

Iron-deficiency Anemia in Pregnant Women: What preventing Practitioners from using IV Iron Sucrose

Hema Divakar

ABSTRACT

Background: Severe anemia in pregnancy results in relatively poor maternal and fetal outcome. Maternal effects are preterm labor, preeclampsia, sepsis and postpartum hemorrhage and increase need of blood transfusion. In India, the decision to recommend appropriate supplementation for IDA in pregnant women is left to the health care personnel and based on the individual maternal condition.

Objective: To assess the problems/limitations of health care practitioners to treat IDA with IV iron sucrose in pregnant women and to suggest ways forward for expansion of its use with confidence.

Materials and methods: The questionnaire included 18 questions altogether related to treatment, influencing factors for treatment, risk factors, attitudes and awareness about parenteral iron sucrose supplementation. All data were entered into an electronic database without personal identifiers to maintain confidentiality. The data was analyzed by using SPSS version 17.0.

Results: The survey consisted of responses from 107 health care professionals from urban and rural practitioners in India. Out of 107, 28.1% respondents said that the majority of the anemic patients were between 9.9 and 7.0 mg/dl Hb—moderate category. A total of 78 (72.90%) said that they would recheck Hb levels 4 weeks after oral iron treatment for checking the patient's response. Of the respondents, 42.52% of them said that the women were compliant and took supplementation as per prescription. All respondents agreed that there could be a mean 58% reduction of blood transfusions by using IV iron sucrose. Many respondents (74, 79.44%) expressed interest to have more information from recent research to expand the indications for use.

Conclusion: Dissemination of information related to IV iron sucrose to all practitioners and reduction in costs would help them to expand the use with confidence and avert many complications related to maternal and fetal health due to gestational anemia.

Keywords: Routine iron and folic acid supplementation, KAP, Blood transfusion, Preterm labor, IV iron sucrose postpartum hemorrhage.

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INTRODUCTION

Iron-deficiency anemia (IDA) is the most common nutritional deficiency problems affecting pregnant women worldwide.¹ The high prevalence of iron and other micronutrient deficiencies among women during pregnancy in developing countries is of concern and maternal anemia is still a cause of considerable perinatal morbidity and mortality.² Most women begin their pregnancy with partially or completely depleted iron reserves. During pregnancy, there is a greater demand for iron to meet the requirement of red blood cell mass expansion in the mother, fetal and placental blood and blood loss at delivery.³ Also, iron deficiency would be exaggerated because of the ability of fetus to extract its requirement in obligatory one way direction even from iron deficient mothers.

Severe anemia in pregnancy results in relatively poor maternal and fetal outcome. Maternal effects are preterm labor, preeclampsia, sepsis and postpartum hemorrhage and increase need of blood transfusion.⁴ Recent study reported a fetal mortality rate of 50% at 7 months, 28% at 8 months and 24% at 9 months of gestation.⁵ Mild to moderate degrees of iron-deficiency anemia can impact motor and mental development in children and adolescents.^{6,7} There is some evidence that iron deficiency without anemia affects cognition in adolescent girls.⁸ Therefore, it is very important to manage gestational anemia before it may lead to far reaching complications in the neonate and infants. International organizations have been campaigning routine iron and folic acid supplementation for every pregnant woman in areas of high anemia prevalence.^{9,10} Apart from maintaining balanced diet, general treatment includes iron supplementation by either oral or intramuscular or intravenous routes. Interventions to control IDA include iron supplementation and iron fortification, health and nutrition education, control of parasitic infections and improvement of sanitation.¹¹ Though, the National Nutritional Anemia Control Program (NNACP) in India was launched in 1970, anemia continues to be a major public health problem. The program was unsuccessful due to the lack of effective health education and supervision.¹² In most developing countries like India, the decision to recommend appropriate supplementation for IDA in pregnant women is left to the health care personnel and is based on the individual maternal condition.¹³ It is known that intravenous iron treated IDA of pregnancy and restored iron stores faster and more effectively than oral iron with no serious adverse reaction

(SAEs).¹⁴ Intravenous iron therapy is safe, convenient more effective than intramuscular iron therapy in treatment of iron-deficiency anemia during pregnancy.¹⁴

Potentially, given the incidence of moderate and severe IDA in pregnancy, there is scope to treat a larger number of women with IV iron sucrose. This study was aimed to assess the problems/limitations of health care practitioners to treat IDA with IV iron sucrose in pregnant women and to suggest ways forward for expansion.

