

Original Research

Hysteroscopic Suture Fixation of the Levonorgestrel-Releasing Intrauterine System Reduces Re-Expulsion and Improves Outcomes in Women With a History of Prior Expulsion

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Abstract

Background: The levonorgestrel-releasing intrauterine system (LNG-IUS) is an effective contraceptive and non-surgical treatment for various gynecological conditions. However, its high expulsion rate remains a concern, particularly in women with a history of prior expulsion. This study aimed to evaluate the effectiveness of non-absorbable suture fixation under hysteroscopic guidance to reduce expulsion rates. **Methods:** A total of 73 women with a history of LNG-IUS expulsion were enrolled between August 2022 and August 2023 at the Women's Hospital, Zhejiang University School of Medicine. All participants underwent hysteroscopic suture fixation of the LNG-IUS. Postoperative assessments were conducted on days 1, 3, and 7 using electronic questionnaires, along with outpatient follow-up and ultrasonography at 1, 3, and 6 months. **Results:** All 73 procedures were successfully performed as outpatient (day) surgeries, with a mean duration 37.81 ± 14.90 min, without encountering any complications. Follow-up was conducted for all 73 patients at 6 months, with 70 patients undergoing postoperative imaging, primarily using ultrasonography. Low rates of expulsion (4.29%) and downward-shift (7.14%) were observed. Decreased menstrual bleeding or amenorrhea was reported by 68 patients (93.15%). Among the 47 patients with preoperative dysmenorrhea, complete symptom relief was achieved in 39 cases (82.97%). **Conclusions:** In patients with a history of LNG-IUS expulsion, hysteroscopic suture fixation of the LNG-IUS not only lowers the rate of re-expulsion but also alleviates associated symptoms.

Keywords: progesterone-releasing intrauterine devices; hysteroscopic surgery; intrauterine device expulsion

1. Introduction

The levonorgestrel-releasing intrauterine system (LNG-IUS) is a long-acting, reversible contraceptive (LARC) that is inserted into the uterine cavity. It has been used in clinical practice for over 30 years and functions by locally and gradually releasing levonorgestrel (LNG) within the uterus, thereby exerting sustained progestogenic effects for 5 to 8 years. These effects include thickening of the cervical mucus and inhibition of endometrial maturation [1]. In addition to its high contraceptive efficacy, the LNG-IUS is also a first-line, non-surgical treatment for several benign gynecological conditions due to its prolonged progestogenic action on the endometrium. These conditions include adenomyosis [2], endometriosis [3], and endometrial hyperplasia (EH) [4]. It is also effective in treating menorrhagia, and prevents the recurrence of endometrial polyps (EPs) [5,6].

However, the high rate of LNG-IUS expulsion is a concern. Women presenting with dysmenorrhea, menorrhagia, or adenomyosis experience a higher rate of LNG-IUS expulsion, ranging from 8.10% to 31.10%, compared to those using the LNG-IUS for contraception alone [7]. Patients with a history of LNG-IUS expulsion have a

markedly higher risk of re-expulsion, ranging from 27.60% to 57.00% [8,9]. Consequently, a substantial majority (58.60%–84.50%) of these women discontinue its use after expulsion [7,8,10].

Currently, there is no effective strategy to significantly reduce the recurrence of LNG-IUS expulsion in women with high-risk factors. Although pre-treatment with gonadotropin-releasing hormone analogs (GnRHa) can shrink the uterine volume, this does not substantially reduce the expulsion rate, which remains at 13.30%–14.00% [7,11]. Some combination therapies have shown additional benefits for adenomyosis, including the relief of symptoms such as dysmenorrhea and menorrhagia, while also reducing the expulsion risk. For instance, LNG-IUS placement after GnRHa and high-intensity focused ultrasound (HIFU) reduced the 2-year expulsion rate to 6.38% [12], concurrent endometrial ablation reduced it to 1.90% [13], and laparoscopic adenomyomectomy combined with LNG-IUS showed an expulsion rate of 3.80% [14]. However, these approaches may not be suitable for women requiring LNG-IUS monotherapy.

Zhu *et al.* [15] first introduced hysteroscopic suturing of the LNG-IUS in a patient with adenomyosis in 2021,



effectively preventing expulsion. Subsequent small-scale studies reported lower expulsion rates, ranging from 0.00% to 8.33% [15–19]. However, not all patients in these studies had a history of LNG-IUS expulsion.

The present study enrolled women with at least one prior LNG-IUS expulsion who wished to continue its treatment. The LNG-IUS was sutured to the uterine cavity under hysteroscopic guidance and using non-absorbable sutures to preserve therapeutic efficacy and reduce the risk of re-expulsion. The aim of this prospective observational study was to evaluate the feasibility, expulsion rate, and adverse effects of this fixation procedure.

2. Materials and Methods

2.1 Participants

This prospective, single-arm study enrolled patients who underwent hysteroscopic LNG-IUS suture fixation at the Women's Hospital, Zhejiang University School of Medicine, from August 2022 to August 2023. The study protocol was approved by the ethics committee of the hospital (IRB-20220332-T), and all participants provided written informed consent. Surgical procedures were performed by experienced senior physicians in the ambulatory surgery department.

The inclusion criteria were: (a) a history of LNG-IUS expulsion; and (b) a desire to have the LNG-IUS inserted for the treatment of conditions such as menorrhagia, dysmenorrhea, adenomyosis, EH, and recurrent EPs.

The exclusion criteria were: (a) pregnant or uncertain pregnancy status; (b) acute infection of the female reproductive tract; (c) recent uterine injury or perforation; (d) cervical or uterine malignancies; (e) progesterone-dependent tumors; (f) acute liver disease or liver tumors; (g) allergy to LNG-IUS components; and (h) inability to undergo postoperative follow-up.

