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CLINICAL ARTICLE

Bilateral uterine artery ligation via minilaparotomy for heavy menstrual bleeding

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Abstract

Objective: To assess the safety and short-term efficacy of bilateral uterine artery ligation (UAL) via minilaparotomy for the management of heavy menstrual bleeding (HMB). **Methods:** A prospective study of 30 women with HMB who underwent UAL. The primary outcome was cumulative treatment failure 12 months after the procedure. Treatment failure was defined as the need for hysterectomy during the follow-up period. **Results:** At 12 months, 6 women had undergone hysterectomy for bleeding, for a cumulative failure rate of 20% (95% CI, 9%–38%). The number of bleeding days was significantly reduced by 11.9 ± 1.5 days ($P < 0.001$) and hemoglobin level significantly increased by 1.3 ± 0.15 g/dL ($P < 0.001$). Of the 30 women, 24 (80%) were satisfied with the results. No major complications were reported during the procedure or median follow-up period of 13.2 months. **Conclusion:** Bilateral UAL is a safe and effective minimally invasive procedure that can provide an alternative treatment for HMB.

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1. Introduction

Heavy menstrual bleeding (HMB) is a common gynecologic problem that affects 1 in 3 women worldwide [1]. The management of HMB is tailored to the severity of bleeding, its impact on the woman's health and health-related quality of life, as well as her future fertility wishes [2]. Another important determinant in the selection of HMB treatment is the presence of other

pathology such as fibroids, which affect the uterine cavity, or pathology such as adenomyosis, which may affect the response to treatment. Current available methods include medical treatment, surgical treatment, and minimally invasive alternatives to surgery [3]. The inconsistent efficacy, adverse effects, and low patient compliance with medical treatments hamper their long-term use [4]. Hysterectomy remains the definitive treatment for HMB, particularly in women who do not wish to conceive. However, hysterectomy has potential short- and long-term negative effects, both on psychological and psychosexual functions. This requires a comprehensive re-evaluation of its use in benign indications [5,6]. Hysterectomy can be followed by

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depression and immediate postoperative anxiety that can significantly affect a woman's quality of life [7]. In Egyptian women, conserving the uterus may be important for gender identity, sexuality, marital relations, and self-esteem [8]. Preoperative anxiety in these women has been related to an increased chance of postoperative anxiety and depression [8].

In women who wish to preserve their fertility the surgical options are limited [9]. Over the past 2 decades, uterine artery embolization (UAE) has become an established method to treat life-threatening postpartum hemorrhage, bleeding after gynecologic surgery, pelvic arteriovenous malformation, and cervical pregnancy [10]. Reported adverse effects included impairment of ovarian function and premature ovarian failure. These reports limit its use as a treatment for fibroids in women who wish to preserve their fertility [11].

Uterine artery ligation (UAL) is an effective, minimally invasive procedure that directly reduces uterine blood supply and menstrual blood flow. Indirectly it acts through reducing prostaglandin levels in the endometrium [9]. Despite its successful use to control postpartum hemorrhage, its efficacy in the treatment of HMB is, to date, still unclear. The procedure can be performed using minilaparotomy with basic laparotomy instruments. It can be performed with local anesthesia or light sedation [12,13]. These factors lower the cost, reduce anesthesia-related complications, and make UAL an appealing procedure in low-income settings. The objective of the present study was to investigate the safety and short-term efficacy of bilateral UAL using minilaparotomy for the management of HMB.

2. Materials and methods

We conducted a prospective study to evaluate the safety and efficacy of bilateral UAL for the treatment of HMB. The study was approved by the local Internal Review Board. All participants in the study gave their consent and were counseled regarding the risks and the experimental nature of the procedure. Inclusion criteria were women who had subjective heavy menstrual bleeding for more than 6 months with or without chronic symmetrically enlarged uterus who had received medical treatment for at least 6 months in the form of either a combined oral contraceptive (Microcept; Sedico, Egypt) for 21 days starting on the 5th menstrual day and then stopped for 7 days and repeated for at least 3 cycles, or 5 mg norethisterone acetate

(Steronate nor; Sedico, Egypt) 3 times a day from the 5th day to the 25th day then stopped and repeated for at least 3 cycles. All patients had a poor response to treatment and there was no evidence of atypia at dilatation and curettage. Patients were excluded if they declined to participate, had a local organic lesion such as fibroids or adenomyosis, were younger than 35 years, or wanted to remain fertile. Organic lesions were identified via clinical and ultrasound examination, and hysteroscopic procedures where necessary.

