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Efficacy of Intravenous Administration of Iron Sucrose for Treatment of Iron Deficiency Anaemia in Patients With Abnormal Uterine Bleeding

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SUMMARY

Iron deficiency anaemia (IDA) is the most common nutritional disorder in the world and is more prevalent among the female population in developing countries compared to developed countries. IDA in India accounts for more than 51% among the adult women population. This condition in females with gynaecological ailments not only delays the elective surgical procedures, but also increases the morbidity in patients. Depending on the available resources, the most common method of diagnosing IDA in individuals involves determining the blood haemoglobin and/or haematocrit levels. Among the red cell indices, mean corpuscular volume and mean corpuscular haemoglobin are the two most sensitive indices of iron deficiency. The traditional choice of treatment for IDA involves administration of iron supplements to the patients. The oral therapy is time-consuming and probably not enough in severe cases of anemia. Parenteral injections of iron-dextran/sorbitol complex have its own limitations and disadvantages. Blood transfusion is the last resort, but involves the risk of cross reactions and viral infections. Considering the advantages and limitations of the available options, intravenous iron sucrose therapy has been reported to be safe, convenient more effective than intramuscular or intravenous iron-dextran/sorbitol complex in treatment for iron deficiency anaemia. The present study encompasses the efficacy and safety of intravenous administration of iron sucrose in the management of iron deficiency anaemia in patients with various gynaecological ailments.

The study concludes that iron sucrose complex can be considered as a "first choice" in the treatment of iron deficiency anemia in preoperative patients and provides a safe as well as effective alternative to blood transfusion.

Key words: **gynaecological ailments, iron deficiency anemia, haematological parameters, iron sucrose complex**

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INTRODUCTION

Iron deficiency anaemia (IDA) is the most common and widespread nutritional disorder in the world. IDA is widely prevalent in developing countries affecting around 52% of the female population and 23% of the women in developed countries (1-3). The highest prevalence of IDA is reported in South Asian countries (4). In India, IDA accounts for more than 51% among the adult female population (5). In such females, menstrual disorder like menorrhagia or polymenorrhoea due to gynaecological ailments can lead to severe anemia. This type of complicated condition not only delays the surgery, but also increases the morbidity in patients.

In females, the main sources of iron loss are abnormal uterine bleeding, menstruation and parturition. The clinical manifestation of iron deficiency anaemia (IDA) includes the loss of appetite, weakness, easy fatigability, breathlessness, dyspnoea, palpitation and congestive cardiac failure in severe cases. Clinical examination shows varying degree of pallor, edema of legs, pan systolic murmurs; crepitations may be heard at the base of the lungs due to congestion. Functionally, the lack of mobilizable iron stores will eventually cause a detectable change in classical laboratory tests, including an estimation of haemoglobin level, hematocrit/packed cell volume (PCV), red blood cell count (RBC), mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), total iron-binding capacity, transferrin saturation, and zinc-erythrocyte protoporphyrin. The peripheral blood smear may show an abundant presence of small pale stained red blood cells with anisocytosis and poikilocytosis suggestive of microcytic hypocromic anaemia along with slightly raised reticulocyte count. Decrease in serum ferritin, serum iron level, transferrin saturation and increase in total iron binding capacity can also be observed in this condition. In addition to routine hematology, estimation of ferritin, transferring and serum iron levels is necessary to evaluate the iron storage in patients with iron deficiency anaemia (1, 6).

It is important to manage iron deficiency anemia and prevent delay of surgery in patient with gynaecological ailments. Apart from maintaining balanced diet, general treatment of IDA includes iron supplementation by either oral or intramuscular (I/M) or intravenous (I/V) routes. The usual management of IDA is the replacement of iron by oral supplementations. The oral therapy is time-consuming and is probably not enough in severe cases of anemia. Parenteral injections of iron-dextran/sorbitol complex have its own limitations and disadvantages. Blood transfusion is the last resort and can be used only in severe cases of anemia in symptomatic patients (7, 8). On the other hand, blood transfusion, although it can promptly and reliably treat anemia, entails a lot of dangers like cross reactions and viral infections. Considering the advantages and limitations of the available options, intravenous iron sucrose therapy is reported to be safe, convenient and more effective than I/M or I/V iron - dextran/sorbitol therapy in treatment of iron deficiency anaemia (9-14).

