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Original Research

An Innovative Surgical Technique: Anchoring Levonorgestrel-Releasing Intrauterine System Using a Specialized Fixation Needle

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Abstract

Background: Numerous surgical techniques have been proposed to enhance the stability of intrauterine system (IUS) and reduce the incidence of displacement and expulsion, however, challenges remain. We aim to explore improved therapeutic strategies for levonorgestrel-releasing intrauterine system (LNG-IUS) displacement or expulsion cases. **Methods**: This study proposes a novel method utilizing a specialized fixation needle to anchor the Mirena intrauterine device (IUD) within the uterine muscle layer. From June 2022 to December 2022, patients underwent hysteroscopic suturing for Mirena fixation, serving as the control group. From January 2023 to June 2023, 38 patients underwent hysteroscopic anchoring of Mirena using a specialized fixation needle, constituting the experimental group. **Results**: A total of 59 patients were included in the study. The experimental group included 38 patients, aged 31 to 51 years, with a median age of 41.5 (interquartile range: 36, 46) years. Comparison of treatment outcomes between the two groups showed significant improvements in Visual Analog Scale (VAS) scores, Pictorial Blood Assessment Chart (PBAC) scores, and hemoglobin (Hb) levels after treatment in both the experimental and control groups (all $p < 0.001$). Moreover, in the control group, 90.48% (19/21) of patients had normal contraceptive device positions during postoperative follow-up. In the control group, 2 patients (9.52%) experienced IUD displacement postoperatively. While, in the experimental group, 97.37% (37/38) of patients had normal contraceptive device positions during postoperative follow-up. However, 2.63% (1/38) experienced sudden excessive menstrual bleeding and IUD expulsion at 3 months postoperatively, requiring total hysterectomy. **Conclusions**: Hysteroscopic anchoring of the LNG-IUSs using a specialized fixation needle addresses the issue of device expulsion, offering a more straightforward and accessible alternative to traditional hysteroscopic suturing methods. Moreover, similar to hysteroscopic suturing of Mirena, this technique effectively relieves dysmenorrhea and heavy menstrual bleeding symptoms in patients.

Keywords: levonorgestrel-releasing intrauterine system; expulsion; migration; fixation procedure; anchoring

1. Introduction

The levonorgestrel-releasing intrauterine system (LNG-IUS) was developed through a collaboration between the Steroid Laboratory of the University of Helsinki, Finland, and the International Contraceptive Research Committee of the Population Council in the United States. It was first introduced to the market in Finland in 1990 and subsequently in China in 2000. The LNG-IUS is widely recognized for its efficacy in contraception, the treatment of menorrhagia and dysmenorrhea, and the prevention of endometrial hyperplasia during estrogen replacement therapy [1]. Designed for up to 5 years of continuous use, the LNG-IUS has become an integral component of gynecological practice. However, the clinical application of LNG-IUS is not without challenges. One significant concern is the device displacement or expulsion, which can lead to treatment failure and require alternative interventions. Studies have reported varying prevalence rates of LNG-IUS expulsion, ranging from approximately 2% to over 10%, depending on patient-related factors such as parity, uterine size, and underlying conditions like adenomyosis [2,3]. This complication is particularly prevalent in patients with adenomyosis, as an enlarged uterine cavity increases the risk of LNG-IUS displacement or expulsion [2,4]. Patients with adenomyosis exhibit higher displacement rates due to the abnormal uterine anatomy and altered contractility, leading to suboptimal therapeutic outcomes and increased morbidity.

