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COMPARISON OF EFFECTIVENESS OF ORMELOXIFENE WITH NORETHISTERONE IN TREATMENT OF AUB

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INTRODUCTION

In the medical literature, AUB is described as an episode of abnormal uterine bleeding that is not due to any clinically evident organic, systemic, or iatrogenic cause (Pelvic pathology, e.g. tumor, inflammation or pregnancys excluded). [1] Although the prevalence varies widely, a 10-percent incidence rate among new patients entering the outpatient clinic appears reasonable. The bleeding may be abnormal in terms of frequency, volume, or duration, or it may be a mix of any of these characteristics. Because the diagnosis is dependent on the exclusion of a 'organic lesion,' the incidence varies depending on the level of care and facilities available to rule out such a lesion. AUB is currently defined as a condition characterized by abnormal uterine bleeding following an ovulation as a result of hypothalamo-pituitary-ovarian axis malfunction (endocrine origin). [1]

It is estimated that up to 30% of reproductive-age women experience blood loss greater than 80mL during the menstrual cycle, which accounts for 70% of all gynaecological visits by premenopausal women. An ovulatory AUB is caused by a malfunction of the HPO axis. Despite the fact that hysterectomy is an effective treatment option, long-term complications such as early ovarian insufficiency and urinary dysfunction have raised questions. As a result, the vast majority of women are looking forward to receiving successful conservative medical treatment. In the therapy of AUB, pharmacological treatments such as oral progestogens in combination with danazol, a GnRH agonist, prostaglandin synthasize inhibitors, antifibrinolytics, and ethamsylate are utilised. [1,2]

Norethisterone is a progestogen that is commonly used in the treatment of AUB . Given that it is a hormone preparation, there have been reports of side effects such as stroke, heart illness, breast cancer, dementia, fluid retention, break through bleeding, and spotting. [1,2]

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Ormeloxifene is an estrogen-receptor modulator (SERM) with estrogenic actions on the vaginal, cervical, and cervix. The uterus and breast tissue are shown to have an antioestrogenic effect. In certain quarters, it's also known as centchroman. It's a non-steroidal, non-hormonal supplement. It is required to take it once a week when used as a contraceptive. The normal dose for initial therapy is 60mg given twice a week for three months, then once a week for the next three months until the disease is cleared. It causes fewer uterine side effects, prevents bone loss, and raises the risk of breast cancer. Has a protective impact against lipids and cardiovascular disease, as well as assisting in the maintenance of cognitive function in the brain. It is the most appropriate drug for women in their premenopausal years. 1,2 As a result, we conducted research to see how effective ormeloxifene and norethisterone are in treating AUB in people of all ages, including children.

1. AIM & OBJECTIVES

2.1 AIM

Aim of the study is to compare the effectiveness of ormeloxifene with norethisterone in treatment for AUB in all age groups.

2.2 OBJECTIVE

To compare treatment efficacy and usefulness of ormeloxifene & oral progesterone in AUB treatment.

MATERIAL AND METHODS

4.1 STUDY AREA: The present study was conducted at Department of Obstetrics and Gynaecology, Vinayaka Mission's Medical College, Karaikal.

4.1.2 STUDY POPULATION: Women presenting with AUB were included.

4.1.3 STUDY DESIGN: Prospective comparative study

4.1.4 STUDY PERIOD: July 2020 to December 2021

4.1.5 SAMPLE SIZE:120 (all age groups).

Randomly allocated to 2 groups -60 subjects each

GROUP 1- Treated with 60 mg ormeloxifene twice in a week for 3months followed by 60mg ormeloxifene once in a week for next 3 months.

GROUP 2- Treated with norethisterone 5mg twice daily for 21days for 6cycles.

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4.1.6 INCLUSION CRITERIA:

Women with complaints of heavy menstrual blood loss. (All age groups)

RESULTS

Table 1: Distribution of patients based on the age among the two groups

	Ormeloxifene		Norethisterone		T Test	P Value
	Mean	SD	Mean	SD		
Age	30.53	5.37	31.43	5.18	-0.93	0.35

Mean age in ormeloxifene and norethisterone groups were 30.53 + 5.37 and 31.43 + 5.18 years respectively with p value of 0.35 i.e., statistically not significant.