The present study was undertaken to determine the efficacy and safety of intravenous administration of iron sucrose in the management of iron deficiency anaemia in patients with various gynaecological ailments.

MATERIALS AND METHODS

The study was conducted in the Department of Obstetrics and Gynecology at Aarupadai Veedu Medical College & Hospital (AVMC & H), Pondicherry, India. This prospective observational study was carried out from October 2009 to March 2011 to evaluate the safety and efficacy of I/V iron sucrose in the treatment of iron deficiency anemia caused by abnormal uterine bleeding in 52 patients with gynaecological ailments. All the patients were admitted for correction of anaemia prior to surgery and the target was to increase the haemoglobin level to 11 g/dl.

Inclusion criteria:

- Patients willing to participate in the study.
- All the patients from the Obstetrics and Gynecology department with indications for major gynaecological surgery having the haemoglobin level of less than 9 g/dl.
- All the patients from the Obstetrics and Gynecology department receiving the medical treatment for various gynaecological ailments having the haemoglobin level of less than 9 g/dl.

Exclusion criteria:

- Patients not willing to participate in the study.
- Out of 52 patients, one developed hypotension and other one developed urtecarial rashes on receipt of first dose of I/V iron sucrose. These two patients were not administered iron sucrose and were subsequently eliminated from the present study.
- Patients suspected for anaemia due to any other cause than iron deficiency.
- Patients with infection, nephritis, CRF, hemoglobinopathies and chronic bleeding due to any cause other than menstrual disorders.
- Patients with history of hypersensitivity to iron preparations.
- Patients with any neoplastic condition.
- Patients who are having other diseases (inclusive of cardiac failure, renal failure) along with anemia.
- Anaemic patients other than from Obstetrics and Gynecology ward of AVMC & H, Pondicherry, India.

Study procedure:

1. The informed consent was obtained from all the studied patients. The inpatients who had satisfied the above criteria were clinically examined by the obstetrician for any signs of anaemia.
2. Blood samples from the patient were sent to the laboratory for estimation of hemoglobin, hematocrit, RBC count, MCV, MCH, and peripheral blood smear for reticulocyte count and any RBC abnormalities on day one, before the start of therapy.
3. The patients who satisfied the criteria for inclusion (haemoglobin levels less than 9 g/dL) in the study were intravenously administered with 100 mg on day 1 and 200 mg of iron sucrose on day 3 and day 8 in the concentration of 100 mg of iron sucrose in 100 cc of normal saline.
4. The parameters studied in succession on days 4, 10 and 30 included haemoglobin level, haematocrit, RBC count, MCV and MCH. The blood smear examination and the reticulocyte count were done on days 4 and day 10.
5. Follow-up clinical evaluation of the patient was also done on the 4th, 10th and 30th day after treatment for symptomatic relief such as increase in appetite, decreased fatigability, palpitations and improvement in the outlook of the patient, sense of well being.
6. Differences between the initial and final levels of haemoglobin, haematocrit, RBC count, MCV, MCH and reticulocyte count in the treated patients were recorded and the data collected was statistically analysed using paired "t" test.
7. One week after treatment and on the 30th day, the liver function enzymes were estimated and tests for detection of proteins in urine were also performed in all the patients receiving treatment.
8. All the patients were observed for any adverse reactions while they were on medication.

RESULTS

The study comprised 50 female patients (n=50) with gynaecological ailments showing iron deficiency anemia.

The number of patients with different gynaecological ailments presented in Table 1 depicts that the highest number of patients was recorded with dysfunctional uterine bleeding and fibroid uterus (36% each) followed by adenomyosis (18%) and endometrial hyperplasis (10%).

The age wise distribution presented in Table 2 indicates that the highest number (40%) of patients belonged to age group between the age of 41-45, followed by 46-50 years and 36-40 years of age, making 24% and 12%, respectively.

The haemoglobin concentration before treatment in different patients depicted in Table 3 indicate that the number of patients with Hb level between 6-7 g/dL was 23 (46%) followed by range 7-8 g/dL accounting for 18 (36%) patients and the number of patients whose Hb level between 5-6 was only 6 (12%).

The changes in haematological parameters following administration of I/V iron sucrose are presented in Table 4.

