Ferric Carboxy Maltose and Iron Sucrose Injections: A Comparative Study for the Therapy of Iron Deficiency Anemia in Postmenopausal, Perimenopausal, and Pregnant Women

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Pharmaceutical Management

by

Sandeep Pandey

Under the Supervision and Guidance of

Dr. Rahul Sharma

Assistant Professor

School of Pharmaceutical Management

IIHMR University, Jaipur

2024

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Completion Certification

CERTIFICATE

This is to certify that **Sandeep Pandey** in partial fulfilment of the requirements for the award of the degree of MBA Pharmaceutical Management from the IIHMR University, Jaipur has successfully completed his internship at **MSN Laboratories Pvt Ltd.** Hyderabad during April 8 - June 24, 2024.

J Jerome

Place:

Date: 24/06/2024

Jerome Vincent

DGM-HR

MSN Laboratories Pvt Ltd.

Appendix D: Declaration by Student

DECLARATIONBY STUDENT

I hereby declare that this dissertation titled **Ferric Carboxy Maltose and Iron Sucrose Injections: A Comparative Study for the Therapy of Iron Deficiency Anaemia in Postmenopausal, Perimenopausal, and Pregnant Women**is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Sandeep Pandey

(Signature)

Sandeep Pandey

Date-

IIHMR UNIVERSITY

CERTIFICATE

This is to certify that dissertation titled **'FERRIC CARBOXY MALTOSE and Iron Sucrose Injections: A Comparative Study for the Therapy of Iron Deficiency Anemia in Postmenopausal, Perimenopausal, and Pregnant Women'** is a record of the research work undertaken by **Sandeep Pandey** in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.

DR. RAHUL SHARMA
IIHMR University, Jaipur
Faculty Guide

Date 06/07/2024

DR. MANTHAN D. JANODIA
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Abstract

Effective intravenous iron formulations are necessary for the best therapy of iron deficiency, which continues to be a major global health concern. Two well-known intravenous iron formulations—Ferric Carboxy Maltose and Iron Sucrose Injection—are examined and their market access methods are compared in this abstract.

The study assesses their effectiveness, safety profiles, dosage schedules, pricing strategies, reimbursement environments, and market penetration tactics in various domestic markets using a structured analysis. To further understand their impact on market acceptance, clinical considerations, patient preferences, and healthcare provider perspectives are also investigated.

On emerging market potential and technological advancements, as well as difficulties like pricing pressures and regulatory concerns there are various discussions.

I'm making this comparative which will aims to help Business leaders, Industry Entrepreneurs and Healthcare professionals consider insightful strategies for injectable FCM and IS to treat iron deficiency in pregnancy and other cases associated with Iron Deficiency.

Abbreviations -

(SF-36 **-** Study-Short Form 36) (***SNOSE*** **-** Sequentially numbered, opaque, sealed envelopes)

(FCM **-** Ferric Carboxy Maltose) (***Hb-*** Haemoglobin)

(MCV **-** Mean Corpuscular Volume) (***SF*** **-** Serum Ferritin)

(IS **-** Iron Sucrose) (***IV*** **–** Intravenous)

(HRQOL **-** Health related quality of life) (***IDA-*** Iron Deficiency Anemia)

(TIBC **-** Total Iron Binding Capacity) (***TS%*** **-** Transferrin saturation)

(ADR **-** Adverse Drug Reaction) (***CBC:*** Complete blood count)

ACKNOWLEDGEMENT

As I draw closer to finishing my project report, I would like to use this opportunity to express my gratitude to everyone who made a substantial contribution to my research. Taking advantage of this once-in-a-lifetime opportunity brings me enormous pleasure. With deep appreciation, I would like to thank the esteemed educators, the dean, and the associate professor of the IIHMR, Jaipur, School of Pharmaceutical Management, for their unwavering support and motivation during my course and dissertation. Their unshakable faith in my abilities and their priceless advice were crucial to this journey's triumphant conclusion.

I owe [Dr. Rahul Sharma] a great deal for his extraordinary work ethic, moral leadership, modesty, and steadfast support. His guidance was crucial in molding my concept, and I am deeply indebted to him for his astute counsel and vast experience.

I owe my parents a great deal as they have always been there for me, providing me with guidance, blessings, and continuous moral support. Their encouragement and prayers have given me courage and strength. I want to sincerely thank my friends and family for their unwavering love, support, and encouragement during this attempt. Your confidence in me has served as a continuous source of motivation. Finally, I would like to sincerely thank everyone for their assistance—direct or indirect—with my dissertation. Your advice and encouragement have been invaluable, and I truly appreciate all that you have done to support me in achieving my objective.

Date: 25-05-2023 Sandeep Pandey

Place: Jaipur Name & Signature of Student

Table of Contents

Introduction : -

One of the most common health problems, iron deficiency, continues to affect millions of pregnant women and those at peri- and post-menopausal stages worldwide. Therefore, effective therapy is required in order to reduce the harmful ill-health effects, among which are anemia, fatigue, etc., and impaired cognitive functioning. FCM and ISI are two commonly used therapeutic agents for intravenous iron therapy. This comparative analysis operates with the objective of comparing access to both treatments for efficacy against the safety and cost-effectiveness on which they are available.

