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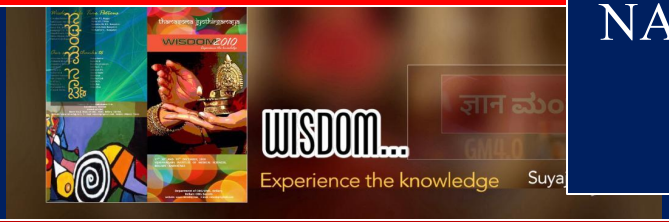
DR. JOSHI SUYAJNA D. HOD- DNB- BALLARI

LIVE LAPAROSCOPY WORKSHOP – IN NK – 2002 – BELLARY
LIVE ULTRASOUND WORKSHOP - IN NK- 2004 - BELLARY
MUSKCON 2007- IN BELLARY



NATIONAL LEVEL POSTGRADUATE CME IN BELLARY
2008 to 2012 - FIVE EDITIONS

Special Awards & Achievements:

1. 'Single dose magnesium sulphate' for Eclampsia- VIMS regimen
2. Joshi's classification MgSO4 regimens for Eclampsia
3. 'Rule of 15' - Labetalol IV regimen for HYPERTENSIVE CRISES
4. Joshi's Three stage management protocol for Eclampsia
5. Eradication of PREGNANCY ANAEMIA with IV FCM- 1000 mg – Safe Motherhhood initiative

31-08-2025

NBE - Senior Teacher Par Excellence Award 2024- ANBAI

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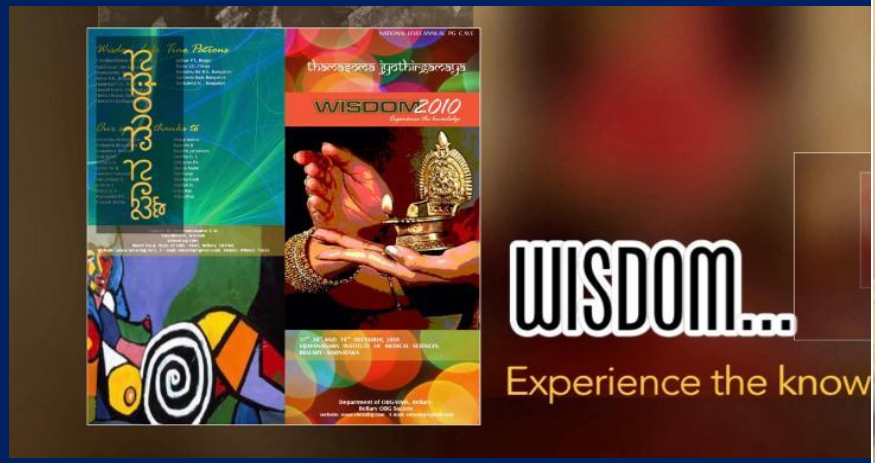

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FCM BEFORE LAPAROSCOPIC SURGERY

1. PRE-OPERATIVE ANAMIA
2. BLOODLESS MEDICINE
3. HAZARDS OF BLOOD TRANSFUSION

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FCM BEFORE LAPAROSCOPIC SURGERY

4. • INFORMATION ON PARENTERAL IRON
5. • PREVNTT - LANCET
6. • REVIEW OF VIMS STUDY

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INTRODUCTON

WHO DEFINITION OF ANEMIA

- Adult male-<13 g/dl
- Adult female-<12g/dl
- Adult pregnant female<11 g/dl

PREVELENCE OF ANAMIA IN INDIA AS PER :

The National Health Survey-5 (2019-2021)

In women (19-49 years)- 57%

IRON DEFICIENCY ANAMIA IS THE MOST COMMON TYPE

METHODS TO TREAT IRON DEFICIENCY BEFORE LAP

- DIETARY IRON
- ORAL PREPARATIONS
- PARENTERAL PREPARATION
- BLOOD TRASFUSION

CURRENT PRACTICE

- TREATMENT OF PERIOPERATIVE ANAEMIA

BLOOD TRANSFUSION

CURRENT CONCEPT

- TREATMENT OF PRE-OPERATIVE ANAEMIA

PARENTERAL IRON

FCM BEFORE LAP

FCM BEFORE LAPAROSCOPIC SURGERY

1. • PRE-OPERATIVE ANAMIA
2.
3.