All participants underwent preoperative laboratory tests, including complete blood count, coagulation profile, screening of sexually transmitted diseases (STDs), liver and kidney function tests, and electrolyte analysis. They also underwent cervical cancer screening, electrocardiography, breast ultrasound, and transvaginal ultrasound to exclude contraindications for hysteroscopic surgery and LNG-IUS placement. In addition, all participants underwent preoperative assessment of female reproductive hormones to exclude perimenopausal women. The uterine volume was calculated using the formula: $0.52 \times \text{transverse diameter} \times \text{longitudinal diameter} \times \text{anteroposterior diameter}$ (mL) [9].

2.2 Materials

The procedure involved the use of a LNG-IUS (Mirena®, 52 mg; Bayer Inc., Turku, Finland); a 3-0, 17 mm non-absorbable polyester needle suture (ETHIBOND EXCEL® MX552; Ethicon Inc., Raritan, NJ, USA); a 6.25 mm, 0° operative hysteroscope with a 3 mm instrumental working channel (MyoSure®, REF 40-250; Ho-

logic Inc., Marlborough, MA, USA); a 3 mm endoscopic needle holder (KANGJI®; Kangji Inc., Hangzhou, Zhejiang, China); a 3 mm knot pusher without suture opening (KANGJI®; Kangji Inc., Hangzhou, Zhejiang, China); and 3 mm endoscopic scissors (KANGJI®; Kangji Inc., Hangzhou, Zhejiang, China).

2.3 Hysteroscopic Suture Fixation With the LNG-IUS Procedure

Based on existing reports, hysteroscopic suturing can be performed through the operative channel of the hysteroscope, or via a paracervical route adjacent to the hysteroscope [15,16]. Drawing from the technique reported by Zhu *et al.* [15], we modified the procedure by introducing a hysteroscopic view-assisted knot-push technique, leading to improved surgical efficiency.

Hysteroscopy was initially conducted to identify intrauterine masses such as EPs or submucosal fibroids. Any necessary surgical interventions were subsequently performed. In cases with insufficient uterine septum and adenomyosis with distortion of the uterine cavities, a portion of the fundal myometrium was incised during hysteroscopy to ensure an adequately sized uterine cavity. Subsequently, hysteroscopic suture fixation of the LNG-IUS was performed after satisfactory observation of the uterine cavity. The LNG-IUS was securely positioned at the base of the uterine cavity by using a knot pusher under hysteroscopic guidance, with normal wing expansion and the absence of active bleeding. After successfully placing 6 knots under hysteroscopic guidance, the LNG-IUS string and suture were severed, and the surgical instruments withdrawn.

Oral antibiotics were administered within 48 h postoperatively, and all patients who underwent hysteroscopy were discharged on the same day.

2.4 Follow-up

Electronic questionnaires were sent to patients on postoperative days 1, 3, and 7, and an intelligent information platform was used to facilitate assessment of their postoperative condition. Outpatient follow-up and ultrasound assessments were also conducted at 1, 3, and 6 months after the procedure. These follow-up sessions were designed to evaluate parameters including menstrual flow, severity of dysmenorrhea, abnormal bleeding, non-menstrual lower abdominal pain, and other potential adverse effects. Additionally, the results of postoperative ultrasound or other imaging examinations were documented during follow-up assessments.

Upon completion of the 5-year therapeutic duration, the LNG-IUS requires hysteroscopic suture division for removal, or replacement with renewed fixation. If the patient requests premature removal of the suture-fixed LNG-IUS during follow-up, the same hysteroscopic suture transection procedure must be performed prior to extraction.

2.5 Statistical Analysis

Statistical analysis was performed using SPSS 20 software (IBM Corporation, Armonk, NY, USA). The results are presented as the mean \pm standard error of the mean, and n (%). Statistical significance was considered to be $p < 0.050$. For all continuous variables in the baseline characteristics, normality assumptions were systematically verified using the Shapiro-Wilk test prior to comparative analyses. An independent samples *t*-test was used to compare the operation time and hospital stay duration between patients with or without additional hysteroscopic procedures.

2.6 Sample Size Calculation

The required sample size was calculated using the formula for a single-arm study with a binary outcome based on a target value approach:

$$n = \frac{\left(Z_{1-\alpha/2} \sqrt{p_0(1-p_0)} + Z_{1-\beta} \sqrt{p(1-p)} \right)^2}{(p - p_0)^2}$$

where n is the required sample size, p_0 is the target (null) proportion, p is the anticipated response rate under the alternative hypothesis, $Z_{1-\alpha/2}$ is the critical value for a two-sided significance level (e.g., 1.96 for $\alpha = 0.05$), and $Z_{1-\beta}$ is the critical value corresponding to the desired power (e.g., 0.84 for 80.00% power). Patients with a history of LNG-IUS expulsion were previously reported to have a re-expulsion rate ranging from 27.60% to 57.00% [8,9]. In contrast, clinical studies on hysteroscopic suture fixation of the LNG-IUS have reported a maximum expulsion rate of 8.33%, and a downward displacement rate of 16.67% [15–19]. Based on the two-proportion Z-test with a significance level of $\alpha = 0.05$ (two-tailed) and 80.00% power, the minimum required sample size was calculated as 62 participants, using the following parameters: p_0 (baseline LNG-IUS re-expulsion rate in patients with LNG-IUS expulsion history): 0.42 [(27.60% + 57.00%)/2]; and p (post-surgical malposition rate [expulsion + displacement] with suture fixation): 0.25 (8.33% + 16.67%), the minimum required sample size was calculated to be 62 participants. After adjusting for an anticipated 20.00% dropout rate, the final required sample size was increased to 74 participants.

