RESEARCH PAPER

Comparative Efficacy of a Herbal Anti-Fibrinolytic Formulation and Tranexamic Acid for the Management of Heavy Menstrual Bleeding of Endometrial Origin: A Randomized Controlled Clinical Study

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Abstract

Background: Heavy menstrual bleeding (HMB) is a frequent and clinically meaningful form of abnormal uterine bleeding in reproductive-aged women. It affects physical functioning, emotional well-being, productivity and risk of iron-deficiency anemia. Tranexamic acid is an established non-hormonal antifibrinolytic therapy, but repeated menstrual-cycle use, symptom recurrence and patient preference for non-hormonal and integrative approaches justify evaluation of safe herbal alternatives. Objective: To convert a randomized dissertation dataset into a journal-style research paper evaluating the comparative clinical efficacy of a herbal anti-fibrinolytic formulation containing Patha (Cissampelos pareira), Dhamasa (Fagonia cretica), Indrayava (Holarrhena antidysenterica) and Dadim Pushpa (Punica granatum flower) versus tranexamic acid in HMB of endometrial origin. Methods: Thirty women fulfilling eligibility criteria were randomized into two equal groups. Group A received the herbal formulation as Vati, 2.5 g orally three times daily for 5 days in each menstrual cycle for three cycles. Group B received tranexamic acid 500 mg orally three times daily for 5 days in each menstrual cycle for the same duration. Outcomes included pain, digestive power, duration of menstrual flow, menstrual-flow interval and PBAC score. Results: Both groups improved, but Group A showed numerically greater improvement in pain (66.23% vs 44.95%), duration of menstrual flow (91.89% vs 76.92%), menstrual-flow interval (42.35% vs 30.00%) and PBAC score (74.07% vs 72.93%). Between-group comparisons favored Group A for pain, duration, menstrual interval and PBAC, whereas digestive power did not differ significantly. Conclusion: In this small randomized dataset, the herbal anti-fibrinolytic formulation demonstrated clinically relevant and statistically supported improvements comparable or superior to tranexamic acid across major HMB outcomes. Larger, multicenter trials with objective fibrinolytic biomarkers, blinded assessment and longer follow-up are required before definitive clinical recommendations.

Keywords: heavy menstrual bleeding; abnormal uterine bleeding; tranexamic acid; anti-fibrinolytic; PBAC; Asrigdara; Raktapradara; Cissampelos pareira; Fagonia cretica; Holarrhena antidysenterica; Punica granatum.

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Introduction

Heavy menstrual bleeding is a symptom-based clinical entity rather than a single diagnosis. In contemporary gynecology it is usually discussed within the wider framework of abnormal uterine bleeding, where the volume, frequency, regularity and duration of bleeding are described in patient-centered language. FIGO terminology has been influential because it moved clinical communication away from imprecise historical labels and toward standardized descriptions of abnormal bleeding patterns and etiologies [1-5]. The commonly cited objective threshold of more than 80 mL menstrual blood loss per cycle remains useful for research, but in practice HMB is also defined by interference with a woman's

physical, emotional, social or material quality of life [1,3]. This distinction matters because a woman may experience clinically important impairment even when blood loss is not precisely measured by laboratory methods.

The clinical burden of HMB is not limited to blood loss. Recurrent heavy bleeding may result in anemia, fatigue, limitation of daily activities, menstrual anxiety and repeated healthcare consultations. Studies of menstrual blood loss and quality of life have consistently shown that women seek care not only because of the volume of bleeding but because of pain, unpredictability, need for frequent pad changes, clot passage, social restriction and fear of embarrassing leakage [17,18]. These outcomes are especially important in settings where women balance household, educational and occupational responsibilities and where access to advanced diagnostic or surgical care may be limited. Therefore, an intervention that reduces bleeding while also improving associated menstrual symptoms has practical value.

Pathophysiologically, HMB may arise from structural causes such as polyps, adenomyosis, leiomyomas or malignancy/hyperplasia, and from non-structural causes including coagulopathy, ovulatory disorders, endometrial dysfunction, iatrogenic factors and entities not otherwise classified [2,5]. The present research paper focuses on HMB of endometrial origin, a subgroup in which excessive bleeding occurs despite exclusion of major structural pathology. Endometrial hemostasis depends on vasoconstriction, platelet function, coagulation, local repair and controlled fibrinolysis. If endometrial fibrinolytic activity is excessive, the fibrin matrix formed to arrest menstrual bleeding is degraded too rapidly, producing prolonged or heavy bleeding. This mechanism provides the biological rationale for antifibrinolytic treatment [6-11].

Tranexamic acid is a synthetic lysine derivative that blocks lysine-binding sites on plasminogen and reduces conversion to plasmin at fibrin surfaces. In menstrual medicine, it is attractive because it is non-hormonal, is taken only during bleeding days and can reduce menstrual blood loss without suppressing ovulation [9-12]. Randomized trials and systematic reviews support its efficacy in reducing menstrual blood loss, and clinical guidelines include it among non-hormonal medical options for HMB [1,9-12]. Nonetheless, tranexamic acid does not address every symptom, is not suitable for all patients, and may cause gastrointestinal discomfort, headache or other adverse effects in some users. Patient preference, cost, cultural acceptance and desire for holistic management remain relevant factors in treatment selection.

