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Research Article

Transfusion Incidence and Functional Outcome Post Bilateral Total Knee Arthroplasty: Can Preoperative Intravenous Iron Supplementation Make a Difference?

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Abstract

Introduction: This prospective study examines the correlation between intravenous iron supplementation's effects on transfusion rates, Hb and PCV levels in the early postoperative period, and treatment outcomes. Additionally, we provide functional post operative outcome by TUG test, knee ROM test, and New KSS score.

Methods: The 19 patients in group B served as the study group, while the 15 patients in group A served as the control group for the study. On the first postoperative day, patients in the control group (group A) received intravenous iron. Patients in Group B were split into B1 (4 weeks), B2 (3 weeks), and B3 (2 weeks). On the day of surgery, on postoperative days 1, 3, and 14, as well as six weeks later, HB and PCV levels were measured. Day 4 and 14 TUG score and Knee ROM measured. After 90 days, a new KSS score was recorded.

Results: HB and PCV levels were shown to be greatly improved by IV iron supplementation four weeks prior to surgery, with reduced day 1 reductions. Two weeks before surgery, IV iron supplementation demonstrated a substantial increase in their haematocrit level and a decrease in day 1 decline. On days 4 and 14, Group A's TUG test and ROM were higher, although this difference was not statistically significant. Compared to no transfusion, Group B1 had a greater success rate, although this difference was not statistically significant.

Although it was less than in group A, the percentage of transfused patients in groups B1, B2, and B3 was not statistically significant. Furthermore, while this was not statistically significant, earlier preoperative intravenous iron supplementation was associated with a better success rate. Studies using a larger sample size and iron supplements at high doses may highlight the difference.

Keywords: Total Knee Arthroplasty; IV Iron Supplementation; Transfusion Incidence; Functional Outcome; Ferric Carboxy Maltose; Haemoglobin; Preoperative; PCV

Introduction

The most prevalent kind of arthritis, both in industrialised and developing nations, is osteoarthritis (OA). It is a chronic, progressive illness that gradually destroys the cartilage in the joints, causing the bones to rub against one another and to become stiff and painful, limiting movement, and eventually leading to joint deformity. Knee, hip, hand, foot, and spine joints are the ones most frequently impacted by the condition. It is linked to both modifiable and unmodifiable risk factors, including trauma, gender, bone density, genetic predisposition, obesity, and physical inactivity.

Total knee arthroplasty (TKA) replaces the articular surface of the knee joint with an artificial implant that enables smooth, frictionless movement along an anatomically correct axis, correcting the deformity brought on by OA. One of the most effective surgical treatments is total knee arthroplasty [1]. When non-surgical remedies, such as medication and the use of walking aids, have not worked, total knee arthroplasty should be explored. An efficient and secure technique that lets you go back to your regular activities while reducing pain and correcting foot abnormalities.

In surgical patients, both preoperative and postoperative anaemia are widespread [2]. Patients who are anaemic are more likely to have allogeneic blood transfusions (ABT); [3-5]. Higher postoperative infections, longer lengths of stay (LOS), and increased mortality were all independently linked with increased preoperative anaemia and ABT incidence [2,6-12].

According to research conducted in northern England, major orthopaedic procedures involving the hip, knee, and total joint replacement (THA, TKA, and hip fracture repair) that required blood transfusion accounted for 8% of all units used [13]. The demand for perioperative patient blood management strategies to enhance patient outcomes and lessen the requirement for ABT is rising [14]. An unmet medical need for Hb 13 g/dl has been discovered, and preoperative anaemia should definitely be corrected. Additionally, before conducting elective surgery, it boosts RBC volume [15]. In order to lessen the need for ABT, surgery may be accompanied with intravenous or oral iron treatment, recombinant human erythropoietin (rHuEPO) therapy, and autotransfusion modalities such preoperative autologous blood donation (PAD) and intraoperative or postoperative cell rescue (CS). It's been recommended to address anaemia beforehand [16].