3. Results

3.1 Patient Baseline Characteristics

A total of 74 women with at least one prior LNG-IUS expulsion (range: 1–5) were enrolled in the study. One patient was excluded due to a confirmed diagnosis of uterine carcinoma, resulting in a final cohort of 73 patients who underwent successful LNG-IUS suture fixation. As shown in Table 1, the age of participants ranged from 25 to 52 years, with an average of 41.34 years. The average body mass index (BMI) for 65 patients was calculated to be 24.43 kg/m², with 38.46% (25/65) classified as overweight (BMI >25

kg/m²). Furthermore, 70 patients were multiparous, with an average of 1.45 children. The preoperative uterine volume was available for 67 patients and showed an average of 168.28 mL, with 52.24% (35/67) having a volume >150 mL. The average depth of the uterine cavity recorded during surgery was 8.95 cm. Anemia was present in 21 of the 73 patients (28.77%), with an average hemoglobin level of 97.90 g/L.

The decision to perform suture fixation of the LNG-IUS in 73 patients was based primarily on specific clinical indications: 67.12% (49/73) had heavy menstrual bleeding, 64.38% (47/73) experienced dysmenorrhea, 73.97% (54/73) were diagnosed with adenomyosis, 9.59% (7/73) had concomitant EH, and 4.11% (3/73) had a history of recurrent EPs.

3.2 Procedure Feasibility and Complications

All surgeries were successfully completed, without complications such as fluid overload, significant bleeding, or uterine perforation. The mean duration of the entire procedure, including corresponding hysteroscopic steps, was 37.81 \pm 14.90 min. The mean duration of the total hospital stay was 5.63 \pm 1.31 h. Of the 73 patients, 47.95% (35/73) underwent hysteroscopic LNG-IUS suture fixation only. The remaining patients received additional hysteroscopic procedures, including polyp removal in 22 cases, submucosal fibroid excision in 2 cases, uterine adhesiolysis in 3 cases, septum resection in 4 cases, hysteroscopic incision of a unicornuate uterus in 2 cases, and removal of an earlier partial expulsion of the LNG-IUS in 8 cases (Fig. 1A). In the patient group that underwent additional hysteroscopic procedures, the mean operation time and hospital stay were 38.68 \pm 18.04 min and 5.82 \pm 1.43 h, respectively, compared to 36.86 \pm 12.15 min and 5.43 \pm 1.15 h in the group without additional procedures ($p = 0.616$ and $p = 0.206$, respectively) (Fig. 1B).

The follow-up electronic questionnaire conducted on postoperative days 1, 3, and 7 revealed that none of the patients experienced lower abdominal pain, significant vaginal bleeding, fever, nausea, vomiting, or the need for readmission.

3.3 Expulsion and Downward Shift

As of February 2024, all 73 patients (100.00%) had undergone a 6-month follow-up assessment, either through telephone consultation or an in-person visit to the clinic.

Of these, 70 (95.89%) underwent postoperative imaging examinations, primarily ultrasound. Three cases (4.29%) exhibited LNG-IUS expulsion or partial expulsion, and 5 cases (7.14%) exhibited a downward shift of the LNG-IUS, with an average distance of 1.46 cm on ultrasound. The LNG-IUS remained *in situ* in 62 patients (88.57%).

Hysteroscopic re-suturing with “two-point” fixation was performed in the three patients who experienced ex-

Table 1. Baseline characteristics of patients with a history of LNG-IUS expulsion (n = 73).

Variable	Value
Age (years) [mean ± SD]	41.34 ± 5.46
BMI (kg/m ²) [mean ± SD]	24.43 ± 3.02
Parity [n (%)]	
Parous	70/73 (95.89)
Non-parous	3/73 (4.11)
Number of prior LNG-IUS expulsions [median]	1.00
1 [n (%)]	55/73 (75.34)
2 [n (%)]	15/73 (20.55)
3 [n (%)]	2/73 (2.74)
4 [n (%)]	0/73 (0.00)
5 [n (%)]	1/73 (1.37)
Ultrasonic uterine size (cm ³) [mean ± SD]	168.28 ± 91.57
Cases with ultrasonic uterine size >150 mL	35/67 (52.24)
Depth of uterine cavity exploration (cm) [mean ± SD]	8.95 ± 1.01
Depth of uterine cavity exploration ≥8.50 cm	47/70 (67.14)
Anemia [n (%)]	21/73 (28.77)
HGB level with anemia (g/L) [mean ± SD]	97.90 ± 7.58
HGB level without anemia (g/L) [mean ± SD]	126.30 ± 12.59

LNG-IUS, levonorgestrel-releasing intrauterine system; HGB, hemoglobin; BMI, body mass index.

pulsion (Fig. 2A). During re-suturing, the LNG-IUS was expelled into the cervical canal, with intact thread loops and knots still in place (Fig. 2B). Transvaginal ultrasound examinations conducted at 4, 6, and 8 months post-operatively in these cases, respectively, indicated the LNG-IUS was still *in situ*.

3.4 Efficacy and Adverse Effects

At the 6-month follow-up, 11/73 (15.07%) patients reported amenorrhea, and 57/73 (78.08%) reported a significant reduction in menstrual flow. Of the 47 patients who had preoperative dysmenorrhea symptoms, 82.97% (39/47) experienced complete relief, and 14.89% (7/47) had partial relief. Of the 7 patients diagnosed with EH, four underwent repeat hysteroscopic evaluation after surgery, with histopathology confirming complete reversal (CR). Additionally, none of the three patients with EPs experienced a recurrence during the follow-up period (Fig. 3A).

One patient (1.37%) was diagnosed with adenomyosis in a unicornuate uterus with a rudimentary horn (type IIC), and continued to experience unrelieved dysmenorrhea for 5 months postoperatively. Despite the LNG-IUS remaining *in situ*, the patient ultimately opted to undergo uterine resection. Two patients (2.74%) reported an increase in menstrual flow during their most recent follow-up, despite the LNG-IUS being in place. One of these patients required hospitalization and conservative treatment, while the other received additional treatment with dienogest.