The primary outcome measure was cumulative treatment failure within 12 months of UAL. Treatment failure was defined as the need for another operation during the 12-month follow-up period. Other outcomes measured were a change in menstruation or hemoglobin concentration (g/dL). Patients were asked to grade their satisfaction with the treatment on a scale from very satisfied, somewhat satisfied, neither satisfied nor dissatisfied, somewhat dissatisfied, or very dissatisfied. Operative date and the occurrence of any major complication during or after the procedure were also recorded. Major complications included mortality, intestinal injury, bladder injuries, and any related postprocedural complication that required readmission.

All patients received 1 g amoxicillin intravenously 20 minutes prior to the procedure. The patients were placed in the dorsal lithotomy position with 55 degrees abduction of the thigh and 15 degrees flexion of the hip. The procedure was carried out under general anesthesia. Skin, subcutaneous tissue, and the anterior rectus sheath were opened via a 5-cm minilaparotomy incision, coinciding with the transverse suprapubic incision line. The 2 recti muscles were separated and the posterior rectus sheath opened. Gentle manipulation of the uterus was performed using a cervical elevator inserted vaginally. The loose peritoneum over the vesicouterine pouch was incised horizontally. Gentle blunt dissection of the peritoneum over the isthmus and cervix was done downward and extended laterally. Special care was used during mobilization of the peritoneum at the edges of the uterine angles to expose the ascending branch of the uterine artery and to avoid including the ureters in the sutures. The uterus was held and retracted upward and laterally by an assistant. The uterine artery pulsations were palpated digitally at the level of the internal os. A rounded needle holding a chromic catgut suture size 2-0 was passed from posterior to anterior, through the tissues of the cervix, and ligated as a simple stitch. This was followed by another stitch below it at a distance of not more than 1 cm (Fig. 1). The procedure was repeated on the

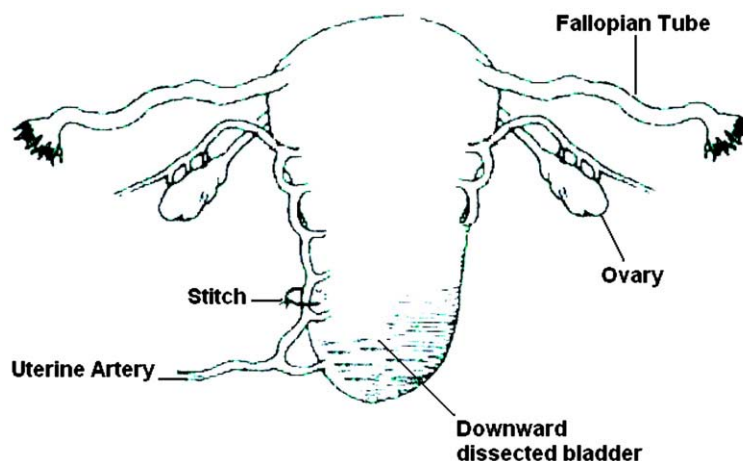


Figure 1 Uterine artery ligation (UAL) procedure: placing the stitch at level of the internal os.

Table 1 Clinical data for the study participants (n=30) ^a

Variable	Data	95% Confidence Interval
Age, y	41.5±3.6 40 (37–48)	40.2–42.8
Parity	5.0±1.7 5.0 (2–9)	4.3–5.6
Previous medical treatment		
Estrogen/progestins, %	17 (57)	39–73
Progestins, %	13 (43)	27–61
Pattern of bleeding		
Regular, %	17 (57)	39–73
Irregular, %	13 (43)	27–61
Amount of bleeding		
Excessive, %	24 (80)	62.7–90.4
Spotting, %	6 (20)	9.5–37.3
Duration of bleeding, days	17±7.1 15 (8–30)	14.3–19.7
Hemoglobin, g/dL	8.3±0.6 8.3 (7–9.3)	8.1–8.5
Pathology		
No abnormality, %	24 (80)	62.7–90.4
Simple hyperplasia, %	6 (20)	9.5–37.3
Follow-up, mo.	12.5±4.0 13.2 (3.1–17.3)	11.0–14.0

^a Values are given as mean±SD or median (range) for continuous variables, and number (percentage) for categorical variables.

other side. Neither visceral nor parietal peritonization was performed. The 2 recti muscles were approximated with interrupted sutures. The anterior rectus sheath was closed with a set of continuous sutures. Skin and subcutaneous tissues were closed.