Both parenteral and oral iron supplements are options. After intravenous iron treatment, clinical investigations have demonstrated quicker hematologic responses and replenishment of iron reserves. In contrast to blood transfusions, intravenous replenishment has fewer adverse effects, such as headache, nausea, vomiting, and injection site responses, but it may cause circulatory overload, allergic reactions, electrolyte imbalances, infections, and metabolic acidosis.

The key results of total knee arthroplasty are knee range of motion (ROM) and physical performance. Measures of joint function and functional ability taken prior to surgery are reliable indicators of the outcome. The time it takes a patient to get out of an armchair, walk ten feet, turn around, and get back into the same chair is measured by the TUG test. Patients were told to go along at a pace that felt secure and at ease. The time needed to finish the TUG was assessed using a stopwatch and was accurate to the nearest tenth of a second. The TUG has a strong test-retest reliability and is frequently used to assess mobility in older persons.

Doctors and people collaborated to design the new Knee Society Knee Scoring System. Versions that are both pre- and post-operative. Then, patients record their expectations, functional activity, and level of satisfaction. To more accurately describe the expectations, satisfaction, and physical activity of contemporary patients receiving total knee arthroplasty, the Knee Society developed and verified a fresh knee rating system. The new score has adequate depth and flexibility to account for various patient lives and activities.

Method

All participants were chosen to receive a slow IV infusion of 500 mg intravenous iron (ferric carboxy maltose) in 100 ml saline over the course of 45 minutes in an outpatient clinic if their haemoglobin levels were between 9.5 and 15 g/dl. In this study, that involves bilateral total knee arthroplasty, we enlisted 34 patients and then randomly assigned them to one of two groups: group A, which included 15 control patients, and group B, which included 19 study participants.

Based on whether preoperative iron supplementation was administered, the population was split into two groups.

On the first postoperative day, patients in the control group (group A) received intravenous iron (ferric carboxy maltose). 2-4 weeks before to surgery, patients in the study group (group B) received intravenous iron (ferric carboxy maltose) on an outpatient basis under the care of a doctor. Three subgroups of the study group (Group B) were established based on the time of intravenous iron supplementation.

Four patients representing Group B1 got intravenous iron four weeks prior to surgery. Seven patients representing Group B2 got intravenous iron three weeks prior to surgery. Eight patients from Group B3 got intravenous iron two weeks prior to surgery.

To maintain study consistency, the same preoperative, intraoperative, and postoperative protocols were used.

On the day of operation, one day after surgery, and three days following surgery, HB and PCV levels were assessed. On the fourth postoperative day, the TUG evaluation was conducted and the Knee ROM test was recorded.

The patient was instructed to have her sutures taken out on postoperative day 14, and the TUG score, together with her ROM, HB, and PCV values, were assessed.

Six weeks following their operation, the levels of HB and PCV were once again assessed.

After 90 days, the patient was contacted back for follow-up, and a fresh KSS exam was completed and documented.

Results

Based on the proper statistical analysis tests, functional performance was evaluated.

On their third and fourteenth days, TUG's test time in Group A were lower than they were in Group B. On days 4 and 14, there was no statistically significant distinction between the two groups.

On days 4 and 14, group A's ROM in both knees was better than that of group B. However, there was no statistically significant distinction between the groups on the fourth and fourteenth days.

There have been many studies comparing the clinical outcomes of TKA surgery, but none have examined the functional outcomes of preoperative IV iron supplementation, which would have allowed us to evaluate the findings of the present study.

Based on proper statistical analysis procedures, the effect of preoperative intravenous iron supplementation on surgical transfusion rates and its effect on Hb and PCV levels were evaluated. There was a statistically significant decline in HB and PCV levels when comparing mean HB and PCV levels throughout Group B with changes in HB and PCV levels, as shown by a p-value under 0.05.

In Group B1, separate comparisons of mean HB and PCV and changes in HB and PCV levels did not demonstrate statistical significance.

A comparison of the mean PCV levels and changes in PCV levels in Group B3 did not reveal any statistically significant differences.

