



## ANALYSIS OF HEMATINIC PREPARATIONS SELLING IN INDIA

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### Abstract

To study the hematinic formulations available in Indian market according to dosage form, iron salt content, elemental iron content, frequency of administration, price and rationality. Hematinic formulations published in Indian Drug Review 2012 were classified according to the route of administration into oral (solid /liquid) and parenteral. These were further examined for rationality where the rational preparations were those which contained iron  $\pm$  folic acid  $\pm$  vitamin C. The cost of 100 mg - 200 mg daily dose of elemental iron in a formulation was calculated and average cost of various iron salts was compared. In the published formulations we found variation in dose, frequency of administration and price to consumer. Of the 513 formulations studied, 290 (56.53%) were oral solids, 198(38.59%) were oral liquids, and 25(4.87%) were parenteral. The formulations contained different iron salts viz. ferrous sulphate, ferrous sulphate dried, carbonyl iron, and ferrous fumarate. Out of 513 preparations, 89 (17.34%) did not contain proper concentration, and in 41(7.99%) the price was not mentioned. Out of 290 oral solid formulations 279 (96.2%) were found to be rational, and 11 (3.7%) were irrational. Carbonyl iron was contained by 88 preparations (27.58%) and was most commonly used salt in oral solid formulations. Out of 290 oral solid, 61 (21.03%) preparations required administration >three times a day to achieve the therapeutic concentration. Average cost of the rational preparation was more than average cost of irrational preparation, except in case of parenteral preparations.

**Keywords:** Hematinic, Rational, Iron salts.

### Introduction

Iron deficiency in humans is a common nutritional problem responsible for anemia. It may occur due to nutritional iron deficiency, increased blood loss, or interference with iron absorption.<sup>1</sup> Its prevalence in the US is 1-4% while in developing economies it may affect up to 20-40% of infants and pregnant women.<sup>2</sup> In India, iron deficiency has multifactorial etiology of poverty, ignorance, helminthiasis, amoebiasis, malabsorption and multiple pregnancies. Patients of mild and moderate iron

deficiency anemia respond to treatment with oral iron supplementation.<sup>3</sup> Hematinics are the medicines used for treatment of anemia. Hematopoiesis needs adequate supply of iron, copper, folic acid, vitamin B12, vitamin C, pyridoxine, riboflavin and hematopoietic growth factors.<sup>4</sup> Indian market has many formulations of different iron salts available over the counter which are consumed prophylactically or therapeutically. Not all are thought to be rational. Hence we

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thought it worthwhile to study this group of the medicines.

### Methodology

The information about hematinic formulations was taken from Indian Drug Review (IDR) 2012. The formulations were analyzed according to route of administration, rationality, and cost of daily treatment.

The formulations were classified according to oral and parenteral route of administration. The oral formulations were further sub classified into solid and liquid. The formulations were divided according to the contents:

1. Iron salt alone.
2. Iron salt + folic acid + others (vitamins, minerals, essential amino acids and other chemicals).
3. Iron salt + folic acid + vitamin C + others.
4. Iron salt + others.
5. Folic acid + others.

In those cases where the information about the type of iron salt content, quantity or price was not mentioned, the formulations were excluded from cost analysis. For comparison of cost, only the

elemental iron content was considered since the therapeutic response depends on elemental iron content which differs significantly in various formulations. The recommended therapeutic dose of elemental iron being 100-200 mg iron per day in three divided doses,<sup>5</sup> for comparison cost of 100-200 mg daily dose of elemental iron in a given formulation was calculated.

Along with the iron deficiency, usually folic acid deficiency is also seen in anemia, where vitamin C helps in increasing iron absorption. Hence formulations having iron salts + folic acid + vitamin C were considered to be rational.<sup>6,7</sup> The average cost of rational iron formulations was calculated and compared with irrational ones. Analysis was done with the help of simple proportion method.

### Results

It was seen that formulations containing iron salt alone, were few in number. There were irregularities in dose, suggested frequency of administration and cost of formulations. Out of 515 formulations listed in IDR 2012 under hematinic section, 513 were hematinic and two were non hematinic.

**Table No. 01: Rational iron formulations**

| Contents                                | Oral solid<br>(n = 290;56.23%) | Oral liquid (n = 198;38.59%) | Parenteral<br>(n = 25; 4.87%) |
|---|--------------------------------|------------------------------|-------------------------------|
| Iron salts only                         | 5 (1.72 %)                     | 34 (17.17 %)                 | 23 (92 %)                     |
| Iron salt + folic acid +others          | 165 (56.89 %)                  | 120 (60.60 %)                | 2 (8 %)                       |
| Iron salt + folic acid + vit C + others | 114 (39.31 %)                  | 19 (9.59 %)                  | 0                             |
| Iron salt + others                      | 4 (1.37 %)                     | 23 (11.61 %)                 | 0                             |
| Folic acid + others                     | 2 (0.68 %)                     | 0                            | 0                             |
| Hematinic                               | 0                              | 2 (1 %)                      | 0                             |

Out of 513 formulations, 56.5% (n=290) were oral solid, 38.5% (n=198) were oral liquid and 4%(n=25)were parenteral formulations. Among the 290 oral solid formulations, iron salts + folic acid + other ingredient combination was the commonest formulation available (56.89%,n=165). Second most common formulation was iron salt + folic acid + vitamin C + other ingredient (39.31%,n=114). Rest of the oral solid iron formulations contained only iron salts (1.72%,n=5), or iron salts + other ingredient (1.37%,n=4), or folic acid (0.68%,n=2).

