A Budget Impact Analysis of Iron Polymaltose and Ferric Carboxymaltose Infusions

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Abstract

Objective: To compare the direct costs of ferric carboxymaltose (FCM) infusions, and iron polymaltose (IPM) infused via either a slow or rapid infusion; and explore potential savings associated with increased uptake of the least-expensive option at a local hospital.

Setting: Hospital staff responsible for manufacturing, administering, and monitoring iron infusions, and the patients that received them at the Royal Hobart Hospital in 2018.

Method: Frequency analysis identified the most prescribed iron infusion doses. A time-motion methodology was used to calculate the direct costs for each protocol at these doses. Finally, a budget-impact analysis of encouraging increased use of the least-expensive infusion protocol was conducted.

Main outcome measures: Total direct costs for each infusion protocol at common doses. Potential budget savings associated with switching to the lowest costing of these infusion protocols where possible.

Results: The most common doses were 0.5g, 1g, 1.5g and 2g. At these dose points, FCM infusions are the least expensive, but only if national health subsidies are applied. In cases where they do not apply, IPM prepared from ampoules and infused using the rapid protocol ('IPM Ampoules Rapid') is the least expensive. Switching all applicable FCM infusions and IPM infusions administered using the slow infusion protocol to IPM Ampoules Rapid is projected to yield up to $12,000 worth of savings annually.

Conclusions: Increased use of the IPM Ampoules Rapid protocol when government-subsidised options are not available is projected to have cost-saving outcomes. Investigation of implementation strategies to increase the use of this protocol are warranted.

Impacts On Practice

- This study demonstrates the total direct costs of both the FCM and IPM infused via either a slow or rapid infusion protocol. While there has been a number of studies outlining the safety and efficacy of these infusion protocols, their cost implications have not been fully investigated previously.
- Amidst the increasing use of intravenous iron, this study outlines which is the overall lowest costing iron infusion protocol, identifying factors contributing to this (e.g. different dose points, health subsidies) and the potential associated costs savings with promoting increased use of lower-costing protocols. Effort should be made to be flexible in using the most cost-optimal infusion protocol in different scenarios, whilst also maintaining safety. Interventions to increase the use of lower-costing infusion protocols should be explored.

Introduction

Iron deficiency anaemia (IDA) is a common health problem. Between 1990-2010, approximately 32.9% of the global population had anaemia, most commonly caused by iron deficiency [1]. Given the proportion of people affected by IDA and the considerable financial implications of large-scale intravenous iron use, cost-efficient interventions are necessary to both minimise the associated treatment burden, as well as to allow greater access to treatments.

In Australia, there are three main types of intravenous iron products available: iron sucrose, iron polymaltose (IPM) and ferric carboxymaltose (FCM). This article will only focus on IPM and FCM as iron sucrose use is limited to specialist settings in Australia [2]. Both IPM and FCM have good efficacy and safety profiles and there is no conclusive evidence indicating one is superior over the other [3-6]. They differ significantly in procurement costs as well as in their requirements for manufacturing, administration and monitoring; together this may have budget and patient flow implications.

Current protocols recommend that up to 2.5g of IPM be given slowly over 2 to 3 hours, and for up to a total duration of 5 hours [7,8]. In contrast, FCM can be given in a single 15-minute infusion but it is restricted to doses of 1g, of which only one can be administered weekly [9,10]. FCM typically has a less demanding monitoring regimen of observations: at baseline, immediately after the infusion and 30 minutes later. Comparatively, locally, patients' vital signs are recorded by nurses every 10 minutes for the first 30 minutes, then half-hourly until a standard IPM infusion is completed [8]. Local safety protocols dictate that any infusion requiring more than five ampoules of medication be manufactured in the pharmacy department, where they are made in the sterile suite (infusions made up by nurses on the ward are not). Due to the currently available proprietary formulations, this only commonly applies to IPM infusions, and not FCM, because the usual dose range (1+ gram) requires at least ten IPM ampoules, but only two FCM ampoules [7,9].

