ORIGINAL ARTICLE

Endometrial Ablation vs Levonorgestrel Therapy in Management of Simple Endometrial Hyperplasia in Perimenopausal Women with Abnormal Uterine Bleeding

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Abstract

Background: ***Variations from regular menstrual cycles that continue for at least six months after menarche in reproductive-aged women who are not pregnant are referred to as abnormal uterine hemorrhage. At least 30% of reproductive-aged women seek medical attention for this issue.***

Aim and objectives: ***To evaluate the efficacy of endometrial ablation vs levonorgestrel treatment for the treatment of uncomplicated endometrial hyperplasia in postmenopausal women experiencing abnormal vaginal bleeding.***

Patients and methods: ***One hundred participants were included in this prospective interventional trial from November 2023 to September 2024 from the Al-Azhar University Hospitals' outpatient obstetrics and gynecology clinics. The systematic random method was used for sample collection.***

Results: ***Both treatment groups showed a notable decrease in endometrial thickness ($p < 0.001$). In contrast to Group 2, which had levonorgestrel medication, Group 1, which underwent endometrial ablation, demonstrated a more significant reduction. The mean rank for endometrial thickness pre-treatment was 44.78 for Group 1 and 56.22 for Group 2, while post-treatment, it was 31.74 for Group 1 and 69.26 for Group 2. This indicates that endometrial ablation was more effective in reducing endometrial thickness.***

Conclusion: ***Our study showed that there were fewer adverse effects and better results in reducing endometrial thickness and controlling menstrual blood loss. While endometrial ablation showed better outcomes in our study, it is a surgical procedure that permanently affects the endometrium, which may not be suitable for all patients.***

Keywords: Endometrial ablation; Uterine bleeding; Perimenopausal women; Levonorgestrel therapy

1. Introduction

Nonpregnant women of childbearing age who experience deviations from menstrual-like bleeding patterns that last for six months or more are said to be experiencing abnormal uterine bleeding. At least 30% of reproductive-aged women seek medical attention for this issue. Health care costs rise and quality of life falls as a result of this prevalent illness. Endometrial polyps, fibrosis, anovulation, submucous fibroids, and endometrial hyperplasia are common causes of irregular uterine bleeding.[1]

Despite its benign appearance, endometrial hyperplasia (EH) carries the risk of cancer. Simple EH is the most prevalent kind. As a prevalent diagnosis, endometrial hyperplasia (EH) affects 5–15% of women with gynecological issues, such as irregular uterine bleeding. Noninvasive proliferation of the uterine lining causes an abnormal morphologic pattern of glands of varied sizes and shapes in EH, a precancerous condition.[2]

Endometrial hyperplasia is estimated to occur at 133 cases per 100,000 woman-years, and its frequency rises with age. It is most common in women between the ages of 50 and 54 and is quite uncommon in women younger than 30. The conventional four-tier categorization of simple and complex hyperplasia with and without atypia has been revised in light of recent genetic discoveries that shed light on its etiology.[3]

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Prior research has demonstrated that endometrial resection and ablation are beneficial procedures for long-term therapy of endometrial hyperplasia without atypia. Endometrial hyperplasia without atypia can be safely treated by endometrial ablation. The difficulty in verifying total endometrial destruction is one drawback of this method. Obliteration of the endometrial cavity, which can make continued surveillance problematic, is especially worrisome for individuals with persistent risk factors for endometrial cancer.[4]

In perimenopausal women experiencing abnormal uterine bleeding, this study was a contrast of endometrial ablation with levonorgestrel treatment for the management of simple endometrial hyperplasia.

2. Patients and methods

A total of one hundred individuals were enrolled in this prospective interventional trial between November 2023 and September 2024 at Al-Azhar University Hospital (Al-Hussien) outpatient obstetrics and gynecology clinics. We used a systematic random sampling procedure to gather our samples.

