Myomectomy Using Hysteroscopic Tissue Removal System (MyoSure System) improves Outcome and Quality of Life of women with Abnormal Uterine Bleeding

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Abstract
Objectives: To evaluate outcome of submucous myomectomy using the Hologic MyoSure® hysteroscopic tissue removal system (HTRS) and to determine its effect on patients' quality of life (QOL).

Patients & Methods: This prospective-retrospective study included 24 women in childbearing period who presented by abnormal uterine bleeding (AUB) secondary to uterine fibroid (UF). Women were clinically evaluated and then underwent transvaginal fluid-infused ultrasonography for measuring fibroid size and extent of myometrial invasion and only women with UF of Stage 0 or 1 according to FIGO classification were enrolled in the study. Similar data of patients had submucous UF resected by conventional hysteroscopic monopolar loop resectoscope were extracted off files. Intraoperative (IO) data included operative time and amount IO bleeding and of distending fluid. PO pain was graded using Likert 5-point scale and moderate-to-severe pain was managed using intramuscular morphine. At 6th month of follow-up hemoglobin concentration (Hb. Conc.) was re-estimated and percentage of improvement in relation to preoperative concentration was calculated. Patients' satisfaction concerning the impact of uterine bleeding on QOL was evaluated using the SF-36 questionnaire.

Results: Mean operative time was significantly shorter with significantly lesser amount of blood loss, but significantly higher amount of distending fluid in comparison to corresponding data of control patients. Nine patients required rescue analgesia; 3 in study versus 6 in control groups and mean duration of hospital stay was non-significantly shorter in study patients. PO SF-36 score was significantly higher in comparison to preoperative scoring. Percentage of increase of Hb. Conc. was significantly higher in study compared to control patients.

Conclusion: Myomectomy for stage 0-1 UF with <50% myometrial invasion in women in childbearing period who require to preserve their fertility is feasible using MyoSure HTRS. MyoSure device provided faster, safer myomectomy with more acceptable short-term outcome.

Keywords: Submucous uterine fibroid, Myomectomy, Hysteroscopic tissue removal system, quality of life

Introduction
Uterine fibroids (UF) are common monoclonal neoplasms of the uterus (1). UF are hormonal-dependent tumors of uterine smooth muscle and connective tissue with fibroblast components and substantial amount of fibrous extracellular matrix (2). Despite being asymptomatic and require no intervention in majority of cases (3), symptomatic UF can cause significant morbidity including menstrual abnormalities, iron deficiency anemia, bulk symptoms and may adversely impact fertility (4). For women in reproductive age, UF represent a major health problem through affecting their reproductive system structure and function (5).

About 30% of women with UF will request treatment due to symptoms, but current management strategies mainly involve surgical interventions (6). The choice of treatment must be individualized based on symptoms, size and location of fibroids, age, need and desire of fertility preservation, the availability of therapy, and the experience of the therapist (3). Hysterectomy by the least invasive approach possible is the definitive treatment for symptomatic UF and is associated with a high level of satisfaction for patients who did not wish to preserve their fertility (7).

However, for women who wish to retain their uterus and/or to enhance or retain fertility, multiple uterine-preserving therapies have been introduced, including laparoscopic or hysteroscopic myomectomy (8), uterine artery embolization (9),
radiofrequency, laser, cryotherapy ablation \(^{(7)}\) and magnetic resonance guided high-intensity focused ultrasound myolysis \(^{(10)}\).

Myomectomy induced substantial improvement in health-related quality of life (QOL), regardless of route of myomectomy, but return to usual activities was much earlier with hysteroscopic than laparoscopic or abdominal myomectomy \(^{(11)}\). Hysteroscopic myomectomy is a minimally invasive, low-cost, low-risk procedure, and is associated with high patient satisfaction \(^{(12)}\). Hysteroscopic morcellation of submucosal UF is an effective method to manage women with abnormal uterine bleeding (AUB) \(^{(13)}\).

