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Original Research Article

Comparative efficacy and safety of ferric carboxymaltose, iron sucrose and iron sorbitol in treatment of iron deficiency anemia in Indian pregnant women

Keval Ashok Patil^{1*}, Manpreet Kaur Tehalia²

¹Department of Obstetrics and Gynecology, Matruseva Superspeciality Center, Miraj, Maharashtra, India

²Department of Obstetrics and Gynecology, Al Ameen Medical College and Hospital, Vijayapur, Karnataka, India

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*Correspondence:

Dr. Keval Ashok Patil,

E-mail: dr.kevalpatil@gmail.com

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ABSTRACT

Background: There's paucity of data on comparative efficacy and safety of ferric carboxymaltose (FCM), iron sucrose (IS) and iron sorbitol (ISr) in management of iron deficiency anemia (IDA) in pregnancy. Present study assessed the efficacy and safety of these iron preparations in management of IDA in Indian pregnant women.

Methods: This was a single-centre, parallel-group, open-label, randomised clinical trial. Total 150 pregnant women of 24 to 34 weeks of gestation with IDA and hemoglobin between 6.5 to <9.0g/dL, were randomised to three groups to receive either FCM, IS or ISr. Primary outcome was improvement in hemoglobin and serum ferritin levels with FCM, IS and ISr. Comparative improvement in other hematological parameters, tolerability and safety were also analysed.

Results: At 2 weeks, significant increase in hemoglobin of 1.86 g/dL was noted with FCM compared to 1.24 and 0.83 g/dL with IS and ISr respectively. At 6 weeks, increase in hemoglobin with FCM (4.02 g/dL) was almost two times of that with ISr (2.08 g/dL) and almost 1.4 times of that with IS (2.87g/dL). Significant improvement in serum ferritin was noted with FCM (25.59 µg/L) compared to IS (18.86 µg/L) and ISr (13.84 µg/L) at 2 weeks and also at 6 weeks (87.71 vs. 65.22 vs. 43.5 µg/L). Improvement in other hematological parameters was also significantly more with FCM compared to IS and ISr. Minor adverse effects were seen with IS and FCM. No serious adverse effects were reported in any group.

Conclusions: FCM 1000 mg rapidly corrects hemoglobin and replenishes iron stores in pregnant women with moderate to severe anemia reporting in third trimester.

Keywords: Anemia, FCM, India, IDA, Iron sucrose, Pregnancy

INTRODUCTION

Anemia is one of the most common and major health problem worldwide. South Asian countries have the highest prevalence of anemia in the world and India is at the top among them.¹ In India, most commonly affected group by anemia is pregnant women, almost two-third of all pregnant women are anemic.²

IDA is the most common cause of anemia in pregnancy.³ The prevalence of IDA is 18% in developed countries and

35-75% in developing countries.⁴ Almost 53.7% Indian pregnant women are anemic as reported in NHFS-5 survey.⁵ The reasons for high prevalence are low quantities of iron in diet; malabsorption; phytates, phosphates, tannins, and polyphenols in food; repeated pregnancies; poor iron stores at birth; frequent infections like malaria and hookworm infestations.^{6,7}

The adverse physiological and psychological outcomes of IDA in the mothers include impaired cardiovascular function, reduced immune function, tiredness, increased

chances of peripartum blood transfusion, impaired cognitive performance and increased depressive episodes. The adverse effects seen in the fetus or the infants are preterm birth, fetal growth restriction, intrauterine fetal death, low APGAR scores, and neonatal infection.⁸⁻¹⁴ Maternal iron deficiency in late pregnancy and around childbirth has also been associated with childhood developmental delay.¹⁵

Prophylactic oral iron supplementation for approximately six months is recommended during pregnancy to avoid IDA and its complications.¹⁶ Oral iron preparations are preferred for mild to moderate anemia however, significant gastrointestinal side effects affecting compliance to therapy is noted.¹⁷ Also, they may not be effective when rapid iron repletion is required.¹⁸ Therefore, various parenteral iron preparations are used in the pregnant women not responding to the oral iron therapy.¹⁹

