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RESEARCH ARTICLE

A study on tranexamic acid among patients with heavy menstrual bleeding attending tertiary care hospital

AR Jameela Ponmalar, Rema V Nair, Nadiya Hameed Farooq

Corresponding author: Dr AR Jameela Ponmalar, Assistant Professor, Department of Obstetrics & Gynecology, Sree Mookambika Institute of Medical Sciences, Kulasekharam, Kanyakumari District, Tamil Nadu, India; Email: jameelaprasanth@gmail.com

ABSTRACT

Background: Heavy menstrual bleeding (HMB) is considered to be a public health challenge among women in the reproductive age group and it is the most commonly expressed complaints of women in our Gynecology OPD. The impact of HMB on a woman's quality of life has been well established and any intervention aims to improve this. Various methods including hormonal medications, antifibrinolytics, NSAIDS and surgical procedures are tried for the treatment of HMB. **Aim and objective:** The aim of the study is to determine the safety and efficacy of Tranexamic acid (TA) in the treatment of HMB. **Materials and methods:** This prospective observational study was carried out in 50 patients, who came to Obstetrics and Gynecology outpatient Department with complaints of regular excessive menstrual bleeding. The data collection process includes measurement of blood loss during menstruation, duration of bleeding, number of sanitary pads changed per day, Hb estimation and recording the symptomatic complaints they had during each cycles. **Results:** The study pointed out that there was significant decrease in menstrual bleeding, noticed in 35 out of 50 women. The mean PBAC score reduced from 150 ± 20 to 82 ± 12 and the mean amount of menstrual bleeding reduced from 120 ± 20 to 60 ± 15 ml, after treatment with tranexamic acid. Seventy percentage of women showed reduction in menstrual bleeding by 40 to 50%. The percentage of patient who had haemoglobin more than10 gm% increased from 8% to 18 %. Sanitary pad usage reduced from 30±5 to 20±5 and duration of flow reduced from 8±2 to 7± 2. Patients acceptability 70 %. No serious side effects were reported. **Conclusion:** In this study, oral TA 3 grams per day was generally well tolerated when used for up to 5 days and exhibited a favorable safety profile. The patients also had potential improvement in their quality of life. TA is a first line oral, nonhormonal, cost effective, nonsurgical alternative in women presenting with cyclical HMB.

Keywords: Tranexamic acid, heavy menstrual bleeding, menorrhagia.

Heavy menstrual bleeding (HMB) is defined as loss of excessive menstrual blood of more than 80 ml per cycle, interfering with a woman's quality of life and her productivity at work [1]. It can be presented alone or in association with other symptoms. It is estimated that the prevalence of HMB in women of reproductive age group is approximately 18 - 38% and the prevalence is seen to peak just before menopause [2]. Uterine pathologies, coagulative disorders, ovulatory dysfunction, inherited bleeding disorders are the common causes for HMB [3]. According to a study, 60% of women with menorrhagia will undergo hysterectomy within 5 years of their consultation with a gynecologist, accounting for up to 75% of all hysterectomy procedures that is performed globally [4\].

The mean duration of menses is 4.7 days; 89% of the cycle lasts 7 days. The average blood loss per cycle is 35 ml, and the major component of menstrual bleeding is endometrial tissue. An 80 ml per cycle is used as a definition of heavy menstrual bleeding and recurrent bleeding with loss exceeding 80 ml per cycle results in anemia [5]. Excess blood loss can result in anxiety, severe discomfort, embarrassment, inability to carry out day to day activities and also significant

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medical risks. In such conditions, treatment, either medical or surgical must be undertaken to eliminate the underlying cause, thus lowering the morbidity in reproductive aged women.

Studies have shown that fibrinolytic activity of the enzymes in the endometrium appear to play a major role in hemostasis, endometrial shedding and its repair. The endometrial extracts showed increased activity of plasmin and plasminogen activator, which suggested fibrinolysis in the menstrual fluid [6]. This lead to the evaluation of antifibrinolytic agents as an ideal treatment option for the treatment of menorrhagia by FDA. Tranexamic acid, having established efficacy in reducing menstrual blood loss has been thus used for the treatment of HMB. It is a competitive plasminogen inhibitor and stabilizes the fibrin matrix [7]. The drug is generally well tolerated, however gastrointestinal side effects may limit its use [8]. Hence the efficacy and safety of TA in the treatment of HMB has been evaluated in this study.