Our study demonstrated that administration of iron sucrose caused increase in all the estimated haematological parameters. On the 30th day after treatment, average Hb level (Figure 1), Hematocrit (Figure 2), RBC count (Figure 3) increased from 6.95±0.72 g/dl to 12.10±0.69 g/dl, 21.19±2.33% to 37.33±2.45%, 3.48±0.37x10^6 cell/cu.mm to 5.56±0.41x10^6 cell/cu. mm, respectively. The red blood cells indices also showed increasing trends after the administration of iron sucrose. On the 30th day, the MCV (Figure 4) increased from 65.62±3.04 fL to 87.92±7.03 fL and the MCH (Figure 5) values also increased from 23.85±2.6 pg to 35.58±6.56 pg.

The study demonstrated that following administration of iron sucrose, increase in the base line level of all the estimated haematological parameters was observed (Mean increase in Hb was 5.15±0.55 g/dL, hematocrit was 16.14±2.16%, RBC count was 2.08 ±0.55x10 cell/cu. mm, MCV was 22.30±5.62 fL, MCH was 11.73±5.52 pg). The results were analysed by paired 't' test method and the difference was found to be statistically significant ($p<0.001$).

Figure 1 indicates the high rate of reticulocytosis following I/V administration of iron sucrose. The reticulocyte count (Figure 6) increased to 7.18.±1.29 cells on day 4 from initial 1.78±0.77 cells, and on day 10 the reticulocyte count was 2.80±0.76, indicating accelerated erythropoiesis in the treated patients. The overall sense of well-being in all the patients improved dramatically from the 3rd day onwards. There were no serious reactions to the treatment except a few patients complaining of mild gastritis. No abnormal levels of liver function enzymes and proteinuria were detected following the administration of iron sucrose.

Table 1. *Number of patients with different gynaecological conditions*

Diagnosis	No of patients	Percentage of patients (%)
Dysfunctional uterine bleeding	18	36
Fibroid uterus	18	36
Adenomyosis	9	18
Endometrial hyperplaisa	5	10

Table 2. *Age wise distribution of patients*

Age group	No of patients	Percentage of patients (%)
25-30	3	6
31-35	4	8
36-40	6	12
41-45	20	40
46-50	12	24
51-55	5	10

Table 3. *Range of haemoglobin concentration in different patients before treatment*

Range of Hb (g/dL)	No of patients	Percentage of patients (%)
5-6	6	12
6-7	23	46
7-8	18	36
8-9	3	6

Table 4. *Changes in haematological parameters following intravenous administration of iron sucrose (n=50)*

Parameters	0 DAY	4 DAY	10 DAY	30 DAY	Mean increase on 30th day	P-value
Hb (g/dL)	6.95 ± 0.72	7.75 ± 0.74	9.67 ± 0.77	12.10 ± 0.69*	5.15 ± 0.55*	< 0.001*
PCV (%)	21.19 ± 2.33	23.65 ± 2.41	29.59 ± 2.71	37.33 ± 2.45*	16.14 ± 2.16*	< 0.001*
RBC (x 10^6 cells/cu.mm	3.48 ± 0.37	3.88 ± 0.38	4.81 ± 0.43	5.56 ± 0.41*	2.08 ± 0.55*	< 0.001*
MCV (fL)	65.62 ± 3.04	68.98 ± 2.61	79.56 ± 5.51	87.92 ± 7.03*	22.30 ± 5.62*	< 0.001*
MCH (pg)	23.85 ± 2.6	26.26 ± 3.2	34.00 ± 5.07	35.58 ± 6.56*	11.73 ± 5.52*	< 0.001*

The values presented are Mean ±SD
* Significant (using paired "t" test)