In recent years, an alternative 'rapid infusion' protocol of IPM has been implemented at several sites in Australia [11]. Studies report that this protocol is not inferior in efficacy or safety compared to the standard IPM protocol [12-15]. This protocol approves administering doses ≤1.5g over 75 minutes, and doses up to 2g over 105 minutes, with fewer monitoring requirements compared to the slow IPM protocol [7].

Aim of the study

Given the range of options now available, the aim of the present study was to calculate and compare the direct costs of each infusion type at different doses, and to explore the potential budget savings associated with a tertiary hospital switching to the lowest costing of these infusion protocols where possible.

Method

Population

A time-motion study was conducted at Royal Hobart Hospital (RHH) in late 2018 to early 2019 to ascertain the labour and consumable requirements needed for both the established FCM and slow IPM infusion protocols. Relevant dispensing data from 2018 was also used in the analyses described below.

Drug procurement costs

FCM infusions were prepared from ampoules containing 500mg/10mL of FCM. The slow IPM infusions were administered using either bags made on site from ampoules containing 100mg/2mL of IPM or by using premix bags containing 1000mg/500mL of IPM. The wholesale price of each drug formulation in Australian Dollars (AUD) in 2019 was $142.80, $2.50, and $101.30 for a single FCM ampoule, IPM ampoule and IPM premix bag, respectively.

Labour

Only time spent preparing and administering infusions (including monitoring patients receiving the infusions) was recorded; interruptions were ignored. This aspect was conducted using an external observer with a stopwatch and worksheets (*Appendix A*). It was planned that twenty timed observations would be made of both the FCM and IPM slow protocols each between November 2018 to March 2019; this sample size was based on studies of similar designs [16-18].

Consumables

For FCM manufacturing, a 20mL syringe, one 19-Gauge sharp needle, one 250mL sodium chloride (NaCl) 0.9% bag, one drawing up needle, two pairs of gloves and an alcohol swab were used. By contrast, consumables used in IPM manufacturing constituted of one 500mL NaCl 0.9% bag, two 21-Gauge needles, one 0.8-micron filter, one additive cap, five iso wipes, one drawing up needle, two pairs of gloves and a light-protective bag. Sterile suite garments were not costed into the IPM calculations as many different infusions are made in one 'sitting', and the suite costs are considered part of the normal pharmacy department costs for daily work.

The consumables used during administration of FCM and IPM infusions were the same: a cannula, a tourniquet, an extension set, a giving set, two alcohol swabs, one cotton wool ball, one pressure pad and a 500mL NaCl 0.9% bag. These costs were obtained from the site Supply and Purchasing Officer. The cost of the volumetric pump and tourniquets were not included as they are standard reusable hospital equipment.

Analyses

All calculations were performed using Microsoft Excel version 2010 (Microsoft Corporation, Redmond, WA, USA). The time recorded from observations were summarized as means with standard deviation (SD). Pharmacy and nursing labour costs were calculated by multiplying the mean times taken in the preparation, administration, and monitoring of infusions, by the respective average hospital wage award for the staff type attending to these tasks. A frequency analysis was conducted using the dispensing data to ascertain the iron doses and protocols most commonly prescribed at the study site in 2018.

At the time of study, there were three different intravenous iron therapy at the study site: FCM, IPM prepared from ampoules and infused using the slow protocol (IPM Ampoules Slow), and IPM prepared from premix bags, also infused using the slow protocol (IPM Premix Slow). The approval of an IPM rapid protocol would increase this to five, with the addition of IPM prepared from ampoules and infused using the rapid protocol (IPM Ampoules Rapid) and IPM prepared from premix bags, also infused using the rapid protocol (IPM Premix Rapid).

The cost of each protocol at the most commonly prescribed doses was calculated by combining relevant drug acquisition, labour and consumables costs. For FCM infusions, labour and consumables costs were doubled when doses were above 1g. Since IPM rapid infusions were not implemented at the RHH at the time the study was being conducted, its direct costs were estimated by extrapolating data from observed infusions (*Appendix A*).

