Health care resource use associated with ferric maltol and IV iron treatment for iron deficiency anaemia in patients with inflammatory bowel disease

P685

Stefanie Howaldt[1], Ian Jacob[2], Mark Sampson[3], Fatma Akriche[4]

[1]MZV für Immunologie, Hamburg, Germany; [2]Health Economics and Outcomes Research Ltd, Cardiff, United Kingdom; [3]Shield Therapeutics PLC, London, United Kingdom; [4]Norgine Ltd, Rueil Malmaison, France.

Background

Iron deficiency anaemia (IDA) is common in patients with inflammatory bowel disease (IBD). IDA imposes a substantial economic burden on health care payers resulting primarily from increased medical costs and increased rates of hospital admission.[1]

Most guidelines recommend oral iron as first-line treatment for IDA, with intravenous (IV) iron infusion if oral treatment is ineffective or poorly tolerated.[2] Owing to the risk of hypersensitivity reactions, IV iron must be administered in a setting where full resuscitation facilities are available.[3] Patients should be observed for at least 30 minutes after administration.[3]

Intolerance to ferrous (Fe^{2+}) oral iron is common, due to oxidation of unabsorbed iron and consequent damage to the gastrointestinal (GI) tract from reactive oxygen species.[4,5] Ferric maltol (FM), a stable oral complex of ferric (Fe^{3+}) iron and maltol, is designed to reduce exposure to elemental iron and thus limit GI damage.[5] It is approved in the EU for the treatment of iron deficiency in adults.[6]

In order to understand the economic impact of treatment with oral FM versus IV iron (ferric carboxymaltose [FCM]), this post hoc exploratory analysis compared the associated health care resource use (HCRU) using data from a randomised controlled trial (NCT02680756).[7]

Trial design and primary findings

Patients with IBD and IDA (haemoglobin [Hb] ≥8.0 g/dL and ≤11.0 g/dL for women or ≥8.0 g/dL and ≤12.0 g/dL for men, and ferritin <30 ng/mL or ferritin <100 ng/mL with transferrin saturation <20%) were randomised to FM (30 mg b.d.) or IV FCM (as per local Summary of Product Characteristics [SmPC] or prescribing information) in an open-label, Phase 3b non-inferiority study. The primary endpoint was Hb responder rate (proportion of patients achieving a ≥2 g/dL increase or normalisation of Hb at week 12).

250 patients were randomised: 125 to FM (per-protocol [PP] n=86) and 125 to IV FCM (PP n=92). The Hb responder rate for oral FM was non-inferior to IV FCM in the PP population (74% vs 83%); risk difference was -0.1 (two-sided p=0.017; 95% CI -0.2, 0.0), within the pre-defined non-inferiority margin of 20% difference.

Methods

Analysis of healthcare resource use

FCM dosing is based on weight and Hb level, set out in an algorithm in the SmPC/prescribing information. A single administration should not exceed 1000 mg of iron (20 mL FCM) or 20 mg iron/kg bodyweight.[3] Thus, patients may require more than one administration to complete their initial treatment, or if initial treatment is not sufficiently effective.

HCRU was assessed based on the total costs of iron therapy (drug plus administration costs), in a post hoc analysis of individual patient data from the Phase 3b trial up to the primary endpoint assessment at week 12. Costs were calculated for a German setting.

IV iron (FCM)

- Administration costs were based on the number of clinic visits made to receive IV iron. Scheduled study visits were only counted if the patient received IV iron at the visit. Administration cost was calculated based on 15 minutes of health care provider time, costed at €12.65.[8]
- Drug acquisition cost per mg of IV iron was calculated using the German list price for FCM (€141.88 per 500 mg iron) giving a cost per mg of €0.284.[9]
- Total per-patient treatment costs were calculated as: (Number of visits * 12.65) + (Total dose * 0.284).

Ferric maltol

- The acquisition cost of FM was calculated per capsule, based on a list price of €94.57 per pack of 56 30 mg capsules, giving a price per capsule of €1.69.[9] FM is a self-administered oral treatment and therefore does not incur administration costs.
- The mean daily dose of FM for the 12-week period was calculated using compliance data based on dispensing and capsule return records (number taken = number dispensed - number returned).
- Total per-patient treatment costs were calculated as: (number of capsules taken) * (price per capsule).