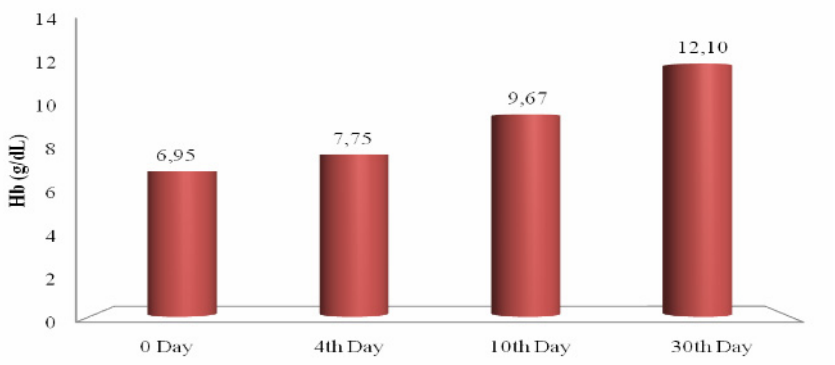

Figure 1. *Hemoglobin concentration following I/V iron sucrose*

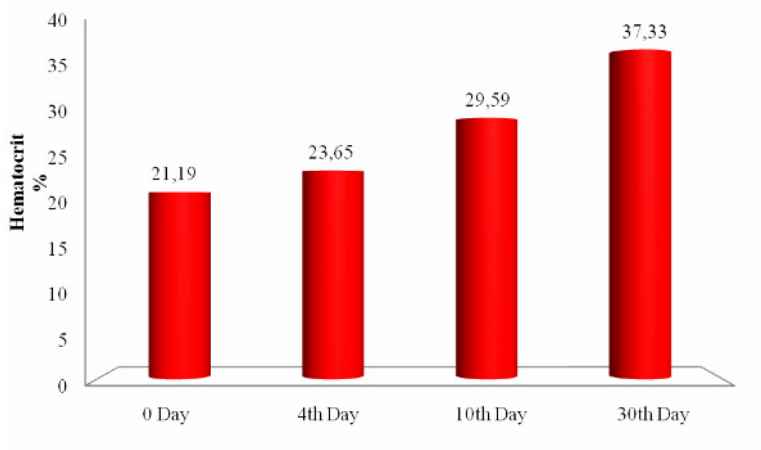

Figure 2. *Hematocrit value following I/V iron sucrose*

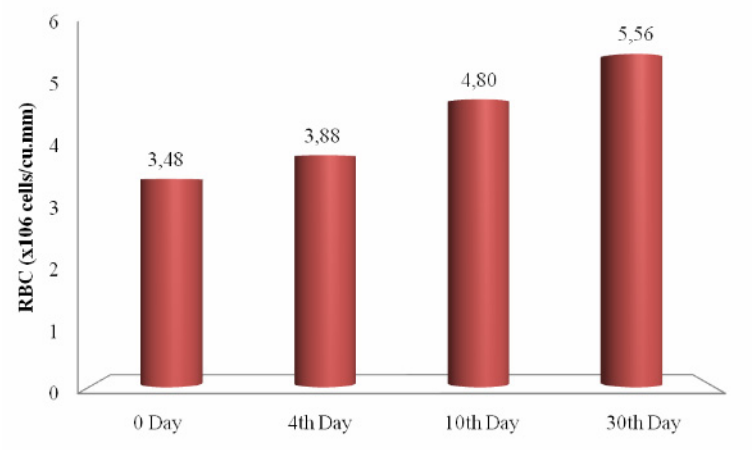

Figure 3. *Red blood cell count following I/V iron sucrose*

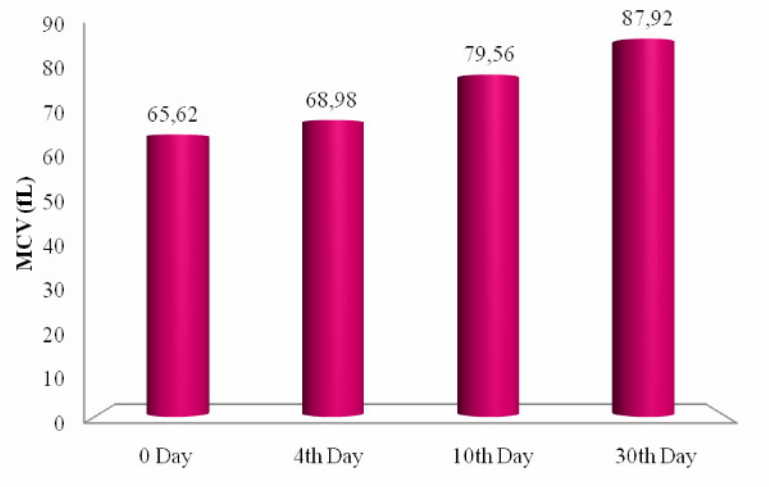

Figure 4. *Mean corpuscular volume following I/V iron sucrose*

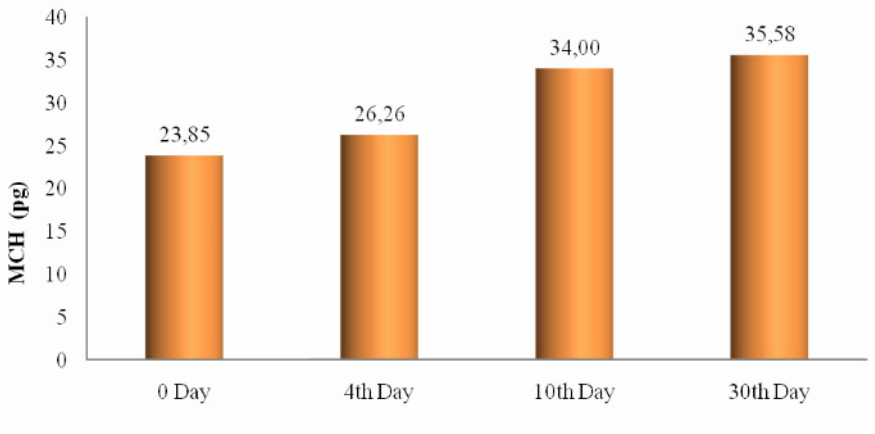

Figure 5. *Mean corpuscular hemoglobin following I/V iron sucrose*

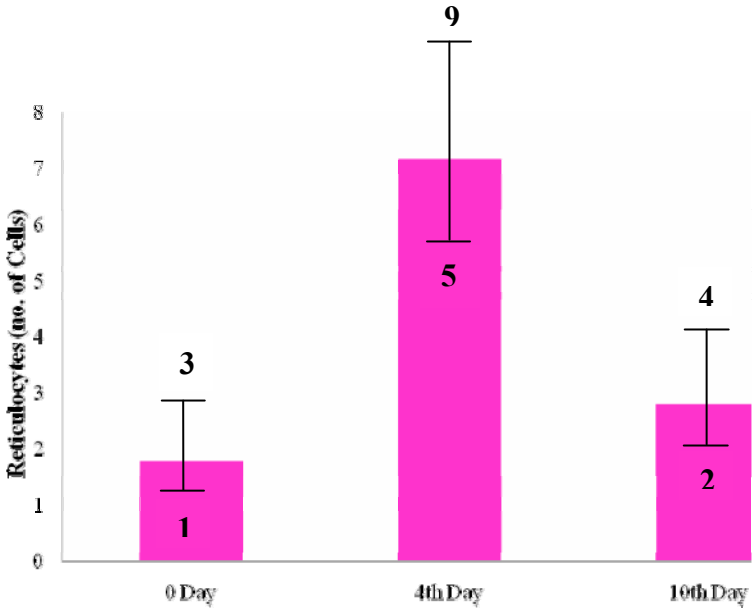

Figure 6. *Reticulocyte count.following I/V iron sucrose*

DISCUSSION

According to WHO, more than 50 percents of women in fertile age have iron deficiency anaemia (4, 12). Studies pertaining to prevalence and documentation of IDA among the female population with respect to gynecological ailments in different geographical areas are essential to help clinicians.

Our observation in the present hospital setup indicated that a maximum number of patients with gynaecological ailments scheduled for elective surgical procedures suffer from IDA.

Worldwide, variations in the prevalence of IDA can be due to the availability of laboratories for analysing clinical specimens, and the occurrence of factors other than iron deficiency that cause anaemia require that iron-related indicators be divided into three categories. These categories of indicators are applied in settings considered to be resource-poor, resource-intermediate, or resource-adequate. Resource-adequate settings correspond to the commonly used term "developed country", while the other two settings are usually classified as situations which are typical of "less developed" countries. The reason for this differentiation is due to the wide variation of resources among and within "less developed" countries (15).

