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Endometrial preservation in hysteroscopic myomectomy; a new technique versus the classical resectoscopic technique, a randomized controlled trial

Mahmoud Yousry Mahmoud Aly[1], Tamer Hanafy Mahmoud[2], Yasser Saad El Kassar[2], Mohamed El Mahdy Abd El Moneim[2]

[1]Assistant lecturer of Obstetrics and Gynecology, Department of Obstetrics and Gynecology, Faculty of Medicine, Alexandria University, Egypt; [2]Professor of Obstetrics and Gynecology, Department of Obstetrics and Gynecology, Faculty of Medicine, Alexandria University, Egypt.

Correspondence: *Mahmoud Yousry Mahmoud Aly*, MS. Assistant lecturer of Obstetrics and Gynecology, Department of Obstetrics and Gynecology, Faculty of Medicine, Alexandria University, Egypt. El-Gish Rd, Al Azaritah, El-Shatby Maternity Hospital, Qism Bab Sharqi, Alexandria, Egypt. Tel: +201210084870; E-mail: myousry201@gmail.com

Abstract:

Background: hysteroscopic myomectomy is the gold standard treatment of submucous fibroid. Intrauterine adhesions (IUAs) represents the major long term complication of hysteroscopic myomectomy. To date, little focus has been placed on the role that the resection technique could have in causing fibrous reactions after hysteroscopic myomectomy. The main ***aim*** of this study is to compare a new proposed surgical approach for hysteroscopic myomectomy to the classical approach as regards efficiency, operative time, complications, and prevention of post-operative intrauterine adhesions. ***Methods*****:** This prospective study was carried out for 60 women diagnosed with grade (0) or (1) submucous fibroid with a diameter < 3 cm, randomly assigned into one of two groups, group (1) 30 women underwent hysteroscopic myomectomy through a new proposed endometrial preservation approach and 30 women in group (2) underwent classical hysteroscopic myomectomy through the slicing technique. ***Results***: no significant statistical difference between the two

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techniques as regard the operative time, fluid deficit, intraoperative complications, or postoperative intrauterine adhesions. ***Conclusion***: The proposed technique offers comparable results to the classical technique as regards postoperative outcomes in terms of ultrasonographic and hysteroscopic endometrial appearance as well as incidence of IUA, with no significant increase in operative time or risk of complications.

Keywords: submucous fibroid, hysteroscopic myomectomy, intrauterine adhesions.

Introduction

Uterine leiomyoma or fibroid is the most common female genital tract pathology with a prevalence ranging from 5.4% to 77%, according to age, ethnicity and diagnostic method. Fibroids are one of the major causes of infertility, apart from being a source of abnormal uterine bleeding and pelvic pain (1).

It is globally accepted that submucosal fibroids are of clinical significance. They constitute 5-10% of fibroids (2). Submucosal fibroid location and distortion of the endometrial cavity (either submucosal or cavity compressing intramural myomas) are most predictive of defective fertility and possible benefits of surgical excision, and are candidate for myomectomy in the subfertile patient (3).

The gold standard treatment for a submucous leiomyoma is hysteroscopic myomectomy, although it was performed for the first time in 1976 (4), over the years, new techniques for hysteroscopic resection of submucous myoma have been described with the aim of restoring the physiologic anatomy of the uterine cavity while avoiding both short-term and long-term complications (5).

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Intrauterine adhesions (IUAs) represents the major long term complication of hysteroscopic myomectomy ranging from 1 to 13% (6). Several measures have been proposed to reduce the risk of post-operative IUAs; avoidance of forced cervical manipulation and trauma of healthy endometrium and myometrium surrounding the fibroid, as well as minimizing the usage of electrosurgery especially during the removal of fibroids with extensive intramural involvement and multiple fibroids on opposing endometrial surfaces (7). An early second-look hysteroscopy after any hysteroscopic surgery is another effective preventive and therapeutic strategy. Several pharmacologic (conjugated estrogen, levonorgestrel releasing intrauterine device) and barrier agents, including foley catheter, hyaluronic acid gel and hyaluronic acid and carboxymethyl cellulos (Seprafilm) have been used to reduce IUA development. No single modality has been proven to be unequivocally effective at preventing post-operative adhesion formation for hysteroscopic surgery (8).

To date, little focus has been placed on the role that the resection technique could have in causing fibrous reactions after hysteroscopic myomectomy (9). The classical resectoscopic resection involves a slicing technique which could lead to unnecessary injury to the covering endometrial as well as the surrounding myometrium, which is -at least theoretically- may impair the reproductive potentials. (10).