According to the aforementioned findings, preoperatively administered IV iron supplementation did not significantly improve the HB and PCV values for Group B as a whole, but subdividing Group B revealed that IV iron supplementation given at 4 weeks prior to surgery, operations (group B1) had significantly improved HB and PCV levels, and there was less decline in HB and PCV levels at the first postoperative day. It should be observed that 2 weeks of preoperative IV iron supplementation (group B3) did not significantly enhance HB levels, however on postoperative day 1, PCV levels significantly improved and HB and PCV levels decreased less. Although it was not statistically significant, group B1 had a greater success rate than the other groups when we analysed the findings in terms of transfusion incidence and compared all groups.

Groups B1, B2, and B3 had fewer transfused patients than group A when comparing groups based on transfused blood units, however this difference was not statistically significant.

Additionally, we discovered that the rate of transfusions was greater when intravenous iron supplementation was administered 4 weeks before to surgery as opposed to 3 weeks (71.4%) and 2 weeks (25%). Despite the fact that these figures were not statistically significant, a success score of 75% was attained.

Discussion

One of the most frequently done orthopaedic surgical procedures is total knee arthroplasty (TKA). Providing individuals with osteoarthritis the finest pain treatment available outside of the realm of medicine. The degree to which the afflicted patient's functional ability is enhanced relative to their pre-operative condition determines if TKA was successful. The results of a total knee arthroplasty are influenced by a wide range of ffactors. It is also recognised that the patient's psychological condition before to surgery influences the result of TKA. In order to assess the effectiveness of intravenous iron treatment (IVIT) on transfusion and recovery profiles following orthopaedic surgery, Shin HW, Park JJ., *et al*. (2019) [17] conducted a study. According to their findings, intraoperative IVIT appeared to lower the percentage of transfused patients and RBC units. LOS was shortened and infection rate decreased, but mortality was unchanged.

By examining patients in his two phases of a blood preservation programme, Petis SM., *et al*. 2017 [18], evaluated the impact of oral iron supplementation on preoperative anaemia and prior to total knee arthroplasty (TKA). It was decided to adopt blood preservation techniques. They came to the conclusion that oral iron therapy lessened the need for other blood- conserving treatments before TKA and the incidence of perioperative anaemia.

E. Bisbe., *et al*. (2014)[19] performed a randomised controlled study to assess the effectiveness of his intravenous FCM as a post-TKA anaemia therapy. In this study, the researchers came to the conclusion that postoperative IV FCM gives a considerable advantage over oral ferrous sulphate, particularly in patients with preoperative iron insufficiency, postoperative severe anaemia, or both.

In order to look into a potential connection between IV iron and allogeneic blood transfusions, Manuel Muoz., *et al*. (2014) [20] reviewed a large series of orthopaedic patients undergoing elective lower extremity arthroplasty and suggested very brief-term perioperative IV iron administration for this condition. Orthopaedic surgery on the lower extremities is linked to fewer allogeneic blood transfusions and shorter hospital stays.

The evidence pertaining to the effectiveness and safety of intravenous injection was evaluated by P. Beris., *et al*. in 2008 [21]. Iron administration to raise haemoglobin levels in surgical patients, lessen the need for blood transfusions, and establish a consensus statement for the use of intravenous perioperative injections. The panel suggested IV perioperative iron delivery for a patient having orthopaedic surgery who is most likely to experience severe postoperative anaemia.

There hasn't been much research on the subject of individuals who have bilateral total knee arthroplasty performed in a single session and whose functional results have been reported.

Analysis of Functional Outcomes in Correlation with Intravenous Iron Supplementation.

- No statistically significant results have been found for preoperative IV iron supplementation across a number of functional outcome modalities.
- There have been many studies comparing the clinical outcomes of TKA surgery, but none have examined the functional outcomes of preoperative IV iron supplementation, which would have allowed us to evaluate the findings of the present study.
- These results were in line with those of Vuille Lessard E., *et al*. (2012) [22] who demonstrated that early postoperative patients in the HB-deficient group had a longer 6-meter walking time, while the difference was not statistically significant.

