Efficacy of hysteroscopic levonorgestrel-releasing intrauterine device fixation in the treatment of adenomyosis: A cohort study

PAN XU[1,2*], SHANSHAN LING[1*], E HU[1], LINA MA[1], JIE LIU[1] and BIXIA YI[1]

[1]Department of Gynecology, Affiliated Jinhua Hospital of Wenzhou Medical University, Jinhua, Zhejiang 321000, P.R. China; [2]School of Medicine, Zhejiang University, Hangzhou, Zhejiang 310006, P.R. China

Received February 27, 2024; Accepted May 20, 2024

DOI: 10.3892/br.2024.1797

Abstract. The present study aimed to investigate the efficacy of hysteroscopic levonorgestrel-releasing intrauterine device (LNG-IUD) fixation surgery in the treatment of adenomyosis through a cohort study. The cohort study was performed at the Affiliated Jinhua Hospital of Wenzhou Medical University (Jinhua, China). A total of 31 women with adenomyosis were initially recruited from June 2020 to June 2022 and divided into an experimental group and a control group. The experimental group underwent hysteroscopic LNG-IUD fixation surgery and the control group underwent conventional implantation of the levonorgestrel-releasing intrauterine system. The assessed efficacy outcomes included the time of LNG-IUD expulsion, postoperative vaginal bleeding time, dysmenorrhea, and the menstrual blood loss score (MBLS). A total of 31 participants completed the research. The LNG-IUD expulsion rate was 6.25 and 60% ($P<0.05$) in the experimental and control group, respectively. The LNG-IUD in place time was 20.50 months (Q_1, 15.75; Q_3, 24.00) in the experimental group and 10.00 months (Q_1, 6.50; Q_3, 15.00) in the control group ($P<0.05$); the time of vaginal bleeding after surgery in the experimental and control groups were 12.50 days (9.25, 16.25) and 120.00 days (75.00, 120.00), respectively ($P<0.05$). Multiple-factor Cox regression analysis revealed that the LNG-IUD expulsion in patients with adenomyosis is associated with the hysteroscopic LNG-IUD fixation surgery [hazard ratio (HR), 1954.09], uterine cavity depth (HR, 16.63), MBLS (HR, 1.14), history of gonadotropin-releasing hormone agonist treatment in the previous 6 months (HR, 2.10), history of vaginal delivery (HR, 1.79) and history of cervical laceration (HR, 3.69). In conclusion, hysteroscopic LNG-IUD fixation reduces the rate of LNG-IUD expulsion, prolongs the time of LNG-IUD in the uterine cavity, reduces the time of postoperative vaginal bleeding, relieves the symptoms of dysmenorrhea and reduces the menstrual volume in the patients with adenomyosis. The present trial was retrospectively registered in the Chinese Clinical Trial Registry on 28th December 2023 (registration no. ChiCTR2300079233).

Correspondence to: Dr Pan Xu, Department of Gynecology, Affiliated Jinhua Hospital of Wenzhou Medical University, 267 Danxi East Street, Jinhua, Zhejiang 321000, P.R. China
E-mail: xupan033@163.com

*Contributed equally

Key words: adenomyosis, levonorgestrel-releasing intrauterine system, levonorgestrel-releasing intrauterine device, hysteroscopy, fixation surgery

Introduction

The endometrial tissue is generally confined to the inner lining of the uterus and sheds during menstruation, however, in adenomyosis, the endometrial tissue infiltrates the muscle layer of the uterus. The condition is characterized by the presence of endometrial tissue invasion into the myometrium, causing an enlarged uterus and symptoms of dysmenorrhea, and heavy or prolonged menstrual bleeding (1,2); however, some women with adenomyosis may not experience any noticeable symptoms. The exact cause of adenomyosis is unknown, however hormonal imbalances, tissue injury and repair mechanisms, and inflammation are hypothesized to play a role (3,4). According to previous studies, mutated epithelial cells localized in the entopic endometrial glands appear to play important roles in the pathophysiology of adenomyosis (3,4). A total of 21 longitudinal studies evaluating 25,600 women reported the overall prevalence of isolated adenomyosis as 10% (5) and the incidence was reportedly highest for women aged 41-45 years of age (6).

