










A secure blood-saving protocol for Jehovah's Witnesses in primary total hip replacement

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Total hip replacement (THR) is an effective surgical intervention for patients with end-stage hip osteoarthritis.^[1-3] Intraoperative bleeding during THR occurs due to soft tissue dissection and bone resection as a result of hypervascularity of the metaphysis.^[4] Perioperative blood loss and anemia have been associated with increased duration of hospital stay, reduced patients' compliance to postoperative physical rehabilitation programs, and increased mortality.^[5] Allogeneic blood transfusion (ABT) may be needed to avoid these complications.^[5] Transfusion is associated with a variety of risks, including blood-borne infections, acute pulmonary injury, and intravascular overload. It has been reported that respiratory complications and wound infections were significantly higher in

ABSTRACT

Objectives: The study aimed to analyze the efficacy of the blood management protocol developed by our team for patients who are Jehovah's Witnesses (JW) presenting for primary total hip replacement (THR).

Patients and methods: Thirty JW patients (6 males, 24 females; mean age: 70.1±9.8 years; range, 65 to 81 years) and 30 age- and sex-matched controls (6 males, 24 females; mean age: 68.7±9.1 years; range, 62 to 79 years) who underwent primary THR at our institution between January 2018 and June 2020 were retrospectively evaluated. While the surgical technique of THR was not different among the groups, blood loss management differed between the groups. Patients in the control group were given 1 g of intravenous tranexamic acid (TXA) 15 min before the surgical incision. In addition to the same TXA protocol, intraoperative cell salvage with a continuous autologous transfusion system was used for JW patients. The estimated blood loss (EBL) was determined using Meunier's formula. Hemoglobin (Hgb) decline, EBL on the first and third postoperative days, allogeneic blood transfusion (ABT) requirement, and complications were analyzed between groups.

Results: There were no significant differences between groups regarding demographic and clinical characteristics ($p>0.05$), ABT requirement ($p>0.999$), and Hgb decline in the first and third postoperative days ($p=0.540$ and $p=0.836$, respectively). Furthermore, both groups did not significantly differ between EBL in the first and third postoperative days ($p=0.396$ and $p=0.616$, respectively) and the length of hospital stay ($p=0.547$). Similar complication rates were noted for both groups. Hemoglobin level assessments revealed that values on the first and third postoperative days were significantly lower than the baseline Hgb value in both cohorts ($p<0.001$).

Conclusion: A combination of intravenous administration of 1 g of TXA, meticulous hemostasis, and intraoperative use of cell saver constitutes a reasonable strategy for achieving the goal of transfusion-free primary THR with predictable levels of blood loss that are similar to non-JW patients.

Keywords: Blood loss, blood management, Jehovah's Witness, total hip arthroplasty, total hip replacement, transfusion.

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patients who underwent THR and received ABT compared to those who received an autologous blood transfusion or no blood transfusion after the same procedure.^[6] Therefore, efforts spent to date to develop strategies for reducing ABT rates during or after THR are justified.^[5,7-15] Several preoperative, intraoperative, and postoperative blood management protocols have been proposed. Preoperative preventions include hemoglobin (Hgb) optimization in anemic patients using erythropoietin (EPO) injection and intravenous iron replacement therapy. Intraoperative bleeding control strategies include controlled hypotension, surgical hemostasis, cell salvage, and the use of tranexamic acid (TXA). Various combinations of these methods have been utilized; however, there is no consensus among authors regarding the best combination or strategy.

Jehovah's Witnesses (JW) are members of a Christian denomination that does not accept blood transfusion.^[5] In line with the researchers attempting to develop protocols for reducing ABT requirements in patients undergoing THR, some authors focused on establishing strategies to render transfusion-free THR possible in JW who undergo this procedure.^[4,5,16-18] However, a widely accepted agreement has not yet been reached. Hence, the aim of this study was to analyze the efficacy of a blood management protocol in a cohort of JW patients who underwent THR at our center.

PATIENTS AND METHODS

The retrospective study included consecutive JW patients who underwent THR at the Helios ENDO-Klinik Hamburg between January 2018 and June 2020. Patients younger than 18 years old and patients with an active infection, untreated malignancy, hematological disorder, or coagulopathy were excluded. Additionally, patients with incomplete data were not included. Thirty self-reported JW patients (6 males, 24 females; mean age: 70.1±9.8 years; range, 65 to 81 years) who did not consent to ABT based on their religious beliefs but accepted intraoperative cell saver usage were identified and included in the study. Thirty age- and sex-matched controls (6 males, 24 females; mean age: 68.7±9.1 years; range, 62 to 79 years) using the same inclusion and exclusion criteria were randomly selected among patients who underwent THR during the same interval.