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PRE-OPERATIVE ANAEMIA

- Preoperative anaemia affects 30–60% of all patients undergoing major elective surgery and is associated with an increased risk of:
- blood transfusion,
- in-hospital complications,
- delayed hospital discharge, and poor recovery

30–60%

FCM BEFORE LAPAROSCOPIC SURGERY

1

2

- HAZARDS OF BLOOD TRANSFUSION

3

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BLOOD TRASFUSION COMPLICATIONS

- Blood transfusions are life-saving medical procedures that involve transferring blood or blood products intravenously from a donor to a recipient.
- Approximately 10% of recipients may experience adverse effects, also known as transfusion reactions or complications.
- Understanding these complications is crucial for safe transfusion practice and ensuring optimal patient outcomes.

Types of Transfusion Reactions

Acute Reactions: Occur during or within 24 hours of transfusion.

- 1. Hemolytic Reactions: Caused by ABO incompatibility, leading to red blood cell destruction. Can be life-threatening.
- 2. Febrile Non-Hemolytic Transfusion Reactions (FNHTR): Characterized by fever and chills, often due to recipient antibodies against donor leukocytes.
- 3. Allergic Reactions: Range from mild urticaria to severe anaphylaxis, caused by recipient response to donor

Types of Transfusion Reactions

- 4. **Transfusion-Related Acute Lung Injury (TRALI):** A serious condition involving acute lung injury and hypoxia, often linked to donor antibodies that damage the recipient's immune cells in the lungs.
- 5. **Transfusion-Associated Circulatory Overload (TACO):** Fluid overload leading to acute respiratory distress, particularly in patients with pre-existing cardiac or renal conditions.

TYPES OF TRANSFUSION REACTIONS

- Delayed Reactions: Occur more than 24 hours after transfusion.
  - Delayed Hemolytic Transfusion Reactions **(DHTR):** Slower destruction of red blood cells, often due to antibodies not detected before transfusion.
  - Transfusion-Associated Graft-versus-Host Disease **(TA-GVHD):** A rare but serious complication where donor T-lymphocytes attack recipient tissues.
  - Post-transfusion Purpura **(PTP):** Thrombocytopenia (low platelet count) and purpuric rash, usually seen within 1-24 days post-transfusion.

Hazards of blood transfusion A

. Hemolytic reactions	1 in 40,000
. Febrile reactions	3-4%
. Anaphylactic reactions	1 in 20,000
. TRALI	0.1-0.2%
. HBV	1 in 50,000
. HCV	1 in 3000
. HIV	1 in 1,50,000