Treatment options for adenomyosis may include pain management with medications, hormonal therapies, and, in severe cases, surgical interventions such as hysterectomy or conservative surgery (1,2,7). The levonorgestrel-releasing intrauterine system (LNG-IUS) has demonstrated some effectiveness (1,2,7) with several studies revealing that LNG-IUS can effectively reduce menstrual bleeding, pelvic pain and other symptoms associated with adenomyosis (1,2,7). Furthermore, it is considered a non-surgical treatment option, making it particularly beneficial for women who wish to preserve their fertility (8-11). However, it is important to note that LNG-IUS may not be suitable for all women with adenomyosis, especially in patients with an oversized uterine cavity (uterine cavity depth, >10 cm) (9). Levonorgestrel-releasing intrauterine device (LNG-IUD) expulsion is the main factor

affecting long-term efficacy (12). However, at present there are no current procedures to resolve this issue. Therefore, the present study aimed to use a new method (hysteroscopic LNG-IUD fixation surgery) to prevent LNG-IUD expulsion and to improve the efficacy.

In the present study, by comparing hysteroscopic LNG-IUD fixation intervention surgery and conventional implantation of the LNG-IUD in patients with adenomyosis, efficacy outcomes including the time of LNG-IUD expulsion, postoperative vaginal bleeding time, uterine volume, dysmenorrhea, hemoglobin (HGB), and menstrual volume were observed.

Materials and methods

Sample size calculation. Through preliminary experiments, it was revealed that the LNG-IUD expulsion rate of the conventional method reached 50% in the treatment of patients with adenomyosis, while the LNG-IUD expulsion rate after hysteroscopic LNG-IUD fixation was 0%. By accepting a type 1 error i) of 0.05 and a type 2 error ii) of 0.1, the number of patients required for each group was 16. A drop-out rate of 10% was estimated and therefore, it was calculated that a total of 35 subjects were required.

General information. The patients with adenomyosis who underwent hysteroscopic LNG-IUD fixation surgery were classified as the experimental group and the patients who received conventional implantation of the levonorgestrel-releasing intrauterine system were classified as control group. A total of 35 patients with adenomyosis were recruited to the Department of Gynecology of the Affiliated Jinhua Hospital of Wenzhou Medical University (Jinhua, China) from June 2020 to June 2022 with 17 cases in the control group and 18 cases in the experimental group. During the intervention period, a total of 4 cases dropped out, of which 2 cases were in the control group and 2 cases in the experimental group, leaving 15 cases in the control group and 16 cases in the experimental group. The present study was approved by The Medical Ethics Committee of Affiliated Jinhua Hospital of Wenzhou Medical University (Jinhua, China) (approval no. IBR-2020033-R), and all patients signed informed consent.

The inclusion criteria were as follows: i) Patients with symptoms of menorrhagia and dysmenorrhea met the criteria of transvaginal ultrasonography [a globular shaped-uterus with multiple areas of shadowing (increased and decreased echogenicity), difficulty distinguishing the outer myometrium from the junctional zone, as well as cystic changes within the junctional zone and myometrium] (2,7); ii) patients were willing to take part in the present study and signed informed consent; iii) patients were female and aged 30-50 years; and iv) patients suffered from adenomyosis and had refused hysterectomy surgery. The exclusion criteria were as follows: i) Patients with contraindications for progesterone therapy and hysteroscopy, including severe coagulation disorders, severe heart, liver or kidney diseases, or mental disorders; ii) patients who had suffered from female genital tuberculosis, endometrial polyps, submucous myoma and endometrial carcinoma; and iii) patients with postmenopausal status.