The most commonly used parenteral iron preparations in India for treatment of IDA associated with pregnancy, are intravenous (IV) FCM, IV IS and intramuscular (IM) ISr.²⁰⁻²² Indian Ministry of Health and Family Welfare, released operational guidelines of an intensified national iron plus initiative (I-NIPI), Anemia Mukht Bharat. This guideline provides protocols for management of anemia during pregnancy.²³ As per the guidelines, parental iron (IV IS or FCM) may be considered as the first line of management in pregnant women with mild (10-10.9 g/dL) or moderate anemia (7-9.9 g/dL) detected late in pregnancy or in whom compliance to oral iron is likely to be low. Also, IS or FCM is considered as a second-line treatment in case no improvement is observed with the oral iron supplement. In severe anemia (5.0-6.9 g/dL), IS or FCM is recommended as first-line treatment.²³ There is paucity of data of comparative efficacy and safety of these three iron preparations in management of IDA, particularly in pregnancy. Therefore, to assess the efficacy and safety of FCM, IS and ISr in the treatment of IDA in Indian pregnant women this study was designed as a parallel group study. Since this was an observational study, it was open-labelled and to avoid selection bias of investigator, the patients were randomised to either of the three groups.

METHODS

Study design

A single centre, parallel group, open label, randomised clinical trial at tertiary care teaching institute and research centre.

Patient characteristics

Pregnant women of 24 weeks to 34 weeks of gestation undergoing antenatal care at a tertiary care teaching institute and research centre with hemoglobin levels between 6.5 g/dL to <9.0 g/dL, with no prior iron therapy or iron therapy received more than 6 weeks with no clinical

benefit prior to enrolment. Pregnant women with anemia not linked to iron deficiency, intolerance to iron derivatives, women with history of asthma, thromboembolism, seizures, drug abuse, renal or hepatic dysfunction were excluded.

Duration of study

The study was conducted between October 2013 and June 2015.

Randomisation

Participants were enrolled and randomly assigned using a computer-generated randomisation table, to receive either FCM or IS or ISr.

Treatment characteristics/procedures

FCM was administered as a single dose infusion of 1000 mg over 15 minutes in 100 ml normal saline. IS was administered as infusion of 200 mg/day over 20 minutes in 100 ml normal saline for 5 days (total 1000 mg). After giving a test dose of 0.5 ml deep IM before 1st dose, ISr was administered as intramuscular administration of 75 mg/day for subsequent 13 days (total 1000 mg). Participants were observed for any immediate adverse events. All participants were followed up 2 weeks and 6 weeks after drug administration for blood parameters and also observed for any delayed adverse effects.

Outcomes

Primary outcome

It was to compare the efficacy of FCM, IS and ISr in terms of improvement in mean hemoglobin levels and serum ferritin levels.

Secondary outcome

To compare improvement in reticulocyte count, red blood cell (RBC) count, packed cell volume (PCV), mean corpuscular hemoglobin (MCH), mean corpuscular volume (MCV), mean corpuscular hemoglobin concentration (MCHC) and compare the side effects of these three drugs.

The hemoglobin, ferritin levels, reticulocyte count, red blood cell (RBC) count, packed cell volume (PCV), mean corpuscular hemoglobin (MCH), mean corpuscular volume (MCV), and mean corpuscular hemoglobin concentration (MCHC) were recorded at baseline, 2 weeks and 6 weeks interval after administration of parenteral iron. Efficacy of the three drugs was assessed as difference in these parameters from baseline to 2 weeks and from baseline to 6 weeks. Safety of the drugs was assessed as the incidence of any adverse event during the study duration.

Ethical considerations

This study was conducted in accordance with principles of the declaration of Helsinki, international conference on harmonization-good clinical practice (ICH-GCP) guidelines, and Indian regulatory guidelines (Indian council of medical research (ICMR) and Indian GCP guidelines. Ethics committee approval was obtained from the institutional ethics committee and written informed consent was obtained from each participant before starting the study.

Statistical analyses

All the values for the continuous variables are mentioned as mean \pm SD and the changes in values from baseline are mentioned as mean difference \pm SD. The values at baseline, 2 weeks, 6 weeks, changes from baseline for all continuous variables were compared using one-way ANOVA test and post hoc analysis was done using post-hoc Tukey's test. Paired t test was carried out to see the trend of parameters with time. $P < 0.05$ was taken as significant. The statistical analysis was done using SPSS version 20 software.

