

Outcome of Cesarean Myomectomy: Is it a Safe Procedure?

Myomexstirpation bei Kaiserschnitt: Ein sicheres Verfahren?

Authors

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ABSTRACT

Objective Myomectomy performed during cesarean section is still controversial because of the potential for associated complications, especially with large myomas. Many obstetricians avoid performing cesarean myomectomy procedures because of the risk of uncontrollable hemorrhage. However, the prevalence of pregnant women with myomas is increasing, leading to an increase in the likelihood that physicians will encounter this issue. The aim of this study was to compare outcomes and complications of patients who either had or did not have cesarean myomectomy.

Method A total of 361 patients were evaluated in this retrospective study. Patients who had cesarean section with myomectomy and patients had cesarean section without myomectomy were compared with regard to demographics, drop in hemoglobin levels, complications, blood transfusion rates and duration of operation. These parameters were also compared when the diameter of the myoma was larger than 5 cm. Values of $p < 0.01$ and $p < 0.05$ were considered statistically significant.

Results While maternal age and gravidity were similar in both groups ($p > 0.05$), the mean myoma diameter was smaller and the duration of operation was longer in the group who underwent cesarean myomectomy ($p < 0.05$). The reduction in hemoglobin level, rate of complications, and number of transfusions were similar in both groups ($p > 0.05$).

Conclusion This study shows that myomectomy during cesarean section does not increase complications or transfusion rates and appears to be a safe procedure.

ZUSAMMENFASSUNG

Zielsetzung Die Frage, ob eine Myomektomie zusammen mit einer Kaiserschnittentbindung durchgeführt werden sollte, wird wegen der potenziell damit verbundenen Risiken immer noch kontrovers diskutiert, insbesondere wenn es sich um sehr große Myome handelt. Viele Geburtshelfer vermeiden es, eine Myomektomie zeitgleich mit einem Kaiserschnitt durchzuführen, weil dieser Doppeleingriff das Risiko birgt, dass es zu einer unkontrollierten Blutung kommt. Die Prävalenz von schwangeren Frauen mit Myomen nimmt aber zu und damit auch die Wahrscheinlichkeit, dass Ärzte mit diesem Problem konfrontiert werden. Ziel dieser Studie war es, die Ergebnisse und Komplikationen von Patientinnen zu vergleichen, die sich einer Kaiserschnittentbindung entweder mit oder ohne gleichzeitiger Myomektomie unterzogen.

Method Es wurden insgesamt 361 Patientinnen in dieser retrospektiven Studie untersucht. Patientinnen, die mit Kaiserschnitt entbanden und sich gleichzeitig einer Myomektomie unterzogen, wurden mit Patientinnen verglichen, die sich nur einer Sectio caesarea unterzogen. Patientendaten, der Rückgang der Hämoglobinwerte, Komplikationen, Bluttransfusionen und Operationsdauer wurden für beide Gruppen verglichen. In einer separaten Analyse wurden diese Parameter auch für Patientinnen in beiden Gruppen mit einem Myom-

durchmesser von mehr als 5 cm verglichen. Die p-Werte $< 0,01$ und $< 0,05$ wurden als statistisch signifikant bewertet.

Ergebnisse Mütterliches Alter und die Anzahl vorheriger Schwangerschaften waren bei beiden Gruppen ähnlich ($p > 0,05$). Der mittlere Myomdurchmesser war kleiner und die Operationsdauer war länger bei der Gruppe, die sich einer Kaiserschnittentbindung mit gleichzeitiger Myomektomie un-

terzogen ($p < 0,05$). Der Abfall der Hämoglobinwerte, die Komplikationsrate und die Anzahl an Bluttransfusionen waren in beiden Gruppen ähnlich ($p > 0,05$).

Schlussfolgerung Diese Studie zeigt, dass die Durchführung einer Myomektomie während einer Kaiserschnittentbindung ein sicheres Verfahren darstellt, welches die Komplikationsraten und Transfusionsraten nicht erhöht.