**Objectives**

This study aimed to evaluate the applicability and outcome of submucous myomectomy using the Hologic MyoSure® hystrosopic tissue removal system (HTRS) and to determine the effect of outcome on patients’ QOL.

**Setting**

Obstetrics & Gynecology Department, Al Jahra Hospital, Kuwait

**Design**

Retro-prospective comparative study

**Patients & Methods**

The study protocol was approved by the Local Ethical Committee at March 2018, to include all women presenting to gynecology outpatient clinic with recurrent abnormal uterine bleeding, excessive menstrual bleeding or prolonged menstrual bleeding for evaluation. Prior to enrolment, all women fulfilling the inclusion criteria were asked to sign a written fully informed consent concerning acceptance to undergo myomectomy using the MyoSure device.

All women eligible for evaluation underwent determination of demographic data, obstetric history, past history concerning bleeding and gave blood sample for estimation of hemoglobin concentration (Hb. Conc.). Then, all women underwent abdominal and/or transvaginal fluid– infused ultrasonography for measuring fibroid size that was confirmed during diagnostic hysteroscopy prior to resection. Fibroid staging was conducted according to the FIGO classification system into Stage 0 if fibroid was pedunculated and intracavitary, Stage 1 if fibroid extended intramural to <50% of myometrium and Stage 2 if fibroid extended intramural to >50% of myometrium \(^{(14)}\). During diagnostic hysteroscopy, a punch-biopsy was obtained for histopathological examination to exclude malignant and pre-malignant lesions.

Inclusion criteria included women in childbearing period with submucous fibroid of stage 0 or 1, wishing to maintain their fertility and presented with uterine bleeding that deleteriously affected their Hb. Conc. Exclusion criteria included pre-malignant or malignant lesions, presence of pelvic or vaginal infection, Hb. Conc. <8 gm/dl, previous hysteroscopic surgery and myoma located nearby a uterine scar, hemorrhagic disorders, hemoglobinopathies, endocrinopathies, body mass index (BMI) ≥35 kg/m\(^2\), diabetes mellitus, hypertension, kidney or cardiac disease, or allergy to anesthetic drugs.

**Procedure**

Myomectomy was conducted using the MyoSure Lite Hysteroscopic Tissue Removal System (Hologic Inc., Malborough, MA, USA); a device approved by US FDA for resection and removal of intrauterine tissue including polyps measuring 3-cm or less in diameter and consisted of hand-held hysteroscopic system including a
hysteroscope and a disposable morcellator within a hollow stainless steel tube with 6.25 mm outer diameter and a shaft of 3 mm in diameter that drives the cutting blade and was connected to mechanical drive (15). The procedure of morcellation was conducted according to the instructions of the manufacturer (16) as follows, under hysteroscopic guidance; the uterine cavity was distended using physiological saline (0.9% NaCl) as distending medium, the cutting blade was put in contact with the myoma through a side-facing 10.2 mm long and 1.5 mm deep channel on the morcellator distal shaft. Upon motor activation, the blade guard covering the window retracts, and the hardened stainless steel blade engages its dual cutting motion, rotating at 8,075 rpm while oscillating at 3 cycles/sec. The excised tissue was removed through the shaft via the cutting port at rate of 7 g/min using 300 mmHg suction pressure and 100 mmHg intrauterine pressure.

**Collected intraoperative (IO) and postoperative data**

The collected IO data included duration of surgery determined since patient was fully anesthetized till end of the procedure and removal of the device. Amount of distending fluid used as judged by the volume collected in the suction chamber, incidence of IO bleeding, complications and need for shift to open surgery.

All patients were admitted to post-anesthetic care unit until fully recovered and shifted to inpatient ward until discharge. Immediate PO data included incidence of vaginal bleeding, PO pain that was graded using Likert 5-point scale ranging between no to severe pain and was managed using morphine 5 mg intramuscular for moderate-to-severe pain, and duration of PO hospital stay.