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- BLOODLESS MEDICINE

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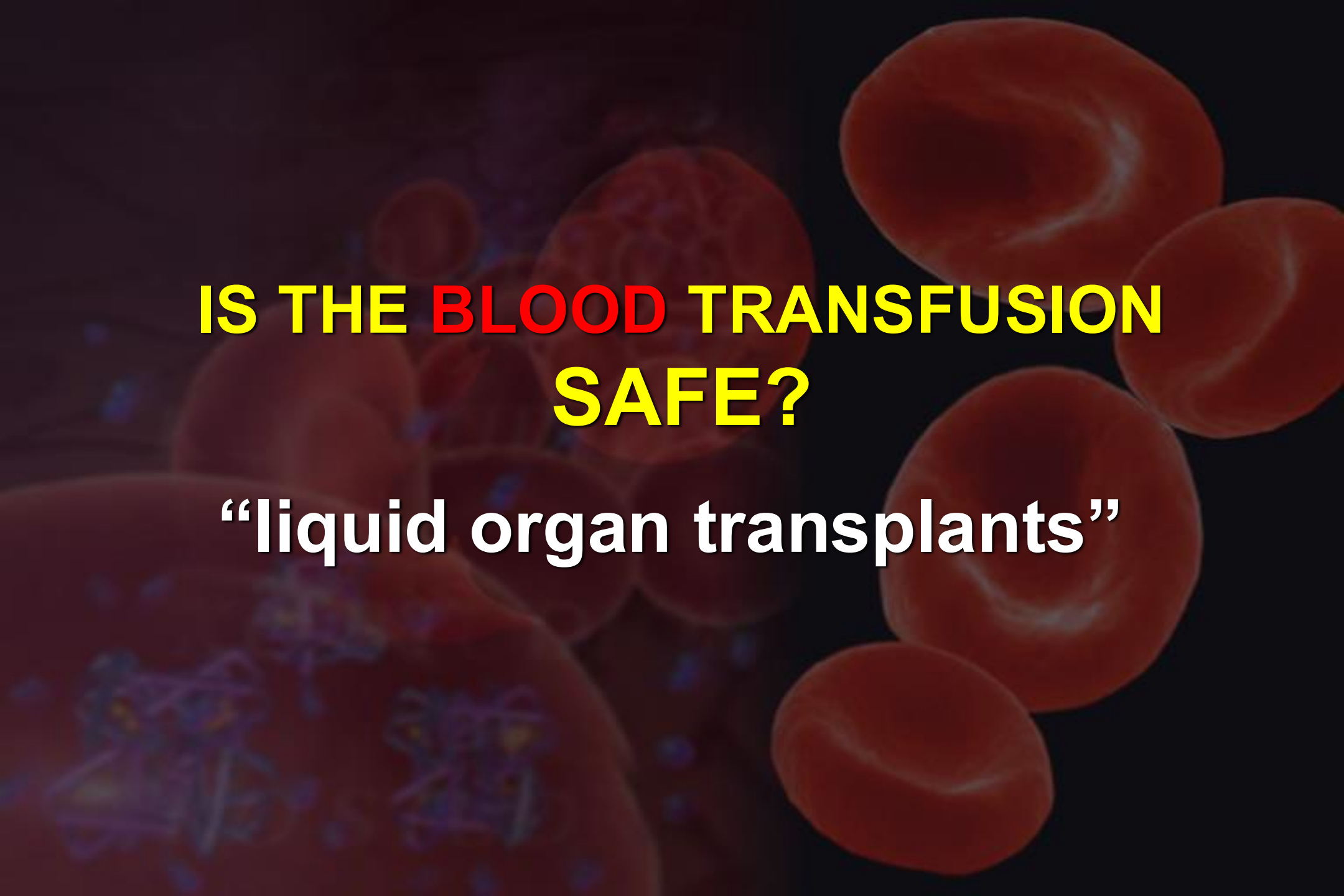
IS THE BLOOD TRANSFUSION SAFE?
“liquid organ transplants”

BLOODLESS MEDICINE

- There is little justification for the use of a preoperative blood transfusion:

- simply to facilitate elective surgery…

WHO manual on BLOOD Transfusion

BLOODLESS MEDICINE

SHOT - Serious Hazards Of Transfusions

- 24 month study in UK and Ireland
- 424 hospitals surveyed
- 39% (164) responded

- **366 major adverse events reported**
- **52% were due to "wrong blood to patient"**
- **22 total deaths**

Immunomodulation

- The transfusions may trigger

  S.I.R.S. OR M.O.F. if they increase the circulation of inflammatory cytokines.

- interleukin-8 accumulates in stored blood as the leukocytes break down;
- it is also released by the body in response to free hemoglobin in transfused blood.

Arch Surg 1997;132:620-5.

Researchers Find Deadline in Blood

theherald.com.au, 24 Nov, 2010

THE OLDER BLOOD(>14 DAYS)

IS NOT INFECTED BUT RATHER,

WEAKENS THE IMMUNE SYSTEM AND MAKES PATIENTS MORE VULNERABLE TO HOSPITAL INFECTIONS.

Transfusion can lead to microchimerism

- blood recipient harbors small amounts of the donor's genetic material.
- implicated in the development of autoimmune disease
- may possibly increase the risk of

Non-Hodgkin's lymphoma
chronic lymphocytic leukemia.

FCM BEFORE LAPAROSCOPIC SURGERY

Parenteral iron

'the solution'

Fills rift between

'oral iron and blood transfusion'

BLOODLESS MEDICINE

FCM BEFORE LAPAROSCOPIC SURGERY

4
- INFORMATION ON PARENTERAL IRON

5

6

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CLASSIFICATION OF INTRAVENOUS IRON CARBOHYDRATE COMPLEX PREPARAION

	Type I	Type II	Type III	Type IV
Example	Ferric carboxymaltose Iron dextran Ferumoxytol	Iron sucrose	Sodium ferric gluconate Iron(III)-citrate Iron(III)-sorbitol	Iron(III)-citrate + iron(III)-sorbitol + iron dextrin Sodium ferric gluconate + iron sucrose
Preparations	Ferinject®* InFeD® Cosmofer® Imferon® Dexferrum® Feraheme®	Venofer® Fesin®		Jectofer® Ferrlecit®
Characteristics	Robust Strong	Semi-robust Moderately strong	Labile Weak	Mixtures containing at least two different iron complexes
Molecular weight (Daltons)	>100,000	30,000–100,000	<50,000	<50,000