RESULTS

Total 150 patients of IDA were identified and randomised in three groups between October 2013 and June 2015 (Figure 1).

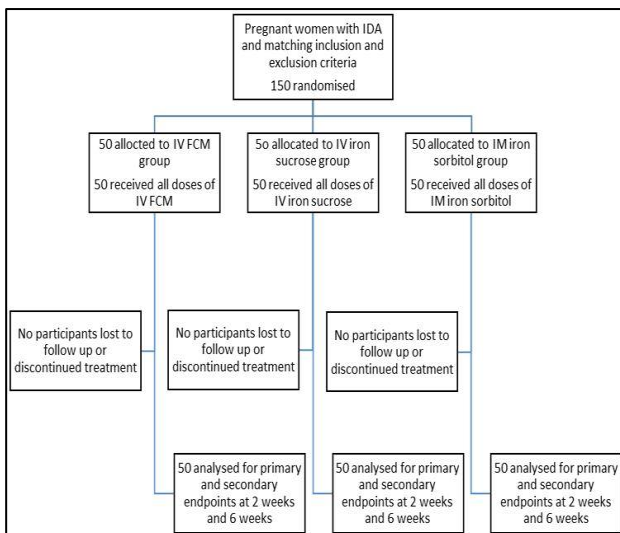


Figure 1: Study flow chart.

Abbreviations: IDA-Iron deficiency anemia; IV-Intravenous; FCM-Ferric carboxymaltose; IM-Intramuscular.

Demographic details and baseline hematological characteristics are mentioned in the Table 1. Baseline hemoglobin level observed was the similar in all the groups.

In all the three groups, the hemoglobin and serum ferritin levels at 2 weeks and 6 weeks after iron therapy were

significantly higher compared to baseline (Table 2). The mean hemoglobin and mean serum ferritin levels at two weeks and six weeks in FCM group were significantly higher compared to the IS as well as the ISr groups (Table 2).

In FCM group, significant increase in hemoglobin of 1.86 g/dL was noted compared to 1.24 and 0.83 g/dL in IS and ISr group respectively, at 2 weeks ($p < 0.001$). At 6 weeks, almost two times more increase in hemoglobin was noted in FCM group compared to ISr group (4.02 vs. 2.08 g/dL; $p < 0.001$) and almost 1.4 times higher hemoglobin noted in FCM group compared to IS group (4.02 vs. 2.87 g/dL; $p < 0.001$) (Figure 2). At 2 weeks, an increase of 25.59 μ g/L in serum ferritin was observed in FCM group. This increase in serum ferritin was significantly higher compared to increase of 18.36 μ g/L in IS group and 13.84 μ g/L in ISr group ($p < 0.001$). Similarly, at 6 weeks, increase in serum ferritin noted in FCM group was 87.71 μ g/L, which was significantly higher than that observed in IS group and ISr group (65.22 μ g/L and 43.5 μ g/L respectively; $p < 0.001$) (Figure 3).

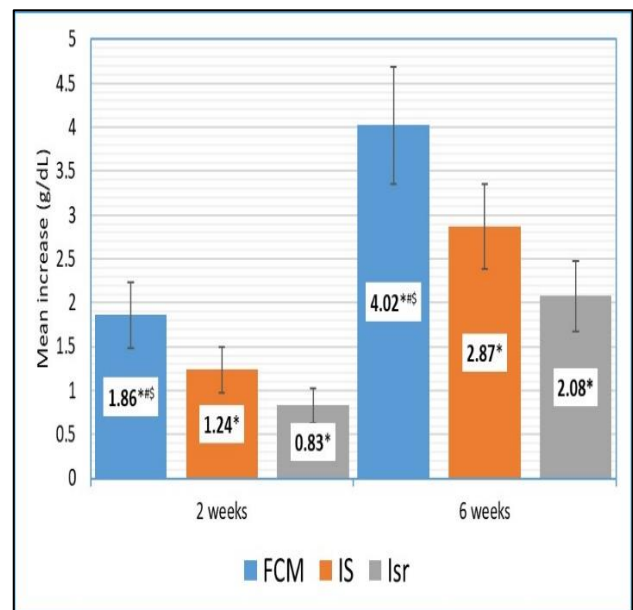


Figure 2: Increase in hemoglobin after parenteral iron therapy.

