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CLINICAL ARTICLE

Factors affecting the spontaneous expulsion of the levonorgestrel-releasing intrauterine system

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ABSTRACT

Objective: To estimate the incidence of, and identify risk factors for, spontaneous expulsion of the levonorgestrel-releasing intrauterine system (LNG-IUS). **Methods:** Pre-insertion characteristics for 481 women who received the LNG-IUS at a single institution in the Republic of Korea between 2003 and 2011 were analyzed retrospectively. The median duration of follow-up was 13.4 months. Kaplan–Meier plots were constructed to estimate the time to occurrence of spontaneous expulsion in multiple subgroups. **Results:** The overall crude incidence of spontaneous LNG-IUS expulsion was 9.6%. The cumulative incidence was 7.9%, 9.1%, and 9.6% at 1, 2, and 3 years, respectively. It was significantly higher in women with adenomyosis (9.1%, 10.6%, and 11.1%) or uterine leiomyoma (14.5%, 15.8%, and 15.8%) than in those with a normal uterus (3.6%, 4.1%, and 4.6%) ($P = 0.008$). Women with heavy menstrual bleeding (11.0%, 12.7%, and 13.4%), dysmenorrhea (8.1%, 9.0%, and 10.0%), or pre-insertion receipt of gonadotropin-releasing hormone agonists (13.3%, 16.0%, and 17.3%) also had higher cumulative incidences than those without these conditions ($P < 0.05$). Most (84.5%) women with a spontaneous expulsion chose to discontinue the device. **Conclusion:** Clinicians need to be aware of the risk factors for spontaneous LNG-IUS expulsion because this can lead to a discontinuation of its use.

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1. Introduction

The levonorgestrel-releasing intrauterine system (LNG-IUS) was initially developed as a contraceptive device, but it is currently widely used for the symptomatic management of heavy menstrual bleeding (HMB) and/or dysmenorrhea [1]. Its use reduces menstrual blood loss more effectively than other medical therapies [2]. In addition, the LNG-IUS and endometrial ablation seem to reduce menstrual blood loss to a similar extent [2,3].

Although the LNG-IUS is effective for the management of various menstruation-related symptoms, some women experience spontaneous expulsion, and in others, premature removal is necessary because of persistent symptoms. In the latter situation, most women receive alternative medical or surgical treatment. During LNG-IUS use, treatment failure is usually defined as spontaneous expulsion or intentional removal. The overall treatment failure rate was reported to be 11% within 1 year and 28% within 2 years [4,5]. Discontinuation rates

because of adverse effects range from 5% to 20% within 1 year [1]. Partial or complete expulsion rates range from 4.4% to 9.9%, but vary depending on observation time [1,6,7].

Some women opt for re-insertion of the LNG-IUS if spontaneous expulsion occurs; therefore, spontaneous expulsion does not always lead to treatment failure. In a report from the Republic of Korea [8], spontaneous expulsion of the LNG-IUS was observed during a follow-up examination in 31.1% of 103 women with adenomyosis-associated HMB or dysmenorrhea. However, 17 patients requested re-insertion of the LNG-IUS. After the exclusion of women with premature LNG-IUS removal, hysterectomy, or natural menopause, the LNG-IUS continuation rate was 74.8%. In the Asian-Pacific region, the overall continuation rate was 87.6% at 12 months among 483 women with idiopathic HMB [9].

Spontaneous expulsion of an intrauterine device is closely related with contraceptive failure risk [10]. In addition, spontaneous expulsion of the LNG-IUS may give rise to persistent symptoms and has financial implications for the patient. It may also lead to earlier discontinuation of the LNG-IUS. To maximize the efficacy of the LNG-IUS, it is therefore important to identify the risk factors associated with its spontaneous expulsion.

Unfortunately, there is little evidence concerning risk factors for LNG-IUS expulsion. In a previous study [7], parity and a larger uterine sounding depth were associated with an incorrect positioning of the LNG-IUS, whereas older age and hypermenorrhea were not. Another

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study [6] failed to demonstrate an association between endometrial cavity length and expulsion of the LNG-IUS.

It is largely unknown whether the incidence of spontaneous expulsion is affected by uterine lesions such as adenomyosis or leiomyoma and symptoms such as HMB or dysmenorrhea. Uterine cavity distortions in women with leiomyoma could make retention of the LNG-IUS within the cavity more difficult and increase the likelihood of expulsion. It is also possible that HMB may cause a spontaneous expulsion because of its washing-out effect. The present study aimed to identify risk factors contributing to the spontaneous expulsion of the LNG-IUS.

2. Materials and methods

A total of 481 women who underwent placement of an LNG-IUS (Mirena; Bayer HealthCare, Leverkusen, Germany) were selected retrospectively. The LNG-IUS was inserted between January 1, 2003, and December 31, 2011, at the Seoul National University Bundang Hospital, Seongnam, Republic of Korea. The study included only those women who revisited the hospital at least once after the insertion. The LNG-IUS was mostly inserted by senior residents, but in some selective women it was inserted by fellows or professors. The ultrasonography examination was usually performed 1 month later by a professor. All women underwent interval insertion with the exception of one woman who had a postabortion insertion at 6 weeks. No insertion was performed immediately postpartum. Informed consent was not needed because of the retrospective design of the present study; however, the Institutional Review Board of the study hospital approved the use of the patients' medical records.