Analysis of transfusion incidence during IV iron supplementation:

- Changes in HB and PCV on days 1 preoperative and 1 postoperative in both groups served as the primary endpoint for determining transfusion occurrence. Results for the two groups' mean changes in HB and PCV levels from preoperative to postoperative Day 1 were equivalent.
- We split group B into three subgroups according to the time of IV iron supplementation because the results were identical in both groups, and we did for the purpose of additional observation.
- With 4 weeks of preoperative medication, Group B1 (n = 4) demonstrated a significant difference in HB and PCV outcomes, while Group B3 (n = 8) demonstrated a significant difference in PCV result with 2 weeks of preoperative medication. Similar findings to group B were shown in group B2.
- We draw the conclusion that intravenous iron supplementation 4 weeks before to surgery considerably improves preoperative HB and PCV levels and decreases changes in HB and PCV levels 1 day after surgery based on the aforementioned data.
- A considerable improvement in their PCV levels preoperatively and a decrease in change in HB and PCV levels on postoperative day 1 are both recognized, despite IV iron therapy two weeks before to the surgery showing no significant improvement in HB.
- We also contrasted the prevalence of transfusion between groups A and B. Groups B1, B2, and B3 had fewer transfused patients than group A when comparing groups based on transfused blood units, however this difference was not statistically significant.
- Comparing Group B, which got intravenous iron supplements before surgery, to Group A, there was an overall decrease in the frequency of blood transfusions.
- Preoperative intravenous iron supplementation led to greater success scores at 4 weeks (75%), compared to 3 weeks (71.4%), and 2 weeks (25%).
- These results correspond with those made public by Shin HW, Park JJ, and others [17] (2019) to assess the effectiveness of intravenous iron treatment (IVIT) during orthopaedic surgery on transfusion and recovery profiles, as well as IVIT and oral iron therapy. They came to the conclusion that IVIT dramatically decreased the proportion of transfused patients by 31% and decreased the number of RBC units transfused per person by 0.34 units. IVIT dramatically decreased postoperative infections by 33% and reduced LOS by 1.6 days. In orthopaedic surgery, perioperative IVIT decreases the proportion of transfused patients and transfused RBC units, shortens the length of stay, and lowers infection rates, but it does not seem to affect mortality.
- These outcomes were in line with those found in 2017 research by Petis SM., et al. [18], which found that oral iron therapy decreased the incidence of blood transfusions, the need for additional blood-sparing treatments before TKA, and the burden of perioperative anaemia. In this study, 1974 of his TKAs from his two phases of the blood preservation programme were examined. Patients at risk for perioperative anaemia were treated with intravenous (IV) iron in the first phase. Therapies including preoperative iron supplementation were part of the second phase. Preoperative Hb levels rose by 7 g/L (P0.001) after oral iron treatment.
- Patients with Hb 130 g/L were substantially less common (P 0.001). Use of IV iron dropped from 5% to 2% (P 0.001).
- Additionally, their findings agree with those of Manuel Munoz., *et al*. [20] A 2014 study assessed the possible relationship between intravenous iron and standard allogeneic blood transfusions in orthopaedic patients having elective lower limb arthroplasty. When compared to traditional iron therapy, intravenous iron therapy decreased the ABT rate in elective arthroplasty (8.9% vs. 30.1%; p = 0.001). Without raising surgical morbidity or mortality, it lowers ABT rates and their LHS.
- These outcomes matched those reported by P. Beris., *et al*. [21] in their 2008 investigation of the effectiveness and security of intravenous injections. Based on moderate- to low-quality data, it is recommended to provide iron intravenously (IV) during the perioperative phase to patients undergoing orthopaedic surgery who are at risk for severe postoperative anaemia.

Appendix A

ABBREVATIONS

- NKSS = New Knee Society Score
- TKA = Total knee Arthroplasty
- TUG = Timed up and go test
- ROM = Range of motion
- FCM = Ferric Carboxy-Maltose
- LOS = Length of Hospital Stay
- I.V = Intra-Venous
- ABT = Allogeneic blood transfusions
- THA = Total hip arthroplasty
- RHuEPO = recombinant human erythropoietin
- PAD = preoperative autologous blood donation
- CS = Cell Salvage
- IDA = Iron Deficiency Anemia
- OA = Osteoarthritis
- PCV = Hematocrit
- IVIT = intravenous iron therapy