The aim of this study was to compare a new proposed surgical approach for hysteroscopic myomectomy to the classical approach as regards efficiency, operative time, complications, and prevention of post-operative intrauterine adhesions.

Patients & methods

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This study is a prospective randomized controlled study performed at The Unit of Endoscopy of El Shatby Maternity University Hospital in Alexandria.

Sample size:

Sample size was calculated by staff members of the high institute of public health, Alexandria University .A minimal total hypothesized sample size of 60 eligible women undergoing hysteroscopic myomectomy (30 per group) is needed to compare a new proposed surgical approach for hysteroscopic myomectomy to the classical approach as regards efficiency, operative time, complications, post-operative endometrial quality and prevention of post-operative intrauterine synechia with an assumption of obtaining an effect size of 10%, with 0.05 probability of type I error and power of 80% using Chi-square test.

Participants:

The study was conducted for 60 women seeking pregnancy admitted from the outpatient clinic planned for hysteroscopic myomectomy and after signing their informed consents they were randomly assigned – through computer generated randomization – into one of the two groups (30 per group) according to the surgical approach to myoma resection.

Group 1: Hysteroscopic myomectomy using the new proposed technique.

Group 2: Hysteroscopic myomectomy using the classical technique.

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Inclusion & exclusion criteria:

- We included women aged 18 – 42 years with a single submucous myoma G0 or G1 of a size ranging from 0.5 cm to 3 cm with a free myometrial margin between the myoma and the uterine serosa of at least 10 mm.
- Women with previously diagnosed uterine anomalies, with history of previous hysteroscopic surgeries, with active genital tract infection, undergoing concomitant abdominal or laparoscopic surgery involving the uterus, and women with cervical myoma or broad ligament myoma were excluded from the study.

All the included women underwent a thorough preoperative evaluation including detailed history taking, gynecological examination, basic laboratory investigations (full blood count, coagulation profile, and other relevant tests), and a detailed 2D/3D transvaginal sonography assessing size and verification of grade of myoma, endometrium, uterine cavity and exclusion of any concomitant pathology.

The surgical procedure:

The standard procedure in all patients undergoing either of the surgical approaches involves:

- Vaginal administration of 2 tablets of misoprostol, 8 hours prior to the operation.
- General or spinal Anaesthesia.
- Patient placed in lithotomy position.
- Dilatation of cervical canal using hegar's dilators.

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- Surgical procedures were performed using a 9 mm resectoscope with 30◦ optical system (Hopkinsii; Karl Storz Tuttlingen, Germany).
- The adequate distension of the uterine cavity was ensured by the automatic irrigation system Hydromat (Karl Storz), which guaranteed a constant intracavitary pressure between 90 and 120 mm Hg. Glycine 1.5% solution was used as the distension medium as monopolar electrode was used. The procedure was interrupted only if the deficit of glycine reaches 1200 ml.
- The resectoscope was placed in the uterine cavity to observe the relationship among the position and size of the myoma and intima of the uterine cavity as well as evaluate the overlying endometrium.
- If complete resection of the myoma was not achieved in one session, a second session was scheduled.
- At the end of surgery, no anti-adherence mixtures was placed.

I- The new approach (for patients in group 1):

The new proposed technique (illustrated in figure 1) involved a single incision over the surface of the myoma, followed by extension of the incision through the entire thickness of the myoma, such that the fibroid is split into two halves reaching the myoma bed. Shaving of the fibroid from inside out was then carried out, sparing the outer surface with covering endometrium. Monopolar right angle electrode was used to split the myoma, then a loop electrode was used in shaving of the myoma.

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II- The classical approach (for patients in group 2):

The classical approach involved slicing the myoma into chips using a monopolar loop electrode starting from the outer surface including the covering endometrium till reaching the myoma bed.

