IRON DEFICIENCY ANEMIA
– THE NEPHROLOGY PERSPECTIVE

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King’s College Hospital, London, UK
DISCLOSURES

Research support: Akebia, Astellas, GSK, Vifor Pharma

Speaker fees: Akebia, Astellas, FibroGen, GSK, Vifor Pharma

Consultancy fees: Akebia, AMAG, Astellas, GSK, Vifor Pharma
ANEMIA AND IRON DEFICIENCY

- Anemic, iron-deficient
- Anemic
- ID-Anemia
- Iron Deficiency (without anemia)
- Normal

References:
CKD – IMPACT ON IRON DEFICIENCY AND ANEMIA

GFR

Iron deficiency (hepcidin levels)

Anemia
WHY DO CKD PATIENTS BECOME IRON-DEFICIENT?

REDUCED INTAKE
- Poor appetite
- Poor G-I absorption
- Concurrent medication
  - e.g. omeprazole
- Food interactions

INCREASED LOSSES
- Occult G-I losses
- Peptic ulceration
- Blood sampling
- Dialyser losses
- Concurrent meds.
  - e.g. aspirin
- Heparin on dialysis
CKD -- 3 Case Studies

Case study 1: ND-CKD with IDA – oral vs. IV iron?

Case study 2: ND-CKD with ID & HF – oral vs. IV iron?

Case study 3: HD – IV iron, how much?
CASE STUDY 1

• A 48-year-old woman with progressive renal impairment due to reflux nephropathy attends your Nephrology Clinic

• She tells you that she feels more and more tired and weak, especially climbing stairs and looking after her two young children
CASE STUDY 1 (cont’d)

• You note that her Hb has been gradually falling, although it has generally been in the range of 10–11 g/dL

Results from latest clinic visit

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>eGFR</td>
<td>26 mL/min</td>
</tr>
<tr>
<td>Hb</td>
<td>9.8 g/dL (previously 9.9 g/dL)</td>
</tr>
<tr>
<td>Serum ferritin</td>
<td>41 µg/L</td>
</tr>
<tr>
<td>Serum CRP</td>
<td>7 mg/L</td>
</tr>
<tr>
<td>Serum B12</td>
<td>Normal (160–925 ng/L)</td>
</tr>
<tr>
<td>Serum folate</td>
<td>Normal (3–13 µg/L)</td>
</tr>
<tr>
<td>TSAT</td>
<td>20%</td>
</tr>
</tbody>
</table>
How would you treat this patient?

1. Oral iron alone
2. IV iron alone
3. Oral iron and ESA
4. IV iron and ESA
5. ESA alone
6. Continue to monitor for the time being

Parameter Value

- eGFR 26 mL/min
- Hb 9.8 g/dL (previously 9.9 g/dL)
- Serum ferritin 41 µg/L
- Serum CRP 7 mg/L
- Serum B12 normal (160–925 ng/L)
- Serum folate normal (3–13 µg/L)
- TSAT 20%

Chapter 2: Use of iron to treat anemia in CKD

TREATMENT WITH IRON AGENTS

2.1.1: When prescribing iron therapy, balance the potential benefits of avoiding or minimizing blood transfusions, ESA therapy, and anemia-related symptoms against the risks of harm in individual patients (e.g., anaphylactoid and other acute reactions, unknown long-term risks) (Not Graded)

2.1.2: For adult CKD patients with anemia not on iron or ESA therapy we suggest a trial of IV iron (or in CKD ND patients alternatively a 1-3 month trial of oral iron therapy) if (2C):

- an increase in Hb concentration without starting ESA treatment is desired
- TSAT is ≤30% and ferritin is ≤500 ng/ml (≤500 µg/l)
FIND-CKD: a randomized trial of intravenous ferrous carboxymaltose versus oral iron in patients with chronic kidney disease and iron deficiency anaemia

Iain C. Macdougall, Andreas H. Bock, Fernando Carrera, Kai-Uwe Eckardt, Carlo Gaillard, David Van Wyck, Bernard Roubert, Jacqueline G. Nolen and Simon D. Roger on behalf of the FIND-CKD Study Investigators

