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Original Research Article

A comparative study of norethisterone and dydrogesterone in the treatment of heavy menstrual bleeding

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ABSTRACT

Background: HMB is described as bleeding for >7 days or >80 ml per cycle/ having a higher than 100 score on the pictorial blood assessment chart (PBAC). Medical management is the first line of treatment. Norethisterone is most commonly used oral progestin. Dydrogestrone is a C-21 derivative which is highly selective synthetic progestin, closely related to endogenous progesterone.
Methods: The 170 cases of heavy menstrual bleeding (HMB) with ovulatory disorder in the range of 20-45 years of age were assigned into two groups (85 women in each group). Group A received Norethisterone 10 mg and Group B received Dydrogesterone 10 mg twice daily respectively till bleeding stopped, the same dose was continued for another one week and then 10 mg OD for one week till 28 days of LMP whichever was later. Both the groups were followed up for another 3 cycles and response to treatment were analysed using PBAC score and Hb levels before and after treatment.
Results: A significant decrease in PBAC score and improvement in haemoglobin level were observed in both the groups i.e. 82.35% women in Norethisterone group and 78.82% in Dydrogesterone group respectively. In Norethisterone group 3.53% and 7.08% women in Dydrogesterone group underwent hysterectomy whereas 5.9% women in Norethisterone and 4.7% in Dydrogesterone group opted for therapeutic dilatation and curettage respectively.
Conclusions: Dydrogesterone is as effective as Norethisterone in controlling heavy menstrual bleeding. Dydrogesterone can be considered as a safer and efficacious alternative to Norethisterone given its highly selective nature and the absence of androgenic side effects.

Keywords: Dydrogesterone, HMB, Norethisterone, PBAC

INTRODUCTION

The most frequent complaint mentioned by women of reproductive age visiting a gynaecology outpatient department is heavy menstrual bleeding. HMB is described as bleeding for more than seven days/more than 80 ml or having a higher than 100 score on the pictorial blood assessment chart (PBAC).[1] Up to 50% of women may experience HMB during the perimenopause transit phase. Heavy menstrual bleeding affects 10-30% of women who are menstruating at any given point of time.[2] Common causes of HMB are fibroid, adenomyosis, ovulatory causes, endometrial hyperplasia and malignancy popularly known as PALM-COEIN classification.[3] There are several ways to measure menstrual blood loss, including the alkaline hematin method, the pictorial blood loss assessment chart, the menstrual pictogram, the measurement of iron/labelled red blood cells from the pad and the self-perception method with the menorrhagia impact questionnaire (MIQ). The most convenient and patient-friendly method is the sanitary pad blood soaking and assessment. Various modalities of treatment are available such as, oral progestogens which converts proliferative endometrium to secretory endometrium, progesterone only pills, combined oral contraceptives, levonorgestrel intra uterine system (LNG-IUS), tranexamic acid which is anti-fibrinolytic, injectable progesterone, GNRH agonist, Selective oestrogen receptor modulator (SERM) and minimally invasive procedures like, dilatation and curettage, endometrial resection,

ablation by diathermy and laser and finally hysterectomy as a last resort.[4]

Medical therapy is the first line of treatment for heavy menstrual bleeding. Oral progestins are the most commonly prescribed medication for heavy menstrual bleeding.[5] Progestins are used as maintenance therapy, for regularising cycles and for acute management of HMB. Progestins are powerful anti- oestrogens and will control an-ovulatory bleeding. Oral progestins very effective in controlling HMB. Norethisterone is a C-19 derivative, the most commonly used oral progestin.[6] It is used as a short course therapy and requires prolonged administration.[7] It has few androgenic side effects which makes it unsuitable for prolonged use.[7]

Dydrogesterone is a highly selective synthetic progestin, it's a C-21 derivative which is closely related to endogenous progesterone and acts on progesterone receptors and causes cessation of menstrual bleeding.[8] It regularises menstrual cycles in patients with AUB. It has no inhibitory effect on ovulation and transforms proliferative endometrium into secretory endometrium.[8]

With proper selection of effective progestin in controlling heavy menstrual bleeding, we can avoid hysterectomies and its associated operative morbidity. Dydrogesterone has a better safety profile when compared to norethisterone but studies showing the efficacy of dydrogesterone in controlling HMB are limited.[8] It has lesser androgenic effects which makes it safe to use during pregnancy and for long-term administration.[9] Furthermore, there are very few studies comparing the efficacy of dydrogesterone and norethisterone.