The total direct costs per infusion for each infusion protocol were compared to each other at the common dose points to determine the lowest costing infusion protocol. In Australia, prescriptions that meet Pharmaceutical Benefits Scheme (PBS) requirements are subsidised by the government. The maximum claimable quantity for IPM and FCM are 500mg and 1000mg respectively i.e. higher doses are not subsidised for the average patient [19,20]. Furthermore, PBS reimbursements only apply to hospital dispensed medication as long as the medication is prescribed and dispensed on the day of discharge or if the patient is an outpatient. Thus, the difference in costs with (FCM-PBS and IPM-PBS) and without PBS reimbursement (FCM-NPBS and IPM-NPBS) were also accounted for in these analyses.

The potential budget savings associated with increasing use of the lowest costing of these infusion protocols was then calculated. This analysis was carried out based on the inference that these protocols are not inferior to each other in terms of safety and efficacy.

Results

Frequency analysis

Excluding iron sucrose prescriptions, there were a total of 1,274 iron infusions prescribed at the study site in 2018, the majority comprising of FCM infusions (1,136 or 89.16%), and specifically PBS-reimbursed FCM infusions (1,100, 86.34%, N=1,274). The next most common form of iron infusion was the premix IPM bags (105, 8.24%), followed by IPM infusions made on site from ampoules (33, 2.59%).

Forty patients received FCM repeat doses within a month (31 days) of their first dose. Taking into account FCM's 1g limit per week,[10] these were defined as part of their initially prescribed dose. No patients who received an IPM infusion received a repeat dose within the month of their first dose. The most common doses prescribed for any iron infusion (i.e. IPM and FCM combined) were 1g (1,042 infusions (84.44%)), 500mg (115 infusions (9.32%)), 2g (45 infusions (3.65%)) and finally, 1.5g (17 infusions, (1.38%), N=1,234); these four dose points accounted for approximately 98.78% of doses.

Direct costs comparison

The average labour times associated with each infusion type are listed in *Table 1*. *Table 2* outlines the total direct cost breakdown for each infusion protocol at the four aforementioned common dose points. PBS reimbursements were greater than the drug acquisition costs for FCM at all doses, making it the lowest costing infusion at all dose points. Conversely, when not attracting PBS subsidies it was the most expensive protocol; IPM Ampoules Rapid had the lowest total direct cost at all common dose points for non-subsidised infusions.

Budget-impact analysis

The annual cost of FCM-NPBS was approximately $11,804.94 (*Table 3*). If these infusions were changed to IPM Ampoules Rapid infusions (assuming no clinical contraindications to IPM existed), the projected annual cost would be reduced to $4,312.65, amounting to a total of up to $7,492.29 in saving.

The annual costs of IPM Ampoules Slow and IPM Premix Slow were $4,717.62 and $17,926.30 respectively (*Table 4*). Converting these to IPM Ampoules Rapid infusions would reduce the projected annual cost to

$18,158.78 i.e. a saving of $4,485.14 annually.

Together the budget impact of swapping all infusions that did not attract PBS subsidies to IPM Ampoules Rapid infusions would amount to a saving of up to $11,977.43. Cost-savings of approximately $7,053 annually would still be possible in an alternate scenario where all FCM-NPBS and IPM slow infusions were switched to IPM rapid infusions, using IPM premix bags in place of FCM bags and IPM ampoules only where they are currently used (*Appendix B*).

Table 1: Average labour time for single infusions (hours).

Infusion protocol[a]	Mean time spent (in hours) ± Standard Deviation			Total labour (Hours)
	Technicians	Pharmacists	Nurses	
FCM 1.0g[b]	-	-	0.45 ± 0.14	0.45
IPM Ampoules Slow ≤0.5g[c]	-	-	1.17 ± 0.26	1.17
IPM Ampoules Slow >0.5 to 2.5g[c]	0.77 ± 0.34	0.19 ± 0.07	0.96 ± 0.19	1.92
IPM Ampoules Rapid ≤0.5g[c]	-	-	0.97 ± 0.23	0.97
IPM Ampoules Rapid >0.5 to 1.5g[c]	0.77 ± 0.34	0.19 ± 0.07	0.76 ± 0.17	1.72
IPM Ampoules Rapid >1.5 to 2g[c]	0.77 ± 0.34	0.19 ± 0.07	0.90 ± 0.19	1.86
IPM Premix Slow ≤2.0g[d]	-	-	0.96 ± 0.19	0.96
IPM Premix Rapid ≤1.5g[d]	-	-	0.76 ± 0.17	0.76
IPM Premix Rapid >1.5 to 2g[d]	-	-	0.90 ± 0.19	0.90