Inclusion criteria:

The following groups of people are eligible for endometrial sampling: endometrial biopsy done in all patients with SEH in all biopsies, women between the ages of 47 and 54, women who are currently menstruating and experiencing abnormal uterine bleeding, women who are perimenopausal and experiencing thickened endometrium, and any woman who has histological evidence of simple endometrial hyperplasia.

Exclusion criteria:

For example, if you are pregnant or think you might be pregnant, you should not use Mirena. If you have any of the following conditions: an inflammatory disease of the genital tract, abnormal bleeding in the genital area, an allergic reaction to any of the ingredients in Mirena, a uterine anomaly (congenital or acquired), a history of hormone-dependent cancers (such as breast cancer), a history of uterine or cervical neoplasia, an acute liver disease, or a tumor in the liver, you should not use the drug.

Sample Size:

Our research is based on work done by Taha et al.,[4] The following assumptions were taken into account when using Epi Info STATCALC to determine the sample size: A power of 80% and a 95% two-sided confidence level. odds ratio computed=1.115, with a margin of error of 5%. Epi-Info yielded a maximum sample size of 93 in the end. Because of the potential for subjects to drop out during follow-up, the sample size was raised to 100.

Patients were divided into 2 groups:

For Group A, endometrial ablation was performed on 50 perimenopausal women who had abnormal uterine bleeding. In Group B, 50 women who were perimenopausal and experiencing abnormal uterine bleeding were given levonorgestrel medication.

Methodology in detail:

All those who were a part of this research had to endure:

Every patient was interviewed thoroughly to get their informed permission. We also took their medical, surgical, familial, and personal histories, as well as any complaints they may have had. Full body assessment, including taking vitals (heart rate, blood pressure, temperature, and respiration rate) and looking for symptoms of illness (such as pale skin, yellowing of the eyes, swelling of the lymph nodes, and jaundice).

To check the ovaries and uterus, a transvaginal ultrasound was performed. The patient was placed in the lithotomy position when her bladder was empty. A Mindray DC-60 machine equipped with a V 11-3B transvaginal probe (7 MHz) was used for the evaluation. We measured the endometrium in a sagittal plane, which allowed us to see all the way to the endocervical canal. For women who experience menstruation, the examination was conducted on the third day of their period. A thickness greater than 11 mm was deemed abnormal.

For Group A, endometrial ablation was performed on 50 perimenopausal women who had abnormal uterine bleeding. A second-generation ablation technology called a bipolar radiofrequency device (NovaSure) was used to perform EA. The operation was carried out by a gynecologist under the supervision of an anesthesiologist in the operating room or in the outpatient clinic using local anesthesia or conscious sedation.

Group B: Levonorgestrel treatment was administered to fifty perimenopausal women who had abnormal uterine bleeding.

Anesthesiologists were not used when inserting the 52-mg levonorgestrel intrauterine system (Mirena) by either general practitioners or gynecologists in the outpatient department. The patients in both groups reported and compared their endometrial thickness following therapy, as well as any side symptoms.

Outcomes:

After 24 months of the trial, we calculated the average blood loss using the Pictorial Blood Assessment Chart (PBAC)-score. We compared the two groups' rates of hyperplasia regression six

months following the intervention. When endometrial hyperplasia returns to normal, along with secretory alterations and atrophy, this is called regression.

Statistical methods:

Data was entered and coded using SPSS version 25, a statistical software. For numerical variables, we used the mean and standard deviation; for categorical ones, we used the number of occurrences and the percentages of each. We used an unpaired t-test to compare the groups (Chan, 2003a). The chi-square (x2) test was used to compare categorical data. When the anticipated frequency was less than 5, an exact test was utilized instead (Chan, 2003b). For statistical significance, a p-value of less than 0.05 was used.

Ethical considerations:

Two committees, one from the obstetrics and gynecology department and one from the university's medical school, reviewed and approved the study's protocol. Following an explanation of the study's goals and methods, all participants gave their verbal and written consent to participate. Everyone involved in the study was careful to protect participants' privacy and confidentiality.