Patients received 1 dose of 10 mg pethidine intramuscularly for postoperative analgesia, followed by 400 mg ibuprofen every 12 hours for 24 hours. Patients were allowed to drink fluid after 6 hours, and to eat after intestinal motility was verified by passing flatus or auscultation of intestinal sounds. Patients were discharged after 24 hours and stitches were removed on the next visit after 7–8 days. Follow-up visits every 3 months were arranged. Patients who could not attend follow-up visits were contacted by telephone to assess the different outcomes.

Data are presented as mean, standard deviation (SD), and 95% confidence intervals (CI) along with median and range for continuous variables, and as percentage and 95% CIs for categorical variables. The primary outcome of the study was the rate of hysterectomy at 12 months. Time to event was the primary endpoint for that outcome. The Kaplan Meier method was used to calculate the cumulative failure rate and the corresponding 95% CI. To explore the possible predictors of the outcome after the procedure, Cox proportional hazard models were used to compare different subgroups of patients based on age, amount of bleeding, and pattern of bleeding. Changes in the duration of bleeding and hemoglobin were compared before and after the procedure using Wilcoxon signed rank test. Significance level was set at $P<0.05$ for all analyses, which were performed using JMP software version 7.0 (SAS Institute Inc, Cary, NC, USA).

3. Results

Between August 2006 and May 2007, 30 women with heavy menstrual bleeding were included in the study. The mean age of the women was 41.5±3.6 years with a median parity of 5.0 (range, 2–9) (Table 1). The procedure time was 32.3±4.5 minutes (95% CI, 30.5–34.0 minutes; range 26–50 minutes). Hospital stay in days was 1.2±0.4 (95% CI 1.1–1.4 days; range, 1.0–2.0 days). Only 8 patients (26.7%) had to stay overnight after the procedure (95% CI, 14.2%–44.4%).

The median follow-up was 13.2 months (range, 3.1–17.3 months). At 12 months, 6 women had undergone hysterectomy for bleeding. The total cumulative failure at 12 months was 20% (95% CI, 9%–38%). Women with irregular bleeding (menometrorrhagia and spotting) were more likely to undergo hysterectomy after the procedure compared with those who had regular bleeding, with a hazard ratio of 7.5 (95% CI, 2.3–15.6; $P=0.027$); while women with spotting were more likely to undergo hysterectomy after the procedure, with a hazard ratio of 9.8 (95% CI, 4.3–12.4; $P=0.007$) (Fig. 2). The study included 7 patients with symmetrically enlarged uteri where the uterine cavity ranged between 8.5 cm and 10.0 cm. None of these 7 patients needed further treatment during the follow-up period.

Significant improvement in the duration of bleeding was reported, with a reduction of 11.9±1.5 days (95% CI, 8.9–14.9; $P<0.001$). Bleeding days decreased from 17±7.1 days (range, 8–30 days) before the procedure to 5.1±3.3 days (range, 2.0–15.0) after the procedure ($P<0.001$).

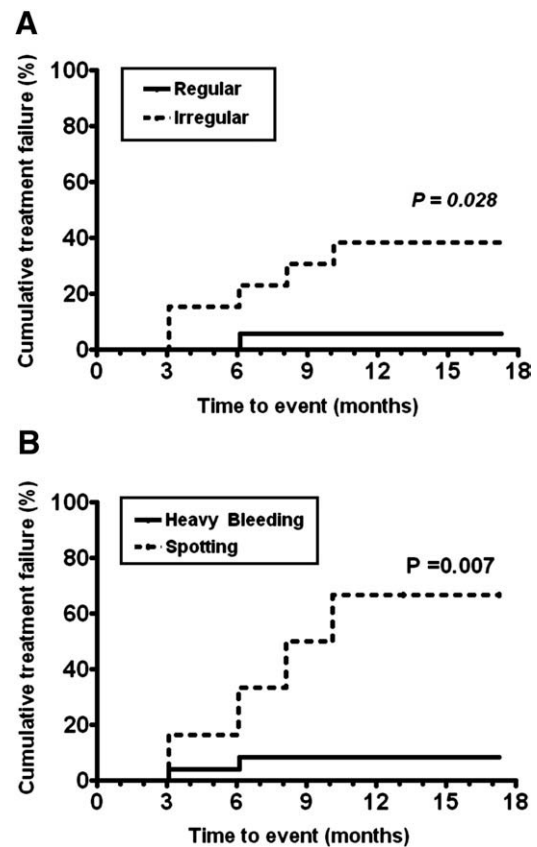


Figure 2 Failure rate of UAL in various subgroups: (A) women with regular compared with irregular bleeding; (B) women with excessive bleeding compared with spotting.

