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Dr. Anil Gupta, a graduate of the University of Toronto's Faculty of Medicine, is a primary care physician, researcher, and author with over 19 years of experience as a principal investigator in more than 150 clinical trials. His passion for clinical research led him to play a key role in groundbreaking studies on COVID-19 treatments during the pandemic. Dr. Gupta was the lead author of two major publications in the *New England Journal of Medicine (NEJM) and Journal of the American Medical Association (JAMA)*, focusing on the efficacy and safety of the SARS-CoV-2 neutralizing antibody, sotrovimab. Additionally, he contributed as a lead collaborator to the KidCOVE study evaluating the mRNA-1273 vaccine for children aged 6–11. His extensive research background includes a trial on Vitamin B-12 deficiency in South Asians published in CFPC May,2004. Reflecting on his work, Dr. Gupta takes pride in demonstrating that family doctors can make significant contributions to clinical research, proving that groundbreaking studies are not limited to specialists.

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Comparative Study of Ferrous Fumarate, Ferrous Ascorbate, and Polysaccharide Iron for Treating Iron Deficiency Anemia in Adults

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Iron deficiency anemia (IDA) is a highly prevalent condition encountered in clinical practice and represents a major global health concern, affecting an estimated 1.92 billion individuals worldwide. Despite its prevalence and the availability of various oral iron formulations with wide cost variations, comparative data on their efficacy and tolerability remain limited.

This randomized, open-label trial conducted across two centres evaluated the efficacy, tolerability, and adherence of three oral iron supplements in improving hemoglobin and ferritin levels in adults with IDA. The study compared ferrous fumarate (Eurofer, 100 mg elemental iron, $15.87 for 90 tablets), ferrous ascorbate (EBMfer, 100 mg elemental iron, $68.97 for 90 tablets), and polysaccharide iron (FeraMAX, 150 mg elemental iron, $77.97 for 90 tablets). A total of 111 participants aged ≥18 years were randomly assigned into one of three treatment groups and monitored over a 12-week period.

Both ferrous fumarate (p=0.001) and ferrous ascorbate (p<0.001) demonstrated significantly greater hemoglobin and ferritin levels compared to polysaccharide iron. Specifically, ferrous fumarate led to mean increases in hemoglobin and ferritin of 11.59 g/L (95% confidence interval [CI]: 7.87–15.3, standard deviation [SD]: 10.7) and 19.21 µg/L (95% CI: 7.82–28.6, SD: 29.8), respectively. Ferrous ascorbate showed mean increases in hemoglobin and ferritin levels of 17.14 g/L (95% CI: 13.5–20.8, SD: 10.7) and 23.51 µg/L (95% CI: 16.5–30.5, SD: 20.3), respectively. Polysaccharide iron showed mean increases in hemoglobin and ferritin of 3.56 g/L (95% CI: -0.06–7.18, SD: 10.4) and 3.21 µg/L (95% CI: -0.07–6.48, SD: 9.39), respectively.

Adverse events occurred more frequently with ferrous fumarate (13 events) compared with ferrous ascorbate (8 events) and polysaccharide iron (6 events). The most commonly reported side effects across all groups were constipation and bloating, well-documented side effects of iron supplements.

These findings demonstrate that ferrous fumarate and ferrous ascorbate significantly outperformed polysaccharide iron in improving hemoglobin and ferritin levels. Given its lower cost and comparable efficacy, ferrous fumarate may be the most cost-effective option and warrants consideration in updates to Canadian treatment guidelines.

Introduction

Iron deficiency anemia (IDA) remains a major global health concern, affecting over 1.92 billion individuals and contributing significantly to morbidity and diminished quality of life.[1] This condition disproportionately impacts vulnerable populations, including females of reproductive age, children, and older adults, leading to impaired cognitive and physical performance.[2] IDA can arise from various causes, including blood loss and dietary factors.[2]

In our clinical experience, IDA is a frequently encountered condition. We have observed significant variability in how patients with IDA respond to different iron supplements, which prompted us to closely examine the existing literature.

Despite the high prevalence of IDA and the availability of multiple oral iron formulations, comparative data on their efficacy remains limited. Among the studies that do exist, several have reported notable differences in outcomes. However, many of these studies were published in lesser-known medical journals, often years ago, and may not be widely recognized or referenced.

