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Validation of a Point-of-Care Ferritin Card Test Against Venous Sampling for the Diagnosis of Iron Deficiency and Iron Deficiency Anaemia in Low- and Middle-Income Countries

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ABSTRACT

Objective: Iron deficiency (ID) and iron deficiency anaemia (IDA) remain pervasive health issues in low- and middle-income countries (LMICs), with significant implications for maternal health. This study aimed to validate a qualitative point-of-care (POC) ferritin card test against standard venous ferritin estimation for detecting ID and IDA, and to assess its role in guiding injectable iron therapy in resource-limited settings. Methods: We enrolled 75 women aged 14–62 years, each undergoing haemoglobin (Hb) testing, venous ferritin estimation (laboratory-based), and POC ferritin card testing using a finger-prick sample. Hb <9 g/dL was the threshold for initiating injectable iron therapy under standard protocol, while ferritin <30 ng/mL was considered indicative of depleted stores. The POC device was validated for specificity, sensitivity, and repeatability using known QC standards from the manufacturer's Certificate of Analysis. Results: Hb testing alone identified 13/75 (17.3%) women as candidates for injectable iron therapy. Ferritin testing detected an additional 24/75 (32.0%) women with depleted stores despite normal Hb, increasing the total eligible for treatment to 37/75 (49.3%). The POC card test demonstrated strong concordance with venous ferritin across predefined cut-off ranges. Operational benefits included rapid turnaround time (<5 minutes), no electricity requirement, and low per-test cost. Conclusion: The POC ferritin card test reliably detects iron deficiency in women with normal Hb, substantially increasing the number identified for early intervention. Its integration into maternal health screening in LMICs could significantly improve outcomes by enabling timely treatment.

Keywords: Ferritin, Iron Deficiency, Point-of-Care Testing, Anaemia, Women's Health, Low-Resource Settings, Injectable Iron.

INTRODUCTION

Iron deficiency (ID) is the most common nutritional disorder globally, affecting more than 30% of the world's population, particularly women of reproductive age (WHO, 2020). Iron deficiency anaemia (IDA) is associated with fatigue, impaired cognitive and physical performance, adverse pregnancy outcomes, and increased maternal mortality (Stevens et al., 2013). While haemoglobin (Hb) estimation is widely used for anaemia screening, it fails to detect early iron depletion, as Hb levels remain normal until iron stores are severely depleted. Serum ferritin measurement is recognised as the gold standard biomarker for iron stores, with WHO defining ID as ferritin <15 ng/mL in adults (WHO, 2011). However, access to laboratory-based ferritin testing is limited in LMICs, particularly in rural and primary care settings.

Point-of-care (POC) diagnostic devices offer a practical alternative to laboratory assays, enabling decentralised screening with minimal infrastructure. This study evaluates the diagnostic accuracy of a POC ferritin card test compared to standard venous ferritin estimation, and its utility in identifying candidates for injectable iron therapy in women who would otherwise be missed using Hb testing alone.

METHODS

This validation study was conducted among 75 women aged 14–62 years in both urban and rural healthcare settings in Karnataka, India. Following informed consent, participants underwent: (1) Hb measurement using a standard portable analyser; (2) venous blood sampling for quantitative ferritin estimation via laboratory assay; and (3) finger-prick testing using a qualitative ferritin POC card test (Medifactories, India). Ferritin cut-off categories were defined as: <15 ng/mL (severe depletion), 15–30 ng/mL (low stores), 30–100 ng/mL (normal), >100 ng/mL (high). Hb <9 g/dL was used as the threshold for initiating injectable iron therapy according to standard clinical protocol.

The POC ferritin card test was evaluated for specificity, analytical sensitivity, diagnostic sensitivity, and repeatability using QC reference samples, as documented in the manufacturer's Certificate of Analysis. The device delivers results in under five minutes, requires no electricity, and allows visual interpretation of ferritin range.

RESULTS

Using Hb estimation alone, 13/75 (17.3%) women qualified for injectable iron therapy. Ferritin testing identified an additional 24/75 (32.0%) women with ferritin <30 ng/mL, despite Hb ≥9 g/dL. This increased the total number eligible for therapy to 37/75 (49.3%). The ferritin POC card test demonstrated high concordance with venous ferritin measurement across all ferritin categories.

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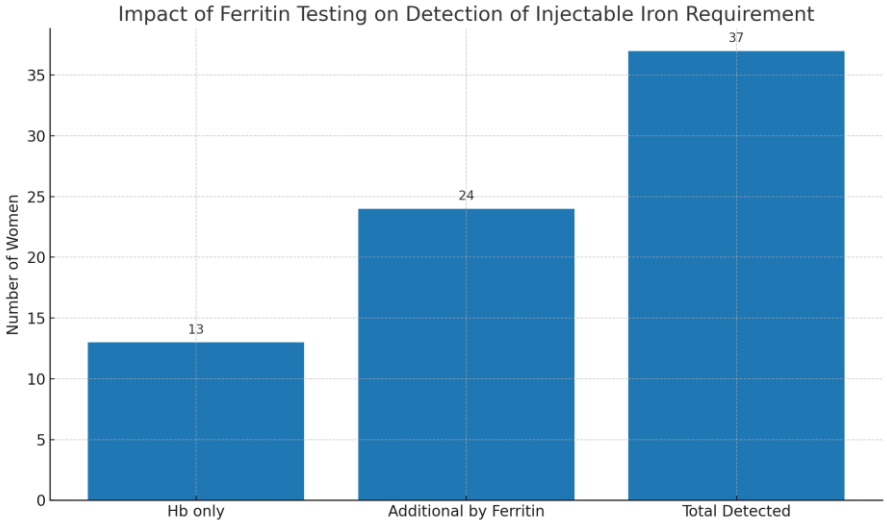

DISCUSSION

The findings confirm that ferritin testing identifies a substantial number of women with depleted iron stores who would otherwise be missed if Hb testing alone were used. Given that iron supplementation is most effective before the onset of anaemia, ferritin-based screening allows earlier and more targeted intervention. The POC ferritin card test provides a low-cost, rapid, and portable solution for LMIC settings, with minimal training requirements.

This aligns with WHO's call for innovative diagnostic strategies to combat anaemia in high-burden countries. Our data suggest that integrating ferritin POC testing into primary healthcare services could significantly expand the reach of injectable iron therapy, improving maternal health outcomes.

CONCLUSION

The ferritin POC card test is a validated, reliable, and operationally feasible alternative to laboratory-based ferritin assays in low-resource settings. By enabling early detection of iron deficiency, even in women with normal Hb, it can guide timely administration of injectable iron and prevent progression to IDA.

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Table 1: Concordance between Point-of-Care Ferritin Card Test Ranges and Venous Ferritin Values

Card Test Range (ng/mL)	count	mean	min	max
10-30	13	18.55	11.1	29.1
30-100	9	61.91	36.9	138.0
<15	2	7.35	6.6	8.1

Table 2: Women Detected for Injectable Iron Therapy by Detection Method

Detection Method	Number of Women	Percentage (%)
Hb only (<9 g/dL)	13	17.3
Additional by Ferritin (<30 ng/mL)	24	32.0
Total Detected (Hb + Ferritin)	37	49.3

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