

Cost-effectiveness of Parenteral Iron Therapy for First-line Management of Iron Deficiency Anemia among Pregnant Women in a Natural Programme Setting in Gujarat



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Policy Brief

Summary

Parenteral iron therapy is recommended to manage moderate and severe grades of anemia. This brief explains findings from an health technology assessment study to assess the cost-effectiveness of Intravenous Iron Sucrose (IVIS) and Ferric Carboxymaltose (FCM) in management of moderate and severe anemia in two districts of Gujarat – Banaskantha and Devbhumi Dwarka. An incremental mean change in Hb was noted in the FCM group (11.80 g/dl from 6.7 g/dl) followed by IVIS (11.45 g/dl from 8.2 g/dl) at the time of the fourth follow-up. The mean Hb was reduced from the baseline (9.55 g/dl from 9.99 g/dl) in control arm. Per beneficiary (undiscounted) cost for IVIS was INR 7,260, INR 7,185 for FCM, and INR 4,038 for OI group. IV iron sucrose was found to be costly but more effective than the oral therapy for the treatment of moderate and severe anaemia. The ICER was calculated at INR 783.11 which is 0.049% of the country's per capita GDP (INR 1,61,458). Further, IVIS was well tolerated as side effects are less compared to that of oral iron.

Recommendations

Study findings on clinical efficacy remains inconclusive due to multifactorial clinical outcomes. Considering the limited sample size and lack of blinding, larger studies are needed to validate the results findings. Future studies on clinical efficacy would be critical in establishing effect of rise in hemoglobin level on maternal and birth outcomes.

Introduction

Maternal anemia is a major public health issue in India. Specifically, iron-deficiency anemia (IDA) during pregnancy is a significant public health concern because of its association with perinatal mortality, preterm birth, neonatal low-birth-weight, and maternal mortality and morbidity.¹ Through intravenous iron sucrose (IVIS) administration, parenteral therapy has emerged as an effective alternative to oral treatments in pregnant women.² Apart from its quick absorption, intravenous (IV) mode is also known to impart a lesser incidence of hypersensitive reactions.³ A systematic review conducted by Radhika et al (2019)⁴ showed IVIS to be highly effective than OI therapy. Recently ferric carboxy maltose (FCM) has also emerged as an effective treatment for IDA during pregnancy and the postpartum periods.^{5,6}

Policy Implications and Novelty

- IVIS is indicated in the national guideline (I-NIPI)⁷ for the treatment of moderate and severe anemia. However, there is no evidence on cost-effectiveness of IVIS in local context.
- Present study aligns with I-NIPI guideline and generates evidence on IVIS for treatment of maternal anemia in natural program setting.

- The study outcomes has pontial in contributin to the the Anaemia Mukht Bharat (Anaemia Free India) strategy to achieve the ambitious target of 50% reduction of anaemia among women of reproductive age by 2025.

Aim of the study

The study aims to compare clinical efficacy and cost-effectiveness of the IVIS and FCM therapy with oral iron therapy among pregnant women with IDA in a programmatic setting at Banaskantha and Devbhoomi Dwarka district of Gujarat, India

Objectives of the study

Primary objective of the study is to measure change in mean hemoglobin level post treatment from baseline.

Secondary objectives:

- To measure incidence of morbidity and mortality associated with iron deficiency anemia
- To measure treatment compliance to IVIST and FCM
- To measure health-related quality of life (HRQoL) using EQ-5D tool

METHODS

The observational study was undertaken prospectively at Banaskantha and Devbhoomi Dwarka districts of Gujarat during 2020-21. Cost-effectiveness analysis was done using decision-analytic modelling with a societal perspective on health care costs and benefits. The target population for the study were registered pregnant women between 14-18 weeks' gestation period who were enrolled from both districts. During the study period, patients with moderate and severe anemia were recruited. The study followed a natural programme setting without manipulating the study environment. Classification and treatment of IDA

among pregnant women was as per national guidelines.

Intervention scenario (IVIS or FCM interventions) was compared with routine care scenario (where OI therapy was provided). A sample of 32 patients in each arm in two districts or 192 patients were enrolled and 144 patients were followed-up until post-partum phase.

Both the programme cost i.e. the cost borne by the health system as well as the cost incurred by the patients were taken into consideration.