The consequences of LNG-IUS displacement extend beyond ineffective treatment, significantly impacting the quality of life of affected women. Patients may experience recurrent symptoms such as heavy menstrual bleeding and pain, leading to physical discomfort and emotional distress [5]. Furthermore, the need for additional medical interventions, including potential hysterectomy, adds to the psychological burden and imposes substantial healthcare costs on both individuals and healthcare systems. Current solutions to address LNG-IUS displacement or expulsion are limited. Although some methods have been proposed to enhance device fixation, these approaches often present drawbacks, such as increased procedural complexity, potential adverse effects, and varying degrees of effectiveness [6]. Therefore, there is an urgent need for innovative strategies that

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can reliably secure the LNG-IUS while minimizing complications and preserving the device's intended benefits. In response to these challenges, numerous surgical techniques have been proposed to enhance the stability of intrauterine system (IUS) and reduce the incidence of displacement and expulsion. These advancements include: (1) altering the shape or design of the IUS to better conform to the uterine anatomy, thereby reducing the likelihood of movement. (2) Applying biocompatible adhesives to secure the IUS to the uterine wall, although concerns about tissue irritation and potential adverse effects have limited their widespread adoption. (3) Utilizing mechanical devices such as clips or sutures to anchor the IUS, which have shown promise but require additional training and carry the risk of uterine perforation. (4) Innovations in hysteroscopy, including the development of specialized tools and methods to ensure precise placement and fixation of the IUS, have significantly improved procedural outcomes. Each of these approaches has provided valuable insights into improving IUS stability; however, challenges remain. The search for a reliable method that minimizes complications while preserving the device's intended benefits continues to drive innovation.

In this study, we aim to evaluate an innovative surgical technique involving the anchoring of the LNG-IUS using a specialized fixation needle in patients who have previously experienced Mirena displacement or expulsion. By exploring this method under hysteroscopy, we aim to develop enhanced therapeutic strategies that address the limitations of current practices and improve the management of LNG-IUS-related complications, especially in challenging cases like adenomyosis. Our findings could pave the way for improved patient care, reduced healthcare expenditure, and ultimately better health outcomes for women relying on the LNG-IUS for contraception and symptom management.

2. Material and Methods

2.1 Study Design and Patients

Patients with a history of Mirena displacement or expulsion who visited our hospital from June 2022 to June 2023 were selected for hysteroscopic Mirena fixation. They were divided into two groups: the control group, consisting of 21 patients who underwent hysteroscopic Mirena suturing fixation from June 2022 to December 2022, and the experimental group, consisting of 38 patients who underwent hysteroscopic anchoring of Mirena using a specialized fixation needle from January 2023 to June 2023. Initially, 30 cases were considered for each group. A retrospective analysis of their clinical data was conducted, comparing surgical duration, uterine distention fluid volume, postoperative expulsion and displacement rates, as well as hemoglobin (Hb) levels. Additionally, patients were followed up via telephone to assess pre- and postoperative pain scores and menstrual volume.

Inclusion criteria: (1) patients with a history of Mirena displacement or expulsion, diagnosed with conditions such as adenomyosis, abnormal uterine bleeding, endometrial polyps, or endometrial hyperplasia, who were adequately informed about the surgical risks, the effects, and potential side effects of the LNG-IUS, and who provided informed consent for the reinsertion of LNG-IUS. (2) Temporary absence of fertility requirements. (3) Tolerance to surgical anesthesia. (4) Desire to preserve uterine integrity. (5) No contraindications to medication use. Exclusion criteria: (1) pregnancy or suspected pregnancy. (2) Confirmed or suspected reproductive tract tumors. (3) Acute infections of the reproductive tract. (4) Breast tumors or related diseases.

2.2 Preoperative Preparation

Prior to the procedure, comprehensive preoperative examinations were conducted, including a complete blood count, coagulation function tests, an immunological panel assessment (including four tests for hepatitis B immunity, including hepatitis B and C, syphilis, and acquired immunodeficiency syndrome (AIDS)), routine vaginal discharge analysis, electrocardiogram, gynecological ultrasonography, liver and kidney function tests, electrolyte levels assessment, and blood glucose measurement.