MATERIALS AND METHODS

An 18 question online survey (www.abcofobg.com) was developed to assess providers' knowledge, practices and attitudes related to understanding and management of IDA. The final sample consisted of 107 respondents. The questionnaire included 18 questions altogether related to treatment, influencing factors for treatment, risk factors and parenteral iron sucrose supplementation. All data were entered into an electronic database without personal identifiers to maintain confidentiality. The data was analyzed by using SPSS version 17.0.

RESULTS

The survey consisted of responses from 107 health care professionals from urban and rural practitioners in India.

Prevalence

Out of 107, 28.1% respondents said that the majority of the anemic patients were between 9.9 and 7.0 mg/dl Hb—moderate category.

Influencing Factors on a Scale of 1 to 5

Table 1 summarizes the IDA treatment influencing factors on a scale of 1 to 5. Safety was ranked no. 1 by 78 (72.90%) respondents, efficacy no. 2 (65, 60.75%), compliance no. 3 (39, 36.45%), ease of administration no. 4 (38, 35.51%) and cost was ranked no. 5 by 63 (58.88%) respondents.

Treatment of Iron-deficiency anemia

Table 2 summarizes the treatment options of IDA. Overall, 73.54% prescribed oral iron as the first line therapy.

Response to Treatment

Table 3 summarizes responses in treating of IDA. A total of 78 (72.90%) said that they would recheck Hb levels 4 weeks after oral iron treatment for checking the patient's response. Overall 82 (76.64%) respondents said that the response to oral iron therapy was moderate (>1 to <2 gm/dl increase after 4 and 8 weeks).

Table 1: Factors influencing the treatment of iron deficiency anemia with IV sucrose

<i>Rate each influencing factor for your treatment on a scale of 1 to 5 (1—most important; 5—least important)</i>	<i>N = 107</i>	<i>%</i>
• Ranking 1		
– Safety	78	72.90
– Efficacy	20	18.69
– Cost	4	3.74
– Compliance	3	2.80
– Ease of administration	2	1.87
• Ranking 2		
– Safety	15	14.02
– Efficacy	65	60.75
– Cost	8	7.48
– Compliance	14	13.08
– Ease of administration	5	4.67
• Ranking 3		
– Safety	5	4.67
– Efficacy	11	10.28
– Cost	15	14.02
– Compliance	39	36.45
– Ease of administration	37	34.58
• Ranking 4		
– Safety	7	6.54
– Efficacy	6	5.61
– Cost	17	15.89
– Compliance	39	36.45
– Ease of administration	38	35.51
• Ranking 5		
– Safety	2	1.87
– Efficacy	5	4.67
– Cost	63	58.88
– Compliance	12	11.21
– Ease of administration	25	23.36

Compliance and Adverse Reactions

Of the respondents, 42.52% of them said that the women were compliant and took supplementation as per prescription. The respondents also mentioned that the patients stopped taking oral iron mainly because of gastritis (mean 44.58%), constipation (mean 24.75%), diarrhea (mean 16.11%).

Overall, 63.55% (Table 3) respondents agreed that there were adverse reactions (AEs) with oral iron (Fig. 1).

Parenteral Iron

Table 4 summarizes the methodology of parenteral iron supplementation in IDA patients. Many respondents

Table 2: Practitioners opinion in treating iron deficiency anemia

Treatment of iron-deficiency anemia	N = 107	%
• Do your patients have adverse reactions to oral iron?	68	63.55
– Constipation	58	54.21
– Diarrhea	35	32.71
– Gastritis	60	56.07
– Abdominal cramps	23	21.50
– Rashes	4	3.74
– Burning	11	10.28
– Nausea	50	46.73
– Vomiting	34	31.78
– Swelling of feet	1	0.93
– Joint pains	2	1.87
– Chest pain	1	0.93
– Breathlessness	2	1.87
– Giddiness	6	5.61
– Anaphylactic shock	0	0.00
• Do your patients have adverse reactions to parenteral iron?	48	44.86
– Constipation	5	4.67
– Diarrhea	3	2.80
– Gastritis	2	1.87
– Abdominal cramps	8	7.48
– Rashes	28	26.17
– Burning	11	10.28
– Nausea	12	11.21
– Vomiting	11	10.28
– Swelling of feet	7	6.54
– Joint pains	27	25.23
– Chest pain	9	8.41
– Breathlessness	20	18.69
– Giddiness	17	15.89
– Anaphylactic shock	20	18.69
• Do you know of any preparations, where deaths have not been reported?		
– Jectofer	20	18.69
– Jectofer	8	7.48
– Imferon	8	7.48
– Venofer	7	6.54
– IV iron sucrose	81	75.70
– Other	12	11.21
• Ratio (%) of anemic antenatal patients in a day of the total antenatal patients, how many of them are anemic?		
– 10	12	11.22
– 20	20	18.7
– 30	9	8.41
– 40	18	16.82
– 50	15	14.02
– 60	13	12.15
– 70	8	7.48
– 80	9	8.41
– 90	3	2.8
– 100	0	0
• What percentage of the anemic patients fall in the categories listed below?		
– >11	22	20.56
– 10.5-11	20	18.7
– 0-10.4	21	19.63
– 9.9-7	30	28.1
– 6.9-4	7	6.54
– <4	7	6.54

