EVALUATION OF EFFICACY OF INTRAVENOUS IRON SUCROSE THERAPY AMONG CHILDREN WITH IRON DEFICIENCY ANEMIA.

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ABSTRACT:

Background: Background: Several intravenous iron preparations are available for treatment, including iron dextran, iron gluconate, and iron sucrose. While these preparations effectively increase hemoglobin levels and restore iron stores, iron dextran use is associated with potential side effects, including immune and dose-related anaphylactic reactions in about 1% of patients treated. **Material & Methods:** The present cross sectional, prospective study was carried out at department of pediatrics, at our tertiary care hospital. The study duration was of six months from July 2013 to December 2013. In this prospective study we enrolled 100 children of age group of 1-15 years of children with diagnosis of iron deficiency anemia unresponsive to oral iron treatment and enrolled by simple random sampling. **Results:** In the present study, out of total enrolled participants, on the basis of Range of Hb (g/dl) it was found that 18% children had Hb 5-6 g/dl, 36% children had Hb 6-7 g/dl, 32% children had Hb 7-8 g/dl, and 14% children had Hb 8-9 g/dl. On the basis of changes in hematological parameters following intravenous administration of iron sucrose it was found that mean increase after 30 days of therapy was 5.2 ± 0.7 g/dl in Hb, 16.5 ± 2.4 % in PCV, 2.13 ± 0.6 x106 cells / cu mm in RBC count, 11.9 ± 5.4 pg in MCH and 22.4 ± 5.7 fL in MCV. There was no mortality reported in present study. **Conclusion:** We concluded from the present study that, the administration of iron sucrose was deemed safe, demonstrating only minor, transient, and reversible side effects, even among small children.

Keywords: Iron deficiency anemia, Iron sucrose, Haemoglobin.

INTRODUCTION:

The Iron deficiency is a prevalent cause of anemia resulting from nutritional deficiencies, affecting approximately 17% of children under the age of 5 years. Recent research conducted in Israel revealed a prevalence of 15.5% among infants aged 9-18 months **(1).** Various factors contribute to iron deficiency anemia in children, including inadequate nutrition, intestinal malabsorption, and blood loss. Consumption of substances that inhibit intestinal iron absorption, such as phytates or cow's milk protein, can also lead to iron deficiency **(2).** Treatment for iron deficiency anemia typically involves improving nutrition and administering iron orally, intramuscularly, or intravenously **(3).**

Several intravenous iron preparations are available for treatment, including iron dextran, iron gluconate, and iron sucrose **(4).** While these preparations effectively increase hemoglobin

levels and restore iron stores, iron dextran use is associated with potential side effects, including immune and dose-related anaphylactic reactions in about 1% of patients treated **(5).** Additionally, serum iron and ferritin levels may remain significantly elevated for an extended period after iron dextran administration. Iron gluconate administration may lead to mild adverse effects, but fatal allergic reactions are rare **(6).** Iron gluconate or iron sucrose generally exhibit fewer side effects compared to iron dextran. Iron gluconate has been successfully administered to patients who previously experienced severe reactions, including anaphylaxis, to iron dextran **(7).**

In contrast, iron sucrose treatment is effective and safe for pediatric patients with iron deficiency anemia who have not responded to oral iron therapy. It can also be safely administered to pregnant women and individuals undergoing predialysis or hemodialysis, with or without erythropoietin therapy (8). To evaluate the efficacy and safety of iron sucrose infusions in pediatric patients with iron deficiency anemia unresponsive to oral iron treatment, we conducted the present study.

MATERIALS & METHODS

The present cross sectional, prospective study was carried out at department of pediatrics, at our tertiary care hospital. The study duration was of six months from July 2013 to December 2013. A sample size of 100 was calculated at 95% confidence interval at 10% acceptable margin of error by epi info software version 7.3. In this prospective study we enrolled 100 children of age group of 1-15 years of children with diagnosis of iron deficiency anemia unresponsive to oral iron treatment and enrolled by simple random sampling. Institutional Ethics Committee Clearance was obtained before start of study and written and informed consent from their mother and father for the study was obtained from all the patients. Strict confidentiality was maintained with patient identity and data and not revealed, at any point of time.

Iron deficiency anemia defined as hemoglobin level less than 2 standard deviations in comparison to normal 15.5%. Non-compliance to oral iron treatment in children was defined as a child put on at least two different oral preparations and now not taking iron treatment, for a minimum period of 3 months. These cases were investigated as per study guideline and follow up period was of 3 months. All data were entered in the MS office 2010 spread sheet and Epi Info v7. Data analysis was carried out using SPSS v22. Qualitative data was expressed as percentage (%) and Pearson's chi square test was used to find out statistical differences between the study groups and sensitivity, specificity, positive predictive value and negative predictive value were calculated. If the expected cell count was < 5 in more than 20% of the cells then Fisher's exact test was used. All tests were done at alpha (level significance) of 5%; means a significant association present if p value was less than 0.05 and highly significant if p value less than 0.01.