2.3 Surgical Procedures

Experimental group: (1) after the patient emptied their bladder and assumed the lithotomy position, successful general anesthesia was induced via intravenous administration. Standard disinfection of the external genitalia and vagina was then performed. (2) A standard 7 mm hysteroscope was employed to examine the uterine cavity. Physiological saline solution was used as the distension medium. After placing a vaginal speculum and clamping the cervix with a tenaculum, hysteroscopy was performed to assess the morphology, size, and endometrial thickness of the uterine cavity. Any endometrial polyps or areas of thickened endometrium were addressed first under hysteroscopy to restore the normal uterine cavity shape. (3) For patients with downward displacement of LNG-IUS, the device was removed, and a new one was inserted. A 3–0 polyglactin suture was wrapped around the intersection point of the "T" of the LNG-IUS and tied securely, leaving a 1.5–2.0 cm tail, which was then knotted 5–6 times. Subsequently, a large knot was tied using the 5–6 knots to create an anchoring knot. The LNG-IUS was then folded and reinserted into the uterine cavity using the inserter, after which the inserter was withdrawn. (4) After inserting the hysteroscope, a specialized fixation needle (as shown in Fig. 1A,B) was used to push the anchoring knot into the uterine muscle layer by 1.0–2.0 cm. (5) The tail of the LNG-IUS was cut 2 cm from the external os of the cervix. The fixation was completed, as shown in Fig. 1C. The methods to prevent expulsion are: (1) placement of Mirena after gonadotropin-releasing hormone (GnRh) injection to reduce the uterus; and (2) fixation of Mirena using sutures. However, the method (1) increases patient costs, and the postmenopausal symptoms increased patients' anxiety, making it unacceptable for many patients.

