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Safety and efficacy of ferric derisomaltose and its effect on blood transfusions in women with severe anaemia from heavy menstrual bleeding

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Objective: This study investigates the safety and efficacy of ferric derisomaltose (FDI) and its effect on blood transfusion requirements in women with severe anaemia secondary to heavy menstrual bleeding (HMB).

Methods: Medical records of women aged ≥18 years who were admitted to Tuen Mun Hospital with severe iron deficiency anaemia (a haemoglobin level of <8.0 g/dL and a mean corpuscular volume of <80 fL) secondary to HMB in the periods before (1 July 2014 to 30 June 2018) and after (1 July 2018 to 30 June 2022) the introduction of FDI were retrospectively reviewed.

Results: In total, 1373 and 983 patients were admitted before and after the introduction of FDI, respectively. The mean number of blood units transfused per patient decreased from the pre-FDI period to the post-FDI period (2.02 vs 1.19, p<0.001). The decrease remained significant after adjusting for age, ethnicity, baseline haemoglobin, and leiomyoma. In 384 patients who received FDI, 55 (14.3%) had a hypersensitivity reaction (HSR), 41 of which were mild. There were no cases of cardiac or respiratory arrest or allergic reaction necessitating adrenaline administration. The occurrence of an HSR was not associated with the number of known drug allergies (p=0.076), ethnicity (p=0.563), or age (p=0.06). After FDI administration, the mean haemoglobin level increased from 6.2 g/dL to 10.6 g/dL (p<0.001), whereas the mean ferritin increased from 22.5 μg/L to 149 μg/L (p<0.001) at 3 to 4 weeks.

Conclusion: Intravenous FDI is safe and effective for treating severe iron deficiency anaemia secondary to HMB. FDI significantly reduces the requirement for blood transfusions. 14.3% of patients had an HSR. FDI mitigates the burden on blood transfusion services and supports patient blood management principles.

Keywords: Anemia, iron deficiency; Blood transfusion; Ferric derisomaltose; Iron isomaltoside 1000; Menorrhagia

Introduction

Heavy menstrual bleeding (HMB) is defined as regular excessive menstrual blood loss that affects the physical, social, emotional, or material quality of life of patients[1]. It affects approximately 18% to 38% of women of reproductive age[2,3]. Iron deficiency anaemia (IDA) is a common complication of HMB, present in up to 63% of HMB cases[3].

Severe anaemia is defined by the World Health Organization as a serum haemoglobin level of <8.0 g/dL in non-pregnant women aged >15 years[4]. Blood transfusions are commonly used to rapidly raise haemoglobin levels and can be lifesaving in acutely haemorrhagic, haemodynamically unstable patients. However, blood transfusions are associated with potentially serious morbidities such as anaphylaxis, sepsis, transfusion-related acute lung injury, transfusion-associated circulatory overload, and even mortality[5]. Nonetheless, the demand for blood has increased in the past decade owing to an ageing population[6], while the supply of blood products has decreased to critical levels amidst the COVID-19 pandemic that reduces social activities and blood donations[7].

In patients with chronic well-compensated anaemia, intravenous iron therapy is safe and effective and avoids the risks associated with blood transfusions[8-10]. Compared with the oral route, the intravenous route raises haemoglobin levels more quickly and reduces the rate of IDA recurrence[10]. Intravenous iron therapy is recommended in clinical guidelines across multiple specialities including gastroenterology[11], oncology[12], cardiology[13], and for pregnant women[14]. However, its use for HMB is poorly established, and the treatment and screening for IDA are inconsistent. In clinical guidelines for HMB worldwide, approximately one-third offer guidance on iron therapy and one-fifth recommend intravenous iron therapy[15].

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Several formulations of intravenous iron therapy are available in Hong Kong. Iron sucrose (Venofer; Vifor, St Gallen, Switzerland) is safe and effective for severe anaemia secondary to HMB[16]. However, iron sucrose is limited by its multiple-dosage regimen and the use of the Ganzoni formula, which is shown to underestimate iron requirements[17]. Ferric derisomaltose (FDI), also known as iron isomaltoside 1000 (Monofer; Pharmacosmos, Holbaek, Denmark), is taken in a single dose and requires a simple calculation based on weight and can elevate haemoglobin levels more rapidly and effectively than iron sucrose[18].