Among 198 oral liquid formulations the commonest had iron salts + folic acid + other ingredient (60.60%,n=120). The second commonest formulation was containing only iron salt (17.17%,n=34). Other oral liquid formulations contained iron salt + folic acid + vitamin C + other ingredient (9.59%,n=19), and iron salt + other ingredient comprised (11.61%,n=23). In parenteral formulations (92%,n=23) formulations contained only iron salts while (8%, n=2) formulations contained iron salts + folic acid + other ingredient.

**Table No. 02: Irrationality in dose and cost of iron formulations**

| Total (n=513)       | Rational (n=420) |           | Irrational (n=93) |          |
|---------------------|------------------|-----------|-------------------|----------|
|                     | Dose             | Price     | Dose              | Price    |
| Oral solid (n=290)  | 9                | 21        | 2                 | 1        |
| Oral liquid (n=198) | 31               | 11        | 30                | 3        |
| Parenteral (n=25)   | 2                | 0         | 15                | 5        |
| <b>Total</b>        | <b>42</b>        | <b>32</b> | <b>47</b>         | <b>9</b> |

Among the 513 hematinic formulations, 420 were found to be rational and 93 were irrational. Out of 513 hematinic formulations, 89 (42 rational +47

irrational) formulations were not in proper dose and in 41 (32 rational +9 irrational), the price was not mentioned.

**Table No. 03: Average cost of rational and irrational iron formulations**

| Formulations | Essential   | Irrational |
|--------------|-------------|------------|
| Oral solid   | 12.7[n=249] | 7.4[n=8]   |
| Oral liquid  | 11.6[n=62]  | 9.1[n=26]  |
| Parenteral   | 0[n=0]      | 180[n=3]   |

It was found that the mean average price of oral solid and liquid rational formulations was higher than the irrational ones. However the price of irrational parenteral formulations was higher.

### Discussion

Iron deficiency anemia is the commonest problem in India but is easily treatable with iron salts in oral or parenteral formulations. In this study among the 488 oral iron preparations the most common iron salt in solid formulation was found to be carbonyl iron in > 30% formulations(n=88) as it gives high bioavailability and has less side effects.<sup>2</sup> The second most common iron salt was ferrous fumarate which gives 33% elemental iron/100 mg elemental iron.<sup>8</sup> Other salts present in oral iron formulations were ferrous sulfate, ferrous sulfate dried, sodium feredetate, ferrous ammonium citrate, polysucrose and fe(III) hydroxide polymaltose complex. The solid formulations were tablet, capsule, spansule, while the liquid formulations were syrup, drops, suspension, and tonic.

Out of 513 formulations, 89 showed irregularities in dose, either dose was not properly mentioned or these had lower /higher doses than the recommended. It is known that because of low content of iron salt in formulation, there is lesser elemental iron absorption. Thus more than three doses / day are required to achieve the therapeutic levels, leading to increase in cost of therapy and also reducing patient compliance. From the oral liquid formulations, 21 were available as drops.

Since this is a pediatric formulation, the dose depends on the age and weight of child, which was not possible to calculate in this study hence these were excluded from cost analysis.

The average cost of oral solid and liquid rational formulations were higher than irrational formulations. But the cost of irrational parenteral formulations was higher. The higher cost of oral solid, oral liquid acceptable preparation might be because of addition of more than one ingredient. These findings are similar to previous reports.<sup>5,6</sup>

### Conclusion

Our findings reveal that daily expenditure incurred on procurement of rational preparations will be more than that of irrational preparations. Thus cheaper purchase price may be one of the reasons leading to more purchase and consumption of irrational preparations. Hence the drug regulation authorities must weed out the irrational formulations so as to avoid the side effects and reduce the cost of therapy. Such intervention will also increase the quality of life of patients consuming these preparations.

The rational use of medicines stands for prescription of the right medicine in right dose, at right price, to the right patient and at right time. Indian pharmaceutical market is flooded with various combinations of iron and nutrients under hematinic section and patients are being made to consume unnecessary medicines. Hence the drug regulatory authorities must weed out the irrational

formulations so as to avoid the side effects and reduce the cost of therapy which will increase the quality of the life of patients.

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