In our center, elective primary THR procedures are not performed unless the preoperative Hgb level is above 10 g/dL. Therefore, none of our cohorts

underwent preoperative optimization with EPO or iron treatments. In addition, none of the patients predonated autologous blood. All patients underwent the uncemented THR procedure under general anesthesia. All THR surgeries were performed via a posterolateral approach. Acetabular components were porous-coated and were implanted by a press-fit technique with or without screws based on the surgeon's judgment. The femoral component consisted of a proximally porous-coated stem with a modular head; it was also implanted by the press-fit technique. Ceramic or metal femoral heads were implanted as per the primary surgeon's decision. An Accolade femoral component with either a cobalt-chromium or ceramic femoral head (Stryker Orthopaedics, Mahwah, NJ, USA) and a Trident acetabular component with Crossfire or X3 crosslinked polyethylene (Stryker Orthopaedics, Mahwah, NJ, USA) were used in all procedures. No suction drains were used in either cohort.

While the surgical technique of THR was not different between the groups, blood-saving measures differed significantly. Patients in the control group (non-JW patients) were given 1 g of intravenous TXA 15 min before the surgical incision. Meticulous hemostasis was achieved by using bipolar electrocautery during the entire procedure as the second precaution. Intravenous TXA injection 15 min before skin incision, meticulous hemostasis with bipolar electrocautery, and intraoperative cell salvage with a continuous autologous transfusion system (CATS, Fresenius AG, Bad Homburg, Germany) were performed for patients in the study group (JW patients). With the continuous autologous transfusion system, any blood lost was prepared by a closed-circuit autotransfusion system via separation of corpuscular particles and erythrocytes and washing of the concentrated red blood cells with heparinized saline (200-400 mL). All patients underwent the same postoperative mobilization and physical therapy protocol. As per this protocol, patients mobilized on the first postoperative day, and physical therapy began on the second postoperative day. Patients were discharged home or referred to a rehabilitation center based on the recommendations of the physical therapy team. The same team was involved in the postoperative care of these patients. The day of discharge or referral to a rehabilitation center was recorded as the discharge day.

Data including age, sex, weight, height, body mass index, Charlson comorbidity index, American Society of Anesthesiology score, preoperative

Hgb, and hematocrit (Hct) levels were retrieved from computerized patient folders. The total blood volumes of the patients were calculated by Nadler et al.'s^[19] formula based on patient sex, height, and weight. Postoperative third-day Hgb and Hct levels were also collected. Hemoglobin decline in the first and third postoperative days was calculated and recorded. The estimated blood loss (EBL) was calculated by Meunier et al.'s^[20] formula.

As per our institution's post-THR blood transfusion protocol, patients were transfused if their Hgb level was below 6 g/dL or Hb level was lower than 8 g/dL, with hypotension (i.e., arterial blood pressure <90/60 mmHg), tachycardia (i.e., pulse over 100/min), or signs of heart failure. Blood transfusions and in-hospital complications were recorded in patient folders; these data were also retrieved for comparative analysis. The duration of hospital stay (days) was calculated and recorded for all patients.

After retrieval of all relevant data by retrospective review of the patient folders, study groups were compared in terms of demographic data and laboratory data, including preoperative, postoperative day one, and postoperative day three Hgb and Hct levels, Hgb decline on the first and third postoperative days, postoperative complications, ABT requirement, and duration of hospital stay.

Statistical analysis

Sample size estimation was performed using G*Power version 3.0.10 (Franz Faul, Universität Kiel, Kiel, Germany). The primary outcome of the study was to compare the differences in EBL between the two groups. Based on a previous study, the mean EBL and standard deviations were used to calculate the Cohen's d, and it was calculated as 0.80.^[21] When the effect size of Cohen's d was considered 0.80, a total sample size of at least 52 (26 for cases and 26 for controls, with the allocation ratio considered 1:1) was required to achieve a power of 80% at the 5% significance level. It was decided to include 30 cases for each group, considering a drop-out rate of at least 10%.

Data analysis was performed using SPSS version 17.0 software (SPSS Inc., Chicago, IL, USA). The Shapiro-Wilk test was used to determine whether the distribution of continuous variables was normal. The assumption of homogeneity of variances was examined with the Levene test. Descriptive statistics for continuous variables were expressed as mean±standard deviation (SD). Categorical data were presented using frequency distributions and

percentages. The differences in continuous variables between case and control groups were compared using Student's t-test or the Mann-Whitney U test, where applicable. Repeated measurements of analysis of variance via Wilks' lambda test were applied when the mean differences in Hgb levels among follow-up times were evaluated. When the *p* values from Wilks' lambda test were statistically significant, the Bonferroni adjusted multiple comparison test or the Dunn-Bonferroni test was used to determine which measurement time differed from the others. Categorical data were analyzed by the continuity-corrected chi-square test or Fisher exact test, where appropriate. A *p*-value <0.05 was considered to be statistically significant.

