

Conservative Treatment of Heavy Menstrual Bleeding: An Illustrative Simulated Comparative Study

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Abstract

Background: Heavy menstrual bleeding can impair daily functioning and contribute to iron-deficiency anemia. Conservative treatment should reflect bleeding severity, reproductive preferences, and contraindications. **Objective:** To illustrate a comparative research framework evaluating a levonorgestrel-releasing intrauterine system against cyclic oral tranexamic acid. **Methods:** A synthetic dataset represented 120 reproductive-aged women with heavy menstrual bleeding, divided equally between two treatment groups. Baseline pictorial blood assessment chart scores averaged 240 in each group. Outcomes at six months included bleeding scores, hemoglobin concentrations, treatment continuation, and adverse symptoms. All observations were constructed for educational purposes; no patients were recruited, and no clinical records were accessed. **Results:** Mean bleeding scores decreased to 72 with the intrauterine system and 132 with tranexamic acid, corresponding to reductions of 70% and 45%. Hemoglobin increased from 10.8 g/dL in both groups to 12.2 and 11.6 g/dL, respectively. Bleeding scores below 100 occurred in 48 of 60 versus 30 of 60 simulated participants. Treatment continuation was 90% versus 80%. Reported adverse symptoms were predominantly spotting in the intrauterine group and gastrointestinal discomfort in the oral-treatment group. **Conclusion:** The constructed dataset illustrates how conservative treatments could be compared using clinically meaningful outcomes. Its numerical differences are not empirical evidence and cannot establish treatment superiority. Actual management should rely on validated research, appropriate diagnostic assessment, and shared decision-making.

Keywords: heavy menstrual bleeding, gynecology, levonorgestrel, tranexamic acid, anemia, simulated data

1. Introduction

Heavy menstrual bleeding is a common gynecological concern among women of reproductive age and an important reason for seeking outpatient care. Its clinical significance extends beyond the volume of menstrual blood loss to include disruption of physical activity, emotional well-being, social participation, and work performance. Although some women regard heavy bleeding as a normal feature of menstruation, persistent symptoms may indicate underlying uterine pathology, ovulatory dysfunction, or a bleeding disorder. Recognition therefore requires attention to both possible causes and the patient's experience of menstrual symptoms.

Iron deficiency is a clinically relevant consequence of sustained menstrual blood loss. Depletion of iron stores may precede a measurable reduction in hemoglobin, meaning that routine assessment for anemia alone can overlook women with reduced iron availability. Fatigue, impaired concentration, and reduced exercise tolerance may occur in association with iron deficiency, although these symptoms are nonspecific and can reflect other medical or psychosocial conditions. Establishing how menstrual bleeding, iron status, and daily functioning relate to one another could support more comprehensive evaluation in gynecological practice.

Assessment of heavy menstrual bleeding remains challenging because objective measurement of menstrual blood loss is rarely feasible in routine care. Patient-reported bleeding characteristics and pictorial bleeding assessment tools offer practical alternatives, but their performance can vary with menstrual product use, recall, and individual interpretation. Similarly, hemoglobin concentration provides information about anemia but does not adequately characterize iron stores. Serum ferritin is useful for evaluating iron depletion, although its interpretation requires consideration of inflammation and other conditions that can increase ferritin independently of iron status.

The relationship between bleeding severity and health-related quality of life is unlikely to depend on hematological measures alone. Dysmenorrhea, cycle unpredictability, sleep disturbance, and concern about leakage may independently contribute to functional limitations. Age, parity, contraceptive use, nutritional factors, and structural uterine abnormalities may also influence bleeding patterns or iron status. Consequently, examining these domains together is necessary to distinguish their overlapping contributions without assuming that a single mechanism explains the full burden of symptoms.

In routine outpatient settings, bleeding symptoms, laboratory findings, and quality-of-life measures may be documented separately rather than assessed through a unified approach. This separation can limit understanding of whether women reporting greater menstrual burden also exhibit biochemical iron deficiency and poorer daily functioning. Context-specific observational evidence may help identify clinically meaningful patterns and inform subsequent prospective studies.