Ayurveda describes excessive menstrual bleeding under entities such as Asrigdara and Raktapradara. Although the conceptual vocabulary differs from modern gynecology, several therapeutic goals overlap: arrest excessive bleeding, restore normal menstrual rhythm, reduce pain, support endometrial healing and improve the patient's general state. Classical principles emphasize Pitta and Rakta involvement, with Apana Vata contributing to disturbed expulsion and menstrual pain [24-29]. Herbs with Kashaya rasa, Rakta-stambhaka, Pitta-shamaka, Grahi and Rakta-prasadana actions are traditionally selected for bleeding disorders. These traditional principles can be translated into contemporary research questions by examining clinical endpoints such as bleeding duration, PBAC score and symptom relief.

The herbal formulation evaluated in the dissertation contains Patha, Dhamasa, Indrayava and Dadim Pushpa. The selection is pharmacologically plausible. Pomegranate flower is rich in astringent polyphenolic constituents and has been investigated in HMB in a randomized clinical context [19-21]. Cissampelos pareira and related Cissampelos species are discussed in ethnopharmacological literature for anti-inflammatory, antimicrobial, analgesic and traditional gynecological uses [22,23]. Holarrhena antidysenterica and Fagonia species are traditionally used in disorders involving bleeding, inflammation and tissue repair, and are described in pharmacopeial and Dravyaguna sources [24-26]. The combination therefore represents a multi-ingredient approach aimed at hemostasis and symptom regulation rather than a single-target drug effect.

The present manuscript reformats and critically interprets a randomized controlled dissertation study conducted in Pune, India. It does not invent new data. All numerical outcomes in the Results section are derived from the summarized tables of the dissertation dataset. The purpose is to present the available study information in a standard research-paper format, with transparent acknowledgement of limitations, while preserving the distinction between observed clinical signals and definitive therapeutic proof.

Literature Review

The international literature on abnormal uterine bleeding emphasizes the importance of classification before treatment. FIGO's PALM-COEIN system is particularly useful because it separates structural causes, which can often be identified by imaging or histopathology, from non-structural causes that may depend on systemic disorders, ovulatory function or endometrial hemostasis [2,5]. In the present study, the phrase 'endometrial origin' indicates that major structural causes were excluded by selection criteria and investigations. This framing is important because a trial of hemostatic or antifibrinolytic therapy is most interpretable when malignancy, pregnancy-related bleeding, fibroids requiring procedural care and thyroid dysfunction have been excluded.

Normal menstruation requires a tightly coordinated sequence of steroid withdrawal, inflammatory mediator activation, vasoconstriction, matrix breakdown and rapid endometrial repair. Modern endometrial biology recognizes menstruation as an inflammatory and reparative event in which local immune cells, cytokines, prostaglandins, matrix metalloproteinases, fibrin

deposition and fibrinolytic processes interact [6-8]. Excessive or prolonged bleeding may occur when this system is not balanced. In endometrial-origin HMB, the uterus may appear structurally normal, yet local hemostasis is insufficient. This explains why conventional imaging may not reveal the disease mechanism and why functional treatments, including tranexamic acid, remain important.

Tranexamic acid has a well-established mechanistic position in HMB. Its antifibrinolytic activity stabilizes the fibrin clot by limiting plasmin-mediated degradation. Trials such as the randomized study by Lukes and colleagues and the earlier BMJ trial comparing ethamsylate, mefenamic acid and tranexamic acid provide clinical evidence that menstrual blood loss can be substantially reduced without a hormonal mechanism [9,10]. Systematic reviews further support the use of antifibrinolytics, while noting that comparative evidence, safety monitoring and patient-specific contraindications must be considered [11,12]. This literature establishes tranexamic acid as a valid control intervention for a non-hormonal clinical trial.

Validated measurement of menstrual blood loss is a recurring challenge. The alkaline hematin method is regarded as a laboratory reference method, but it is impractical in routine clinical settings. Pictorial Blood Assessment Charts were developed to provide a simple, low-cost and patient-reported method for quantifying menstrual loss [14,15]. Later systematic review work showed that pictorial methods are widely used in trials, although chart design, scoring thresholds and diagnostic performance vary [16]. In the present study, PBAC was appropriately chosen as a practical quantitative endpoint. However, because PBAC is semi-quantitative and behavior-dependent, interpretation is strengthened when PBAC changes are considered alongside duration of bleeding, pain and other clinical symptoms.

The literature also highlights the multidimensional nature of HMB outcomes. Blood loss reduction is the primary therapeutic target, but symptom relief and quality-of-life improvement determine whether a patient considers treatment successful [17,18]. Pain can accompany HMB due to uterine contractions, prostaglandin activity, pelvic congestion or associated dysmenorrhea. Cycle irregularity and prolonged bleeding can produce anxiety even when hemoglobin remains acceptable. For these reasons, a study focused only on menstrual volume would under-report the clinical benefit or limitation of an intervention. The current dataset included pain, digestive power, menstrual-flow duration, menstrual interval and PBAC, allowing a broader clinical picture.