Table 2: Distribution of patients based on the duration of menorrhagia among the two groups

	Ormeloxifene		Norethisterone		T Test	P Value
	Mean	SD	Mean	SD		
Duration of menorrhagia (Months)	12.96	6.80	12.06	6.81	0.72	0.47

Mean duration of menorrhagia in ormeloxifene and norethisterone groups were 12.96 + 6.80 and 12.06 + 6.81 months respectively with p value of 0.47 i.e., statistically not significant.

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Table 3: Distribution of patients based on the PBAC among the two groups

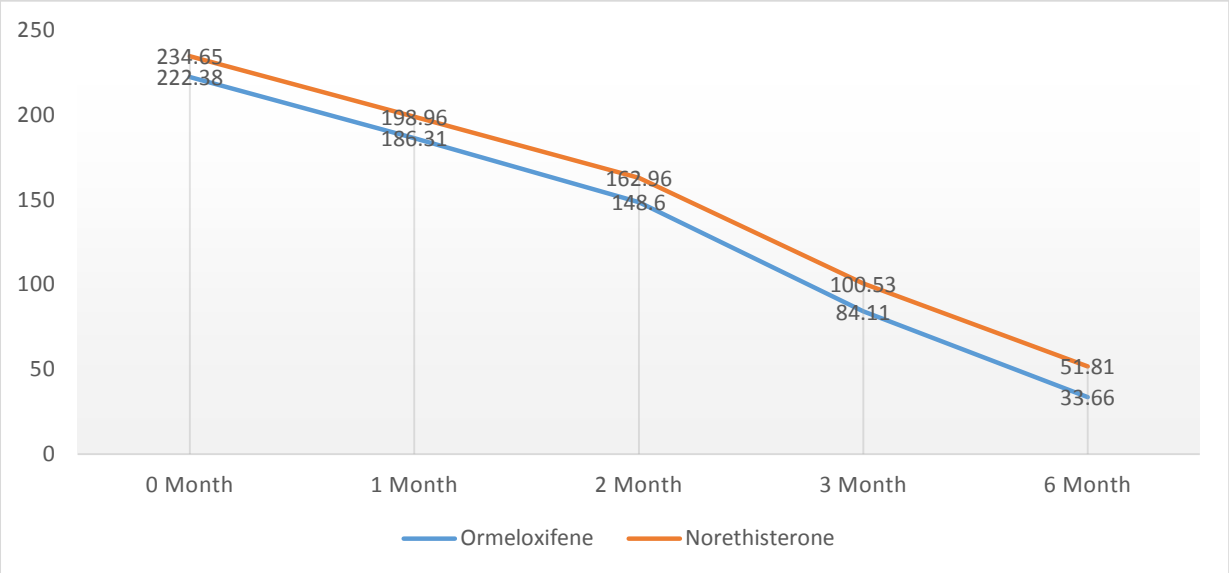
\ PBAC	Ormeloxifene		Norethisterone		T Test	P Value
	Mean	SD	Mean	SD		
0 Month	222.38	69.06	234.65	62.66	-1.01	0.31
1 Month	186.31	57.99	198.96	53.30	-1.24	0.21
2 Month	148.60	46.41	162.96	44.19	-1.73	0.08
3 Month	84.11	26.33	100.53	27.45	-3.34	**0.001**
6 Month	33.66	13.43	51.81	14.30	-7.16	**0.001**

In ormeloxifene group, mean PBAC decrease was 188.72 (84.9% decrease) i.e., from 222.38 in 0 Month to 33.6 in 6 Months.

In norethisterone group, mean PBAC decrease was 182.84 (77.9% decrease) i.e., from 234.65 in 0 Month to 51.81 in 6 Months.

The association between the PBAC and the groups was found to be statistically significant at 3rd Month and 6th Month.

