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ORIGINAL ARTICLE

**Dan Yu · Tin-Chiu Li · Enlan Xia · Xiaowu Huang · Jie Zheng**

# A prospective randomized controlled trial on the effectiveness of routine Foley balloon tamponade on the reduction of bleeding after hysteroscopic resection of myoma

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**Abstract** This prospective randomized controlled trial was designed to evaluate the effectiveness of routine Foley catheter tamponade on the reduction of blood loss after hysteroscopic resection of myoma. Fifty-six women scheduled for hysteroscopic resection of myoma were randomly assigned to two groups. There were no differences between the two groups in demographic variables. After the resection was completed, a Foley catheter was inserted into the uterus. In group I (drainage group), 5 ml of saline was introduced into the balloon to drain the cavity for 20 h ($n$=28). In group II (tamponade group), 10–40 ml of saline was introduced into the balloon not only as a means of drainage but also as tamponade in the cavity for 6 h, and then the volume was reduced to 5–7 ml to continue to drain the cavity for a further 14 h ($n$=28). Bleeding during the procedure was objectively measured by using the ferricyanide hemoglobin method. The amount of bleeding at 6 and 20 h after the procedure was measured via the collecting bag. Overall, the mean (±SD) total blood loss during the procedures was 48.5±38.2 ml. The mean (±SD) postprocedure blood loss in the tamponade group was 9.9±13.1 ml at 6 h and 21.1±25 ml at 20 h, which was at both times significantly ($P$<0.05) less than the blood loss in the drainage (control) group, which was 25.1±25.7 ml at 6 h and 52.0±49.9 ml at 20 h. We conclude that routine Foley catheter tamponade effectively reduces blood loss in the early postoperative period.

**Keywords** Foley catheter · Uterine tamponade · Blood loss · Hysteroscopic myomectomy

D. Yu (✉) · E. Xia · X. Huang · J. Zheng
Hysteroscopic Center, Fuxing Hospital,
Capital University of Medical Sciences,
Beijing, 100038, People's Republic of China
e-mail: yudanny2006@yahoo.com.cn
Tel.: +86-10-88062265
Fax: +86-10-63486922

T.-C. Li
The Jessop Wing, Royal Hallamshire Hospital,
Sheffield, S10 2SF, UK

## Introduction

Hysteroscopic myomectomy has been considered the gold standard for treating symptomatic submucous fibroids [1]. It is effective in reducing menstrual flow, increasing the pregnancy rate, and reducing the miscarriage rate in women with submucous fibroids. However, several complications may be encountered during and after the procedure, including uterine perforation, hemorrhage, fluid overload resulting in electrolyte imbalance, and, rarely, gas embolism. Although the overall risk of significant bleeding from all types of hysteroscopic surgery considered together has been shown to be low, at 0.25–0.61% [2, 3], the risk of significant bleeding resulting from hysteroscopic resection of myoma is deemed to be higher, 2–4% [4, 5].

Several methods can minimize blood loss during and after operative hysteroscopy, including using higher distending pressures in the uterine cavity, coagulating bleeding vessels, or injecting dilute oxytocin or vasopressin solution into the cervical stroma or vein. Goldrath et al. first used Foley balloon tamponade for gynecologic endoscopic surgery [6]. After a case of laser resection of the endometrium, heavy bleeding was controlled by using a Foley balloon tamponade in the cavity. In cases of uncontrolled bleeding following hysteroscopic procedures, hysterectomy or uterine artery embolization may rarely be necessary.

This study was designed to measure blood loss during and after hysteroscopic myomectomy and to assess the effectiveness of routine Foley catheter uterine tamponade in reducing early postoperative bleeding.

## Patients and methods

The study was performed at the Hysteroscopic Center of Fuxing Hospital in Beijing, China. From August 2000 to March 2001, 56 patients scheduled for hysteroscopic myomectomy were recruited into the study. All patients presented with a history of heavy menstrual bleeding and suboptimal response to hormone therapy for 6 months. Transvaginal scanning and diagnostic hysteroscopy were

performed before surgery to ascertain the type and number of submucous myomas. Endometrium had been biopsied to exclude malignancy. None of the patients had evidence of coagulation disorders or thyroid dysfunction.