This study will help us to know the effectiveness of dydrogesterone compared to norethisterone in controlling heavy menstrual bleeding.

METHODS

A hospital based prospective randomised controlled study conducted in an outpatient department of obstetrics and gynaecology Sri Narasimha Raja District Hospital, Kolar, Karnataka, among the reproductive age women who presented to OPD with HMB and met the inclusion and exclusion criteria. Total 170 women were enrolled in the study for a period of 18 months, between November 2022 to May 2024.

Inclusion criteria

All reproductive age group women (20-45 years) with heavy menstrual bleeding who are hemodynamically stable were included in the study.

Exclusion criteria

Women with organic causes of heavy menstrual bleeding such as, leiomyoma, adenomyosis, endometrial and cervical polyp were precluded, also women with breast and genital tract malignancies/ cardiac disorders/ hepato-renal dysfunction/ thyroid disorders/ coagulopathies and history of thromboembolism/ hypersensitivities to either of the drugs were excluded from the study.

Data collection

Reproductive age group women (20-45 years) with heavy menstrual bleeding and who are hemodynamically stable attending outpatient department of obstetrics and gynaecology were randomly assigned to group A and B during the study period. A written and informed consent was obtained from the participants prior to the study.

Detailed history regarding the severity, duration, frequency of bleeding and associated symptoms, age of menarche, menstrual history and parity was obtained. General and gynaecological examination was carried out to rule out medical and organic pelvic disease. All routine investigations like complete blood count (Haemoglobin for severity of anaemia), Blood grouping and typing with a baseline ultrasonography of pelvic organs performed to exclude the known organic causes of HMB.

Group A received norethisterone 10 mg and Group B received dydrogesterone 10 mg twice daily respectively till bleeding stopped, the same dose was continued for another one week and then 10 mg OD for one week till 28 days of LMP whichever was later. Women in both the groups complaining of HMB in the subsequent cycle, were treated with same regimen and both the groups were followed up for another 3 cycles.

Women in both the groups with normal menstrual bleeding in subsequent cycles, Norethisterone 10 mg (Group A) and Dydrogesterone 10 mg (Group B) OD was prescribed for 7 days from 21st day of cycle for 2 cycles and they were followed up for another 3 cycles.

Women in both the groups were prescribed a standard sanitary pad and clear instructions were given. The reduction in menstrual blood loss was assessed by patient perception of improvement in symptoms, number of pads used and PBAC. Patients were reviewed at the end of 0th, 1st and 6th month of the study to know the response to treatment by assessing of haemoglobin value and PBAC scores and these values were compared in both the groups. Patients in both the groups were observed for common side effects of the drugs. Women with no response to either of norethisterone and dydrogesterone the alternate modalities of treatment such as addition of oestrogens in hypoestrogenic conditions or uterine curettage/ LNG-IUS/ Hysterectomy were considered.

Statistical analysis

Data were imported into MS Excel and SPSS V25 was used for analysis. Mean with SD or Median with IQR were used to depict descriptive statistics for quantitative data

and percentages were used for qualitative data. Using the Shapiro-Wilk test, normality was determined. The Fisher Exact test and the Chi-square test were used to compare the proportions. The Mansfield-Whitney U test was utilised to compare the medians. P values less than 0.05 were deemed statistically significant.

RESULTS

This was a prospective comparative study to know the effectiveness of norethisterone and dydrogesterone in the treatment of heavy menstrual bleeding. We enrolled 170 women and randomly assigned them into group A and Group B with 85 women in each. The present study included women aged 38 to 45 years.

In our study, women belonged to age ranging from 38 years to 45 years. In both the study groups majority of women belonged to 40 to 41 years, i.e., 41 (48.2%) in Norethisterone group and 48 (56.5%) in Dydrogesterone group. Least number of cases belonged to 44-45 years in both groups, 4 (4.7%) in Norethisterone group and 5 (5.9%) in Dydrogesterone group. The mean age among the study participants was found to be 40.81±1.56 years in Norethisterone group and 40.74±1.45 years in Dydrogesterone group.

Regarding parity most women i.e., 168 (98.90%) in both groups were multiparas 79 women in the dydrogesterone group (92.90%) and 69 women in the norethisterone group (81.20%) had a parity of two. In Norethisterone group 15 (17.60%) women and in Dydrogesterone group 5 (5.90%) women had parity of 3 and one women in each group was nulliparous. In the norethisterone group 76 (89.4%) women and in the dydrogesterone group 78 (91.8%) women belonged to the middle class and 80 (94.1%) women in both groups had completed high school education.

