

Pharmacoeconomics and Utilization of Intravenous Iron Sucrose in a Tertiary Care Hospital

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Abstract

Background: Rational utilization of parenteral iron with meticulous calculated doses will promote appropriate utilization of healthcare resources. The aim is to study utilization of intravenous Iron Sucrose at patient level and hospital level

Methods: This prospective-observational study was conducted over 6 months. Case-records of 125 indoor patients were reviewed for intravenous (IV) Iron Sucrose prescription and patient details and treatment details for patients were procured.

Results: 125 patient records were divided in (Antenatal care and Non Antenatal care) ANC and Non ANC groups; and their Mean age was 36(S.D $\pm$ 16) years. IV Iron Sucrose was prescribed the most in anemic pregnant patients 41(32.8%) followed by severely debilitated patients on other injectable drugs 37(6%). The Total administered dose was more than the Standard calculated dose in an alarming 84(67.2%) of the patients. Utilisation of IV iron sucrose in Defined Daily Dose per 100 bed days (DDD/100 bed days) was found to be 0.42 in total patients whereas it was 0.59 in ANC and 0.36 in Non ANC groups.

Conclusion: This research highlighted that overutilization and administering more than the required dose of IV iron sucrose, could be effectively tackled by calculation of its standard dose by Ganzoni's formula. Studying the monthly trends and comparing utilization of parenteral iron with the help of DDD/100 bed days by hospitals can help in comparing utilization and also assist for budgetary preparedness of hospitals. There is also a dire need to formulate universally accepted guidelines for the use of parenteral iron in general adult population.

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Introduction

Drug utilization research was defined by WHO in 1977 as *'the marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences'* (1).

Amongst the various reasons that lead to Iron deficiency Anemia (IDA), oral iron replacement is usually mainstay treatment but some cases like intolerance to oral iron, abnormal absorption due to surgery or gastrointestinal diseases, significant bleeding, noncompliance, etc. may make oral iron treatment in some patients inadequate. Such patients will benefit from parenteral iron presence of functioning erythropoiesis (2,3). Apart from the better tolerability of parenteral compared to oral iron, the

decision for IV or oral iron as therapy depends on the type of iron deficiency (absolute vs. functional), the urgency to achieve a treatment effect, tolerability and costs (4). Globally, a study shows parenteral iron usage prevalence of 8% while another study shows it to be 20% in chronic kidney disease (CKD) patients suffering from anemia (5). Many parenteral iron formulations have been studied and compared over the years which show Iron Sucrose has the least association with adverse drug reactions (ADR), better efficacy and better tolerability in general population as well as in patients with comorbidities like CKD, inflammatory bowel disease (IBD), anemia associated with cancer and its treatment etc. who need rapid iron supply and in whom oral iron preparations are ineffective or not tolerated (1,4-12). Studies state diverse dosing regimens and durations for IV iron sucrose despite

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availability of various formulae and guidelines for specific indications; which may lead to wastage as well as overdose (1,4-12). Therefore, this study focused on the vigilance of utilization of IV iron sucrose at a resource limited setting such as our tertiary care hospital in Pune, India. Accordingly, this research was aimed at analysing the utilization of IV iron sucrose at patient level and hospital level with an objective to study the same with respect to the patient profile, comorbidities, demographic characteristics and clinical conditions among patients who received intravenous iron sucrose.

Methods

This was a prospective, observational study of utilization of IV iron sucrose for six months from March 2022 to August 2022 in a tertiary care hospital in Pune, India. The study commenced after obtaining prior approval from the Institutional Ethics Committee of this aforementioned study setting. Adult indoor patients who had been prescribed intravenous iron sucrose for treatment were divided into (Antenatal care and Non Antenatal care) ANC and Non ANC groups. Consent was taken. Indoor case papers of these patients were prospectively reviewed and patient details like demographic data, comorbidities, severity of anemia, hospital registration number, etc. and treatment details like total dose of IV Iron Sucrose administered, duration of treatment, number of doses prescribed, frequency of dosing and indication of IV Iron Sucrose were procured. Adverse drug reactions (ADR) encountered by the patients were reported. The entire collected data was recorded in an Excel Sheet.

Total iron deficit (TID) of Iron sucrose was calculated using the Ganzoni's formula:

$TID (mg) = \text{Weight (kg)} \times (15 - \text{Actual Hb (g/dl)}) \times 2.4 + \text{Iron deposits (500 mg)} (13).$

This was compared with the actual total dose administered to the patient.

Sample size:

Globally, a study shows parenteral Iron usage prevalence of 8% (14).

So, formula to get sample size (15,16):

This formula generates the sample size, n , required to ensure that the error, d , does not exceed a specified value. To solve for n , we must input " Z ," " p ," and " d ."