Results

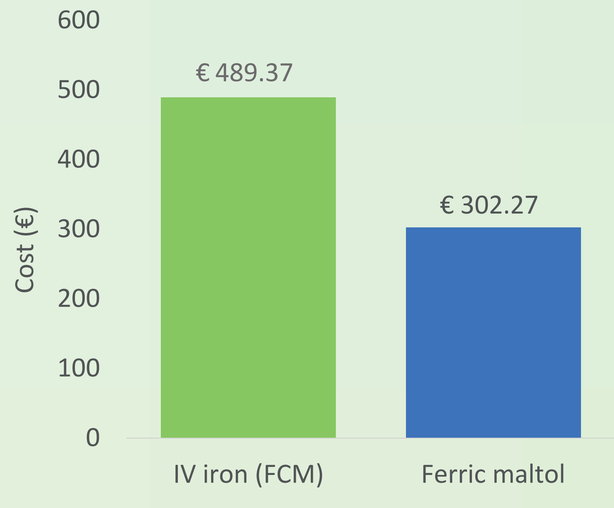
- HCRU data were analysed for 125 and 119 patients in the FM and IV FCM arms respectively, based on data availability for the required time points. At week 12, 87% of FM patients were still receiving treatment. In the IV FCM arm, 45% and 36% required a repeat dose at weeks 4 and 12 respectively.
- Patients made a mean of 2.30 visits for IV iron treatment during the 12-week period, and the mean total dose of IV FCM received was 1621 mg (Table 1). Patients in the FM arm used a mean of 179 tablets (Table 1).
- Drug acquisition costs were higher in patients treated with IV FCM (mean €460.24 per patient) than with FM (mean €302.27 per patient). In addition, patients in the IV FCM arm incurred a mean of €29.09 in administration costs, whereas there was no such cost with FM.
- Mean total treatment costs per patient were higher in the IV FCM arm than the FM arm, at €489.37 and €302.27, respectively (Table 1; Figure 1).

Table 1: Drug acquisition and administration costs for IV iron and ferric maltol up to week 12

Total (per patient)	IV iron (FCM)	Ferric maltol
Treatment visits (n)		
Mean (SD)	2.30 (0.88)	NA
Median (IQR)	2 (2-3)	NA
Administration cost (€)		
Mean	29.09	NA
Median	25.30	NA
IV iron dose (mg)		
Mean (SD)	1620.59 (490.95)	NA
Median (IQR)	1500 (1500-2000)	NA
Capsules taken		
Mean (SD)	NA	178.86 (47.74)
Median (IQR)	NA	168 (161.5-218.5)
Drug aquisition cost (€)		
Mean (SD)	460.24 (139.43)	302.27 (80.68)
Median (IQR)	426 (426-568)	283.92 (272.94-369.27)
Total drug treatment cost (€)		
Mean	**489.37 (147.19)**	**302.27 (80.68)**
Median	**451.30 (451.30-593.30)**	**283.92 (272.94-369.27)**

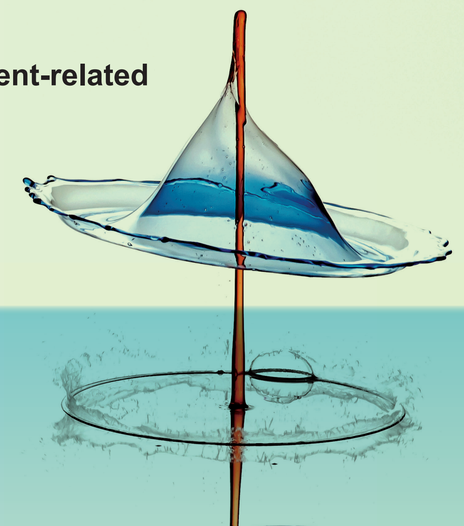
IQR, interquartile range; SD, standard deviation; NA, not applicable

Figure 1: Mean total per-patient drug costs (acquisition + administration)



Conclusions

- **Mean total per-patient drug costs (acquisition + administration) were approximately 1.6 times higher for treatment with IV FCM than FM, when modelled for a German setting. The higher cost of IV FCM is driven by higher drug cost and costs of IV administration. As an oral treatment FM has no administration-related costs or resource use, thus reducing the burden on payers and local health care services.**
- **The administration costs presented here do not take into account clinic overheads or consumables; actual cost differences are therefore likely to be greater than reported.**
- **FM is associated with substantially lower treatment-related HCRU costs than IV FCM, and may provide a cost-saving oral alternative to IV iron in patients with IBD.**



Acknowledgements: The authors acknowledge the contribution of Ben Wilding of HEOR Ltd.

References: 1. Smith J. Am J Managed Care. 2010;16:S59-66; 2. Peyrin-Biroulet L, Williet N, Cacoub, P. Am J Clin Nutrition. 2015;102:1585-94; 3. Vifor Pharma. Ferinject (ferric carboxymaltose): Summary of Product Characteristics. 2019; 4. Gasche C et al. Inflammatory Bowel Diseases. 2015;21(3):579-88; 5. Stallmach A, Buning C. Expert Opin Pharmacother. 2015;16(18):2859-67; 6. Norgine Ltd. FERACCRU(®): Summary of Product Characteristics. 2019; 7. Howaldt S et al. United Eur Gastroenterol J 2019;7(8 Suppl); 8. Froessler B et al. Risk Management and Healthcare Policy. 2018;11:77; 9. Lauertaxe. Preiseinformation 2016 30/08/2019.

Disclosures: Mark Sampson is an employee and stockholder at Shield Therapeutics PLC. Fatma Akriche is an employee of Norgine Ltd. Ian Jacob is an employee of Health Economics and Outcomes Research Ltd. and received funding from Norgine Ltd. to undertake the analysis outlined in this study. Stefanie Howaldt has nothing to declare.
Presented at ECCO (Vienna, Austria) 12-15 February 2020.