[a]Twenty FCM infusions were observed (both manufacturing + administration) and six IPM Ampoules Slow were time-stamped (manufacturing only). The labour time for the remaining infusion protocols were extrapolated from the FCM observations and IPM protocol data. [b]Time for nurses to prepare, administer and monitor one infusion. [c]Time for technicians to prepare one infusion, pharmacists to check one infusion, and nurses to administer and monitor one infusion. [d]Time for nurses to administer and monitor one infusion.

The time spent by pharmacy staff dispensing stock to patients' names was not included, as this process is consistent across all protocol types. NB: FCM = Ferric Carboxymaltose; IPM = Iron Polymaltose

Table 2: Breakdown of direct costs per infusion of each infusion protocol at commonly prescribed doses.

Dose point (mg)	Infusion protocol	Drug cost (AUD)	Labour Cost (AUD)		Consumables cost (AUD)		Total cost (AUD)
			Nurses	Pharmacy staff	Manufacture	Administration	
500	FCM-NPBS	142.80	18.07	-	3.81	17.18	181.86
	FCM-PBS	-11.14**	18.07	-	3.81	17.18	27.92
	IPM Amp Slow-NPBS	12.50	38.54	-	15.52	17.38	83.94
	IPM Amp Slow-PBS	-11.58**	38.54	-	15.52	17.38	59.86
	IPM Amp Rapid-NPBS	12.50	30.51	-	15.52	17.38	75.91
	IPM Amp Rapid-PBS	-11.58**	30.51	-	15.52	17.38	51.83
	IPM Premix Slow*	101.30	38.54	-	-	17.38	157.22
	IPM Premix Rapid*	101.30	30.51	-	-	17.38	149.19
1000	FCM-NPBS	285.60	18.07	-	3.81	17.18	324.66
	FCM-PBS	-22.27**	18.07	-	3.81	17.18	16.79
	IPM Amp Slow	25.00	38.54	37.10	15.52	17.38	133.54
	IPM Amp Rapid	25.00	30.51	37.10	15.52	17.38	125.51
	IPM Premix Slow	101.30	38.54	-	-	17.38	157.22
	IPM Premix Rapid	101.30	30.51	-	-	17.38	149.19
1500	FCM-NPBS	428.40	36.14	-	7.63	34.35	506.52
	FCM-PBS	-33.41**	36.14	-	7.63	34.35	44.71
	IPM Amp Slow	37.50	38.54	37.10	15.52	17.38	146.04
	IPM Amp Rapid	37.50	30.51	37.10	15.52	17.38	138.01
	IPM Premix Slow*	202.60	38.54	-	-	17.38	258.52
	IPM Premix Rapid*	202.60	30.51	-	-	17.38	250.49
2000	FCM-NPBS	571.20	36.14	-	7.63	34.35	649.32
	FCM-PBS	-44.54**	36.14	-	7.63	34.35	33.58

	IPM Amp Slow	50.00	38.54	37.10	15.52	17.38	158.54
	IPM Amp Rapid	50.00	36.14	37.10	15.52	17.38	156.14
	IPM Premix Slow	202.60	38.54	-	-	17.38	258.52
	IPM Premix Rapid	202.60	36.14	-	-	17.38	256.12

**Assuming full-bags are dispensed patients, but only part-bags administered. **Negative figures represent net profits considering 2019 October PBS reimbursement and patient co-payments.*

NB: AUD = Australian Dollars; FCM = Ferric Carboxymaltose; FCM-NPBS = Non-PBS subsidised FCM; FCM-PBS = PBS-subsidised FCM; IPM Amp Slow-NPBS = Non-PBS subsidised IPM Ampoules Slow; IPM Amp Slow-PBS = PBS-subsidised IPM Ampoules Slow; IPM Amp Rapid-NPBS = Non-PBS subsidised IPM Ampoules Rapid; IPM Amp Rapid-PBS = PBS-subsidised IPM Amp Rapid; IPM = Iron Polymaltose; PBS = Pharmaceutical Benefits Scheme.