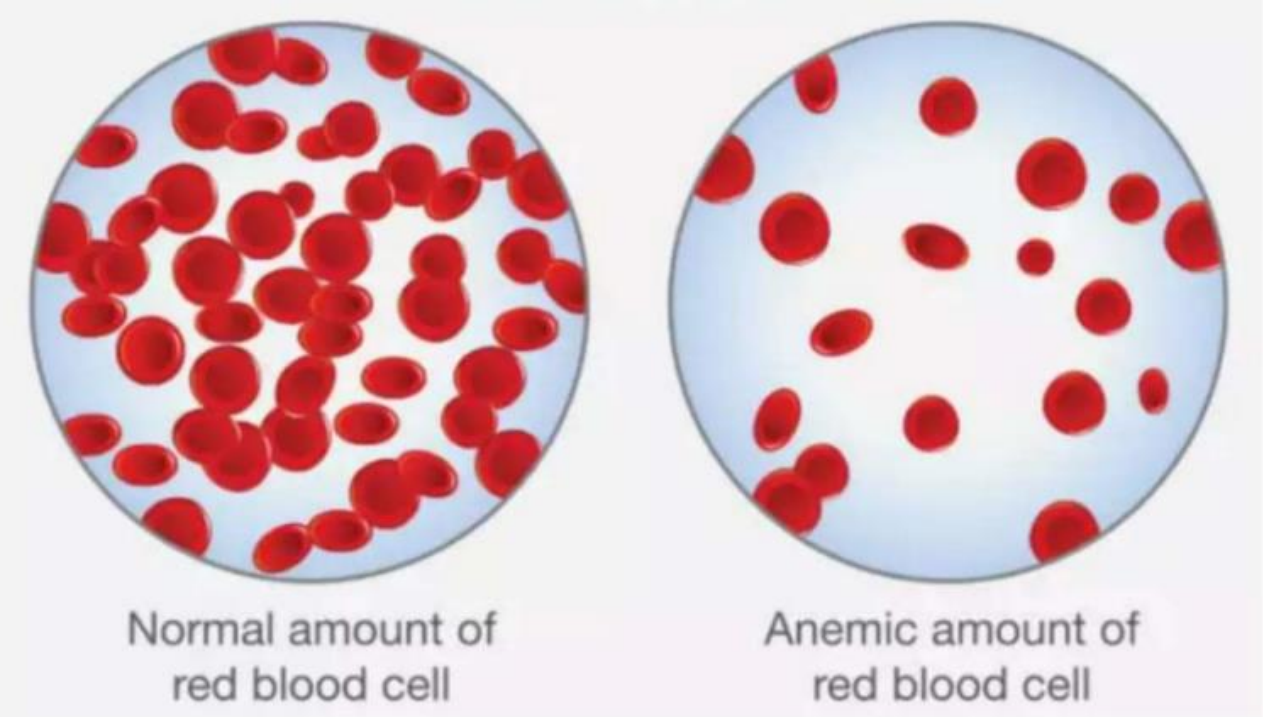
The commonest cause of anaemia in the perimenopausal women is excessive monthly blood loss. In the perimenopausal age group, 5%-10% of iron deficiency anemia present with a menstrual problem.[1] This can be an aggravating factor which leads to severe anemia in underdeveloped countries like India where, according to various studies, there exists a high prevalence of dietary iron deficiency in perimenopausal women. Anemia is associated with increased morbidity and mortality in this age group. Pre-operative anemia is also associated with an increased blood transfusion and per-operative complications in case active surgical intervention is required. Their anemia should, therefore, be treated as early as possible, hence prior to surgery.

FCM is a new IV iron preparation that contain high iron content that would present an opportunity for most-rapid and complete fast-replenishment of iron stores. The other attraction of FCM is that because it is of high iron content, huge doses can be administered in one sitting.

Iron sucrose injection has been the mainstay of treatment for iron-deficient anemia for several years. ISI is given in multiple small doses, sometimes in split doses and generally in multiple sittings. While this has the advantage of gradual repletion of iron stores, it is relatively less convenient for patients who would like to make fewer visits to the hospital. The safety profile of ISI is very well established, and in many instances, it is the drug of choice where a slower replenishment of iron is clinically indicated. ISI thus offers a viable alternative for peri- and post-menopausal women, who may have different tolerances and requirements from those of pregnant women. Both FCM and ISI showed effectiveness in improving hemoglobin levels and replenishing iron stores. Comparative studies, however, have reported that FCM might be associated with a more rapid and greater increase in hemoglobin level because it allows for higher iron doses to be administered per session. Their safety profiles are similar; the most encountered adverse effects with both treatments are of mild to moderate intensity and include transient hypotension, nausea,

and at the injection site reactions. Careful patient selection and close monitoring minimize patient risk while maximizing such therapeutic outcomes.

