

Roller-ball endometrial ablation versus levonorgestrel releasing intrauterine system in the management of abnormal uterine bleeding

Abstract

Objective. The aim of this study was to evaluate the efficacy of the levonorgestrel intrauterine system (LNG-IUS) of abnormal uterine bleeding management in comparison to endometrial ablation. **Methods.** This prospective study was conducted on 58 patients. They randomly received either surgical treatment as roller-ball endometrial ablation (31 patients, group 1) or drug therapy as LNG-IUS (27 patients, group 2). Pictorial blood assessment chart (PBAC) scores and hemoglobin levels were measured before roller-ball endometrial ablation or LNG-IUS treatment. Both measurements were taken before and after one year. **Results.** PBAC scores dropped, while hemoglobin levels increased in both groups after one year. There was no statistical difference between the two groups ($p > 0.05$). No major complications occurred with either treatment modality. **Conclusions.** In the management of abnormal uterine bleeding, LNG-IUS and endometrial ablation appear to have similar therapeutic effects up to one year after treatment. Therefore, treatment should be tailored to the individual needs and preferences of the woman.

Keywords: levonorgestrel, uterine bleeding, endometrial ablation, hemoglobin, therapy

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Introduction

Abnormal uterine bleeding affects 20-30% of women in premenopausal period and is, therefore, the most common complaint encountered by gynecologists^(1,2). While the pharmacological approach is the very first line of treatment option, the success rates of treatment show variability and a significant number of patients do not respond to conservative treatments. As a consequence, about 180,000 hysterectomies are performed in the United States alone each year^(3,4). Even though hysterectomy cures the menorrhagia efficiently, postoperative complication rates are approximately 9%, while 1% of them are critical. The mortality rate is around 0.38 per 1000⁽⁵⁾.

It is the goal of modern medicine to find and use efficient and less invasive techniques in the treatment of abnormal uterine bleeding, which enable patients to return to their life as soon as possible⁽⁶⁾. Roller-ball endometrial ablation (RBEA) causes permanent destruction of the endometrium, which has a success rate of 85-90%⁽⁷⁾. The levonorgestrel intrauterine system (LNG-IUS), an intrauterine hormone system, is an effective option for treatment, which is used in the patients who do not respond to oral hormone therapy⁽⁸⁾.

In this study, our aim was to compare RBEA and LNG-IUS for the treatment of abnormal uterine bleeding.

Methods

The prospective study was conducted on 58 patients who were admitted to the Gynecology Clinic of Istanbul University School of Medicine with abnormal uterine bleeding which have not responded to medical treatment (i.e. oral

progesterone, combined oral contraceptive, non steroid anti-inflammatory drugs, and so forth). Research ethics committee approval was obtained before data collection commenced and informed consent was obtained from each patient prior to the procedure.

Patients were randomized chosen in a 1:1 ratio to either receive LNG-IUS or RBEA treatment.

They were followed-up to one year after treatment. Pelvic examination and transvaginal ultrasound (TVUS) were performed. All patients were also tested for pregnancy. One month before the treatment starting, endometrial sampling with pipelle curette was performed. Furthermore, Papanicolaou test (Pap smear) was used to detect any potential malignancy.

Inclusion criteria for the study were: higher 35 years old, regular menstrual cycle, and a score of 100 in Pictorial Bleeding Assessment Chart (PBAC). Exclusion criteria included: ongoing pregnancy, pelvic infection, an abnormality in the uterus, uterine cavity and/or suspicious endometrial pathology which was screened by TVUS, an abnormal cervical or endometrial histology, an accompanying pathology that may require a hysterectomy (i.e. adnexal mass, uterine prolapse etc.), contraindication to the administration of anesthetic agents and desire to preserve fertility. Consequently, the group with abnormal uterine bleeding was mainly composed of patients with dysfunctional uterine bleeding and patients with endometrial hyperplasia.

A number of 31 patients (group 1) had a RBEA by an obstetrics and gynecologist specialist and LNG-IUS (Mirena®, Bayer Pharma AG, Berlin, Germany) was placed in

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the first fifteen days of their menstrual cycle to 27 patients (group 2).

Gonadotropin-releasing hormone (GnRH) analogues to prepare the endometrium for endometrial ablation were not used in the RBEA group.

PBAC scoring system was used to assess the amount of bleeding in the patients. All patients were asked to complete their PBAC during menstrual cycle, and they were given both verbal and written instructions on how to complete their chart. While completing the PBAC, patients took into account the number of pads used and necessity for frequent changing (every 30 minutes to 2 hours). PBAC was scored as described by Higham et al.⁽⁹⁾. Follow-up visits were scheduled every three months. During these follow-ups, potential adverse effects and bleeding patterns were investigated.

PBAC scores and hemoglobin levels were noted before and after one year insertion or operation. At one year interval after the treatment, satisfaction of the patients was evaluated by means of asking patients to assess both baseline and current status in a simple five-point satisfaction scale using the terms “very satisfied”, “satisfied”, “neutral”, “unsatisfied” and “very unsatisfied”.

Statistical analysis was performed using the SPSS for Windows, version 16 (SPSS Inc., Chicago, IL, USA). Parametric variables were evaluated by chi-square test and Student’s t-test, while non-parametric variables were evaluated by the Mann Whitney U-test. $p < 0.05$ was considered statistically significant.

Results

Endometrial biopsy and curettage results of the patients were as follows: in RBEA group, seven patients had simple non-atypical endometrial hyperplasia, 15 patients had estrogen (E2) effect, seven patients had progesterone effect and two patients had dysfunctional changes; in LNG-IUS group, three patients had simple non-atypical endometrial

hyperplasia, 13 patients had estrogen (E2) effect, seven patients had progesterone effect, four patients had dysfunctional changes.