Herbal therapy for HMB requires scientific caution. Multi-herb formulations may contain constituents with astringent, anti-inflammatory, antioxidant, vascular-stabilizing or tissue-healing effects, but the pharmacological profile of a finished formulation is not equivalent to the sum of isolated plant reports. Dadim Pushpa is especially relevant because Punica granatum flower has been studied for anti-hemorrhagic activity in HMB of endometrial origin [19]. Pomegranate literature also supports the presence of tannins and polyphenols that may influence vascular integrity and local inflammatory pathways [20,21]. This does not prove antifibrinolysis in the biochemical sense, but it supports biological plausibility for reduced bleeding.

Patha, generally identified with Cissampelos pareira in the dissertation, has a history of use in Ayurvedic gynecological and inflammatory conditions. Ethnopharmacological literature on Cissampelos species describes alkaloids and other constituents with anti-inflammatory and smooth-muscle related biological activities [22,23]. Dhamasa, identified as Fagonia cretica in the study, is used traditionally in bleeding and inflammatory conditions. Indrayava, identified as Holarrhena antidysenterica, is classically recognized for Grahi and Stambhana properties in Ayurvedic materia medica and pharmacopeial sources [24-26]. These ingredients are therefore consistent with a formulation intended to reduce excessive flow and support tissue stability.

Ayurvedic classics and pharmacopoeial texts provide conceptual and identity support but cannot replace modern clinical evaluation [24-29]. The present paper therefore positions Ayurveda as the rationale for selecting the formulation and modern trial methodology as the means of testing the clinical signal. This is a useful model for integrative research: traditional terminology may guide drug selection and interpretation, while validated clinical outcomes, randomization, comparator arms and transparent statistics determine whether the intervention warrants further investigation.

Materials and Methods

Study design and setting. The source study was a randomized controlled clinical study conducted in the Department of Prasuti Tantra Evam Stri Roga, Bharati Ayurved Hospital, Bharati Vidyapeeth (Deemed to be University), College of Ayurveda and Hospital, Dhankawadi, Pune, India. Patients attending the outpatient department with abnormal uterine bleeding and symptoms consistent with HMB of endometrial origin were screened for eligibility. The design involved two parallel groups: an herbal anti-fibrinolytic trial group and a tranexamic acid control group. The dissertation recorded screening, counselling, written informed consent, case-record documentation, randomization, follow-up, observation, comparison, statistical analysis and conclusion as sequential study steps [30].

Participants. The target population comprised women of reproductive age between menarche and menopause. Inclusion criteria were age 18-45 years, complaints of excessive or prolonged menstrual bleeding or intermenstrual bleeding, and hemoglobin more than 9 g/dL. Exclusion criteria included thyroid dysfunction,

cervical pathologies such as fibroid, carcinoma or polyp, fibroid uterus and malignancy, intrauterine contraceptive device use, and threatened abortion, spontaneous abortion or pregnancy-related bleeding. These criteria were clinically reasonable because they restricted the study to HMB-like presentations in which conservative medical therapy could be ethically evaluated [30].

Sample size and allocation. The dissertation calculated sample size using a prevalence-based formula and rounded the sample to 15 patients per group. Therefore, 30 participants were enrolled in total. Group A received the herbal formulation and Group B received tranexamic acid. The small sample size should be considered exploratory. It permits a preliminary comparison of clinical signals but cannot establish population-level equivalence, non-inferiority or long-term safety. The manuscript therefore interprets p values as supportive of the observed dataset rather than definitive evidence for practice-changing superiority.

Interventions. The study drug was Stamban Churna Vati prepared from Patha, Dhamasa, Dalimbpushpa/Dadim Pushpa and Indrayava. Each ingredient was taken in equal quantity in the preparation process. Standardized and authenticated powders were mixed with neutral binders (acacia and starch), homogenized and compressed into Vati. Group A received 2.5 g of the herbal Vati orally three times daily after meals for 5 days in each menstrual cycle, for three consecutive cycles. Group B received tranexamic acid 500 mg orally three times daily for 5 days in each menstrual cycle, also for three consecutive cycles [30]. Water was used as the anupana/vehicle in both groups.

Outcome measures. Subjective criteria included pain during menstruation, digestive power, duration of menstrual flow, menstrual history including interval between cycles and PBAC score. Objective investigations included hemoglobin, thyroid function test, ultrasonography and coagulation-related tests such as bleeding time, clotting time, prothrombin time and international normalized ratio. In this paper, the analyzable outcomes were those summarized in the dissertation result tables: pain, digestive power, duration of menstrual flow, menstrual-flow interval and PBAC score. PBAC was treated as the main semi-quantitative bleeding endpoint because it directly reflects menstrual blood loss burden [14-16].

