

Original Article

A PROSPECTIVE STUDY OF COMPARISON OF HORMONAL V/S NON-HORMONAL TREATMENT IN ABNORMAL UTERINE BLEEDING

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ABSTRACT

Objective: Abnormal Uterine Bleeding (AUB) is a common problem among women in the reproductive age group. It can be characterized by variations in duration, frequency, regularity of menses, or volume of menstrual blood loss. AUB can have a significant impact on quality of life, causing pain, discomfort, social embarrassment, and loss of productivity. It may require surgical interventions, including hysterectomy. Hormonal and non-hormonal treatments are available options for managing AUB.

Methods: This study aimed to compare the effectiveness of hormonal and non-hormonal treatments in abnormal uterine bleeding. The research question addressed in this study was: "Which treatment is better, hormonal or non-hormonal, in abnormal uterine bleeding?"

Results: The study findings provided insights into the comparative efficacy of hormonal and non-hormonal treatment options for abnormal uterine bleeding. The results contributed to understanding the optimal approach for managing this condition and improving patient outcomes.

Conclusion: Based on the results of this study, conclusions can be drawn regarding the superiority of either hormonal or non-hormonal treatment in the management of abnormal uterine bleeding. The findings will help guide healthcare professionals in selecting appropriate treatment options for their patients.

Keywords: Abnormal uterine bleeding, AUB, Hormonal treatment, Non-hormonal treatment

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INTRODUCTION

Abnormal Uterine Bleeding (AUB) is a common problem among women of reproductive age, characterized by changes in the duration, frequency, regularity, and volume of menstrual bleeding. It can have a significant negative impact on the quality of life for affected individuals, leading to pain, discomfort, social embarrassment, and reduced productivity. AUB can be classified as acute or chronic, with acute cases requiring immediate intervention to control bleeding, and chronic cases persisting for at least six months [1]. The PALM-COEIN classification system helps identify the underlying causes of AUB. PALM refers to structural pathologies, including Polyps, Adenomyosis, Leiomyoma (fibroids), and Malignancy (and Hyperplasia). COEIN encompasses non-structural etiologies such as coagulopathy (bleeding disorders), ovulatory disorders, endometrial causes, iatrogenic causes, and cases that cannot be classified otherwise [2].

Around 90% of AUB cases are associated with anovulatory cycles, where the corpus luteum fails to form, resulting in irregular and sometimes profuse bleeding. Hormonal treatments, such as estrogen and progestin oral contraceptives, progestin-only therapy, or estrogen therapy, are the primary options for managing acute anovulatory bleeding. Progestogens, synthetic derivatives of progesterone, are particularly useful in stabilizing the endometrium and promoting its atrophy. They can be administered through various routes and doses, depending on individual circumstances [3, 4]. Ormeloxifene/Centchroman is a non-steroidal anti-estrogen that acts as a selective estrogen receptor modulator (SERM). It binds strongly to estrogen receptors, counteracting the stimulating effects of estrogen on uterine tissue. Ormeloxifene has minimal side effects and does not impact the vagina, bone, cardiovascular system, or central nervous system, making it an alternative treatment option for heavy AUB [5, 6].

Non-hormonal treatments, such as non-steroidal anti-inflammatory drugs (NSAIDs), can also reduce menstrual blood loss in cases of mild bleeding. However, their effectiveness may be lower compared to hormonal therapies. Tranexamic acid, an antifibrinolytic agent, is

as effective as combined oral contraceptives in reducing menstrual bleeding. It can be administered intravenously or orally, but caution is needed in patients with specific medical conditions. Aminocaproic acid is another option but is less potent than tranexamic acid [7].

Danazol and GnRH analogues are highly effective in treating AUB but are reserved for short-term use due to their strong side effects. Long-term use of danazol can lead to hirsutism, while GnRH analogues are associated with irreversible bone loss. These medications are primarily used in severe cases of anemia before considering other treatment options. The optimal treatment approach for AUB, comparing hormonal and non-hormonal therapies, remains uncertain. Further research is needed to determine which approach is more effective, considering individual patient factors and preferences [8-10].