Z is confidence level (e.g., $Z = 1.96$ for 95% confidence)

d is the precision/error taken as 5%

P is the prevalence taken as 8%

So, $Z = 1.96$ $P = 8\%$ $d = 5\%$ $n = \frac{Z \times Z \times P(1-P)}{d \times d}$

10% Attrition Rate applied: 11.3 Final sample size is $113.09 + 11.3 = 125$.

All indoor patients above 18yrs of age requiring iron sucrose for treatment were included in the study. All patients below 18yrs of age were excluded from the study.

Collected data was analysed using the Statistical Package for Microsoft Excel 2019 (Version 2204) for analysis of demographic parameters. Age is presented as mean ($\pm$ S.D) whereas other demographic data is expressed as percentage of whole. Defined Daily Dose per 100 bed days (DDD/100 bed days) was also calculated for IV Iron Sucrose. The Chi-Square test of independence was performed to examine the relation between severity of anemia and the gender of the patient in Non ANC group, Mann-Whitney U-test compared the total administered dose and standard calculated dose and Spearman's rank correlation was done by using Spearman's Rho (ρ) calculator to analyse the association between the monthly trend of patient admission in the hospital and units of intravenous iron sucrose used. These statistical tests were performed on Social Science Statistics website (17).

Results

125 patients were enrolled for the study - 41 ANC and 84 Non ANC patients.

The Mean age with Standard Deviation of the study population was calculated and was found to be 36 (SD + 16) years. Majority of patients (35 each) were between the age group 18-25 years and 26-35 years, followed by the 36-45 years of age (19 patients).

Out of total 125 patients enrolled, 44 were males and 81 were females. As regards to the Non ANC population, $n = 84$, the analysis revealed that males were 44 and females were 40 in the Non ANC group.

14 patients (11.2%) (Five Non ANC and nine ANC) out of total 125 receiving intravenous iron sucrose had Hypertension, whereas only 9 patients (7.2%) (five Non ANC and four ANC) had Diabetes Mellitus (DM) along with anaemia. 4 patients (3.2%) each had HIV (three Non ANC and one ANC) and eclampsia; while CKD, liver cirrhosis and AKI (one Non ANC and two ANC) were found in 3 patients (2.4%) each.

Maximum patients – 30(24%) were diagnosed as ANC with anemia, followed by 27 patients (21.6%) who were

prescribed intravenous iron sucrose post operatively. Some patients- 20(16%) were found to be diagnosed and were being treated exclusively for anemia. Bleeding 7(5.6%), infection 4(3.2%), CKD 4(3.2%), liver cirrhosis 3(2.4%) and AKI 3(2.4%) were the diagnosis of very few patients.

Indications for starting intravenous iron sucrose therapy were evaluated and a major chunk consisted of 41(32.8%) iron deficient ANC patients. The second most common group was that of severely debilitated patients of stroke, intracranial bleed, post-gynaecological operations, liver cirrhosis, etc. who were on other injectable drugs 37(29.6%). 15(12%) patients were on total parenteral nutrition, 4(3.2%) patients were on erythropoietin, 4(3.2%) were post abdominal surgery.

Study of severity of anemia in the 41 ANC patients who were prescribed intravenous iron sucrose showed that 34 patients (82.92%) had severe anemia while 7 patients (17.07%) had moderate anemia (Table 1).

Evaluation in Non ANC group - males (44) and females (40) reflected that the patients with severe anemia both males (23) and females (35) were prescribed intravenous iron sucrose more than the patients of moderate anemia which consisted 21 males and 5 females (Table 1).

A total of 11.28% of the total ANC patients and of 3.79% of the total Non ANC patients were prescribed intravenous iron sucrose in the study duration.

An average of 2156.09 mg of intravenous iron sucrose was prescribed to ANC patients while an average of 1990.46 mg of intravenous iron sucrose was prescribed to Non ANC patients in the study duration.

Total dose administered to the patient and Standard calculated dose of the patient according to the Ganzoni's formula were assessed and following numbers were allotted for the sake of calculation, if the Total administered dose was .

As per the standard calculated dose: 0

Less than standard calculated dose: 1

More than standard calculated dose: 2

It was observed that 84(67.2%) patients received more than the Standard calculated dose, 27(21.6%) received as per the Standard calculated dose while only 14(11.2%) received less than the Standard calculated dose.

Mann-Whitney U-test was used to compare the total administered dose of intravenous iron sucrose with standard calculated dose in the study population. The value of U is 5065. The difference was statistically

significant with z-score of -4.8 and ***p-value < .00001.

Hence, the patients received statistically significant more amount of Total dose of intravenous iron sucrose as compared to the Standard calculated dose which was supposed to be given.

