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KEY PRACTICE POINTS 2024
INDIAN PERSPECTIVE

Iron deficiency anemia in women with heavy menstrual bleeding: Replenishing iron stores and improving quality of life with Iron supplementation

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IRON DEFICIENCY ANEMIA IN WOMEN WITH HEAVY MENSTRUAL BLEEDING: REPLENISHING IRON STORES AND IMPROVING QUALITY OF LIFE WITH IRON SUPPLEMENTATION

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Background

Heavy menstrual bleeding (HMB) is characterized by excessive menstrual blood loss (exceeding 80 mL per menstruation), which disrupts the woman's physical, social, and/or emotional well-being.[1,2] It is associated with various adverse functional outcomes, including lower productivity, reduced ability to perform daily activities, and limitations on social life.[3] The 2021 NICE guideline (National Institute for Health and Care Excellence) recognizes the major negative impact of HMB on a woman's quality of life.[4]

Nearly 50% of women of reproductive age are affected with HMB and the prevalence may increase as menopause approaches.[2,5,6] Approximately 1 out of every 20 women aged 30–49 years seek consultation with their general practitioner annually regarding HMB.[1] The classification for the severity of anemia is mentioned in the Table 1.[7]

Table 1. Severity of anemia[7]

Severity of anemia	Hemoglobin (Hb) level (g/dL)
Mild	>10
Moderate	8–10
Severe	6.5–7.9
Life-threatening	<6.5

Women experiencing HMB lose iron at a rate 5–6 times greater per cycle compared to those with regular menstruation. This elevated blood loss contributes to the depletion of iron stores and the subsequent development of iron deficiency anemia (IDA). Mild IDA may be asymptomatic, whereas symptomatic IDA can manifest as weakness, fatigue, headaches, hair loss, brittle nails, and shortness of breath.[8] The factors contributing to the widespread occurrence of anemia

in India encompass menorrhagia in women, insufficient consumption of dietary iron and folic acid, and limited absorption of iron from the phytate-rich Indian diet.[9,10] Women lacking sufficient iron stores due to nutritional deficiencies and heavy blood loss are at increased risk of developing severe IDA.[10] According to the International Federation of Gynecology and Obstetrics (FIGO) 2023 statement on Iron deficiency (ID) and anemia in women and girls, HMB was considered a major risk factor for IDA.[5]

Given the variability in reporting of HMB and IDA, the condition often goes undiagnosed and untreated.[2,6,11] However, IDA in women with HMB can be reversed.[12]

Objective

This consensus meeting aims to formulate validated key practice points for developing IDA treatment approach in women with HMB.

Methodology

The task force comprised of 9 experts in the field of Obstetrics and Gynecology formed. The task force reviewed the existing literature and developed the consensus statement based on published literature, their individual clinical experience, and focused discussion within the task force. The task force members followed a well-defined grading system (Table 2) for the critical appraisal of evidence and grading strength of consensus statements. The consensus statements developed by the task force were presented to a larger group consisting of 39 experts in the field of Obstetrics and Gynecology. There was deliberation on each consensus point and later accepted, modified, or deleted. Thus, this document provides much-required insights and useful, practical, and accurate feasible guidance that aids a practicing clinician across the country.

Table 2. Level of evidence and grading strength of recommendations

Grades of recommendation	Level of evidence	Type of Study
A	1a	Systematic review of (homogenous) randomized controlled trials
A	1b	Individual randomized controlled trials (with narrow confidence intervals)
B	2a	Systematic review of (homogenous) cohort studies of "exposed" and "unexposed" subjects
B	2b	Individual cohort study/low-quality randomized control studies
B	3a	Systematic review of (homogenous) case-control studies
B	3b	Individual case-control studies
C	4	Case series, low-quality cohort, or case-control studies
D	5	Expert opinions based on non-systematic reviews of results or mechanistic studies

Relationship between HMB and ID/IDA

The chronic blood loss suffered by women with HMB is a primary factor leading to the onset of IDA. Present evidence revealed a relationship between HMB and IDA.[2]

Clinical evidence

- A secondary analysis of a randomized trial with the participation of women with HMB (n=236) revealed that 27% of the participants had anemia and out of which 60% of the women were severely iron deficient, which was determined by low serum ferritin.[13]
- A study conducted by Kocaoz et al., investigated the prevalence and impact of HMB on anemia, and the quality of life in women of reproductive age. The study included 306 women of reproductive age and found that 37.9% of the women suffered from HMB. The median serum ferritin level was lower in patients with HMB compared to patients without HMB (11.45 vs. 19.65, $p<0.0001$). The research from the study also revealed that as the duration of menstruation decreased significantly in both ferritin levels and physical functions ($p<0.05$). The study concluded that anemia is common in patients with HMB.[14]
- A Quantitative cross-sectional pilot study involving 44 premenopausal women revealed that 50% of the participants suffered from HMB, ID was present in 68.2% of the participants and 18.2% of which were anemic. In patients with HMB significantly lower levels of hemoglobin (Hb) ($p=0.015$), hematocrit ($p=0.003$), and ferritin ($p=0.012$) were observed. The results from the study suggested a significant relationship between the perceived heaviness of menstrual flow and anemia ($p=0.021$).[15]

PRACTICE POINT

For screening of anemia in women with HMB

HMB is a major contributor to the development of anemia and clinicians should actively screen for anemia in women with HMB (Grade A/ Level 1b).