**Patients' grouping**

Thirty-seven female patients presented with abnormal uterine bleeding, 13 patients were excluded and 24 patients had enrolled in the study. For comparative purpose, similar data of patients had submucous fibroid and had operated up on recently prior to introduction of MyoSure to the hospital using conventional hysteroscopic monopolar loop resectoscope were extracted off files of patients of cross-matched demographic and preoperative clinical data. Data were collected by an assistant who was blind about the target of the study and not included as an author as Control group (Fig. 1).
Follow-up
All patients were followed-up for at least 6-months for the last case operated up on. Follow-up data included the following items
1. Inquiry about persistence or recurrence of bleeding.
2. Hb. Conc. was re-estimated at 6th month to be compared versus the preoperative concentration and to calculate the percentage of improvement as PO minus preoperative concentration and the difference was divided by the preoperative concentration.
3. Patients' satisfaction by the outcome concerning the impact of uterine bleeding on quality of life was evaluated using the SF-36 questionnaire consisted of 36 questions (Appendix 1) measures eight scales: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health (17); the answer of each question was scored (Appendix 2) and one summary score was given for each patients.

Statistical analysis
The obtained data are presented as numbers, percentages and mean±SD. Variance in parametric data of patients of studied groups was analyzed using One-way analysis of variance (one-way ANOVA test). Intra-group variance was analyzed using paired t-test. Non-parametric data were presented as numbers and were analyzed using Chi-square test with Yates correction. Statistical analyses were performed using Statistical analysis was conducted using the IBM SPSS (Version 23, 2015; IBM, South Wacker Drive, Chicago, USA) for Windows statistical package. P value <0.05 was considered statistically significant.

Results
There was non-significant (p>0.05) difference between extracted data and that of enrolled patients as shown in table 1.

Table (1): Preoperative data of patients of both groups

<table>
<thead>
<tr>
<th>Data Group</th>
<th>Control</th>
<th>Study</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>33±5.7</td>
<td>34.5±6.3</td>
<td>0.391</td>
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</tbody>
</table>
All surgeries were conducted uneventfully with no intraoperative complications or need for shift to open surgery. Mean operative time was significantly (p=0.001) shorter with significantly (p=0.018) lesser amount of blood loss, but the procedure required significantly higher (p=0.022) amount of distending fluid in comparison to corresponding data of control patients. Mean duration of PACU stay was non-significantly shorter in study than in control women. In both groups, no patient had severe pain, 11 patients had no pain, 28 patients had mild and 9 patients had moderate pain with non-significant difference between both groups. These nine patients required rescue analgesia with non-significant difference between both groups. During ward stay, no patient complained of vaginal bleeding. Mean duration of hospital stay was non-significantly shorter in patients of study compared to control group (Table 2).

Table (2): Operative and immediate PO data of patients of both groups

<table>
<thead>
<tr>
<th>Data Group</th>
<th>Control</th>
<th>Study</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative time (min)</td>
<td>48.7±15.5</td>
<td>29.8±8.7</td>
<td>0.001</td>
</tr>
<tr>
<td>Operative blood loss (ml)</td>
<td>56.7±12.9</td>
<td>46.5±15.7</td>
<td>0.018</td>
</tr>
<tr>
<td>Amount of expanding fluid (ml)</td>
<td>165.8±91.1</td>
<td>282.1±223.2</td>
<td>0.022</td>
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<tr>
<th>Immediate PO</th>
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<tr>
<td>PACU stay (min)</td>
<td>23.8±5.8</td>
<td>22.1±5.3</td>
<td>0.302</td>
</tr>
<tr>
<td>Pain scoring</td>
<td></td>
<td></td>
<td>0.539</td>
</tr>
<tr>
<td>No</td>
<td>5 (20.8%)</td>
<td>6 (25%)</td>
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<tr>
<td>Mild</td>
<td>13 (54.2%)</td>
<td>15 (62.5%)</td>
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<tr>
<td>Moderate</td>
<td>6 (25%)</td>
<td>3 (12.5%)</td>
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<tr>
<td>Severe</td>
<td>0</td>
<td>0</td>
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<tr>
<td>PO hospital stay (hr)</td>
<td>27.5±6.1</td>
<td>24.9±7.5</td>
<td>0.198</td>
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</table>