Treatment methods. The control group received conventional implantation of the LNG-IUS whereby the LNG-IUS was inserted into the uterine cavity of patients during menstruation on cycle days 5-7 by a senior gynecologist. The patients took the bladder lithotomy position and the operator used iodophor solution to sterilize the vulva and vagina, and then routinely spread the disinfection towel. The cervix was exposed using a vaginal speculum, and the cervix was disinfected again with iodophor solution. The diluted lidocaine was injected into the cervix at 4 and 7 o'clock directions after grasping and stabilizing the cervix. The operator used a probe to probe the uterine cavity after determining the position of the uterus and then used a dilatation stick to dilate the cervix to the number six dilation stick. Using a specialized inserter, the operator guided the LNG-IUS through the cervix and into the uterus. The LNG-IUD is a small T-shaped device made of flexible plain plastic. The appropriate length of tail wire was left, with the excess removed. Prior to withdrawal of the vaginal speculum, the cervix was checked for active bleeding. After insertion of the LNG-IUD, the healthcare provider performed an ultrasound exam to confirm that the LNG-IUD was properly positioned within the uterus.

The experimental group received hysteroscopic LNG-IUD fixation surgery during the last days of the menstrual cycle. To make the LNG-IUD fixing device the operator used one end of the 3/0 Prolene line to fix the LNG-IUD longitudinal arm and left the other end of the 3/0 Prolene, with a length of 1 cm, with a knotted head. The body position, anesthesia method (Local anesthesia with diluted lidocaine) and the early placement process of the LNG-IUD fixation device in the experimental group were the same as those in the control group. A 5.0 mm outer diameter of hysteroscopy (Richard Wolf GmbH) was used to fix the knotted head to the myometrium of the fundus utilizing a hysteroscopic puncture needle under local anesthesia. The intrauterine pressure was controlled within 100 mm Hg and the distension medium was normal saline. Transabdominal ultrasonography was used throughout the operation.

Participants were surveyed for follow-up at 3, 6 and 12 months after surgery either through telephone interviews or in-person visits to the clinic. The follow-up process was carried out until June 2023.

Evaluation indicators. The LNG-IUS expulsion was confirmed by vaginal ultrasound examination. The time that the LNG-IUD was in place was calculated from the first day post-surgery to the time of LNG-IUD expulsion confirmed by vaginal ultrasound examination. The uterine volume was calculated by color Doppler ultrasound examination using the formula for an ovoid: Volume=D1 (cm) x D2 (cm) x D3 (cm) x0.52 ml. The depth of the uterine cavity was measured by a uterine cavity probe during the operation. The menstrual volume was evaluated using the menstrual blood loss score (MBLS) (13). MBLS was calculated using the following formula: Days with heavy menstruation/total days with heavy menstruation x the quantity of menstruation pads used=MBLS. The quantity of menstruation pads used was evaluated according to the following scoring system: Mini pad equivalent to 1, normal pad equivalent to 1.5, super pad equivalent to 2 and night pad or super plus pad equivalent to 3. The degree of dysmenorrhea was evaluated using the visual analogue scale (VAS) (14).

Table I. Comparison of the clinical characteristics of patients before treatment. The experimental (underwent hysteroscopic LNG-IUD fixation) and control groups (underwent conventional implantation of LNG-IUD).