Materials and method

This study was an observational study which was conducted in Sree Mookambika Institute of Medical Sciences Hospital, Kulasekharam. For this, a total of 50 women aged 18 to 45 years, those fulfilling the selection criteria, was selected among those attending the outpatient department between September 2020 to September 2021, with complaints of cyclical excessive menstrual bleeding for two or more consecutive cycles. Patients with bleeding during regular cycles of 21 to 35 days with each menstruation lasting for ≤10 days were included. We have obtained both the informed and written consent from the study participants.

Inclusion criteria:

- Women aged 18 to 45 years with complaints of HMB with duration of cycle between 21 to 35 days and menstrual periods not more than 10 days duration.

Exclusion criteria:

- Patients who had history of clinically significant menstrual disorders, intermenstrual bleeding, anovulatory dysfunctional uterine bleeding, endometrial polyps, precancerous or cancerous lesions of the endometrium.
- Patients on long term drug therapy and patients with history of prior uterine surgeries.
- Systemic diseases like myocardial infarction, ischemic disease, cerebrovascular disease, stroke, transient ischemic attack, thrombosis or coagulopathy.
- Patients with existing renal or hepatic disorders and gastrointestinal ulcers.

Procedure: Complete history regarding previous as well as present menstrual cycles, obstetric, past medical, surgical and family history should be elicited. General physical examination, per abdomen, per speculum and per vaginal examinations was done. Routine investigations like complete hemogram, urine analysis, thyroid, renal and liver function test, peripheral smear, urine pregnancy tests were done for all patients. Transabdominal and transvaginal ultrasonography was performed in indicated patients. Assessment of menstrual blood loss was done using pictogram for two pre-treatment menstrual cycles, serving as controls and was compared with 2 post-treatment cycles. Patients were advised to use similar type of sanitary pads with similar absorbent capacities during the study period.

Tranexamic acid 1 gm thrice daily was started from day 1 to day 5 of their cycle for the next two consecutive cycles. Patients were asked to keep a note on the number of pads or tampons soaked or changed per day and record them in the pictogram provided, based on which PBAC (scored as 1, 5, or 20 respectively); and tampons (scored as 1, 5 or 10 respectively) passage of clots (assigned ascending scores from 1-5) and episodes of flooding are also recorded. When used as a diagnostic test for HMB, a score of >100 defines HMB. Patients were enquired about adverse effects with the use of the drug and if any, were recorded.

Data collected and entered in software Excel 16.0 Statistical Analysis was done using the software SPSS trial version 20.0. Statistical test used are descriptive statistics (mean, SD, frequency, percentage).

Results

This was a prospective observational study conducted in 50 women, attending the Out Patient Department of Obstetrics and Gynecology, between the age group of 18-45 years, presenting with the complaints of heavy menstrual bleeding to assess the safety and efficacy of tranexamic acid, in terms of reduction of blood loss during menstruation in subsequent cycles, improvement in Hb level, and in health-related quality of life as reflected by the acceptance of treatment. Tab tranexamic acid 1 gram thrice daily for first 5 days of menstruation who had objective blood loss of more than 80ml in each menstrual cycle and PBAC score of more than 100 per cycle for total of 50 women with abnormal excessive uterine bleeding. 42% of patients with HMB were within the age group of 39- 45 years. Parous women (90%) were affected more than unmarried or nullipara. 60% women were sterilized after two live children, 40% women with symptoms were overweight with BMI of 25 -29-9 kg/m2. Thirty six percent of women were diagnosed with uterine pathologies and 22% women had ovarian pathologies. 33 out of 50 women had cycle length of >7 days (66%), Effect of the drug on the Hb level and amount of blood loss was estimated. Menstrual blood loss was significantly reduced (40 to 50%) in 35 study participants (70%) as shown in table1.