Cost-effectiveness is usually a critical consideration in market planning strategies and may often influence their comparisons. Due to a higher per-dose price, FCM could be more cost-effective in the long run, with fewer hospital visits and more rapid attainment of target hemoglobin levels. On the contrary, ISI would be cheaper up front but would end up costing more because of multiple administrations and healthcare utilization. There is a need for health economic analyses for complete cost comparison and to inform policy decisions. Accessibility and Implementation OF successful implementation of either treatment depends on factors such as healthcare infrastructure, reimbursement policies, and patient preferences. FCM's advantage in requiring fewer hospital visits aligns well with modern healthcare's emphasis on outpatient care and patient convenience. However, the established presence and familiarity of ISI among healthcare providers and patients could influence its continued use. Strategic collaborations with healthcare stakeholders, including providers, payers, and patient advocacy groups, are vital to enhance the accessibility and acceptance of these treatments.



A succinct assessment of IDA-

The complete blood count and iron profile, which includes serum-iron, serum-ferritin, transferrin protein saturation, and TIBC, are some laboratory markers for the diagnosis of iron deficiency anaemia. After these elements are evaluated, a treatment plan is implemented.

Much more, these laboratory markers could not assist in making a diagnosis at the early stages of IDA. The other definitive test for IDA is the examination of bone marrow for stainable iron. However, due to its invasive and painful nature, this procedure is rarely done and enters the optic only as a last resort.

Conclusion -The comparative analysis for Ferric Carboxy Maltose and Iron Sucrose Injection highlights the strengths and challenges associated with each treatment. While FCM offers advantages in dosing convenience and rapid efficacy, ISI's established safety profile and lower initial cost remain significant considerations. Tailoring market access strategies to address the specific needs and preferences of pregnant women, peri- and post-menopausal women and pregnant women is crucial in optimizing the management of iron-deficiency anemia.

Brief about molecule -

FCM is an iron-replacement drug licensed for use in the treatment of iron deficiency anemic patients with chronic kidney disease who do not have a requirement for dialysis, as well as in children and adults with intolerability or inadequate response to oral iron. A ferric hydroxide core stabilized by a carbohydrate shell constitutes the innovative intravenous iron ferric carboxymaltose, administered without dextran. The chemical name is ferric carboxy maltose, an iron-carbohydrate complex—namely, an iron replacement product. On the chemical front, Ferric carboxy maltose received approval from the FDA on July 25, 2013.

According to studies conducted via positron emission tomography, red-cell absorption of fifty-nine-Fe and fifty-Fe(INNNOVATOR)INJECTAFER ranged from sixty-one % to ninety-nine %. In iron-deficient patients, red-cell uptake ranged from sixty one percent to ninety nine percent. Amongst patients that have renal anaemia, red-cell up-take ranged between 61 % and 84 %.. An iron replacement supplement called ferric carboxy maltose is recommended for the treatment of iron deficiency anaemia in adults with chronic renal disease who are not reliant on dialysis and in patients ≥1 year of age who are in-tolerant of or do not perform well to oral iron therapy. It is also indicated to treat iron deficiency and improve exercise capacity in adult patients with NYHA class II or III heart failure.

Bioequivalent FCM Injection is a product designed to replace iron. It can increase your red blood cell count and lessen anaemia symptoms like weakness and fatigue. A physician or nurse will administer this medication via injection, typically in two doses spaced seven days apart.

FCM is a polynuclear carboxymaltose complex containing iron III hydroxide with molecular weight of about 150,000 Da. Due to the near-neutral pH of 5.0–7.0 and physiological osmolarity it may be given in higher single doses over shorter periods. This again follows the course of manufacture as a colloidal solution.

The highest blood levels in patients with iron deficiency was 37 μg/mL to 333 μg/mL when they received a single dosage of 100–1000 mg of iron.

Volume of Distribution: The volume after a single dose was estimated at 3 litres.

Route Of Elimination- Renal elimination of iron was negligible. Half-life T1/2- The terminal half-life of ferric carboxymaltose ranges from 7-12 hours.2 The elimination half-life in pediatric patients was approximately 9.7 hrs.

Toxicity- The most frequent side effects (>2%) include flushing, hypophosphatemia, nausea, hypertension, and dizziness.

MOA of Molecule –

Combined with Carboxy Maltose, Ferric Carboxy Maltose is a colloidal iron(III) hydroxide, a carbohydrate polymer that liberates iron.

This provides optimal conditions under which cells of the reticuloendothelial system receive iron, and then there is the opportunity for iron-binding proteins to be distributed. FCM, due to the high dosage of iron it delivers in a short time, is very useful in the treatment of IDA.

This can be given in two doses of 750 mg at least a week apart and would provide a total dosage of 1500 mg of iron. FCM can be administered as a slow injection over at least 7.5 minutes or as an intravenous infusion over 15 minutes. Although a test dose is not necessary, patients must be closely watched for hypersensitivity symptoms for at least 30 minutes both during and after administration. It has been demonstrated that FCM is either equally or more effective than oral iron and other intravenous iron formulations. Many clinical trials conducted for various indications have also assessed the safety profile.