Follow-up and analysis. The treatment period covered three consecutive menstrual cycles. The dissertation reported before-treatment and after-treatment values for most clinical scores and serial visit values for PBAC. Non-parametric tests were used for ordinal clinical scores, with Wilcoxon signed rank tests for within-group changes and Mann-Whitney U tests for between-group comparisons. PBAC comparisons used paired t tests for serial changes and an independent comparison for after-treatment means. This paper reproduces the reported statistics without recalculating from raw patient-level data because individual observations were not available. Graphs were generated directly from the reported group means and percentage improvements.

Table 1. Study design and intervention summary.

Component	Herbal formulation group (Group A)	Tranexamic acid group (Group B)
Participants	15 women with HMB of endometrial origin	15 women with HMB of endometrial origin
Intervention	Patha, Dhamasa, Indrayava and Dadim Pushpa Vati	Tranexamic acid tablet
Dose	2.5 g orally TDS for 5 days in each cycle	500 mg orally TDS for 5 days in each cycle
Duration	3 consecutive menstrual cycles	3 consecutive menstrual cycles
Vehicle/anupana	Water	Water
Primary bleeding endpoint	PBAC score and duration of menstrual flow	PBAC score and duration of menstrual flow
Supportive outcomes	Pain, digestive power and menstrual-flow interval	Pain, digestive power and menstrual-flow interval

Results

Participant profile. The final analyzed sample consisted of 30 participants, with 15 in each treatment arm. The demographic distribution showed that most participants were in the active reproductive age range. The 36-45 year age group was most represented in both arms, contributing 46.67% of Group A and 53.33% of Group B, while 80% of the total study population fell between 26 and 45 years. Housewives constituted 50.0% of the total sample, workers 33.3% and students 16.7%. Married women made up 83.3% of the study population. Pittavata Prakruti was the most common Prakruti category overall, recorded in 30.0% of participants. These findings are consistent with the clinical expectation that HMB is frequently encountered during reproductive years and may be prominent in the later reproductive phase [30].

Pain outcome. Pain improved significantly within both groups. Group A improved from a mean score of 5.533 before treatment to 1.867 after treatment, representing a 66.23% reduction. The Wilcoxon signed rank result was $Z = -3.426$ with $p = 0.001$. Group B improved from 7.267 to

4.000, representing a 44.95% reduction, with Z = -3.473 and p = 0.001. The between-group comparison favored Group A: Mann-Whitney U = 12.00, Z = -4.297 and p = 0.000. Although baseline pain was higher in Group B, the percentage and between-group statistics suggest that the herbal group had a stronger overall pain-relief signal in this dataset.

Digestive power. Digestive power was a supportive outcome and did not show meaningful statistical change. Group A changed from 2.400 to 2.733, corresponding to 13.88% improvement, but this was statistically insignificant (Z = -1.387, p = 0.166). Group B remained at 2.400 before and after treatment, with p = 1.000. Between-group comparison was also non-significant (Mann-Whitney U = 76.50, Z = -1.685, p = 0.092). Therefore, digestive power should not be presented as a confirmed therapeutic outcome of the formulation. This negative result is important because it demonstrates that the measured benefit was not universal across all parameters.

Duration of menstrual flow. Duration of menstrual flow was one of the strongest outcomes. Group A reduced from a mean of 2.467 to 0.200, representing 91.89% improvement, with Z = -3.408 and p = 0.00003. Group B reduced from 2.600 to 0.600, representing 76.92% improvement, with Z = -4.170. The between-group comparison favored Group A with Mann-Whitney U = 6.00, Z = -4.582 and p = 0.000. This result is clinically important because prolonged bleeding is a major source of inconvenience and anemia risk, and shortening the duration of flow may improve patient experience even when total blood loss is not measured by laboratory methods.

Menstrual-flow interval. Group A showed improvement in menstrual-flow interval between cycles from 1.133 to 0.200, corresponding to 42.35% improvement, with Z = -2.889. Group B improved from 0.667 to 0.467, corresponding to 30.00% improvement, but this was interpreted as statistically insignificant. Between-group comparison showed Mann-Whitney U = 30.00, Z = -2.964 and p = 0.003, favoring Group A. This finding suggests a possible regulatory effect on cycle-related symptoms rather than only immediate hemostatic action, but it should be interpreted cautiously because the clinical scale and raw distribution were not available for independent verification.

PBAC outcome. PBAC showed progressive reduction in both groups across follow-up visits. In Group A, the mean PBAC score declined from 286.933 at baseline to 203.667 at the second visit, 141.267 at the third visit and 74.400 after treatment. The corresponding improvements were 29.02%, 50.77% and 74.07%, with paired t values of 6.584, 10.356 and 13.410. In Group B, PBAC declined from 320.600 at baseline to 244.933, 167.267 and 86.800 after treatment, corresponding to 23.60%, 47.83% and 72.93% improvement, with t values of 12.294, 19.746 and 18.831. Between-group comparison of after-treatment PBAC showed Group A at 74.40 +/- 16.40 and Group B at 86.80 +/- 9.70, with t = -2.521 and p = 0.018, favoring Group A.

Table 2. Demographic profile of the randomized participants.