In conclusion, AUB is a common issue affecting women of reproductive age, with significant implications for quality of life and healthcare costs. It can be classified as acute or chronic, with various underlying causes. Treatment options include hormonal therapies, such as progestogens or ormeloxifene, and non-hormonal options like NSAIDs, tranexamic acid, or aminocaproic acid. Danazol and GnRH analogues are effective but limited by side effects. Finding the optimal treatment approach for AUB requires further research and consideration of individual patient factors.

MATERIALS AND METHODS

This was a multicenter, randomized, open-label, parallel-group, active-control trial attending gynecological OPD for a period of two years. The study protocol for all procedures was approved by the Institutional Review Board for Ethical Clearance and was carried out in accordance with the World Medical Association's Code of Ethics based on the Declaration of Helsinki of 1975, as revised in 2000. All patients were requested to sign a written consent form prior to initiation of the study.

Study duration: February 2021 to October 2022

Type of study: Prospective observational study

Study centre: Department of Obstetrics and Gynaecology,

Sample size: 100

Menstrual blood loss of 80 ml or more per cycle was confirmed in at least two screening menstrual cycles before participants were randomised in a 1:1 ratio to receive either hormonal (Only progesterone/Danazole/OCP) or non-hormonal (Mefenamic acid/Tranexamic acid/Ethamsylate) treatment.

The subjects were selected according to the following inclusion and exclusion criteria:

Inclusion criteria

Reproductive age group females with Heavy Menstrual Bleeding (11-45yrs) Exclusion criteria:

1. Patients with age more than 45 y
2. Bleeding disorders
3. Hormonal disorders (eg. diabetes mellitus, thyroid)
4. Bleeding due to intra uterine devices
5. Bleeding due to polyp or atypical endometrial hyperplasias
6. Patients who refuse to give consent Ethical clearance:

The study protocol for all procedures was authorised by the hospital's Institutional Review Board for Ethical Clearance and was carried out in line with the World Medical Association's Code of Ethics based on the 1975 Declaration of Helsinki, as revised in 2000. Prior to the start of the study, all patients were requested to sign a written consent form.

Case selection

The data was obtained using a pre-designed structured interviewer-administered questionnaire that was pretested and modified before being used in the study. The patients were interviewed with questions about their demographics, socioeconomic situation, medical history, and previous use of drugs and supplements.

RESULTS

The most common complaint across both groups at the start was excessive menstrual bleeding. After three months, none of the patients in the hormonal group complained of severe menstrual bleeding, but 12% of the subjects in the non-hormonal group did. After six months, 26% and 2% of individuals in the Non-Hormonal and Hormonal groups, respectively, reported significant menstrual bleeding. When menstruation patterns were analysed statistically between groups at 3 and 6 mo, p0.05 was shown to be statistically significant.

Table 1: Parity among the study groups

Parity	Non-hormonal (n=50) N (%)	Hormonal (n=50) N (%)	Total N (%)
P1L1	2 (4.0%)	1 (2.0%)	3 (3.0%)
P1L1 A1/A2/A3	1 (2.0%)	0 (0.0%)	1 (1.0%)
P2L1	2 (4.0%)	0 (0.0%)	2 (2.0%)
P2L2	19 (38.0%)	14 (28.0%)	33 (33.0%)
P2L2A1/A2/A3	10 (20%)	3 (6%)	13 (13%)
P3L3A1/A2/A3	14 (28%)	21 (42%)	35 (35%)
P4L3	1 (2.0%)	0 (0.0%)	1 (1.0%)
P4L4	0 (0.0%)	6 (12.0%)	6 (6.0%)
P4L4A1/A2/A3	1 (2.0%)	2 (4.0%)	3 (3.0%)
P5L5	0 (0.0%)	1 (2.0%)	1 (1.0%)
P6L5	0 (0.0%)	1 (2.0%)	1 (1.0%)
P6L6A1/A2/A3	0 (0.0%)	1 (2.0%)	1 (1.0%)

The table shows the parity distribution among the study subjects. P2L2 was found among 33% of the subjects.