A 2004 trial revealed that ferrous fumarate significantly improved hemoglobin levels (28.4 g/L) compared to (6 g/L) with polysaccharide iron, though it was associated with a higher incidence of gastrointestinal side effects.[3] Similarly, a 2017 study in pediatric patients reported anemia resolution in 29% of children treated with ferrous sulfate, whereas only 6% of those receiving polysaccharide iron achieved resolution.[4]

In Canada, clinical guidelines for IDA management recommend selecting a supplement based on cost and tolerability rather than efficacy, despite evidence suggesting otherwise.[5-8] Commonly reported side effects of oral iron supplements include constipation, nausea, vomiting, abdominal discomfort, and dark or black stools.[5,7]

This study aimed to address knowledge gaps by comparing the effectiveness of three ferrous salts—ferrous fumarate (EuroFer), ferrous ascorbate (EBMFer), and polysaccharide iron (FeraMax)— in improving hemoglobin and ferritin levels in adults with IDA over a 12-week period. These formulations were selected because ferrous fumarate and polysaccharide iron are commonly recommended options in Canadian practice, while ferrous ascorbate, a formulation commonly used in other regions, has shown promising results and is also available in Canada.

Materials and Methods

Study Design

A randomized, open-label, parallel-group trial was conducted between February and December 2024 in a clinical practice setting at two family practices located in northwest Toronto and the Peel region—areas known for their highly diverse populations. Participants were recruited through referrals from local physicians and community advertisements.

The study received approval from the Advarra Central Institutional Review Board (CIRBI). Written informed consent was obtained from all participants before enrolment. The study was conducted and analyzed in accordance with the Consolidated Standards of Reporting Trials (CONSORT).

Following a one-week screening period, eligible participants were randomly assigned in a 1:1:1 ratio to receive one of the three iron supplements once daily for 12 weeks: ferrous fumarate (100 mg elemental iron, $15.87 for 90 tablets), ferrous ascorbate (100 mg elemental iron, $68.97 for 90 tablets), or polysaccharide iron complex (150 mg elemental iron, $77.97 for 90 tablets). Randomization was stratified by treatment arm using block randomization to ensure balanced group allocation. Treatment assignments were generated using a predefined, computer-generated randomization sequence. Study medications were obtained from a local pharmacy and provided to participants at no cost.

At the baseline visit, participants received standardized instructions on how to take their assigned iron supplements. All participants were advised to take one tablet daily. Those in the ferrous fumarate and polysaccharide iron groups were instructed to take their supplement on an empty stomach along with a source of vitamin C—such as orange juice, lemon water, or an over-the-counter vitamin C supplement—to enhance absorption. Participants in the ferrous ascorbate group were informed that additional vitamin C was not necessary because it is already included in the formulation.

Hemoglobin and ferritin levels were measured at baseline and at week 12, marking the end of the study. One week after the baseline visit, participants received a follow-up phone call to monitor for adverse effects and reinforce adherence. Participants who experienced side effects were offered the option of switching to alternate-day dosing. Throughout the study, participants were encouraged to contact the research staff if they experienced any adverse effects. At the final visit (week 12), participants were instructed to return any unused medication for pill counting to assess adherence. All reported adverse events were documented.

Inclusion and Exclusion Criteria

Inclusion Criteria:

Adults aged ≥18 years with confirmed IDA, defined as hemoglobin levels of ≤135 g/L for males and ≤120 g/L for females, and serum ferritin levels of <30 µg/L) were eligible for inclusion. The initial ferritin cutoff of <15 µg/L was updated to <30 µg/L based on a Canadian consensus statement.

Exclusion Criteria
1. Medical Conditions:
• Hemoglobin level of ≤80 g/L
• History of hematological disorders (e.g., aplastic anemia or megaloblastic anemia)
• Chronic renal disease, inflammatory disorders, or severe chronic conditions affecting safety
• History of intestinal malabsorption, hemochromatosis, or gastrointestinal surgery
• Significant bleeding or history of occult blood in stool
• Severe psychological disorders that may interfere with study participation
2. Iron Supplementation:
• Use of any other oral or intravenous iron supplements during the study
3. Prohibited Medications:
• Use of proton pump inhibitors, cholestyramine, colestipol, or initiation of anticoagulants within the past 6 months
4. Blood Transfusion/Donation/Intravenous Iron Therapy:
• History of blood transfusion, blood donation, or intravenous iron therapy within the past 4 months
5. Pregnancy and Conception:
• Pregnant individuals, those actively trying to conceive, or those undergoing fertility treatment
6. Hypersensitivity:
• Known or suspected hypersensitivity to iron or any formulation components
7. Surgical and Blood Sampling Considerations:
• Recent or planned surgery or difficulties with blood sampling
8. Alcohol/Drug Abuse:
• Evidence of alcohol or drug abuse likely to interfere with study adherence

Table 1. Summary of Exclusion Criteria for the Iron Supplementation Clinical Trial; *courtesy of Anil Gupta, MD, CCFP, FCFP, Amisha Gandhi, Ind. Elec. Eng., Vishwas Kini, MD, CCFP, Kira Gupta-Baltazar, BSc (Hons) and Karen Tu, MD, CCFP, FCFP.*

Exclusion Criteria:

Outlined in **Table 1**, exclusion criteria included severe anemia (hemoglobin ≤80 g/L), hematological disorders, chronic illnesses, pregnancy, and known hypersensitivity to iron. The study protocol is provided in Supplement 1.

