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Myomectomy for Fibroids during Cesarean Section: A Randomized Controlled Trial

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ABSTRACT

Background: There is a considerable debate about the management of myoma during cesarean section (CS). Recently, several studies indicated the safety and feasibility of undertaking myomectomy during CS.

Objectives: To evaluate the safety, accessibility, and short-term morbidity of myomectomy for fibroids during cesarean section.

Patients and Methods: This was a randomized controlled trial that included 72 patients who were admitted to the Obstetrics & Gynecology Department, Menoufia University Hospital with uterine fibroids during pregnancy; who were randomly allocated equally into a group of cesarean myomectomy (CM; n=36) and another group of CS only (n=36). The operative events and the outcome were recorded and analyzed.

Results: CM group showed a longer duration of surgery and longer hospital stay, higher amount of blood loss, and higher mean pain sores, with a highly statistically significant difference (p = 0.000). No cases in both groups required blood transfusion or ICU admission. No statistically significant differences were noted between both groups as regards the fetal outcome measures (p=0.583 & 0.601).

Conclusion: CM is safe and applicable in selected cases without deleterious maternal complications. Special precautions ought to be paid during the procedure, particularly in the intramural type and with large fibroids.

Keywords: Cesarean myomectomy, Fetal outcome, Maternal outcome, Safety, Uterine fibroid.

INTRODUCTION

Uterine leiomyomas (fibroids) are benign neoplasms derived from the myometrium of the uterus and they are hormone-responsive. They were documented to be the commonest tumor involving the female reproductive tract. Uterine leiomyomas are considered to be a major concern impacting the quality of life of the affected females [(1)].

When women with uterine leiomyomas get pregnant, they usually have concerns about the potential leiomyoma-related pregnancy adverse events. However, the inconsistent association between uterine leiomyomas and the obstetric outcome was revealed by several studies [(2)].

Both uterine leiomyomas and the cesarean section (CS) rates have been elevated all over the world. Therefore cesarean myomectomy (CS); the leiomyoma surgical removal in the same setting of the CS, has been increasingly considered worldwide and suggested by some authors to be a routine procedure. However, CM is still claimed to be a high-risk surgery, that should be indicated in selected cases and performed by experienced surgeons only[(3)].

The current literature conflicting results are indicating the trial to provide any strong evidence on the CM safety and applicability [(4)].

This study aimed to evaluate the safety, accessibility, and short-term morbidity of myomectomy for fibroids during cesarean section.

PATIENTS AND METHODS

This is a randomized controlled trial that was performed at the Department of Obstetrics & Gynecology in Menoufia University Hospital during the period from January 2019 to July 2021. The sample size was calculated based on the results of a previous pilot study to compare between cesarean myomectomy versus no intervention on the amount of operative blood loss and the need for blood transfusion. The estimated sample size was 36 patients in each group.

Ethical Considerations:

The current study was commenced after the approval of the university research ethics committee of Menoufia University and following the declarations of Helsinki. Informed written consent was obtained from each patient included in the study.

Inclusion Criteria:

Patients who attended our antenatal clinic during the first half of pregnancy and formally diagnosed with uterine fibroids and those who referred to our hospital for further assessment were included. All patients had an obstetric indication for cesarean delivery at term, such as previous CS and breech presentation).

Exclusion Criteria:

Patients with chronic medical disorders, bleeding tendency, placenta previa, multiple

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pregnancies, prior myomectomy, or myomas at the cornual area were excluded from the study.

Eighty-nine patients were allocated to the study, and then 17 patients were excluded according to eligibility criteria. Finally, 72 patients were included and divided into two equal groups; group 1 included patients who underwent CM, and group II included patients who underwent cesarean section (CS) only as a control group.

Assignment to each group was conducted via randomization which was implemented after developing a study allocation sequence for the study participants before commencing the study with the use of random allocation software in a 1:1 ratio. The study allocation sequence was distributed in sequenced closed opaque envelopes. Each envelope contained a single assignment for either cesarean myomectomy or cesarean section alone.

Cesarean myomectomy was performed at the time of cesarean section**.** It was done after delivery of the fetus unless the myoma was overlying the lower uterine incision and interfering with the uterine transverse incision. In such situation, myomectomy was performed before delivery of the fetus to facilitate cesarean incision. After the fetus delivery, the patient had oxytocin infusion, and the cesarean incision was closed, and then myomectomy was performed. Following myomas enucleation, meticulous closure of their cavities was achieved with closely applied sutures by the use of vicryl (polyglactin 910, Eticon Inc., Johnson and Johnson, USA) l/0 or 2/0. The patients were maintained on oxytocin infusion at a rate of 20 drops/min after surgery.