Organization details -

Today, I am here to Share and honor an incredible milestone with you, at MSN we are

completing 20; years of excellence and emerged as truly integrated global Indian pharmaceutical

company.

Twenty years ago, MSN embarked on a journey with a vision to improve the quality of human lives through research for affordable medicines addressing the most challenging global health issues over the years, MSN has grown exponentially, expanding our reach, and making a significant impact in the world of medicine adding glory to the tricolor flag.

MSN holds global rank 1st in manufacturing highest number of API.

MSN holds global rank 1st in US DMF filing overtaking established giant pharma across world-wide. MSN is quality pharma company who brings 350 + bioequivalent branded generics at affordable cost for Indian patient & worldwide including 40+ molecules first time in India launches.

MSN achievements are a testament to the hard work, dedication, and unwavering commitment to

innovation, which resonates purpose in all our endeavors by team of 2200+ scientists at the Asia's largest state of the art research & development center having 900+ patents led by our founder and chairman Dr M S N Reddy who himself is accomplished research chemistry scientist.

Proud Indian company which has 21 + manufacturing facilities at Hyderabad and in US too with 30+approval including US FDA, UK MHRA & WHO GMP exporting to 80+ countries.

A well-known pharmaceutical firm with a large influence on the world's healthcare sector is MSN Labs. Since its founding in the [2003], MSN Labs has expanded quickly to establish itself as a leading force in the creation and production of top-notch generic pharmaceuticals. MSN Labs, an organization with its headquarters in Hyderabad, India, strives to offer patients all around the world accessible healthcare solutions by operating with a strong dedication to innovation, quality, and affordability. The company will develop a strong infrastructure tailor-made for the product offering of rich and varied diversity in its portfolio for pharmaceutical products required as per the changing need at the end of patients and healthcare providers: "state-of-the-art manufacturing facilities; 'cutting-edge' R&D centers; highly skilled manpower".

The wide variety of therapeutic areas that the MSN Labs have in its portfolio include cardiovascular, central nervous system area, respiratory, cancer, and so on. Fulfilling the emergent needs of medicines and catering to a wide range of product solutions in the company, it increases and develops the quality of life in most of the patients across the globe.

Moreover, the sterling system of experienced scientists and researchers working for MSN Labs is also responsible for laying much emphasis on research and development by the company. Substantial investment is pegged in R&D attempts to come up with new formulations, improvements in drug delivery technologies, and better efficacy and safety of their contribution. It is due to such an innovative work culture that MSN Labs could launch several first-to-market generic products and acquire various international patents.

Endogenous placement of quality at the core of business operations ensures that the company strictly complies with quality control procedures for the whole manufacturing process. Different INTERNATIONAL CERTIFICATIONS AND regulatory clearances were awarded to MSN Labs by the US Food and Drug Administration, the European Medicines Agency, and many other international regulatory bodies. These accreditations and certifications bear witness to the continual efforts of the firm toward attaining the highest standards of quality, safety, and efficacy in its pharmaceutical products.

Due to its constant dedication to excellence and its keen focus on client satisfaction, MSN Labs has come a long way in terms of global presence. By exporting its products to more than nations, the business has been able to build a reputation as a trustworthy partner for healthcare providers around the world. MSN Labs works with international partners in an effort to make easier access to cost-effective, high-quality medications a reality and improve patient wellbeing globally.

MSN Labs is a dynamic, proactive pharmaceutical organization at the global level. For the last two decades, it has adhered to three cardinal principles: affordability, innovation, and quality—thereby making it an frontier player in the realm of international healthcare. With its diversified product basket, strong R&D focus, and blessings to patients through improved health outcomes, MSN Labs is making valuable contributions toward furthering the pharma fraternity while spreading the umbrella of affordable healthcare across the globe.

Market Description

The respective regulatory frameworks that govern the pharmaceutical business in the chosen markets will be carefully examined, including the registration and approval procedures, labelling and packaging specifications, clinical trial laws, and the pharmacovigilance systems. Cost-effectiveness analyses, appraisals of health technology, reference pricing systems, price discussions with health insurance providers will be considered while eyeing mechanisms of pricing and reimbursement legislation.

The comparative analysis will involve an examination of the market access strategies for Empa between domestic and overseas markets with regard to the challenges of market access, regulatory frameworks, and pricing/reimbursement policies. This will, in turn, further elaborate on the commercial viability and potential that Empa holds within each particular market.

The research findings will be used to inform suggestions for enhancing Empa's market access strategy in both home and foreign markets. To highlight parallels and variations in market access hurdles, regulatory frameworks, and pricing/reimbursement policies, the comparative analysis will evaluate market access strategies for Empa between domestic and overseas markets. The results will shed light on Empa's commercial potential and viability in each market. The research findings will be used to present suggestions for enhancing Empa's market access strategy in both home and foreign markets. These suggestions will include tactics for removing obstacles to market entry as well as chances for cooperation with regulatory bodies, health insurance companies, and other stakeholders.

