic pain and infertility [4,5]. These myomas contribute to one of the leading indications for hysterectomy. A wide range of options for management exist, comprising of pharmacological treatment using oral contraceptives, NSAIDs (nonsteroidal anti-inflammatory drugs), aromatase inhibitors and GnRH agonists or surgical procedures such as myomectomy, hysterectomy and embolization of uterine artery [6,7]. There have been few technological advancements and that have led to emergence of techniques such as radio-frequency ablation and image guided ultrasound thermal therapy [8,9]. However, the choice of treatment for reproductive aged women with symptoms needing to preserve their fertility is still myomectomy.

There are two main approaches of performing myomectomy i.e., abdominal/open and laparoscopic. There have been recent evidence indicating that laparoscopic myomectomy is associated with shorter recovery time, lower risk of post-operative complications and overall similar clinical outcomes when compared to open myomectomy [10,11]. However, it is a skill-intensive procedure and time consuming and therefore, not routinely adopted for use in gynaecologic surgeries. The current study was conducted with the aim to evaluate and compare various intra and post-operative outcomes among these two surgical approaches for uterine myomas.

MATERIAL AND METHODS

We utilized retrospective data collected between February 2016 to December 2018 on subjects undergoing myomectomy at Department of Obstetrics and Gynecology, Hi-tech medical college and hospital, Bhubaneswar, Odisha. Required data for 60 women undergoing laparoscopic myomectomy and 80 undergoing laparoscopic myomectomy was available. As this was a secondary analysis of data collectively routinely as part of the hospital procedures, ethical clearance was not required. Subjects were women of the reproductive age who had fibroids and wished to preserve their uterus.

Both transvaginal and abdominal ultrasound-based data on the number, size and localization of the fibroid was available. All the patients were operated under general anaesthesia and had received Cefazolin (intravenous 2 g) as a prophylactic antibiotic prior to starting the procedure. The same set of obstetricians performed the surgery in both the groups. In all the subjects, standard hospital procedures were followed. Data was collected on the age, education, occupation, family income, place of residence, marital status, history of any abdominal surgery, indication for the current surgery, body weight, height, body mass index, number and location of fibroids and presence of adhesions on ultrasound. In addition of these, data was also collected on the preoperative and post-operative haemoglobin levels.

Summary of the procedure adopted for open myomectomy

A 10-12 cm low transverse incision was done at the time of abdominal myomectomy. This was followed by crosswise opening of the subcutaneous fat and the fascia. The parietal peritoneum was opened longitudinally on the midline. This was followed by a careful examination of the uterus and the adnexa, and a linear incision was made on the most prominent part of the fibroid. After identification of the myoma capsule, enucleation was done. The ensuing defects in the uterus was sutured (in single or double

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layer, depending on the depth of the uterine wound) with the help of interrupted sutures. The serosa was approximated with 3-0 polyglactin 910. There was no use of any pharmacological vasoconstrictor or any mechanical vascular occlusion prior to uterine incision. In order to reduce the risk of adhesions post-operatively, an attempt was made to perform uterine incisions either in the fundus or on the anterior wall of the uterus.

Summary of the procedure adopted for laparoscopic myomectomy

In laparoscopic myomectomy, through use of a Veress needle, carbon dioxide insufflation was done in order to create pneumoperitoneum. This was followed by a standard umbilical incision to introduce the laparoscope. The laparoscope was connected to a camera for video monitoring. Also, two suprapubic trocars (5 mm) were inserted on each side of the umbilicus. Uterine cannulation was done, to provide adequate exposure, in case the myomas were located in the posterior part of the uterus. After identification of the most prominent part of the myoma, a longitudinal incision was made, and the incision was extended until it reached the capsule. Enucleation of the myoma was done and the uterine wall then sutured in one or two layers using an interrupted suture of polyglactin 910. Adequate haemostasis was achieved under video laparoscopy and irrigation of the pelvic cavity was done using a suction-irrigator.

Outcomes and statistical analysis

The outcomes of interest were related to intra-and post-operative parameters such as estimated blood loss, duration of surgery, need for blood transfusion, duration of hospitalization, indicators of recovery and post-operative complications.