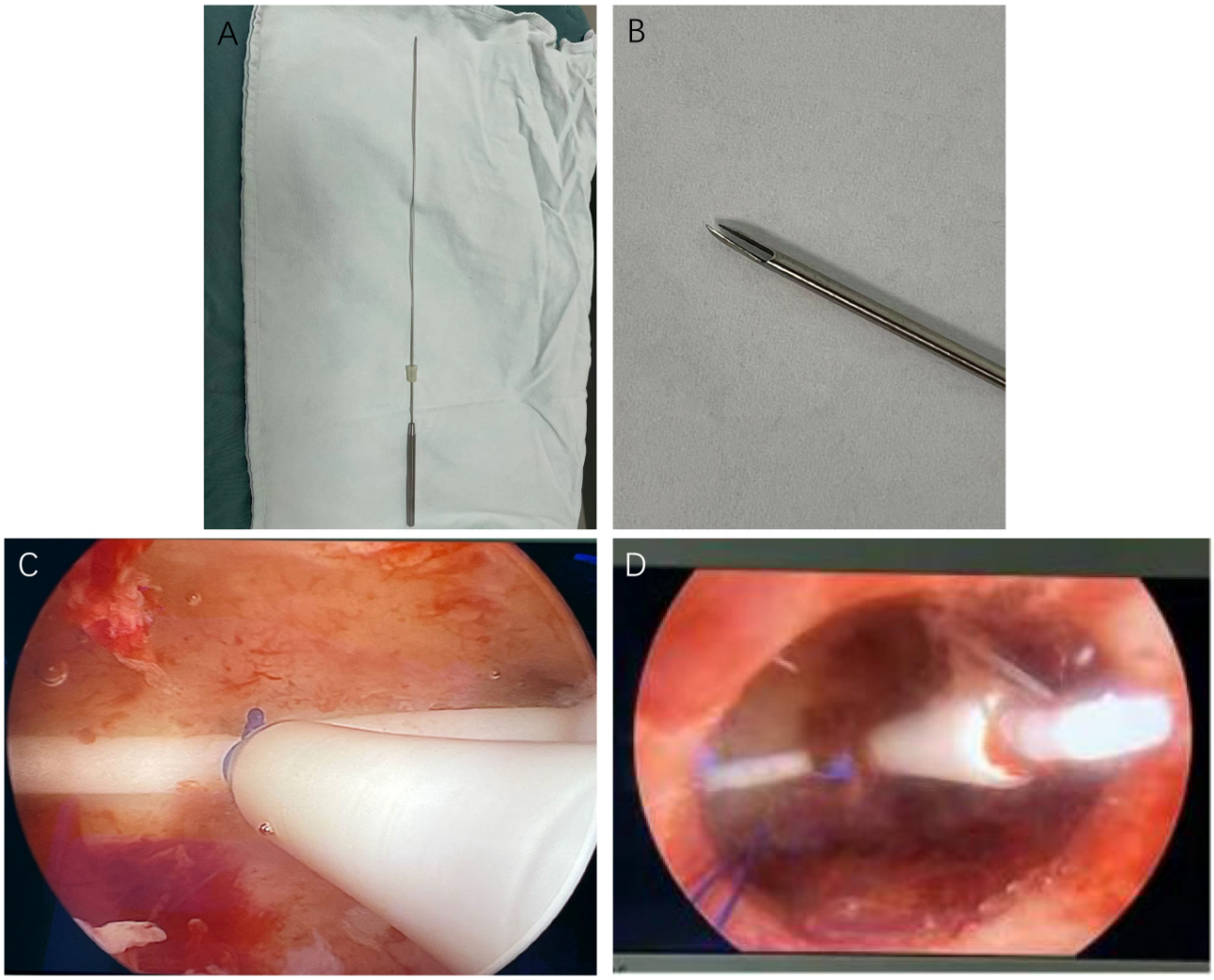

Fig. 1. Specialized fixation needle and its use. (A) Overview of the specialized fixation needle. (B) Tip of the specialized fixation needle. (C) Hysteroscopic anchoring of Mirena with specialized fixation needle. (D) Hysteroscopic suturing for fixation of Mirena.

Control group: (1) and (2) were with same as the corresponding steps (1) and (2) in the experimental group. A 6.0 mm hysteroscope (Hologic, Bedford, MA, USA), was used for uterine cavity examination. (3) For patients with downward displacement of LNG-IUS, the device was removed, and a new one was inserted. The LNG-IUS was removed from the inserter, and a 3–0 non-absorbable suture was wrapped around the intersection point of the "T" of the LNG-IUS and tied securely. The LNG-IUS was then folded and reinserted into the inserter. (4) The LNG-IUS was inserted into the uterine cavity using the inserter, which was then removed. Subsequently, the needle was inserted into the uterine cavity. (5) After inserting the hysteroscope, a needle holder was used to clamp the needle, and a stitch was placed at the posterior wall of the uterine fundus. The knot was tied outside the body, tightened, and secured using a pusher. (6) The tail of the LNG-IUS was then cut 2 cm from the external os of the cervix. The fixation was completed, as shown in Fig. 1D.

Postoperatively, all patients underwent daytime surgery and were discharged within 24 hours. For patients who received over 4000 mL of uterine distention fluid during surgery, furosemide was administered to prevent fluid overload. Vital signs and electrolyte levels were closely monitored, and no infections, water intoxication, or intestinal perforations occurred as postoperative complications. All patients underwent ultrasound follow-up at 1 month, 3 months, 6 months, and 1 year postoperatively, with the overall follow-up period ranging from 6 months to 1 year postoperatively.

2.4 Measurements

(1) Hb levels before and after treatment: a fasting venous blood sample of 5 mL was collected before treatment and 6 months after treatment for a complete blood count. (2) Severity of dysmenorrhea and menstrual volume before and after treatment: the severity of dysmenorrhea and menstrual volume were compared between the two groups

Table 1. Comparison of general information.