On 1 July 2018, FDI was introduced in the gynaecology ward of Tuen Mun Hospital in Hong Kong. We aimed to evaluate the effect of FDI's introduction on blood transfusion requirements in patients with HMB as well as FDI's safety and efficacy.

Materials and methods

We performed a retrospective study to compare periods before (1 July 2014 to 30 June 2018) and after (1 July 2018 to 30 June 2022) the introduction of FDI at the gynaecology ward of Tuen Mun Hospital in Hong Kong. Through the clinical data analyses and reporting system, data of women aged ≥18 years admitted with severe IDA (defined as a haemoglobin level of <8.0 g/dL and a mean corpuscular volume of <80 fL) secondary to HMB were extracted. Patients with anaemia resulting from other causes (such as ruptured ectopic pregnancies, autoimmune or bone marrow diseases, drug-induced anaemia, and haemodynamic instability) were excluded, as were those with contraindications to intravenous iron (such as anaphylaxis to intravenous iron, iron storage disorders, chronic liver disease, first-trimester pregnancy, and active infections). Data collected included age, ethnicity, duration of admission, type of admission (emergency or clinical), cause of HMB, and baseline haemoglobin and ferritin levels. The proportions of women who received blood only, FDI only, both, or neither were calculated. Additionally, the number of blood units transfused were recorded. Patients were stratified by their haemoglobin levels in g/dL (7.0-7.9, 6.0-6.9, 5.0-5.9, 4.0-4.9, and ≤3.9).

Before the introduction of FDI, patients with HMB and severe IDA were managed with blood transfusion alone or without any blood transfusion. After the introduction of FDI, patients were given the option of intravenous iron therapy if they had a haemoglobin level of <8.0 g/dL or had anaemic symptoms in the absence of contraindications and were haemodynamically stable, with or without a previous blood transfusion. Patients could receive more than one management modality. A single dose of FDI at 20 mg per kg of the patient weight (maximum of 1000 mg) was administered as an intravenous infusion diluted in 500 ml 0.9% sodium chloride solution over 60 minutes. Patients were monitored at regular 15-minute intervals up to 1 hour after the transfusion for any hypersensitivity reaction (HSR) or adverse reactions. HSRs were treated according to international guidelines[19,20]. HSRs were categorised based on their timing (acute [within 30 minutes of FDI administration] and delayed) and severity (mild, moderate, and severe) [Table 1]. Patients with asthma or allergies to ≥2 drugs were administered 125 mg intravenous methylprednisolone before FDI administration to reduce the risk of HSR. Similarly, patients with inflammatory arthritis were given the same dose of methylprednisolone, followed by a short oral course of prednisolone (1 mg/kg per day) for 4 days.

Patients' levels of haemoglobin, mean corpuscular volume, ferritin, iron, iron saturation, and total iron binding capacity were assessed before FDI administration and 3 to 4 weeks later. The primary outcome was the difference in the mean number of units of red blood cells or whole blood transfused per patient between the pre-FDI and post-FDI periods. Secondary outcomes included changes in haemoglobin and iron panels 3 to 4 weeks after FDI administration, the incidence of HSRs and their management, and the association between HSRs and the number of known drug allergies.

Table 1. Severity of hypersensitivity reactions (adapted from Rampton et al[19])

Severity	Symptoms
Mild	Itching, flushing, urticaria, sensation of heat, slight chest tightness, hypertension, back/joint pains
Moderate	As in mild reaction + transient cough, flushing, chest tightness, nausea, shortness of breath, tachycardia, hypotension
Severe	Sudden onset and rapid aggravation of symptoms + wheezing/stridor, periorbital oedema, cyanosis, loss of consciousness, cardiac/respiratory arrest

Univariate analysis was performed using the Chi-squared test or the Mann-Whitney *U* test to assess the distribution of descriptive variables and the crude difference in the number of units of blood products transfused between the two study periods. To adjust for potential confounders, multivariate linear regression analysis was conducted with the study period as the predictor. Within-group comparisons were made using the paired *t* test. A p value of <0.05 was considered statistically significant. R (version 4.2.2) was used for the statistical analyses.