Characteristic	Group A	Group B	Total / interpretation
Sample size	15	15	30 participants
Most common age group	36-45 years: 7 (46.67%)	36-45 years: 8 (53.33%)	80% were 26-45 years
Occupation	Housewife 7; Student 2; Worker 6	Housewife 8; Student 3; Worker 4	Housewives 50.0% overall
Marital status	Married 13; Unmarried 2	Married 12; Unmarried 3	Married 83.3% overall
Predominant Prakruti	Pittavata and other Pitta-Vata types common	Pittavata common	Pittavata 30.0% overall

Table 3. Comparative clinical outcomes after three menstrual cycles.

Outcome	Group A before	Group A after	Group A improvement	Group B before	Group B after	Group B improvement	Between-group result
Pain	5.533	1.867	66.23%	7.267	4.000	44.95%	U = 12.00, Z = -4.297, p = 0.000
Digestive power	2.400	2.733	13.88%	2.400	2.400	0.00%	U = 76.50, Z = -1.685, p =

							0.092
Duration of menstrual flow	2.467	0.200	91.89 %	2.600	0.600	76.92 %	U = 6.00, Z = -4.582, p = 0.000
Menstrual-flow interval	1.133	0.200	42.35 %	0.667	0.467	30.00 %	U = 30.00, Z = -2.964, p = 0.003
PBAC score	286.933	74.400	74.07 %	320.600	86.800	72.93 %	t = -2.521, p = 0.018

Table 4. PBAC score trajectory across follow-up visits.

Visit / endpoint	Group A PBAC mean	Group A improvement	Group B PBAC mean	Group B improvement
Baseline	286.933	Reference	320.600	Reference
Second visit	203.667	29.02%	244.933	23.60%
Third visit	141.267	50.77%	167.267	47.83%
After treatment	74.400	74.07%	86.800	72.93%

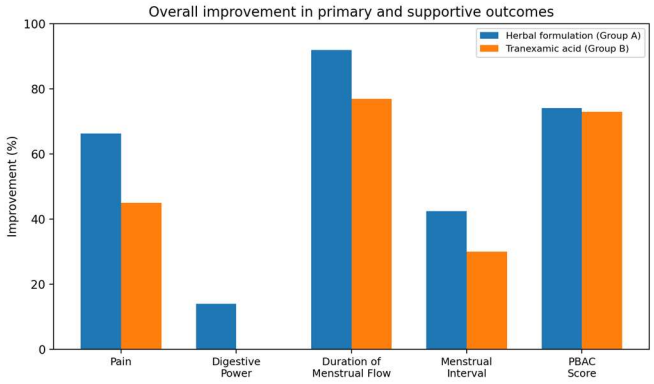

Figure 1. Overall improvement in Group A and Group B across measured outcomes.

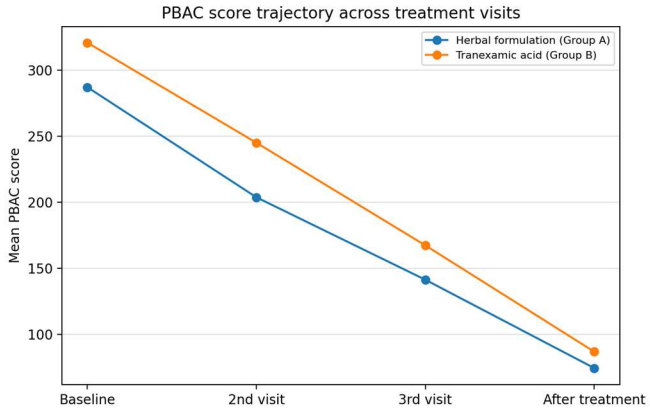

Figure 2. Mean PBAC score trajectory from baseline to after treatment.

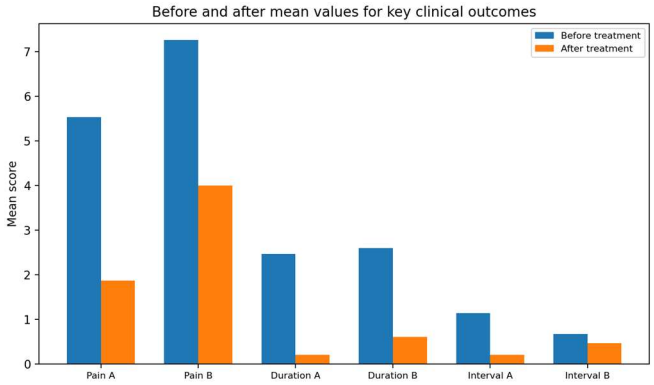

Figure 3. Before-treatment and after-treatment mean values for pain, duration and menstrual interval.

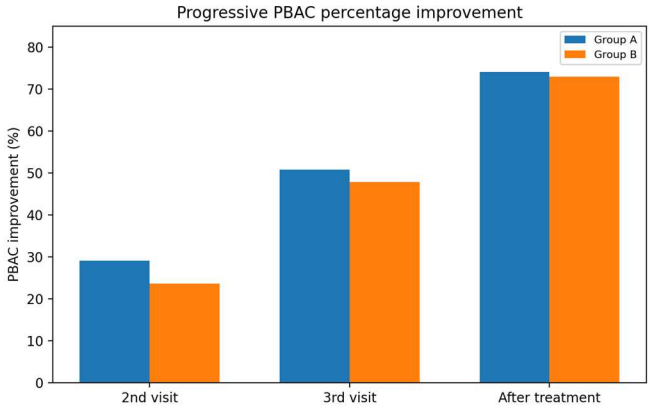

Figure 4. Progressive PBAC percentage improvement at each follow-up point.