Variable	Experimental group (n = 38)	Control group (n = 21)	Z (*p*)*
	Median (Q25, Q75)	Median (Q25, Q75)	
Age (years)	41.5 (36, 46)	42.0 (37, 44)	–0.008 (0.9937)
BMI (kg/m^2)	22.76 (21.48, 25.40)	23.05 (21.52, 25.59)	–0.206 (0.8369)
Uterine size (cm^3)	249.24 (175.45, 386.32)	355.71 (231.66, 456.30)	–0.989 (0.3224)
Uterine cavity depth (cm)	9 (9, 10)	10 (8, 11)	–0.636 (0.5247)

* Wilcoxon signed-rank tests. BMI, body mass index.

before treatment and 6 months after treatment. The severity of dysmenorrhea was assessed using the Visual Analog Scale (VAS), where 0 points indicated no pain, 1–3 points indicated mild pain, 4–6 points indicated moderate pain, and 7–10 points indicated severe pain. Menstrual volume was evaluated using the Pictorial Blood Assessment Chart (PBAC) method. In this method, light flow was defined as staining covering $\leq$1/3 of the sanitary pad area, moderate flow as staining covering 1/3 to 3/5 of the pad area, and heavy flow as extensive staining covering most of the pad area. Corresponding scores were 1, 5, and 20, respectively. A score $>$100 confirmed menstrual volume $>$80 mL, with the score directly proportional to menstrual volume. (3) Ultrasound follow-up at 1 month, 3 months, 6 months, and 1 year after treatment: ultrasound examinations were conducted at these intervals to assess whether the intrauterine device (IUD) had migrated or been expelled.

2.5 Statistical Methods

Statistical analysis was conducted using SPSS (Statistical Product and Service Solution) software, version 26.0 (IBM Corp., Chicago, IL, USA). Descriptive statistics for continuous variables are presented as median (Q25, Q75) based on normality tests (Kolmogorov-Smirnov test). Between-group and within-group comparisons were performed using Wilcoxon signed-rank tests. Statistical significance was considered at a level of $p < 0.05$, and $p < 0.001$ was considered extremely statistically significant.

3. Results

3.1 General Information

A total of 59 patients were included in the study. The experimental group included 38 patients, with ages ranging from 31 to 51 years and a median age of 41.5 (36, 46) years. Within this group, there were 17 cases of expulsion and 21 cases of migration. Notably, 3 patients who received gonadotropin-releasing hormone agonist (GnRH-a) pre-treatment with three injections still experienced migration after Mirena insertion. Additionally, 1 case involved migration despite six injections of GnRH-a and subsequent repositioning of the Mirena device. Among the 35 cases of adenomyosis, 3 cases were accompanied by endometrial polyps, and 3 cases had a solitary endometrial polyp. The control group included 21 patients, ages ranged from 34 to 43 years, with a median age of 42 (37, 44) years. Preoperatively, there were 12 cases of expulsion and 9 cases of migration. Among these, 3 patients received GnRH-a pre-treatment with three injections, while 1 case experienced both migration and expulsion despite undergoing one year of oral mifepristone before Mirena insertion. Among the 20 cases of adenomyosis in this group, 3 were accompanied by endometrial polyps, and 1 case presented with abnormal uterine bleeding. A between-group analysis of baseline patient characteristics showed no statistically significant differences ($p > 0.05$) (Table 1).

3.2 Intraoperative Characteristics

Intraoperative findings showed that all 38 cases in the experimental group and 21 cases in the control group underwent surgery successfully. The average surgical duration was significantly shorter in the experimental group [25 (20, 30) minutes] compared to the control group [60 (50,75) minutes], with statistical significance ($p < 0.001$). The experimental group also used significantly less uterine distention fluid intraoperatively [1000 (800, 1500) mL] compared to the control group [3800 (2500, 3850) mL] ($p < 0.001$) (Table 2).

3.3 Comparison of VAS Scores, PBAC Scores, and Hb Levels

Comparison of treatment outcomes between the two groups showed significant improvements in VAS scores, PBAC scores, and Hb levels after treatment in both the experimental and control groups (all $p < 0.001$). However, there were no statistically significant differences in VAS scores, PBAC scores, and Hb levels between the two groups, either before or after treatment (all $p > 0.05$) (Table 2).