Table 2. Patient characteristics before and after the introduction of ferric derisomaltose (FDI) for heavy menstrual bleeding

	Pre-FDI (n=1373)*	Post-FDI (n=983)*	p Value
Age, y	44.1±6.9	43.8±6.7	0.278
Ethnicity			<0.001
Chinese	1252 (91.2)	838 (85.2)	
Southeast Asian	81 (5.9)	99 (10.1)	
South Asian	36 (2.6)	41 (4.2)	
Caucasian	4 (0.3)	5 (0.5)	
Type of admission			0.002
Emergency	909 (66.2)	709 (72.1)	
Clinical	464 (33.8)	274 (27.9)	
Duration of admission, d	1.5±4.3	1.4±1.7	0.962
Cause of heavy menstrual bleeding			
Leiomyoma	618 (45.0)	404 (41.1)	0.058
Adenomyosis	151 (11.0)	127 (12.9)	0.080
Cervical cancer	26 (1.9)	18 (1.8)	1.000
Endometrial polyp	22 (1.6)	20 (2.0)	0.392
Endometrial hyperplasia	16 (1.2)	3 (0.3)	0.042
Endometrial cancer	2 (0.1)	12 (1.2)	0.002
Not yet classified	190 (13.8)	166 (16.9)	0.048
Haemoglobin, g/dL	6.4±1.1	6.1±1.2	<0.001
7.0-7.9	508 (37.0)	263 (26.8)	
6.0-6.9	428 (31.2)	330 (33.6)	
5.0-5.9	270 (19.7)	226 (23.0)	
4.0-4.9	105 (7.6)	119 (12.1)	
≤3.9	62 (4.5)	45 (4.6)	
Ferritin, µg/L	21.6±61.9	23.1±125.9	0.800
Units of blood transfused per patient			
0	186 (13.5)	326 (33.2)	
1	66 (4.8)	276 (28.1)	
2	754 (54.9)	269 (27.4)	
3	295 (21.5)	95 (9.7)	
4	54 (3.9)	13 (1.3)	
5	18 (1.3)	3 (0.3)	
Management			
Blood transfusion alone	86.5	45.4	
No blood transfusion or intravenous iron therapy	13.5	15.6	
Intravenous iron therapy alone	-	17.7	
Blood transfusion and intravenous iron therapy	-	21.4	

* Data are presented as mean ± standard deviation, No. (%) of patients, or % of patients. Total may not equal to 100% because of missing data.