Discussion

This randomized clinical dataset suggests that the herbal anti-fibrinolytic formulation produced clinically meaningful improvement in HMB of endometrial origin and performed at least comparably to tranexamic acid across the principal bleeding endpoints. The strongest signals were observed for duration of menstrual flow and PBAC score. Group A showed a 91.89% improvement in duration of menstrual flow and a 74.07% reduction in PBAC score, while Group B showed 76.92% and 72.93% improvement respectively. Because PBAC is directly related to menstrual blood loss and duration reflects patient-experienced bleeding burden, the convergence of these two outcomes strengthens the interpretation that the herbal formulation had a genuine hemostatic effect in the study population.

The comparison with tranexamic acid is important. Tranexamic acid is not a weak comparator; it is an evidence-based antifibrinolytic treatment supported by randomized trials, systematic reviews and clinical guidelines [1,9-12]. A herbal intervention that produces similar PBAC improvement in a small trial should therefore be considered promising, though not yet definitive. The after-treatment PBAC difference favored the herbal group, with a statistically significant comparison ($p = 0.018$). However, the absolute difference between 74.40 and 86.80 is moderate, and baseline PBAC was higher in the tranexamic acid group. Therefore, the result should be framed as a positive comparative signal rather than conclusive superiority.

The pain result is notable because tranexamic acid primarily targets fibrinolysis and does not directly act as an analgesic. Group A's greater improvement in pain may reflect the anti-inflammatory, Vata-regulating or Shoolahara rationale attributed to the constituent herbs. In modern terms, the possibility is that vascular stabilization, reduction in excessive endometrial breakdown, reduced prostaglandin-associated irritation or improved pelvic tissue response may decrease pain. Nonetheless, this mechanism remains hypothetical because prostaglandins, inflammatory markers and uterine contractility were not measured. Future trials should include validated dysmenorrhea scales, rescue analgesic use and quality-of-life instruments to better characterize this secondary benefit.

The duration of menstrual flow improved strongly in both arms, but more prominently in Group A. From a patient perspective, reduction in the number of bleeding days may be as important as reduction in total volume. Fewer bleeding days reduce the need for menstrual products, improve mobility and lessen the risk of missed work or household activities. From a biological perspective, shorter duration suggests faster restoration of endometrial hemostasis. Tranexamic acid achieves this by stabilizing fibrin. The herbal formulation may act through a combination of astringent tannins, vascular tone, anti-inflammatory activity and traditional Stambhana/Grahi actions. Such multi-pathway action is plausible but requires biochemical validation.

The menstrual-flow interval outcome suggests that the herbal formulation may have influenced cycle regularity. The between-group p value was significant, and the percentage improvement favored Group A. This result is interesting because antifibrinolysis alone would be expected to reduce active bleeding but not necessarily improve cycle rhythm. Ayurvedic interpretation attributes this to regulation of Apana Vata and Artava Vaha Srotas. In biomedical terms, any effect on endometrial stability, inflammatory signaling or ovulatory rhythm would need to be demonstrated through hormonal and ultrasound monitoring. Because the present study did not include such measurements, the menstrual-interval finding should be considered hypothesis-generating.

Digestive power did not significantly improve. This is scientifically useful because it suggests outcome specificity. The formulation was designed primarily for bleeding control rather than for correcting Agni or gastrointestinal function. The absence of a statistically meaningful digestive result also reduces the likelihood that the study simply recorded generalized positive reporting across all parameters. It is appropriate to mention digestive power descriptively but not as a core efficacy claim. A peer-reviewed paper should distinguish primary and secondary outcomes and avoid overstating non-significant data.

The trial is aligned with existing literature on PBAC use. PBAC instruments are not perfect substitutes for laboratory blood-loss measurement, but they are practical for clinical trials and are widely used [14-16]. The progressive fall in PBAC in both arms indicates that participants experienced sustained improvement across treatment cycles rather than an isolated after-treatment change. The trajectories are clinically coherent: Group A improved from 286.933 to 74.400, and Group B from 320.600 to 86.800. Since PBAC values above 100 are commonly used to indicate heavy bleeding in many research contexts, the after-treatment

means falling below 100 in both groups suggest clinically relevant control of bleeding. However, the exact PBAC cut-off depends on chart design and scoring instructions, so interpretation should remain chart-specific [16].

The herbal formulation's plausibility rests on both traditional and phytochemical grounds. Dadim Pushpa is important because pomegranate flower has prior clinical evidence in HMB and contains polyphenolic and tannin-rich constituents [19-21]. Astringent compounds may reduce capillary leakage or support local tissue contraction. Patha and related Cissampelos species are recognized in ethnopharmacology and Dravyaguna literature for multi-dimensional biological activity [22,23,25]. Indrayava and Dhamasa are traditional choices for conditions involving inflammation, bleeding and tissue support. Still, combination products raise additional scientific questions: standardization, batch consistency, marker compounds, herb-drug interactions and dose-response relationships. These should be addressed before broad application.