Two patients in LNG-IUS group requested the removal of the instrument at the end of three months due to bleeding. Afterwards, these patients were treated by hysteroscopic endometrial resection. At the end of one year, treatment of seven patients (25%) in LNG-IUS group was unsuccessful. Therefore, three of seven patients had a hysterectomy, while three patients had hysteroscopic endometrial resection and one patient received adjunct medical treatment. The most common side-effect due to the usage of LNG-IUS was spotting, especially in the first three months. In LNG-IUS group, 18 patients (66%) were available for follow-up after one year. Amenorrhea and hypomenorrhea rates were 38.8% and 61.1%, respectively; the satisfaction with bleeding pattern was 62% (including “satisfied” and “very satisfied” patients according to the five point satisfaction scale) (Tables 1 and 2).

One patient in RBEA group did not show up for the follow-up. Six patients (19%) still had bleeding, and they were operated again. Four of these six patients had endometrial resection, and two were hysterectomized. One patient had endometrial collection due to synechia; drainage was performed once the cervix was dilated. In RBEA group, 24 patients (80%) were available for follow-up after one year. Amenorrhea and hypomenorrhea rates were 29% and 70%, respectively; the satisfaction with bleeding pattern was 70% (including “satisfied” and “very satisfied” patients according to the five point satisfaction scale) (Tables 1 and 2).

Hemoglobin (Hb) concentration before the treatments was reported as 9.9 ± 1.7 g/dl in the RBEA group and 10.2 ± 1.6 g/dl in the LNG-IUS group, while PBAC scores were found as 440 in RBEA group and 480 in LNG-IUS group. After the treatments, Hb concentrations increased (11.0 ± 1.6 g/dl for RBEA and 11.1 ± 1.5 g/dl for LNG-IUS) while PBAC

Table 1

Comparison of RBEA and LNG-IUS for hypomenorrhea, amenorrhoea and patient satisfaction rates one year after treatments

	RBEA	LNG-IUS	p
Hypomenorrhea	70% (17/24)	61.1% (11/18)	0.06
Amenorrhoea	29% (7/24)	38.8% (7/18)	0.08
Patient Satisfaction	70% (22/31)	62% (17/27)	0.08

Table 2

Comparison of RBEA and LNG-IUS for additional treatments

	RBEA	LNG-IUS	p
Continuation of initial treatment	24/30 (%80)	18/27 (%66)	>0.05
Adjunct Medical Therapy	0	1/27 (%3)	>0.05
Hysteroscopic Resection	4/30 (%13)	5/27 (%18)	>0.05
Hysterectomy	2/30 (%6)	3/27 (%11)	>0.05

Table 3

Comparison of RBEA and LNG-IUS for Hemoglobin (Hb) counts before and after treatments

	Hemoglobin (Hb)		p
	RBEA	LNG-IUS	
Before treatment	9.9±1.7 (31 patients)	10.2±1.6 (27 patients)	>0.05
One year after treatment	11.0±1.6 (24 patients)	11.1±1.5 (18 patients)	>0.05

Table 4

Comparison of PBAC scores before and after treatments

	PBAC		p
	RBEA	LNG-IUS	
Before treatment	440 (31 patients)	480 (27 patients)	>0.05
One year after treatment	55 (24 patients)	70 (18 patients)	>0.05

scores decreased (55 for RBEA and 70 for LNG-IUS) in both groups. On the other hand, no significant difference could be found in the Hb concentrations and PBAC scores between the groups ($p > 0.05$) (Tables 3 and 4).

Discussion

One study in which both RBEA and LNG-IUS were compared prospectively in the treatment of resistant hypermenorrhea, founded 46% and 40% rates of amenorrhea, while the satisfaction rate was 93% and 73%, respectively⁽¹⁰⁾. There was no statistical difference between the two groups, being well correlated with our results.

In the study of Rosati et al.⁽¹¹⁾, the rate of amenorrhea after endometrial ablation was 47.8%, which was higher than our findings (29%). In another study, 200 patients treated with RBEA were followed-up to 2.5 years having the necessity to repeat the procedure and hysterectomy rates were 90%, 4% and 5%⁽¹²⁾. Similarly, in our study, treatment failed in two patients (6%) in RBEA group and three patients (11%) in LNG-IUS group. All five of these patients were treated again by hysterectomy. It can be argued that less surgical intervention was needed in RBEA group, yet the difference is not statistically significant. Another prospective, non-randomized study, showed that 63 patients suffering from menorrhagia were followed-up to four years after LNG-IUS treatment, presenting amenorrhea, further treatment and intervention (hysterectomy) rates of 28.5%, 71.4% and 15.8%⁽¹³⁾. In contrast, in our study, four patients in RBEA group (13%) and five patients in LNG-IUS group (18%) were treated with hysteroscopic endometrial resection due to treatment failure.

Interestingly, one of the advantages of LNG-IUS is its additional benefit as a contraceptive method. Endometrial ablation affects fertility because it destroys endometrium, but it cannot be used as a birth-control method. Furthermore, RBEA is an invasive procedure and requires an experienced gynecologist and administration of anesthetics in

comparison with LNG-IUS, which is a simpler treatment modality, without the need of anesthesia.

Conclusions

The results of our study showed the efficacy of the LNG-IUS in the management of abnormal uterine bleeding which appears to have similar therapeutic effects to that of endometrial ablation up to one year after treatment. Therefore, treatment should be tailored to the individual needs and preferences of the woman. ■

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