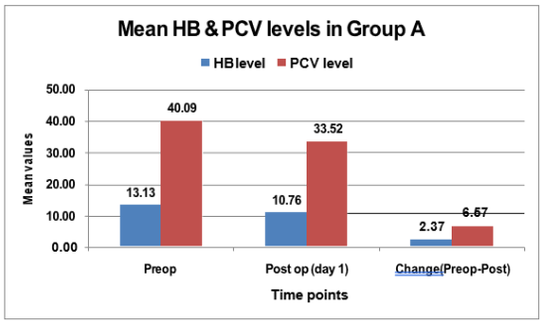
Appendix B

Images and charts

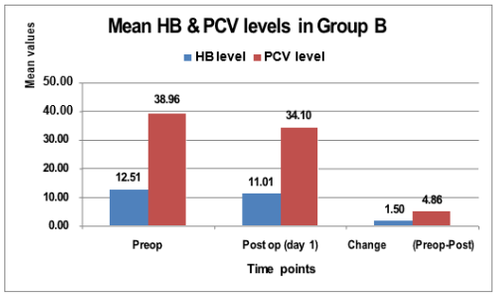
(B.1) Injection Encicarb (Ferric Carboxy Maltose) 500mg

(Source: https://www.indiamart.com/proddetail/ferric-carboxy-maltose-injection-18143722891.html)

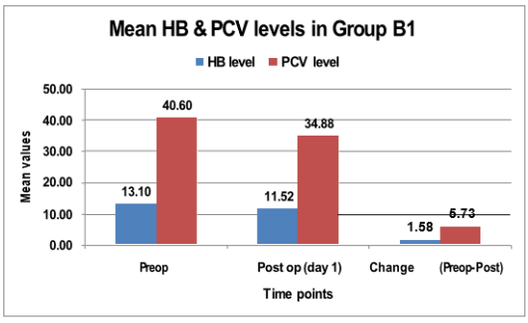
(B.2) Change in HB & PCV in Group A



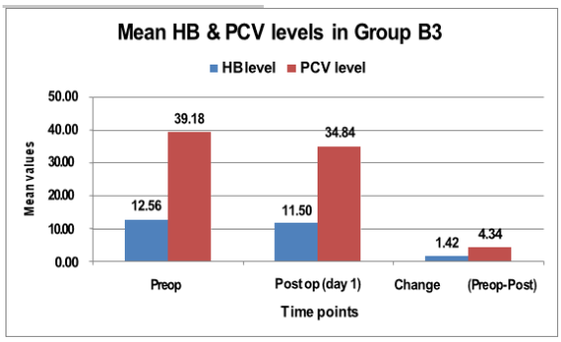
(B.3) Change in HB & PCV in Group B



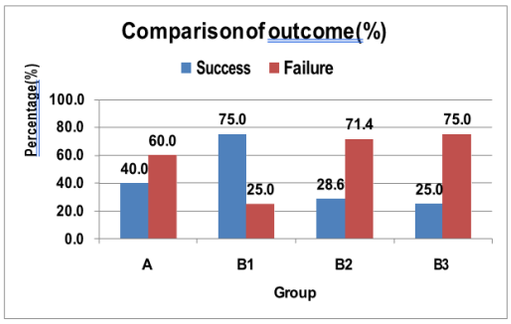
(B.4) Change in HB & PCV in Group B1



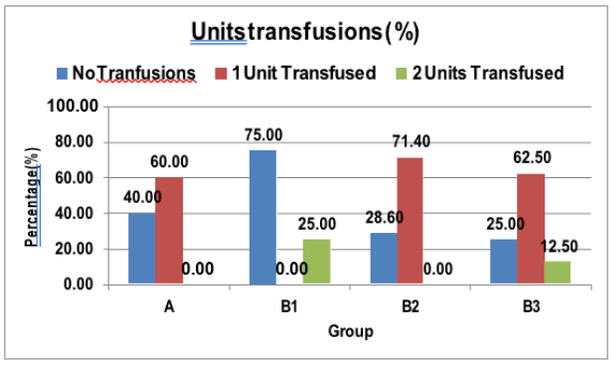
(B.5) Change in HB & PCV in Group B3



(B.6) Comparison of outcome percentages in Group A, Group B1, Group B2 and B3



(B.7) Comparison of Number of units transfusions among Group A, Group B1,Group B2 and Group B3.