ADRs due to IV iron sucrose were noted only in 3 female patients (2.4%) out of total 125. Two females belonged to Non ANC group and one belonged to ANC group. The ADRs were mild, with patients showing symptoms like fever, chills, rash, angioedema and mild chest pain. All ADRs were treated with Inj. Avil and Inj. Hydrocortisone and all patients recovered. The causality assessment report of all 3 ADRs was 'Possible' by Naranjo Causality Assessment Scale (18).

134.52 mg intravenous iron sucrose was given on an average daily to the patients during the study duration. DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults (19).

DDD/100 bed days = $\frac{\text{No of units administered in a given period} * 100}{\text{DDD} * \text{No of days} * \text{No of beds} * \text{occupancy index}}$

DDD * No of days * No of beds * occupancy index

The utilization of intravenous iron sucrose in total patients showed DDD per 100 bed days to be 0.42, whereas subgroup analysis showed DDD per 100 bed days was 0.59 for ANC group and 0.36 for Non ANC group. DDD per 100 bed days was calculated which can be used to evaluate and compare the incidence of anemia in other hospitals.

The mean duration of intravenous iron therapy was calculated to be 10.224 days where maximum 84 patients (64.8%) received intravenous iron sucrose therapy for 5 to 10 days.

sucrose used. Done by applying Spearman's Rank Correlation coefficient test by using Spearman's Rho (ρ) calculator, where we measured the monthly trend of patient admission in the hospital and units of intravenous iron sucrose used. It highlighted how the use of intravenous iron sucrose changed according to the patient admissions (**Rho: 1).

The per day cost of intravenous iron therapy per patient was calculated to be 523.4 INR, making cost of intravenous Iron Sucrose therapy for 125 patients for 6 months' study duration to be 6,69,007.44 INR. Excess dose administered and hence, extra expenditure per patient was 248.12 mg and 649.44 INR respectively. Thus, the economic burden that could've been reduced for 125 patients in 6 months was 81,180 INR which is significant in a resource limited setting of a tertiary care hospital.

The Chi-Square test of independence was performed to examine the relation between severity of anemia and the gender of the patient in Non ANC group. Women were more likely than men to have severe anemia [χ^2 (1, N = 84) = 12.166, $p = .000487$] (Table 2) (17).

Mann-Whitney U-test analysis results compared the total administered dose and standard calculated dose and

showed that the total dose administered to the patients was significantly more than the standard calculated dose (U: 1247, Z-score: 11.8, p -value < .00001) (17).

Spearman's Rank Correlation coefficient calculation by using Spearman's Rho (ρ) calculator showed a positive association between the monthly trend of patient admission in the hospital and units of intravenous iron sucrose used. ($\rho = 1$) (17).

Table 1. Severity of Anemia in Non ANC and ANC groups

Severity of Anemia	Number of patients (ANC)	Number of patients (Males - Non ANC)	Number of patients (Females- Non ANC)
Mild	0	0	0
Moderate	7	21	5
Severe	34	23	35

N=125

Table 2. χ^2 test examination of the relation between severity of anaemia and the gender of the patient in Non ANC group

Gender	Severe	Moderate	Total
Male	23	21	44
Female	35**	5	40
Total	58	26	84

N=84

** $\chi^2 = 12.166$, Significant at $p = .000487$.

Females were more likely than men to have severe anaemia.

Discussion

The research findings reflected that our study population was an adult general population with a mean age of 36 (SD + 16) years and an average pre-infusion Hb of 6.25 (SD + 1.84) g/dl. The study overall, showed a higher female preponderance whereas subgroup analysis of the Non ANC group showed a male preponderance. The indication for IV iron sucrose was maximum in the ANC group 41(32.8%), which had patients of Anemia in pregnancy, followed by a set of patients from the Non ANC group which consisted of debilitated patient on other injectable drugs 37(29.6%). The patient records reflected that no specific guideline was followed for the treatment of anemia in our study population which comprised of heterogeneous adults. Our results showed that females were more in the severe anemia group and they belonged to both ANC and Non ANC groups. In stark contrast, the moderate anemia group consisted more of males from the Non ANC category. This explains the higher IV iron sucrose utilization (11.28 %) and a higher dose (2156.7 mg) found in the ANC group as compared

to the Non ANC group. Astonishingly, out of total 125, 84(67.2%) patients received more than the Standard calculated dose, 27(21.6%) received as per the Standard calculated dose while only 14(11.2%) received less than the Standard calculated dose. The DDD per 100 bed days for IV iron sucrose was 0.36 in Non ANC group and 0.42 in ANC group. The association between hospital patient admissions and units of intravenous iron sucrose showed significant positive association. ADRs were observed with a with a common finding of fever in a meagre 3(2.4%) patients on administration of IV iron sucrose.