Variables	Total (n=31)	Control (n=15)	Experimental (n=16)	Statistical test	P-value
Uterine volume (ml), Mean ± SD	300.98±125.92	287.79±128.41	313.35±126.42	t=-0.56	0.581
Age (years), M (Q_1, Q_3)	44.00 (41.00, 46.00)	44.00 (40.50, 45.50)	44.50 (41.75, 47.00)	Z=-1.15	0.248
Uterine cavity (cm), M (Q_1, Q_3)	9.00 (9.00, 10.00)	9.00 (8.25, 10.00)	9.50 (9.00, 10.00)	Z=-1.72	0.086
VAS, M (Q_1, Q_3)	5.00 (3.50, 6.00)	6.00 (4.00, 6.00)	4.00 (2.75, 5.25)	Z=-1.86	0.063
MBLS, M (Q_1, Q_3)	12.00 (8.79, 18.00)	10.00 (6.43, 14.50)	15.00 (11.43, 18.75)	Z=-1.86	0.063
History treatment of GnRh-a in the past 6 months, n (%)				Fisher's exact test	0.066
No	12 (38.71)	3 (20.00)	9 (56.25)		
Yes	19 (61.29)	12 (80.00)	7 (43.75)		
History of vaginal delivery, n (%)				Fisher's exact test	1.000
No	11 (35.48)	5 (33.33)	6 (37.50)		
Yes	20 (64.52)	10 (66.67)	10 (62.50)		
History of cervical laceration, n (%)				Fisher's exact test	0.113
No	22 (70.97)	13 (86.67)	9 (56.25)		
Yes	9 (29.03)	2 (13.33)	7 (43.75)		
Menorrhagia, n (%)				Fisher's exact test	0.484
No	1 (3.23)	1 (6.67)	0 (0.00)		
Yes	30 (96.77)	14 (93.33)	16 (100.00)		
Dysmenorrhea, n (%)				Fisher's exact test	0.600
No	4 (12.90)	1 (6.67)	3 (18.75)		
Yes	27 (87.10)	14 (93.33)	13 (81.25)		

A total of 31 women with adenomyosis were recruited at the Affiliated Jinhua Hospital of Wenzhou Medical University (Jinhua, China) from June 2020 to June 2022. Mean ± SD, comparisons were performed using an independent-sample t-test. M (Q_1, Q_3), comparisons were performed using an independent-sample Wilcoxon rank sum test. Severity was marked with a VAS of 1 to 10 (0 indicating no pain and 10 indicating intolerable pain). SD, standard deviation; t, t-test; M, median; Q_1, 1st quartile; Q_3, 3rd quartile; Z, Mann-Whitney test; VAS, pain visual analogue scale; MBLS, menstrual blood loss score; GnRh-a, gonadotropin-releasing hormone agonist.

A history of gonadotropin-releasing hormone agonist (GnRH-a) treatment in the previous 6 months, a history of vaginal delivery and cervical laceration was recorded, and the incidence of perioperative complications such as air embolism, intravascular absorption syndrome of surgical hysteroscopy, infection and uterine perforation were observed.

Statistical analysis. Continuous variables of clinical characteristics were expressed as the mean ± SD or the median (Q_1,Q_3), and were evaluated using the independent sample t-test or Kruskal-Wallis test. Dichotomous variables between the groups were evaluated using the Fisher's exact test. Kaplan-Meier estimates were used to generate survival curves comparing patients who underwent hysteroscopic LNG-IUD fixation with the control group, and it was followed by the log-rank test. Univariable and multivariable associations [hazard ratio (HR) and associated 95% confidence interval (CI)] with IUD in-place variables were assessed using Cox regression analyses. $P<0.05$ was considered to indicate a statistically significant difference. Statistical analyses were performed using the statistical software SPSS 25 (IBM Corp.). Data processing and analysis were also performed using R version 4.3.0, along with Storm Statistical Platform (www.medsta.cn/software).

Results

General data. A total 31 patients with adenomyosis completed the research with 15 cases in the control group and 16 cases in the experimental group. Basic characteristics including age, uterine volume before treatment, uterine cavity depth, dysmenorrhea pain of VAS and MBLS before treatment were compared between the two groups. As demonstrated in Table I, no significant differences were observed between the two groups. The outcome was observed for 15.8±7.8 months post-surgery.

Table II. Comparison of the therapeutic outcomes after treatment of the experimental and control groups. The experimental (underwent hysteroscopic LNG-IUD fixation) and control groups (underwent conventional implantation of LNG-IUD).