This randomized study was approved by our hospital, and each participant provided informed consent. All patients were randomly allocated by a computer-generated randomization table to receive either drainage or tamponade by Foley catheter immediately after surgery. The volume of saline introduced into the balloon was determined before the operation. For drainage, 5–7 ml of saline was introduced into the balloon, whereas for tamponade, 10–40 ml of saline was introduced, with the volume being determined by the volume of submucous myoma measured by preoperative transvaginal ultrasound.

Before surgery, the classification (location) and size of the myomas were recorded. The classification was based on the European Society for Gynaecological Endoscopy classification of submucous myomas (Wamsteker et al.) [7]: type 0, no intramural extension; type I, intramural extension <50%; and type II, intramural extension ≥50%. The myoma size was determined from preoperative ultrasound examination. If there were multiple submucous myomas, the size referred to the summation of the diameter of each individual fibroid, and the classification (location) was based on that of the largest myoma.

Surgery was done in the early proliferative phase of the patient's menstrual cycle. Under epidural anesthesia, the cervix was dilated to 10–12 mm, and 5% glucose or 5% mannitol was used as a distension medium under constant pressure of 80–100 mmHg. Myomas were resected with the use of a 9-mm Olympus resectoscope with the cutting power setting at 80–100 W. The entire procedure was monitored by ultrasound to ensure safety. The operating time, amount of fluid deficit, volume of outflow fluid (with 1,000 IU of heparin added to each collecting bucket to prevent clotting), and weight of specimen(s) were recorded.

Immediately after the procedure, the uterine cavity was emptied and a Foley catheter inserted into it. In group I (drainage group), 5–7 ml of saline was introduced into the balloon so that the catheter could provide continuous drainage for any bleeding for 20 h, after which time the Foley catheter was removed. In group II (tamponade group), 10–40 ml of saline was introduced into the balloon for about 6 h so the balloon could tamponade the cavity. At 6 h postoperation, the Foley catheter balloon was deflated to 5–7 ml, as in the drainage group, and the catheter was left for drainage until 20 h postoperation.

Blood loss during the operation was calculated by dividing the concentration of hemoglobin in the outflow distention fluid by the concentration of hemoglobin in the patient's blood immediately before the procedure, and then multiplying this quotient by the total amount of outflow fluid collected, according to the following formula [8]:

$$bloodloss\ (ml) = \left(\frac{Hb(outflow)}{Hb(blood)}\right) \times Volume(outflow)(ml)$$

Blood losses at 6 h and 20 h postoperation were measured from the blood collected via the Foley catheter in the collecting bag.

### Statistics

The amount of blood loss in each group during and after the operation is presented as mean±SD. The differences in blood loss between groups I and II were compared by using a two-sample independent *t*-test. Factors affecting blood loss during the operation were analyzed with one-way analysis of variance. The significance level was set at $P<0.05$. All analyses were performed using SPSS software.

## Results

Fifty-six patients were recruited and randomized. There were no differences between the two groups in terms of age, weight, parity, or size of the myomas (Table 1).

The mean (±SD) blood loss during the procedure was 48.5±38.2 ml from all subjects ($n$=56), 45.6±36.9 ml in the drainage group ($n$=28), and 51.4± 39.9 ml in the tamponade group ($n$=28). There were no significant differences in operating time or intraoperative blood loss between the two groups ($P>0.05$). However, blood loss at both 6 h and 20 h postoperation in the tamponade group was significantly less than in the drainage group ($P<0.05$; Table 2).

The results of further analysis of the data based on myoma size are shown in Table 3. The blood losses in women with small myomas (≤3.5 cm) and in those with large myomas (>3.5 cm) are shown in Table 4. Blood losses during and after surgery in women with large myomas were significantly ($P<0.05$) greater than in women with small myomas. The amount of bleeding in the tamponade group at 6 and 20 h postoperation was significantly ($P<0.01$) less than in the drainage group, both in subjects with large and with small myomas.