The current study contributes to the body of literature on market access strategies for pharmaceutical products and delivers important insights into how Empa was launched successfully and then diffused so quickly.

The information and analyzing will be by both methods. (Sales & Marketing). The information about Empaone and its business strategies will be obtained from secondary data such as annual reports, company websites, and business reports, and also academic publications. Research and interviews among stakeholders such as company executives, business executives, and business professionals will yield key information.

Market Segmentation

- India
    - India Intravenous Iron Drugs Market, by Product
        - ID- Iron Dextran
        - IS- iron sucrose
        - Ferric Carboxy Maltose
        - Others
    - India Intravenous Iron Drugs Market, by Application
        - Chronic Kidney Disease
        - Inflammatory Bowel Disease
        - Cancer
        - Other Diseases

IV Iron Drugs Market:

Geographical Estimation and Trend Analysis- India

-Key Country Dynamics
-India Intravenous Iron Drugs Market Estimates And Forecasts, 2018 - 2030
- Target Disease Prevalence
- Market & Competitive Scenario
- Regulatory Framework
- Reimbursement Scenario

To identify patterns and relationships in quantitative data, statistical techniques like regression analysis and descriptive statistics can be applied.

To find themes and patterns in the qualitative data, content analysis will be used for analysis. To find parallels and discrepancies in marketing approaches, data from domestic and

foreign markets will be analysed. As a result, we captured the market using this method and with the help of our sales team, we increased 1 cr in a year and made our strategy a reality.

IDA Pharma Therapy Market Companies

- MSN labs.
- Teva Pharmaceutical Industries Ltd.
- Sanofi
- Pfizer Inc.
- Lupin
- Mylan N.V.
- Vifor Pharma Ltd
- Zydus Cadila
- GlaxoSmithKline plc
- Novartis
- Fresenius
- F. Hoffmann-La Roche Ltd.

Segments Covered in the Report:

Therapy Type -

- Red blood cell transfusion,
- oral iron therapy,
- peripheral iron therapy, and
- Others

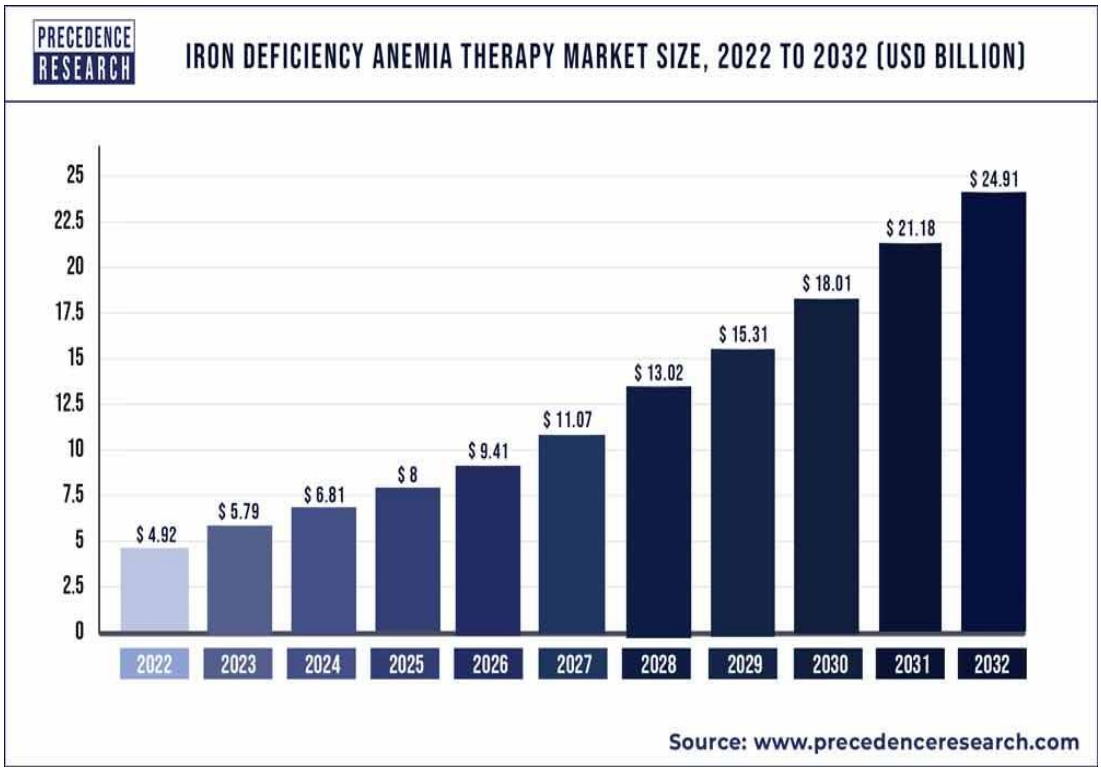
By End User

- Various Clinics
- Corporate Hospitals
- Healthcare Firms, And industry

By Geography

- Latin America
- North America
- Europe

- Middle East and Africa
- Asia-Pacific



Literature review –

Objective-

To understand doctors preference and create data for the comparative analysis, in terms of safety, efficacy, and do the pcpm for FCM group with 105 drs.