Worldwide, the most common method of diagnosing IDA in individuals involves determining the blood haemoglobin or haematocrit levels. Individual management in resource-poor countries is likely to be based mainly upon either haemoglobin or haematocrit assessment - or both - and upon their response to initial iron therapy. Among all the red cell indices measured by electronic blood counters, MCV and MCH are the two most sensitive indices of iron deficiency (16-18). Considering the feasibility and available resources, estimation of haemoglobin level, haematocrit, RBC count, MCV, MCH, reticulocyte count and peripheral smear examination was performed in the present study to determine IDA and for evaluation of the treated patients after I/V administration of iron sucrose.

In resource-adequate situations, the usual practice involves the use of further specific and more sensitive tests like serum ferritin, transferrin saturation, and bone-marrow iron estimation for individual assessment of IDA (1, 19-23). However, these biochemical parameters were not studied in the present study considering the high cost involved and the socioeconomic status of the patients.

Poor dietary intake, menstrual blood loss, pregnancy and delivery are the main causes of anemia in women. About 30% of anemic women have iron deficiency anemia with hemoglobin levels below 10 g/dL, and about 10% of anemic women have hemoglobin levels below 8g/dL (24). In the present study, most of the patient had Hb level below 8 g/dL before the start of treatment.

The traditional choice of approach for the treatment of IDA involves administration of iron supplements to the patients. Oral iron supplementations are not sufficiently in order to reverse anemia promptly due to gastrointestinal disturbances, poor compliance for prolonged treatment and poor absorption. Intramuscular and intravenous injections of iron- dextran/sorbitol complex are painful, incites local inflammatory reaction leading to abscess formation, phlebitis, lymphadenopathy and adverse reactions like pyrexia, headache, nausea, vomiting and allergic reactions (25).

Till recently, blood transfusion was the only available method in order to treat severely anaemic patients. Blood transfusion is a reliable method with excellent results in the treatment of anemia, but involves high risk for transmission of viral infections and serious transfusions cross reactions (26, 27).

Recent evidence from the studies conducted suggests that iron sucrose can be effective and safe choice of therapy for patients with IDA (24, 26-28).

Following intravenous administration, this compound is dissociated into iron and sucrose by the reticuloendothelial system, and iron is transferred from the blood to a pool of iron in the liver, blood circulation and bone marrow within 5 minutes. Ferritin, an iron storage protein, binds and sequesters iron in anontoxic form, from which iron is easily available. Iron binds to plasma transferrin, which carries iron within the plasma and the extracellular fluid to supply the tissues. The transferrin receptor, located in the cell membrane, binds the transferrin iron complex, which is then internalized in vesicles. Iron is released within the cell, and the transferrin-receptor complex is returned to the cell membrane. Transferrin without iron (apotransferrin) is then released into the plasma. The intracellular iron becomes (mostly) hemoglobin in circulating red blood cells. The time interval for elimination is 5 to 6 hours and the renal metabolism is minimal accounting for less than 5% of the total dose. The rapid metabolism and availability of this compound for erythropoiesis is responsible for the correction of anemia. The sucrose component is eliminated mainly by urinary excretion (10, 29, 30). Since iron disappearance from the serum depends on the need for iron in the iron stores and iron-utilizing tissues of the body; serum clearance of iron is expected to be more rapid in iron-deficient patients. Studies showed that in patients with IDA, I/V iron sucrose get incorporated into haemoglobin of RBC's to give desired effect within 3 to 4 weeks after treatment (31).

Our study showed that I/V iron sucrose was effective in achieving target Hb of 11g/dL in all the patients and corroborated with the findings of earlier reports (11, 28, 32).

Studies on intravenous administration of 300 mg of iron sucrose in three days to 104 postpartum patients with IDA showed complete reversal of anemic status in four weeks time after significant increase of mean

values of hemoglobin and ferritine blood levels from 8.8 gr/dl and 38 μg/l to 12.6 g/dL and 115 μg/l respectively (10).

Kiran et al. (11) reported increase in haemoglobin level from 7.27±0.67 g/dL on 0 day to 10.8±0.36 g/dL on the 30th day following I/V administration of 100 mg of iron sucrose for three alternative days in a week to 15 postpartum patients with IDA.