Conclusion

The preoperative HB and PCV levels dramatically improved and the postoperative day 1 postoperative HB and PCV levels changed less when patient got intravenous iron supplementation four weeks prior to surgery.

The ROM score in the knee and TUG test time were both faster in Group A. In research including more patients, the distinction could be substantial.

When we compared groups A and B1 outcomes in terms of transfusion incidence, we discovered that group B1 had a greater success rate. Studies with a larger sample size of patients indicate that the differences may be important.

When comparing groups based on the number of transfused blood units, groups B1, B2, and B3 had a lower percentage of transfused patients than group A. Research involving more patients might indicate that there are variances.

A higher outcome was observed when IV iron supplementation was started earlier in the preoperative period. Studies with larger patient populations and higher tolerated dosages of iron supplementation may have shown differences that are significant.

Recommendations

To minimise transfusion frequency patients planned for bilateral TKA should have their HB and PCV levels evaluated preoperatively and, if possible, receive intravenous iron supplementation at least 4 weeks before to surgery.

Acknowledgements

None.

Conflict of Interests

None.

Funding

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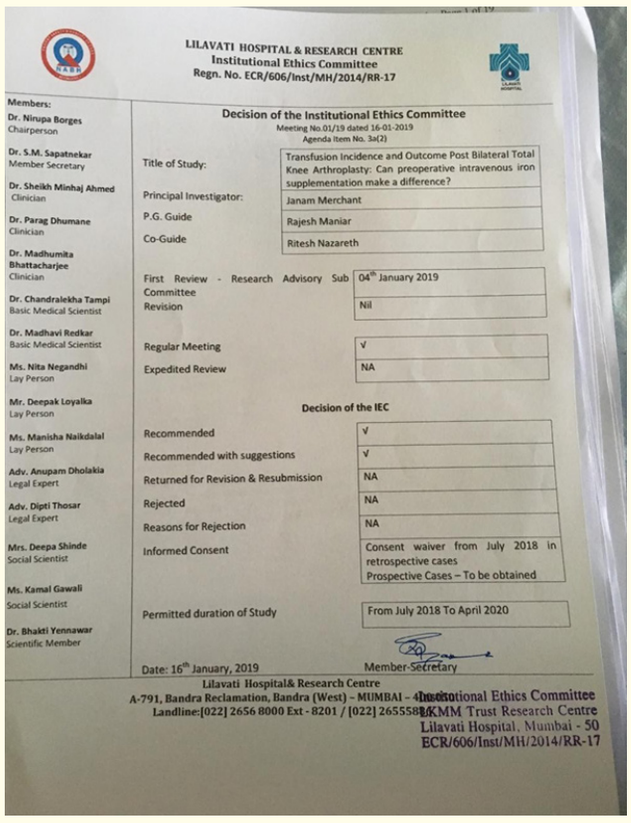
Institutional Ethical Committee Approval



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Decision of the Institutional Ethics Committee
Meeting No.01/19 dated 16-01-2019
Agenda Item No. 3a(2)

Title of Study:	Transfusion Incidence and Outcome Post Bilateral Total Knee Arthroplasty: Can preoperative intravenous iron supplementation make a difference?
Principal Investigator:	Janam Merchant
P.G. Guide	Rajesh Maniar
Co-Guide	Ritesh Nazareth
First Review - Research Advisory Sub Committee	04th January 2019
Revision	Nil
Regular Meeting	√
Expedited Review	NA

Decision of the IEC

Recommended	√
Recommended with suggestions	√
Returned for Revision & Resubmission	NA
Rejected	NA
Reasons for Rejection	NA
Informed Consent	Consent waiver from July 2018 in retrospective cases Prospective Cases – To be obtained
Permitted duration of Study	From July 2018 To April 2020

Date: 16th January, 2019
Member-Secretary

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Figure 1

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