(62, 57.94%) used IV iron sucrose for severe anemia when the patient showed intolerance to oral iron. 44.86% said that there were minor AEs to parenteral iron. Many respondents (81, 75.70%) agreed that there were no death with IV iron sucrose preparations (Fig. 1).

Reduction in Blood Transfusion Rates

All respondents agreed that there could be a mean 58% reduction of blood transfusions by using IV iron sucrose.

Reasons for using IV Iron Sucrose

As presented in Figure 2, the main reasons to use IV iron sucrose were efficacy (83, 77.57%), less blood transfusions needed to be done (79, 73.83%), no AEs (58, 54.21%).

Reasons for not using IV Iron Sucrose

The reasons for not using IV iron sucrose more frequently to treat IDA were cost (69, 64.49%). Many respondents (74, 79.44%) expressed interest to have more information from recent research to expand the indications for use (Fig. 3 and Table 4).

DISCUSSION

There are a large number of practitioners—30% are seeing moderate anemia in majority of pregnant women indicating that there is a prevalence of moderate category of anemia in a significant number of pregnant Indian women.

To treat anemia in pregnancy, the clinicians ranked safety as top priority (72.90%) and cost as a least priority (58.88%) (Fig. 4). Overall, 73% of practitioners used oral iron therapy as the first line, even in moderately severe

anemia in pregnancy. The method of assessment of the response to oral iron was by rechecking Hb levels at 4 to 8 weeks, which is a practical and pragmatic method. Though the grade B recommendation states that 2 gm/dl should be considered as satisfactory response, 76% of clinicians said that the response was between 1 to 2 gm/dl which points toward suboptimal response or failed response.

Gastritis, constipation and diarrhea were the main reasons for noncompliance and 48% of clinicians agreed that there was a lack of compliance and 63% of the clinicians endorsed that there were AEs when patients are on oral iron