3.4 Prognosis and Efficacy Assessment

In the control group, 90.48% (19/21) of patients had normal contraceptive device positions on postoperative follow-up. 2 patients (9.52%) experienced IUD displacement postoperatively, with 1 case occurring in the 6th month and the other in the 5th month after surgery. Both cases were subsequently managed using the experimental group's method of Mirena fixation and have remained without displacement since then. In the experimental group, 97.37% (37/38) of patients had normal contraceptive device

Table 2. Comparison of surgical duration, uterine distention fluid, VAS scores, Hb level, and PBAC.

Variable		Experimental group (n = 38)	Control group (n = 21)	Z (*p*)*
		Median (Q25, Q75)	Median (Q25, Q75)	
Intraoperative characteristics				
Surgical duration (min)		25 (20, 30)	60 (50, 75)	–5.596 (<0.001)
Uterine distention fluid (mL)		1000 (800, 1500)	3800 (2500, 3850)	–6.239 (<0.001)
Postoperative characteristics				
VAS	Preoperative	6.5 (3, 9)	8 (3, 9)	–0.185 (0.8533)
	Postoperative	1 (1, 1)	1 (1, 1)	1.681 (0.0928)
	Z (*p*)*	–5.061 (<0.001)	–3.623 (<0.001)	/
Hb (g/L)	Preoperative	114.5 (96, 135)	115.0 (107, 123)	–0.143 (0.8867)
	Postoperative	127 (120, 136)	127 (125, 136)	–0.420 (0.6743)
	Z (*p*)*	–4.209 (<0.001)	–3.781 (<0.001)	/
PBAC	Preoperative	156 (56, 345)	173 (132, 320)	–0.800 (0.4239)
	Postoperative	32 (0, 78)	38 (13, 50)	–0.064 (0.9490)
	Z (*p*)*	–5.029 (<0.001)	–3.997 (<0.001)	/

* Wilcoxon signed-rank tests. Hb, hemoglobin; PBAC, Pictorial Blood Assessment Chart; VAS, Visual Analog Scale.

positions on postoperative follow-up, while 2.63% (1/38) experienced sudden excessive menstrual bleeding and IUD expulsion at 3 months postoperatively, which required total hysterectomy (**Supplementary Table 1**).

4. Discussion

Heavy menstrual bleeding and dysmenorrhea are common menstrual symptoms that can significantly reduce quality of life and hinder daily activities and work productivity [7–9]. British practice guidelines recommend the LNG-IUS as first-line therapy for heavy menstrual bleeding [10], and the LNG-IUS is also recommended for dysmenorrhea in both European [11] and Japanese [12] guidelines. The expert consensus in China recommends the LNG-IUS for dysmenorrhea and heavy menstrual bleeding [1]. However, studies on the Mirena device have reported varying expulsion rates. Some studies have indicated a low cumulative expulsion rate of 2.9% after one year [13], while others have reported higher rates, such as 6.3% after one year [14]. Moreover, a study conducted in Japan reported a higher cumulative expulsion rate of 8.7% after one year [15], with this rate significantly elevated (14.5%) in patients with underlying conditions like uterine fibroids [16]. As the likelihood of reinsertion following Mirena expulsion decreases, alternative treatment strategies should be considered. The most probable treatment option in such cases is hysterectomy, which poses significant trauma and impact on patients. In our study, 6 out of 59 cases had a history of repeated expulsion and displacement, highlighting the challenges associated with recurrent Mirena expulsion and displacement under conventional management approaches.