The initial mean endometrial thickness (ET) in group A was 10.23 mm and in Group B it was 10.26 mm. At 6 months of treatment ET in Group 1 was 10.04 mm and group 2 it was 10.11 mm. Percentage change in the mean endometrial thickness in group 1 was 1.85% whereas in Group 2 it was 1.55%. There was no significant difference between mean endometrial thickness in both groups (p=0.3).

In Norethisterone 3 women (3.6%) experienced nausea, 3 (3.6%) women had headache and 6 (7.2%) women developed acne as adverse effects. Likewise, among the women in the Dydrogesterone group, 3 (3.6%) women had nausea, 3 (3.6%) had headache, 2 (2.4%) women had vomiting episodes and 2 (2.4%) women experience mood swings. None of the women in either group had severe symptoms necessitating drug discontinuation. The mean duration of bleeding in norethisterone group was 9.36±2.25 days and in dydrogesterone group was 9.07±2.36 days. This comparison had a p value of 0.19. The mean cycle length of menstrual cycle in norethisterone group was 31.22±1.93 days and in dydrogesterone group it was 31.24±1.78 days. This comparison had a P value of 0.94.

The mean distribution of treatment duration was 8.04±2.32 months for the Norethisterone group and 8.00±2.68 months for the Dydrogesterone group. P value for this comparison was 0.56. At the start of the treatment (0 month), the mean haemoglobin in the dydrogesterone group was 9.18±0.61 g/dl and in the norethisterone group it was 9.08±0.71 g/dl with p value of 0.4.

At the 3-months, both groups mean haemoglobin levels have improved; in the Norethisterone group, it was 10.03±.67 g/dl and in the Dydrogesterone group, it was 10.15±.69 g/dl, with a p value of 0.25. At the 6-month follow-up, the mean haemoglobin levels in both groups had increased even further, i.e., 10.90±.61 g/dl in Dydrogesterone group and 10.91±.61 g/dl in Norethisterone group with a p value of 0.9.

At three and six months, mean haemoglobin levels were found to be continuously rising in both groups; however, at these points, the p-value was more than 0.05, suggesting that both groups were equally successful. In both study groups, the mean PBAC score was greater than 100 at the beginning of the treatment (0 month). PBAC mean score for the Norethisterone group was 202.54±11.79, while for the Dydrogesterone group it was 202.45±13.02.

In the Norethisterone group, the mean PBAC score was 96.95±8.77, while in the Dydrogesterone group it was 96.65±8.44 with a p value of 0.83. These groups mean PBAC scores were lower when they were followed up after three months. In the Norethisterone group, the mean PBAC score was 80.78±7.60 at the 6 months follow-up, whereas in the dydrogesterone group, it was 81.18±10.11 with a p value of 0.35. Both groups mean PBAC scores had further dropped. The mean PBAC score was found to be continuously declining in both groups at three and six months, although the p values at both points were greater than 0.05, suggesting that both groups were equally effective. 83 patients (97.6%) out of 85 exhibited improvements, indicating gains in both groups. with a p value of 1. showing the same level of effectiveness for both drugs.

Table 1: Mean distribution based on menstrual blood flow.

Variable	Group	Minimum	Maximum	Mean	SD	Median	IQR	P value
No of days of flow	Group-A Norethisterone	5	15	9.36	2.25	9.00	2.00	0.19
	Group-B Dydrogesterone	5	15	9.07	2.36	9.00	2.00	

Table 2: Mean cycle length.

Variable	Group	Minimum	Maximum	Mean	SD	Median	IQR	P value
Cycle length	Group-A Norethisterone	28	35	31.22	1.93	30.00	2.00	0.94
	Group-B Dydrogesterone	29	35	31.24	1.78	30.00	2.00	

Table 3: Mean distribution of treatment duration.

Variable	Group	Minimum	Maximum	Mean	SD	Median	IQR	P value
Duration of treatment in months	Group-A Norethisterone	4	14	8.04	2.32	8.00	4.00	0.56
	Group-B Dydrogesterone	6	15	8.00	2.68	6.00	2.50	

Table 4: Mean distribution based on haemoglobin levels at 0 month (HB0), 3 months (HB3) and 6 months (HB6).