Table 1:Effect of drug on the percentage reduction of menstrual blood loss

Effect of drug on the %of reduction of menstrual blood loss	No. of Women	Percentage
<35 %	4	8%
35%-40%	6	12%
40%-45%	18	36%
45%-50%	17	34%
50%-55%	3	6%
55%-60%	2	4%

Table 2: Effect on HB

Findings	No. of women	%
Hb (gm%) before treatment		
<10	36	72
10	10	20
>10	4	8
Hb (gm%) after treatment		
<10	20	40
10	21	42
>10	9	18
Total	50	100%

Table 3: Effect of drug on PBAC scoring and amount of blood loss

Effect of drug on PBAC scoring	Mean± SD
Before treatment	150 ± 20
After treatment	82 ± 12
Effect of drug on the amount of bleeding (ml)	
Before treatment	120 ± 20
After treatment	60 ± 15

Table 4: Effect on usage of sanitary pads

Parameters	Before treatment	After treatment
No of pads /cycle	30±5	20±5
Duration of flow	8±2	7±2

The percentage of patients who had Hb% more than 10gram%, increased from 8% to 18% after treatment with tranexamic acid and iron therapy (table 2).The mean PBAC score reduced from 150±20 to 82 ± 12 and the mean amount of menstrual bleeding reduced from 120±20 to 60±15 ml, after treatment with tranexamic acid (table 3). Sanitary pad usage reduced from 30±5 to 20± 5 and duration of flow reduced from 8±2 to 7±2 (table 4). Patients acceptability was 70 %. Minor gastrointestinal side effects were observed among 4(8%) out of 50 women indicating that side effects are very minimal with the usage of TA.

Discussion

In this study, we have assessed the effectiveness of tranexamic acid in reducing the menstrual blood loss in women with complaints of HMB, using pictorial blood loss assessment chart. It was simple and cost effective method, as most of the patients in the study group were from rural areas and belonged to lower socioeconomic status.

Patient satisfaction rates and acceptance of the drug, determined by their willingness to continue the treatment even after the study period was noted. The dosage of tranexamic acid used in our study was 3 grams per day whereas 3.9 gms were used in most of the other studies [9 - 11]. Leminen H et al in a study had mentioned that the dosage should not exceed 4 grams per day [6]. Freeman EW et al [12] compared the efficacy of the oral formulations of the drug at different dosages and found that at lower doses of 650 mg, the mean menstrual blood loss was 26% and at higher dosage of 1300 mg, it was 39%. It was also mentioned that 4 to 4.5g was the dosage used in studies that compare the efficacy of TA either with other medical therapies or with placebo.

Majority of the women who presented with complaints of HMB in our study were between 39 – 45 years, which was similar to findings by Vani PYS [4].

In our study, 70% women showed 40 – 50% reduction in menstrual blood loss after treatment with TA. Similar results were also noted in other studies by Naoulu et al [12] with 34 – 54% reduction and by Perriera L et al [13] with a 40.4 % (69.6 ml) reduction of blood loss when TA was used as a treatment option. Winkler [14] in his study had shown 94% subjective decrease after third treatment with TA, which was higher compared to our study.

In a comparative study done by Preston JT et al [15], the mean blood loss was reduced by 45% (175 to 97ml) with tranexamic acid, whereas in our study, it was 50%(120- 60), indicating the efficacy of the drug. It is also reported that tranexamic acid remains as an effective form of medical therapy as it normalizes blood loss in women losing 80 to 200 ml. Reduction in menstrual blood loss was maintained throughout the study period.

The PBAC is the most commonly used and the best available method in assessing the blood loss during menstruation. Higham et al [16] first described PBAC in 1990 as a simplest non-laboratory method in diagnosing HMB with a sensitivity of 86% and specificity of 89. A score of more than 100 indicates HMB. The mean PBAC score in our study reduced from 150±20 to 82±12 after treatment. In a prospective randomised study by Kriplani A et al, [17] the mean pictorial blood loss assessment chart (PBAC) score decreased from the pre-treatment score of 356.9 to 141.6 after treatment with TA, with 60.3% mean reduction in blood loss. Another study by Madhu J et al,[18] where the efficacy of tranexamic acid was compared with mefenamic acid, showed that the PBAC score reduced by 50% in TA group and only by 31% in mefenamic acid group, proving tranexamic acid to be more efficacious.