3. Results

Table 1. Demographic data of group 1.

		FREQUENCY	PERCENT
PAST MEDICAL HISTORY	Hypertension	10	20
	Asthma	5	10
	Hypothyroidism	5	10
	Diabetes	5	10
	None	25	50
	Total	50	100
PAST SURGICAL HISTORY	C-section	6	12
	Appendectomy	5	10
	Tubal ligation	1	2
	Hysteroscopy	5	10
	Laparoscopy	5	10
	Myomectomy	5	10
	LEEP procedure	5	10
	Endometrial biopsy	4	8
	None	14	28
	Total	50	100
FAMILY HISTORY	Diabetes	10	20
	Hypertension	10	20
	Thyroid disease	9	18
	Breast Cancer	9	18
	None	12	24
	Total	50	100

Table 2. Demographic data of group 2.

		FREQUENCY	PERCENT
PAST MEDICAL HISTORY	Hypertension	12	24
	Asthma	9	18
	Hypothyroidism	8	16
	Diabetes	9	18
	None	12	24
	Total	50	100
PAST SURGICAL HISTORY	C-section	33	66
	None	17	34
	Total	50	100
FAMILY HISTORY	Diabetes	8	16
	Hypertension	9	18
	Thyroid disease	20	40
	None	13	26
	Total	50	100

The mean age of group (1) was 48.20 ± 1.78 (SD) ranging from (47 to 50 years) while the mean age of group (2) was 48.32 ± 1.15 (SD) ranging from (47 to 50 years), (Table 1&2).

Table 3. Wilcoxon test for group 1.

		N	Mean Rank	Sum of Ranks	p-value
Endometrial Thickness post treatment - Endometrial Thickness treatment	Negative Ranks	50a	25.50	1275.00	0.001
	Positive Ranks	0b	.00	.00	
	Ties	0c			
	Total	50			

Related samples Wilcoxon Signed Rank test was used to determine the significance of change between preoperative and postoperative levels in group (1) where 50 patients have endometrial thickness post treatment less than endometrial thickness pretreatment (p value .000) which means that there was different between pre and post endometrial ablation in group (1), (Table 3).

Table 4. Wilcoxon test for group 2.

		N	Mean Rank	Sum of Ranks	p-value
Endometrial Thickness post treatment - EndometrialThicknesspretreatment	Negative Ranks	50a	25.50	1275.00	0.001
	Positive Ranks	0b	.00	.00	
	Ties	0c			
	Total	50			

Related samples Wilcoxon Signed Rank test was used to determine the significance of change between preoperative and postoperative levels in the group (2) where 50 patients had endometrial thickness post-treatment less than endometrial thickness pretreatment (p-value .000) which means that there was difference between pre and post levonorgestrel therapy in group (2), (table 4).

Table 5. Mean blood Loss of group 1.

MEAN BLOOD LOSS	Frequency	Percent
130	5	10
135	5	10
140	5	10
145	9	18
150	10	20
155	5	10
160	5	10
165	5	10
170	1	2
TOTAL	50	100

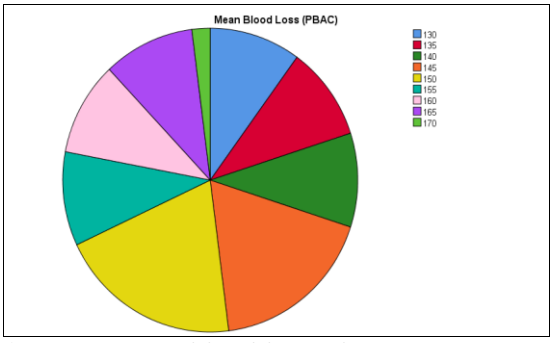

Figure 1. Mean blood loss of group 1.