Table 3: Projected budget implications of switching FCM-NPBS infusions to IPM Ampoules Rapid infusions (PBS) at the study site.

Dose (mg)	Number of FCM-NPBS infusions conducted in 2018	Cost per infusion (AUD)		Annual cost of FCM-NPBS infusions (AUD)	Projected annual cost if switched to IPM Ampoules Rapid (AUD)
		FCM-NPBS	IPM Ampoules Rapid		
500	6	181.86	75.91*	1,091.16	455.46
1000	27	324.66	125.51	8,765.82	3,388.77
1500	-	506.52	138.01	-	-
2000	3	649.32	156.14	1,947.96	468.42
				11,804.94	4,312.65

NB: AUD = Australian Dollars; FCM-NPBS = Non-PBS subsidised Ferric Carboxymaltose; IPM = Iron Polymaltose.

**IPM-NPBS figure was used.*

Table 4: Projected budget implications of switching current slow IPM infusions to IPM Ampoules Rapid infusions at the study site.

Dose (mg)	No of infusions			Cost per infusion (AUD)			Actual annual cost of		Projected annual cost if switched to IPM Ampoules Rapid**
	IPM Amp Slow	IPM Premix Slow	Total[a]	IPM Amp Slow	IPM Premix Slow	IPM Ampoules Rapid[b]	IPM ampoules slow (AUD)	IPM Premix slow (AUD)	
2450	1	-	1	171.04	-	168.63	171.04	-	168.63
2000	1	14	15	158.54	258.52	156.13	158.54	3,619.28	2,341.95
1950	1	-	1	158.54	-	156.13	158.54	-	156.13
1850	2	-	2	156.04	-	153.63	312.08	-	307.26
1800	3	-	3	153.54	-	151.13	460.62	-	453.39
1650	2	-	2	151.04	-	148.63	302.08	-	297.26
1600	1	-	1	148.54	-	146.13	148.54	-	146.13
1500	11	-	11	146.04	-	138.01	1,606.44	-	1,518.11
1250	1	-	1	141.04	-	133.01	141.04	-	133.01
1200	2	-	2	138.54	-	130.51	277.08	-	261.02
1150	1	-	1	138.54	-	130.51	138.54	-	130.51
1000	5	91	96	133.54	157.22	125.51	667.70	14,307.02	12,048.96
800	1	-	1	91.44	-	120.51	91.44	-	120.51
500	1	-	-	83.94	-	75.91	83.94	-	75.91
							4,717.62	17,926.30	18,158.78

***Projected annual costs for IPM Ampoules Rapid by multiplying [a]total number of current IPM infusions and [b]cost per IPM Ampoules Rapid (NB: none of the infusions in this table attracted PBS subsidies).*

NB: IPM= Iron Polymaltose; AUD= Australian Dollars.

Discussion

Our findings reveal that FCM infusions amass the lowest cost from the hospital perspective, but only if PBS subsidies apply. When prescriptions cannot be subsidised, IPM Ampoules Rapid is the least expensive protocol, irrespective of the dose prescribed. The potential savings associated with increasing use of the IPM Ampoules Rapid protocol could allow up to $12,000 to be re-directed for other patient care purposes. Other similarly sized hospitals without protocols in place requiring infusions with more than 5 ampoules be made in the pharmacy sterile suite would stand to save more. Currently however, these local protocols do exist, and an increase in the use of the IPM Ampoules Rapid protocol would require more infusions to be manufactured in the pharmacy's sterile suite each year – an extra 174 infusions annually, based on 2018 data. If there was resistance to this, for example due to hospital and staff capacity constraints, then changing all FCM-NPBS infusions and IPM

infusions of doses up to 2g to their respective IPM rapid counterpart would still result in a saving of up to $7,053 annually for the hospital (*Appendix B*).