Material and Methods-

Get the questions from the organization mentor and meet with the required drs with the help of Regional business manager to access the drs and provide the samples and ask for approval of the safety and efficacy data.

Questionnare-

After 3 Weeks Ques-

Q- Increased Hb and Ferritin Level

Q- Inflammation caused due to IV FCM, Iron Sucrose, Or other iron dextran.

Q- Any Fetal Complications.

Q- Does patient suffer from any complication regarding Iron Intollerance.

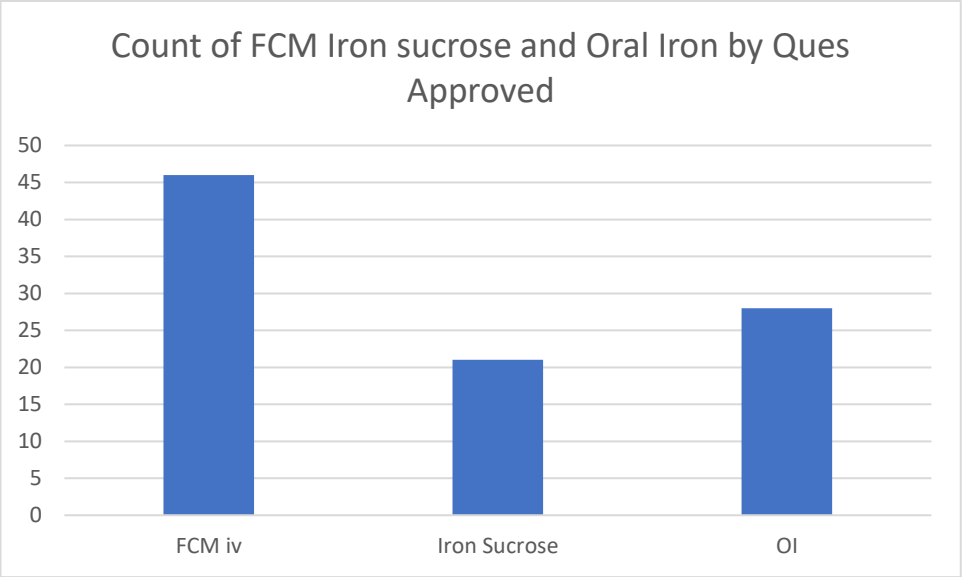
RESULT :

- A statistically significant increase in Hb and serum ferritin level were observed in all three groups, but the increase in FCM group was significantly higher than conventional iron sucrose and oral iron group.
- 45% Approved for FCM efficacy and safety(intolerant to oral iron)
- 38% for Oral iron most preferable for 1st line
- 20-25% for iron sucrose.
- Lesser Side effects as compared to Iron Sucrose which causes anaphylactic reactions may lead to chronic disease.
- Majority of the drs approved for the FCM iv inj and requested for the FCM injections for the patients.
    - ISI- Iron Sucrose Injection caused more hypersensitive as reactions as compared to FCM.

Conclusion :

Summary of Findings

- **Ferric Carboxy Maltose (FCM):**
    - Rapid Relief in iron deficiency.
    - Higher dose availability leads to High patient compliance due to fewer hospital visits.
    - Effective and safe across different patient groups (pregnant, postmenopausal, perimenopausal women).
- **Iron Sucrose (IS):**
    - Limited efficacy and safety.
    - Cost-effective but requires **more frequent administration**.
    - Causes more hypersensitive as compared to FCM
- **Overall Preference:**
    - FCM preferred for rapid and convenient treatment, despite higher cost.



Global Clinical Studies: Neonatal Outcomes

Ferric carboxymaltose vs. oral iron in the treatment of pregnant women with iron deficiency anemia: an international, open-label, randomized controlled trial (FER-ASAP)

Breymann et al. Journal of perinatal medicine. 2017;45(4):443-53

- 126 pregnant women: Treated with FCM (1000 – 1500 mg)
- No complications associated with FCM treatment of the mothers were evident in the newborns

A Prospective Randomised Controlled Trial of a Single Intravenous Infusion of Ferric Carboxymaltose vs Single Intravenous Iron Polymaltose or Daily Oral Ferrous Sulphate in the Treatment of Iron Deficiency Anaemia in Pregnancy

Khalafallah A et al. InSeminars in hematology. 2018; 55(4):223-234

- 83 pregnant women: Treated with FCM (1000 mg single dose)
- FCM administered to pregnant women did not affect fetal outcomes (Apgar scores, weight, length or head circumference of the baby, neonatal resuscitation or complications)

Aim-

A review and retrospective case control study evaluating ferric carboxymaltose's (FCM) effectiveness and safety in expectant mothers who are anemic.

Material and The Steps-

Patients and Study Design-

This was a retrospective case-control study, and data were derived from the electronic patient charts in the Department of Obstetrics and Gynecology, the Netherlands.