Statistical analysis

All analysis was done using STATA v.15.0 (TX, USA). Baseline characteristics were presented as either mean (SD) or median (IQR) for continuous variables and as proportion for categorical variables. Regression analysis was done to document the association of surgery type (laparoscopic vs. open) with the outcomes. Mean difference (MD) was reported for continuous outcomes and odds ratio (OR) for categorical outcomes. All effect sizes were reported along with 95% confidence intervals. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 140 subjects were included in this study with 60 in the laparoscopic group (LM) and 80 in the open myomectomy group (OM). The baseline characteristics of the subjects in the two groups was statistically similar (Table 1). The mean (SD) age of the subjects in the LM and OM groups was 35.1 (2.9) and 36.8 (3.1) years respectively. Majority of the women in both the groups were unemployed (≥85%) and resided in an urban setup (>80%). Around one-third of the women in both the groups reported having a previous abdominal surgery. Abnormal uterine bleeding was the common indication for surgery in both the groups (58% in LM and 55% in OM group). The mean body mass index (BMI) as well as the median years of education and annual family income was statistically similar across both the groups (Table 1).

Table 1: Distribution of socio-demographic variables across the two study groups

Variables	Laparoscopic myomectomy (N=60)	Open myomectomy (N=80)
Age (years)	35.1 (2.9)	36.8 (3.1)
Weight (Kg)	72.3 (10.7)	71.0 (11.3)
Body mass index (BMI) (Kg/m2)	25.8 (4.1)	26.1(5.8)
Median years of women education (IQR)	6 (4-8)	6 (5-8)
Occupation, n (%) Employed Unemployed	 6 (10.0) 54 (90.0)	 12 (15.0) 68 (85.0)
Annual family income (USD), Median (IQR)	6543 (3100, 8912)	6200 (2975, 7911)

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Place of residence, n (%) Urban Rural	 49 (81.7) 11 (18.3)	 67 (83.8) 13 (16.2)
Married, n (%)	47 (78.3)	64 (80.0)
Had previous abdominal surgery, n (%)	18 (30.0)	27 (33.7)
Indication for current surgery, n (%) Abnormal uterine bleeding Infertility	 35 (58.3) 25 (41.7)	 44 (55.0) 36 (45.0)

IQR- inter-quartile range; values are mean (SD) unless specified otherwise.

The mean (SD) number of fibroids [LM, 2.7 (1.2); OM 2.5 (0.9)] and the mean diameter of the largest fibroid (in cm) [LM, 5.6 (1.0); OM 5.9 (1.4)] was similar in the two groups (Table 2). A higher proportion of subjects undergoing LM (40.0%) had FIGO type V fibroid compared to those undergoing OM (35.0%). A higher proportion with type IV fibroids was noted for those in the OM group (37.5%), compared to LM group (31.7%). Proportion of subjects with adhesions present were slightly higher in OM group (11.3%), compared to LM group (8.3%) (Table 2).

Table 2: Distribution of the type of surgery according to characteristics of the fibroid

Variables	Laparoscopic myomectomy (N=60)	Open myomectomy (N=80)
Mean (SD) number of fibroids	2.7 (1.2)	2.5 (0.9)
Mean (SD) size of the fibroids (cm)	2.1 (0.8)	2.5 (1.1)
Mean (SD) diameter of the largest fibroid (cm)	5.6 (1.0)	5.9 (1.4)
FIGO type, n (%) Type III Type IV Type V Type VI	 5 (8.3) 19 (31.7) 24 (40.0) 12 (20.0)	 10 (12.5) 30 (37.5) 28 (35.0) 12 (15.0)
Presence of adhesions, n (%)	5 (8.3)	9 (11.3)

Those undergoing LM had lower blood loss (in ml) (Mean difference, MD -21.0; 95% CI: -37.5 to -4.47) and a higher surgical time (in min) (MD 13.0 ; 95% CI : 3.0 to 23.1), compared to OM (Table 3). The duration of hospitalization (in days) was comparatively lower in those undergoing LM (MD -2.42; 95% CI : -2.47 to -2.37). The women undergoing LM had higher odds of being free from analgesic at 2nd post-operative day (OR 5.90 ; 95% CI :2.82 to 12.3), discharged by 3rd to 5th post-operative day (OR 4.74 ; 95% CI :2.27 to 9.91) and fully recuperated at day 7 (OR 2.43; 95% CI :1.22 to 4.82) (Table 3 ; Figure 1). The two groups did not differ with respect to change in haemoglobin levels pre and post-operatively, risk of need for blood transfusion and post-operative complications (Table 3).