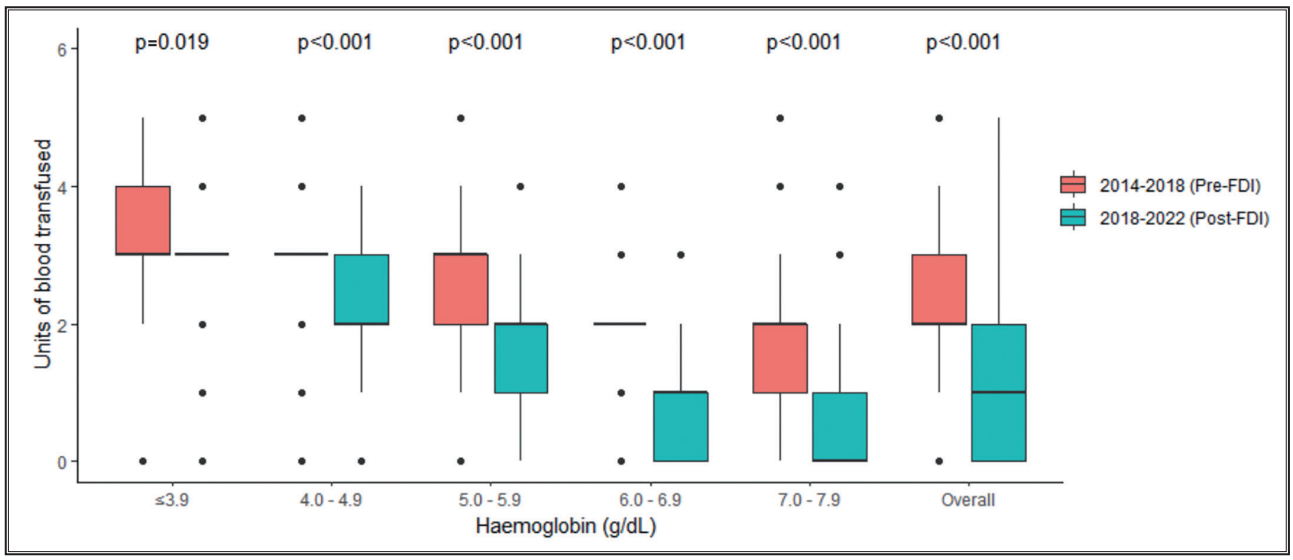

Figure 1. Medians and interquartile ranges of units of blood transfused per patient in each category of haemoglobin level before and after the introduction of ferric derisomaltose (FDI).

Results

In total, 1373 and 983 patients were admitted before and after the introduction of FDI, respectively. The two groups were comparable in terms of baseline characteristics, except for Chinese ethnicity, type of admission, and cause of HMB involving endometrial hyperplasia and endometrial cancer (Table 2).

The mean number of blood units transfused per patient decreased from the pre-FDI period to the post-FDI period (2.02 [95% confidence interval (CI)=1.96-2.07] vs 1.19 [95% CI=1.12-1.25], p<0.001). The decrease remained significant in the multivariate linear regression analysis, with a mean decrease of 1.07 (95% CI=0.97-1.16) units of blood transfused, after controlling for age, ethnicity, baseline haemoglobin, and leiomyoma. 55% of patients in the pre-FDI group received two units of blood, whereas 33.3% of patients in the post-FDI group did not receive any blood transfusion, and 28.1% received one unit of blood (Table 2). The proportions of patients with blood transfusions in every category of haemoglobin level also decreased in the post-FDI period (Figure 1).

Of the 983 patients in the post-FDI group, 446 (45.4%) received blood transfusion alone, 174 (17.7%) received FDI alone, 210 (21.4%) received both treatments, and 153 (15.6%) received neither (Table 2). The proportion of patients managed with blood transfusion alone decreased from 86.5% in the pre-FDI period to 45.4% in the post-FDI period.

Table 3. Hypersensitivity reactions after ferric derisomaltose administration in 55 patients

Hypersensitivity reactions	Value*
Severity	
Mild	41 (10.7)
Moderate	11 (2.9)
Severe	3 (0.8)
Type	
Acute	24 (43.6)
Delayed	31 (56.4)
Onset time, min	31.3±46.1
Development during the 60-min transfusion period	32 (58.2)
Management	
Discontinued if occurred during transfusion	24 (75.0)
No actions needed	20 (36.3)
Resumed at half rate	4 (7.2)
Topical crotamiton	2 (3.6)
Oral chlorphenamine	3 (5.5)
Intravenous chlorphenamine	1 (1.8)
Intravenous hydrocortisone	11 (20.0)
Inhaled salbutamol	1 (1.8)
Oxygen supplementation	2 (3.6)

* Data are presented as mean ± standard deviation or No. (%) of patients

Of the 384 patients who received FDI with or without a blood transfusion, 22 (5.7%) had drug allergies. Only one (0.3%) patient required methylprednisolone prior to FDI administration. 55 (14.3%) patients had an HSR, 41 of which were mild (Table 3). When HSRs occurred within 60 minutes of FDI administration, 75.0% of cases were managed by stopping the infusion and 7.2% of cases by resuming infusion at half the rate. The most common medication for HSRs was intravenous hydrocortisone (20.0%). There were no cases of cardiac or respiratory arrest or allergic reaction necessitating adrenaline administration. The occurrence of a HSR was not associated with the number of known drug allergies (p=0.076), ethnicity (p=0.563), or age (p=0.06).