Introduction

Uterine myoma is the most common pelvic tumor in women; its prevalence increases between the ages of 30 and 39 years [1]. Myomas reach their largest dimensions during the reproductive years and the reported incidence of myomas in pregnancy is 0.05–5% [2]. Given that maternal age at pregnancy is increasing and the incidence of myoma also increases with age, the likelihood is rising that obstetricians will encounter pregnant patients with myomas and will need to treat the associated complications [3–7]. Although the rate of myomectomy procedures performed during cesarean sections is increasing, many obstetricians are reluctant to perform this combined procedure as they are worried about the potential morbidity and mortality rates due to uncontrollable bleeding [1]. The majority of authors are opposed to removing large or intramural myomas during cesarean section [6, 8]. However, a patient who undergoes myomectomy during cesarean section will not require a second operation. This lowers the overall cost and prevents the risk of myoma-related complications in subsequent pregnancies [9]. In addition, myomectomy during C-section accelerates puerperal involution and reduces fibroid-related complications which can develop in later life, such as menorrhagia, anemia and pain [10]. Myomas with diameters of more than 5 cm have been reported to be related to pre-term labor, premature rupture of membranes and postpartum hemorrhage [10, 11]. Most studies have shown that myomectomy can be safely carried out if various factors such as uterine contractility, anatomic localization, number and diameter of myomas, and the presence of large vascular structures are taken into account [12, 13].

The aim of this study was to retrospectively evaluate the experience of a non-tertiary care center of myomectomy performed during cesarean section and to investigate the safety and feasibility of cesarean myomectomy.

Method

This retrospective study was conducted in a single center. The patient records for the period between 2000 and 2015 were examined. The records of all cesarean sections performed in that period were evaluated.

Investigated parameters and data collection

Patient data such as age, gravidity, week of gestation, duration of operation, duration of hospitalization, indication for cesarean section, and the diameter and localization of myomas were noted. Informed consent was obtained from all patients diagnosed with

uterine myoma prior to surgery. The patients served by our hospital are generally low-income patients living in rural areas. Patients do not always seek medical help, because they often have serious difficulties in accessing the healthcare center. Therefore, if a myoma is diagnosed during surgery we are inclined to perform a myomectomy, as it would otherwise require a surgical procedure at a later date. Nevertheless, we avoid performing myomectomy if we consider it to be unnecessary or are of the opinion that this would result in a greater risk for the patient. The assessment depends entirely on the surgeon's knowledge and experience.

Prepartum to postpartum changes in hemoglobin levels and complications were recorded. Organ damage, hemorrhage and uterine atony were considered complications. The focus was on recorded complications (e.g., organ damage, hemorrhage and uterine atony), postoperative drop in hemoglobin levels, and blood transfusion requirements. The women were divided into two groups according to whether cesarean myomectomy was performed or not. All operations were performed by surgeons who are very experienced in managing bleeding complications. The indication for myomectomy was made by the surgeon, based on his knowledge and experience. The two groups were compared with regard to duration of hospitalization, transfusion rates, complications, and differences in the drop in hemoglobin levels. Additional parameters compared in this study were age, gravidity, week of gestation and the number and diameter of the myomas.

These parameters were also compared for cases with a myoma diameter of more than 5 cm [14]. Myomectomy was performed using the classic techniques of blunt and sharp dissection. After incising the tissue over the myoma to enter the fibroid pseudocapsule, blunt and sharp dissection was carried out using scissors. Bleeding was controlled by suturing the myoma bed with no. 1 absorbable sutures. As the study was retrospective, approval by the Ethics Committee was not required. The study was approved by the institutional review board.

Statistical analysis

Statistical analysis was done using the NCSS 2007 software (Number Cruncher Statistical System; Kaysville, Utah, USA). Student's t-test was used to compare differences in age, gravidity and week of gestation between the two groups "cesarean myomectomy" and "no myomectomy". Mann-Whitney U-test was used to compare the duration of the operation, length of hospital stay, numbers and diameters of myomas, and preoperative and postoperative differences in hemoglobin levels between the two groups. Multivariate logistic regression analysis was used to compare variables. Myoma type and the time of diagnosis were assessed using Pearson's Chi-square test, and transfusion rates were compared

with Yate's Continuity Correction test. Differences in hemoglobin levels in cases with myoma diameters of 5 cm and above were evaluated by Mann-Whitney U-test, and Fisher's exact test was used to compare complications and transfusion rates. Values of $p < 0.01$ and $p < 0.05$ were considered statistically significant.