Table 2: Menstrual pattern among the study groups after 6 mo

Baseline pattern	Non-hormonal (n=50)		Hormonal (n=50)	
	N	%	N	%
Amenorrhea	9	18	13	26
Heavy Menstrual Bleeding	13	26	1	2
Irregular Bleeding	19	38	12	24
Spotting	9	18	18	36
Normal	0	0	6	12

DISCUSSION

This study aimed to compare hormonal and non-hormonal treatments for abnormal uterine bleeding (AUB) in women. AUB can be treated with both medical and surgical interventions, and both methods are safe and effective. However, surgical interventions like hysterectomy should be considered only after other options have been explored, as they carry minimal but higher risks of complications such as organ injury, hemorrhage, infection, and mortality [11]. The study enrolled women aged 18 y or older with heavy menstrual bleeding. The participants were divided into two groups: one group received non-hormonal treatment, while the other group received hormonal treatment [12]. The subjects were followed up for six months, and the final sample included 50 subjects in each group.

The average age of the participants in the non-hormonal group was 29.56 y, while in the hormonal group, it was 38.51 y. These findings were consistent with previous studies that reported the prevalence of AUB in women aged 36-45 y. Other studies also showed that AUB

commonly affected women in their 40s [13]. The study evaluated the effectiveness of the treatments by measuring menstrual blood loss. In the non-hormonal group, the median blood loss at baseline was 153.8 ml, which reduced to 115.18 ml after six months. In the hormonal group, the baseline median blood loss was 150.24 ml, which decreased to 7.4 ml after six months [14]. The hormonal group experienced a significantly greater reduction in blood loss compared to the non-hormonal group after three and six months.

Various medications were used in the hormonal treatment group. Tranexamic acid was shown to be effective in reducing menstrual blood loss by 40-59% from baseline. Ormeloxifene also led to a significant reduction in blood loss. Progesterone-only pills were considered safe and effective, while danazol was found to reduce menstrual losses by up to 80% [15]. The management of heavy menstrual bleeding depends on the severity of anemia. For mild cases, hormonal intervention is optional, while for moderate cases, hormonal intervention and iron supplementation are recommended. Severe cases require inpatient management, and hormonal

interventions like combined oral contraceptive pills or intravenous estrogen may be used [16].

In adolescent women, hormonal contraceptive methods are the mainstay of chronic management for AUB and heavy menstrual bleeding. After three months of treatment, none of the subjects in the hormonal group complained of heavy menstrual bleeding, while 12% of the subjects in the non-hormonal group still experienced it. At six months, 26% of the non-hormonal group and 2% of the hormonal group reported heavy menstrual bleeding. The difference in menstrual patterns between the groups was statistically significant [17]. No deaths or serious adverse events related to the treatments were reported during the study. However, hormonal treatment had more overall complications compared to non-hormonal treatment, although the difference was not significant. The study had limitations, including a small sample size and short-term follow-up. Further longitudinal studies with larger sample sizes are needed to validate these findings [18].

In conclusion, both hormonal and non-hormonal treatments are effective in managing abnormal uterine bleeding. Clinicians should discuss medical management options, including hormonal treatment, with patients before considering surgical interventions. Further research is needed to expand our understanding of these treatments and their long-term effects.

CONCLUSION

Abnormal menstrual bleeding in adolescents requires proper diagnosis, counseling, and follow-up. Anatomical abnormalities should be ruled out, and appropriate medical or surgical treatments should be administered. Early intervention in school-aged girls can help them manage this experience without impacting their health and academics. Hormonal treatment has been found to be more effective in reducing menstrual blood loss compared to non-hormonal treatment. This trial contributes to the existing evidence supporting the use of hormonal treatment for abnormal uterine bleeding.

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AUTHORS CONTRIBUTIONS

All the authors have contributed equally.

CONFLICT OF INTERESTS

Declared none

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