In the 384 patients who received FDI with or without a blood transfusion, the mean haemoglobin level increased from 6.2 (95% CI=6.11-6.20) g/dL to 10.6 (95% CI=10.6-10.7) g/dL (p<0.001) and the mean ferritin increased from 22.5 (95% CI=16.9-28.2) µg/L to 149 (95% CI=126-172) µg/L (p<0.001) at 3 to 4 weeks after FDI administration (Figure 2).

Discussion

To the best of our knowledge, this is the first study to evaluate the real-world effect of intravenous iron therapy on blood transfusion requirements for severe IDA secondary to HMB. Before the availability of intravenous iron, there was a substantial reliance on blood transfusions to manage severe anaemia. Since the introduction of FDI, blood transfusion requirements have reduced overall and in each category of haemoglobin level. Notably, this reduction persisted even when the mean baseline haemoglobin level was significantly lower in the post-FDI group than in the pre-FDI group (6.1 vs 6.4 g/dL). Previous studies also reported a significant reduction in the number of blood transfusions given after the introduction of FDI in peri-operative patients[10] and emergency department patients[21].

Our study supports the three-pillar approach to patient blood management, which comprises reducing blood product usage, improving patient outcomes, and minimising costs[22]. Since 2010, the World Health Assembly has advocated these principles to its 193 member states[23].