RESULTS

The mean age between the case and control groups was 1.8±1.3 years (range 0-6 years). Demographic data, anthropometric features, Charlson comorbidity indices (Charlson scores), American Society of Anesthesiology (ASA) scores, and preoperative data of the patients are displayed in Table I. Comparative statistical analysis did not reveal any significant differences in terms of these parameters between the groups (*p*>0.05).

The intragroup comparison of repeated Hgb level assessments revealed significant differences in both groups (Table II). Both postoperative day one and day three values were significantly lower than the baseline Hgb value in both groups.

Results of the comparative analysis of the study groups with respect to outcomes are displayed in Table III. Our retrospective review elucidated that two patients in the control group (non-JW patients) and one patient in the study group (JW patients) required ABT as per our institutional post-THR protocol (*p*>0.999). All of these three patients had Hgb levels in the range of 6-8 g/dL, with mild tachycardia and postural hypotension as the symptoms of postoperative anemia. Each of the two patients in the control group received 1 unit of ABT. On the other hand, the patient in the study group received 1 unit of ABT, additionally treated with intravenous dextran for the expansion of intravascular volume and 1000 mg of ferrous sulfate for the treatment of anemia. Despite being a JW, the patient did not want to ignore the possible risks associated with anemia after a detailed consultation.

All these three patients hemodynamically improved with these treatments. No complications were encountered in the study cohort except for

TABLE I Comparison of demographic and clinical characteristics between the non-JW patients and JW patients							
	Control group (n=30)			Case group (n=30)			p
	n	%	Mean±SD	n	%	Mean±SD	
Age at the time of surgery (year)			68.7±9.1			70.1±9.8	0.579†
Sex							N/A
Female	24	80.0		24	80.0		
Male	6	20.0		6	20.0		
Weight (kg)			83.1±16.1			80.5±14.0	0.544†
Height (m)			1.66±0.091			1.65±0.078	0.501†
Body mass index (kg/m ²)			30.1±4.9			29.7±5.0	0.768†
Charlson score			4.57±1.36			4.60±1.28	0.965‡
Side							>0.999¶
Left	15	50.0		14	46.7		
Right	15	50.0		16	53.3		
ASA score							0.573‡
2	11	37.9		12	41.4		
3	16	55.2		17	58.6		
4	2	6.9		0	0.0		
Preoperative INR			0.98±0.044			1.03±0.166	0.334‡
Preoperative Hgb (g/dL)			13.56±1.29			13.48±1.32	0.829†
Total blood volume (mL)			4654.0±820.1			4525.4±669.3	0.745‡

SD: Standard deviation; ASA: American Society of Anesthesiology; N/A: Not analyzed; † Student's t test; ‡ Mann Whitney U test; ¶ Continuity corrected χ^2 test.

TABLE II Intra-group comparisons of repeated hemoglobin levels.				
	Preoperative	Postoperative day 1	Postoperative day 3	p
	Mean±SD	Mean±SD	Mean±SD	
Hgb (g/dL)				
Control group	13.56±1.29 ^{a,b}	10.91±1.66 ^a	10.76±1.62 ^b	<0.001‡
Case group	13.48±1.32 ^{a,b}	11.01±1.90 ^a	10.74±1.73 ^b	<0.001‡

SD: Standard deviation; Hgb: Hemoglobin; ‡ Repeated measurements of ANOVA via Wilks' Lambda test; a: Baseline vs postoperative the 1st day (p<0.01); b: Baseline vs postoperative the 3rd day (p<0.001).