Table 3: Intra and post-operative outcomes among the two study groups

Outcomes	Laparoscopic myomectomy (N=60)	Open myomectomy (N=80)	Effect size (95% CI); P-value
Estimated blood loss (ml)	232 (46)	253 (51)	MD -21.0 (-37.5 to -4.47) (P=0.01)
Differences in pre and post-operative Hb (g/dl)	1.98 (0.17)	2.0 (0.13)	MD -0.02 (-0.07 to 0.03) (P=0.43)
Operative time (min)	107 (31)	94 (29)	MD 13.0 (3.0 to 23.1) (P=0.01)
Need for blood transfusion, n (%)	1 (3.3)	3 (3.8)	OR 0.44 (0.05 to 4.3) (P=0.47)
Duration of hospitalization (days)	3.29 (0.18)	5.71 (0.11)	MD -2.42 (-2.47 to -2.37) (P<0.001)

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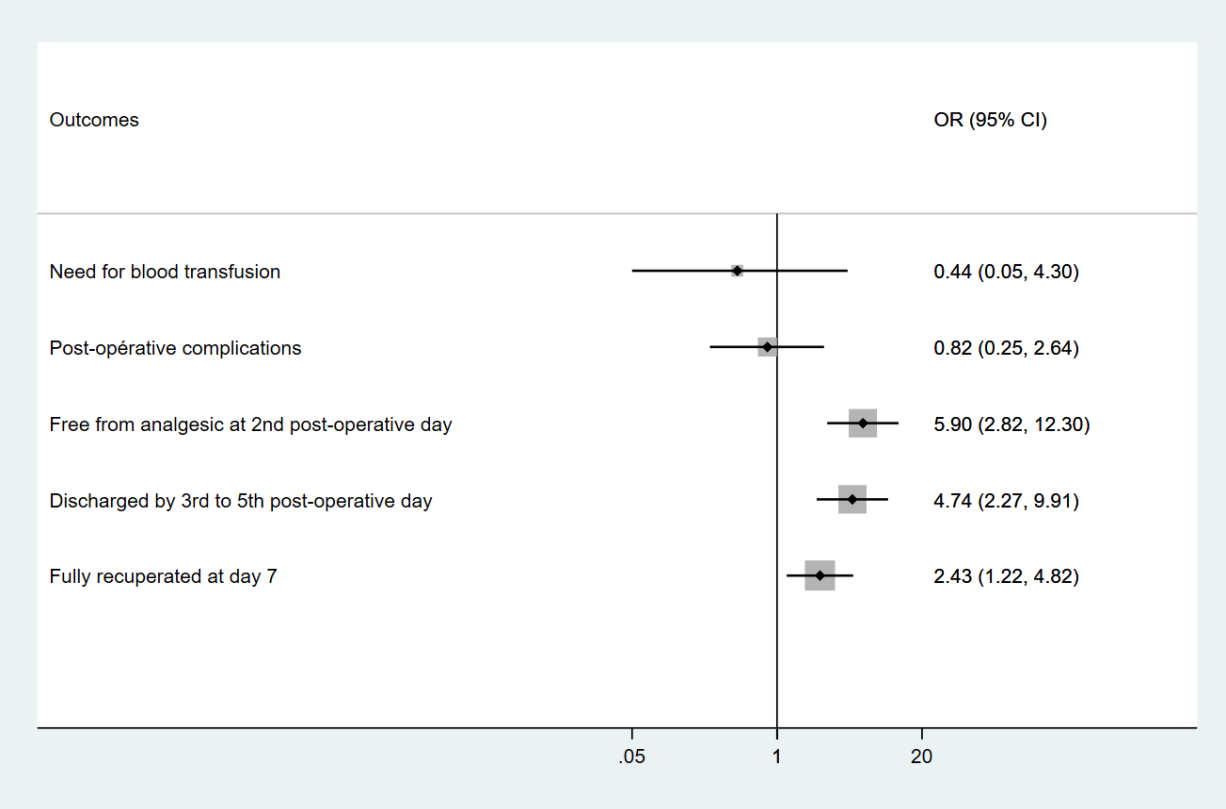
Outcomes	Laparoscopic myomectomy (N=60)	Open myomectomy (N=80)	Effect size (95% CI); P-value
Post-opérative complications, n (%) *	5 (8.3)	8 (10)	OR 0.82 (0.25 to 2.64) (P=0.74)
Patients free from analgesic at 2nd post-operative day, n (%)	43 (71.7)	24 (30.0)	OR 5.90 (2.82 to 12.3) (P<0.001)
Patients discharged by 3rd to 5th post-operative day	45 (75.0)	31 (38.8)	OR 4.74 (2.27 to 9.91) (P<0.001)
Patients fully recuperated at day 7, n (%)	51 (85)	42 (52.5)	OR 2.43 (1.22 to 4.82) (P=0.02)