To address this issue, a novel technique has recently been developed, effectively resolving the problem of LNG-IUS expulsion [17–19]. To prevent expulsion, gynecologists suture the Mirena device into the uterine cavity. Hence, this method was used as the control group in our study. Theoretically, this procedure, which involves suturing into the muscle layer, minimizes the risk of expulsion and displacement, resulting in a very low occurrence rate [18]. In our study, only 2 out of 21 cases experienced displacement, supporting this viewpoint. However, this technique has its drawbacks. Firstly, the operation time is relatively long, with an average duration of over 60 minutes, and the average use of irrigation fluid exceeds 3200 mL. Despite the advantages of hysteroscopy, such as direct visualization, accurate positioning, organ preservation, and protective function, it is associated with several complications, with water intoxication being one of the most common. Severe cases may lead to clinical symptoms such as congestive heart failure, pulmonary edema, and even death [20]. According to the 2023 Chinese clinical practice guidelines for hysteroscopy diagnosis and surgery [21], water intoxication is related to prolonged operation time and excessive use of irrigation medium. Diuresis and dehydration are the primary measures to prevent water intoxication, rapidly eliminating the absorbed irrigation fluid from the body, reducing cardiac burden, and preventing cerebral edema and pulmonary edema [22]. Therefore, patients in our study who used more than 4000 mL of irrigation fluid were administered diuretics to prevent water intoxication. Secondly, a special cold knife operating system is required, and our hospital uses the American Holodej Miao Shu system (Model 10-500: H1935H13D0, Haoluojie Medical Technology (Beijing) Co., LTD., Beijing, China). Which costs approximately 1368 USD. The needle holder needs to be customized, with each one costing 273 USD. Moreover, if ring removal is required, the suture must be removed under hysteroscopy again, increasing both the economic burden and surgical risk for patients. Thirdly, the depth of suturing cannot be fully controlled. In our study, 2 cases of IUD displacement occurred again despite using the experimental group's fixation method. The suture was observed to be

intact in the uterine cavity during the operation, suggesting that the depth of suture fixation was insufficient to reach the muscle layer. Fourthly, there is a long learning curve, which is not conducive to widespread adoption. In 2023, Huang *et al*. [23] conducted an *ex vivo* simulation training of hysteroscopic suture fixation of the levonorgestrel system, demonstrating a learning curve for hysteroscopic suture fixation of Mirena. It was found that doctors with experience in single-port laparoscopic surgery and hysteroscopic suturing significantly shortened the learning curve for hysteroscopic suturing. The chief surgeon in our hospital has over 30 years of experience and is proficient in laparoscopic suturing, but lacks experience in hysteroscopic suturing and single-port laparoscopy. After suturing 21 cases, a stable level has not yet been reached.

Currently, on the market, there is the GyneFix IUD, specifically designed to prevent the expulsion of IUDs. It was invented by Belgian gynecologist Dirk Wildemersch. At the top of the surgical suture, there is a small knot, which is implanted into the uterine muscle layer 1.0 cm deep using an inserter. According to literature [24], the Genie Ring is suitable for various sizes and shapes of uterine cavities, and when inserted correctly, the failure of anchoring and expulsion of IUDs is rare. Based on this principle, we used a 3–0 polypropylene suture to create an anchoring knot at the "T" intersection of the Mirena device and placed it into the uterine cavity. After insertion, a specially designed anchoring needle, as shown in Fig. 1A,B, is inserted into the uterine cavity via the operating channel of the hysteroscope. Under direct visualization with the hysteroscope, the knot is pushed into the muscle layer to a depth of approximately 1.0–1.5 cm. The unique features of the special anchoring needle include: (1) the front end of the anchoring needle is forked, with one long and one short prong (as shown in Fig. 1B). Under direct visualization with the hysteroscope, the long end is positioned downward and the short end upward, facilitating the secure fixation of the knot onto the inserter. This procedure can be easily performed by gynecologists with regular hysteroscopy experience. (2) The inserter can be inserted through the operating channel of a regular hysteroscope, requiring no special equipment and thus not adding significant costs to hospitals. (3) The anchoring needle is simple to manufacture, with a customization cost of 164 USD. It can be sterilized repeatedly without incurring additional costs for patients. In our study, this method was used as the experimental group.