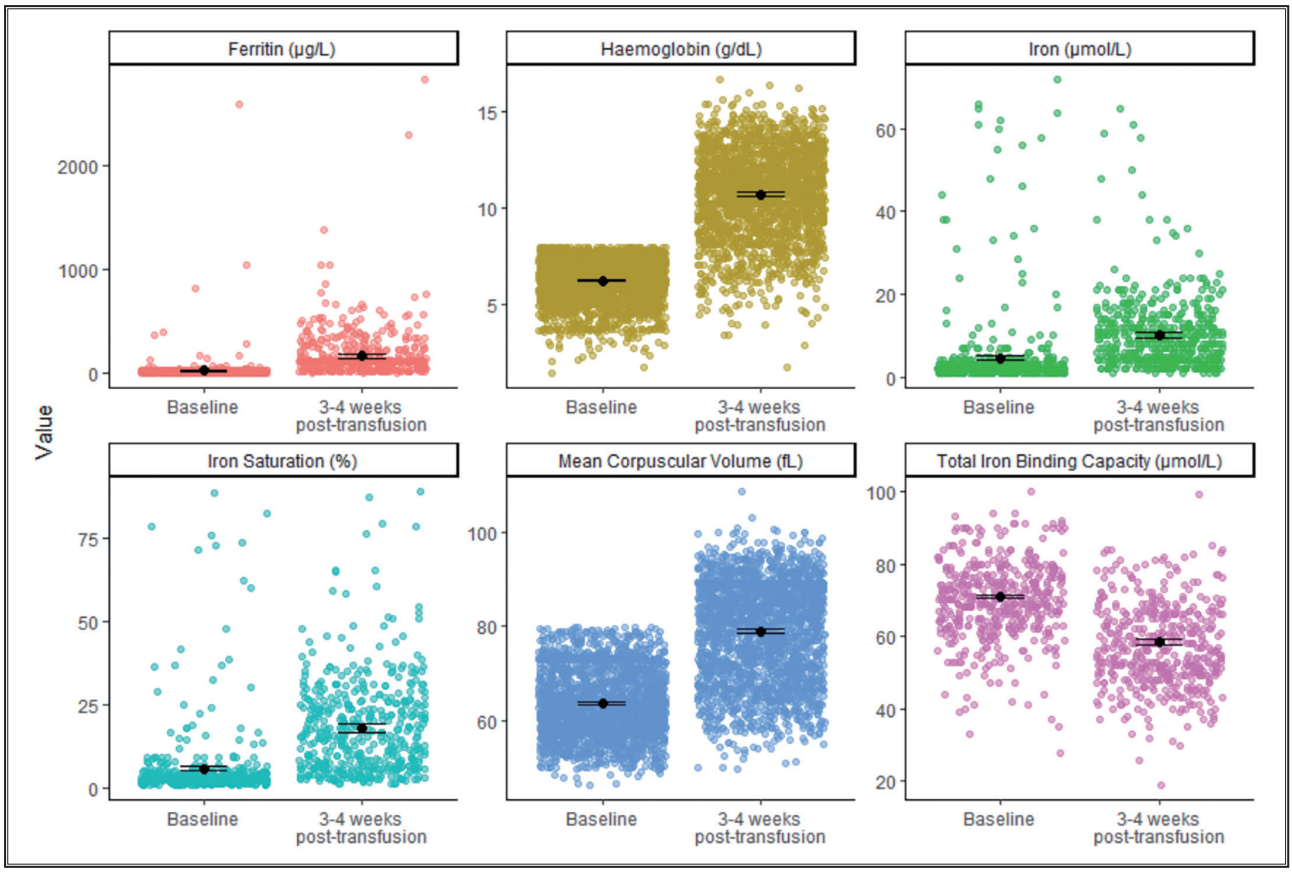

Figure 2. Scatterplots showing changes in means and 95% confidence intervals of haemoglobin, mean corpuscular volume, ferritin, iron, iron saturation, and total iron binding capacity from baseline to 3 to 4 weeks after transfusion of ferric derisomaltose.

The Hong Kong Society of Clinical Blood Management recommends single-unit transfusion and transfusing the minimum amount necessary to achieve clinical stability[6]. FDI does not increase the length of hospital stay, therefore requiring no additional hospitalisation costs.

The proportion of Chinese patients was significantly lower in the post-FDI group than in the pre-FDI group (85.2% vs 91.2%). This may be because the travel restrictions during the COVID-19 pandemic reduced medical tourism from Mainland China, which comprises a large proportion of admissions. Moreover, the post-FDI group involved a smaller sample size, a higher proportion of emergency admissions, a lower mean haemoglobin level, and more cases of endometrial cancer. Again, this may again be attributable to the COVID-19 pandemic, which reduced health-seeking behaviours, delayed disease presentation, and reduced hospital admissions by up to 21%[24].

The efficacy of FDI has been reported in both trial and real-world settings[8-10,25]. The rate of HSRs was higher in our study, compared with others (14.3% vs 0.3%-4.7%)[9,26]. This may be due to differences in the definition and classification of HSRs and the method of reporting. In the largest study of real-world FDI use involving 7342 patients from the United Kingdom in 2022, the incidence of HSRs was lower in the anaemic group than in the non-anaemic group (0.3% vs 0.9%)[9]. Our patients were severely anaemic and had a much higher incidence of HSRs. In a study of 126 postpartum women (88% were Chinese) with a mean age of 33 years treated with FDI, the incidence of HSR was 3.2%[27]. The mean age of our patients treated with FDI was 43.8 years; older age is a known risk factor for HSR[19,20].

Future research to evaluate the association of the Chinese ethnicity and HSRs secondary to FDI is warranted. Other formulations that are associated with fewer HSRs such as ferric carboxymaltose can be considered[25,28]. In addition, the wider use of methylprednisolone as a premedication warrants further investigation. Nonetheless, severe HSRs are uncommon and can be minimised with adequate and timely management.

One limitation of this study was the involvement of a single formulation in a single centre only. However, the sample size was large, and the FDI dosage and administration protocol were standardised. The study was not designed to investigate the incidence of HSRs or their associations. The period before the introduction of FDI reflects the real-world clinical practice and hence was chosen for comparison; patients who refused blood transfusions for personal or religious reasons, or who were contraindicated for blood transfusions were included.

Conclusion

Intravenous FDI is safe and effective for treating severe iron deficiency anaemia secondary to HMB. FDI significantly reduces the requirement for blood transfusions. 14.3% of patients had an HSR. FDI mitigates the burden on blood transfusion services and supports patient blood management principles.

Contributors

All authors designed the study, acquired the data, analysed the data, drafted the manuscript, and critically revised the manuscript for important intellectual content. All authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

Conflicts of interest

All authors have disclosed no conflicts of interest.

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Data availability

All data generated or analysed during the present study are available from the corresponding author upon reasonable request.

Ethics approval

This study was approved by the Hospital Authority Central Institutional Review Board (reference: CIRB-2023-014-3). The patients were treated in accordance with the tenets of the Declaration of Helsinki. The patients provided written informed consent for all treatments and procedures and for publication.

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