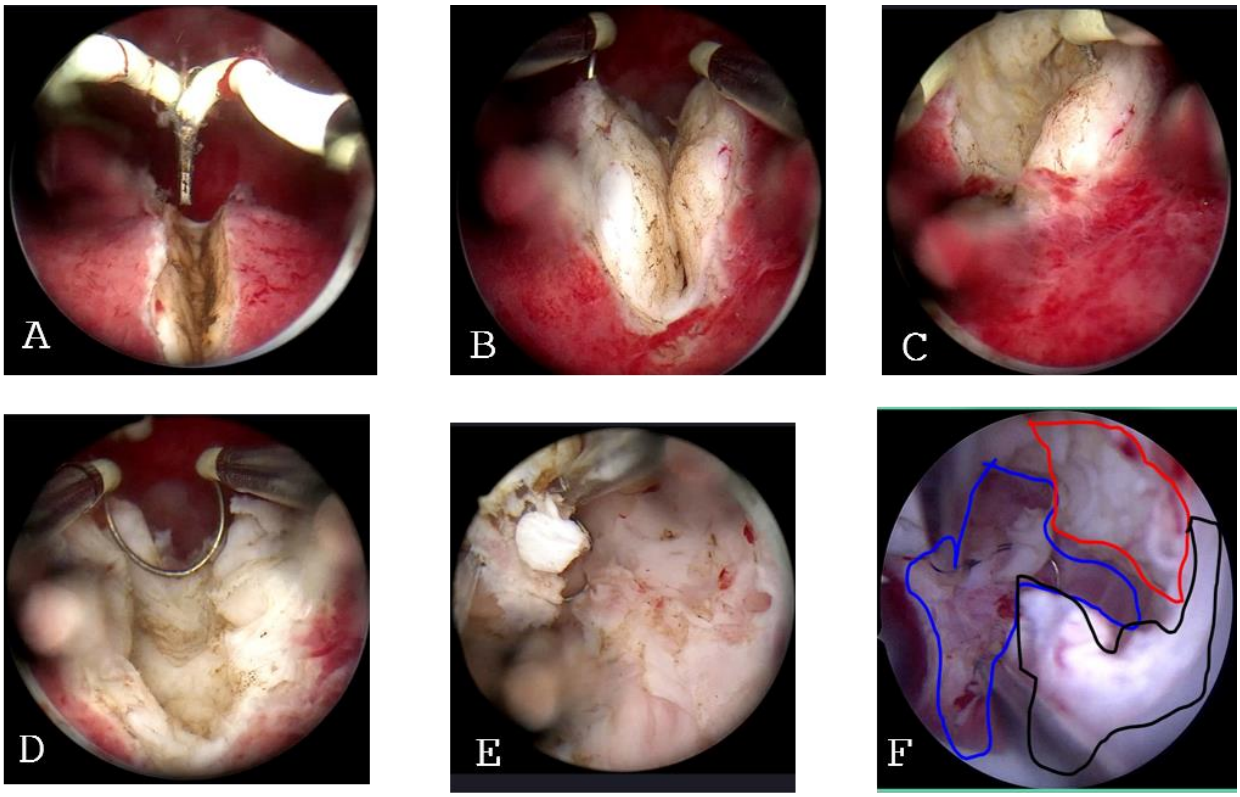

Figure (1): Endometrial preservation technique of hysteroscopic myomectomy.

A: Vertical incision of the endometrium overlying the myoma using Collin's knife electrode to expose the myoma. **B**: Vertical splitting of the myoma down to just above its base also using the Collin's knife, which allows lateral spread of the 2 myoma halves with lateral retraction of the overlying endometrium. **C**: Slicing of the myoma from inside out in a "pealing" fashion using the loop electrode, avoiding the retracted overlying endometrium. **D**: Note the bulk of the myoma excised from the middle, with

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the endometrium retracted laterally. **E**: This process is continued until the entire myoma is excised and pseudocapsule is visualized. **F**: Note retracted floating endometrial covering laterally, highlighted by the black marker. Also note the difference in gross appearance and colour between pseudocapsule (highlighted by blue) vs. myoma tissue (highlighted by red).

III- Follow up of cases:

- All patients underwent a transvaginal ultrasound followed by office hysteroscopy 1-2 months after the procedure to assess uterine cavity, endometrium and the development of any intrauterine synechia. Evaluation of intrauterine synechia was done according to the American Fertility Society (AFS) Scoring System (11).

Statistical analysis of the data

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0**. (**Armonk, NY: IBM Corp**).** Qualitative data were described using number and percent. The **Shapiro-Wilk test** was used to verify the normality of distribution. Quantitative data were described using range (minimum and maximum), mean, and standard deviation, median and interquartile range (IQR). Significance of the obtained results was judged at the 5% level.