Results

Demographics

There was a total of 23 150 births in the period between 2000 and 2015 at this non-tertiary center, of which 8755 were cesarean deliveries. Myoma was diagnosed during or prior to cesarean section in 361 cases and these cases were included in our study. The total number of myomas, including cases with multiple myomas, was 415. The mean patient age was 30 years, mean gravidity was 3, and mean week of gestation was 39. Diagnosis was made during surgery in 196 (54.3%) cases and in the antenatal period in 165 (45.7%) cases. The minimum duration of operation was 20 minutes and the maximum duration was 110 minutes. Mean length of hospital stay was 2 days, and myoma diameters ranged from 1 to 12 cm. The myoma type was intramural in 180 cases and subserosal in 181 cases (► **Table 1**). All patients received 20 units of oxytocin infusion intraoperatively and 40 units postoperatively. Prophylactic cefazolin 1 g was administered preoperatively. Indications for cesarean section are listed in ► **Table 2**.

Comparison of patients with and without cesarean myomectomy

A total of 212 patients underwent cesarean myomectomy, and 149 patients did not have concomitant myomectomy. The type of anesthesia used in the cesarean myomectomy group was general anesthesia in 104 patients and spinal anesthesia in 108 patients; in the non-myomectomy group 73 patients had general anesthesia and 76 patients received spinal anesthesia.

In the cesarean myomectomy group, the duration of operation was longer and the mean diameter of the myoma was smaller ($p < 0.05$). However, transfusion and complication rates were similar for the two groups ($p > 0.05$) (► **Table 3**). A statistically significant difference in preoperative and postoperative hemoglobin levels was recorded for both groups ($p < 0.05$). The drop in hemoglobin levels was similar for both groups ($p > 0.05$) (► **Table 4**). Cases with myoma diameters of 5 cm and above were compared for the two groups. The operation took longer in the cesarean myomectomy group ($p < 0.05$), but no differences were found with regard to complication rates, transfusion requirements and drop in hemoglobin levels ($p > 0.05$) (► **Table 5**). All other parameters with the exception of gravidity, parity and week of gestation had no impact on myomectomy (► **Table 6**). At operation, the size of the uterine fibroid determined whether myomectomy was performed or not. The impact of gravidity, parity, and week of gestation on myomectomy can be explained by their effect on myoma size. We noted that as the number of previous pregnancies, parity and week of gestation increased, the diameter of the fibroids decreased (► **Table 7**).

Bleeding and uterine atony were recorded in 21 cases: 7 of these complications occurred in the cesarean myomectomy

► **Table 1** Patient characteristics, operation times, duration of hospitalization, number of myomas.

	Min–Max (median)	Mean ± SD
Age (years)	13–52 (30)	30.32 ± 5.78
Gravidity	1–10 (3)	3.37 ± 1.67
Parity	0–9 (2)	2.28 ± 1.61
Age of gestation (week)	32–42 (39)	38.31 ± 1.65
Duration of operation (min)	20–110 (34)	38.38 ± 11.22
Duration of hospitalization (days)	1–24 (2)	2.31 ± 1.93
Number of myomas	1–4 (1)	1.19 ± 0.47
Myoma diameter (in cm) (n = 434)	1–12 (3)	3.35 ± 2.25

► **Table 2** Indications for cesarean section.

	n (%)
Foot presentation	2 (0.6)
Cephalopelvic disproportion	30 (8.3)
Placental abruption	5 (1.4)
Fetal distress	35 (9.7)
Previous cesarean section	243 (67.3)
Patient's request	1 (0.3)
Cord prolapse	1 (0.3)
Breech presentation	31 (8.6)
Previous myomectomy	1 (0.3)
Patient with diagnosed myoma	1 (0.3)
Oblique presentation	3 (0.8)
Oligohydramnios	2 (0.6)
Preeclampsia	3 (0.8)
Placenta previa	1 (0.3)
Transverse presentation	2 (0.6)

group and 14 occurred in the non-myomectomy group. Hypogastric artery ligation was done in 8 cases. There were no incidents of damage to surrounding organs, no maternal deaths, and hysterectomy was not required in any case.

Discussion

This study shows that there was no difference in the rate of complications, transfusion rates and drop in hemoglobin levels between the cesarean myomectomy group and the non-myomectomy group, and in those with myoma diameter greater than 5 cm.