Variables	Total (n=31)	Control (n=15)	Experimental (n=16)	Statistical test	P-value
Uterine volume after three months of treatment, Mean ± SD	279.97±117.88	283.50±106.27	276.66±131.26	t=0.16	0.875
Time of postoperative vaginal bleeding (day), M (Q_1, Q_3)	20.00 (10.00, 120.00)	120.00 (75.00, 120.00)	12.50 (9.25, 16.25)	Z=-2.65	0.008
LNG-IUD in place time (months), M (Q_1, Q_3)	15.00 (10.00, 23.00)	10.00 (6.50, 15.00)	20.50 (15.75, 24.00)	Z=-2.59	0.009
VAS after treatment, M (Q_1, Q_3)	1.00 (1.00, 2.50)	3.00 (1.50, 3.50)	1.00 (0.00, 1.00)	Z=-3.30	<0.001
MBLS after treatment, M (Q_1, Q_3)	1.20 (1.00, 4.17)	3.33(2.00, 6.90)	1.00 (1.00, 1.05)	Z=-3.56	<0.001
LNG-IUD expulsion, n (%)				-	0.002
No	21 (67.74)	6 (40.00)	15 (93.75)		
Yes	10 (32.26)	9 (60.00)	1 (6.25)		
HGB before treatment, Mean ± SD	88.55±21.69	91.27±24.46	86.0±19.19	t=0.67	0.509
HGB after treatment, Mean ± SD	125.87±18.94	120.4±21.39	131.0±15.24	t=-1.60	0.121
Increased HGB, Mean ± SD	37.32±24.35	29.13±24.12	45.0±22.64	t=-1.89	0.069

A total of 31 women with adenomyosis were recruited at the Affiliated Jinhua Hospital of Wenzhou Medical University (Jinhua, China) from June 2020 to June 2022. Severity was marked with a VAS of 1 to 10 (0 indicating no pain and 10 indicating intolerable pain). SD, standard deviation; t, t-test; M, median; Q_1, 1st quartile; Q_3, 3rd quartile; Z, Mann-Whitney test; LNG-IUD, levonorgestrel-releasing intrauterine device; VAS, pain visual analogue scale; MBLS, menstrual blood loss score; HGB, Hemoglobin.