Iron preparations in higher/excess dose following intravenous administration might cause liver necrosis, renal, suprarenal and pulmonary damage. The slow release of elementary iron from the complex can lead to the mild allergic. The minimal undesirable effect observed in the treated patients can be easily managed. In addition, the tissue accumulation of iron-sucrose in parenchymatous organs is much lower as compared to iron- dextran/ sorbitol complex. Iron sucrose complex gets rapidly incorporated into the bone marrow for erythropoiesis in comparison to other iron complexes (24, 27, 33). Unlike intravenous iron- dextran/sorbitol complex, anaphylactic reactions are virtually unknown with iron sucrose (27, 34).

Our study indicated that intravenous iron supplementation is highly effective in treating iron deficiency anaemia. There is irrefutable evidence that I/V iron sucrose results in a much more rapid resolution of iron deficiency anaemia, has minimal side-effects, and because it is administered intravenously, it circumvents the problems of compliance.

CONCLUSION

Iron sucrose complex has been able to raise the haemoglobin to satisfactory level in anaemic women and can be considered safe and well tolerated choice of treatment of IDA. Given the demonstrated safety and efficacy of IV iron sucrose in a broad spectrum of diseases associated with IDA, the current paradigm that oral iron is the first-line therapy should be reconsidered. Intravenous iron sucrose offers advantages over oral or I/M or I/V iron- dextran/sorbitol complex for the treatment of IDA across a wide range of disease states associated with absolute and functional iron deficiency. Furthermore, I/V iron sucrose can be the preferred method of iron replacement as an adjunct to patients with gynaecological ailments with IDA. However, the safety profiles about the multiple dosing as well as long-term toxicity studies with their repeated administration remains to be unexplored and need further detailed studies.

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EFIKASNOST INTRAVENOZNOG DAVANJA SUKROZE GVOŽĐA U LEČENJU ANEMIJE USLED NEDOSTATKA GVOŽĐA KOD BOLESNICA SA ABNORMALNIM KRVARENJEM IZ MATERICE

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Anemija usled nedostatka gvožđa (IDA-eng.) je najčešći nutritivni poremećaj u svetu i javlja se češće kod žena u zemljama u razvoju nego u razvijenim zemljama. Anemija usled nedostatka gvožđa je kod odrasle ženske populacije zastupljena sa 51%. Ovo stanje kod žena sa ginekološkim tegobama ne samo da odlaže elektivne hirurške procedure, već utiče i na povećanje stope morbiditeta. U zavisnosti od dostupnih procedura, najčešća metoda kod dijagnostikovanja IDA uključuje određivanje hemoglobina u krvi i/ili nivoa hematokrita. Među indeksima eritrocita, srednja vrednost zapremine eritrocita (MCV-eng.) i srednja vrednost količine hemoglobina u eritrocitima (MCH-eng.) dva su najsenzitivnija pokazatelja nedostatka gvožđa. Tradicionalni izbor u lečenju anemije usled nedostatka gvožđa podrazumeva davanje suplemenata gvožđa. Oralna terapija je vremenski zahtevna i verovatno nedovoljna kod ozbiljnih slučajeva anemije. Davanje parenteralnih injekcija gvožđe-dekstran/sorbitol kompleksa ima svoja ograničenja i mane. Transfuzija krvi je poslednja opcija, jer uključuje rizik od unakrsnih reakcija i virusnih infekcija. Uzimajući u obzir prednosti i ograničenja dostupnih mogućnosti, intravenozno davanje sukroze se pokazalo kao bezbedna, pogodna i efektivnija terapija u poređenju sa intravenoznim ili intramuskularnim davanjem kompleksa gvožđe-dekstran/sorbitol u lečenju anemije usled nedostatka gvožđa. Ova studija prikazuje efikasnost i bezbednost intravenoznog davanja sukroze gvožđa u lečenju ove anemije kod bolesnica sa različitim ginekološkim tegobama.

U studiji se dolazi do zaključka da se parenteralna terapija anemije kompleksom gvožđa može smatrati "prvim izborom" u lečenju anemije usled nedostatka gvožđa kod bolesnica u preoperativnom periodu i da ova terapija predstavlja bezbednu i efikasnu zamenu za transfuziju krvi.

Ključne reči: **ginekološke tegobe, anemija usled nedostatka gvožđa, hematološki parametri, kompleks, parenteralna terapija anemije kompleksom gvožđe-saharoza**