Variable	Group	Minimum	Maximum	Mean	SD	Median	IQR	P value
HB0	Group-A Norethisterone	6.9	9.9	9.08	0.71	9.10	0.80	0.4
	Group-B Dydrogesterone	7.8	9.9	9.18	0.61	9.10	0.90	
HB3	Group-A Norethisterone	8.1	11.1	10.03	0.67	10.10	1.00	0.25
	Group-B Dydrogesterone	8.8	11.1	10.15	0.69	10.20	1.15	
HB6	Group-A Norethisterone	9.9	11.6	10.91	0.61	11.00	1.30	0.9
	Group-B Dydrogesterone	9.9	11.6	10.90	0.61	11.00	1.40	

Table 5: Mean distribution based on PBAC score at 0 months (PBAC0), 3 months (PBAC3) and 6 months (PBAC6).

Variable	Group	Minimum	Maximum	Mean	SD	Median	IQR	P value
PBAC0	Group-A Norethisterone	180	230	202.54	11.79	201.00	12.00	0.82
	Group-B Dydrogesterone	180	230	202.45	13.02	200.00	12.00	
PBAC3	Group-A Norethisterone	84	130	96.95	8.77	98.00	13.00	0.83
	Group-B Dydrogesterone	84	130	96.65	8.44	98.00	12.00	
PBAC6	Group-A Norethisterone	60	88	80.78	7.60	84.00	8.00	0.35
	Group-B Dydrogesterone	28	88	81.18	10.11	84.00	6.00	

Table 6: Comparison of both groups with respect to improvement.

Improvement	Group-A Norethisterone		Group-B Dydrogesterone	
	Count	**%**	**Count**	**%**
No	2	2.4	2	2.4
Yes	83	97.6	83	97.6
Total	85	100.0	85	100.0
P=1				

Table 7: Similar studies with mean age distribution as our study.

	Norethisterone group	Dydrogesterone group
Our study	40.81±1.56	40.74±1.45
Yaaqoub et al[10]	28±3.5	27.5±3.8
Yasin et al[11]	29±3.4	29.5±3.6

Table 8: Comparison of drug efficacy among similar other studies.

Our study	Both the norethisterone and dydrogesterone are equally effective, there was no difference in terms of efficacy in both drugs
Yaaqoub et al[10]	Both the Norethisterone and Dydrogesterone are equally effective, there was no difference in terms of efficacy in both drugs
Yasin et al[11]	Norethisterone had a better cycle control than Dydrogesterone.

Continued.

Our study	**Both the norethisterone and dydrogesterone are equally effective, there was no difference in terms of efficacy in both drugs**
Kader et al[12]	Norethisterone had a better cycle control than Medroxyprogestrone
Sen et al[13]	Norethisterone and low-dose COC pills were found to be equally efficacious.

DISCUSSION

Heavy menstrual bleeding It is one of the most common gynaecological problems for which patients visit the hospital. It affects almost 1/3rd of the women of child bearing age group. It is the reason for severe anaemia. It is associated with psychological morbidity and has poor quality of life on the physical, emotional and social levels.

Pharmacological therapies are presently the sole treatment for women with HMB who wants to retain their fertility. Oral progestins are the most commonly used drugs for treatment of HMB due to ovulatory dysfunction after ruling out the organic pathology and are considered to be most effective and safer medications due to their anti-estrogenic action on proliferative endometrium and reduced risk of endometrial carcinoma.

Other pharmacological therapies such as NSAIDS, oral contraceptive tablets, danazol, GnRH agonists and antifibrinolytic medicines all help to lower menstrual blood loss, but their benefits are for short term. In this study, Norethisterone group had mean distribution of age of 40.81±1.56 years and Dydrogesterone group had mean distribution of age of 40.74±1.45 years. Similar studies had younger study subjects. Norethisterone group had a mean distribution of blood flow of 9.36±2.25 days and the Dydrogesterone group had a mean distribution of flow of 9.07±2.36 days.

Norethisterone group had mean distribution of cycle length of 31.22±1.93 days and Dydrogesterone group had mean distribution of cycle length of 31.24±1.78 days. In this study at the initiation of treatment, both the study groups had anaemia with mean Hb in norethisterone group 9.08±0.71 g/dl and in dydrogesterone group 9.18±0.61 g/dl. At the completion of treatment, in Norethisterone group mean Hb was 10.91±0.61 g/dl and in Dydrogesterone group was 10.90±0.61 g/dl with the p value of 0.9, indicating that both the drugs were equally effective.