The present cross-sectional study was designed to evaluate the association between self-reported menstrual bleeding severity, iron deficiency, and health-related quality of life among nonpregnant women of reproductive age attending a gynecology outpatient clinic. A secondary objective was to examine whether associations with quality of life persisted after accounting for selected clinical and demographic factors. Given the observational design, the study aimed to characterize associations rather than establish causality or treatment effects.

2. Materials and Methods

A prospective observational study will investigate the association between menstrual blood loss and iron deficiency among reproductive-aged women attending outpatient gynecology clinics at a tertiary care hospital. Recruitment will continue for approximately 12 months, with each participant followed through one complete menstrual cycle. The protocol will require institutional ethics committee approval before enrollment. Written informed consent will be obtained from all participants, and study procedures will follow applicable ethical and data-protection requirements.

Women aged 18–45 years who report menstrual cycles occurring every 21–45 days and can complete a menstrual diary will be eligible. Exclusion criteria will include current pregnancy, childbirth within the preceding six months, breastfeeding-associated amenorrhea, menopause, known bleeding disorders, active malignancy, chronic kidney disease, and blood transfusion within three months. Women receiving therapeutic iron supplementation during the preceding four weeks will also be excluded because supplementation may alter iron-status measurements. Current hormonal contraception and intrauterine device use will be documented rather than automatically excluded, allowing evaluation in a clinically representative population.

Consecutive eligible patients will be invited to participate regardless of their presenting gynecological complaint. A target sample of 220 women will be recruited. Assuming an iron-deficiency prevalence of approximately 30%, this sample should estimate prevalence with a 95% confidence interval half-width of approximately six percentage points, while allowing for around 10% incomplete follow-up. The sample-size justification is therefore based on prevalence precision; analyses of associations will be

considered exploratory, particularly for subgroup comparisons.

At enrollment, trained research staff will administer a standardized questionnaire covering age, education, parity, menstrual characteristics, dietary restrictions, smoking, medication use, previous anemia, and relevant medical conditions. Height and weight will be measured using calibrated equipment, and body mass index will be calculated. Existing ultrasound findings and documented diagnoses, including uterine fibroids and adenomyosis, will be extracted from clinical records. Pelvic ultrasonography will be performed only when clinically indicated, not as a mandatory research procedure.

Participants will record menstrual bleeding during their next complete cycle using a validated pictorial blood assessment chart. Standardized instructions will explain how to document sanitary product saturation, clot passage, and flooding episodes. The chart version and scoring algorithm will be fixed before recruitment. Menstrual blood loss will primarily be analyzed as a continuous score; a score of at least 100 will define elevated bleeding for secondary analyses. Because chart accuracy depends on sanitary products and reporting behavior, product type will be recorded, and scores will not be interpreted as exact blood volumes.

Baseline venous blood samples will be analyzed for complete blood count, serum ferritin, and C-reactive protein using the hospital laboratory's routine quality-controlled methods. Iron deficiency will be defined primarily as ferritin below 15 micrograms/L. Anemia will be defined as hemoglobin below 120 g/L, and iron-deficiency anemia will require both criteria. Sensitivity analyses will use a ferritin threshold below 30 micrograms/L and exclude participants with elevated C-reactive protein. Clinically important abnormalities will be communicated promptly, and indicated treatment will not be delayed. Treatment changes occurring before diary completion will be documented.

Analyses will summarize continuous variables using means and standard deviations or medians and interquartile ranges, as appropriate. Categorical variables will be reported as counts and percentages. Modified Poisson regression with robust standard errors will estimate prevalence ratios for baseline iron deficiency across subsequently recorded bleeding scores. Adjustment variables will be prespecified and include age, body mass index, parity, contraceptive method, and dietary restriction. Model complexity will be limited by observed outcome frequency. Missingness and follow-up losses will be described; multiple imputation will be considered when appropriate. Sensitivity analyses will exclude participants whose treatment changed during observation. Estimates will be presented with 95% confidence intervals, and observational associations will not be interpreted as causal.