Graph1: Distribution of patients based on the PBAC among the two groups



Distribution of patients based on the ET among the two groups

ET (Day 1 - 3)	Ormeloxifene		Norethisterone		T Test	P Value
	Mean	SD	Mean	SD		
0 Month	4.53	0.77	4.48	0.74	0.31	0.74
3 Month	4.29	0.74	4.32	0.71	-0.20	0.83
6 Month	3.90	0.67	3.99	0.66	-0.73	0.46

In ormeloxifene group, mean ET decrease was 0.63 (13.9% decrease) i.e., from 4.53 in 0 Month to 3.90 in 6 Months.

In norethisterone group, mean ET decrease was 0.49 (10.9% decrease) i.e., from 4.48 in 0 Month to 3.99 in 6 Months.

The association between the ET and the groups was found to be statistically not significant.

Graph 3: Distribution of patients based on the ET among the two groups

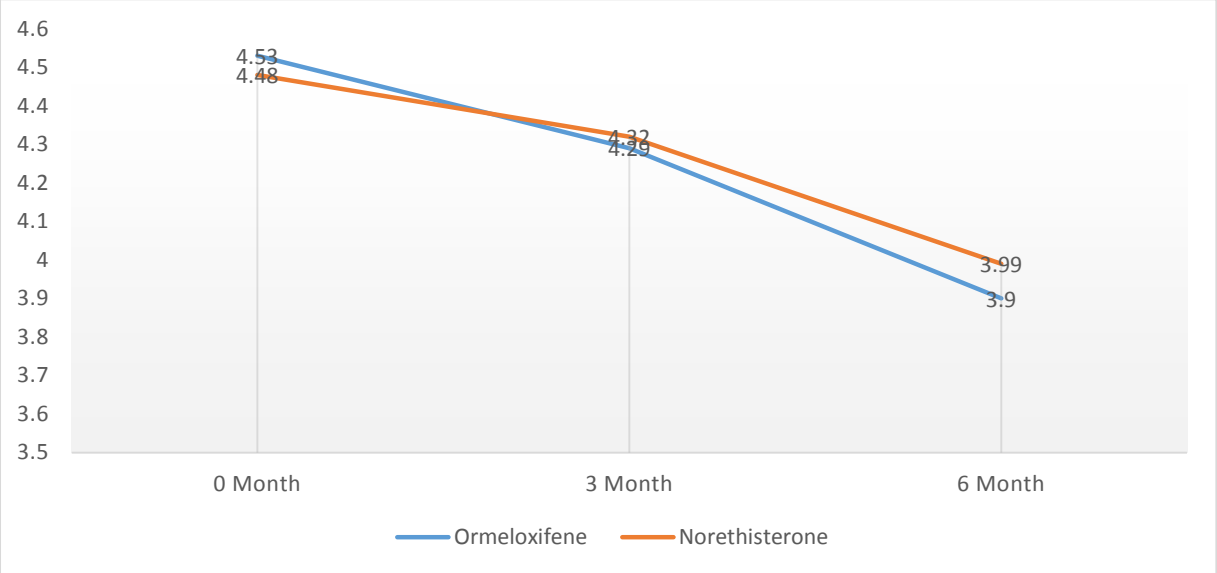


Table 6: Distribution of patients based on the FBS levels among the two groups

FBS	Ormeloxifene		Norethisterone		T Test	P Value
	Mean	SD	Mean	SD		
0 Month	96.16	39.14	93.88	39.16	0.31	0.75
3 Month	94.58	35.00	93.76	31.86	0.13	0.89
6 Month	91.90	24.36	91.13	25.19	0.16	0.86

In ormeloxifene group, mean FBS decrease was 4.26 (4.4% decrease) i.e., from 94.16 in 0 Month to 91.90gm/dl in 6 Months.

In norethisterone group, mean FBS decrease was 2.75 (2.9% decrease) i.e., from 93.88 in 0 Month to 91.13 gm/dl in 6 Months.

The association between the FBS and the groups was found to be statistically not significant.