The used tests were:

1 - Chi-square test: For categorical variables, to compare between different groups

2 - Fisher's Exact or Monte Carlo correction: correction for chi-square when more than 20% of the cells have expected count less than 5

3 - Student t-test: For normally distributed quantitative variables, to compare between two studied groups

4 - Paired t-test: For normally distributed quantitative variables, to compare between two periods

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5 - Mann Whitney test: For abnormally distributed quantitative variables, to compare between two studied groups

Results

The study included 60 women underwent hysteroscopic myomectomy, 30 women in each study arm, table (1) demonstrates the main study results. There were no drop out of patients during the study. The mean age for patient in group (1) was 37.63 ± 3.67 years vs 36.10 ± 5.29 years in group (2) with no significant statistical difference. 65 % (39/60) of women were multiparous and 35 % (21/60) were nulliparous. 71.7 % (43/60) of women complained of heavy menstrual bleeding.

In group (1), 7(23.3%) were grade 0, 15(50.0%) were grade I and 8(26.7%) were grade II while in group (2), 19(63.3%) were grade 0, 7(23.3%) were grade I and 4(13.3%) were grade II. The mean myoma size was 2.0 ± 0.57 cm in group (1) versus 2.62 ± 1.05 cm in group (2).

Operative time in group (1) ranged between 6.0 – 38.0 minutes with a mean of 19.37 ± 7.68 minutes while in group (2) ranged between 6.0 – 30.0 minutes with a mean of 16.93 ± 6.88 minutes. There was no statistically significant differences between groups (P=0.201). Mean glycine used in group (1) was 11.95 ± 4.40 L while in group (2) was 12.60 ± 5.28 L. There was no statistically significant differences between groups (P=0.606). Mean glycine deficit in group (1) was 0.51 ± 0.46 L while in group (2) was 0.73 ± 0.69 L. There was no statistically significant differences between groups (P=0.233). No intraoperative complications happened in both groups.

Complete myoma resection was achieved in 28 cases (93.3%) of group (1) versus 25 cases (83.3%) in group (2), (P=0.424). Second look office hysteroscopy performed 1 – 2 months revealed intrauterine synechiae in 13.3 % (8/60) of cases, 4 cases in each group.

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Table (1): Main study results

Parameter	Group (1) 30 women	Group (2) 30 women	p value
Age (mean) years	37.63 ± 3.67	36.10 ± 5.29	0.197
Parity Nulliparous Multiparous	 13 (43.3%) 17 (56.7%)	 8 (26.7%) 22 (73.3%)	0.176
Main complaint(s) HMB Infertility Both	 13 (43.3%) 11 (36.7%) 6 (20%)	 20 (66.7%) 6 (20%) 4 (13.3%)	0.187
Myoma size (mean) cm	2.62 ± 1.05	2.0 ± 0.57	0.006*
Operative time (mean) minutes	19.37 ± 7.68	16.93 ± 6.88	0.201
Mean glycine used (liters)	11.95 ± 4.40	12.60 ± 5.28	0.606
Glycine deficit (liters) Mean Median	 0.5±0.46 0.50 (0.0 – 1.0)	 0.73±0.69 0.50 (0.0 – 1.0)	 0.233
Complete Myoma resection	28 (93.3%)	25 (83.3%)	^{FE}**p** 0.424
Postoperative IUAs	4 (13.3%)	4 (13.3%)	1.00

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Discussion

Hysteroscopic myomectomy is considered the gold-standard treatment option of the submucosal fibroid. Transcervical resection of myomas (TCRM) is commonly performed for the treatment of women with infertility or abnormal uterine bleeding caused by submucous fibroids. Amongst the merits of TCRM are the minimally invasive approach, same-day discharge and quick recovery. However, the procedure is associated with disruption of the endometrium, and subsequent complications such as intrauterine adhesions and loss of functional endometrium (12).

In our study, carried out over 60 patients, 30 of which underwent hysteroscopic myomectomy using the new proposed technique whereas the remainder utilizing the classical resectoscopic technique, both techniques showed comparable mean operative time (19.5 minutes vs 17 minutes), volume of distension fluid required (11.95 L vs 12.6 L), fluid deficit (0.51 L vs 0.73 L), as well as comparable postoperative outcome and hysteroscopic gross appearance.

Whilst intrauterine adhesions following TCRM is a well-recognized problem, loss of functional endometrium is not widely appreciated and there is no significant data in the literature. Loss of functional endometrium usually represents itself as thin or hyperechogenic endometrium in natural or assisted reproduction (ART) cycles (13).

Taskin et al. reported that most cases of adhesions in a non-gravid uterus are the result of surgery; they found IUA in 45.5% of women who underwent hysteroscopic resection of multiple fibroids or in 31.3% if a single fibroid was removed (14).

During the resection of submucous myomas by hysteroscopy, the main trigger of post-surgical IUA development is the use of the resectoscope on the endometrial bed, and cold hysteroscopic resection was shown to produce a lower rate of IUA ~ 4.2% (9).