RESULTS

In the present study, we enrolled 100 children of age group of 1-15 years of children with diagnosis of iron deficiency anemia unresponsive to oral iron treatment by simple random sampling. Out of the total enrolled children 54%

were males and 46% were females. Mean weight of study participants was 21.3 ± 3.8 kg. Out of total, 32% were in group of one to five years, 30% were in the age group of 5-10 years, 38% were in the age group of 10-15 years. (Table 1)

Table 1: Distribution of study participants according to study parameters.

Parameters		No. of patients
Gender	**Male**	54%
	Female	46%
Age group	**1-5years**	32%
	5-10 years	30%
	10-15 years	38%

In the present study, out of total enrolled participants, on the basis of Range of Hb (g/dl) it was found that 18% children had Hb 5-6 g/dl, 36% children had Hb 6-7 g/dl, 32% children had Hb 7-8 g/dl, and 14% children had Hb 8-9 g/dl. There was no mortality reported in present study. (Table 2)

Table 2: Distribution of study participants according to Range of Hb (g/dl).

Range of Hb (g/dl)	No. of patients
5-6	18%
6-7	36%
7-8	32%
8-9	14%

In the present study, out of total enrolled participants, on the basis of changes in hematological parameters following intravenous administration of iron sucrose it was found that mean increase after 30 days of therapy was 5.2 ± 0.7 g/dl in Hb, 16.5 ± 2.4 % in PCV, 2.13 ± 0.6 $x10^6$ cells / cu mm in RBC count, 11.9 ± 5.4 pg in MCH and 22.4 ± 5.7 fL in MCV. (Table 3)

Table 3: Distribution of study participants according to changes in hematological parameters following intravenous administration of iron sucrose.

Parameters	Mean increase after 30 days of therapy
Hb (g/dl)	5.2 ± 0.7
PCV (%)	16.5 ± 2.4
RBC ($x10^6$cells/cu.mm)	2.13 ± 0.6
MCH (pg)	11.9 ± 5.4
MCV (fL)	22.4 ± 5.7

DISCUSSION

In the present study, we enrolled 100 children of age group of 1-15 years of children with diagnosis of iron deficiency anemia unresponsive to oral iron treatment by simple random sampling. Out of the total enrolled children 54% were males and 46% were females. Mean weight of study participants was 21.3 ± 3.8 kg. Out of total, 32% were in group of one to five years, 30% were in the age group of 5-10 years, 38% were in the age group of 10-15 years. Similar findings were reported in a study conducted by G

Chandler et al conducted to assess the children with megaloblastic anemia and found that during the course of this study, comprising four phases, a total of 335 iron infusions were administered to 249 patients. In the initial phase (Phase I), 89 patients received a 200 mg dose via intravenous infusion over a span of 2 hours, with no reported adverse events **(9).**

In the present study, we enrolled 100 children of age group of 1-15 years of children with diagnosis of iron deficiency anemia unresponsive to oral iron treatment by simple random sampling. Out of the total enrolled children 54% were males and 46% were females. Mean weight of study participants was 21.3 ± 3.8 kg. Out of total, 32% were in group of one to five years, 30% were in the age group of 5-10 years, 38% were in the age group of 10-15 years. Similar findings were reported in a study conducted by Joseph Meyerovitch et al conducted to assess the children with megaloblastic anemia and found that a notable correlation between the incidence of anemia in infants and the occurrence of anemia in their respective mothers. Additionally, infants diagnosed with anemia were observed to utilize significantly fewer iron preparations compared to their non-anemic counterparts **(10).**

In the present study, out of total enrolled participants, on the basis of changes in hematological parameters following intravenous administration of iron sucrose it was found that mean increase after 30 days of therapy was 5.2 ± 0.7 g/dl in Hb, 16.5 ± 2.4 % in PCV, 2.13 ± 0.6 $x10^6$ cells / cu mm in RBC count, 11.9 ± 5.4 pg in MCH and 22.4 ± 5.7 fL in MCV. Similar findings were reported in a study conducted by A Pollak et al conducted to assess the children with megaloblastic anemia and found that a noticeable trend towards elevated levels of hemoglobin (Hb) and hematocrit (Hct) was observed, particularly evident in the intravenous iron group when compared to the oral iron group. Additionally, the intravenous iron group exhibited significantly higher reticulocyte counts. Over the course of treatment, plasma ferritin levels experienced a significant increase within the intravenous iron group, while conversely, a notable decrease was observed in the other group receiving oral iron **(11).**

CONCLUSION

We concluded from the present study that, the administration of iron sucrose was deemed safe, demonstrating only minor, transient, and reversible side effects, even among small children. However, further research involving a larger population, particularly focusing on patients below one year of age, is necessary to ascertain the safety and efficacy of intravenous iron therapy in this age group.

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