It has been repeatedly stated in the literature that routine myomectomy during cesarean section should be avoided and should only be carried out in carefully selected patients [15]. However, there are several advantages to carrying out myomectomy proce-

► **Table 3** Comparison of myomectomy and non-myomectomy groups.

		Cesarean myomectomy (n = 212)	Non-myomectomy (n = 149)	p
Age (years)	Mean ± SD (median)	30.26 ± 5.50 (30)	30.40 ± 6.17 (31)	^a 0.823
Gravidity	Mean ± SD (median)	3.41 ± 1.50 (3)	3.31 ± 1.89 (3)	^b 0.135
Parity	Mean ± SD (median)	2.27 ± 1.38 (2)	2.30 ± 1.89 (2)	^b 0.334
Age of gestation (week)	Mean ± SD (median)	38.47 ± 1.42 (39)	38.09 ± 1.92 (38)	^a 0.031*
Duration of operation (minutes)	Mean ± SD (median)	41.28 ± 13.41 (40)	36.34 ± 8.87 (34)	^b 0.002**
Length of hospital stay (days)	Mean ± SD (median)	2.42 ± 2.45 (2)	2.15 ± 0.70 (2)	^b 0.825
Number of myomas	Mean ± SD (median)	1.16 ± 0.38 (1)	1.24 ± 0.58 (1)	^b 0.301
Myoma diameter (cm) (n = 361)	Mean ± SD (median)	3.07 ± 2.21 (2)	3.81 ± 2.36 (3)	^b 0.001**
Type of myoma n (%)	Intramural	116 (54.7)	64 (43.0)	
	Subserosal	96 (45.3)	85 (57.0)	^c 0.028*
Diagnosis obtained by n (%)	Ultrasonography	109 (51.4)	56 (37.6)	^c 0.009**
	Laparotomy	103 (48.6)	93 (62.4)	
Transfusion required	No	199 (93.9)	142 (95.3)	^d 0.724
	Yes	13 (6.1)	7 (4.7)	
Complications	No	205 (96.7)	135 (90.6)	^d 0.594
	Yes	7 (3.3)	14 (9.4)	

^a Student's t-test, ^b Mann-Whitney U-test, ^c Pearson's χ^2 test, ^d Yates's Continuity Correction test

* p < 0.05, ** p < 0.01

► **Table 4** Drop in hemoglobin levels between groups.

		Cesarean myomectomy mean ± SD	Non-myomectomy mean ± SD	p
Hemoglobin level (g/dL)	Preoperative	11.42 ± 1.26	11.73 ± 1.46	^a 0.025*
	Postoperative	10.17 ± 1.42	10.35 ± 1.42	^a 0.236
	^c p-value	0.001**	0.001**	
	Difference (median)	1.24 ± 0.75 (1.1)	1.38 ± 0.81 (1.2)	^b 0.111

^a Student's t-test, ^b Mann-Whitney U-test, ^c Paired samples t-test

* p < 0.05, ** p < 0.01

dures during cesarean delivery. First and foremost, it removes the need for a second operation. Routine myomectomy during cesarean section also reduces the risk of complications such as premature birth, dystocia or uterine atony in subsequent pregnancies and even increases the possibility of vaginal birth in a subsequent pregnancy [16]. As regards patients who underwent myomectomy, we left the decision about the mode of delivery in any subsequent pregnancy to the obstetrician who will treat the patient in future. There was no follow-up of patients after the puerperal phase so we have no data about the mode of delivery in subsequent pregnancies and whether myomectomy was required at a later time.

The decision to perform myomectomy was based on the localization of the myoma, the diameter of the myoma, the number and size of the vascular structures nourishing the myoma, and the impact on uterine contractility [15]. However, when opting

for myomectomy, the experience of the surgeon and the proximity to a tertiary center must be taken into account. To ensure the safety of cesarean myomectomies, procedures must be in place to reduce bleeding and the incision must be carefully planned [15].

In a study by Roman et al. [17], cesarean myomectomy was carried out in 111 patients and cesarean section only was performed in 257 patients. No difference was seen between the two groups with regard to postoperative fever, bleeding, hemoglobin changes, and the duration of the operation and hospitalization. However, the authors of the study stated that removal of extended fundal and intramural myomas should be avoided during cesarean delivery [17]. Despite the small mean diameter of myomas removed in the myomectomy group, there are reports in the literature that myomas with a size of up to 30 cm have been resected. It has been suggested in the literature that large myomas should be removed if they are located in the lower segment and

► **Table 5** Comparison of large myomas in the myomectomy and non-myomectomy groups.