The common adverse effects were similar to those observed with normal LNG-IUS placement. Irregular uterine bleeding (spotting) is defined as spotting or bleeding last-

ing more than 8 days per menstrual cycle, or more than 24 days within a 90-day period [20]. Irregular uterine bleeding in the form of spotting was reported by 52 of the 73 patients (71.23%). Additionally, 6 patients (8.22%) reported increased vaginal discharge, 5 patients (6.85%) experienced non-menstrual lower abdominal pain, and 2 patients (2.74%) complained of breast swelling. Weight gain was also observed in 2 patients (2.74%) (Fig. 3B).

4. Discussion

This study included 73 women who had previously benefited from LNG-IUS treatment but had experienced at least one episode of LNG-IUS expulsion. A documented history of LNG-IUS expulsion may be a more appropriate indication for hysteroscopic LNG-IUS suture fixation than other reported high-risk factors, such as adenomyosis, uterine fibroids, dysmenorrhea, an enlarged uterine cavity (uterine volume >150 mL), being overweight (BMI >25 kg/m²), or heavy menstrual bleeding [7–9,21–23]. Repeated insertions and expulsions of the LNG-IUS place a significant financial burden on both the patients and health-care system, while also increasing the risks associated with related procedures. All patients in this study expressed a strong desire to undergo suture fixation of the LNG-IUS in order to prevent a recurrence of the expulsion. In addition to a history of expulsion, the patients also presented with other known high-risk factors for LNG-IUS expulsion, including dysmenorrhea (64.38%), menorrhagia (67.12%), adenomyosis (73.97%), a uterine volume >150 mL (52.24%), and being overweight (38.46%).

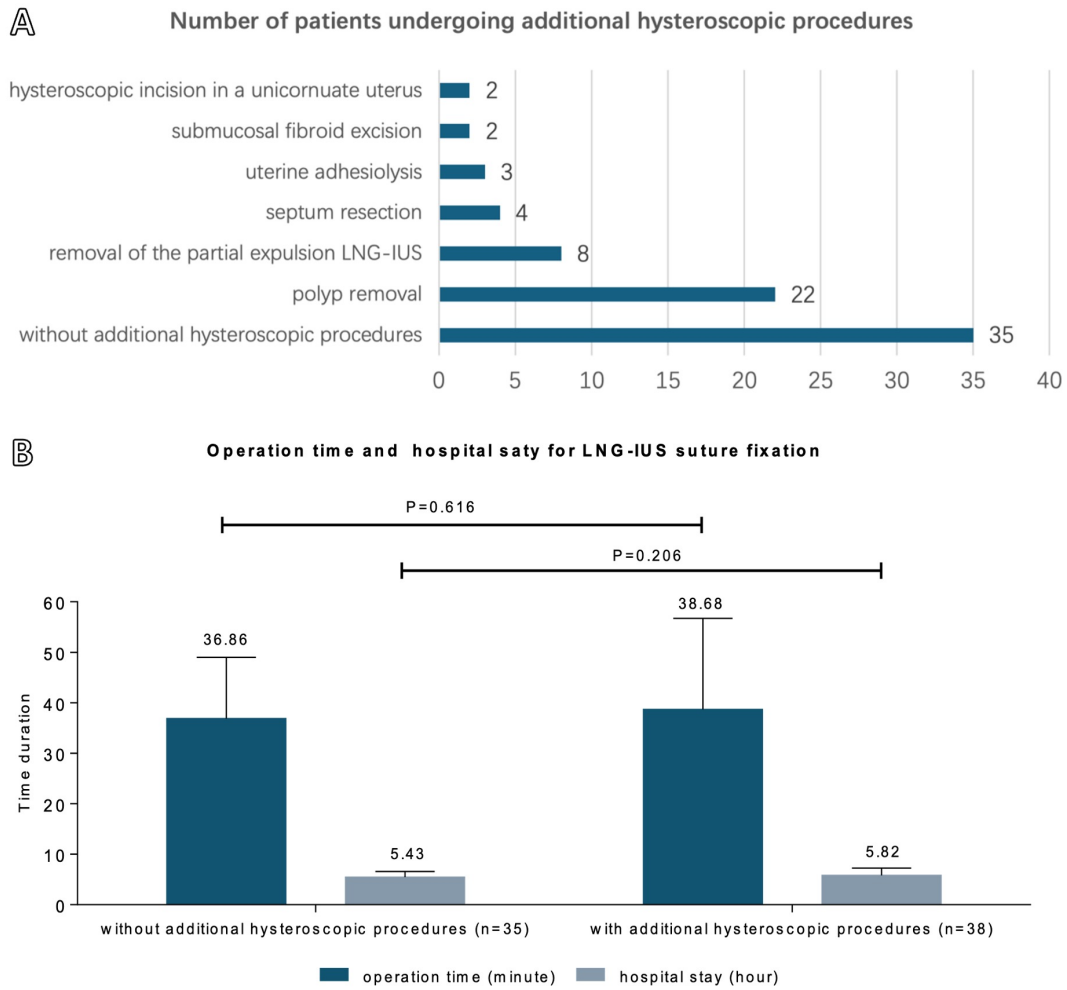


Fig. 1. Additional hysteroscopic procedures and surgical outcomes in LNG-IUS suture fixation. (A) Number of patients undergoing additional hysteroscopic procedures. (B) Operation time and hospital stay for LNG-IUS suture fixation, with or without additional hysteroscopic procedures. LNG-IUS, levonorgestrel-releasing intrauterine system.