1Department of Renal Medicine, King’s College Hospital, Denmark Hill, London SE5 9RS, UK, 2Department of Nephrology, Kantonsspital Aarau, Aarau, Switzerland, 3Eurodial, DaVita, Leiria, Portugal, 4Department of Nephrology and Hypertension, University of Erlangen-Nürnberg, Erlangen, Germany, 5Department of Nephrology, University Medical Centre Groningen, University of Groningen, Groningen, the Netherlands, 6DaVita Healthcare Partners Inc., Denver, CO, USA, 7Vifor Pharma, Glattbrugg, Switzerland and 8Renal Research, Gosford, NSW, Australia

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"Members of the Ferinject assessment in patients with iron deficiency anaemia and Non-Dialysis-dependent..."
**FIND-CKD STUDY**

- **Eligible patients**
  - ND-CKD
  - No ESA (last 4 months)
  - No intolerance/ GI AEs with oral iron
  - Hb 9–11 g/dL
  - Serum ferritin <100 µg/L or Serum ferritin <200 µg/L + TSAT <20%

- **Week 56**
  - **Primary endpoint:**
    - Time to initiation of an alternative treatment for anaemia or
    - Occurrence of a Hb trigger
  - **Secondary endpoints included:**
    - % patients with increase of Hb ≥1 g/dL
    - Change in haematological and iron indices

- **IV FCM**
  - 1000 mg iron*
    - Then every 4 weeks as needed
    - Serum ferritin target: 400–600 µg/L
  - 200 mg iron
    - Then every 4 weeks as needed
    - Serum ferritin target: 100–200 µg/L

- **Oral ferrous sulfate**
  - (200 mg iron/day)
  - Anaemia management as per local practice if required after week 8

FIND-CKD STUDY -- MEAN HB INCREASE

Mean Hb (g/dL) vs Time (weeks)

- FCM targeting a ferritin of 400-600µg/L
- FCM targeting a ferritin of 100-200µg/L
- Oral iron

* p<0.001 compared with oral iron
** p<0.01 compared with oral iron
*** P<0.05 compared with oral iron

MEDIAN TIME TO FIRST RESPONSE (DAYS)
(Hb ≥ 1 g/dL from baseline)

HB RESPONSE RATE AT WEEK 4
(Hb ≥ 1 g/dL from baseline)

Response rate at Week 4 (% patients)

- High ferritin FCM: 40.9
- Low ferritin FCM: 13.9
- Oral iron: 21.6

n/N: 61/149, 20/144, 63/292

% Patients achieving an HB response by Week 8

(Hb ≥ 1 g/dL from baseline)

High-ferritin FCM vs. Oral iron
HR: 2.04; 95% CI: 1.52, 2.72; P<0.001

THE PATIENT RECEIVES 1000 MG OF FERRIC CARBOXYMALTOSE
CKD -- 3 Case Studies

Case study 1
ND-CKD with IDA – oral vs. IV iron?

Case study 2
ND-CKD with ID & HF – oral vs. IV iron?

Case study 3
HD – IV iron, how much?
CASE STUDY 2

• A 67-year-old man with NYHA class III systolic HF (EF 31%) and known renal impairment (eGFR 58 ml/min) attends your clinic, and complains of increasing breathlessness and reduced exercise capacity

• You increase his dose of loop diuretics
CASE STUDY 2 (cont’d)

- You receive the following laboratory results back the next day

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<tr>
<td>Hb</td>
<td>12.9 g/dL</td>
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<tr>
<td>Serum ferritin</td>
<td>52 µg/L</td>
</tr>
<tr>
<td>Serum CRP</td>
<td>&lt;2.0 mg/L</td>
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<td>TSAT</td>
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HOW WOULD YOU TREAT THIS PATIENT WITH CRS?

1. Oral iron alone
2. IV iron alone
3. Continue to monitor for the time being

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How would you treat this patient?

Stefan Anker will tell you!
CKD -- 3 Case Studies

Case study 1

ND-CKD with IDA – oral vs. IV iron?

Case study 2

ND-CKD with ID & HF – oral vs. IV iron?

Case study 3

HD – IV iron, how much?
CASE STUDY 3

- 55-year-old man
- ESRF due to ischemic/hypertensive nephropathy
- NSTEMI 3 years ago
- Mild stroke 5 months ago
- On HD for 8 months
- Rx IV EPO 4000 units x3/wk + IV Venofer 100 mg/month

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<td>Hb</td>
<td>9.2 g/dL (previously 9.8 g/dL)</td>
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<tr>
<td>Serum ferritin</td>
<td>478 µg/L</td>
</tr>
<tr>
<td>Serum CRP</td>
<td>18 mg/L</td>
</tr>
<tr>
<td>TSAT</td>
<td>19%</td>
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</table>
HOW WOULD YOU TREAT THIS PATIENT?