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To date, there is no well-defined best optimum technique for hysteroscopic myomectomy. There have been various mixed retrospective and prospective observational studies to have data on clinical improvement, complications, recurrence and patient satisfaction after hysteroscopic myomectomy (15, 16). Literature on techniques that preserve the functional endometrium during TCRM is scarce (12).

Bipolar electrosurgery system exerts a precise tissue effect, since both electrodes are built into the thermal loop itself; hence, the current passes through the tissue interspersed between the two electrodes, thus minimizing the risk of damage to the adjacent tissues, and it has been suggested that electrical injury and intrauterine synechiae formation may be minimized with its use (17).

A prospective randomized trial comparing unipolar vs. bipolar hysteroscopic myomectomy in infertile women, conducted in 2017, involving 60 women with submucous fibroids, revealed a statistically insignificant improvement in fertility parameters in the bipolar group, and concluded that the use of bipolar electrosurgery is associated with comparable fertility outcomes, yet with a much better surgical safety profile. The incidence of adhesions after hysteroscopic myomectomy was found to be lower in the bipolar group (6.7%) as compared to that in the unipolar group (13.3%) (17).

Touboul *et al*., (18) found that the incidence of uterine synechiae after bipolar hysteroscopic resection of fibroids was 7.5%. The incidence of adhesions after unipolar system use was higher in a study by Taskin *et al*. – 31.3% in patients with solitary fibroid and 45.5% in those with multiple fibroid (14).

The "cold Loop" technique for hysteroscopic myomectomy was conceived by Mazzon with the aim of preserving muscle fibers in the myometrium, ensuring complete removal of the myoma without excessive thermal damage to the myometrium (19).

The safety and efficacy of cold loop myomectomy is well-recognized and several studies were conducted to evaluate it (9, 19 – 21) including 2 large retrospective studies, one in 2014, involving 688 women, which reported a 4.23% incidence of synechiae, a lower

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incidence than reported in literature (9), and a later and larger one in 2015 which concluded that the use of a cold loop in resectoscopic myomectomy is associated with a low rate of minor intraoperative complications and an absence of major complications, and that this could be of primary relevance with a view to fertility and future pregnancies (19).

Another technique published by Lasmar in 2001 has the name of "direct mobilization of the myoma", which entails enucleation of the entire fibroid after incising the endometrium over the myoma till reaching the pseudocapsule, and then slicing it (22), This technique shares many similarities with Mazzon's Cold Loop technique with the same concept of psuedocapsule preservation.

Litta et al. developed a new technique of hysteroscopic myomectomy with enucleation en Toto, based on similar surgical principles to our technique, but primarily used in cases of submucous fibroids with large intramural component (G2) by favoring intracavitary protrusion of that part following and elliptical incision of the overlying endometrium (23).

The new proposed technique follows the previously discussed techniques for hysteroscopic myomectomy as regards the concept of maximizing fertility outcomes post operatively, adopting the principle of minimizing damage to the endometrium and pseudocapsule preservation whilst adding some modifications to the surgical technique. Whereas Lasmar and Litta describe enucleation of the myoma en Toto, the technique proposed involves splitting of the myoma down to its base and chipping from inside out while it is fixed to its bed, in order to avoid wobbling around to minimize unnecessary endometrial injury.

The longitudinal incision over the myoma using the Collin's knife electrode allows the fibroid to bulge into the uterine cavity with simultaneous retraction of the overlying endometrial lining laterally. This maneuver, followed by vertical splitting of the myoma down to its bed, enables access to the entire fibroid without the need for excising excess endometrial and myometrial tissue surrounding the myoma, and also facilitates chipping

of the fibroid from inside out while maintaining the desired fixed position of the fibroid during the chipping process.

Conclusion: The proposed technique offers comparable results to the classical technique as regards postoperative outcomes in terms of ultrasonographic and hysteroscopic endometrial appearance as well as incidence of IUA, with no significant increase in operative time or risk of complications. In light of such results, and given that the proposed technique has at least a theoretical benefit over the classical technique in minimizing endometrial damage, and hence preserving maximal fertility potential post operatively, it is worth further studying on a large scale of patients and with longer duration of follow up.

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Conflict of Interest: The authors declare that they have no competing interests.

Ethics Approval: Approval was obtained from the ethics committee of Faculty of medicine, Alexandria University in 2022. Approval number was 021664.

Acknowledgements: Not applicable.

Consent to Participate: Informed consent was obtained from all participants included in the study.

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