The histological examinations confirmed the diagnosis of myoma. The pathologists were blind to the ultrasound findings and clinical characteristics of the patients.

The operative time was calculated from skin incision to skin closure. Operative events were registered, the amount of blood loss was calculated by the difference in the towel's weights; their weight was assessed before and after using a sensitive balance, then this was added to the amount of blood in the suction machine and the myomas characteristics were recorded. Postoperative pain severity was assessed according to the visual analogue score.

Figure (1): A case of submucous myoma removed after delivery of the baby and placenta.

Statistical analysis

Data of the patients were collected, and suitable statistical analysis was done. Statistical analysis of the data was performed using the SPSS software version 22 (IBM, SPSS, Chicago, IL, USA). Descriptive statistics: Mean, standard deviation, and percentages were calculated. The student t-test was used to assess the difference between the two groups. ANOVA test was used to assess difference among more than two groups, Chi-square and Fisher's exact tests were used for comparison of categorical data, and Pearson correlation test was used to correlate between numerical parameters. The result was considered as statistically non-significant if p-value > 0.05.

RESULTS

There were no statistically significant differences noted between both groups, neither in the participants' demographic and clinical data nor in the characteristics of uterine fibroids (site, size, type, and number) ($p > 0.05$) **(Table 1).**

Table (1): Demographic and clinical data of the studied subjects including their fibroids characteristics

		C Group N= 36	CM Group N = 36	Test	p-value
Age		28.58 ± 5.13	28.31 ± 6.09	t = 0.21	0.841
Gravidity		3.28 ± 1.23	2.78 ± 1.48	t = 1.56	0.123
Parity		2.08 ± 1.27	1.75 ± 1.5	t = 1.016	0.308
Gestational age at delivery		38.70 ± 1.26	38.51 ± 0.95	t = 0.76	0.447
Weight		81.7± 12.02	83.72 ± 12.4	t = - 0.72	0.472
Height		1.62 ± 0.05	1.60 ± 0.17	t = 0.7	0.494
BMI		30.99 ± 3.95	35.3 ± 22.18	t = -1.15	0.261
Preoperative Hb		11.37 ± 0.76	11.48 ± 1.31	t = -.452	0.646
Indication of surgery	Elective	29 (80.6%)	28 (77.8%)	X2 = 0.084	0.772
	Emergency	7 (19.4%)	8 (22.2%)		
Fibroid Characteristics					
Site					
Board ligament		1 (2.8%)	0 (0%)	X2 = 1.24	0.743
Cervical		1(2.8%)	1(2.8%)		
Lower		8 (22.2%)	10 (28%)		
Upper		26 (72.2%)	25 (69.4%)		
Size					
< 4 cm		2 (5.6%)	2 (5.6%)	X2 = 0.27	0.874
4-7 cm		24 (66.7%)	22 (61.1%)		
≥7 cm		10 (28%)	12 (33.3%)		
Mean ± SD		5.36 ± 1.38	6.08 ± 2.183	t = -1.68	0.098
Type					
Intramural		18 (50%)	18 (50%)	X2 = 0.364	0.834
Submucous		2 (5.6%)	1 (2.8%)		
Subserous		16 (44.4%)	17 (47.2%)		
Number					
Single		28 (77.8%)	29 (80.6%)	X2 = 0.77	0.998
Multiple		8 (22.2%)	7 (19.4%)		
Mean ± SD		1.22 ± 0.42	1.28 ± 0.61	t = -0.45	0.656

X2: Chi-square test, t: student-t-test

There was no statistically significant difference noted between both groups as regards the anesthesia type or the incidence of postoperative fever (p=0.492 & 0.164, respectively). The CM group exhibited a longer surgery and hospital stay duration (p=<0.001 & 0.002, respectively). They showed also a larger mean amount of blood loss, a larger number of cases indicating drain insertion, a larger mean amount of fluid in drain (p = <0.001), and higher mean pain sores, with a highly statistically significant difference (p = 0.005). Statistically significant lower mean postoperative Hb value was noted also in the CM group (p=0.022). No cases indicated blood transfusion or required ICU admission (p>0.05). No statistically significant differences were noted between both groups regarding the fetal outcome measures (Apgar score and fetal weight) (p=0.583 & 0.601, respectively) **(Table 2).**