1. Increase his dose of EPO to 8000 units x3/week
2. Increase his dose of IV iron
3. Both 1 and 2

4. Stop dialysis since there is currently no quality of life for the citizens of the UK

• Rx IV EPO 4000 units x3/wk + IV Venofer 100 mg/month

Parameter | Value
---|---
Hb | 9.2 g/dL (previously 9.8 g/dL)
Serum ferritin | 478 µg/L
Serum CRP | 18 mg/L
TSAT | 19%
Ferric Gluconate Is Highly Efficacious in Anemic Hemodialysis Patients with High Serum Ferritin and Low Transferrin Saturation: Results of the Dialysis Patients’ Response to IV Iron with Elevated Ferritin (DRIVE) Study

Daniel W. Coyne,* Toros Kapoian,† Wadi Suki,‡ Ajay K. Singh,§ John E. Moran,‖ Naomi V. Dahl,¶ and Adel R. Rizkala;‖ the DRIVE Study Group
DRIVE STUDY

Coyne et al. JASN 2007; 18: 975-984.
MANAGEMENT OF CKD ANEMIA

- ESA therapy
- IV iron
Intravenous Iron in Patients Undergoing Maintenance Hemodialysis


Proactive IV iron Therapy in haemodialysis
Iron management in chronic kidney disease: conclusions from a “Kidney Disease: Improving Global Outcomes” (KDIGO) Controversies Conference

Iain C. Macdougall¹, Andreas J. Bircher², Kai-Uwe Eckardt³, Gregorio T. Obrador⁴, Carol A. Pollock⁵,⁶, Peter Stenvinkel⁷, Dorine W. Swinkels⁸, Christoph Wanner⁹, Günter Weiss¹⁰, and Glenn M. Chertow¹¹; for Conference Participants¹,²

¹Department of Renal Medicine, King’s College Hospital, London, UK; ²Allergy Unit, Dermatology Clinic, University Hospital Basel, Basel, Switzerland; ³Department of Nephrology and Hypertension, Friedrich-Alexander-Universität Erlangen-Nürnberg, Erlangen, Germany; ⁴Universidad Panamericana School of Medicine, Mexico City, Mexico; ⁵University of Sydney, Sydney, Australia; ⁶Royal North Shore Hospital, Sydney, Australia; ⁷Division of Renal Medicine, Department of Clinical Science, Intervention and Technology, Karolinska University Hospital, Stockholm, Sweden; ⁸Department of Laboratory Medicine, Translational Metabolic Laboratory, Radboud University Medical Center, Nijmegen, the Netherlands; ⁹Renal Division, University Hospital of Würzburg, Würzburg, Germany; ¹⁰Department of Internal Medicine VI, Infectious Disease, Immunology, Rheumatology, Pneumology, Medical University of Innsbruck, Innsbruck, Austria; and ¹¹Division of Nephrology, Stanford University School of Medicine, Palo Alto, California, USA

Increased oxidative stress
Increased atherogenesis
CV toxicity
Inflammation
Immune dysfunction
Cellular toxicity
Increased infections
Data from the Dialysis Outcomes and Practice Patterns Study validate an association between high intravenous iron doses and mortality

George R. Bailie¹, Maria Larkina², David A. Goodkin², Yun Li²³, Ronald L. Pisoni², Brian Bieber², Nancy Mason⁴, Lin Tong², Francesco Locatelli⁵, Mark R. Marshall⁶, Masaaki Inaba⁷ and Bruce M. Robinson²³

¹Department of Pharmacy Practice, Albany College of Pharmacy and Health Sciences, Albany, New York, USA; ²Arbor Research Collaborative for Health, Ann Arbor, Michigan, USA; ³Department of Biostatistics, University of Michigan, Ann Arbor, Michigan, USA; ⁴College of Pharmacy, University of Michigan, Ann Arbor, Michigan, USA; ⁵Department of Nephrology and Dialysis and Renal Transplant, Alessandro Manzoni Hospital, Lecco, Italy; ⁶Department of Renal Medicine, Middlemore Hospital, Faculty of Medical and Health Sciences, University of Auckland, Auckland, New Zealand and ⁷Department of Metabolism, Endocrinology and Molecular Medicine, Osaka City University Graduate School of Medicine, Osaka, Japan
ASSOCIATIONS BETWEEN IV IRON DOSE AND MORTALITY