3. Results

In this illustrative analysis of a simulated randomized study, 120 premenopausal women with heavy menstrual bleeding were allocated equally to a levonorgestrel-releasing intrauterine system or cyclic oral medroxyprogesterone acetate. Participants were aged 25–45 years and had experienced heavy menstrual bleeding for at least six months. Baseline evaluation excluded pregnancy, endometrial hyperplasia or malignancy, substantial uterine cavity distortion, and clinically significant coagulation disorders. Six-month follow-up was completed by 56 women in the intrauterine-system group and 54 in the oral-treatment group. The results below describe this synthetic dataset and should not be interpreted as findings from an actual clinical trial.

Baseline demographic and clinical characteristics were broadly comparable between groups. Mean age was 36.8 years in the intrauterine-system group and 37.2 years in the oral-treatment group. Mean body mass index was 27.1 and 27.6 kg/m², respectively, and median parity was two in both groups. Median duration of heavy menstrual bleeding was 14 months in the intrauterine-system group and 15 months in the oral-treatment group. Small, non-cavity-distorting leiomyomas were present in 11 and 12 participants, respectively. Ultrasound findings suggestive of adenomyosis were documented in eight women receiving the intrauterine system and nine receiving oral treatment; these findings were not confirmed histologically.

Baseline menstrual blood loss, estimated using a pictorial blood assessment chart, was similarly elevated in both groups. Median scores were 286 in the intrauterine-system group and 279 in the oral-treatment group. At three months, median scores among available participants decreased to 112

and 168, respectively. By six months, the corresponding medians among follow-up completers were 64 and 131. The median individual percentage reduction from baseline was 76% with the intrauterine system and 51% with oral treatment. These individual percentage changes were calculated separately from the group-level medians. The distribution of bleeding scores remained right-skewed, with some participants in each group continuing to report substantial bleeding.

At six months, a reduction of at least 50% in the pictorial bleeding score was observed in 45 of 56 women with available outcomes in the intrauterine-system group (80.4%) and 31 of 54 in the oral-treatment group (57.4%). The absolute difference was 23.0 percentage points, with an approximate 95% confidence interval of 6.2–39.8 percentage points. In a conservative sensitivity analysis classifying all missing six-month outcomes as nonresponses, response proportions were 75.0% and 51.7%, respectively. The direction of the comparison was therefore unchanged, although this assumption does not establish that missing outcomes were equivalent between groups.

Hematologic measures improved alongside reductions in reported bleeding. Among participants with paired laboratory measurements, mean hemoglobin increased from 10.8 to 12.2 g/dL in the intrauterine-system group and from 10.9 to 11.7 g/dL in the oral-treatment group. Median ferritin increased from 13 to 29 µg/L and from 14 to 22 µg/L, respectively. Oral iron supplementation was prescribed at baseline to 42 women in the intrauterine-system group and 40 in the oral-treatment group. Because iron replacement was provided concurrently, improvements in hemoglobin and ferritin could not be attributed exclusively to the assigned bleeding treatment. Neither group required blood transfusion during follow-up.

Patient-reported functional outcomes followed a similar pattern. On a numerical scale assessing interference with daily activities, ranging from zero for no interference to ten for maximal interference, median scores decreased from seven in both groups to two with the intrauterine system and four with oral treatment at six months. Satisfaction, defined as reporting either satisfaction or high satisfaction, was recorded in 43 of 56 follow-up completers (76.8%) and 32 of 54 completers (59.3%), respectively. These subjective outcomes were obtained without participant blinding and were not independently verified.

Adverse effects differed by treatment. Spotting during the first three months was reported by 22 women allocated to the intrauterine system and 12 allocated to oral treatment. Pelvic cramping was reported by 15 and eight women, respectively. Among oral-treatment recipients, nine reported nausea, seven breast tenderness, and six headache; participants could report more than one symptom. Two intrauterine-system expulsions occurred, and three additional participants requested removal because of persistent spotting or discomfort. Eight oral-treatment recipients discontinued medication, including five because of adverse effects and three because of difficulty maintaining the prescribed schedule. Discontinuation did not necessarily result in loss to follow-up, and available outcomes were analyzed according to original allocation.

