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Ormeloxifene in the management of AUB

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Abstract
Objective: To study the efficacy and safety of ormeloxifene in the medical management of AUB.
Methods: 50 women with HMB who satisfied inclusion criteria were included in the study.
Ormeloxifene 60 mg tablet twice a week for the first 12 weeks and then once a week for 12 weeks was given for every patient.
The outcome was assessed by assessment of menstrual blood flow by PBAC score, Hb level and endometrial thickness.
Results: The PBAC score was significantly reduced in 85 % of patients. The mean Hb concentration was significantly increased from 8.6 to 11.8 g/dl. The mean endometrial thickness was reduced from 10.14 mm to 7.35 mm.
Conclusion: Ormeloxifene is an effective and user friendly drug for medical management of AUB.

Keywords: Ormeloxifene, management of AUB, estrogen receptor modulator (SERM)

Introduction
Abnormal uterine bleeding is one of the most common gynecological symptoms encountered on day to day basis. AUB can cause significant social embarrassment and have a substantial effect on health related quality life.
AUB leads to loss of productivity [1]. In India the prevalence of AUB is around 17.9% [2]. Many drugs for AUB are available but response to treatment varies. Various drugs used are NSAIDS, tranexamic acid, hemostatic progestins, oral contraceptives, danazol and GnRH agonists.
LNG IUS is considered to be first line and reference treatment in medical management, but its cost limits its widespread use [3]. Ormeloxifene is a nonsteroidal, non hormonal, pharmacologically inert, selective estrogen receptor modulator (SERM). It has anti estrogenic and antiproliferative action on endometrium, hence used as quick and effective hemostat for AUB [4].

Materials and Methods
This prospective clinical study was conducted in Navodaya medical college hospital and research centre, Raichur from January 2018 to February 2019. Ethical committee approval was obtained.

Inclusion Criteria
All cased of AUB-N

Exclusion Criteria
Presence of any pelvic pathology on ultrasound such as fibroid, adenomyosis, polyp, adnexal mass uterine size > 8 weeks Coagulopathies Use of IUCD and COC Active bleeding necessitating emergency treatment 50 patients meeting the inclusion criteria were selected after baseline investigations. Informed written consent was taken. PBAC score, Hb in g/dl and endometrial thickness was noted at first visit. Tablet ormeloxifene 60mg twice a week was given for the first 3 months followed by once a week for next 3 months. Follow up was made at 1 month, 3 months and 6 months. At each visit days of bleeding, length of cycle, PBAC score was noted. Hb and endometrial thickness was assessed only at end of 6 months.

Results
Out of 50 women, 4 patients were lost to follow up at the end of 1 month (n=46) As seen in the

table 1, majority of patients, 40 (80%) had PBAC score of >300 and 8 (16%) had PBAC score of >100 indicating HMB. At the end of 3 months 10(21.73%) had amennorrhea and 14(21%) still had HMB. At the end of 6 months, 15(32.6%) had amennorrhea and 10(21.73%) had scanty flow and 6(13%) had HMB.

As seen in table 2, the median PBAC score decreased from 280 before treatment to 65 after 3 months and 32 after 6 months. This was found to be statistically significant (P>0.001).

As shown in table -3 the decrease in endometrial thickness (mm) between pretreatment (10.14mm) and 24 weeks post treatment (7.35mm) was statistically significant.

As can be seen in the table 4, there was an increase in mean Hb from 8.6 g/dl before treatment to 11.8 g/dl 24 weeks post treatment.

Table 1: Assessment of blood loss by PBAC score

S.No	PBAC score	Menstrual blood flow	Pre treatment N=50	1 month N=46 4 lost to follow up	3 months (n=46)	6 months (n=46)
1	0	Nil	0 (0%)	0 (0%)	10(21.73%)	15(32.6%)
2	0-10	Scanty	0 (0 %)	0 (0%)	5 (10.86%)	10(21.73%)
3	10-100	Moderate	2 (4%)	22(47.82%)	17(36.95%)	15(32.6%)
4	100-300	Heavy	8 (16%)	10(21.73%)	8(17.39%)	4(8.69%)
5	>300	Very heavy	40 (80%)	14(30.43%)	6(13.04%)	2(4.34%)

Table 2: comparison of median PBAC score between pretreatment level and post treatment level at 24 weeks

S.No	Duration	Median(n=46)
1	Pretreatment	280
2	3 months	65
3	6 months	32

P value <0.01

Table 3: Comparison of mean endometrial thickness (mm) between pretreatment level and post treatment at 24 weeks.

Duration	Mean endometrium
Pre treatment	10.14
24 weeks (post treatment)	7.35

P value <0.05

Table 4: Comparison of mean Hb between pre-treatment level and post treatment at 24 weeks.

Duration	Mean Hb(g/dl)
Pretreatment	8.6
Post treatment	11.8

P value <0.05

Discussion

Majority of our patients (40/46, 80 %) in our study had PBAC score in the very heavy range (>300) at the time of recruitment. This is similar to study done by Soniya P *et al* in 2017 [5] where (42/49, 85.7%) had PBAC score in the very heavy range.

There was a statistically significant decrease in median PBAC score in our study. This was also seen in study by Kumari A *et al* who observed that with treatment with ormeloxifene, median PBAC score improved from 265 before treatment to 27, 6 months post treatment [6].

In our study, the mean endometrial thickness decreased from 10.14 mm pretreatment to 7.35 mm post treatment. A statistically significant reduction in ET (<0.001) was also seen in study by Tapasi P *et al*. [7].

The mean HB (g/dl) in our study statistically increased from 8.6 g/dl pretreatment to 11.8 g/dl 24 weeks post treatment. Devi L.T *et al* also observed a increase in mean Hb from 8.2 to 9.6 post treatment [8]

Lack of response and loss of follow up

In the present study 4.34 % patient had no improvement in symptoms after treatment for 24 weeks. also 13% had PBAC score of >100 even 6 months after treatment.

4 patients were lost to follow up.

Conclusion

Ormeloxifene has excellent safety profile as it is a nonsteroidal, nonhormonal drug, with its twice weekly dosing. It is user friendly, and increases patient compliance too. It is definitely a better alternative for patients who do not want surgery or have medical complications which contra indicate the use of steroidal drugs. Hence, ormeloxifene is a safe and effective option for treatment of menorrhagia.

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