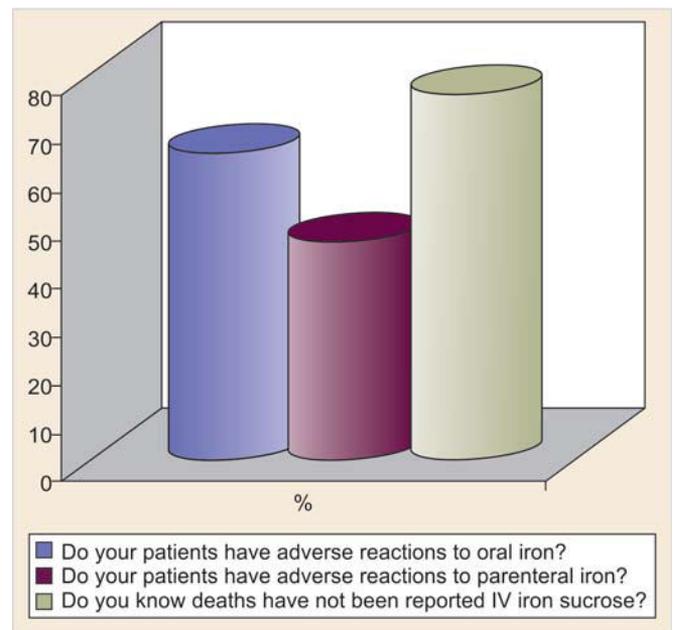


Fig. 1: Treatment of iron-deficiency anemia

Table 3: Risk factors in treating iron deficiency anemia

Risk factors in treating IDA	N = 107	%
• How many patients do you prescribe oral iron for IDA in a day?		
– Prescribed	69.00	73.54
– Mean	16.69	
• When do you recheck Hb levels for the patient's response to oral iron		
– 4 weeks after prescribing oral iron	78	72.90
– 8 weeks after prescribing oral iron	22	20.56
– Other	7	6.54
• How is the response of the woman to oral iron therapy?		
– Moderate (> 1 to < 2 gm/dl increase after 4 and 8 weeks)	82	76.64
– Moderate (> 1 to < 2 gm/dl increase after 4 and 8 weeks)	5	4.67
– Significant (> 2 gm/dl increase after 4 and 8 weeks)	20	18.69
• How is the woman's compliance to oral iron therapy? (mean)		
– Compliant (always takes as per prescription)	42.52	39.74
– Most often compliant (takes most of the times)	34.01	31.79
– Not compliant (does not follow prescription)	13.17	12.31
– Most often not compliant (sometimes follows prescriptions)	10.28	9.61
• Patients stop taking oral iron because of these side effects (mean)		
– Gastritis	44.58	41.66
– Diarrhea	16.11	15.06
– Constipation	24.75	23.13
– Other	14.54	13.59

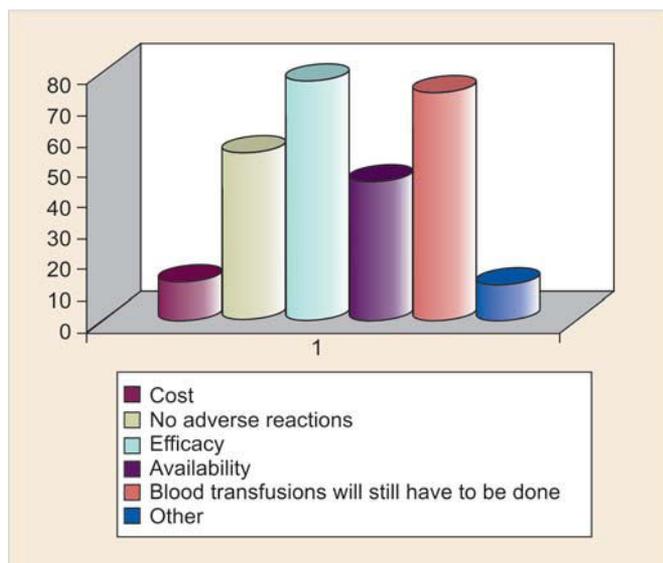


Fig. 2: What are the reasons for using IV iron sucrose to treat IDA?

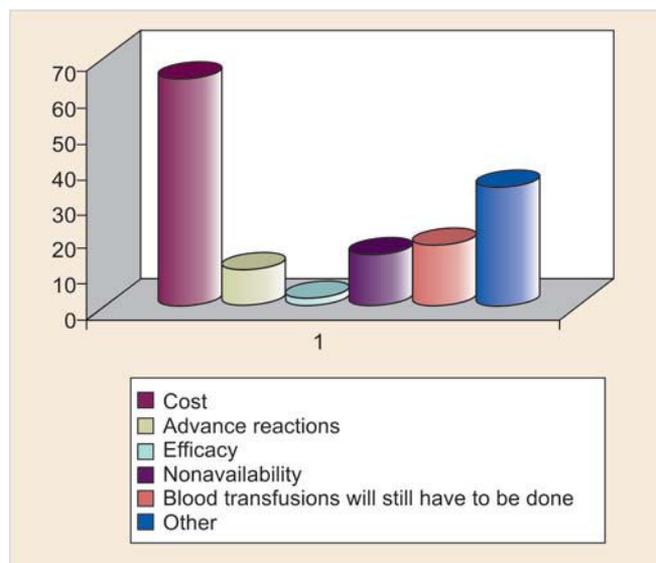


Fig. 3: What are the reasons for not using IV iron sucrose more frequently to treat IDA?