In the experimental group of this study, VAS scores, PBAC scores, and Hb levels showed significant improvement after treatment compared to pre-treatment levels. Moreover, there were no significant differences in VAS scores, PBAC scores, and Hb levels between the experimental and control groups, both before and after treatment. This indicates that the treatment in the experimental group resulted in significant alleviation of dysmenorrhea symptoms, reduction in menstrual volume, and correction of anemia in patients, similar to the outcomes observed in the control group. The advantages of this approach are as follows: (1) simple operation: requiring only experience with hysteroscopy, it does not involve a long learning curve, making it more conducive to widespread adoption. (2) Precise positioning under direct hysteroscopic visualization: the placement of the Mirena device is more accurate, requiring less operating space and being unaffected by uterine cavity morphology. (3) Cost-effectiveness: the removal of the Mirena device is similar to that of a regular IUD, without the need for additional hysteroscopy. The customized anchoring needle is cost-effective, can be sterilized and reused, and does not require the purchase of special instruments. It can be operated using a regular 7 mm hysteroscope, providing better economic benefits for both patients and hospitals. (4) Reduced operation time and fluid usage: the procedure has significantly shorter average operation time and requires less fluid usage compared to the control group. This approach reduces patient operation and anesthesia time, minimizes anesthesia risks, decreases the use of fluid, and lowers the risk of fluid overload. Limitations: theoretically, the anchoring needle may pose a risk of uterine perforation and damage to nearby organs due to its sharpness. However, the depth of insertion and length of the remaining suture are controllable, and in this study, no such injuries were observed. Additionally, any potential perforation would likely be small and manageable, with appropriate measures, such as uterine contraction and hemostatic agents for treatment [23]. In one case in this study, an increase in menstrual bleeding occurred three months postoperatively, resulting in the expulsion of the IUD and the need for subsequent total hysterectomy. During surgery, thickening of the uterine muscle layer was observed at the uterine base, indicating insufficient fixation depth. Therefore, adjustments were made, and in future operations, ultrasound measurements of uterine muscle layer thickness were communicated with the radiologist to determine the appropriate length of the remaining suture for proper fixation depth. This approach can help prevent uterine perforation, minimize the risk of organ damage, and reduce the likelihood of device expulsion. After these improvements, 30 additional cases were completed, with operation times ranging from 8 to 15 minutes, similar to those of regular hysteroscopic procedures. As of the current follow-up period, ranging from 1 to 9 months, there have been no instances of device expulsion or migration.

This study has several limitations. Firstly, the sample size of this study is small, and it is a single-center study, thus the findings require further research for broader extrapolation. Secondly, although follow-up results are presented for up to one year, it would be valuable to include longer follow-up data to evaluate the long-term durability and efficacy of this new anchoring technique. Thirdly, research comparing the standard application of Mirena with the

experimental group, where Mirena fixation is performed, would provide more robust and relevant data for evaluation.

5. Conclusions

The results of this study demonstrate that anchoring the LNG-IUS using a specialized fixation needle under hysteroscopy guidance significantly improves dysmenorrhea, reduces menstrual blood volume, and ameliorates anemia in affected patients. The rate of expulsion and displacement is low, and the treatment outcomes are comparable to those of hysteroscopic suturing for LNG-IUS fixation. Moreover, a comparison of the two methods reveals that anchoring the LNG-IUS with a specialized fixation needle under hysteroscopy is safer, requires a shorter learning curve, and offers greater economic benefits, making it more suitable for widespread implementation. The findings of this study emphasized the potential for this technique to become a standard practice, provides it is if further validated by multicenter trials.

Declaration of AI and AI-assisted Technologies in the Writing Process

During the preparation of this work the authors used ChatGpt-3.5 in order to check spell and grammar. After using this tool, the authors reviewed and edited the content as needed and takes full responsibility for the content of the publication.

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

ZW and YL contributed to the study conception and design. ZL collected the data and performed the data analysis. WW interpretation of the data and the completion of figures and tables. All authors contributed to the interpretation of the data and the completion of figures and tables. All authors contributed to the drafting of the article and final approval of the submitted version. 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

The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethic Committee of Huzhou Maternity and Child Health Care Hospital (Approval Number: 2022-J-026). All patients provided written informed consent prior to surgery.

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Conflict of Interest

The authors declare no conflict of interest.

Supplementary Material

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.31083/CEOG27055.

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