Table (2): Operative events, maternal outcomes and fetal outcomes in the study patients

	C Group N= 36	CM Group N = 36	Test	p-value
Maternal Outcome				
Anesthesia				
General	2 (5.6%)	0 (0%)	X2 = 2.057	0.492
Spinal	34 (94.4%)	36 (100%)		
Operative time (minutes)				
Mean ± SD	55.28 ± 14.01	69.53 ± 14.38	t = - 4.17	<0.001 *
Blood loss (cm3)				
Mean ± SD	286.9 ± 103.4	875.42 ± 232.44	t = - 4.45	<0.001 *
Postoperative Hb (g/dL)				
Mean ± SD	10.56 ± 0.73	10.2 ± 0.57	t = 2.34	0.022
Drain				
Yes	11 (30.6%)	2 (5.6%)	X2 = 18.225	<0.001 *
No	25 (69.4%)	34 (94.4%)		
Mean ± SD	41.67 ± 89.84	227.78 ± 183.94	t = -5.455	<0.001 *
Fever				
No	32 (88.9%)	35 (97.2%)	X2 = 1.934	0.164
Yes	4 (11.1%)	1 (2.8%)		
Pain score				
Mean ± SD	4.94 ± 1.31	5.92 ± 1.54	t = -2.890-	0.005
Stay length (hours)				
Mean ± SD	48.42 ± 8.94	59.14 ± 8.43	t = -3.28	0.002
Fetal Outcome				
Apgar score at 5 minutes				
Mean ± SD	7.92 ± 14.005	7.77 ± 14.376	0.56	0.583
Fetal weight				
Mean ± SD	3323.6± 403.82	3372.22 ± 385.53	- 0.522	0.601
Admission to NICU				
N (%)	0(0)	0(0)	--	--

X2: Chi-square test, t: student t-test, *: Significant.

Regarding the comparison among the myoma types, no statistically significant differences were found concerning the drain requirement, the occurrence of fever, the type of anesthesia, and the indication of surgery (p=0.121, 0.833, 0.951 & 0.135., respectively). The intramural type was associated with statistically significant longer hospital stay and higher pain scores (p=0.041 & 0.049, respectively), while no statistically significant differences were demonstrated among the three fibroid types regarding mean gestational age at the delivery, mean operative time, mean amount of blood loss and mean postoperative Hb (p=0.149, 0.224, 0.568 & 0.808, respectively). No statistically significant differences among the three fibroid types as regards the fetal outcome measures (p=0.262 & 0.624, respectively) **(Table 3).**

Table (3): Comparison among different myoma types as regards maternal and fetal outcome measures

		Type			X^2	p-value
		Intramural N (%)	**Submucous N (%)**	**Subserous N (%)**		
Drain	No	27 (75%)	3 (100%)	29 (87.9%)	--	0.33[F]
	Yes	9 (25%)	0 (0%)	4 (12.1%)		
Fever	No	33 (91.7%)	3 (100%)	31 (93.9%)	0.37	0.833
	Yes	3 (8.3%)	0 (0%)	2 (6.1%)		
Anesthesia	General	1 (2.8%)	0 (0%)	1 (3%)	0.09	0.951
	Spinal	35(97.2%)	3 (100%)	32 (97%)		
Indication	Elective	29 (80.6%)	1 (33.3%)	27 (81.8%)	4	0.135
	Emergency	7 (19.4%)	1 (66.7%)2	6 (18.2%)		
		Mean ± SD	**Mean ± SD**	**Mean ± SD**	**F**	**p**
Gestational age		38.37 ± 0.969	39.2± 1.71	38.82 ± 1.18	1.93	0.149
Operative time		65.56 ± 16.65	55.33± 14.43	59.91 ± 14.99	1.56	0.224
Hospital stay		29.73 ± 9.63	22.67 ± 2.3	28.81 ± 7.95	3.916	0.041*
Blood loss		798.92 ± 238.78	846.7 ± 225.5	754.5±150.6	0.57	0.568
Postoperative Hb		10.37 ± 0.65	10.63 ± 1.06	10.37 ± 0.69	0.21	0.808
Pain score		5. 78 ± 1.67	5.67 ± 1.52	5 ± 1.19	3.09	0.049*
Fetal weight		3386.5± 391.9	3500 ± 141.6	3295.45±403.6	1.38	0.262
Apgar score		7.81 ± 1.13	7.5 ± 0.71	7.91 ± 1.01	0.486	0.624

[F]: Fisher's exact test, X2: Chi square test, F: ANOVA test, *: Significant.