PARENTERAL IRON PREPARATIONS

- **IRON DEXTRAN COMPLEX**
  - Complex of ferric hydroxide with dextran
  - Reaches RE cells via lymphatics
  - Not preferred now a days because of high incidence of fatal anaphylaxis
- **IRON SORBITAL CITRIC ACID COMPLEX - JECTOFER**
  - Low molecular weight complex
  - enters RE cells from blood
  - CI in kidney disease

Iron products that are administered parenterally

- **IRON SODIUM GLUCONATE**

  Preferred agent for parental i.v therapy , 80% delivered to transferrin within 24 hrs

- **FERUMOXYTOL**

  Carbohydrate-coated,superparamagnetic iron oxide nanopaeticle mainly in treatment of anaemia of chronic kidney disease

- **IRON SUCROSE**

  Complex of ferric hydroxide with sucrose , Given by slow i.v inj/ infusion

Irrefutable evidence

iv SUCROSE

IV iron sucrose results in a much more rapid resolution of IDA and because it is administered intravenously, it circumvents the problems of compliance.

Am J Obstet Gynecol 2002;88:3-10.

Intravenous Ferric Carboxymaltose (FCM) Versus IV Iron Sucrose- or IV Iron Dextran in Treating Iron Deficiency Anemia in Women…… 2011

FCM

Ferric carboxymaltose injection

- Type I – robust iron
- No hypersensitivity
- Higher dose
- Short infusion time
- A test dose is not required
- Closest to the ideal iron

- Approved by UK-MHRA : Jul 2007
- Approved in 38 countries, 29 are in Europe*
- Approved by DCG(I) : Feb 2011

** Expert Opin Pharmacother, 18 Mar 2012a*

Ferric Carboxymaltose

- Macromolecular iron-hydroxide complex of polynuclear iron (III) hydroxide in a carbohydrate shell.

The iron hydroxide is tightly bound within a carbohydrate cage, hence does not relaease ‘ionic iron’ under physiological conditions.

- Structure similar to ferritin.

Macdougall IC and Ashenden M. Adv Chron Kid Dis 2009;16:117–130

Parenteral iron adverse reactions….towards safety

Preparation	Mild	hypersensitivity	Life threatening	Hypersensitivity per million dose
Iron dextran-	**50%**	**0.2-3%**	**0.6-0.7%**	**8.7**
Iron citric acid complex				
Iron Sucrose	**35%**	**0.005%**	**0.002%**	**2.6**
FCM	**15%**	**0.002%**	**NIL**	**1.5**

FCM : Safety

No test dose needed

No "black-box" warning

Allergic reactions :

1.5 cases/million/year

Rarely, minor adverse effects

Ferric carboxymaltose injection- FCM

Composition:

Each ml contains:

- Ferric Carboxymaltose equivalent to
- elemental Iron……50 mg per ml

Presentation:

- Vials of 10 ml [500 mg & 750 mg & 1K)

Storage:

- Store in the original package.
- Do not store above 30°C.
- Do not refrigerate or freeze

FCM BEFORE LAPAROSCOPIC SURGERY

4

5

- PREVNTT - LANCET

6

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PREOPERATIVE INTRAVENOUS IRON TO TREAT ANAEMIA BEFORE MAJOR ABDOMINAL SURGERY (PREVENTT)

Preoperative intravenous iron to treat anaemia before major abdominal surgery (PREVENTT): a randomised, double-blind, controlled trial

Toby Richards, Ravishankar Rao Baikady, Ben Clevenger, Anna Butcher, Sandy Abeysiri, Marisa Chau, Iain C Macdougall, Gavin Murphy, Rebecca Swinson, Tim Collier, Laura Van Dyck, John Browne, Andrew Bradbury, Matthew Dodd, Richard Evans, David Brealey, Stefan D Anker, Andrew Klein