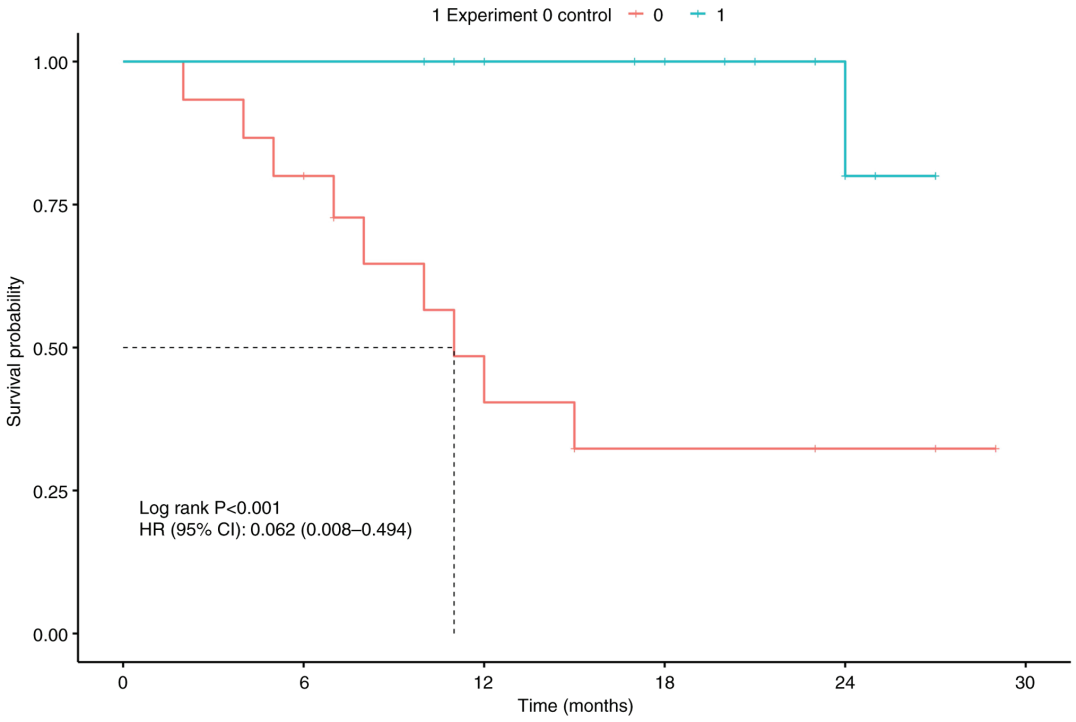

Figure 1. Kaplan-Meier survival curves of the experimental (underwent hysteroscopic LNG-IUD fixation) and control (underwent conventional implantation of LNG-IUD) groups. A total of 31 women with adenomyosis were recruited at the Affiliated Jinhua Hospital of Wenzhou Medical University (Jinhua, China) from June 2020 to June 2022. LNG-IUD; levonorgestrel-releasing intrauterine device; HR, hazard ratio; CI, confidence interval.

Comparison of the therapeutic outcomes post-treatment. The comparison of LNG-IUD expulsion rates between the two groups after intervention measures is revealed in Table II. The LNG-IUD expulsion rate in the experimental group (6.25%) was lower than that in the control group (60%; P<0.05). The Kaplan-Meier survival curve for the LNG-IUD is revealed in Fig. 1: The median in-place time of IUD in the experimental group was significantly higher than that in the control group. The LNG-IUD in-place time was significantly longer in the experimental group than in

Table III. Single-factor Cox regression analysis.

Variables	β	S.E	Z	P-value	HR (95% CI)
Age, years	-0.00	0.08	-0.00	1.000	1.00 (0.86-1.17)
Uterine cavity (cm)	0.32	0.37	0.87	0.383	1.38 (0.67-2.84)
Uterine volume before treatment (ml)	-0.00	0.00	-0.18	0.855	1.00 (0.99-1.00)
VAS before treatment	0.20	0.14	1.44	0.150	1.22 (0.93-1.61)
MBLS before treatment	-0.08	0.05	-1.42	0.156	0.93 (0.83-1.03)
Group experience 1 control 0					
1					Ref
0	2.78	1.06	2.63	0.009	16.11 (2.02-128.15)
GnRh a					
Yes					Ref
No	-1.26	0.79	-1.58	0.114	0.29 (0.06-1.35)
Vaginal delivery					
No					Ref
Yes	0.18	0.71	0.25	0.804	1.19 (0.30-4.77)
Cervical laceration					
No					Ref
Yes	-0.18	0.70	-0.26	0.795	0.83 (0.21-3.29)

A total of 31 women with adenomyosis were recruited at the Affiliated Jinhua Hospital of Wenzhou Medical University (Jinhua, China) from June 2020 to June 2022. The rate of the LNG-IUD expulsion was adjusted for treatment methods, age, uterine size, uterine cavity depth, vaginal delivery and cervical laceration. The experimental (underwent hysteroscopic LNG-IUD fixation) and control groups (underwent conventional implantation of LNG-IUD). HR, hazard ratio; CI, confidence interval; VAS, pain visual analogue scale; MBLS, menstrual blood loss score; GnRh-a, gonadotropin-releasing hormone agonist; LNG-IUD, levonorgestrel-releasing intrauterine device.

the control group at 20.50 (15.75, 24.00) and 10.00 (6.50, 15.00) months, respectively (P<0.05). The uterine volume of the two groups after three months of intervention measures was not significantly reduced and there were no statistical differences between the two groups (P>0.05). The MBLS of both groups was decreased after intervention measures, and the MBLS of the experimental group after treatment demonstrated a greater reduction than the control group, and the groups were significantly different (P<0.05). The VAS of the two groups were both decreased after intervention measures, however the VAS of the experimental group after treatment was reduced more sharply, with significant differences between the two groups (P<0.05). The time of postoperative vaginal bleeding in the experimental group was significantly shorter than the control group at 12.50 (9.25, 16.25) and 120.00 (75.00,120.00) days, respectively (P<0.05). The increased HGB after treatment in the experimental group (45.0±22.64 g/l) was higher than the control group (29.13±24.12 g/l), but there was no statistical difference between the two groups (P=0.069).