Data are presented as mean±SD, number, percentage; P value indicates the significance of difference between both groups; P<0.05 indicates significant difference; P>0.05 indicates non-significant difference.
All patients of study group had attended the follow-up visits for a mean duration of follow-up of 14.8±2.8; range: 10-19 months. Evaluation of patients' satisfaction by the outcome and its impact on their quality of life revealed significantly (p=0.0067) higher PO SF-36 scoring (43.8±17.4) in comparison to preoperative (34.6±9) scoring (Fig. 2). Postoperative Hb. Conc. in control (11.4±0.96 g/dl) and study (11.5±1 g/dl) groups was significantly (p<0.001) higher in comparison to preoperative concentration in both groups with non-significantly (p=0.482) higher PO concentration in patients of study group. However, the percentage of increase of Hb. Conc. was significantly (p=0.030) higher in patients of study (19.9±3.3%) versus control (17.2±4.9%) group (Fig. 3).
Fig. 3: Mean Hb. Conc. estimated at preoperative and end of follow-up with the extent of change in patients of both groups

<table>
<thead>
<tr>
<th>Hb. Conc. (g/dl)</th>
<th>Preoperative</th>
<th>At end of follow-up</th>
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<tr>
<td></td>
<td>Control</td>
<td>Study</td>
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<tr>
<td>8.5</td>
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<td>9</td>
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<td>9.5</td>
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<td>11.5</td>
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<td>12</td>
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<tr>
<th>% of change</th>
<th>Preoperative</th>
<th>At end of follow-up</th>
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<td>8.5</td>
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**Case Presentation**

A patient aged 31 years presented by menorrhagia since 16 months and had 2 offspring and complained of distressing sensation that affected her quality of life and her SF-36 score was 35 and Hb. Conc. was 8.9 g/dl. TVU defined fundal fibroid of stage-1 and 4.6 cm in its wider diameter (Fig. 4a & c) and about 30% myometrial extension. Patient was prepared for myomectomy using MyoSure device (Fig. 4b); fibroid was successfully completely removed (Fig. 4d) within operative time of 35 minutes, and IO blood loss was about 40 ml and amount of distending fluid was 330 ml. Postoperatively, patient had mild pain and was discharged 12 hr and at end of follow-up her SF-36 was 75 and Hb. Conc. was 10.3 g/dl with 15.7% extent of increase.

Hysteroscopic appearance of endometrial cavity with MyoSure control system & fluid control system
Discussion

Myomectomy of stage 0-1 uterine fibroid (UF) using hysteroscopic tissue removal system (HTRS; MyoSure device) did favorably in comparison to data of cross-matched women had myomectomy using conventional hysteroscopic monopolar loop resectoscope and was superior regarding operative time (significantly shorter) and amount of blood loss (significantly lesser). In a similar study, Lee & Matsuzono (19) retrospectively reported similar results with comparable operative time, IO blood loss and patients' satisfaction to the current study and suggested that hysteroscopic intrauterine morcellation of submucosal UF is a safe and effective method for management of menorrhagia and the technique is less time-consuming, especially when managing UF of ≤3.0 cm.

The reported decreased IO blood loss could be attributed to the fact that mechanical morcellators depends on mechanical tissue fragmentation using high velocity rotating machine that generate heat allowing for initiation of blood clotting and its fragmenting nature allowed platelet stimulation and release of its internal constituents thus rapid closure of minute blood vessels could be achieved. Moreover, exposure of blood to the rotating machine allowed initiation of the extrinsic mechanism of blood coagulation. On contrary, conventional resectoscope uses electric energy with high heat generation to permit tissue cutting and coagulation of resultant bleeders and this consumes time, may induce injury of adjacent tissues including the clotted blood vessels with subsequent re-bleeding. Moreover, morcellation starts at the fibroid pseudo-capsule to guard against injury of healthy uterine wall or causing perforation, while the snip-cutting policy of resectoscopes may cause perforation or tissue injury.

