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Original Article

Clinical experiences of the levonorgestrel-releasing intrauterine system in patients with large symptomatic adenomyosis

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ABSTRACT

Objective: The objective of this study was to evaluate the clinical aspects of the levonorgestrel-releasing intrauterine system (LNG-IUS) in patients with large adenomyosis associated with dysmenorrhea and/or heavy menstrual bleeding (HMB).

Materials and methods: Data were collected retrospectively from 48 patients with large adenomyosis (gestational age $\geq$ 12 weeks during pelvic examination) diagnosed via transvaginal ultrasonography between January 2008 and December 2009. Clinical outcomes, including symptomatic changes of dysmenorrhea and HMB, uterine volume change, complications, and the overall success rate were evaluated in each patient after treatment with the LNG-IUS.

Results: The patients' mean age was 41.7 ± 6.1 years, and the median follow-up duration was 20 months (range, 3–50 months). Significant improvements ($p < 0.01$) in dysmenorrhea and HMB were observed. There was no significant change in the uterine volume. The most common side effects were prolonged vaginal spotting ($n = 28$, 58.3%) and LNG-IUS expulsion ($n = 18$, 37.5%). Five (10.4%) patients underwent premature LNG-IUS removal and eight (16.7%) patients underwent hysterectomy. The overall success rate of the LNG-IUS was 68.8%.

Conclusion: The LNG-IUS is a suitable alternative treatment option for the management of dysmenorrhea and HMB prior to hysterectomy, for patients with large adenomyosis.

Introduction

Adenomyosis is a common gynecological disorder characterized by the presence of endometrial glands and/or stroma in the myometrium [1]. It is an important cause of dysmenorrhea and heavy menstrual bleeding (HMB), which occur in ~ 65% of women with adenomyosis and can result in a poor quality of life [2,3]. Traditionally, the diagnosis of adenomyosis was based on clinical findings and pathologic confirmation after hysterectomy. However, transvaginal ultrasonography (TVS) and magnetic resonance imaging have been shown to be accurate, noninvasive methods for diagnosis [3–6]. The development of such imaging techniques, significantly, offers women the options of medical and/or minimally invasive surgical treatments. The various medical treatment modalities for symptomatic adenomyosis include oral contraceptives, danazol, oral progestins, injectable progestins, gonadotropin-releasing hormone agonists, and the levonorgestrel-releasing intrauterine system (LNG-IUS). Minimally invasive surgical methods include uterine artery embolization, endometrial resection/ablation, and magnetic resonance-guided focused ultrasonography [6–10].

The noncontraceptive benefits of the LNG-IUS, particularly the effects on dysmenorrhea and HMB, have been proven to be effective against adenomyosis in many clinical trials; a significant decrease in dysmenorrhea and HMB in a majority of women was observed in five of these trials [2,3,11–13]. In a randomized comparison study, an enhancement in all aspects of the quality of life in hysterectomy patients was observed with the LNG-IUS during the 1-year follow-up [14]. However, there has been only one case report about the treatment of large symptomatic adenomyosis with the LNG-IUS [2]. Therefore, the objective of this study was to specifically evaluate the clinical aspects, including symptomatic

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changes, side effects, and the overall success rate, of the LNG-IUS in patients with large adenomyosis (gestational age ≥ 12 weeks during pelvic examination) associated with dysmenorrhea and/or HMB.

Materials and methods

A total of 48 premenopausal patients (27–53 years) participated in a retrospective study conducted from January 2008 to December 2009. The patients were diagnosed with adenomyosis using TVS and had a uterine size ≥ 12 gestational weeks during the pelvic examination along with symptoms of dysmenorrhea and/or HMB. All patients refused to undergo hysterectomy or use oral contraceptives, and provided informed consent for treatment of symptomatic adenomyosis with the LNG-IUS. This study was approved by the Institutional Review Board of CHA Gangnam Medical Center, CHA University, Seoul, Korea. The diagnostic criteria for adenomyosis with TVS had been reported in previous studies: globular and/or asymmetric thickening of the uterine wall, myometrial cysts, distorted and heterogeneous myometrial echotexture, focal or diffuse heterogeneous myometrial echotexture, a poorly defined endometrial–myometrial junction, and a poorly defined focus of abnormal myometrial echotexture [15,16]. The uterine volume was calculated using the formula for an ellipsoid (volume = 0.52 × length × anteroposterior diameter × transverse diameter).

The LNG-IUS was inserted into the uterine cavity during Days 5–7 of the menstrual cycle of all patients. After insertion of the LNG-IUS, we recommended follow-up visits every 3–6 months during the 1st year and every 6–12 months thereafter. Each follow-up visit typically entailed monitoring symptomatic changes of dysmenorrhea and/or HMB and TVS examinations to confirm the uterine volume and location of the LNG-IUS. Symptomatic changes were evaluated with a visual analog scale (VAS). Preinsertion symptoms of dysmenorrhea and HMB were assessed using a linear scale, with the left extreme defined as “no pain or no bleeding” (0 mm) and the right extreme defined as “worst pain or worst bleeding I have ever felt” (100 mm). The score itself was determined by measuring the distance from the left side of the scale to the point marked by patients as their level of pain and amount of menstrual blood. Any special events, such as an abrupt onset of bleeding or spontaneous LNG-IUS expulsion, were recorded as a complication or side effect. All follow-up data (i.e., symptomatic changes, side effects, and TVS findings) were retrospectively collected and analyzed.