The term ‘up to’ is used in the above paragraph (as well as in the results section) in acknowledgement that switching from FCM to IPM is not always appropriate. FCM is used locally for in-patients in: 1) the management of IDA for women in the second or third trimester of pregnancy where the benefits of treatment are deemed to outweigh the risks to the fetus or 2) patients with known and documented intolerance or allergy to iron polymaltose [10]. FCM may be switched to IPM Ampoules Rapid only in cases of the former indication, where neither FCM nor IPM were found to be superior to one another when used in pregnant women [6].

Physicians are recommended to give greater consideration to the use of intravenous iron due to the introduction of these new infusion therapies which not only have shorter administration duration times, but also favourable safety profiles; however the cost implications have not been previously fully investigated [21]. A study by Khalafallah et al.[22] compared the cost of a 15-minute FCM infusion with a 2-hour IPM infusion in the treatment of IDA during pregnancy. No significant difference between the average overall costs of the two infusion options was found but only a single standardized 1-gram dose was investigated, and the costing incorporated other aspects of patient care over and above the infusion itself. By contrast, our study measured and accounted for the actual labour costs associated with each infusion. Furthermore, it accounted for variations in manufacturing and medication costs at different doses. To the best of our knowledge, our study is the only study which has investigated costs at a range of doses for FCM and various types of IPM protocols. Our findings support the increasing uptake of IPM rapid protocols in Australia [11,15].

Between 2013 and 2017, there has been an increase in the use of intravenous iron which is may be due to the listing of ferric carboxymaltose on the PBS in 2014 [23]. One of the drivers for the increasing FCM use in recent years can be related to its short infusion duration and thus increased capacity for infusions per day compared to IPM infusion protocols, particularly when only 1g of iron is required. For example, a higher number of patients can be administered 1g infusions in a standard workday (7.5 hours) if FCM is administered instead of IPM rapid (10 vs 6 a day, respectively). When doses over 1g are required however, the numbers are more comparable, accounting for FCM patients needing to return for a second infusion at least a week later. Interestingly, Gilmartin et al.[24] found that only 14% of patients who require more than 1g of FCM return for their second dose. From a clinical perspective, IPM rapid infusions may be preferred for patients requiring more than 1g of iron, despite costing more.

The main limitation of this study was the difficulty in IPM data collection due to the ready availability of the premix IPM bags and the local preference for using FCM. Only six IPM infusions were manufactured during the data collection period. Instead of going through the time-motion process, these infusions were time-stamped by pharmacy manufacturing staff; although not ideal, this was sufficient to generate a mean labour time for the manufacturing of IPM infusions. Similarly, no observations were made of the administration and associated patient monitoring for any IPM infusion. We maneuvered around this by extrapolating IPM costs from FCM infusion administration costs. This was possible as the process to set-up the infusions once manufactured is the same, and the parameters involved in monitoring the patient for each infusion type are similar.

Conclusion

The IPM Ampoules Rapid protocol was cheaper than both FCM without government subsidies and the traditional slow IPM infusion protocol. Switching any FCM infusions that do not meet subsidy requirements and IPM slow infusion protocols to IPM Ampoules Rapid at our local study site is projected to yield up to almost twelve thousand dollars' worth of savings annually. Further studies considering all costs beyond the hospital perspective (i.e. patient costs associated with repeat FCM infusions) would be useful to further explore and compare the cost implications of these protocols.

Declarations

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Conflicts of interest

The authors have declared no potential conflicts of interest.

Availability of data and material

The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported. The lead author affirms that no important aspects of the study have been omitted and that any discrepancies from the study as planned have been explained. All authors had full access to all of the data (including statistical reports and tables) in the study.

Code availability

No software or code was used over the course of the study.

Ethics approval

The study was approved by the Tasmanian Human Research Ethics Committee (ref: H0017749).

Consent to participate

No patient personal data was collected in the study.

Consent for publication

All authors consent for this manuscript to be sent for publication.

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