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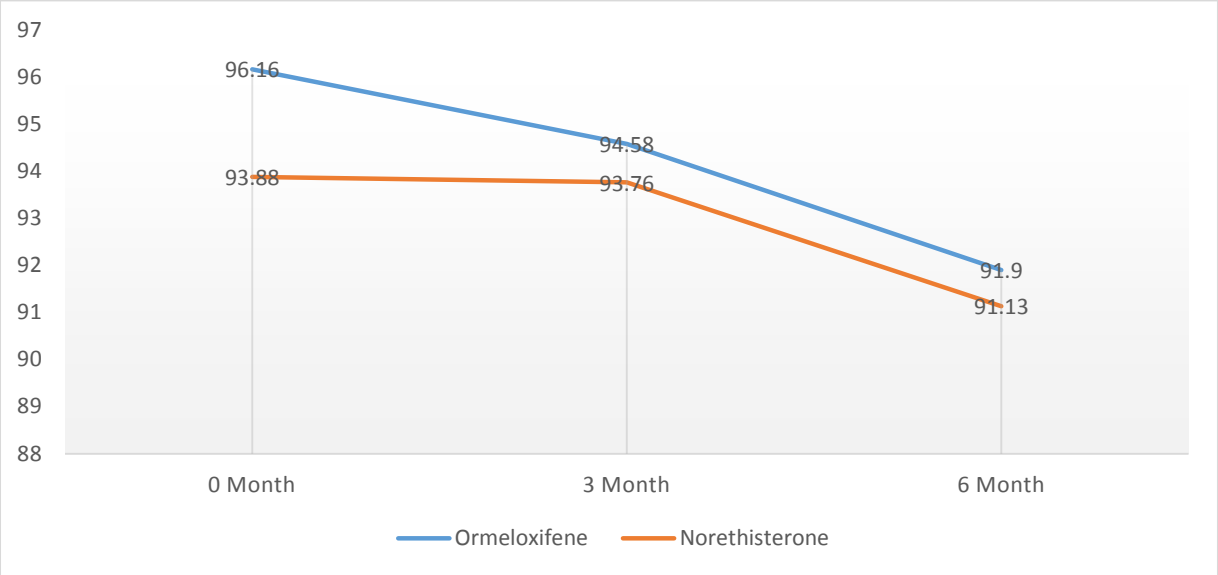
Graph4: Distribution of patients based on the FBS levels among the two groups



Distribution of patients based on the presence of dysmenorrhoea among the two groups

			Group		Total
			Ormeloxifene	Norethisterone	
DYSMENORRHOEA	No	n	52	54	106
		%	86.7%	90.0%	88.3%
	Yes	n	8	6	14
		%	13.3%	10.0%	11.7%
Total		n	60	60	120
		%	100.0%	100.0%	100.0%

Chi-Square: 0.32, P Value: 0.38, Statistically not significant

In ormeloxifene group, 13.3% had dysmenorrhea and in norethisterone group, 10% had dysmenorrhea. The association between them was found to be statistically not significant.

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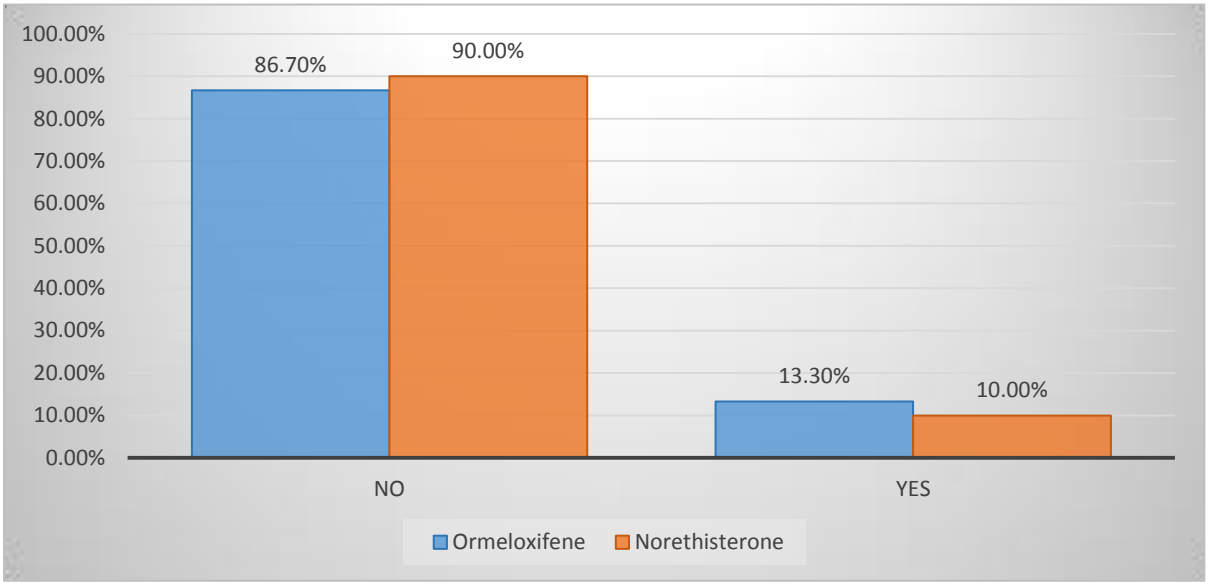
Graph 5: Distribution of patients based on the presence of dysmenorrhoea among the two groups