Statistical analyses were performed using SPSS software for Windows version 20 (SPSS Inc., Chicago, IL, USA). The Shapiro–Wilk test was used to test the normality of the data. Descriptive data were expressed as the mean ± standard deviation. Skewed data were within the median and range. A Wilcoxon signed rank test was used to compare the subjective changes in symptoms and the uterine volume prior to and after the LNG-IUS insertion. Statistical significance was set at $p < 0.05$. All statistical tests were two-sided.

Results

During the study period, a total of 176 patients with dysmenorrhea and/or HMB were diagnosed with adenomyosis using TVS and treated with the LNG-IUS. Among these patients, 48 women showed a uterine volume ≥ 12 gestational weeks during the pelvic examination. The mean age of the 48 enrolled patients was 41.7 ± 6.1 years and the median follow-up duration was 20 months (3–50 months). The median uterine volume before the LNG-IUS insertion was 253.5 mL (range, 201–687 mL). The baseline characteristics and initial symptoms of the patients are listed in Table 1.

Table 1
Patients' baseline characteristics.

Characteristics	Mean ± SD or median (range), *n* (%)
Age (y)	41.7 ± 6.1
Gravidity	3 (0–7)
Parity	2 (0–3)
Body weight (kg)	57.8 ± 8.2
Height (cm)	159.6 ± 4.4
BMI (kg/m^2)	22.7 ± 3.0
Initial uterine volume (cm^3)	253.5 (201–687)
Follow-up duration (mo)	20 (3–50)
Initial symptoms	
Heavy menstrual bleeding (HMB), only	10 (20.8)
Dysmenorrhea, only	8 (16.7)
HMB + dysmenorrhea	30 (62.5)

SD = standard deviation.

Approximately 60% of the patients had both HMB and dysmenorrhea prior to the LNG-IUS insertion.

The mean VAS score for dysmenorrhea and HMB decreased after the LNG-IUS insertion. The mean symptom score for dysmenorrhea remarkably decreased from 5.81 ± 2.96 to 2.86 ± 2.8 after 3 months ($p < 0.01$); after 36 months, the mean symptom score decreased to 1.4 ± 1.65 ($p < 0.01$). The mean score for the subjective symptoms of HMB also decreased continuously similar to dysmenorrhea (from 6.94 ± 2.61 to 3.25 ± 3.02 after 3 months, $p < 0.01$; and to 0.89 ± 1.27 after 36 months, $p < 0.01$; Table 2).

The median uterine volume decreased from 253.5 mL to 232.5 mL after 6 months; after 36 months, it had increased to 267 mL. Nonetheless, these were no significant differences between the initial uterine volume and the volumes at 6 months and 36 months (Figure 1).

The most common side effect was abnormal uterine bleeding. Twenty-eight patients (58.3%) complained of prolonged vaginal spotting. Seventeen patients (35.4%) suffered from lower abdominal pain or lower back pain, and 17 patients (35.4%) reported watery discharge or foul odor from the vagina. However, these side effects were tolerable in most cases. Only three patients who complained of prolonged spotting and one patient who complained of abdominal pain requested the removal of the LNG-IUS.

Eighteen patients (37.5%) reported LNG-IUS expulsion. Most of the patients (11/18 patients) who experienced LNG-IUS expulsion wanted to reuse it because they had been satisfied with its clinical effects; however, four of these 11 patients experienced a second LNG-IUS expulsion. Seven of the 18 patients elected to discontinue using the LNG-IUS because they wanted to observe their symptoms without any interventions. Out of the four patients who experienced a second expulsion, one patient had the LNG-IUS reinserted and after that she did not experience a third expulsion during the follow-up periods. All expulsions occurred during the first 12 months, and most expulsions ($n = 15$) occurred during the first 6 months. There was no significant difference in the uterine volume between the expulsion [266.5 mL (201–687 mL)] and without expulsion [248.5 mL (201–384 mL)] groups ($p = 0.406$).

During the follow-up periods, 22 patients (45.8%) continued to use the LNG-IUS for treating adenomyosis. Five patients (10.4%) withdrew from treatment with the LNG-IUS owing to complications. Two patients (4.2%) had the LNG-IUS removed for a pregnancy trial, and one patient (2.1%) opted for LNG-IUS removal after menopause.

A total of eight patients (16.7%) underwent hysterectomy because of prolonged spotting ($n = 3$; 6.3%), repeated LNG-IUS expulsion ($n = 3$; 6.3%), severe abdominal pain ($n = 1$; 2.1%), and a lack of symptomatic improvement in HMB ($n = 1$; 2.1%).