Safety interpretation is limited. The dissertation states that no significant adverse effects were observed, and both treatments were administered over three menstrual cycles. This is reassuring but insufficient for long-term safety. Tranexamic acid safety concerns include thromboembolic risk in predisposed individuals and caution with contraindications [1,11,12]. Herbal formulations require monitoring for contamination, incorrect botanical identity, variation in active constituents and potential interactions. Future research should include adverse-event definitions, laboratory safety panels, pregnancy screening, coagulation markers and follow-up after treatment discontinuation. Safety should be analyzed with the same rigor as efficacy.

Methodological limitations are important. First, the sample size was small, with 15 participants per arm. Small samples are vulnerable to baseline imbalance, exaggerated effect sizes and unstable p values. Second, the dissertation provided summarized data, not raw patient-level observations. Therefore, this paper could not independently verify normality assumptions, confidence intervals, missing data patterns or effect-size estimates. Third, blinding was not described. Lack of blinding can influence subjective outcomes such as pain and digestive power. Fourth, the study duration was limited to three cycles, so recurrence after discontinuation remains unknown. Fifth, laboratory markers of fibrinolysis, ferritin, quality-of-life scales and endometrial histology were not included.

Despite these limitations, the trial has strengths. It used an active comparator, included a clinically relevant standard drug, evaluated multiple outcomes, followed participants over repeated cycles and used PBAC as a bleeding measure. The intervention was described sufficiently to understand composition, dose and duration. The results were directionally consistent: the herbal group showed improvement in pain, duration, menstrual interval and PBAC, while digestive power did not show significant between-group benefit. This pattern is more credible than an indiscriminate claim of universal improvement. Therefore, the study provides a meaningful basis for a larger confirmatory trial.

A future definitive study should be designed as a randomized, double-blind, double-dummy trial if feasible. It should include a larger sample, stratification by baseline PBAC severity, standardized PBAC training, hemoglobin and ferritin assessment, coagulation and fibrinolytic markers, quality-of-life questionnaires, adverse-event monitoring and follow-up for at least six to twelve months after treatment. Chemical fingerprinting of the herbal formulation should be performed using validated chromatographic methods. A non-inferiority framework against tranexamic acid could be appropriate if the objective is to show comparable bleeding control with additional symptom benefits. Alternatively, a superiority framework could be used for pain or composite menstrual-health outcomes.

The clinical implication of the current evidence is cautious optimism. The herbal formulation should not be represented as an established replacement for tranexamic acid in all patients. However, it can be described as a promising Ayurvedic anti-fibrinolytic/hemostatic formulation that demonstrated favorable preliminary outcomes in a small randomized comparison. For women seeking non-hormonal care and for clinicians practicing integrative gynecology, such findings justify further development, but treatment decisions should remain individualized and should not bypass evaluation for pregnancy, anemia, fibroids, malignancy, coagulopathy or thyroid disease.

Clinical Translation and Future Research Framework

For a journal audience, the translational value of this work lies in its attempt to compare a traditional hemostatic formulation with a recognized non-hormonal drug rather than with placebo alone. Many women with HMB prefer treatments that do not suppress ovulation, do not require intrauterine procedures and can be taken only during symptomatic menstrual days. Tranexamic acid already occupies this position in modern gynecology [1,9-12]. A herbal formulation intended for the same clinical space must therefore be evaluated against tranexamic acid or another active standard. The present study provides an early comparative model, but a future manuscript should specify whether the aim is non-inferiority, superiority for associated symptoms, or adjunctive symptom control. Each of these aims requires a different sample-size calculation and statistical plan.

The distinction between endometrial-origin HMB and other forms of abnormal uterine bleeding should be strengthened in future work. The dissertation excluded several major structural and systemic causes, including thyroid dysfunction, fibroids, cervical pathology, malignancy and pregnancy-related bleeding. That is appropriate for an initial trial, but journal readers would

expect documentation of the diagnostic pathway: pelvic examination, ultrasound findings, hemoglobin values, pregnancy testing where applicable, thyroid profile, coagulation screening and criteria for endometrial evaluation. In reproductive-aged women, the risk of malignancy is lower than in postmenopausal bleeding, yet persistent abnormal bleeding still requires careful triage. Therefore, herbal or non-hormonal treatment should be presented as a management option after appropriate diagnostic exclusion rather than as a substitute for evaluation.

Outcome selection also deserves expansion. PBAC is practical and patient-friendly, but it should be supplemented by hemoglobin, ferritin and quality-of-life instruments in confirmatory research. Hemoglobin indicates current anemia, whereas ferritin can detect depleted iron stores before overt anemia develops. Quality-of-life tools capture the social and emotional burden of heavy bleeding that PBAC alone cannot fully measure [17,18]. A trial designed for publication could therefore define a primary endpoint such as change in PBAC score or proportion of women achieving PBAC below a prespecified threshold, and secondary endpoints such as bleeding days, pain score, hemoglobin, ferritin, quality of life, rescue medication and adverse events. This structure would make interpretation more transparent and clinically meaningful.