The possible impact of other factors on intraoperative blood loss, including the classification (location) of the fibroid, surgery time, and specimen weight, is shown in Table 5. The results showed that the amount of blood loss during the procedure was significantly ($P<0.05$) increased in the resection of a deep (type II) myoma or when surgery time was more than 30 min, but there were no differences ($P>0.05$) in blood loss among subjects whose myomas weighed more or less than 10 g.

**Table 1** Characteristics of patients in the two groups (mean±SD)

| | Drainage group ($n$=28) | Tamponade group ($n$=28) | $P$ |
|---|---|---|---|
| Age (years) | 34.6±7.4 | 38.5±7.6 | >0.05 |
| Weight (kg) | 59.1±7.5 | 58.4±9.2 | >0.05 |
| Parity | 0.9±1.3 | 1.0±0.9 | >0.05 |
| Size of myoma (cm) | 3.6±1.2 | 3.8±1.3 | >0.05 |

**Table 2** Comparison of blood loss (mean±SD) during and after the procedures between the two groups

| | Drainage group ($n$=28) | Tamponade group ($n$=28) | $P$ |
|---|---|---|---|
| Operating time (min) | 34.9±16.5 | 38.4±13.2 | >0.05 |
| Blood loss during procedure (ml) | 45.6±36.9 | 51.4±39.9 | >0.05 |
| Blood loss at 6 h postoperation (ml) | 25.1±25.7 | 9.9±13.1 | <0.05 |
| Blood loss at 20 h postoperation (ml) | 52.0±49.9 | 21.1±25.0 | <0.05 |

**Table 3** Comparison of blood loss (mean±SD) during and after the procedures between different subjects with small (≤3.5 cm) or large (>3.5 cm) myomas

| | Small myomas (≤3.5 cm, $n$=23) | Large myomas (>3.5 cm, $n$=33) | $P$ |
|---|---|---|---|
| Operating time (min) | 20.1±11.6 | 32.6±15.2 | <0.05 |
| Intraoperative blood loss (ml) | 17.0±7.1 | 63.5±35.5 | <0.01 |
| Blood loss at 6 h postoperation (ml) | 7.3±5.6 | 42.3±25.6 | <0.01 |
| | ($n$=14)[a] | ($n$=14)[a] | |
| Blood loss at 20 h postoperation (ml) | 18.2±9.1 | 84.5±53.2 | <0.01 |
| | ($n$=14)[a] | ($n$=14)[a] | |

[a]Drainage group only

## Complications

One patient in the drainage group suffered from moderately severe lower abdominal pain in the immediate postoperative period, which disappeared when the balloon was removed. There were no other complications during the operation or in the early postoperative period in these 56 patients. There was also no incidence of balloon drop-out or infection in the postoperative period. The duration of follow-up ranged from 15 to 20 months, and all patients reported lighter menstrual periods and appeared satisfied with their outcomes.

# Discussion

When Phillips et al. measured blood loss and operating time during hysteroscopic myomectomy [9], they found a mean blood loss of 34.7±3.9 ml and mean operating time of 37.8±1.0 min for small myomas (≤3 cm, $n$=21) and a mean blood loss of 107.1±20.3 ml and mean operating time of 54.2±4.0 min for large myomas (>3 cm, $n$=5). The mean intraoperative blood loss and operating time in our study was 17.0±7.1 ml and 20.1±11.6 min, respectively, for small myomas (≤3.5 cm, $n$=23) and 63.5±35.5 ml and 32.6±15.2 min, respectively, for large myomas (>3.5 cm, $n$=33).