Outcome Measures

The primary outcome was the change in hemoglobin levels from baseline to 12 weeks between participants receiving ferrous fumarate and those receiving polysaccharide iron.

Secondary outcomes included comparisons of changes in hemoglobin levels from baseline to 12 weeks between the ferrous ascorbate and polysaccharide iron groups, changes in ferritin levels across all three groups, and evaluations of tolerability and discontinuation rates among the three oral formulations.

Sample Size

The study was designed with a power of 80% and a significance level of $\alpha=0.05$ to detect a large effect size (0.7). To account for potential dropouts and missing data, the sample size was increased from 99 to 111 participants to ensure robust analysis.

Parameters	Ferrous Fumarate (*Eurofer*)	Ferrous Ascorbate (*EBMfer*)	Polysaccharide Iron (*FeraMAX*)
Age range (years)	18–75	20–83	22–82
Mean age (years)	47	42	47
Age distribution (years)			
(18–30)	4	5	4
(31–50)	19	24	18
(51–70)	5	5	8
(≥71)	4	1	4
Male participants	7 (20.6%)	3 (8.6%)	5 (14.7%)
Female participants	27 (79.4%)	32 (91.4%)	29 (85.3%)
Baseline mean hemoglobin (g/L)	112.06	107.4	111.56
Baseline mean ferritin (ug/L)	15.21	11.77	13.44

Table 2. Demographic and Baseline Hemoglobin and Ferritin Parameters by Iron Supplementation Group; *courtesy of Anil Gupta, MD, CCFP, FCFP, Amisha Gandhi, Ind. Elec. Eng., Vishwas Kini, MD, CCFP, Kira Gupta-Baltazar, BSc (Hons) and Karen Tu, MD, CCFP, FCFP.*

Randomization and Allocation of Intervention Products

Statistical Methods

Statistical analyses were performed using jamovi 2.3.28, alongside R (version 4.1) and its associated statistical packages. Due to violations of normality confirmed by the Shapiro-Wilk test, non-parametric methods were applied. Specifically, the Kruskal-Wallis test and Mann-Whitney U test were employed for between-group comparisons.[9-11]

Results

Participant Flow

Of the 196 individuals screened, 111 were randomized into the study. A total of 103 participants (88 females and 15 males) completed all study procedures. **Figure 1** presents the CONSORT diagram, outlining participant flow through the stages of enrolment, allocation, follow-up, and analysis. **Table 2** includes the demographic data and baseline hemoglobin and ferritin levels for each iron supplementation group.

Primary Outcome

Participants receiving ferrous fumarate experienced a mean hemoglobin increase of 11.59 g/L (95% confidence interval [CI]: 7.87–15.3, standard deviation [SD]: 10.7), compared to 3.56 g/L (95% CI: -0.06–7.18, SD: 10.4) in the polysaccharide iron group. The mean difference of 8.03 g/L significantly favoured ferrous fumarate (p=0.001) (**Table 3**).

Secondary Outcomes

Secondary outcomes are presented in **Table 3**. Participants receiving ferrous ascorbate experienced a mean hemoglobin increase of 17.14 g/L (95% CI: 13.5–20.8, SD: 10.7), compared to 3.56 g/L (95% CI: -0.06–7.18, SD: 10.4) in the polysaccharide iron group. The mean difference of 13.58 g/L favoured ferrous ascorbate (p<0.001).