Variables analyzed included age (mean, 41.3 ± 5.4 years [range, 18–53 years]), previous LNG-IUS use, parity (data missing for 34 [7.0%] women), number of children, mode of delivery (data missing for 39 [9.6%] of 404 parous women), patient-reported HMB (data missing for 145 [30.1%] women), patient-reported dysmenorrhea (data missing for 207 [43.0%] women), associated pelvic endometriosis identified by ultrasonography, use of gonadotropin-releasing hormone (GnRH) agonists before the insertion (mean number, 2.5 ± 1.5 [range, 1–8]), and use of oral contraceptives after the insertion as indicated in Table 1.

The following classification was used to evaluate the effect of underlying uterine lesions: normal uterus, defined as a normal-appearing uterus or a uterus with small myomas not distorting the cavity; adenomyosis, defined as adenomyosis with or without small myomas; and leiomyomas, defined as leiomyomas significantly distorting the cavity. In women with leiomyomas, the mean number of myomas was 2.0 ± 1.6 (range, 1–10) and the mean diameter of the largest myoma was 4.5 ± 1.9 cm (range, 1.2–9.0 cm).

The following three variables were excluded from the analysis because data were missing for more than 50% of women: hemoglobin level within 2 months (data were missing for 313 [65.1%] women; mean value, 10.6 ± 2.5 g/dL [range, 5–16 g/dL]); uterine length measured by ultrasonography (data were missing for 258 [53.6%] women; mean value, 9.0 ± 1.6 cm [range, 5–14 cm]); and uterine length measured by sounding (data were missing for 259 [53.8%] women; mean value, 8.1 ± 1.1 cm [range, 6–12 cm]).

The median duration of follow-up was 13.4 months (range, 0.2–92.8 months). During the follow-up examination, spontaneous expulsion or discontinuation was recorded. Periodic change every 5 years was not considered as a removal. If spontaneous expulsion occurred, the use of additional treatments such as re-insertion or conversion to alternative therapies was recorded. If the LNG-IUS was prematurely removed, the reasons were recorded and alternative therapies were pursued. The duration from insertion to event occurrence was recorded in months. If no event occurred, the last follow-up date was recorded as the number of months since insertion.

Given the retrospective nature of the present study, data on the duration of symptoms and the previous use of medical treatments

Table 1

Distribution of categorical variables among women using the LNG-IUS (n = 481).

Variable	Number (%)
Previous LNG-IUS use	38 (7.9)
Parity	
Parous	404 (84.0)
Not parous	43 (8.9)
Unknown	34 (7.1)
Number of children ^a	
0	3 (0.6)
1	105 (21.8)
2	260 (54.1)
3	36 (7.5)
Mode of delivery ^a	
Previous cesarean delivery	140 (29.1)
Previous vaginal delivery	225 (46.8)
Unknown	39 (8.1)
Uterine lesions	
Normal	195 (40.5)
Adenomyosis	198 (41.2)
Leiomyomas	76 (15.8)
Adenomyosis + leiomyomas	12 (2.5)
Heavy menstrual bleeding	
Yes	283 (58.8)
No	53 (11.0)
Unknown	145 (30.2)
Dysmenorrhea	
Yes	210 (43.7)
No	64 (13.3)
Unknown	207 (43.0)
Associated pelvic endometriosis	12 (2.5)
GnRH agonists before insertion	75 (15.6)
Oral contraceptives after insertion	34 (7.1)

Abbreviations: GnRH, gonadotropin-releasing hormone; LNG-IUS, levonorgestrel-releasing intrauterine system.

^a Parous women only (n = 404).

could not be obtained. Likewise, data on symptom improvement and uterine size changes could not be obtained. The LNG-IUS was usually inserted without performance of an endometrial biopsy; thus, no data about endometrial pathology were collected.

The statistical analysis was performed with SPSS version 18.0 (IBM, Armonk, NY, USA). $P < 0.05$ was considered statistically significant. Kaplan–Meier plots were constructed to estimate the time to occurrence of spontaneous expulsion in multiple subgroups. To compare the duration of follow-up within the subgroups, the Wilcoxon test was used for comparisons between two variables and the Kruskal–Wallis test was used for comparisons between three variables, because the duration of follow-up did not show a normal distribution.

3. Results

The overall crude incidence of spontaneous expulsion was 9.6% (46/481). The earliest expulsion occurred at 7 days and the latest expulsion occurred at 27.2 months. Of the 46 women who had a spontaneous expulsion, seven (15.2%) requested a re-insertion, but re-expulsion occurred in one woman. The majority (84.8%, 39/46) of the women with a spontaneous expulsion chose to discontinue the LNG-IUS.

The cumulative incidence of spontaneous expulsion in the study population was 7.9% (n = 38) at 1 year, 9.1% (n = 44) at 2 years, and 9.6% (n = 46) at 3 years. It was significantly higher ($P = 0.008$) among women with adenomyosis or uterine leiomyomas than among those with a normal uterus (Table 2, Fig. 1A). Symptomatic women also had a significantly higher cumulative incidence than those without symptoms (HMB, $P = 0.002$; dysmenorrhea, $P = 0.016$) (Fig. 1B and C). Finally, the cumulative incidence was higher among women who had received GnRH agonists pre-insertion than among those who did not ($P = 0.021$) (Fig. 1D).

Parity, number of children, mode of delivery, and oral contraceptive use after insertion did not contribute to the occurrence of spontaneous

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