* $P < 0.001$ -Statistically significant increase from baseline analysed using paired t test; #Increase in hemoglobin with FCM significantly more compared with IS ($p < 0.001$ Posthoc Tukey's Test); \$Increase in hemoglobin with FCM significantly more compared with ISr ($p < 0.001$ Posthoc Tukey's test).

Abbreviations: FCM-Ferric carboxymaltose; IS-Iron sucrose; ISr-Iron sorbitol.

Significant improvement in all hematological parameters like RBC count, PCV, MCH, MCHC, MCV and reticulocyte count was noted in all three groups at two and six weeks. Similarly, more improvement was noted in FCM group vs. IS as well as the ISr group shown in the Figure 4.

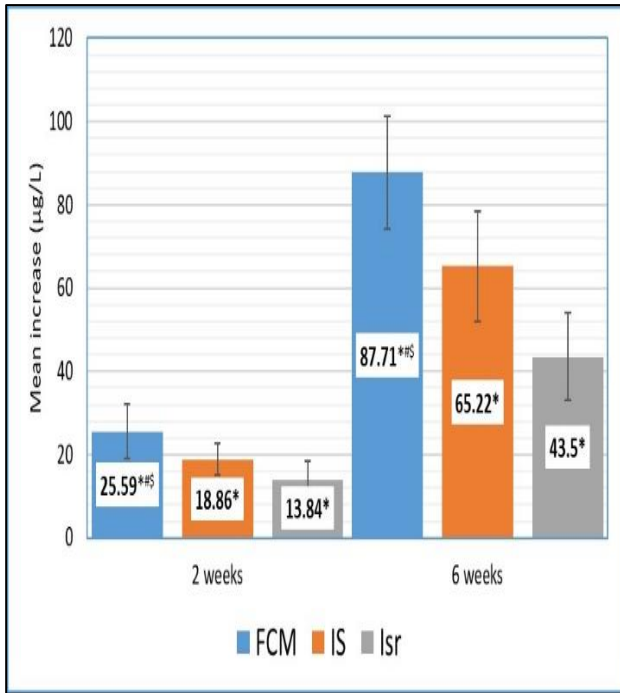


Figure 3: Increase in serum ferritin after parenteral iron therapy.

*P<0.001-Statistically significant increase from baseline analysed using paired t test; #Increase in serum ferritin levels with FCM significantly more compared with IS (p<0.001 Posthoc Tukey's test); §Increase in serum ferritin levels with FCM significantly more compared with ISr (p<0.001 Posthoc Tukey's test).

Abbreviations: FCM-Ferric carboxymaltose; IS-Iron sucrose; ISr-Iron sorbitol.

Total 53 adverse effects were observed throughout the duration of the study. Higher number of adverse effects were seen in the ISr group (n=32) compared to IS group (n=14) and ferric carboxymaltose group (n=7). Local pain (n=12), skin staining (n=10) and local induration (n=4) were seen with ISr and not with ferric carboxymaltose or IS. Minor adverse effects like shivering, local phlebitis,

headache was observed in IS group and ferric carboxymaltose group. Local phlebitis was the most common adverse effect noted in IS group (n=7) and in Ferric carboxymaltose group (n=4). No serious adverse effects were reported in any of the participants.

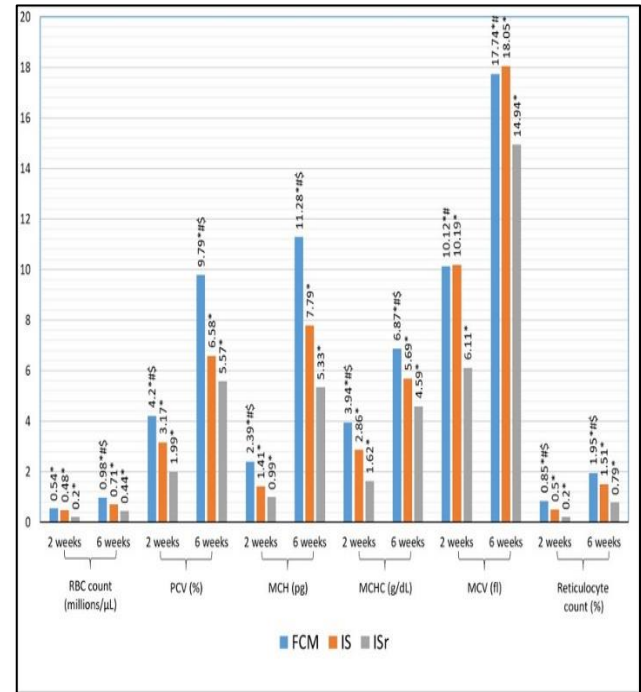


Figure 4: Change in hematological parameters after iron therapy.