Transition probabilities were derived from primary data for clinical indicators for both the intervention and control arms. The transition probabilities in the intervention and control arm were derived from primary study. Time horizon of the study was one year and 3% discounting was applied. One-way sensitivity analysis was carried out by varying model parameters to estimate uncertainty in all parameters.

RESULTS

Cost-effective analysis was done based using the decision tree model. From societal perspective, IVIS incurs an incremental cost of INR 783.11 per QALY gained which is 0.49% of the per capita GDP of India. Thus, IVIS intervention can be concluded to be very cost-effective.

Table 1: Results of cost-effectiveness analysis between IVIS and OI therapy

Outcomes	IVIS	OI
Cost (in INR) per patient treated as per modelling	6768.28	6503.79
Incremental Cost (in INR)	286.05	
Effects	0.368	0.003
Incremental Effects	0.365	
ICER	783.11	

Figure 1 illustrates cost-effectiveness plane. Orange dot indicates ICER value which falls in the North East quadrant. It means intervention is costly than comparator but highly effective.

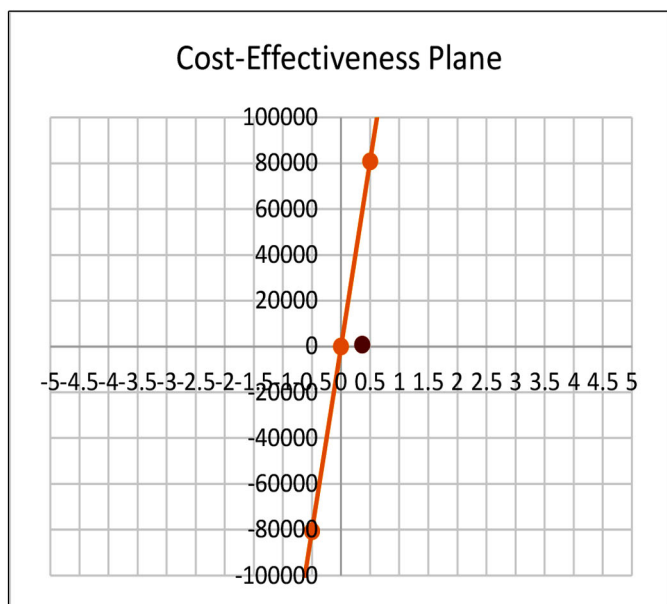


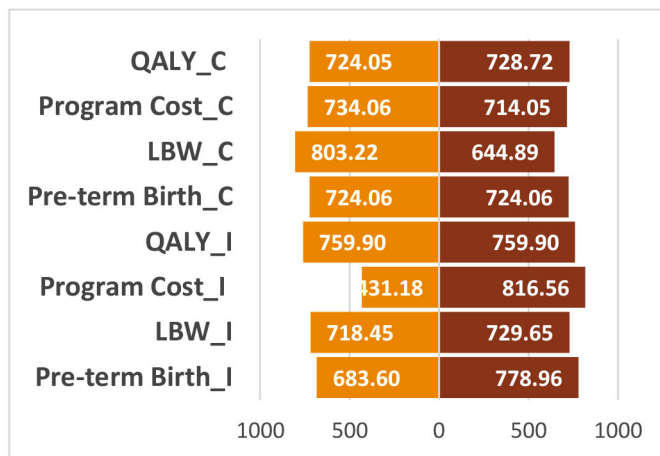
Figure 1: Cost-effectiveness plane of the study

One-way sensitivity analysis was applied. Figure 2 presents results from simulations done as part of one-way sensitivity analysis. The tornado diagram of one-way sensitivity analysis shows that ICER value is slightly changed when the input parameter is changed in multiple indicators. Programme cost of intervention arm, low-birth weight and pre-term birth in control arm are key parameters that influence the model.

Figure 2: Tornado diagram of cost-effectiveness of IVIS and OI therapy

CONCLUSION

IV IST was found to be cost-intensive but more effective than oral therapy for the treatment of moderate and severe anaemia. Further, it is well tolerated as side effects are less compared to that of oral iron. Considering the limited sample size and lack of blinding, larger studies with robust methodologies are needed to validate the results findings. Future studies on clinical efficacy would



be critical in establishing effect of rise in hemoglobin level on maternal and birth outcomes.

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