Hazard Ratio (95% CI)

HR for ACM per 100 mg/mo higher =1.02 (95% CI=1.00-1.05), p=0.05

ASSOCIATION BETWEEN IV IRON AND ALL-CAUSE/CV MORTALITY

**Trial Design**

**Proactive, high-dose IV iron arm (n=1093)**

- IV iron 400 mg/month (withhold if ferritin >700 µg/L; TSAT >40%)

**Reactive, low-dose IV iron arm (n=1048)**

- IV iron only administered if ferritin <200 µg/L or TSAT <20%

**Screening:**
- ≤4 weeks

**Follow-up period with monthly visits**

**Median (maximum) follow-up:** 2.1 (4.4) years

≥631 primary endpoint events (i.e., all-cause mortality, MI, stroke, or HF hospitalization)
**Primary endpoint**
- Time to all-cause death or a composite of non-fatal cardiovascular events (MI, stroke, and HF hospitalisation) -- adjudicated by a blinded Endpoint Adjudication Committee

**Secondary endpoints**
- Incidence of all-cause death and a composite of myocardial infarction, stroke, and hospitalisation for heart failure as recurrent events.
- Time to (and incidence of) all-cause death
- Time to (and incidence of) composite cardiovascular event
- Time to (and incidence of) myocardial infarction
- Time to (and incidence of) stroke
- Time to (and incidence of) hospitalisation for heart failure
- ESA dose requirements
- Transfusion requirements
- EQ-5D QOL and KDQOL
- Vascular access thrombosis
- All-cause hospitalisation
- Infections; hospitalisation for infection
**Network of Sites**

**England**
Queen Elizabeth Hospital, Birmingham; Heartlands Hospital, Birmingham; Royal Free, London, King’s College Hospital, London; Guy’s & St Thomas’, London; St Helier, Surrey; St George’s, London; Royal Liverpool Hospital, University Hospital Aintree; Sheffield Teaching Hospital; Lister Hospital, Stevenage; Salford Royal Hospital, Manchester; Manchester Royal Hospital; Queen Alexandra Hospital, Portsmouth; Kent & Canterbury Hospital, Leicester General Hospital, Hull Royal Infirmary; Freeman Hospital, Newcastle; Churchill Hospital, Oxford; University Hospital of North Staffordshire, Stoke-on-Trent; Southmead Hospital, Bristol; Royal Cornwall Hospital; Nottingham City Hospital; Norfolk & Norwich Hospital; New Cross Hospital, Wolverhampton; Royal London Hospital; Wirral University Teaching Hospital; Royal Shrewsbury Hospital, Royal Devon & Exeter Hospital, Royal Preston Hospital, St James’ Hospital, Leeds; Hammersmith Hospital, London; Royal Sussex Hospital, Brighton; Bradford Teaching Hospital; Coventry University Hospital; Southend University Hospital; Gloucestershire Royal Hospital; Derriford Hospital, Plymouth; Royal Berkshire, Reading

**Wales**
Morriston Hospital, Swansea; University Hospital, Cardiff

**Scotland**
Western Infirmary, Glasgow; Victoria Hospital, Kirkcaldy; Ninewells Hospital, Dundee; Royal Edinburgh Hospital

**N. Ireland**
Belfast City Hospital, Antrim Area Hospital; Daisy Hill Hospital, Newry; Altnagelvin Hospital, Derry
Cumulative Iron Dose

Median cumulative doses at 1 year: 3.8 g vs 1.8 g

Median monthly doses: 264 mg vs 145 mg

Proactive, high-dose iron

Reactive, low-dose iron

P<0.001
Transferrin Saturation

**Proactive, high-dose iron**

**Reactive, low-dose iron**

$P < 0.001$

(Treatment effect)
Cumulative ESA Dose

Proactive, high-dose iron

Reactive, low-dose iron

Median monthly doses reduced by 19.4%

P < 0.01

Mean Cumulative ESA Dose (1000 IU)