Lancet 2020; 1353-61, September 4, 2020

PREVENTT

- **PRE**operative intra**VEN**ous iron **T**o **T**reat anaemia

∉ **Toby Richards, Ravishankar Rao Baikady, Ben Clevenger, Anna Butcher, Sandy Abeysiri, Marisa Chau, Iain C Macdougall, Gavin Murphy, Rebecca Swinson, Tim Collier, Laura Van Dyck, John Browne, Andrew Bradbury, Matthew Dodd, Richard Evans, David Brealey, Stefan D Anker, Andrew Klein**

Toby Richards

Affililation: Division of Surgery, University of Western Australia, Fiona Stanley Hospital, Perth, WA, Australia

STUDY PATTERN : PREVENTT

- a double-blind, placebo-controlled, randomised trial
- to compare the clinical effectiveness of intravenous iron therapy given to patients with anaemia
- 10–42 days before major open elective abdominal surgery.

HYPOTHICATION

- Hypothesised that intravenous iron would be superior to placebo with respect to patient outcomes of :
- blood transfusion,
- death, adverse events,
- and quality of life.

NOT JUST INCREASE OF Hb%

METHODS

- **STUDY DESIGN:**

  A Multicenter,doule-blind,parallel-group,randomised controlled trial

- **Participants:**

  487 adult participants with anemia before major open abdominal surgery at 46 UK tertiary care centers.

  Anemia was defined as hemoglobin less than 13 g/dl for men and 12g/dl

Intervention

Participants were randomly allocated(1:1) to receive a single 1000 mg dose of intravenous ferric caroxymaltose or a placebo (normal saline) 10-42 days before surgery

Unblinded study personnel prepared and administered the drug ,but participants and other clinical and research staff were blinded to treatment allocation.

DISCUSSION

Discussion

The use of intravenous iron in patients with anaemia before major open elective abdominal surgery increased haemoglobin concentrations before surgery but did not reduce the frequency of blood transfusion or mortality in the perioperative period relative to placebo. There was no reduction in the risk of postoperative in-hospital complications or length of hospital stay, and no benefits to quality of life. However, there was a reduced risk of

CONCLUSION

- Preoperative intravenous iron was not found to be superior to placebo in reducing the need for blood transfusion when administered 10-42 days before elective major surgery

IMPLICATIONS

- The study provides high-quqlity evidence suggesting that current guidance on preoperative iron therapy from bodies like NHS England and NICE should be revised.
- The evidence now suggests that preoperative iron therapy is not recommended for anemic patients undergoing major elective surgery

CONCLUSION

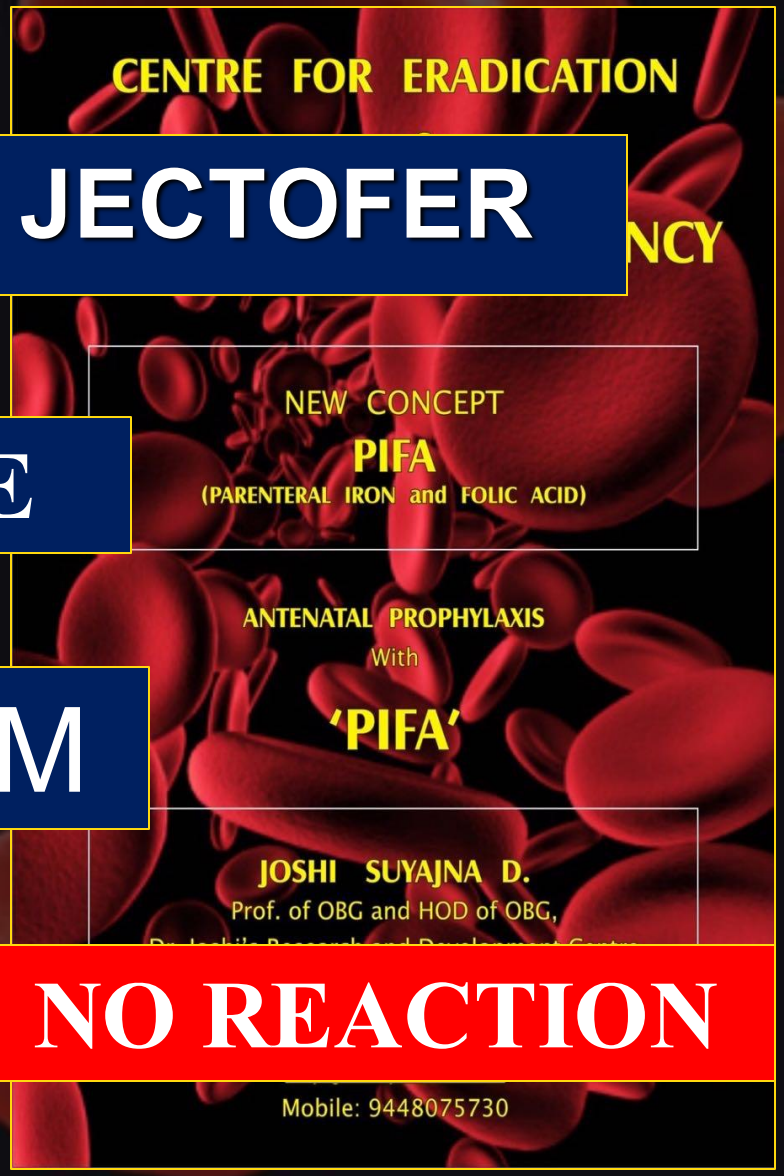
- PREVENTT showed that intravenous iron was **not superior to placebo** when administered to patients with anaemia 10–42 days before elective major abdominal surgery with respect to **reducing blood transfusion or death in the perioperative period.**