Table 4: Practitioners opinion on use of parenteral iron administration

Parenteral iron	N = 107	%
• How many patients do you treat with parenteral Iron (PI) in a day?		
– Treated	14	15.3
– Not treated	79	84.7
– Mean	1.17	
• Which parenteral iron do you use?		
– Jectofer	21	19.63
– Inferon	12	11.21
– Orofer-s	74	69.16
– C-pink s	20	18.69
– Other	20	18.69
• In my practice, I use IV iron sucrose for severe anemia		
– When patient is close to term	58	54.21
– When patient shows intolerance to oral iron	62	57.94
– When patient does not take oral iron regularly	48	44.86
– Other	37	34.58
• What are the reasons for using IV iron sucrose to treat IDA?		
– Cost	13	12.15
– No adverse reactions	58	54.21
– Efficacy	83	77.57
– Availability	48	44.86
– Blood transfusions will still have to be done	79	73.83
– Other	12	11.21
• What is the mean percentage of reductions in blood transfusions when you use IV iron sucrose?	58	61.68
• What are the reasons for not using IV iron sucrose more frequently to treat IDA?		
– Cost	69	64.49
– Adverse reactions	11	10.28
– Efficacy	2	1.87
– Nonavailability	15	14.02
– Blood transfusions will still have to be done	18	16.82
– Other	36	33.64
• Would you want more information from recent research and Indian data to:		
– Start using IV iron sucrose	19	20.56
– Expand the indications for use	74	79.44

therapy. It is clear to the practitioners themselves that administration of oral iron supplementations is not sufficiently enough in order to reverse anemia promptly, due to the limited absorption, the gastrointestinal symptoms and the poor compliance for long treatment of the patients

(Table 5). Intravenous iron treatment is indicated for patients with poor compliance in oral supplementations, in cases with poor iron absorption (bowel operations or diseases), in patients with severe renal impairment and in postpartum hemorrhage.^{15,16}

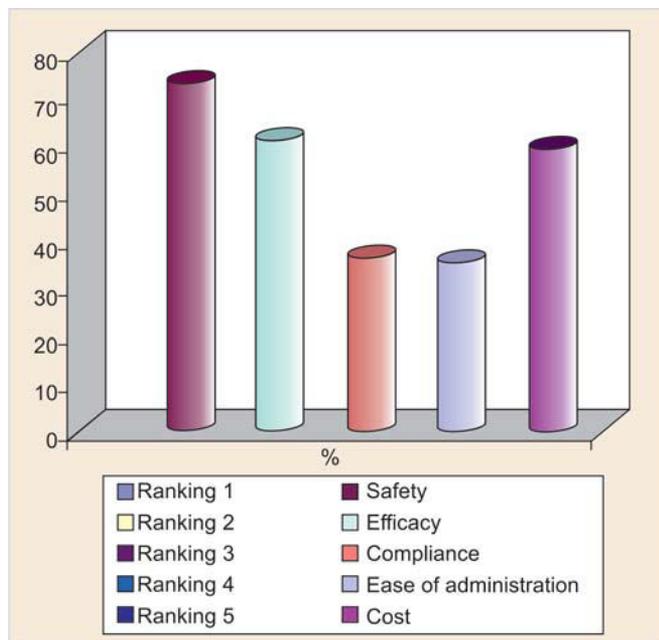


Fig. 4: Influencing factor for your treatment on a scale of 1 to 5 (1—most important; 5—least important)

From the earlier study reports, it is clear that intravenous iron sucrose is safe and effective^{17,18} in the treatment of iron-deficiency anemia during pregnancy than control group taking oral iron supplements. Intravenous iron sucrose group achieved a significantly higher Hb level (128.5 ± 6.6 gm/l vs 111.4 ± 12.4 gm/l; $p \leq 0.001$) in a shorter period (6.9 ± 1.8 weeks vs 14.9 ± 3.1 weeks; $p \leq 0.001$).¹⁷ Also, compared oral with ferrous sulfate, IV iron therapy with an iron sucrose complex significantly increased serum ferritin

level within a short time with fewer AEs than oral iron therapy in women with postpartum iron-deficiency anemia.¹⁹ Despite this information, most practitioners used parenteral IV iron sucrose only in cases of severe anemia <7 gm/dl. Those who used it agreed that IV iron sucrose was efficacious (77.57%), safe (54.21%) and helped to avoid blood transfusions (73.83%). Others were not using (64.49%) it because of its cost (Fig. 3) and require more information on the safety and larger experience for enabling them to use this new molecule with confidence (80%).

Most had the experience with the clinical use of iron dextran, especially the large molecular form and faced complications inclusive of anaphylactic reactions and death.²⁰ They had the fear of using parenteral iron.

Intravenous iron sucrose tolerance seems to be excellent without AE, in accordance with the literature.²¹ The majority of clinicians had poor knowledge and minimal experience with the use of newer preparations like IV iron sucrose. 80% of practitioners had little awareness regarding safety related to the treatment of IDA with IV iron sucrose and were hesitant to use it but were eager to know more.