Screening for anemia in women with HMB

Screening for IDA should be included in the initial evaluation of women with HMB. The evaluation includes a thorough medical history and physical examination, as well as appropriate laboratory tests such as complete blood count (CBC) and peripheral smear to eliminate other causes of anemia, and imaging tests. Gathering a comprehensive medical history facilitates the identification of symptoms associated with anemia, such as fatigue, weakness, and dyspnea.[16] It also enables the evaluation of menstrual bleeding patterns, duration, severity, and associated symptoms like intermenstrual bleeding, pelvic pain, or pressure, providing insights into potential underlying causes of the heavy bleeding. Additionally, it reveals past medical history and treatments, shaping the management approach.[3] Physical examination is crucial for spotting anemia signs and underlying HMB causes, including assessing for pallor, bleeding disorder indicators like petechiae, ecchymosis, and potential abdominal abnormalities like distension, hepatosplenomegaly, or pelvic masses. Laboratory investigations are crucial for confirming the diagnosis, identifying underlying causes, and guiding management.[16] FIGO devised two systems to streamline and standardize the assessment of non-pregnant women of reproductive age experiencing abnormal uterine bleeding. System 1 aims to characterize symptoms such as HMB, while System 2 enables the classification of potential causes or contributors to the symptom.[2]

Measurement of Hb is the most feasible and pragmatic way of detecting the presence of anemia.[5] Any level of Hb in the presence of ID should be investigated.[22] Regular assessment of Hb levels allows healthcare providers to gauge the severity of anemia and track the response to treatment over time. By monitoring Hb levels, healthcare providers can determine if interventions such as iron supplementation or addressing the underlying cause of HMB are effectively increasing Hb levels and improving symptoms. Additionally, ongoing monitoring helps detect any recurrence of anemia or the need for further interventions. Overall, Hb monitoring is essential for optimizing the management

Table 3. Clinical guidelines recommendations on screening for anemia in women with HMB.

Guideline	Recommendations
FIGO 2023[5]	• Recommends screening of anemia in patients with HMB.
NICE guideline [NG88]. 2020[3]	• Recommends routine screening for anemia by carrying out a CBC for all women presenting with HMB.
ACOG 2019[16]	• Routine assessment of anemia and serum ferritin should be carried out in patients with HMB. • Evaluate for anemia in patients with HMB who are presented with dermatological signs such as pallor, bruises, and petechiae.
American Regent. 2019[17]	• The threshold for diagnosing anemia in women is Hb. • Recommends assessment of TSAT if Hb levels are <12 g/dL, or of erythrocyte morphology (with microcytic hypochromic indicating IDA). ID/IDA confirmed if TSAT <20%.
Practice Guideline Canada 2018[18]	• During the initial assessment, evaluate for anemia in patients who show symptoms of light-headedness, shortness of breath with activity, pallor, bruising, striae, hirsutism, and petechiae.
Institute of Obstetricians and Gynaecologists, Ireland. 2018[19]	• The initial assessment should include evaluation for symptoms suggestive of ID, IDA, or anemia such as breathlessness and postural dizziness, facial, conjunctival, and nail-bed pallor. • All patients presenting with menorrhagia should undergo CBC to exclude significant anemia (Hb <10 g/dL).
Australian Commission on Safety and Quality in Health Care. 2017[20]	• Patients with HMB should be assessed for ID and anemia.
European consensus. 2011[21]	• Assess serum iron, total iron binding capacity, and ferritin in patients with menorrhagia.

SF serum ferritin, TSAT transferrin saturation, CBC complete blood count, Hb hemoglobin, HMB heavy menstrual bleeding, ID iron deficiency, IDA iron-deficiency anemia, FIGO International Federation of Gynecology and Obstetrics, NICE National Institute for Health and Care Excellence, ACOG American College of Obstetricians and Gynecologists.

of IDA in individuals with HMB, ensuring their health and well-being are effectively addressed.[5]

PRACTICE POINTS

For monitoring anemia in patients with HMB

- Measurement of Hb is the most feasible and pragmatic way of detecting and monitoring anemia (Grade A/Level 1a).
- Regular monitoring of Hb aids to easily identify the response towards the iron therapy (Grade A/Level 1a).