My experience with PARENETRAL IRON

1975 TO 2002 : IMFERON, JECTOFER

2002 TO 2012: IV SUCROSE

2012 TO 2025 : IV FCM



FROM ANAPHYLAXIS TO NO REACTION

VIMS EXPERIENCE

RCT - Imferon V/S I.V. SUCROSE (2006-2007)

Joshi Suyajna D. et al

Intravenous iron therapy in pregnancy:

Comparison between

I.V. Ferric Carboxymaltose and

I.V. Iron Sucrose.

SINGLE DOSE FCM… 1000 mg

Joshi Suyajna D

FERRIC CARBOXYMALTOSE : A SAFE AND EFFECTIVE ALTERNATIVE IN CORRECTING IRON DEFICIENCY ANEMIA PRIOR TO MAJOR ELECTIVE GYNECOLOGICAL SURGERIES

ejbps, 2016, Volume 3, Issue 11, 499-503. Research Article SJIF Impact Factor 3.881

EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
http://www.ejbps.com

ISSN 2349-8870
Volume: 3
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499-503
Year: 2016

FERRIC CARBOXY MALTOSE A SAFE AND EFFECTIVE ALTERNATIVE IN CORRECTING IRON DEFICIENCY ANEMIA PRIOR TO MAJOR ELECTIVE GYNECOLOGICAL SURGERIES

Dr. Suyajna D. Joshi[1] and Dr. Sangamesh Mathapati[2*]

Published in :EUROPEAN JOURNAL OF BIOMEDICAL AND PHARMACEUTICAL SCIENCES
DOI:2349-8870 VOL:3 ISSUE:11 499-503 Year-2016

Dr Suyajna D joshi and Dr. Sangamesh Mathapati

1) DR SUYAJNA JOSHI D.

- HOD and senior consultant in department of obstetrics and gynecology , District hospital - Ballari Karnataka.
- Retired HOD of department of obstetrics and gynecology in VIMS ,Ballari .
- Written chapters in 11 books and was the editor of FOGSI'S postgraduate obstetrics ,volume one and two.

TEACHER PAR EXCELLENCE

- Awarded the ANBAI senior teacher par excellence award 2024 in recognition of his contributions to DNB teaching program over the years

2) Dr. Sangamesh Mathapati

Assistant Professor, Department of Obstetrics and gynecology,
Shri B M patil Medical College , Vijayapur

OBJECTIVE

- To evaluate the effectiveness and safety of Ferric carboxymaltose in patients with iron deficiency anemia before undergoing major gynecological surgeries

METHODS AND MATERIALS

- **Study Type:** Single-group interventional study
- **Location:** Department of Obstetrics and Gynecology, VIMS Bellary.
- **Duration:** 10 months
- **Subjects:** 100 women with iron deficiency anemia scheduled for major gynecological surgeries

- **Inclusion Criteria:** Hemoglobin (Hb) levels between 6 gm% and 10 gm%
- **Intervention:** A single dose of 1000 mg of FCM was given to each subject in 200 ml of 0.9% normal saline over 20 to 30 minutes

- **Assessment:** Subjects were re-evaluated between 7 and 21 days after the infusion. Side effects and compliance were recorded.
- Data was entered into an excel sheet and analysed using SPSS software version 20.