Intravenous iron sucrose could be the Holy Grail in the eradication of IDA in pregnancy in a setting, such as India. The issue of significant cost, especially when the challenge is to deliver this treatment to rural areas where the vast majority of the women requiring the treatment reside, could be a significant barrier. Oral and/or parenteral iron supplementation has failed to eradicate IDA and cannot be said to be cost-effective. While definitive cost-effective

Table 5: Comparison of erythropoiesis and iron status between the two groups on treatment days 0, 7 and 28¹⁹

	Day	IV group (n = 50)	PO group (n = 25)	p-value	
Erythropoiesis Hb (12-16 gm/dl)	0	8.2 ± 0.6 (6.3-9.0)	8.2 ± 0.5 (7.3-8.7)	0.813	
	7	10.9 ± 1.1 (9.0-13.5)	11.2 ± 0.9 (10.2-12.5)	0.125	
	28	12.5 ± 1.6 (9.5-15.1)	11.8 ± 0.7 (11.0-13.5)	0.200	
Hematocrit (36-50%)	0	24.9 ± 2.4 (20.5-29.6)	25.1 ± 2.54 (21.7-29.8)	0.736	
	7	33.8 ± 3.0 (28.3-40.6)	34.7 ± 3.1 (31.2-38.7)	0.349	
	28	51.6 ± 7.2 (32.0-42.1)	36.5 ± 2.0 (34.2-40.6)	0.206	
MCV (81-99 fl)	0	76.1 ± 12.4 (52.0-97.0)	70.9 ± 9 (56.0-86.9)	<0.01	
	7	81.6 ± 9.2 (66.1-95.6)	80.1 ± 2.1 (77.1-81.7)	0.155	
	28	84.9 ± 8.8 (63.5-95.5)	81.1 ± 3.6 (77.5-90.2)	0.057	
Iron status					
	Serum iron (37-145 mg/dl)	0	42.8 ± 29.3 (19.0-159.0)	34.5 ± 12.4 (20.0-54.0)	0.507
		7	72.7 ± 17.9 (27.0-107.0)	67.8 ± 32.2 (27.0-103.0)	0.435
28		86.2 ± 44.3 (18.0-215.0)	73.5 ± 33.9 (45.0-122.0)	0.166	
tSIBC (274-497 mg/dl)	d0	411.0 ± 105.2 (35-564)	436.7 ± 98.1 (267-569)	<0.01	
	d7	303.5 ± 63.8 (176-420)	334.2 ± 28.1 (309-374)	<0.01	
	d28	287.2 ± 89.1 (93-459)	299.8 ± 83.9 (229-459)	<0.820	
	Ferritin (6-159 ng/dl)	d0	26.7 ± 40.9 (1.5-178.0)	9.9 ± 6.8 (4.4-25.0)	<0.05
	d7	124.0 ± 122.9 (5.9-55.3)	18.6 ± 9.3 (5.9-32.3)	<0.001	
	d28	100.0 ± 79.7 (4.3-252.0)	17.4 ± 14.9 (4.3-34.4)	<0.01	
CRP (0-3 mg/l)	d0	4.1 ± 5.7 (0.0-19.0)	2.8 ± 3.8 (0.0-8.5)	0.236	
	d7	0.8 ± 1.6 (0.0-4.1)	0.8 ± 1.3 (0.0-2.7)	0.670	
	d28	0.1 ± 0.2 (0.0-0.9)	0.1 ± 0.1 (0.0-0.2)	0.626	

Values in brackets are the normal range; Hb: Hemoglobin; MCV: Mean cell volume; tSIBC: Total serum iron-binding capacity; CRP: C-reactive protein

studies for the use of iron sucrose are urgently needed, yet it is difficult to 'cost' the morbidity and mortality suffered by women in the developing world as a result of iron-deficiency anemia, never mind the impact on the next generation with regard to impaired motor and intellectual development associated with IDA in the newborn and child.

Costs could be reduced by administering the iron sucrose as a single bolus intravenous push over 5 minutes and by expanding the usage as against blood transfusions. All these potential solutions require rigorous research and evaluation before they could be implemented.

CONCLUSION

Dissemination of information related to IV iron sucrose to all practitioners and reduction in costs would help them to expand the use with confidence and avert many complications related to maternal and fetal health.

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ABOUT THE AUTHOR

Hema Divakar (Corresponding Author)

Consultant, Department of Obstetrics and Gynecology Divakars Specialty Hospital, Bengaluru, Karnataka, India
e-mail: hema_divakar@yahoo.com