Distribution of patients based on the regularity among the two groups

			Group		Total
			Ormeloxifene	Norethisterone	
REGULARITY	IRMC	n	12	12	24
		%	20.0%	20.0%	20.0%
	RMC	n	48	48	96
		%	80.0%	80.0%	80.0%
Total		n	60	60	120
		%	100.0%	100.0%	100.0%

Chi-Square: 0.001, P Value: 0.59, Statistically not significant

In ormeloxifene group, irregular menstrual cycles were present in 20% patients and in norethisterone group, irregular menstrual cycles were present in 20% patients. The association between them was found to be statistically not significant.

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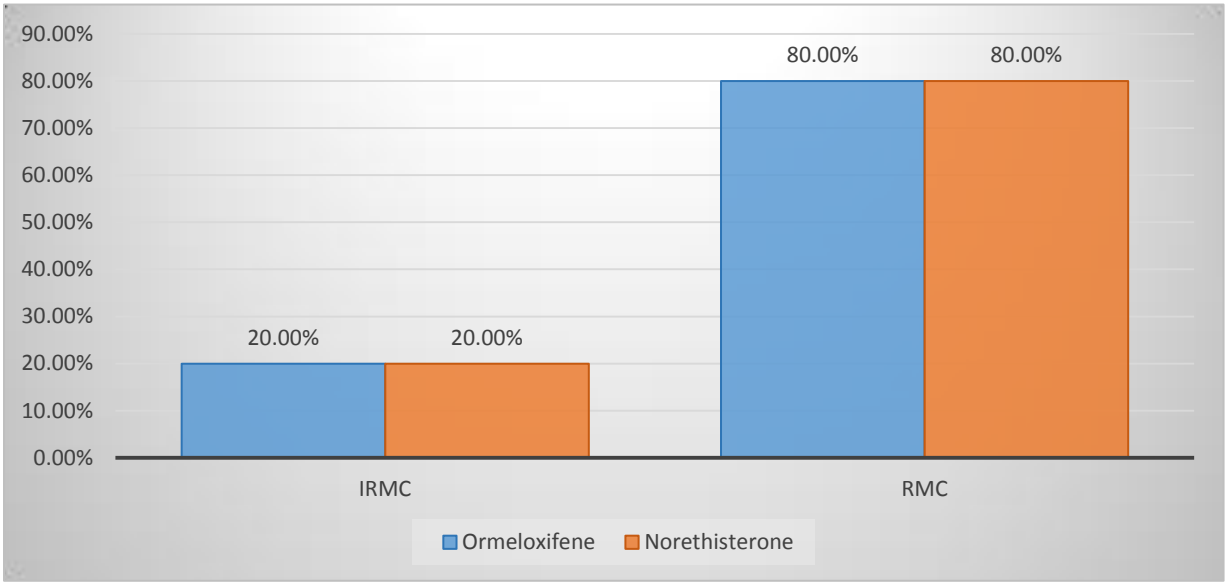
Distribution of patients based on the regularity among the two groups



Distribution of patients based on the side effects among the two groups

			Group		Total
			Ormeloxifene	Norethisterone	
SIDE EFFECTS	Amenorrhea	n	4	0	4
		%	6.7%	0.0%	3.3%
	Headache	n	11	23	34
		%	18.3%	38.3%	28.3%
	Nausea	n	9	16	25
		%	15.0%	26.7%	20.8%
	NIL	n	36	21	57
		%	60.0%	35.0%	47.5%
Total		n	60	60	120
		%	100.0%	100.0%	100.0%

Chi-Square: 14.14, P Value: **0.003**, Statistically significant

Inormeloxifene group, side effects were amenorrhea(6.7%), headache (18.3%)and nausea (15%).