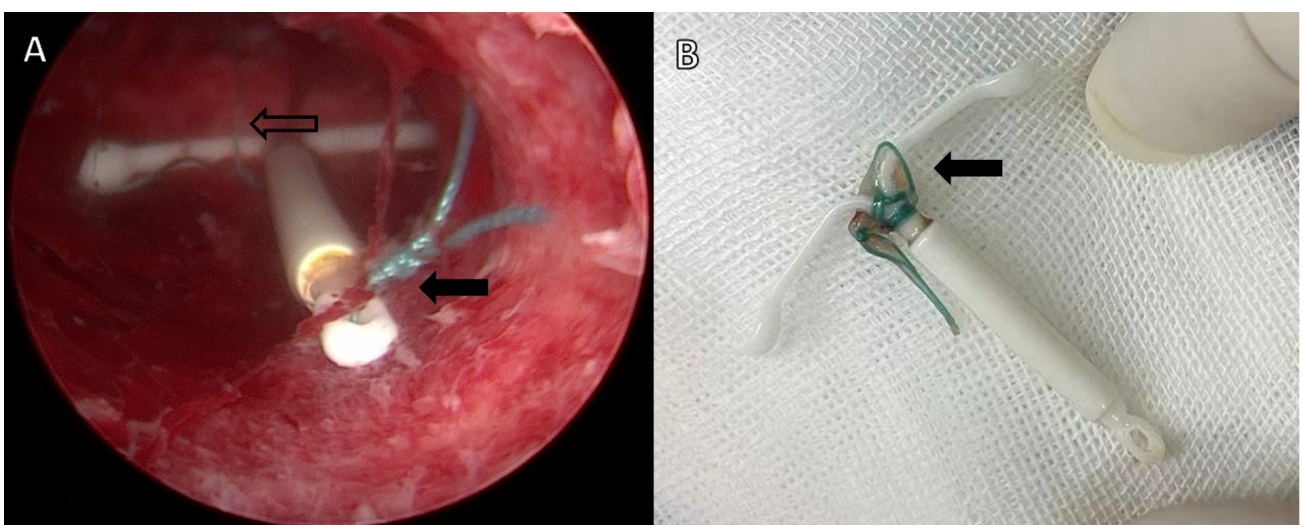


Fig. 2. Hysteroscopic re-suture fixation and expelled LNG-IUS. (A) ‘Two point’ fixation of LNG-IUS. Void arrow: First stitcher. Black arrow: Second stitcher. (B) Expulsed LNG-IUS with intact thread loop and knots. Black arrow: Intact thread loop and knots.

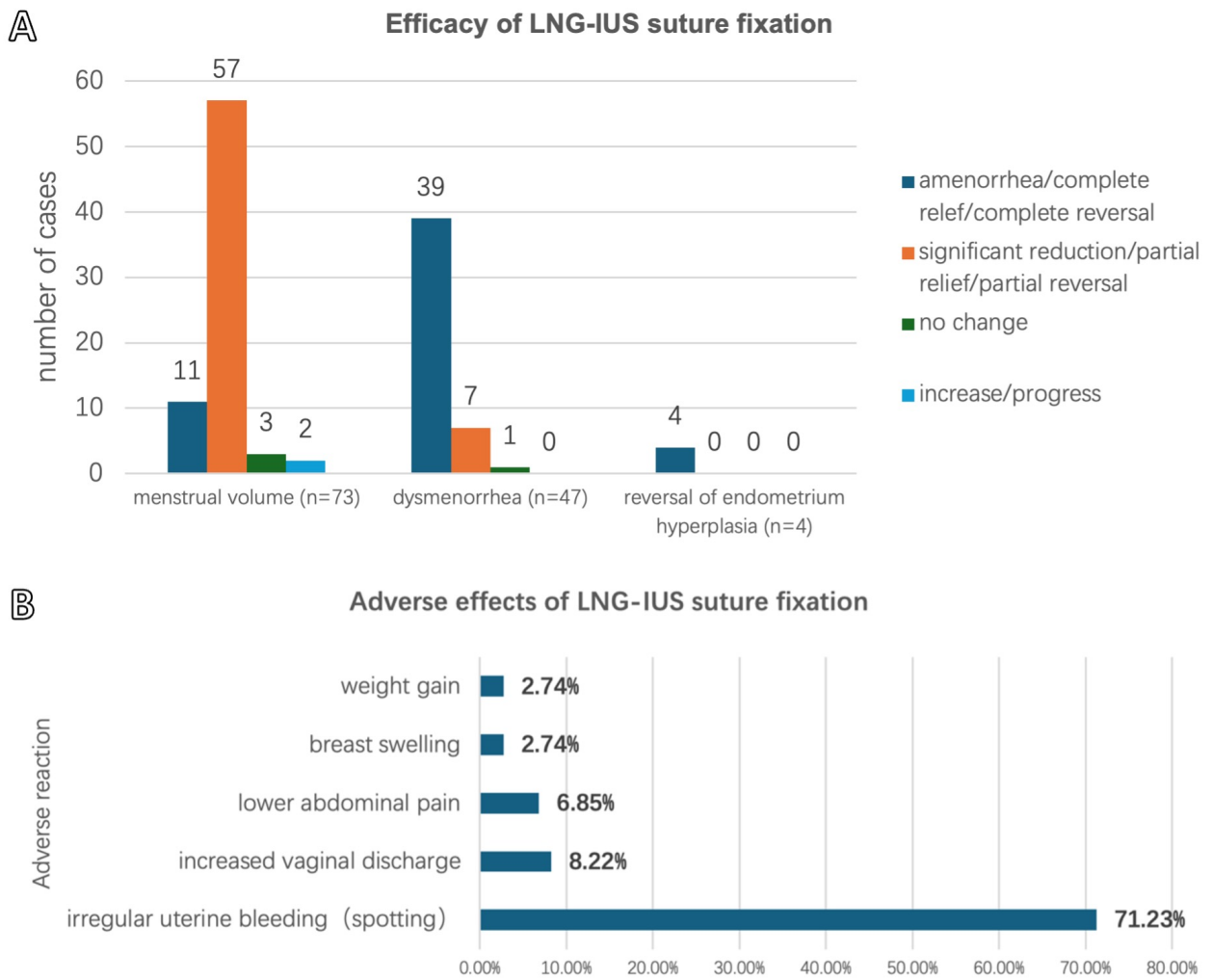


Fig. 3. Clinical outcomes of LNG-IUS suture fixation: efficacy and adverse effects. (A) Efficacy of LNG-IUS suture fixation. (B) Adverse effects of LNG-IUS suture fixation.