There were no complications reported, such as air embolism, intravascular absorption syndrome of surgical hysteroscopy, infection and uterine perforation, in the experimental or control groups.

Cox regression analysis. Compared with the conventional implantation of LNG-IUD, hysteroscopic LNG-IUD fixation surgery is the most important protective factor for LNG-IUD expulsion both in single- and multiple-factor Cox regression analyses, as demonstrated in Tables III and IV. Multiple-factor Cox regression analyses revealed that the LNG-IUD expulsion rate in patients with adenomyosis was associated with hysteroscopic LNG-IUD fixation surgery (HR, 1954.09), uterine cavity depth (HR, 16.63), MBLS (HR, 1.14), a history of GnRh-a treatment in the previous 6 months (HR, 2.10), a history of vaginal delivery (HR, 1.79) and a history of cervical laceration (HR, 3.69; Table IV). The conventional implantation of the LNG-IUS, uterine cavity depth, menorrhagia before treatment, no GnRh-a treatment in the previous 6 months, history of vaginal delivery and cervical laceration are promoting factors of LNG-IUD expulsion.

Discussion

Adenomyosis is a prevalent condition in the field of gynecology, marked by the infiltration of endometrial tissue within the muscular layer of the uterus (2). Prolonged and continuous bleeding can result in anemia and may also lead to mental health issues due to persistent pain during menstruation (2). Given that the condition adversely affects the quality of life through menstrual discomfort, reproductive health and fertility (2), it is imperative to establish long term and effective therapies for adenomyosis. The efficacy and safety of intrauterine placement of LNG-IUS for the treatment of adenomyosis have been validated, most scholars consider that LNG-IUS is the first-line treatment of adenomyosis (1,2). The

Table IV. Multiple-factor Cox regression analysis.

Variables	β	S.E	Z	P-value	HR (95% CI)
Uterine cavity (cm)	2.81	1.68	1.67	0.095	16.63 (0.61-451.34)
Uterine volume before treatment (ml)	-0.01	0.01	-0.95	0.341	0.99 (0.98-1.01)
VAS before treatment	-0.74	0.43	-1.73	0.084	0.48 (0.20-1.11)
MBLS before treatment	0.13	0.11	1.23	0.219	1.14 (0.93-1.40)
Group experimental 1 control 0					
1					Ref
0	7.58	3.00	2.52	0.012	1,954.09 (5.41-705,537.98)
GnRh a					
Yes					Ref
No	0.74	1.39	0.53	0.593	2.10 (0.14-31.75)
Vaginal delivery					
No					Ref
Yes	0.58	1.26	0.46	0.643	1.79 (0.15-20.99)
Cervical laceration					
No					Ref
Yes	1.31	1.23	1.07	0.287	3.69 (0.33-40.71)

A total of 31 women with adenomyosis were recruited at the Affiliated Jinhua Hospital of Wenzhou Medical University (Jinhua, China) from June 2020 to June 2022. The rate of the LNG-IUD expulsion was adjusted for treatment methods, age, uterine size, uterine cavity depth, vaginal delivery and cervical laceration. The experimental (underwent hysteroscopic LNG-IUD fixation) and control groups (underwent conventional implantation of LNG-IUD). HR, hazard ratio; CI, confidence interval; VAS, pain visual analogue scale; MBLS, menstrual blood loss score; GnRh-a, gonadotropin-releasing hormone agonist; LNG-IUD, levonorgestrel-releasing intrauterine device.

majority of patients with adenomyosis present with an enlarged uterine volume and thickened myometrium, increasing the risk of LNG-IUS descension and expulsion, thereby limiting its clinical application and therapeutic efficacy (7,8). Park *et al* (15) reported a relatively high rate of LNG-IUS expulsion in patients with adenomyosis, with rates reaching up to 37.5%. The incidence of expulsion decreased to 21.8% following pretreatment with GnRH-a (10). In the present study, the expulsion rate of LNG-IUD in patients who underwent the conventional method was as high as 60%. This may be related to the excessive uterine volume of the patients recruited in the present study.