The percentage of patients, in our study who had Hb% more than 10gram% increased from 8% to 18% after treatment with tranexamic acid for two cycles. Ken Muse et al [19] in his study reports that 34.1% patients with low haemoglobin at baseline returned to the normal limit after three cycles and 45.7% patients after 27 cycles. In a study by Vani PYS et al [4], after treatment with TA and oral iron the mean haemoglobin level increased from baseline 1.6±1, in women who became anaemic following heavy menstrual bleeding. A study conducted in UP [20] where tranexamic acid was compared with its combination with mefenamic acid, the mean hemoglobin concentration after 6 months of follow up showed an improvement of 26.3% with TA alone, whereas 43% improvement was noticed on its combination with mefenamic acid.

No serious side effects were reported in our study other than a few incidences of gastrointestinal effects (4%). Furthermore, in a double blinded study by Wellington et al [21], 12% of patients who received TA, also reported gastrointestinal adverse effects like diarrhoea, nausea, vomiting and dyspepsia. A long-term follow-up study of 27 cycles (n=723) of treatment with a new formulation of oral tranexamic acid, reported adverse effects like headache, back ache and menstrual discomforts with mild to moderate severity. But it was reported that these adverse effects were unrelated to treatment with tranexamic acid [22]. Hrometz SL[23] also observed similar findings in his study. But unlike other studies, ocular side effects were reported by few proportions of women in a study by Andrea S Lukes [8]. No serious adverse effects were reported in any studies and hence can be used as a safe drug in treating HMB.

Health related qualities of life were also improved in our study participants. In a double-blinded, placebo controlled study by Freeman et al [24] (n=294) administered tranexamic acid for three cycles in doses of 1.95 grams per day for 5 days compared with 3.9 grams per day for 5 days and showed that mean Menorrhagia Impact Questionnaire (MIQ) scores for limitations of activities decreased significantly in both groups compared with placebo. Another randomized control study also assessed the quality of life in women with HMB using validated questionnaires and demonstrated significant improvement after treatment with TA [25].

The duration of blood loss had no change in our study participants after treatment with TA. Similar results were reported by several other studies [26-29]. But Kriplani A et al [17] in his study comparing TA with MPA, states that the duration of bleeding had significantly decreased in both the groups, compared with the baseline.

Tranexamic acid is a well-tolerated and cost effective, non-surgical option for treating HMB and can be used as a first line alternative to other medical and surgical treatments. Tranexamic acid has better pharmacological effect and safety profile, which makes it an ideal treatment option in women with HMB.

Conclusion

The study suggests that tranexamic acid is safe and effective in the treatment of heavy menstrual bleeding. About 90% of menstrual blood loss occurs within the first 3 days of menstruation and in menorrhagia, treatment given during this period will effectively minimise the excessive menstrual blood loss. Our study has shown that there is significant reduction in menstrual blood loss. Tranexamic acid may be used as the first line drug in the management of abnormal uterine bleeding. It is cost effective compared to other modalities and can be offered to women with abnormal uterine bleeding, before opting for surgery.

Conflict of interest: None. **Disclaimer:** Nil.

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AR Jameela Ponmalar [1], Rema V Nair [2], Nadiya Hameed Farooq [3]

[1] Associate Professor, Department of Obstetrics & Gynecology, Sree Mookambika Institute of Medical Sciences, Kulasekharam, Kanyakumari District, Tamil Nadu, India; [2] Professor, Department of Obstetrics & Gynecology, Sree Mookambika Institute of Medical Sciences, Kulasekharam, Kanyakumari District, Tamil Nadu, India; [3] Postgraduate, Department of Obstetrics & Gynecology, Sree Mookambika Institute of Medical Sciences, Kulasekharam, Kanyakumari District, Tamil Nadu, India.