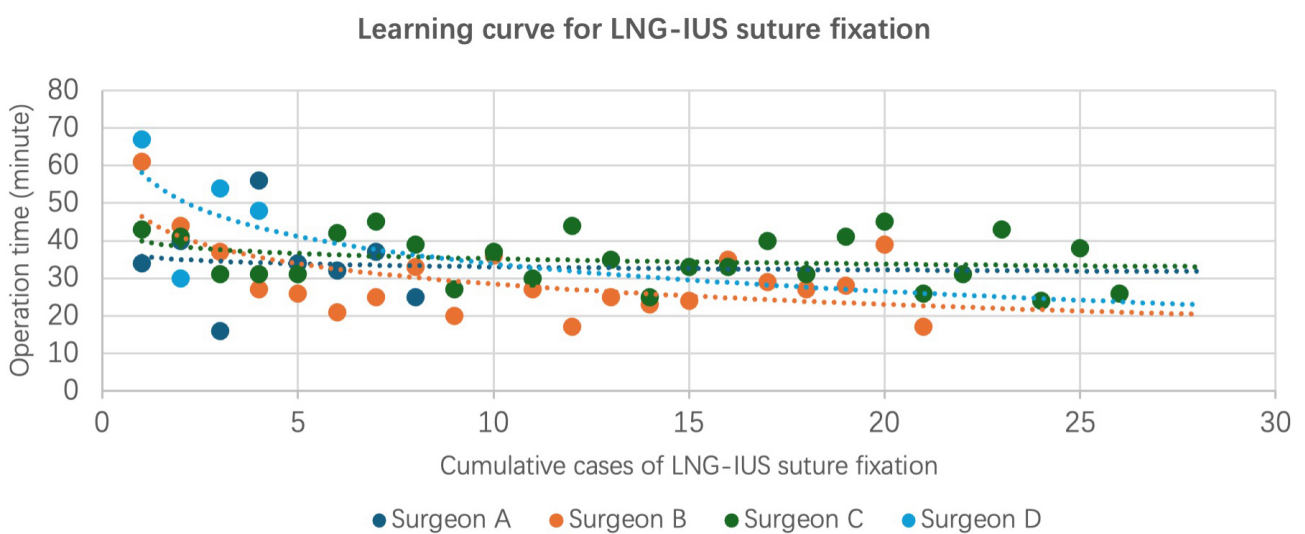


Fig. 4. Learning curve for LNG-IUS suture fixation.

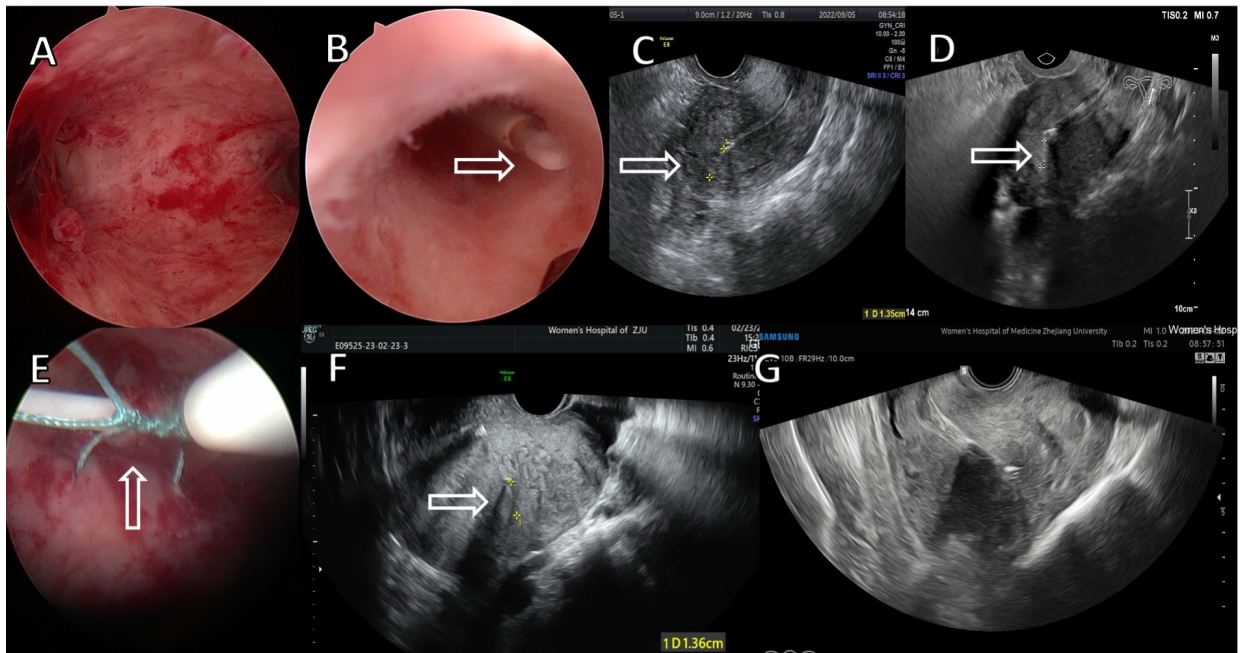


Fig. 5. LNG-IUS downward shift and ‘swing’ phenomenon. (A) Distorted uterine cavity with adenomyosis. Protrusion of the uterine fundus, mimicking a ‘pseudo-septate uterus’ (5 August 2022). (B) Void arrow: Distal tip of the LNG-IUS reaching the internal cervical orifice (5 August 2022). (C) 1.35 cm downward shift of the LNG-IUS at 1-month follow-up (5 September 2022) (void arrows indicate position change). (D) 1.14 cm downward shift of the LNG-IUS at 8-month follow-up (7 April 2023) (void arrows indicate position change). (E) Void arrow: Single case exhibiting a loose thread loop (30 January 2023). (F) Void arrow: 1.36 cm downward shift observed at the 1-month follow-up (23 February 2023). (G) *In situ* position confirmed at the 2-month follow-up time in the same patient (22 March 2023).