The current observational research included adult general population with a mean age of 36 (SD + 16) years in contrast to earlier studies including the younger age group (26-30 years) (20). This difference was observed as the latter was done on pregnant females only, while the current research has heterogeneous population with various comorbidities (21-23). The average pre-infusion Hb was observed to be 6.25 (SD + 1.84) g/dl which is in accordance with observations of similar other studies wherein their observed ranges were 5-7.9 g/dl (21,24). Gender analysis revealed a female preponderance in the study population like similar other studies (25,26). Whereas, a subgroup analysis of Non ANC population in our study revealed male preponderance which reflected higher rate of male admissions in Indian population. The ever-increasing burden of Anemia in pregnancy in developing nations like India was clearly observed when analysis was done for prescription of IV iron sucrose, which is also concluded by other authors time and again (5, 22-29). The chief indications for parenteral iron in the Non ANC group of our study were in debilitated patient group on other injectable drugs 37 (29.6%), as a co-prescription along with parenteral nutrition 15 (12%) and

with erythropoietin in CKD patients 4 (3.2%) (5, 22-29).

Intravenous iron sucrose study in these ANC and Non ANC groups have been studied extensively using different parameters and different guidelines e.g., 'Toward optimized practice' (TOP) guidelines, 'The Swiss Society for Gynaecology and Obstetrics' guidelines, etc. (25,30,31). Such literature highlights the fact that guidelines exist for various indications like anemia in CKD, IBD, pregnancy etc., but there is a need for formulating guidelines for parenteral iron in general adult population. Predominantly females with severe anemia were observed in both ANC and Non ANC groups. The moderate anemia group in the Non ANC category surprisingly had more males as compared to females which was also observed in another similar study (20,21). This incites a need to research the role of testosterone in limiting the severity of anemia in the male population. The high incidence of anemia (around 40-50%) in pregnant women in India irrespective of urban or rural areas have a pressing need on higher utilization rates of IV iron sucrose in hospital setups (32-34). This was observed in our study in the form of higher utilization rates (11.28 %) of IV iron sucrose and also higher average dose (2156.7 mg) administered per patient in the ANC group. This was much higher than the findings of similar other study (20).

An alarming disparity was observed between the **Standard calculated dose** and the **Total administered dose** where the patients received statistically significant 84(67.2%) more amount of Total dose of intravenous iron sucrose as compared to the Standard calculated dose which was supposed to be given. Furthermore, we calculated that 27(21.6%) of the study population received the correct dose as per calculation by Ganzoni's formula and 14(11.7%) patients received less total dose than the standard calculated dose. Dosing errors may be seen as inadequate dosing as per standard calculated dose which was concluded by one of the studies (31). High doses may cause iron toxicity and low doses may not achieve therapeutic success thereby emphasizing the need to strictly follow the method of calculation of iron requirement for individual patient using Ganzoni's formula. This will not only ensure judicious utilization of healthcare services in a tertiary care hospital but also prevent wastage of scarce resources.

As per recommendation by **WHO, DDD per 100 bed days** should unanimously be performed in comparative studies. Usefulness of this indicator is also advocated for benchmarking in and between hospitals regarding drug utilization. Additional utility of this parameter is in

providing guidance for budgetary preparedness for the hospital as per the utilization (19). In the current study, it is also an indirect health marker to understand the severity of anemia in general population and thus contributes to the uniqueness of this study. The monthly trend of IV iron sucrose in DDD per 100 bed days was 0.36 in Non ANC group and 0.42 in ANC group.

The study of association between hospital patient admissions and units of intravenous iron sucrose shows significant positive association indicating that utilization of intravenous iron sucrose altered according to the patient admissions, highlighting the fact that the anemic population comprised of a constant fraction of the total admissions. Numerous studies have time and again emphasized the safety of intravenous iron sucrose (24,35). But this does not provide a waiver to avoid ADR reporting in case of any side effects. In the current study ADRs were observed in a meagre 2.4% patients with a common finding of fever on parenteral administration of iron sucrose. It is thereby essential to promote pharmacovigilance in order to ease the burden on healthcare professionals.

Limited sample size done in a limited time period. Other parenteral iron preparation could not be included as per limited availability in the drug store.

This research highlighted that overutilization and administering more than the required dose of IV iron sucrose, could be effectively tackled by calculation of its standard dose (by Ganzoni's formula). Studying the monthly trends and comparing utilization of parenteral iron with the help of DDD/100 bed days by hospitals can help in comparing utilization and also assist for budgetary preparedness of hospitals. There is also a dire need to formulate universally accepted guidelines for the use of parenteral iron in general adult population.

Conflict of interest

The author declares no conflict of interest, financial or otherwise.

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