The fibroid largest diameter demonstrated a statistically significant negative correlation with the gestational age at delivery (p=0.026), and statistically significant positive correlation with the operative time (p=0.004), the amount of blood loss (p=0.004), the amount of fluid in drain (<0.001), the pain scores (p=0.009) while no statistically significant correlations were noted concerning hospital stay length (p=0.167), and the postoperative Hb levels (p=0.162) **(Table 4).**

Table (4): Correlation of the myoma largest diameter and number with the obstetric outcome

	r	**p-value**
Myoma largest diameter		
Gestational age	- 0.230	0.026*
Operative time	0.313	0.004*
Hospital stay length	0.116	0.167
Blood loss	0.306	0.004*
Postoperative Hb	- 0.118	0.162
Pain score	0.278	0.009*
Amount in drain	0.4	<0.001 *
Myoma number		
Gestational age	- 0.034	0.779
Operative time	0.219	0.065
Hospital stay length	0.049	0.681
Blood loss	0.038	0.749
Postoperative Hb	- 0.048	0.69
Pain score	0.004	0.97
Amount in drain	0.164	0.169

r: Pearson correlation test, *: Significant.

DISCUSSION

Despite the considerable progress in the conservative management of uterine leiomyomas, there are still ongoing debates about myoma management during CS. Recently, several studies indicated the safety and feasibility of undertaking myomectomy during CS [5].

In the current study, both groups were comparable in the demographic, clinical data, the characteristics of uterine fibroids (site, size, type, and number), and the indication for surgery.

Our data indicated that the duration of hospital stay differed significantly between both groups. However, the CM group was only about 11 hours longer than the myomectomy group. In the recent study of **Sakinci *et al.*** [6], hospital stay length and duration of surgery were significantly longer in CM patients when compared with only CS patients. Another study compared cesarean myomectomy and cesarean delivery alone regarding the change of hemoglobin concentration, the need for blood transfusion, and the operative time and found only increased operative time in the cesarean myomectomy group [7].

In addition, in the current study, a significant statistical difference (14 min) in the duration of surgery between the groups was noted. Consistently, in the studies of **Sakinci *et al.*** [6] **and Guler *et al.*** [7]**,** myomectomy added 15, 14 min to the CS duration. **Morzak *et al.*** [8] **and Nargis *et al.*** [9] reported a significant difference regarding the operation time and the hospital stay length In another similar study, the CS duration was only 4.94 minutes longer in the myomectomy group than it was in the non-myomectomy group, which was not a significant difference[10]. Significant or not, all these findings reveal acceptable extensions, particularly when compared to performing a second operation to remove myomas that were not removed during CS.

In the present study, pregnant women who underwent cesarean myomectomy showed the larger mean amount of blood loss, the larger number of cases indicating drain insertion, the larger mean amount of fluid in the drain, and higher mean pain sores, with a highly statistically significant difference. Statistically significant lower mean postoperative Hb value was noted also in group II. Despite these statistically significant differences between both groups in the current study, no cases indicated blood transfusion or required ICU admission.

The present study findings were in agreement with **Simsek *et al.*** [11] who found that myomectomy contributed to the significant change of hemoglobin levels. Inconsistency with this study findings, a meta-analysis was conducted in 2017 by **Pergialiotis *et al.*** [12]**,** examining 19 studies and comparing a total of 2,301 patients who underwent myomectomy during CS with patients who underwent only CS. As a result of the evaluation, it was reported that the group that underwent CS and myomectomy had a greater decrease in Hb.

The recent study of **Salama and Souidan** [13] showed some cases of moderate blood loss that was overcome by ecbolics and bilateral uterine artery ligations with or without the B-lynch technique. Only 6 cases needed ≤ 2 units of blood and did not necessitate hysterectomy.

The CM was reported to have major hemorrhage risk, this was explained to be attributed to the uterine-rich vascularization during pregnancy[14]. The documented CM intraoperative hemorrhage incidence ranged from 0 to 35.3%[15,16].