All patients successfully underwent hysteroscopic LNG-IUS suture fixation, with a mean operative time of 37.81 ± 14.90 min. Additional hysteroscopic procedures were performed concurrently in 52.05% of cases. Analysis of the learning curves of the four primary surgeons indicated that proficiency in the suturing technique was generally achieved after five procedures (Fig. 4). No hysteroscopy-related complications occurred during any of the operations. The procedure was successfully completed as day surgery in all patients, with a mean hospital stay of 5.63 ± 1.31 h. No late complications were observed at the one-week postoperative follow-up time. These findings confirm the hysteroscopic LNG-IUS suture fixation procedure is easy to master and well-suited for implementation in the setting of day surgery.

Patients with a history of LNG-IUS expulsion have a high rate of re-expulsion, ranging from approximately 27.60% to 57.00% [8,9]. In our study, the expulsion rate was successfully reduced to 4.29% through hysteroscopic suture fixation. Similar studies have also reported low expulsion rates following hysteroscopic LNG-IUS suture fixation, ranging from 0.00% to 8.33% (Table 2) [15–19]. However, in the limited number of published clinical studies, not all patients who underwent the procedure had a prior history of LNG-IUS expulsion. In the study by Zhang *et al.* [17], only 25.00% (3/12) of patients had a history of

expulsion, and a re-expulsion rate of 8.33% was observed 6 months postoperatively. In the study by Lv *et al.* [19], 49.40% (39/79) of patients had a history of expulsion, with a re-expulsion rate of 2.60%.

In the present study, three patients experienced a recurrence of LNG-IUS expulsion at 4–5 months postoperatively, corresponding with the high-risk expulsion period reported in a previous study [19]. In our three patients with recurrence of expulsion, the initial suture fixation procedure was performed by three different surgeons. Moreover, the suture thread loops and knots were intact, suggesting the expulsion may have been caused by tearing of the muscular layer. Upon reviewing the operation videos for these cases, we identified that the first two knots were over-pushed, therefore creating excessively tight sutures. Zhang *et al.* [17] have suggested that expulsion could be related to the absorption of absorbable sutures. In a subsequent study, these authors improved fixation by using non-absorbable sutures, resulting in a significantly reduced expulsion rate of 2.60%. However, the specific reasons behind this reduction were not explored in detail [15,19].

Five patients in the present study experienced a downward shift of the LNG-IUS, all of whom had a diagnosis of adenomyosis. One patient had a distorted uterine cavity, with the uterine fundus protruding into the cavity as a pseudo-septate uterus (Fig. 5A). In this case, the LNG-IUS

Table 2. Clinical studies of hysteroscopic LNG-IUS suture fixation.

Author	Publication year/month	Inclusion criteria	N	Follow-up (months)	Symptom improvement	Main adverse reactions	Expulsion/Downward shift
Zhu <i>et al.</i> [15]	2021/5	Adenomyosis	1	12	Obvious dysmenorrhea relief Obvious menorrhagia relief	NA	0
Huang <i>et al.</i> [16]	2023/8	Previous LNG-IUS expulsion history	2	3	Decreased menstrual volume	NA	0
Zhang <i>et al.</i> [17]	2022/11	Adenomyosis	12	6	Decreased menstrual volume Significant dysmenorrhea relief	prolonged vaginal spotting (33.00%) abnormal vaginal discharge (25.00%)	8.30%/16.67%
Cui <i>et al.</i> [18]	2023/9	Adenomyosis	1	6	Dysmenorrhea relief Decreased menstrual flow	NA	0
Lv <i>et al.</i> [19]	2024/1	Adenomyosis	79	12	Improvement of pain and bleeding (97.40%)	irregular bleeding (44.30%) weight gain (29.20%)	2.60%/NA

NA, not applicable.

was fixed at a low position, as the tail reached the internal cervical orifice (Fig. 5B). During follow-up of this patient, transvaginal ultrasound consistently demonstrated that the LNG-IUS remained positioned at least 1 cm from the uterine fundus (Fig. 5C,D). The other cases of downward shift may have been caused by loose formation of the thread loop (Fig. 5E). We also noted the occurrence of an “LNG-IUS swing” phenomenon in two cases with loose thread loops, which has not been reported previously. Both cases exhibited a downward shift in the LNG-IUS during the 1-month follow-up period, although it remained *in situ* at the 2- and 3-month follow-up times (Fig. 5F,G). The loose thread loop could potentially cause the LNG-IUS to swing within the uterine cavity. It is important to note that even when the LNG-IUS shifts downward, it still provides contraceptive and therapeutic benefits [7]. Therefore, we closely monitored the five patients with a downward shift, in light of the continued benefits they were likely to receive from the device.

Consistent with previous findings, our study demonstrated that LNG-IUS suture fixation can reduce the menstrual volume and alleviate dysmenorrhea symptoms (Table 2). A large majority of our patients (68/73, 93.15%) experienced either reduced menstrual bleeding or amenorrhea. Among the 47 patients with preoperative dysmenorrhea, 97.87% (46/47) achieved complete or partial symptom relief, comparable to the relief rate of 97.40% reported by Lv *et al.* [19] in 2024.