*P<0.001-Statistically significant increase from baseline analysed using paired t test; #Significant difference between FCM group and IS group (p<0.01 Posthoc Tukey's test); §Significant difference between FCM group and IS group (p<0.01 Posthoc Tukey's test).

Abbreviations: FCM-Ferric carboxymaltose; IS-Iron sucrose; ISr-Iron sorbitol; RBC-Red blood cell; PCV-Packed cell volume; MCH-Mean corpuscular hemoglobin; MCHC-Mean corpuscular hemoglobin concentration; MCV-Mean corpuscular volume; wks-weeks.

Table 1: Baseline characteristics of study participants.

Characteristics	FCM group (n=50)	IS group (n=50)	ISr group	P value (ANOVA)
Age (years)	25.78±3.67	25.66±3.45	24.94±3.3	0.428
Hb (g/dL)	7.84±0.6	7.95±0.63	8.08±0.76	0.218
RBC count (millions/µL)	3.6±0.46	3.65±0.45	3.76±0.43	0.202
PCV (%)	23.69±1.99	23.93±1.81	24.2±2.47	0.532
MCH (pg)	21.1±2.04	21.16±1.78	21.18±2.09	0.975
MCHC (g/dL)	26±2.15	25.91±2.26	25.96±2.13	0.977
MCV (fl)	70.48±5.28	68.94±6.69	68.49±7.9	0.247
Reticulocyte count (%)	1.35±0.19	1.4±0.23	1.46±0.3	0.074
Sr. Ferritin (µg/L)	14.43±5.83	13.06±4.62	13.71±5.03	0.419

Values expressed as mean ± standard deviation; n=number of study participants.

Abbreviations: ANOVA-Analysis of variance; FCM-Ferric carboxymaltose; Hb-Hemoglobin; RBC-Red blood cell; PCV-Packed cell volume; MCH-Mean corpuscular hemoglobin; MCHC-Mean corpuscular hemoglobin concentration; MCV-Mean corpuscular volume; Sr.-Serum.

Table 2: Change in hemoglobin and serum ferritin levels.

Parameters	Timeline	FCM group (n=50)	IS group (n=50)	ISr group (n=50)	P value (ANOVA)
Hemoglobin (g/dL)	At baseline	7.84±0.6	7.95±0.63	8.08±0.76	0.218
	At 2 weeks	9.70±0.7 [#]	9.19±0.67	8.92±0.76	<0.001*
	Change from baseline to 2 weeks	1.86±0.37 [#]	1.24±0.26	0.83±0.2	<0.001*
	At 6 weeks	11.86±0.8 [#]	10.83±0.7	10.16±0.76	<0.001*
	Change from baseline to 6 weeks	4.02±0.67 [#]	2.87±0.48	2.08±0.4	<0.001*
Serum ferritin (µg/L)	At Baseline	14.43±5.83	13.06±4.62	13.71±5.03	0.419
	At 2 weeks	40.02±8.33 [#]	31.92±6.13	27.56±7.04	<0.001*
	Change from baseline to 2 weeks	25.59±6.65 [#]	18.86±3.82	13.84±4.56	<0.001*
	At 6 weeks	102.13±14.66 [#]	78.28±13.95	57.22±12.77	<0.001*
	Change from baseline to 6 weeks	87.71±13.41 [#]	65.22±13.29	43.5±10.56	<0.001*

Values expressed as mean ± standard deviation; *p<0.001 statistically significant for one-way ANOVA test; n-number of study participants; #Value in FCM group significantly higher compared to iron sucrose group (p<0.001 Posthoc Tukey's test); \$ value in FCM group significantly higher compared to iron sorbitol group (p<0.001 Posthoc Tukey's test).