		Cesarean myomectomy (n = 66)	Non-myomectomy (n = 31)	p
Preoperative Hgb level mean ± SD (median)		11.37 ± 1.25 (11.5)	11.54 ± 1.64 (11.6)	^a 0.563
Postoperative Hgb level mean ± SD (median)		10.04 ± 1.38 (10)	10.12 ± 1.46 (10.2)	^a 0.790
Difference in Hgb level mean ± SD (median)		1.33 ± 0.82 (1.3)	1.42 ± 0.85 (1.1)	^b 0.604
Duration of operation (minutes) mean ± SD (median)		54.42 ± 16.05 (35)	37.98 ± 9.22 (35)	^b 0.001
Complications	No, n (%)	56 (84.8)	29 (93.5)	^c 0.327
	Yes, n (%)	10 (15.2)	2 (6.5)	
Transfusion	No, n (%)	58 (87.9)	29 (93.5)	^c 0.494
	Yes, n (%)	8 (12.1)	2 (6.5)	

^a Student's t-test, ^b Mann-Whitney U-test, ^c Fisher's exact test

p < 0.01

Hgb: hemoglobin (g/dL)

► **Table 6** Effect of parameters on decision for myomectomy.

	OR	95% CI	p
Age	1.009	0.970–1.050	0.656
Gravidity	0.491	0.255–0.945	0.033
Parity	2.023	1.040–3.939	0.038
Week of gestation	0.869	0.763–0.990	0.034
Number of myomas	2.149	1.005–4.593	0.050
Myoma diameter	1.000	0.999–1.000	0.145
Type of myoma (1)	0.660	0.427–1.019	0.061
Preoperative Hgb	2.518	0.979–6.482	0.056
Postoperative Hgb	0.461	0.180–1.176	0.105
Difference in Hgb levels	0.557	0.219–1.421	0.221
Transfusion (1)	2.070	0.141–30.393	0.596
Complications (1)	0.298	0.021–4.284	0.373

Hgb: hemoglobin

block the birth canal or if they are symptomatic [17]. A review of 9 studies reported that cesarean myomectomy was a safe procedure in the hands of experienced surgeons but also emphasized that the removal of large or intramural myomas should be avoided [18]. Another review reported that in the majority of cases, myomectomy carried out to resect peduncular myomas and myomas with diameters of less than 6 cm was safe, but if the myoma had a large diameter, only peduncular myomas and myomas located in the lower segment blocking the birth canal should be resected [19]. A study of 110 cases of cesarean myomectomy compared cases with complications and those without complications. The myoma diameter was found to be larger in the group with complications [1]. Complications were defined as transfusion

of more than 3 units of blood products, postoperative ileus, need for re-operation, and more than 2 days' hospitalization [1]. In another study which evaluated 165 patients, myomectomy was carried out in 65 patients; operating times were longer in the myomectomy group, but there was no increase in postoperative complications compared to the group which did not undergo myomectomy [20]. In the same study, a comparison of the myomectomy group based on the diameter of the myoma found no difference with regard to complications, requirement for blood transfusion, changes in hemoglobin levels and postoperative fever [20]. The authors stated that the removal of myomas larger than 5 cm in diameter during cesarean delivery was safe [20]. In a similar study with fewer cases, cesarean myomectomy was carried out in

► **Table 7** Myoma diameter (centimeters) vs. week of gestation, gravidity, parity.

			Myomectomy	
			No (mean)	Yes (mean)
Week of gestation	32	Size of myoma	3	.
	33	Size of myoma	4	5
	34	Size of myoma	4	4
	35	Size of myoma	4	4
	36	Size of myoma	4	3
	37	Size of myoma	3	3
	38	Size of myoma	4	3
	39	Size of myoma	4	3
	40	Size of myoma	4	3
	41	Size of myoma	3	2
	42	Size of myoma	.	2
Gravidity	1	Size of myoma	.	4
	2	Size of myoma	3	3
	3	Size of myoma	4	3
	4	Size of myoma	4	2
	5	Size of myoma	4	3
	6	Size of myoma	4	3
	7	Size of myoma	6	4
	8	Size of myoma	4	3
	9	Size of myoma	.	1
	10	Size of myoma	4	.
Parity	0	Size of myoma	.	4
	1	Size of myoma	4	3
	2	Size of myoma	4	3
	3	Size of myoma	4	2
	4	Size of myoma	3	3
	5	Size of myoma	5	3
	6	Size of myoma	6	4
	7	Size of myoma	.	3
	8	Size of myoma	.	1
9	Size of myoma	4	.	