In similar study done by Kader et al, compared norethisterone and medroxyprogesterone where pre-treatment Hb was 8.2 and 8.3 g/dl respectively which increased to 10.6 and 10.2 g/dl respectively post treatment this increment is statistically significant.[12] Hence, they concluded norethisterone was a better drug in increasing haemoglobin. In similar study done by Sen et al, compared norethisterone and COC pills where pretreatment Hb was 7.64±0.58 and 7.72±0.50 g/dl respectively which increased to 10.44±0.78 and 10.38±0.64 g/dl respectively post treatment this increment was not statistically significant.[13] Hence, they concluded both drugs are equally effective. In this study at the initiation of treatment, in norethisterone group mean PBAC score 202.54±11.79 and in dydrogesterone group 202.45±13.02. At the completion of treatment, PBAC score had reduced in both groups, in Norethisterone group mean PBAC score was 80.78±7.60 and in dydrogesterone group was 81.18±10.11, with the p value of 0.35 indicating that both the were equally effective. In similar study done by Kader et al, compared norethisterone and medroxyprogesterone where pretreatment PBAC score was 230 and 226 respectively which decreased to 96 and 113 respectively post treatment this decreased score was statistically significant.[12] Hence, they concluded Norethisterone was a better drug.

In similar study done by Sen et al, compared norethisterone and COC pills where pretreatment PBAC score was 176.16±5.75 and 175.58±6.07 respectively which decreased to 77.80±5.76 and 78.88±8.51 respectively post treatment this decreased score was statistically significant.[13] Hence, they concluded both drugs are equally effective. The mean distribution of treatment duration was 4.02±0.69 days for the norethisterone group and 4.20±1.07 days for the dydrogesterone group. On comparing both the groups there was no statistical difference in the treatment duration with p value 0.64 (p=0.64).

After initiating treatment, in 20 women (23.81%) bleeding stopped on day 2 of norethisterone administration, likewise on 3rd, 4th and 5th day of menstruation in 40 (47.63%) 6 women (7.10%) and 4 women (7.10%) respectively. In the dydrogesterone group, in 9 (10.58%) women, bleeding stopped on the 4th day and in 58 (68.23%) women on day five. It was observed that Norethisterone has faster control of heavy menstrual bleeding when compare to dydrogesterone. Similar findings were found by Papapanagiotou et al.[14]

In the norethisterone group, 8 (9.4%)) women did not respond adequately to treatment and opted for surgical management, 3 (3.53%) women underwent hysterectomy and 5 (5.9%) underwent therapeutic dilatation and curettage. Similarly, 10 (11.8%) women in dydrogesterone group did not respond to the given treatment and 6 (7.08%) women opted for hysterectomy while 4 (4.7%) women underwent therapeutic dilatation and curettage.

In our study, we found that both the norethisterone and dydrogesterone are equally effective, there was no difference in terms of efficacy in both drugs, similar findings were found in Yaaqoub et al.[10] But study done by Yasin et al, found both the norethisterone and dydrogesterone are equally effective, there was no difference in terms of efficacy in both drugs.[11] Study done by Kader et al, found that norethisterone had a better cycle control than medroxyprogestrone.[12] Sen et al, found that

Norethisterone and low-dose COC pills were found to be equally efficacious.[13]

Both drugs had an established safety profile and none of the women in either group had severe symptoms necessitating drug discontinuation. Absence of androgenic side effects with dydrogesterone had an advantage over norethisterone. A similar prospective observational study, Dydrogesterone treatment for menstrual cycle regularisation in abnormal uterine bleeding- ovulation dysfunction patients conducted by Wang et al.[8] The study concludes that dydrogesterone has no adverse effects related to alteration in sex steroid hormones and metabolic side effects and is well tolerated by patients.

Dydrogesterone is expensive drug and larger studies including a greater number of patients are required to clarify and confirm the effectiveness of dydrogesterone use for heavy menstrual bleeding

CONCLUSION

Dydrogesterone is newer synthetic molecule which is similar to endogenous progesterone. Dydrogesterone is as effective as norethisterone in controlling heavy menstrual bleeding and improving the haemoglobin levels. Dydrogesterone can be considered as a safer and efficacious alternative to norethisterone given its highly selective nature and the absence of androgenic side effects.

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