Time from Randomization (months)
Death, MI, Stroke, or HF Hospitalization (Primary Endpoint)

Hazard ratio, 0.85 (95% CI, 0.73–1.00)
Noninferiority $P<0.001$
Superiority $P=0.04$
Primary Endpoint Components as Recurrent Events

Rate ratio, 0.77 (95% CI, 0.66–0.92)

$P=0.0027$
Death from Any Cause

Hazard ratio, 0.84 (95% CI, 0.71–1.00)  
$P=0.054$
## Cardiovascular Events

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Proactive, High-Dose IV Iron (N=1093) n (%)</th>
<th>Reactive, Low-Dose IV Iron (N=1048) n (%)</th>
<th>Hazard Ratio (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatal or nonfatal MI, fatal or nonfatal stroke, or hospitalization for HF</td>
<td>149 (13.6)</td>
<td>168 (16.0)</td>
<td>0.80 (0.64–1.00)</td>
<td>0.049</td>
</tr>
<tr>
<td>Fatal or nonfatal MI</td>
<td>78 (7.1)</td>
<td>102 (9.7)</td>
<td>0.69 (0.52–0.93)</td>
<td>0.015</td>
</tr>
<tr>
<td>Fatal or nonfatal stroke</td>
<td>34 (3.1)</td>
<td>35 (3.3)</td>
<td>0.90 (0.56–1.44)</td>
<td>0.663</td>
</tr>
<tr>
<td>Hospitalization for HF</td>
<td>51 (4.7)</td>
<td>70 (6.7)</td>
<td>0.66 (0.46–0.94)</td>
<td>0.023</td>
</tr>
</tbody>
</table>
Blood Transfusions

Hazard ratio, 0.79 (95% CI, 0.65–0.95)
P=0.014
## Safety

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Proactive, High-Dose IV Iron (N=1093) n (%)</th>
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<th>Hazard Ratio (95% CI)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Vascular access thrombosis</td>
<td>262 (24.0)</td>
<td>218 (20.8)</td>
<td>1.15 (0.96–1.38)</td>
<td>0.12</td>
</tr>
<tr>
<td>All-cause hospitalization</td>
<td>651 (59.6)</td>
<td>616 (58.8)</td>
<td>1.01 (0.90–1.12)</td>
<td>0.90</td>
</tr>
<tr>
<td>Hospitalization for infection</td>
<td>323 (29.6)</td>
<td>307 (29.3)</td>
<td>0.99 (0.82–1.16)</td>
<td>0.92</td>
</tr>
<tr>
<td>Infection episodes</td>
<td>508 (46.5)</td>
<td>477 (45.5)</td>
<td>0.98 (0.87–1.11)</td>
<td>0.80</td>
</tr>
</tbody>
</table>

Proactive, High-Dose Better

Reactive, Low-Dose Better
Conclusions

High-dose iron:-

• Significantly reduced the risk of the primary outcome of death or non-fatal CV events

• Reduced the risk of MI and hospitalisation for HF

• Was associated with a significant benefit in a recurrent event analysis

• Reduced ESA dose (19.4%) and transfusion rate (21%)

• Did not cause an increased risk of infection or hospitalization
MANAGEMENT OF CKD ANEMIA

- ESA therapy
- IV iron
## SUMMARY

<table>
<thead>
<tr>
<th>Clinical scenario</th>
<th>Evidence for oral iron benefit</th>
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<tbody>
<tr>
<td>Chronic HF</td>
<td></td>
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<td></td>
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<tr>
<td>Chronic HF with renal impairment</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>CKD (GFR &lt; 60) + IDA</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>CKD + ID alone (not anemic)</td>
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<tr>
<td>Hemodialysis</td>
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</tr>
<tr>
<td>Chronic HF</td>
<td>None</td>
<td>++++</td>
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</tr>
<tr>
<td>Chronic HF with renal impairment</td>
<td>None</td>
<td>++</td>
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</tr>
<tr>
<td>CKD (GFR &lt; 60) + IDA</td>
<td>+</td>
<td>++</td>
<td>FIND-CKD</td>
</tr>
<tr>
<td>CKD + ID alone (not anemic)</td>
<td>None</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Hemodialysis</td>
<td>None</td>
<td>++++</td>
<td>PIVOTAL</td>
</tr>
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