. = No patients in this raw

76 patients and cesarean delivery without myomectomy in 60 patients; the study reported similar rates with regard to blood transfusions, duration of hospitalization and changes in hemoglobin levels [21]. As in our study, the duration of the operation was longer in the cesarean myomectomy group [21]. The authors of that study reported that cesarean myomectomy was a safe alternative [21]. There are some case reports of myomectomy being carried out to treat myomas with extremely large diameters. Lenza et al. [22] reported the successful removal of a myoma with a diameter of 22 cm during cesarean delivery. Similarly, a case was reported where 40 cm myoma was removed after bilateral ligation of the

uterine arteries to reduce the possibility of bleeding [23]. Huang et al. [24] reported the removal of a 5290 g myoma during a 4-hour operation with no complications and a mean blood loss of 1000 cc.

The number of cases in our study was larger than in the above-mentioned studies. In our study, the mean myoma diameter was 3.67 cm in the non-myomectomy group and 2.90 cm in the myomectomy group ($p = 0.001$). The surgeons working in our center at the time of the study were more inclined to remove myomas with small diameters. There are several explanations for this. There was a tendency to remove small myomas because of the risk of possible bleeding. The decision also depended on the skill and experience of the surgeon involved and the conditions in the hospital. The center where our study was conducted is not a tertiary center but a gynecology and pediatric hospital. It had no intensive care unit, but the intensive care facilities of a state hospital in the same city were available, although this would require the transportation of the patient. The hospital also did not have specific surgical technologies which would be useful to control bleeding. As it was thought that small myoma diameters would reduce the power of our study, cases with myoma diameters of 5 cm or above were also examined. 66 cases in the non-myomectomy group and 31 patients in the cesarean myomectomy group had a myoma with a diameter of 5 cm or more. When these two groups were compared, the drop in hemoglobin levels, rate of complications and transfusion requirements were similar in both groups ($p > 0.05$).

Various methods have been recommended to prevent bleeding during cesarean myomectomy. The majority of studies in the literature have reported using high-dose oxytocin intraoperatively and in the postoperative period [17]. Uterine tourniquet, electrocautery, bilateral uterine artery ligation and other intraoperative techniques are also useful in reducing the amount of bleeding [10, 25–27]. Bilateral uterine ligation has been reported to be effective to reduce bleeding, especially if applied before removing large diameter myomas [23, 28]. In a study of 9 cases, the myomectomy was successfully completed without excessive bleeding following previous uterine artery ligation [29]. However, only 1 case in that study treated a myoma with a large diameter, and ligation was applied to the descending uterine artery branches in 2 cases with lower segment localization [29]. Tinelli et al. described an intracapsular myomectomy technique during cesarean myomectomy [30]. They reported that bleeding was not higher compared to the control group [30]. Similarly, Lee et al. [31] showed that the purse-string suture technique could be useful in controlling bleeding. Both devascularization and the intracapsular approach are important myomectomy techniques because they depend entirely on the surgeon, which is especially important in areas which have few centers with high-level technological infrastructure or intensive care units. In non-tertiary centers, the use of these techniques to control bleeding can be effective without incurring additional costs. In the present study, control of bleeding was achieved by suturing the myoma bed, and oxytocin was used intraoperatively and postoperatively for all patients. A total of 17 patients developed uterine atony and bleeding occurred in 4 patients; hypogastric artery ligation was performed in 8 of these patients.

This study is important because of the large number of cases and the separate analysis of cases with myoma diameters of 5 cm and above. In non-tertiary centers or centers with limited facilities, knowledge of the above-mentioned techniques is valuable to control bleeding. Cesarean myomectomy is a safe option in the hands of skilled, experienced surgeons and where the appropriate facilities are available. The main limitations of our study are its retrospective nature and the lack of follow-up data for patients.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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