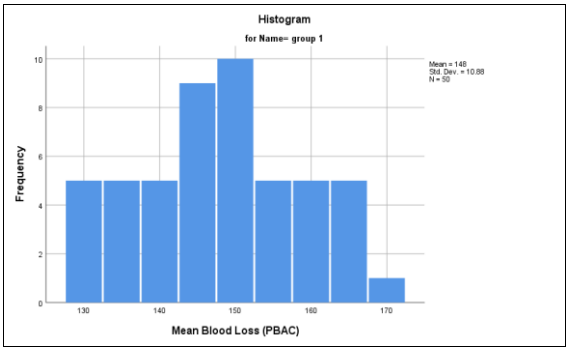

Figure 2. Mean blood loss of group 1.

Table 6. Mean blood loss of group 2.

MEAN BLOOD LOSS	Frequency	Percent
160	9	18
170	16	32
180	1	2
185	8	16
190	8	16
200	8	16
TOTAL	50	100

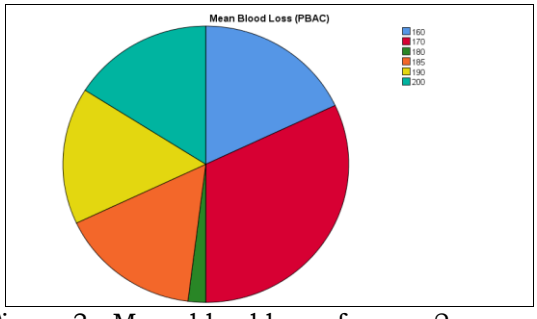

Figure 3. Mean blood loss of group 2.

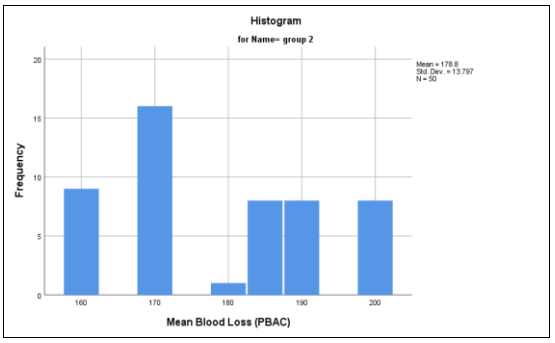

Figure 4. Mean blood loss of group 2.

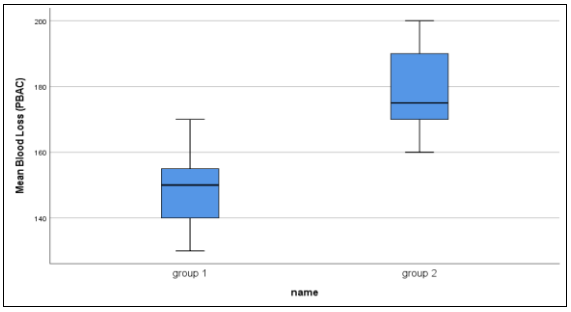

Figure 5. Difference in mean blood loss between group 1 and group 2.

Table 7. Statistical analysis of mean blood loss.

	name	N	Mean	Std. Deviation	Std. Error Mean
Mean Blood Loss (PBAC)	group 1	50	148.00	10.880	1.539
	group 2	50	178.80	13.797	1.951

P value (significance) = 0.004

The mean blood loss in group (1) is less than the mean blood loss in group (2), as shown in group (1) about 5(10%) of patients has mean blood loss 150, 5(10%) has 135, 5(10%) has 140 ,9(18%) has 145, 10(20%) has 150, 5(10%) was 155, 5(10%) was 160, 5(10%) was 165 and 1 patient was 170 while in group (2) about 9(18%) of patients has mean blood loss 160,16(32%) was 170, 1(2%) was 180, 8(16%) was 185, 8(16%) has 190, 8(16%) has 200 which means That group (1) is more better than group 2 according to the mean blood loss as the mean of mean blood loss of group 1 is 148.00 while in group 2 is 178.80, (Table 7).

