Productivity loss in patients with inflammatory bowel disease receiving treatment for iron deficiency anaemia: a comparison of ferric maltol and IV iron

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Background

Iron deficiency anaemia (IDA) is common in patients with inflammatory bowel disease (IBD) and can significantly impair health-related quality of life, including activities of daily living. IDA imposes a substantial economic burden on health care payers.[1]

IV iron is currently the main treatment for patients intolerant or unsuitable for standard oral ferrous (Fe^{2+}) iron. Intolerance to the latter is common, due in part to gastrointestinal damage from reactive oxygen species created by oxidation of unabsorbed iron.[2] Ferric maltol (FM) is a stable oral complex of ferric (Fe^{3+}) iron and maltol designed to provide efficient iron delivery and minimise formation of free iron in the gut, thus reducing the potential for gastric adverse events.[3]

IV iron must be administered in a setting with full resuscitation facilities, due to the risk of hypersensitivity reactions. In addition, patients should be observed for at least 30 minutes after administration.[4]

Dosing is based on weight and haemoglobin (Hb) level, and limitations on dose size mean some patients require more than one administration to complete their initial treatment. Patients may also require additional doses if initial treatment is not sufficiently effective.

Travelling to and receiving IV iron treatment takes time from patients' daily activities, including employment, education and family duties. This exploratory post hoc analysis evaluates the productivity loss associated with treatment with IV iron (ferric carboxymaltose [FCM]), using data on treatment visits from a randomised controlled trial (NCT02680756).[5]

Trial design and primary findings

Patients with IBD and IDA (Hb ≥8.0 g/dL and ≤11.0 g/dL for women or ≥8.0 g/dL and ≤12.0 g/dL for men) were randomised to FM (30 mg b.d.) or IV FCM (as per local Summary of Product Characteristics 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).[5]

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 productivity loss

Productivity loss was calculated based on the number of days lost due to clinic attendance for iron therapy during the 12-week study period. Information on time taken off work or education was collected as part of the study protocol, and post hoc analyses were undertaken using individual patient data.

The costs associated with lost productivity were calculated using the human capital approach and based on the average gross daily income for Germany as published by DeStatis – the German Federal Office of Statistics (€129.17).[6]

Results

Loss of productivity

In patients treated with IV iron (FCM):

- The mean number of days lost per visit was 0.53, and the mean total days lost during the 12-week period was 1.17 (Table 1).
- Half (50%) of patients treated with IV FCM lost at least one full day due to treatment, with 1 in 15 (6.7%) losing 4 to 6 days (Table 2).

When productivity loss was quantified for the German setting, IV FCM treatment was associated with financial losses between €0.00 and €107.21 in 50% of patients, €129.17 and €387.51 in 43% of patients and €516.68 and €775.02 in 7% of patients (Figure 1).

As FM was administered orally by the patient and did not require any clinic-based treatment administration, there was no treatment-linked productivity loss.

Table 1: Number of days lost for IV FCM treatment per visit and in total, up to and including week 12

Total	Mean (SD)	Median (IQR)
Per visit	0.53 (0.49)	1 (0-1)
In total	1.17 (1.39)	0.83 (0-2)

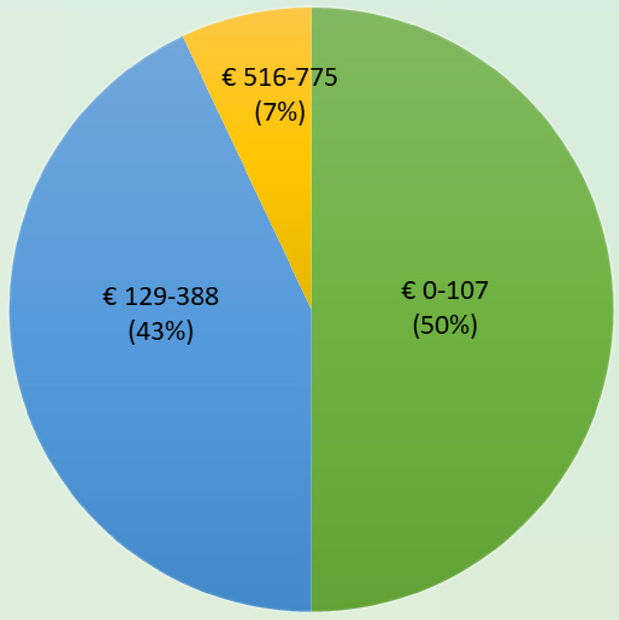
IQR, interquartile range; SD, standard deviation

Table 2: Range of total number of days lost per patient treated with IV FCM over the 12-week study period

Number of days lost	Patients	
	N	%
<1	60	50.4
1-3	51	42.9
4-6	8	6.7

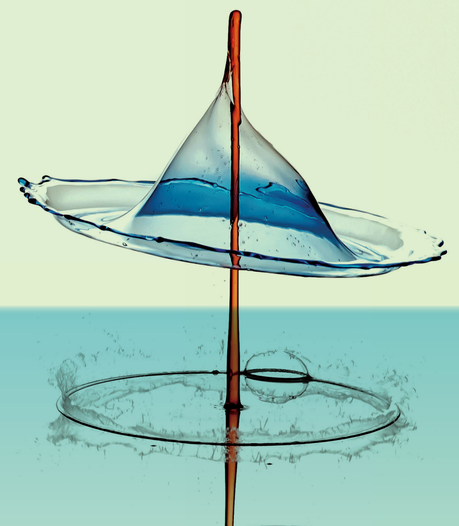
IQR, interquartile range; SD, standard deviation

Figure 1: Monetary value of treatment-related productivity loss with IV FCM, modelled using German income data (% of patients [N=125] in each financial loss category)



Conclusions

- **IV iron treatment with FCM resulted in productivity loss due to the time associated with clinic-based administration. This is made up of travel time and the time required for administration and post-infusion observation.**
- **Additionally, IV iron administration involves indirect costs in the form of travel expenses, which may be met by the patient, the healthcare system or the state. Patients also face the inconvenience of disruption to work and family life.**
- **FM does not incur the productivity loss and other indirect costs associated with clinic-based administration of IV FCM. It may provide a convenient oral alternative to IV iron, as well as additional economic benefits beyond those typically captured in cost-effectiveness and affordability (budget impact) assessments.**



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References: 1. Smith J. Am J Managed Care. 2010;16:S59-66; 2. Gasche C et al. Inflammatory Bowel Dis. 2015;21(3):579-88; 3. Stallmach A, Buning C. Expert Opinion Pharmacotherapy. 2015;16(18):2859-67; 4. Vifor Pharma. Ferinject (ferric carboxymaltose): Summary of Product Characteristics. 2019; 5. Howaldt S, et al. United Eur Gastroenterol J. 2019;7(8 Suppl); 6. DeStatis - Statistisches Bundesamt. Earning by economic activity 2019 30/08/2019.

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