Abbreviations: ANOVA-Analysis of variance; FCM-Ferric carboxymaltose.

DISCUSSION

IDA in mid to late pregnancy is very common in India and can lead to serious maternal and fetal complications. Rapid correction of anemia and repletion of iron stores is advised to avoid these complications. Many guidelines suggest parenteral iron preparations should be preferred over oral iron for treatment of moderate to severe anemia in second and third trimester of pregnancy.^{3,24} In India, both intramuscular and intravenous iron preparations are used for treatment of IDA. The ministry of health and family welfare guidelines for treatment of IDA in pregnancy had recommended IM iron after a test dose for moderate anemia in pregnancy.²⁴ Intramuscular ISr was one of the first line drug for this indication.²⁵ IV iron administration is an alternative treatment option for IDA in pregnancy and has been recommended in various latest guidelines.²⁶ IV iron preparations promise a better and rapid response in treatment of moderate to severe anemia, especially in late second and third trimester. They also minimise need for blood transfusions in antenatal and postpartum period.²⁷

Present study assessed the efficacy and safety of FCM, IS, ISr in management of moderate to severe IDA in Indian pregnant women at tertiary care teaching and research institute. The study highlights that single FCM infusion in third trimester led to increase in hemoglobin levels and also restored the iron stores that were significantly more compared to both IS and ISr. In the present study, all pregnant women reported in third trimester with moderate to severe anemia. Within 6 weeks of treatment, substantial increase of hemoglobin by 4.02 g/dL was noted after single FCM injection which was 2 times and 1.4 times more than ISr and IS respectively. Similarly, significant increase of 87.7 µg/L in ferritin levels was noted in FCM group. This highlights that FCM also replenishes iron stores effectively.

In past few years, multiple studies have been published on usage of FCM in pregnancy which have highlighted efficacy and safety of FCM with dosage upto 1500 mg over a follow-up period of 3 to 12 weeks.²⁸⁻³¹ These studies report rise in hemoglobin levels by 1.54 g/dL to 2.9 g/dL over 3 to 12 weeks and replenishment of iron stores with FCM infusion. In another observational study, the efficacy and safety of FCM in Indian pregnant women with moderate-to-severe anemia was assessed by Gupte et al.³² This study reported significant increase in Hb within 4 to 6 weeks, with a mean dose of FCM of 1057 mg.³² In a comparative observational study, Jose et al reported treatment with FCM resulted in faster replenishment of iron stores and significantly higher rise in Hb compared to IS, over a duration of 12 weeks.³¹

Similar studies by Naqash et al, Agrawal et al, Mahaur et al and Patel et al evaluating the efficacy and safety of FCM in comparison to IS in treatment of moderate to severe anemia in Indian pregnant women, concluded FCM was more effective and safer compared to IS.³³⁻³⁶ Similar findings were reported in our study. Pregnant women with moderate to severe anemia reporting in third trimester, always pose a clinical challenge as there is significant risk of impaired cardiovascular function, compromised immunity, premature delivery, low birth weight and intrauterine fetal death.^{13,14,37} Not only rapid increase in hemoglobin but also replenishment of iron stores is required to avoid these complications. Our study highlights that single injection of 1000 mg FCM, in addition to significantly increasing hemoglobin levels, also replenishes iron stores effectively. Our study also demonstrates FCM is a comparatively safe treatment option for correction of IDA as only a few minor adverse effects as well as no serious adverse effects were reported in study.

To the best of our knowledge this is the first Indian study which significantly compares FCM, IS and ISr. There are few interesting results noted in this study which have significant clinical implications. In the present study, FCM was well tolerated with minor adverse effects. Adverse effects reported in ISr group were more than IS and FCM. Both FCM and IS were well tolerated in this study.

CONCLUSION

This study represents important clinical outcome to resource depleted developing country like India, where the prevalence of anemia is high and limited healthcare resources. In this study FCM single 1000 mg injection represents an important treatment option for correcting anemia and restoring iron stores in pregnant women reporting in late second or third trimester with moderate to severe anemia.

Thus, a single 1000 mg FCM injection in early third trimester is recommended in all pregnant women with moderate to severe IDA.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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