RESULTS

- The most common reason for surgery was AUB(36%), followed by genital prolapse (20%),fibroid(19%), and pelvic inflammatory disease (19%).
- A statistically significant increase was observed in both HB and Serum Ferritin levels (2.28 gm% and 729.8 ng/ml,respectively).

Pre-intervention mean Hb: 8.41 gm%.

Pre-intervention mean s.ferritin:23.83ng/ml

Post –intervention mean Hb:10.69 gm%

Post-intervention mean s.ferritin:753.65 ng/ml

RESULTS

- All blood indices showed significant improvement after the intervention .
- There was clinical improvement in wellbeing.
- Minor side effects were experienced by 10% of the subjects , the pain being the most frequent (5 people)
- No serious adverse events were noted .

CONCLUSIONS: FCM before LAP

- Ferric carboxy maltose is a safe and effective alternative to blood transfusion for correcting iron deficiency anemia in short period before elective gynecological surgeries
- The study's findings are consistent with other studies and demonstrate that FCM is a potent and safe option.
- Using FCM,it is possible to transfuse 1000 mg of iron in single session safely ,making it a more cost-effective and patient –compliant form of parenteral iron preparation compered to exsting options .
- It also facilitates iron replacement and offers additional benefits for both the patient and the healthcare system.

CONCLUSIONS: FCM before LAP

- FCM is a safe and effective alternative to blood transfusion for correcting anemia quickly before surgery.
- FCM -improves recovery, reduces transfusion needs, and is cost-effective compared to other intravenous iron therapies

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IMPRESSIONS : FCM before LAP

- 1. Individualisation of cases is necessary
- 2. Willingness of the patient to wait for 3 to 4 weeks
- 3. Mindset of the Laparoscopic surgeon to wait
- 4. Feasibility of the Pathology to wait 3 to 4 weeks

WILD THINKINGS

A Cochrane review of iron therapy for preoperative anaemia was updated in December, 2019. This review concluded that the use of iron therapy for preoperative anaemia does not show a clinically significant reduction in allogeneic blood transfusion compared with no iron therapy but that further, well designed,

- **Is it necessary to increase the preoperative Hb% above 8 grams ???**

WILD THINKINGS

- **Is it necessary to increase the preoperative Hb% above 8 grams ???**

Most of the well conducted studies have shown
NO ADVANTAGE OF correction of anaemia –with respect to outcome of the surgery-
blood transfusions- complications ….

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THANK YOU

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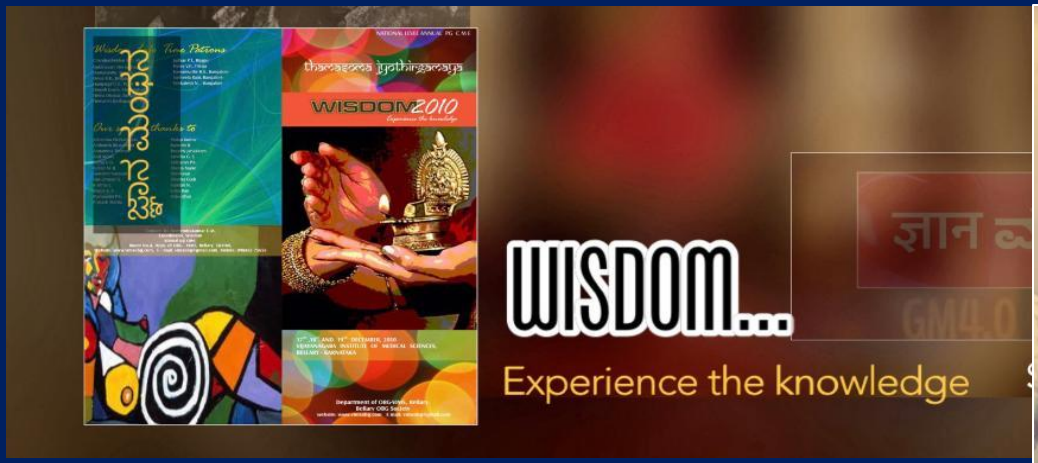

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