In addition, significant increases in hemoglobin levels of 1.3 ± 0.15 g/dL (95% CI, 1.0–1.6; $P < 0.001$) were observed after the procedure. Hemoglobin levels increased from 8.3 ± 0.6 g/dL (range, 7–9.3 g/dL) before the procedure to 9.6 ± 0.8 g/dL (range, 7.4–10.8 g/dL) after the procedure ($P < 0.001$).

Of the 30 patients, 24 (80%) expressed their satisfaction with the results of the procedure. No major complications were reported during the procedure or during follow-up.

4. Discussion

The present study assessed the safety and efficacy of a bilateral uterine artery ligation procedure carried out via minilaparotomy for management of heavy uterine bleeding. We included 30 women older than 35 years who had had unsuccessful medical treatment for at least 6 months. UAL was found to be safe and with a success rate of 80%. In addition, UAL significantly reduced the days of bleeding from 17 ± 7.1 days preoperatively to 5.1 ± 3.3 days postoperatively ($P < 0.001$). Hemoglobin level also improved from 8.3 ± 0.6 g/dL to 9.6 ± 0.8 g/dL within 3 months postoperatively.

UAL via minilaparotomy proved to have a high safety profile, high feasibility, and low cost in our setting. These represent advantages over hysterectomy and other minimally invasive procedures, including endometrial ablation and uterine artery embolization techniques for the management of HMB. The procedure has relatively lower cost, requires average surgical skills, and is suitable for settings in low-income countries. UAL has the potential to treat women with chronic symmetrically enlarged uteri larger than 10 cm in size, for which endometrial ablation would be less effective [14,15]. We included 7 patients with symmetrically enlarged uteri, none of whom required further treatment.

Previous studies have suggested the benefits of UAL to treat HMB in women with larger uteri and those with adenomyosis. Aziz [13] suggested that the increase in cavity surface of a hypertrophic uterus and diffuse intramural fibrosis may be treated by uterine vessel ligation. That study included women of high parity with symmetrical enlargement of the uterus, manifested by menorrhagia [13]. The suggested mechanism was a decrease in blood perfusion per unit volume and decrease in menstrual blood loss. Impaired uterine perfusion via UAL might induce a decline in the level of prostaglandins during menstruation, decrease blood loss, and relieve pain [16,17]. Chin et al. [9] reported good control of menstrual bleeding and adequate relief of dysmenorrhea following laparoscopic UAL for treatment of symptomatic adenomyosis [9].

The uterus has a dual extrinsic blood supply. Uterine arteries supply approximately 42% of blood flow, while ovarian and vaginal arteries supply approximately 58% [18]. Stepwise uterine devascularization including uterine, ovarian arteries, and round ligament ligation, allows good control of postpartum hemorrhage [19,20]. Vascular occlusion is temporary because recanalization and subsequent normal uterine circulation are expected [19]. We propose the same etiology for failures in the current cohort. Ligation of the anastomotic branches of uterine and ovarian arteries in all women undergoing UAL is strongly indicated in women older than 45 years [5,12]. Retrospective series and case reports have shown that arterial ligation harms neither uterine nor ovarian function [19,21]. In addition, Bradley et al. [10] and Hurst et al. [17] have shown that UAL results in a 40% to

60% reduction in uterine volume within 2–4 months post operatively. Less diffuse uterine necrosis and sepsis are expected to occur after UAL compared with women treated with uterine artery embolization [10,17,22,23].

Despite the relatively small sample size in the present study it appears that women with regular bleeding benefit the most from UAL. Women with menometrorrhagia and spotting were more likely to undergo hysterectomy after the procedure. The advantages of the procedure are the reductions in postoperative pain, use of analgesia, hospital stay, and recovery time, along with the potential psychological benefits from the preservation of the uterus [24,25].

The limitations of the present study include the short follow-up period, the small sample size, and inclusion of 2 different types of medical treatments to control bleeding before UAL. Other limitations include the lack of objective evaluation of menstrual blood loss and health-related quality of life assessment following the procedure. We believe that the present study provides initial evidence supporting the efficacy and safety of UAL as a therapy for heavy menstrual bleeding. Further studies are needed to compare UAL via minilaparotomy with transvaginal UAL, laparoscopic UAL, Doppler-assisted transvaginal uterine artery clamping, and hysterectomy (laparoscopy, laparotomy, and transvaginal approaches).

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