Standardization of the herbal product is essential. The dissertation describes ingredient quantities and tablet preparation, but larger trials should add botanical authentication, voucher specimens, limits for microbial load and heavy metals, chromatographic fingerprints and marker-compound ranges. Multi-herb products are especially vulnerable to variability in raw material source, harvest season, storage, particle size and extraction or compression procedure. If the formulation is intended as a reproducible therapeutic candidate, quality specifications must be defined before enrollment begins. This is not only a regulatory issue; it is a scientific requirement. Without standardization, an observed clinical effect cannot be confidently attributed to a stable product, and external replication becomes difficult.

The safety framework should also be strengthened. The current dataset reports no significant adverse effects, but a short three-cycle trial with 30 participants has limited power to detect uncommon events. Tranexamic acid has defined precautions, especially in women with thromboembolic risk factors. Herbal products require attention to gastrointestinal tolerability, allergy, hepatic and renal safety, menstrual-cycle changes and interaction with anticoagulants, hormonal agents or other supplements. A structured adverse-event form, causality assessment, severity grading and follow-up after discontinuation would improve the reliability of safety conclusions. Women should also be counselled to report pregnancy, severe anemia symptoms, passage of very large clots, syncope, pelvic mass symptoms or persistent intermenstrual bleeding.

From an Ayurvedic perspective, the trial is clinically coherent because it links Asrigdara/Raktapradara concepts with measurable outcomes. However, future integrative research should avoid using traditional concepts only as explanatory language after the results are known. Instead, Prakruti, Agni, associated Pitta symptoms, Apana Vata features and Rakta Dushti indicators should be prespecified as exploratory variables. That approach would allow researchers to test whether particular Ayurvedic phenotypes predict better response to the formulation. It may also help identify which patients are most likely to benefit and which require different management. Such stratified analysis would make the research more scientifically valuable than a general claim that the formulation works for all HMB presentations.

A final point concerns statistical reporting. The dissertation gives p values, test statistics and percentage changes, but journal reporting would be improved by confidence intervals, effect sizes and clear identification of primary and secondary endpoints. Percentage improvement is easy to understand but can be influenced by baseline differences, as seen in the PBAC values where Group B began with a higher mean score. Reporting absolute change, relative change and final mean together provides a more balanced interpretation. In future studies, analysis of covariance using baseline score as a covariate could provide a stronger comparison than simple post-treatment testing. Intention-to-treat analysis should also be used if dropouts occur. These measures would align the trial with contemporary reporting expectations and make the evidence more acceptable for peer review.

Finally, dissemination should be careful and ethical. The current findings support further study and suggest therapeutic promise, but they should not be used to encourage unsupervised self-medication in women with abnormal uterine bleeding. HMB may conceal fibroids, endometrial hyperplasia, pregnancy complications, coagulopathy or endocrine disorders. Any manuscript based on this dataset should therefore emphasize that diagnosis and monitoring are mandatory. The appropriate conclusion is that the formulation demonstrated favorable preliminary efficacy and tolerability in a small randomized comparison and deserves larger, standardized, well-controlled trials. This wording protects patients while still recognizing the scientific value of the dissertation results.

Conclusion

In this randomized controlled dissertation dataset, a herbal anti-fibrinolytic formulation composed of Patha, Dhamasa, Indrayava and Dadim Pushpa showed substantial improvement in HMB of endometrial origin. The formulation reduced PBAC score, duration of menstrual flow and pain, and also improved menstrual-flow interval when compared with tranexamic acid. Tranexamic acid

remained effective, as expected from its established antifibrinolytic role, but the herbal formulation produced greater percentage improvement in most measured outcomes.

The most clinically relevant findings were the reduction in PBAC score from 286.933 to 74.400 in Group A and from 320.600 to 86.800 in Group B, and the improvement in bleeding duration by 91.89% in Group A compared with 76.92% in Group B. The between-group PBAC comparison after treatment favored Group A. Digestive power did not show significant improvement and should not be treated as a confirmed efficacy endpoint.

The study supports the need for larger, methodologically rigorous trials. Future investigations should include objective fibrinolytic markers, complete safety monitoring, validated quality-of-life outcomes, longer follow-up, and phytochemical standardization of the herbal formulation. Until such confirmation is available, the findings should be viewed as promising preliminary evidence rather than definitive proof of replacement for standard therapy.

Declarations

Data source: This research paper was prepared from the summarized dissertation dataset titled Comparative Study of Herbal Anti-Fibrinolytic with Tranexamic Acid for the Management of Heavy Menstrual Bleeding of Endometrial Origin: A Randomized Controlled Trial by Dr. Anuja Pawar. No new patient-level data were generated for this manuscript.

Ethics and consent: The source dissertation states that eligible patients were enrolled after written informed consent. Details of ethics committee approval number were not available in the extracted manuscript text.

Conflict of interest: Not reported in the source dissertation. For journal submission, authors should provide a formal conflict-of-interest statement.

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