In norethisterone group, side effects were headache (38.3%) and nausea (26.7%). The association between them was found to be statistically significant.

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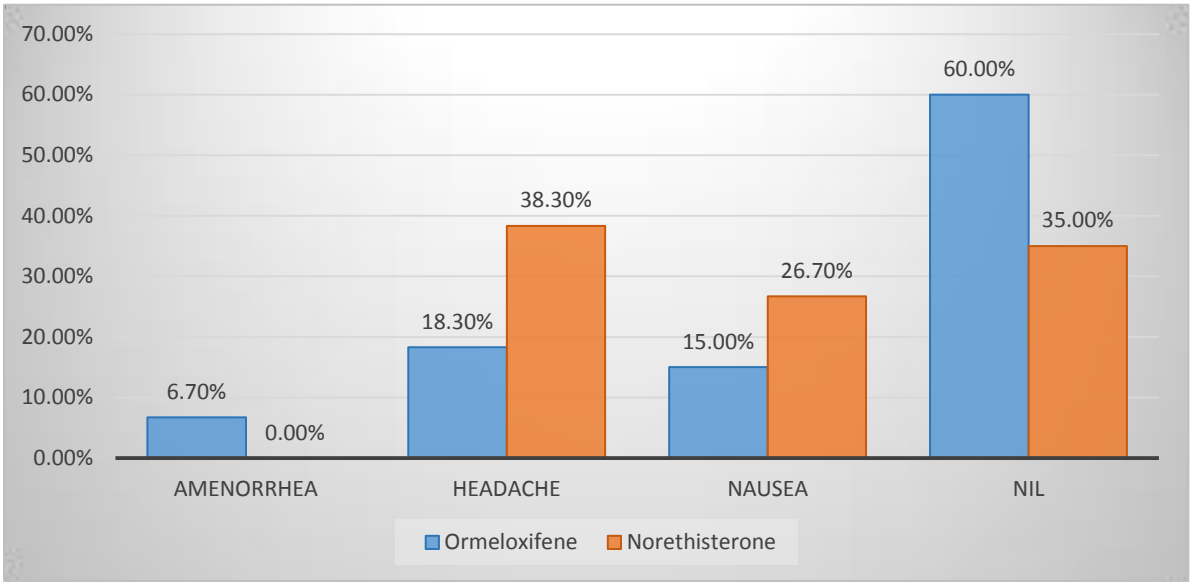

DISCUSSION

The first five years after a woman begins menstruation and as she approaches menopause are the most typical times for dysfunctional uterine haemorrhage, but it may happen at any time. Pharmacological therapies are presently the sole alternatives for women with AUB who want to keep their fertility. Some of the other pharmacological treatments are exclusively effective for anovulatory AUB, whereas others may be beneficial for both. Pharmacological therapies such as NSAIDS, oral contraceptive tablets, progestins, danazol, GnRH agonists, and antifibrinolytic medicines all help to lower menstrual blood loss, but their benefits are only temporary. 28,30,32 We compared the efficiency of ormeloxifene and norethisterone in the treatment of abnormal uterine haemorrhage in our study.

8. CONCLUSION

Ormeloxifene has a higher level of compliance and acceptance, as well as a significant reduction in symptom severity. The norethisterone group had more irregular bleeding and amenorrhoea. Although ormeloxifene caused a brief bout of bleeding in some individuals, it was not substantial.

Surgical treatments such as hysterectomy and endometrialablation can be reduced with effective medicinal management. AUB may potentially be managed safely in the community, with referrals limited to individuals with underlying disease.