Parenteral iron therapy for IDA in women with HMB

According to FIGO and Ministry of Health and Family Welfare (MoHFW), oral iron therapy is the initial recommendation for treating ID and mild-to-moderate IDA along with biannual de-worming. However, oral iron therapy may not always be well tolerated (poor patient compliance, adverse effects) by patients and might not achieve the desired treatment outcomes. The healthcare providers also need to advise patients to increase iron intake through food-based approaches such as dietary diversification and food fortification with iron and avoid substances that can interfere with iron absorption. If oral iron therapy is ineffective or not tolerated, alternative treatment options such as intravenous (IV) iron therapy should be considered.[2,5,23]

Table 4. Clinical guidelines recommendations on the use of iron therapy IV iron

Guideline	Recommendations
FIGO 2023[5]	Consider IV iron therapy when oral iron therapy proves to be ineffective
National Health Mission: Management of maternal anemia with intravenous Iron[24]	Consider IV iron when oral iron therapy is: • Intolerance to oral iron • Poor compliance to oral iron • Inadequate absorption due to gastrointestinal disorders –malabsorption achlorhydria • Lack of response to oral iron
American Regent 2019[17]	Recommends IV iron therapy as if Hb does not increase > 1 g/dL after 2 to 4 weeks of oral iron therapy, and SF < 30 ng/mL and/or TSAT is < 20%.
ACOG 2019[16]	Consider IV iron therapy as a second-line treatment in patients with poor compliance to oral iron therapy.
Health Quality Ontario 2017[25]	**Recommends IV iron therapy as** • First line: To correct severe anemia, including before and after surgery • First line: Prior to surgery, particularly if in need of rapid correction, to increase Hb > 12 g/dL. • Second line: If unresponsive or intolerant to oral iron therapy. The Threshold Hb level for IV iron therapy is Hb ≤ 9 g/dL.

SF serum ferritin, TSAT transferrin saturation, Hb hemoglobin, IV intravenous FIGO International Federation of Gynecology and Obstetrics, ACOG American College of Obstetricians and Gynecologists.

Ferric carboxymaltose (FCM) IV therapy has proven to be more effective in treating anemia over alternative anemia treatment such as oral iron therapy or blood transfusion.

Clinical evidence

A study included 78 patients diagnosed with IDA due to HMB who were intolerant or had an insufficient response to oral iron therapy. Each patient received a total calculated dose of IV FCM based on body weight and current Hb level. Pre-treatment and post-treatment mean (±SD) Hb levels were 8.9 (±1.7) g/dL and 12.3 (±1.2) g/dL, respectively. The mean ferritin level before treatment was 3.93 (±2.7) ng/mL, which increased to 244 (±185) ng/mL after treatment. Similarly, the mean (±SD) transferrin saturation levels improved from 5.7% (±5.0) before treatment to 43.1% (±20.9) after treatment. FCM emerged as an effective and safe treatment option for patients with IDA due to HMB, especially when oral iron therapy is inadequate or not tolerated. Initiating FCM treatment without waiting for the failure or intolerance of oral iron therapy could be both cost-effective and more convenient for patients with HMB and healthcare providers.[26]

In a prospective hospital-based study, 65 women with HMB and IDA were treated with a 1000 mg infusion of FCM in the hospital. Improvements in their Hb and serum ferritin were evaluated 14 days post-infusion. Any side effects experienced were recorded, and results were statistically analyzed using paired t-tests. Results showed a significant increase in mean Hb±SD from 7.71±0.66 gm% to 10.33±1.21 gm% after FCM infusion ($p<0.0001$), with a mean difference of 2.62 gm%. Similarly, mean±SD ferritin levels increased from 26.77±22.0 ng/ml to 254.75±70.00 ng/ml post-infusion ($p<0.0001$), with a mean difference of 227.97 ng/ml. This study highlights the safety and efficacy of FCM in treating anemia associated with HMB, suggesting its consideration as a treatment option to prevent the need for blood transfusion in such patients.[27]

An open-label, multicenter, two-arm study randomized 101 ID anemic women with menorrhagia to receive either a single dose of FCM or multiple doses of iron sucrose. The results from the study revealed that within two weeks of the initial administration, FCM demonstrated comparable effectiveness to iron sucrose in achieving Hb levels of ≥10 g/dL (78.8% vs. 72.3%). In the FCM group, the time taken to achieve Hb levels of ≥10 g/dL was significantly shorter compared to the iron sucrose group (7.7 days vs. 10.5 days). Mean Hb levels were higher in the FCM-treated patients than in the iron sucrose-treated patients with borderline significance.[28]