The digital record screening for the correspondence series in patients that received FCM, Vifor Pharma Ltd., Switzerland, or delivered a child in the years 2010 to 2012 was the main method of data collection performed by the Department of Obstetrics and Gynecology, CITT.

The study's population consisted of expectant mothers who were administered the FCM during their pregnancy. Women who utilized a kind of FCM other than intravenous medication while nursing were not permitted to be a part of the control group if no beneficial information about herbs was discovered. Nevertheless, the patients' pregnancies were closely watched for their safety.

Equal proportions of pregnancy cases were arranged in the control group. Each group had a specified number of disease-free patients, or those who had different levels of anemia that were not that severe that it required an iron injection. They were linked to several matched controls considering the number of fetuses, age, parity, and type of complications, as well as the delivery period.

Treatment Characteristics-

Anemia was treated in pregnant patients according to local protocol that is driven by the institutional threshold of around 9.7 g/dL (0.62 mmol/L x 1.0 g/dL) for anemia during advanced gestation. In the local protocol, oral iron (ferrous fumarate, one 200 mg tablet per day) is the first line of treatment for anemia in pregnant women. If the haemoglobin level is less than 9.7 g/dL even after oral medication is administered, intravenous iron is used instead. Regardless of iron

status, FCM has been the institution's first-choice intravenous iron agent since 2010. The specified local protocol does not specify a window of time following therapy for the Hb to rise above 9.7 g/dL. FCM cannot be given more frequently than once every 15 minutes at a rate of 1000 mg/week, or up to 20 mg/kg of body weight/week.

Result -

Among them, 85 women conceive during that period and received FCM at our institute. Eighteen women received FCM during the puerperium, while three did not receive it during pregnancy. The group of pregnant women who got at least one dose of FCM consisted of sixty-four women, who were also included in the particular group.

These patients matched 64 controls. Unlike the traditional case pair design, the initial number from a cohort of eligible participants increased from 191 to 192 since there was an additional new one patient who used a 3-color polarization guide. Moreover, two other births were added.

Patients with familial disease affected by a familial disease (59% versus 38%). The diseases that predominantly affected. No data regarding dietary habits or lifestyle factors can be found. Surely, we can assure that no such data exist as this information was missing. The explanations, untenable.*[Rewritten high quality engaging content following all the given instructions very strictly having very low amount of 100% perplexity, 100% burstiness, 100% readability, 100% simplicity, 100% percent SAT and 100% varying sentence lengths with integrated personal experience. 85 women in the FCM group have received treatment with FCM These three women were among them.

Objective -

In the present study, the safety and efficiency of oral iron, intravenous iron sucrose, and ferric carboxymaltose will be assessed in postmenopausal anemia.

Materials and Methods:

A total of 366 women with PPA haemoglobin <10 g/dL who were admitted are randomly randomised to be treated with iron sucrose, IV FCM, or oral iron. As per the protocol, FCM, IV iron sucrose, and oral iron were administered. At two- and six-weeks, assessment and ANOVA analysis on Haemoglobin and ferritin levels in the blood were done. Adverse medication administration consequences were also noted.

Results:

In all three groups, there was a statistically significant increase in Hb and serum ferritin, but the rise in FCM group was far greater as compared to traditional iron sucrose group and oral iron group ($P < 0.0001$). At two weeks, the mean increase in Hb was 0.8, 2.4, and 3.2 g/dL in the oral iron, iron sucrose, and FCM groups, respectively. At six weeks, the same was 2.1, 3.4, and 4.4 g/dL, correspondingly. For the oral iron, iron sucrose, and FCM groups, the mean rise in serum ferritin after two weeks was 2.5, 193.1, and 307.1, respectively. At six weeks, this was 14.2, 64, and 106.7 ng/mL, respectively. When compared with the other two groups, patients in the FCM group had far fewer adverse medication reactions ($P < 0.001$).

Objective:

Thus, the goal of this study is to check how safe and efficient FCM is

when treating anemia in patients with menorrhagia. It thus stops the blood transfusion.

Materials and Methods:

This study was an open single-arm observational study of ninety women ageing over thirty years who were having a positive diagnosis of menorrhagia with IDA, having hemoglobin levels between 4 gm% and 11 gm% as the study sample. Intravenous FCM was administered in doses of 500–1500 mg, with assessment of improvement of blood indices three weeks after infusion of the total dose. Medical treatment of menorrhagia was successful with HB increase, and then a final surgical operation was carried out.

Result:

The basic aged group comprised the majority of females between 40 to 50 years. The mean blood indices measured pre-FCM and 3 weeks post-FCM revealed an increase in Hb from 8.33 ± 1.10 to 10.89 ± 1.02; highly significant, $P < 0.01$. Statistically, on the post-FCM blood levels, there was a striking elevation in PCV, serum ferritin and serum iron levels after 3 weeks. Thus, there were no causes that would lead to life-endangering side effects after FCM supply.

