Iron Deficiency Anemia in Pregnancy

A Randomized Comparative Clinical Trial REB#21-64 HC6-24-c260086

Disclosures

• I have no relevant financial or non-financial relationships in the products described, reviewed, evaluated and compared in this presentation.

• I have no other conflicts of interest with the information provided in this presentation.

AND THE OWNER AND

Objectives

- Identify and describe Iron Deficiency Anemia in Pregnancy
- Determine treatment options for Iron Deficiency Anemia

- Explain the short and long term effects of Iron Deficiency Anemia for the mother and baby.
- Create awareness of the Iron Deficiency in Pregnancy Clinical Trial.

Iron Deficiency In Pregnancy

Contraction of the statement of the

- Iron deficiency anemia and iron deficiency (without anemia) are both widely undetected and under treated (upwards of 70 % or higher, depending on demographics)
- IDA affects quality of life, increases morbidity and mortality (of both mother and fetus)
- Associated with poor fetal outcomes (growth, neurological development, fetal iron deficiency)
- It is an underappreciated global health issue (WHO) and requires recognition of higher priority in developed and underdeveloped countries. Anemia in pregnancy is seen worldwide¹.

C. Standard



What Causes IDA?

- Nutritional deficiency: inadequate consumption of dietary iron
- Bleeding: pre-pregnancy (menses), chronic nose bleeds, bleeding disorders (ITP)
- Impaired absorption due to Irritable Bowel Disease(s), gastric surgery, celiac disease, autoimmune diseases or the use of proton pump inhibitors
- Pregnancy increases the need for iron, even higher amounts in multiples (twins or triplets) or pregnancies that are close together, or had borderline iron anemia prior to pregnancy (due to heavy menses, nose bleeds, clotting disorders, use of blood thinners).
- Frequent blood donor



Diagnosis

- Fatigue
- Palpitations
- Loss of breath
- Headache
- Cold intolerance
- Change in mood, depression
- Alopecia
- Nail changes
- Restless leg syndrome
- Eating disturbances: "Pica" or ice craving

LAND DE CONTRACTOR DE CONTRACT

Some signs and symptoms are missed opportunities to detect and treat anemia*

States and share and share



Why is IDA in Pregnancy so Different?

- Plasma volume expands 40-50% by the 30th week of pregnancy
- 20-30% increase in RBC mass
- If IDA is present, less erythrocyte production as consequence, maternal transfer of iron stores to the fetus further depletes iron stores. As the fetus and placenta grow, higher demands exist. This further increases IDA.



Delivery and Beyond

- Delivery: blood loss ranges from 250mls to over 1000 mL- generates further IDA state
- Blood loss may be underestimated during delivery
- If iron deficiency is present, there is an increased risk of post partum hemorrhage (PPH) and further complications including prolonged recovery.
- <u>Consequential</u>: IDA, with increased demands on red cells (heme), cardiac output during delivery (oxygen requirements ↑), increases the risk of PPH, which in turn can result in a medical emergency, low blood pressure, and maternal/fetal demise.



Potential Impacts of IDA

Maternal

- Decreased Cognition/slower thought processes
- Less able to concentrate/pay attention
- Increased incidence of preterm delivery

Charles and the State of the Party of the Pa

- Increased risk of maternal infection
- Maternal depression, post partum depression
- Delayed maternal/fetal bonding (potential consequence)

Fetal

- Increased incidence of preterm delivery
- Intrauterine growth restriction
- Intrauterine demise
- Fetal infection
- Delayed growth and development after birth
- Impaired Neurological development (lifelong)



Oral Iron Treatment (First choice)

- Less than 12 weeks GA: 30-60 mg of elemental iron is required/day (dietary allowance/day)
- Different types of oral iron:
 - Iron salts (cheap, easy to to get OTC), FG: 300 mg = 35 mg elemental iron, FS: 300 mg = 60 mg of elemental iron
- Ferrous Fumerate 300 mg = 100 mg elemental iron (costly)
 - Feramax 150 mg = 150 mg elemental iron (costly)
- Prenatal Vitamin 27 mg elemental iron
- Example: 300 mg of Fe = 35 mg of elemental iron = 4 mg absorbed by the body



56Fe, Fe56, Fe-56, iron isotope of mass 56





Supplement Facts	Supplement Facts	
Serving Size: 1 Tablet Amount per Tablet % Daily Value	Serving Size 1 Tablet Servings Per Container 100	
Iron (as formus sulfato) 65 mg 260%	Each Tablet Contains % Daily Value	
from (as remous suitate) os mg 300%	Iron from 324 mg or Ferrous Gluconate) 37.5 mg 208%	
SUGGESTED USE: Adults: One (1) tablet daily preferably after meals or as directed by the doctor. Children: As directed by the doctor. EACH TABLET CONTAINS: % U.S. RDA* Elemental Iron 65 mg 360 (Equivalent to 325 mg of Ferrous Sulfate) *U.S. Recommended Daily Allowance	Other Ingredients: Microcrystalline Cellulose, Croscarmellose Sodium Hydroxypropyl Methylcellulose, Titanium Dioxide, Triacetin, Magnesium Stearate, Polydextrose, Silicon Dioxide, Riboflavin, Blue #1 Lake, Rei #40 Lake. Directions: As a dietary supplement, take one tablet daily with a meal, o as directed by your healthcare professional.	
INACTIVE INGREDIENTS: croscarmellose sodium, dicalcium phosphate, FD&C red #40 (AI-lake), FD&C yellow #6 (AI-lake), hypromellos magnesium stearate, microcrystalline cellulose, PEG 400, titanium dioxide	Ferrous Gluconate may help treat iron deficiency.f †This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.	
WARNING: Accidental overdose of iron- containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or Poison	WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or a poison control center immediately.	
Control Center immediately.	Git	