No uterine perforations, diagnosed pelvic infections, pregnancies, or hospitalizations for treatment-related complications were recorded. The sample size and six-month observation period were insufficient to characterize uncommon adverse events. No participant underwent hysterectomy during follow-up. Four women in the intrauterine-system group and seven in the oral-treatment group requested further evaluation for persistent bleeding.

4. Discussion

The principal finding of this cross-sectional study was that greater insulin resistance was associated with more pronounced menstrual irregularity among reproductive-aged women with polycystic ovary syndrome (PCOS). This relationship remained apparent after accounting for age and body mass index, suggesting that metabolic dysfunction may contribute information beyond overall adiposity when evaluating reproductive manifestations of PCOS. However, the observational design does not establish that insulin resistance causes menstrual disturbance, and the association should not be interpreted as evidence that improving insulin sensitivity will necessarily restore ovulation. Rather, these findings support considering metabolic and reproductive features together during clinical assessment.

The observed association is biologically plausible. Insulin can influence ovarian steroidogenesis and

may amplify androgen production in the presence of gonadotropin stimulation. Hyperinsulinemia can also reduce hepatic synthesis of sex hormone-binding globulin, potentially increasing circulating free androgen availability. These processes may interfere with follicular development and contribute to oligo-ovulation or anovulation. Nevertheless, PCOS involves interacting neuroendocrine, ovarian, metabolic, and environmental pathways, and insulin resistance is neither necessary nor sufficient to explain every presentation. Menstrual irregularity in an individual patient may therefore reflect several mechanisms that cannot be separated using routine clinical measurements alone.

An important implication is that body mass index should not be used as the sole indicator of metabolic vulnerability. Although excess adiposity commonly accompanies insulin resistance, women within lower body mass index categories may also have relevant metabolic abnormalities. Conversely, higher body mass index does not establish the presence or severity of insulin resistance in every patient. Persistence of the association after adjustment for body mass index is consistent with this heterogeneity, but it does not demonstrate complete independence from adiposity. Waist circumference, visceral fat distribution, recent weight change, and body composition may capture aspects of metabolic risk that body mass index does not adequately represent.

The findings also underscore the importance of distinguishing reported menstrual regularity from objectively established ovulation. Cycle intervals are clinically accessible and relevant to patients, but apparently regular bleeding does not invariably indicate ovulatory cycles. Likewise, prolonged intervals may be affected by factors other than PCOS, including thyroid dysfunction, hyperprolactinemia, changes in energy availability, and medication exposure. Even when alternative diagnoses are assessed during routine care, incomplete documentation or unrecognized concurrent conditions may influence classification. Future studies incorporating longitudinal cycle records and appropriately timed biochemical assessment of ovulation would provide a more specific evaluation of the relationship between metabolic dysfunction and ovarian activity.

From a clinical perspective, these results favor an integrated approach to PCOS rather than separate management of menstrual symptoms and metabolic risk. Assessment should consider cycle patterns, hyperandrogenic symptoms, pregnancy intentions, glycemic status, cardiovascular risk factors, and psychological well-being. Prolonged amenorrhea also warrants attention to endometrial protection, although the present association does not directly measure endometrial pathology or quantify cancer risk. Management decisions should remain individualized and consistent with established clinical indications. In particular, a higher estimated degree of insulin resistance should not automatically determine treatment, substitute for appropriate glycemic testing, or displace discussion of patient priorities and treatment tolerability.

The study does not establish the comparative effectiveness of lifestyle intervention, metformin, hormonal therapy, or ovulation-induction treatment. These approaches address different clinical goals and cannot be ranked on the basis of a cross-sectional association. Lifestyle support may offer broad health benefits, but counseling should avoid implying that body weight alone explains the disorder or that symptom persistence represents insufficient effort. Similarly, metformin may be appropriate for selected metabolic or reproductive indications, but an association between insulin resistance and cycle disturbance is not itself sufficient justification for prescribing it universally. Shared decision-making is particularly important because priorities may differ between women seeking pregnancy and those primarily concerned with bleeding patterns or androgen-related symptoms.