In addition to cases of adenomyosis, our study is the first to include patients with EH. Of the 7 patients with this condition, four required postoperative hysteroscopic evaluation. Follow-up multi-point endometrial biopsies revealed complete histopathological regression in two patients with complex hyperplasia, and in two with atypical hyperplasia. The LNG-IUS remained in place in all four cases. These findings suggest that LNG-IUS fixation may also be a viable treatment option for EH. Moreover, in three patients with recurrent EPs, no recurrence was observed after LNG-IUS fixation, indicating a potential preventive effect. However, due to the absence of a control group, the efficacy of LNG-IUS suture fixation for treating EH and recurrent polyps requires further confirmation through prospective, controlled clinical trials.

Nonetheless, suboptimal treatment outcomes were observed in three patients with adenomyosis. One case involved a unicornuate uterus with a rudimentary horn (type IIC). Despite successful LNG-IUS fixation and no postoperative expulsion, the patient experienced persistent dysmenorrhea and ultimately underwent hysterectomy 5 months later. The other two cases, with uterine volumes of 215.78 mL and 619.11 mL, experienced worsening menstrual bleeding despite proper LNG-IUS placement, requiring additional interventions. Similarly, Lv *et al.* [19] reported two cases in which patients opted for hysterectomy due to unsatisfactory symptom control following LNG-IUS

fixation for adenomyosis. The fixed 52 mg dose of the LNG-IUS could limit its effectiveness in patients with a high adenomyosis burden. Therefore, careful patient selection and thorough preoperative evaluation are essential when considering LNG-IUS fixation for such cases.

In our study, irregular uterine bleeding was defined as spotting lasting more than 8 days within one month, or more than 24 days within 90 days. During the 6-month follow-up period, we observed a relatively high incidence (71.23%) of irregular uterine bleeding. A previous study on LNG-IUS suture fixation reported an irregular uterine bleeding rate of 44.30% at 12 months post-procedure [19]. This exceeds the 24.00% incidence of irregular bleeding observed at 12 months following standard LNG-IUS placement in patients with adenomyosis [10]. However, neither the earlier clinical studies on LNG-IUS suture fixation, nor those on standard placement, have clearly defined what constitutes LNG-IUS—related irregular bleeding. Therefore, the relatively high rate of irregular spotting observed in our study may partly reflect differences in the definition of irregular uterine bleeding. As one of the most common adverse effects associated with standard LNG-IUS placement, irregular uterine bleeding typically decreases over time and is negatively correlated with duration of use [24,25]. The follow-up period in the present study was relatively short compared with the study by Lv *et al.* [19], which may partly explain the higher incidence of irregular uterine bleeding. Although suture fixation of the LNG-IUS may increase the risk of irregular bleeding, confirmation of such an association requires a control group undergoing standard LNG-IUS placement, a longer follow-up period, systematic data collection at predefined intervals, and quantitative evaluation using bleeding diaries. Despite the relatively high incidence of vaginal spotting in our study, no cases of pelvic inflammatory disease were identified during the 6-month follow-up. All patients tolerated the device well, and none required early removal of the levonorgestrel-releasing intrauterine system due to bleeding.

This study represents the largest clinical investigation to date on hysteroscopic suture fixation of the LNG-IUS in patients with a documented history of expulsion. At 6-month follow-up, the rates of expulsion (4.29%) and downward displacement (7.14%) were both relatively low. LNG-IUS suture fixation also improved dysmenorrhea (97.87%, 46/47) and reduced menstrual volume or the onset of amenorrhea (93.15%, 68/73) in the large majority of patients, while proving effective in the treatment of EH and recurrent EPs.

However, several limitations should be acknowledged. First, the absence of a control group prevents direct comparison with alternative treatment approaches, thereby weakening the strength of our conclusions. Unlike previous clinical studies on LNG-IUS suture fixation, all participants in our study had experienced at least one prior LNG-IUS expulsion. These patients opted either for su-

ture fixation in the hope of continued therapeutic benefit, or abandoned LNG-IUS treatment for alternative therapies. Additionally, LNG-IUS is not covered by medical insurance in China, and hence the recruitment of a control group willing to undergo standard re-insertion posed significant challenges. Second, the study population was heterogeneous, with 73.97% (54/73) of patients diagnosed with adenomyosis. As a result, quantitative assessments such as the Pictorial Blood Loss Assessment Chart (PBAC) and Visual Analog Scale (VAS) for dysmenorrhea were not included. This weakened the reliability of our evaluation of symptom improvement. Third, due to the novelty of the surgical technique at the time this study was initiated, the increased incidence of irregular bleeding was not anticipated. Moreover, previous studies lacked clear definitions or evaluation criteria for irregular bleeding [17,19]. Objective tools such as bleeding diaries were not employed to assess spotting frequency or volume, thus limiting the robustness of the safety analysis related to irregular bleeding.

Future studies should adopt more refined subgroup designs based on underlying conditions, and incorporate standardized quantitative measures to better assess the efficacy and safety of this technique.

5. Conclusions

Among patients with a history of LNG-IUS expulsion, hysteroscopic suture fixation demonstrates dual benefits: it reduces the re-expulsion rate to 4.90% while simultaneously alleviating symptoms of dysmenorrhea and menorrhagia.

Availability of Data and Materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Author Contributions

YG and YW designed the research study. BL and YG conducted follow-up visits and collected the data. YG and GX analyzed the data and drafted the manuscript. GX and YW critically revised the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

This study was conducted in accordance with the guidelines of the Declaration of Helsinki. The study was approved by the Women's Hospital of Zhejiang University School of Medicine ethics committee (IRB-20220332-T), and all participants provided written informed consent.

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The uterine image featured in the graphical abstract was sourced from <http://www.album-online.com> (alb11341740) and has been properly licensed.

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Conflict of Interest

The authors declare no conflict of interest.

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