Oral Iron Adverse Effects

- Ferrous Fumerate: 47%
- Ferrous Gluconate: 31%
- Ferrous Sulfate: 32%

Nausea Vomiting Diarrhea/constipation



Case Study

- 32 year old patient, 65 kg
- 10 weeks GA
- 2nd pregnancy in 18 months
- Hgb 115
- TSAT 22%, TIBC 108%
- Serum Ferritin 30
- Feels tired, no nausea or vomiting reported, otherwise well
- Vegetarian

What treatment can you anticipate?

and the state of the

Calculated iron deficit= Ganzoni formula or by simplified table
Total Fe deficit (mg)=[wt (kg) x (target hgb-actual Hgb) x 0.24)]+500

=[(65)x (130-115) x2.4] + 500

=2840 mg (44 mg iron per kg of body weight)

Oral iron?

100-200 mg elemental iron daily (2-3 divided doses)

Ferrous gluconate 37.5 mg per tablet (3 times per day= 112.5



IV Iron in Pregnancy

- Iron Sucrose IV (current standard of practice), off label use for treatment of IDA in pregnancy
- Iron Sucrose: Maximum dose 300 mg up to 1000 mg per week
- Iron Isomaltoside/ferric derisomaltose: 1000 mg one dose, may be repeated x 1 if needed (criteria for use, not included in Sask Formulary: Ministry of Health)
- Requires monitoring of blood work (serum ferritin, TIBC/TSAT, iron) during and following treatment- monitor for iron toxicity
- In pregnancy, fetal bradycardia has been noted with iron infusions. Pre-infusion fetal heart rate, and post infusion fetal heart rate must be monitored and documented
- Fishbane reaction



IV Iron in Pregnancy

- "Fishbane" reaction: chest discomfort, abdominal pain, redness/flushing have been noted in pregnancy. MUST infuse slowly for the first 15 minutes (half rate), recommended to infuse over 1 hour.³
- DON'T mix formulations of IV iron to complete the total dose calculated. Due to differing molecular formulas, this increases the risk of reactions/adverse events and fishbane reactions.
- Report all adverse events/potential adverse events and near misses
- Ferric Derisomaltose requires a 30 day post infusion blood work requisition, if iron remains low, further doses must be considered.



IV Iron in Pregnancy

Iron Sucrose 20 mg elemental iron/mL (typical dose of 300 mg up to 3 times/week) Ferric Derisomaltose: 100 mg/mL elemental iron (typical dose 1000 mg one time)

Remember our patient? 32 years old 68 kg Third trimester= 32 weeks GA Hgb 95, TSAT 6%, TIBC 125%, serum ferritin 4

Treatment of choice? Or only option?

A CONTRACT OF THE PARTY OF THE



Treatment Options

- Calculated Iron Deficit=1071 mg (1100 mg) of elemental iron
- Standard treatment of iron sucrose in divided doses= 300 mg x3 doses, 200 mg x 1 dose.
- Each dose appointment is 3 hours start to finish

- Ferric derisomaltose 1000 mg x 1 dose. Appointment is 1.5 hours start to finish. 30 minutes observation following infusion.
- Costly to administer- Operational Approval, cost for clinical trial covered by Mat/Child portfolio



Feasibility

Patient	System
Time away from work	Staffing/OT as per CBA
Childcare	Chair time
Financial impact (missed work/parking/transportation) Geographical challenges (travel/weather, \$)	Admin time (booking/scheduling)
Administration risk	Equipment \$\$\$
	Administration of drug-risk

What is the cost of proactive care?

VS

The cost of neonatal ICU care, length of stay for mom, delayed discharge for need for transfusion and iron dosing (iron sucrose), post partum depression, delayed bonding and maternal fatigue?

Take-away(s)!



Pregnancy requires higher doses of elemental iron: Supply and Demand A car with an empty gas tank cannot travel.

All IV iron infusions are safer than older formulations (Dextran).

Basic IV medication administration, no further educational learning required. Diligence, vigilance and routine observations are necessary upon administration.





Infuse slowly at half rate for the first 15 minutes to minimize adverse reactions.

Fishbane: Anxiety increases the potential for reactions (provider anxiety and patient anxiety)

Follow protocols for adverse reactions, medical emergencies (know who to call and when to call)

Every patient is everyone's patient. When we treat the pregnant mom we are also treating the baby. What we treat and don't treat has a downstream effect on the patient and outcomes. Care of one patient can determine the care provided to the other.





References

- 1. World Health Organization. The urgent need to implement patient blood management: policy brief. World Health Organization 2021. 25. ISBN 978-92-4-003574-4 (electronic version).
- 2. Society for the Advancement of Blood Management, Inc. SABM; 2020. Iron Corner: Approach to the iron deficient patient. Available from: www.sabm.org/iron-corner
- 3. National Health Service Wales:Cardiff and Vale University Health Board. Anaemia Guideline for Maternity Care in Cardiff and Vale University Health Board. NHS Wales: November 2019. 17.
- 4. Ziola, Kirsti et al, Iron Deficiency in Pregnancy: A commonly unrecognized problem: Poster presentation, Saskatchewan Health Authority 2018.

LEND BERTHERE BUT BUT AND A ALLE OF THE



Thank you to our Clinical Trial Sponsors:

Saskatchewan Centre for Saskatchewan Centre for Patient-Oriented Research





Questions?

<u>Alicia.hanowski@saskhealthauthority.ca</u> Ext 3134





Saskatchewan Health Authority