Thus, the blood loss in our study was less than that reported in Phillips et al.'s study. There may be several possible explanations for this. First, we routinely coagulated the blood vessels on the surface of the myoma prior to resection, with a view to reducing blood loss. Second, reduced operating time is recognized to be associated with reduced blood loss, and we reduced the operating time by combining the electroresection technique with a traditional submucous myomectomy technique. After the submucous myoma was cut into an irregular and long, narrow shape with an electrocutting loop, the fibroid would be grabbed and twisted out by a pair of forceps with ultrasound guidance. Third, after the fibroid was removed, we routinely coagulated any bleeding vessel on its bed in the cavity to ensure a good hemostasis. In our randomized controlled trial, we also analyzed possible factors affecting blood loss and concluded that blood loss during the procedure was significantly increased during resection of a large and a deep myoma or when the surgery took more than 30 min to complete.

Heavy bleeding from the beds of resected submucous myomas after operation is sometimes difficult to control. Goldrath et al. [6] first used a Foley catheter inserted into the uterine cavity as a means of tamponade to reduce excessive bleeding after endoscopic surgery. Since then, Foley catheter tamponade has been used by many hysteroscopic surgeons when there is excessive bleeding after operative hysteroscopy. In our study, we demonstrated that the routine use of Foley catheter tamponade significantly reduced bleeding from the uterus after resection of myoma.

Foley catheter tamponade is simple, inexpensive, and readily available. We recommend cutting the catheter tip beyond the attachment of the balloon to provide a more effective tamponade. To achieve effective tamponade, the

**Table 4** Comparison of blood loss (mean±SD) between the two groups during and after surgery, according to myoma size

| | | Size of myoma (cm) | Intraoperation (ml) | 6 h postoperation (ml) | 20 h postoperation (ml) |
|---|---|---|---|---|---|
| Small myomas (≤3.5 cm) | Drainage group | 2.6±0.5 ($n$=14) | 17.9±5.8 | 7.9±5.5 | 19.5±8.2 |
| | Tamponade group | 2.4±0.5 ($n$=9) | 16.0±8.7 | 2.0±1.9 | 5.1±2.9 |
| | $P$ | >0.05 | >0.05 | <0.01 | <0.01 |
| Large myomas (>3.5 cm) | Drainage group | 4.6±0.7 ($n$=14) | 63.6±37.2 | 42.3±26.6 | 84.5±53.2 |
| | Tamponade group | 4.4±1.2 ($n$=19) | 63.5±35.5 | 7.4±5.3 | 20.9±14.4 |
| | $P$ | >0.05 | >0.05 | <0.01 | 0.001 |

**Table 5** Impact of fibroid classification (location), surgery time, and specimen weight on the amount of intraoperative blood loss (mean±SD; *n*=56)

| | | Blood loss (ml) |
|---|---|---|
| Classification of myoma[a] | Type 0 | 18.8±15.7 (*n*=21) |
| | Type I | 40.9±20.6 (*n*=25) |
| | Type II | 100.2±30.5 (*n*=10) |
| Surgery time[a] | <20 min | 22.5±22.6 (*n*=20) |
| | 20–30 min | 42.6±28.8 (*n*=21) |
| | >30 min | 81.0±36.0 (*n*=15) |
| Specimen weight[b] | ≤10 g | 32.5±27.3 (*n*=18) |
| | >10 g | 60.4±37.1 (*n*=38) |

[a] $P<0.05$, ANOVA
[b] $P>0.05$ (NS)

balloon catheter needs to be filled with an appropriate volume to produce adequate pressure on the surface of the uterine cavity. We believe the volume required is dependent on the volume of the cavity and the size of the myoma prior to resection. Consequently, in our study the volume used in each case (10–40 ml) was approximately the same as the size of the myoma as determined by ultrasound prior to the procedure. If bleeding cannot be effectively controlled by the volume calculated in this way, more saline may be added into the balloon until the bleeding stops. On the other hand, volume that is too large and pressure that is too high can potentially lead to pressure necrosis, especially if the tamponade is applied for too long. We therefore recommend that the pressure be reduced after 6 h of tamponade and that only a small amount of saline, such as 5–7 ml, be left in the balloon to drain the cavity.

## Conclusion

Blood loss during and shortly after hysteroscopic resection of myoma was influenced by the size and the type of submucous myoma. Routine Foley catheter tamponade with 10–40 ml saline in the balloon effectively reduced blood loss in the immediate postoperative period.

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