The present study findings are, however, in discordance with some of the previous studies. **Senturk *et al.*** [17] revealed that CM was not associated with significantly higher bleeding risk than the CS alone. In addition, **Topcu *et al.***[18] revealed no significant difference in the duration of hospital stay. In the study of **Zhao *et al.*** [5], no significant difference was noted in the mean amount of blood between the same groups.

In the present study, no statistically significant differences were noted between both groups as regards the fetal outcome measures (Apgar score and fetal weight). This is in accordance with **Zhao *et al.*** [5] study that performed a comparison of the fetal outcome and showed no statistically significant difference. Furthermore, **Umezurike *et al.*** [19] reported a non-significant difference in the fetal APGAR score.

On comparison among the fibroid types regarding the maternal outcome measures, no statistically significant differences were depicted in the drain requirement, the occurrence of fever, type of anesthesia, and the indication of surgery. The intramural type was associated with statistically significant longer hospital stay and higher pain scores, while no statistically significant differences were demonstrated among the three fibroid types regarding mean gestational age at the delivery, mean operative time, mean amount of blood loss, and mean postoperative Hb. **Kim *et al.*** [20] carried out a retrospective study on non-complicated and complicated women who underwent CM. They reported that the complicated group was significantly more associated with the intramural fibroid type.

The current study revealed no statistically significant differences among the three fibroid types as regards the fetal outcome measures (Apgar score and fetal weight). **Saleh *et al.*** [21] study results agreed with this. They reported that fetal outcome was not affected by the fibroid type.

Regarding the association of the fibroid largest diameter with several outcome parameters, the diameter demonstrated a statistically significant negative correlation with the gestational age at delivery, and statistically significant positive correlation with the operative time, the amount of blood loss, the amount of fluid in the drain, the pain scores while no statistically significant correlations were noted concerning hospital stay length, the postoperative Hb levels, the fetal weight, and the Apgar scores.

In harmony with the current study findings, a trial for determination which myoma to be removed with cesarean delivery, **Zhao *et al.*** [5] in their retrospective study, found that the presence of myoma diameter ≥ 5cm were high dangerous factors for increased post-partum hemorrhage. **Kim *et al.*** [20] retrospective study on non-complicated and complicated women of CM found that the complicated group had a fibroid with a diameter larger than 10 cm. In the recent study of **Sakinci*et al.*** [6], there was a statistically significant and inverse correlation between the size of the myoma and the delivery week, this is consistent with this study findings. The attributed reason may be that the increased contractility of the myometrium as the gestational weeks progress because of the presence of large myomas. **Dedes *et al.*** [22] reported that a myoma larger than 5 cm has the risk for higher blood loss in women undergoing CM. **Morzak *et al.*** [8] found that fibroid size 3 -6 &> 6 cm were significant risk factors for hemorrhage.

Some other studies reported that myoma size was associated with increased pain, higher blood loss, and postoperative hemorrhage [23,24]. This is the same found in the current study.

In contrast to a previous prospective study, **Kwon *et al.*** [25]**,** found that even with large myoma cesarean myomectomy is a secure process. The study of **Sakinci*et al.*** [6] showed a statistically significant positive correlation between the fibroid size and the length of hospital stay.

It was claimed that the probable reason for the low complication rate during CS concerning gynecologic cases was formerly asserted as follows: the human uterus may grow up to 1,000 times in volume and 20 times in weight, but myomas can grow by up to just a quarter of their original size during pregnancy. Thus, myomectomy in CS results in less tissue damage compared with the removal of myomas in the asymptomatic cases without a pregnancy state[26]. This explanation is, however, quite rational and reasonably explains the low complication rate in CS myomectomy.

In this study, the fibroid number demonstrated no statistically significant correlations with the obstetric outcome parameters ($p > 0.05$).

Saleh *et al.* [21] concluded that the myomas size, type, or number did not significantly affect the obstetric outcome. **Qidwai *et al.*[27] and Lai *et al.*** [28] reported that no correlation was depicted between the fibroids number and the obstetric outcome.

CONCLUSION

Cesarean myomectomy is safe, applicable, and can be conducted without severe maternal adverse events or complications. Moreover, it protects patients from having to undergo two separate operations. Special precautions ought to be paid during the procedure, special to the intramural type and the large fibroids.

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