A number of studies have reported on the effect of hysteroscopic LNG-IUS fixation at present. Currently, Gynefix is an available device specifically engineered to minimize the risk of IUD expulsion, because Gynefix can be fixed in the myometrium through a non-absorbable suture knot. However, it is not as clinically effective as LNG-IUS, because it does not contain levonorgestrel. The present study revealed the promising effects of hysteroscopic LNG-IUD fixation surgery in prolonging the in-position time of LNG-IUD with satisfactory results obtained. As aforementioned, only 1 in 16 patients expelled the LNG-IUS after follow-up. LNG-IUD in the uterine cavity was fixed through 3/0 prolene suture to decrease the rate of LNG-IUD expulsion, the suture material used was 3/0 Prolene suture (Johnson & Johnson). It was hypothesized that the patient with LNG-IUS expulsion may be related to the smaller fixed knot. The incidence of the expulsion of the LNG-IUS was comparable to that reported by Zhang *et al* (12), one in 12 patients expelled the LNG-IUS, who performed polydioxanone suture fixation of the LNG-IUS in the uterine cavity using the hysteroscopic cold knife surgery system. However, Peng *et al* (16), using a novel LNG-IUS insertion technique, reported an LNG-IUS expulsion rate in only 10.2% of patients. Hysteroscopic LNG-IUD fixation surgery provides a new option for patients with enlarged uterine volume, heavy menstrual flow and a history of repeated LNG-IUD shedding.

Certain limitations of the present study must be considered. Firstly, the results of the present study were constrained due to the study design being a controlled clinical trial rather than a randomized controlled trial, and therefore, bias could not be minimized. Second, the findings of the present study were limited by the small sample sizes in each group. Moreover, the clinical data was sourced from a single hospital rather than multiple centers. The results of multi-center inclusion of more patients are more convincing. A longer follow-up time is required to verify the long-term effectiveness of the new method. At present, ~50 hysteroscopic LNG-IUD fixation surgeries have been completed by the authors, and further advancements in research will be achieved through longer follow-up times and larger sample sizes.

Hysteroscopic LNG-IUD fixation surgery is an efficient technique that has achieved effective LNG-IUD fixation in the uterine cavity, with the advantages of being easy to operate, having a short learning curve, requiring no special equipment or instruments, causing minimal surgical trauma, having a short operation time, allowing for quick recovery and easy removal. Therefore, this procedure is suitable to be performed in hospitals at all levels.

In conclusion, for patients with adenomyosis experiencing dysmenorrhea or menorrhagia, hysteroscopic LNG-IUD fixation surgery could offer a minimally invasive and efficient alternative for the treatment of adenomyosis, and reduces the risk of LNG-IUS expulsion after a mean follow-up of >1 year. Hysteroscopic LNG-IUD fixation surgery is a favorable factor in reducing LNG-IUD expulsion and relieving the symptoms of dysmenorrhea or menorrhagia and is therefore a technology worth investigating further.

Acknowledgements

Not applicable.

Funding

The present study was supported by The Science and Technology Bureau Foundation of Jinhua (grant no. 2021-4-300).

Availability of data and materials

The data generated in the present study may be requested from the corresponding author.

Authors' contributions

PX, BY and JL performed the study conception and design and provided administrative support. SL and EH provided the study materials and recruited the patients. LM and EH collected and assembled the data. PX and BY performed the data analysis and interpretation. All authors wrote the manuscript. BY, JL and PX performed all the surgical operations. All authors read and approved the final manuscript. PX and BY confirm the authenticity of all the raw data.

Ethics approval and consent to participate

The present study was approved (approval no. IBR-2020033-R) by The Medical Ethics Committee of Affiliated Jinhua Hospital of Wenzhou Medical University (Jinhua, China). All patients signed informed consent.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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