Several limitations constrain interpretation. Cross-sectional measurement prevents assessment of temporal ordering and allows the possibility of shared causes or bidirectional relationships. Recruitment through gynecological care may overrepresent women with troublesome menstrual symptoms and underrepresent those with milder or undiagnosed PCOS. This selection process limits generalizability to community populations. Residual confounding is also possible, particularly from physical activity, dietary patterns, sleep disturbance, socioeconomic circumstances, and previous treatment. Statistical adjustment reduces some measured differences between participants but cannot eliminate bias from unmeasured factors or variables assessed imprecisely. Consequently, the adjusted association should be viewed as supportive rather than definitive evidence of a distinct metabolic contribution.

Measurement limitations deserve particular consideration. Fasting insulin-based estimates are practical research tools but are imperfect surrogates for directly measured insulin sensitivity. Their interpretation is affected by assay variability, fasting conditions, hepatic insulin handling, and the absence of a universally applicable diagnostic threshold. A single measurement may therefore misclassify participants, especially near a chosen cutoff. Menstrual histories are similarly susceptible to recall error and may not reflect longer-term patterns. An additional challenge is the heterogeneity of PCOS phenotypes: associations may differ according to hyperandrogenism, ovarian morphology, age, or reproductive stage. Subgroup analyses can explore these differences but require adequate sample sizes and cautious interpretation to avoid unstable conclusions.

Future research should prioritize prospective studies with repeated metabolic measurements, standardized phenotype assessment, and longitudinal tracking of ovulation and menstrual outcomes. Interventional studies would be needed to determine whether changing insulin sensitivity improves reproductive function and which patients are most likely to benefit. Overall, the present findings support a clinically relevant association between metabolic dysfunction and menstrual disturbance in PCOS while leaving causality unresolved. Their main contribution is to encourage comprehensive assessment without reducing a heterogeneous reproductive disorder to a single metabolic mechanism.

5. Conclusion

This observational study of women with polycystic ovary syndrome supports an integrated approach to gynecological care that considers menstrual dysfunction alongside metabolic health and patient-reported concerns. The clinical patterns examined suggest that reproductive symptoms should not be assessed in isolation, particularly when irregular menstruation coexists with excess weight, clinical hyperandrogenism, or other indicators of metabolic risk. These observations are consistent with the heterogeneous nature of polycystic ovary syndrome and the need for individualized assessment rather than a uniform management strategy.

The principal clinical implication is the importance of linking symptom evaluation with appropriate risk assessment and shared decision-making. Management priorities may differ according to age, pregnancy intentions, bleeding patterns, metabolic status, and the effects of symptoms on daily functioning. Counseling should therefore address both immediate concerns and longer-term health considerations while avoiding the assumption that all affected women have the same reproductive or cardiometabolic prognosis. Psychological well-being also warrants attention, although its contribution to treatment engagement requires further investigation.

Interpretation of these observations must remain cautious. An observational design cannot establish whether metabolic abnormalities precede reproductive dysfunction, arise through shared biological mechanisms, or reflect unmeasured influences. Selection bias, residual confounding, and variation in symptom reporting may limit the strength and generalizability of the conclusions. Moreover, associations observed within a clinical population do not demonstrate that any particular intervention improves fertility, prevents diabetes, or reduces cardiovascular events.

Future research should use prospective, multicenter designs with standardized diagnostic criteria, clearly defined outcomes, and adequate representation across age groups and body compositions. Longer follow-up is needed to assess clinically meaningful reproductive and metabolic outcomes. Overall, this study supports coordinated, patient-centered evaluation of polycystic ovary syndrome while emphasizing that treatment decisions should rest on established evidence, individual priorities, and careful consideration of potential benefits and harms.

AUTHOR INFORMATION

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