Ferritin levels increased by 19.21 µg/L (95% CI: 7.82–28.6, SD: 29.8) with ferrous fumarate, 23.51 µg/L (95% CI: 16.5–30.5, SD: 20.3) with ferrous ascorbate, and 3.21 µg/L (95% CI: -0.07–6.48, SD: 9.39) with polysaccharide iron. The mean increase in ferritin was significantly greater for ferrous fumarate compared to polysaccharide iron, with a difference of 16.00 µg/L (p<0.001), and for ferrous ascorbate compared to polysaccharide iron, with a

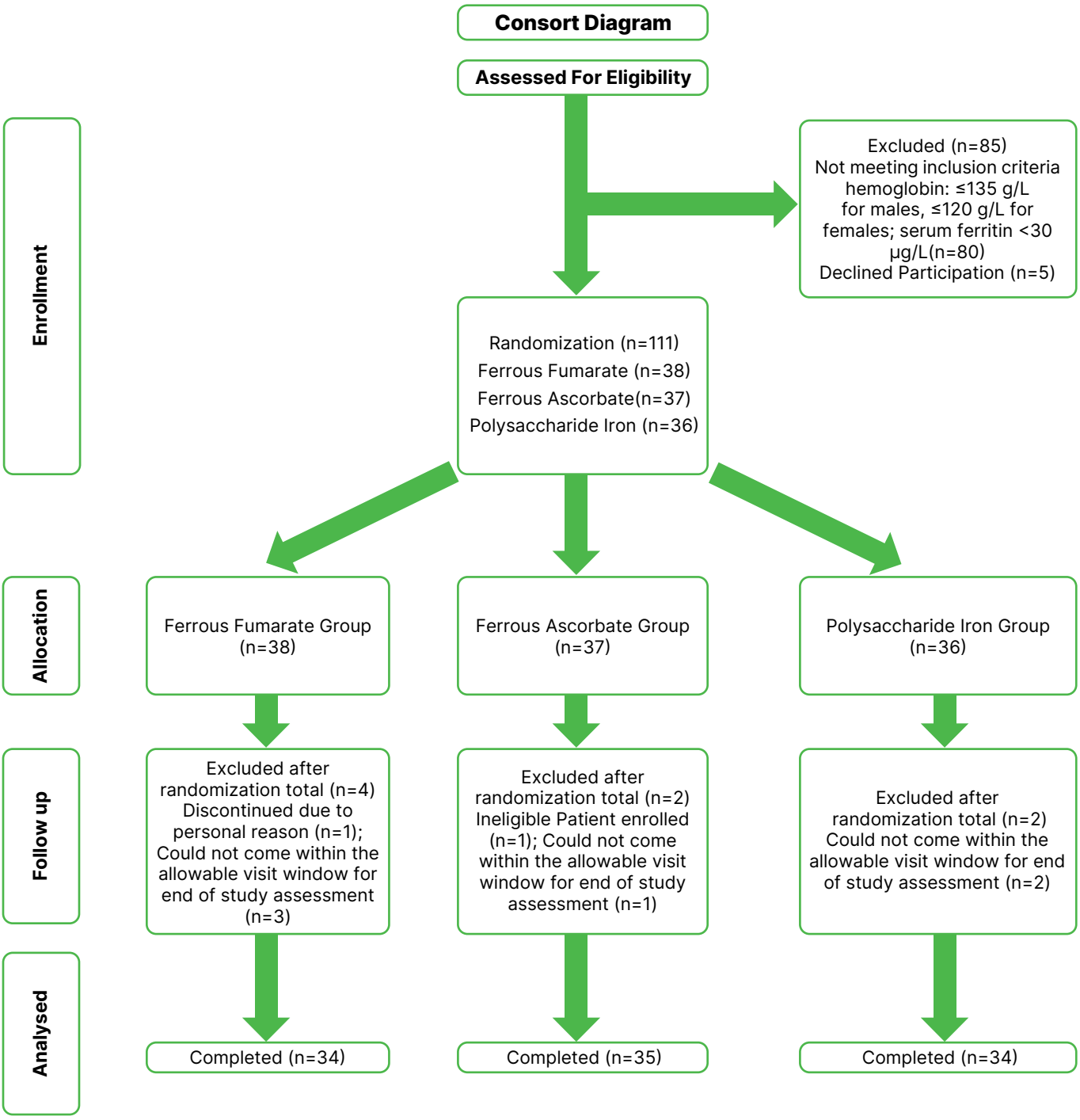

Figure 1. CONSORT Diagram; *courtesy of Anil Gupta, MD, CCFP, FCFP, Amisha Gandhi, Ind. Elec. Eng., Vishwas Kini, MD, CCFP, Kira Gupta-Baltazar, BSc (Hons) and Karen Tu, MD, CCFP, FCFP.*