** Complications consisted of wound infection and haemorrhage*

Figure 1. Forest plot depicting the effect sizes for key outcomes



DISCUSSION

In this study that utilized data from hospital records of 140 reproductive aged women, we found that LM was associated with lower blood loss, shorter hospitalization time, increased odds of being free from analgesic at 2nd post-operative day, discharged by 3rd to 5th post-operative day and being fully recuperated at 1 week post-operatively, when compared to OM. There was no difference with regards to change in haemoglobin levels pre and post-operatively, risk of need for blood transfusion and post-operative complications among the two groups. Laparoscopic myomectomy was associated with a higher operative time. The findings are similar to a previous meta-analysis by Chu Jin et al on this issue [12]. The authors of this meta-analysis included six randomized controlled trials involving 576 subjects and

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documented that laparoscopic myomectomy was associated with lesser reduction in haemoglobin, reduced operative blood loss and that a higher proportion of subjects were fully recuperated at day 15 diminished. Further, those undergoing LM had lower postoperative pain, fewer complications and longer operation time. Another study conducted in Greece included 75 premenopausal women with 48 managed by LM and 27 by OM approach [13]. Similar to ours, this study found the mean estimated blood loss to be significantly lower in LM, the incidence of postoperative complications to be similar and the duration of hospitalization to be shorter in LM, compared to OM approach. The most recent systematic review on this issue by Chen et al also supports the findings of our study. This review included 12 randomized controlled trials with 1783 subjects. Compared with OM, LM was found to be associated with significantly decreased blood loss, reduction in the length of hospital stay and longer duration of operation.

Our study found a shorter hospital stay in those undergoing LM. This is advantageous as increased stay at hospital could increase the risk of hospital acquired infections and as well increase the out-of-pocket expenditure. We found a higher operative time in laparoscopic repair. Laparoscopic approach requires introduction of trocars and appropriate positioning of the instruments, which may be time-consuming. Further, there are also instances where there are extensive adhesions present and adhesiolysis may also lead to higher operative time. There are many factors that could govern the time required for the surgery and the discharge time from the hospital. Some of these factors include the mean number, mean size and maximal fibroid size. In our study, the mean size of the fibroids was 2.1 (0.8) cm and mean myoma number was 2.7 (1.2) in the LM group. Further, the maximal fibroid size was 5.6 (1.0) in the LM group. Mais et al. in their study reported a lower duration of hospitalization and had a mean of 2.4 myomas [14]. Similarly, Seracchioli et al. had a lower discharge time and reported a mean myoma number of 2.7 [15].

LIMITATIONS OF THE STUDY

There are certain limitations of our study. First, we conducted a retrospective study using hospital records. It would have been better to conduct a prospective follow up study. Second, we did not collect data on the cost and expenses. Third, we did not evaluate long term outcomes such as recurrence rate and obstetric/pregnancy outcomes. Fourth, we did not measure and compare the weight of the fibroid between the two groups which may affect the duration of the surgery and the estimated blood loss.

CONCLUSION

The findings of our study suggest that laparoscopic myomectomy could be a potentially useful alternative to the conventional open myomectomy and offers advantage in terms of reduced blood loss, faster post-operative recovery and a shorter duration of hospitalization. Efforts should be made to enhance the skills of the gynaecologists and obstetricians in laparoscopic surgery.

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