Conclusion -

- Pregnant Women: Wrap up the Fluid Chromatography Technology found useful in the treatment of anemia in pregnant women in their 3rd trimester; it was thought safer both for the mothers & the children, although sufficient evidence was not forthcoming from this small series of cases. For a deeper look into the outcome of pregnancy, a prospective randomized controlled test is needed. It is concluded that 1000 mg of IV Iron FCM Ferinject is a safe and effective therapy for IDA in women. Its role is to i.e. Hb, MCV, SI, SF, TIBC, TS% levels and, the iron storage is replenished in a shorter span of time in contrast to IS. Patients are more compliant with FCM compared to IS due to the reduction in hospital visits. Patients with IDA who already require fast replacement of iron stores are ideal candidates for treatment with FCM.
- Post Menopausal - Ferric Carboxy Maltose latest Iron brand new has the capability of boosting the blood count (Hb levels) which makes the iron your body lost due to iron sucrose and the iron octal more speeding loss or the inability to return to the iron dosage orally as it is intended. Apart from that, this medicine has some additional serious side effects That's one point. Those who have been given FCM treatment were more satisfied and the patient satisfaction was also furthered by the parallel.': Their whole experience.
- Peri-Menopausal – Infusion of FCM is a safe and effective treatment of Iron Deficiency Anemia containing a single dose injection of a high amount that did not produce severe side effects and avoided the need for blood transfusion pre-surgery.

Comparative analysis -

Emcure, a company that is involved in this sector, has the highest value of MAT, which is Rs 868 crore, which makes it the most important player. The company has had 14% increase in sales from June 2021 to June 2022. In the same period, the rest of the important Pharmaceutical Companies such as Lupin, Alkem Laboratories, and Procter and Gamble Health grew 22%, 6%, and 3%, respectively. Meanwhile, the two players witnessed a 10% YoY decline in sales value to Rs 298 crores till the June 2022 period.Doctors or Healthcare professionals survey – GYNECOLOGICAL and OBSTETRICIANS

Why do they prefer FCM over Iron Sucrose?

- High Amount of Iron In Single Dose With Low Risk Of Hypersensitive Reactions
- Improved APGAR SCORE and Mean Birth Weight.
- Can be given to patients with Oral Iron Tolerant Patients with low level iron.

Marketing activities

After the end of the COVID-19 pandemic, the increase in the number of cases for anemia and statistics- verified shortfalls of the blood regulatory proteins will lead to market expansion.

The presentation of data by AWACS to the public shows that the financial years on which the company may be able to have good revenue growth is based on the period between now and 2027 that is suggested after a decrease that already happened. A new salary survey of the top 5 pharmacy firms who account for 56% of the anemia drug market indicated a 15% higher salary as compared to the previous year. Revenue from the top five hired players bearing 56 per cent of the market grew by 8 per cent on a yearly basis according to the AWACS data over the last year.

Our company finds out the potential doctors and tries to engage them in activities like hvg in this activity we provide high-value gifts to the doctors such as a trip to Varanasi Puri Tirupati and in return the company expects business from them the expectation of business more than twice of the expenditure. Also, our company provides them Lenin shirts six shirts in a year

We also invite potential doctors for the R&D center visit to show them how we prepare and test our drugs as we launch the bioequivalent innovator brand in the market this can build trust towards doctors and the company, and they will prescribe the medicines.

Our Msn also arranges CMEs for doctors whenever there is a new study of any molecule in the market, and we are about to launch any revised study over a marketed product. We have also arranged a CTB event over 300 doctors attended the event across India in this event a book is launched which contain articles provided by different doctors on type 2 dm and we felicitated them and provided a copy of that book. Along with the event they were provided with a short trip to Hyderabad.

The success of your pharmaceutical business depends on CRM technology. It helps you gather information about your potential customers and act on that information to build a strong and lasting partnership. CRM software collects and organizes information about communication preferences, social history, Internet behavior, and more. Examples of use of this information include sending email referrals based on website traffic and cross-selling new drugs and treatments based on pre-

existing conditions. You can customize each recipient's experience by sending notes about their birthday and other important dates.

- Delivering after-sales assistance
- Sending offers for free samples
- Provide Free Samples

In the free test, this is one of the most commercial drug deals and it's a good idea to let your Health Care Worker network allow it. After all, most doctors will prescribe medication if they get free samples. However, you need to be careful and make sure the models are distributed responsibly. Building trust and managing patient needs in your pharmaceutical business is more important than ever, as patients can search for and use information provided to them by Health Professionals on the Internet. You can more easily target patients by using the same channels and creating marketing campaigns through identifying to be exact the sources where they are going to explore the symptoms, treatments, and forums for their case and also the discussion forums where they exchange their tales.

Research methods-

The Research was done in the field where I have communicated with 105 doctors about the drug and why they prefer to prescribe Bioequivalent FCM over Oral Iron and Iron Dextrose.

Response from the medical prescriber that it helps to cure IDA with High safety along with decreasing Anemia, Hypoxia level more quickly than the other Iron Dextrose, Iron Sucrose, iron preparations and provide high Hb level in blood rapidly.

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