4. Discussion

Two well-established therapeutic options that have greatly contributed to the decline in hysterectomies over the last several decades are the endometrial ablation/resection and the levonorgestrel intra-uterine system (LNG-IUS). These procedures are used when a woman experiences heavy menstrual flow and her uterine cavity is normal.[6]

Modern technology has made endometrial ablation or resection—a minimally invasive surgical procedure—safer, easier, and more accessible, and it is now considered a first-line

option for AUB.[7]

Endometrial thickness reduction, blood loss, and adverse effects were all significantly different between the two treatment regimens, according to the results.

Both treatment groups had a notable decrease in endometrial thickness, according to our data ($p < 0.001$). Nevertheless, when contrasted with the levonorgestrel treatment group (Group 2), the endometrial ablation group (Group 1) showed a more significant reduction. Prior to therapy, the mean endometrial thickness for Group 1 was 44.78, and for Group 2 it was 56.22. After treatment, the corresponding values were 31.74 and 69.26, respectively. Thus, endometrial ablation proved to be the superior method for thinning the endometrium.

These results are in line with what has been found in previous research. To illustrate, El-Agamy et al.,[8] reported that, when compared to medical care, endometrial ablation significantly reduced endometrial thickness in women whose uterine bleeding was abnormal.

As mentioned in an earlier review Yang et al.,[9] According on PBAC scores, the LNG-IUS may provide superior control of bleeding in the long run.

According to one study, at both the nine-month and one-year follow-ups, the median PBAC score was much lower in the LNG-IUS group. Amenorrhea rates were not different in subsequent results.[10]

We found that the two therapy groups had quite different rates and types of side effects. Only 22% of patients who underwent endometrial ablation reported any adverse effects; the most prevalent of these were mild cramping(10%), mild bleeding(10%), and infection (2%). Levonorgestrel treatment was associated with 82% of adverse events, including an increase in body weight (18%), breast tenderness (18%), acne (16%), nausea (16%), and headache (14%).

These findings are consistent with the known side effect profiles of these treatments. For instance, Bergeron et al.,[11] found that endometrial ablation patients had fewer hormonal adverse effects, including breast soreness, mood swings, and acne, compared to LNG-IUS patients. They did, however, mention a minor risk of procedural problems with endometrial ablation, which is in line with our 2% infection rate.

The risk of complications, such as hematometra (2%), perioperative hemorrhage (2%), uterine perforation (1%), and pelvic infection or fever (1%), is less than 5% when endometrial ablation or resection is performed, according to larger cohort studies.[12] at a rate of less than 0.1 percent for LNG-IUS, uterine perforation.[13] In contrast to endometrial ablation/resection, LNG-IUS is associated with a higher incidence of adverse effects.[14]

Among 165 women who suffered from severe menstrual bleeding, the majority of participants liked the endometrial ablation/resection features, and the absence of hormones was cited as the most important consideration when choosing a treatment.[15]

After the LNG-IUS is implanted, the likelihood of side effects typically decreases over time Mansour, [16] nor were they linked to a diminished sense of contentment or well-being. In order to help women make informed decisions and achieve greater levels of satisfaction, it is crucial to provide them with comprehensive information about all available possibilities.[17]

Ergun et al.,[18] it was found that neither treatment method produced any serious side effects. Louie et al.,[19] was found to have a higher rate of treatment failures and problems with endometrial ablation compared to LNG-IUS.

Limitations: Limited follow-up time and a limited sample size. The safety and effectiveness of these treatments over the long term can only be determined by future trials with bigger cohorts and longer follow-up times. Furthermore, our study did not use quality of life measurements.

4. Conclusion

Our study showed that there were fewer adverse effects and better results in reducing endometrial thickness and controlling menstrual blood loss. Treatment decisions should be tailored to each patient's unique needs, goals about future fertility, and any medical conditions that could prevent them from receiving either option. While endometrial ablation showed better outcomes in our study, it is a surgical procedure that permanently affects the endometrium, which may not be suitable for all patients.

Disclosure

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Authorship

All authors have a substantial contribution to the article

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Conflicts of interest

There are no conflicts of interest.

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