A randomized, controlled trial was conducted to evaluate the efficacy and safety of rapid, large-dose IV administration of FCM compared to oral iron in correcting ID anemia due to heavy uterine bleeding. The research study involved 477 women with anemia, ID, and heavy uterine bleeding. The patients were assigned to receive either IV FCM (≤1000 mg over 15 min, repeated weekly to achieve a total calculated replacement dose) or 325 mg of ferrous sulfate (65 mg elemental iron) prescribed orally thrice daily for 6 weeks. The results from the study revealed that in comparison to ferrous sulfate, a higher proportion of patients assigned to FCM exhibited an increase in Hb of 2.0 g/dL or more (82% vs. 62%, 95% CI 12.2–28.3, p<0.001), achieved an increase of 3.0 g/dL or more (53% vs. 36%, p<0.001), attained correction of anemia (Hb ≥ 12 g/dL) (73% vs. 50%, p<0.001), reported greater gains in vitality and physical function and experienced greater improvement in symptoms of fatigue (p<0.05). No serious adverse drug events were observed. FCM was more effective than oral iron therapy in replenishing iron stores.[29]

A systemic review and meta-analysis of randomized control trial of 21 studies revealed a significant improvement in serum ferritin (µg/l) in FCM group compared to oral iron (delta 172.8; 95 % CI 66.7–234.4) and in Hb (g/dl) with respect to ferric gluconate (delta 0.6; 95 % CI 0.2–0.9), oral iron (delta 0.8; 95 % CI 0.6–0.9) and placebo (delta 2.1; 95 % CI 1.2–3.0). All IV iron preparations currently available are deemed safe and effective; however, FCM appears to offer superior and swifter correction of Hb and serum ferritin levels in iron-deficient patients.[30]

Duration of administration of FCM in women with IDA

FCM is indicated for the treatment of ID/IDA when oral iron preparations are ineffective, contraindicated, or when there is a clinical necessity for rapid correction of ID/IDA. Assessment of the effect of FCM on IDA should be deferred until at least 4 weeks after the last FCM infusion to allow sufficient time for erythropoiesis and iron utilization. The maximum tolerated single dose of FCM is 1000 mg of iron (20 ml) per day, with a recommended frequency of administration not exceeding once a week. Numerous studies have demonstrated the efficacy and safety of FCM in swiftly and effectively correcting moderate-to-severe anemia within a span of 4–6 weeks.[31,32]

Real-world evidences

- A real-world study across 269 centers in India assessed the efficacy and safety of FCM for IDA in adolescents and adults. Medical records of 1800 patients were analyzed, showing significant improvements in Hb, serum ferritin, red blood cell count, and other parameters 4 ± 1 week after FCM treatment. Subjects with severe, moderate, and mild IDA showed a significant Hb rise of 3.31 gm/dL, 2.63 gm/dL, and 1.89 gm/dL respectively (p<0.001 for all). Physicians rated FCM efficacy and safety as very good to good in 97.5% and 97.2% of subjects, respectively. Overall, FCM effectively and safely corrected moderate-to-severe anemia within a short 4-week period, supporting its clinical use in real-world settings.[32]
- In a prospective observational study, adult patients with IDA were treated with IV FCM during routine care. Patient-Reported Outcomes Measurement Information System (PROMIS) instruments assessed fatigue, general health status, and physical function before and at 3 and 6 months post-FCM treatment. In the 152 enrolled patients (mean age 47.4 ± 16.0 years, 82.2% female), mean ±SD serum Hb was 10.2 ± 1.4 g/dL at baseline. Significant improvements were observed in fatigue, physical function, and global health at 3 months post-treatment, sustained at 6 months. Hb levels also increased significantly at both time points. Overall, FCM treatment led to meaningful improvements in fatigue, physical function, and global health for IDA patients in routine clinical practice.[33]

SUMMARY

- HMB is characterized by excessive blood loss during menstruation, which can significantly impact a woman's physical, social, and emotional well-being.
- In patients with HMB, the iron is lost at a rate 5–6 times greater per cycle compared to those with regular menstruation, thus the condition often leads to IDA.
- Screening for anemia in women with HMB is crucial, as it facilitates early detection and treatment to prevent complications associated with IDA.
- Various clinical guidelines recommend routine screening for anemia using Hb levels and other additional laboratory tests.
- Treatment with FCM therapy has emerged as an effective treatment option for IDA in women with HMB, especially when oral iron therapy is inadequate or not tolerated.
- FCM has been shown to quickly and effectively replenish iron stores, leading to improvement in Hb levels and improvement in symptoms.
- Real-world studies have demonstrated the safety and efficacy of FCM in correcting moderate-to-severe anemia within a short timeframe, supporting its clinical use in routine practice.
- FCM stands as a potential choice of treatment for IDA in women with HMB.

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