	Mean Hemoglobin Level (*g/L*) at Baseline Visit	Mean Hemoglobin Level (*g/L*) at End of Study Visit	Mean Change in Hemoglobin Level (*g/L*) from Baseline to End of Treatment	Mean Ferritin Level (*µg/L*) at Baseline Visit	Mean Ferritin Level (*µg/L*) at End of Study Visit	Mean Change in Ferritin Level (*µg/L*) from Baseline to End of Treatment	Mean Compliance (*%*)	Reported Adverse Events
Ferrous Fumarate (Eurofer) (n=34)	112.06	123.65	11.59	15.21	34.42*	19.21*	79	13
Ferrous Ascorbate (EBMfer) (n=35)	107.4	124.54	17.14	11.77	35.29	23.51	79	8
Polysaccharide Iron (FeraMAX) (n=34)	111.56	115.12	3.56	13.44	16.64	3.21	89	6

Table 3. Comparison of Hemoglobin, Ferritin, Compliance and Adverse Events Across Iron Supplement Groups from Randomization to End of Study; *courtesy of Anil Gupta, MD, CCFP, FCFP, Amisha Gandhi, Ind. Elec. Eng., Vishwas Kini, MD, CCFP, Kira Gupta-Baltazar, BSc (Hons) and Karen Tu, MD, CCFP, FCFP.*

*****One participant had a post-treatment ferritin level of 197 µg/L, which could be attributed to an acute-phase reaction and may have potentially skewed the average change in ferritin levels. If this outlier is excluded, the average ferritin level (µg/L) at the end of the study would be 29.49, and the average change in ferritin (µg/L) from baseline to the end of treatment would be 13.93.

difference of 20.30 µg/L ($p<0.001$). The difference between ferrous ascorbate and ferrous fumarate was 4.30 µg/L ($p>0.05$), indicating no statistically significant difference.

Compliance Rates

The highest compliance was observed in the polysaccharide iron group (89%), followed by both the ferrous ascorbate and ferrous fumarate groups, each at 79%.

Adverse Events

Adverse events were most frequently observed from the ferrous fumarate group (n=13), followed by ferrous ascorbate(n=8), and polysaccharide iron (n=6). Constipation and bloating were reported across all groups, with abdominal pain and dark stool reported specifically with the ferrous salt formulations.

Discontinuations

Study discontinuations included four participants from the ferrous fumarate group, one from the ferrous ascorbate group, and two from the polysaccharide group. No discontinuations were attributed to adverse events, and no participants were lost to follow-up.

Discussion

This study demonstrates that ferrous salts—specifically ferrous ascorbate (EBMfer) and ferrous fumarate (EuroFer)—were more effective than polysaccharide iron (FeraMax) in improving hemoglobin and ferritin levels in adults with IDA. Notably, ferrous ascorbate was superior to ferrous fumarate in increasing hemoglobin levels.

Tolerability and compliance were highest in the polysaccharide iron group. However, with compliance rates of 79% and 89% for the ferrous salts and polysaccharide iron, respectively, all three formulations were generally well tolerated. Despite lower compliance and more frequent adverse events with the ferrous salts, they still outperformed the polysaccharide iron in improving hematologic parameters.

Although few clinical trials have directly compared the efficacy of different oral iron supplements, our findings align with the limited available evidence suggesting that ferrous salts are more effective than polysaccharide iron formulations in raising hemoglobin and ferritin levels.

We selected three oral iron supplements available in Canada, based on their domestic recommendations and international usage. Current Canadian guidelines advise choosing supplements based on cost and tolerability rather than efficacy. In our study, ferrous ascorbate and polysaccharide iron were similarly priced, whereas ferrous fumarate was approximately one-quarter the cost of either.

To our knowledge, this is the largest randomized interventional study comparing different classes of oral iron formulations. However, not all formulations were included. Additional research is needed to evaluate other commonly used preparations. Moreover, as ferritin was the sole iron marker assessed, it may not provide a comprehensive assessment of iron status.

The study population was drawn exclusively from northwest Toronto and the Peel region, which may limit the generalizability of the findings to the broader Canadian population.

Additionally, participants in the ferrous ascorbate group had lower baseline hemoglobin levels compared to the other two groups, which may have contributed to the greater increase observed in this group.

Conclusion

Ferrous salts—specifically ferrous ascorbate (EBMfer) and ferrous fumarate (EuroFer) —were significantly more effective than polysaccharide iron (FeraMax) in increasing both hemoglobin and ferritin levels. Ferrous ascorbate also demonstrated superior efficacy over ferrous fumarate in improving hemoglobin levels. These findings may inform treatment selection for IDA by integrating considerations of efficacy, cost, and tolerability.

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The study is registered on **ClinicalTrials.gov** (ID: NCT06303531) and approved by the Advarra Institutional Review Board, ensuring compliance with ethical and regulatory guidelines.

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Financial Disclosures

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