Another favor provided by HTRS is that the absence of electric current allowed the use of physiological saline as expanding medium instead of glycine to permit the free wash of tissue fragments without fear of glycine-induced complications that limited the used amount with subsequent decreased field visibility with its related complications. Moreover, the use of saline instead of glycine is more cost-effective thus sparing hospital resources.
In line with the obtained results and explanations, multiple previous studies\(^\text{20-22}\) attributed reduction of risk of complications, such as burns, uterine perforation, massive absorption of glycine, or air emboli during hysteroscopic morcellation using HTRS to the fact that morcellator works with mechanical energy, instead of electrical energy, and involves continuous cutting movements and aspiration.

Thereafter, Yin et al.\(^\text{23}\) out of literature review concluded that HTRS showed a major advantage in successful removal of uterine pathology and total operation time with lower complication profile due to its specific action mechanism and shorter operation time. Recently, Rodríguez-Mias et al.\(^\text{24}\) attributed the low complication rate after complete morcellation of Type-0 UF with a polyp morcellator device to the application of mechanical instead of electrical energy.

Postoperatively, number of patients required rescue analgesia was about 50% of corresponding controls. Moreover, at end of follow-up, patients' satisfaction by outcome and the outcome improved their quality of life with significantly higher SF-36 score in comparison to controls. Moreover, the extent of improvement of Hb. Conc. was significantly higher in study than in control women.

In support of the obtained results, multiple studies approved the efficacy and safety of HTRS as a technique for management of various intrauterine lesions, Liang et al.\(^\text{25}\) reported a success rate of >96% for resecting type II submucosal myomas using MyoSure device and concluded that it is a new, safer, and more efficient operation for this stage of UF and Rosenblatt et al.\(^\text{26}\) found endometrial tissue sampling using the MyoSure HTRS provided larger volumes of higher-quality endometrial tissue specimens for pathology assessment compared to specimens obtained using conventional curettage, in postmenopausal women. Also, Georgiou et al.\(^\text{27}\) reported a complete resection rate for uterine polyps, leiomyomas and retained products of conception using MyoSure device of 98.1%, 73.7% and 100%, respectively and concluded that MyoSure is an efficient, safe and feasible operative hysteroscopic procedure in an office-outpatient setting that is associated with high patient acceptability and, it is highly recommended by the vast majority of the women.

Recently, Rodríguez-Mias et al.\(^\text{24}\) reported successful complete morcellation of Type-0 submucosal leiomyoma with a polyp morcellator device in an outpatient setting with lower risk of complications from the procedure and without use of general anesthesia besides good tolerance by the patient. Also, Vidal-Mazo et al.\(^\text{28}\) documented that office hysteroscopic mechanical myomectomy with MyoSure® morcellator of submucosal fibromas was a highly effective therapy for women, at three years of follow-up and gives satisfactory long-term results with a low recurrence rate and without significant complications.

**Conclusion**

Myomectomy for stage 0-1 UF with <50% myometrial invasion in women in childbearing period who require to preserve their fertility is feasible using MyoSure HTRS. MyoSure device provided faster, safer myomectomy with more acceptable short-term outcome.

**Recommendation**

Wider-scale randomized controlled studies are mandatory to establish these results and to assume that myomectomy using MyoSure device as the gold standard procedure for such cases

**Limitation**
This study was designed as prospective-retrospective study and not as comparative prospective study because the use of conventional resectoscope in our hospital is abandoned.

References
18. SF-36.org. FAQ: is there one summary score that is a combined score for the various subscales in the SF-36® so that a single score could be used for each patient? http://www.webcitation.org/6cfeeipKf (accessed 30 October 2015).