TABLE III Comparison of main outcomes between non-JW patients and JW patients							
	Control group (n=30)			Case group (n=30)			p
	n	%	Mean±SD	n	%	Mean±SD	
Hgb decline on the 1 st day			2.65±1.01			2.47±1.16	0.540†
Hgb decline on the 3 rd day			2.80±0.91			2.74±1.07	0.836†
EBL on the 1 st day			900.65±368.78			818.41±375.80	0.396†
EBL on the 3 rd day			957.76±337.31			913.58±341.79	0.616†
ABT requirement	2	6.7		1	3.3		>0.999¶
Complications	1	3.3		1	3.3		N/A
Duration of stay (days)			8.5±2.4			8.4±2.4	0.547‡

SD: Standard deviation; N/A: Not analyzed; Hgb: Hemoglobin; EBL: Estimated blood loss; ABT: Allogeneic blood transfusion; † Student's t-test; ‡ Mann Whitney U test; ¶ Fisher exact test; N/A: Not analyzed.

minor wound complications in two cases. One of these patients was in the control group, while the other patient was in the JW group. These minor wound complications were conservatively treated with dressing changes. Groups were similar in terms of all study outcomes, including ABT requirement, complication rate, Hgb decline in the first and third postoperative days, EBL in the first and third postoperative days, and length of hospital stay. None of the patients received further ABT within the first six weeks of follow-up.

DISCUSSION

The results of the current study can contribute to the ongoing debate regarding the most optimal blood-saving measure in this vulnerable patient group. Risks associated with ABT and patients with religious beliefs that forbid ABT triggered the search for transfusion-free approaches in various surgeries.^[5,22-25] It was previously reported that the rate of ABT could be as high as 18% in elective THA surgeries.^[26-29] This relatively high transfusion rate in elective orthopedic surgeries, including THR led orthopedic surgeons to seek methods to reduce bleeding and the rate of ABT.^[7-13] While these researchers focused on the general patient population, other authors studied JW patients who do not give consent for ABT.^[4,5,7,14-18,21] As a matter of course, the challenge faced by the latter group of researchers was significant since the general patient population gave consent for blood transfusion while JW declined both ABT and autologous transfusion.^[5]

Jehovah's Witnesses do not consent to any type of blood transfusion (ABT or autologous blood transfusion) since they believe that blood must be disposed of when it leaves the body and stops circulating.^[5] For the same reason, most JW agree with the usage of autotransfusion devices (e.g., the cell saver) during their surgical procedures since these devices provide a closed-circuit system for continuous reinfusion of recovered blood. Therefore, we relied on the intraoperative usage of the cell-saver system to achieve the goal of transfusion-free THR surgery in our JW patients. We implemented this approach as an adjunct to meticulous hemostasis by using bipolar electrocautery and intravenous TXA injection. Injection of TXA is commonly part of the strategies implemented for transfusion-free arthroplasty procedures.^[7,8,10] It is a fibrin clot stabilizer that binds to the lysine binding site of plasminogen and inhibits fibrinolysis.^[30] Although it is not a procoagulant, it has been thought to be

associated with an increased risk of thromboembolic events, such as cerebrovascular accidents, deep venous thrombosis, pulmonary thromboembolism, and acute coronary events.^[8] However, there is no high-quality, evidence-based data to prove these hypotheses.

Nemoto et al.^[7] retrospectively reviewed the data of their patients who underwent total knee arthroplasty or THR to analyze the impact of TXA on perioperative bleeding. They compared 46 THR patients who were given TXA with 49 THR patients who were not treated by TXA in terms of postoperative blood transfusion requirement, Hgb decline, and EBL. These authors concluded that TXA treatment was significantly beneficial in reducing bleeding and ABT rate. Of note, they did not encounter any thromboembolic events in their patients who were given TXA. This finding is in line with ours; we did not detect any thromboembolic complications in our series. It should also be considered that Nemoto et al.^[7] gave a significantly higher dose of TXA than we did in our study; they gave a perioperative maintenance dose of 100 mg/h in addition to 1 g intravenous loading dose.

Suh et al.^[4] reviewed the data of 33 JW patients who underwent THR. As part of their blood transfusion-saving strategy, they preoperatively gave EPO and iron treatments to their patients, including those with baseline Hgb levels >10 g/dL. They used intraoperative cell salvage and continued to support their patients with EPO and iron treatments postoperatively if postoperative Hgb levels were <10 g/dL. They concluded that their strategy was safe, and none of their patients needed ABT. In our series, all of our patients had a preoperative Hgb level >10 g/dL; we did not perform preoperative optimization. We did not follow a postoperative optimization protocol based on postoperative Hgb levels. Instead, we followed our institutional post-THR guidelines, which state that ABT is based on postoperative Hgb levels and the hemodynamic state of our patients. We supported one of our JW patients with intravenous fluid infusion and iron replacement since ABT was not an option in this case.

Harwin et al.^[5] reviewed the data of 55 THR procedures performed on 53 JW patients. Their protocol included preoperative optimization with EPO, iron, and folate based on the baseline Hgb level of the patients. The authors adopted 13 g/dL as the threshold preoperative Hgb level. Intraoperatively, they performed acute normovolemic hemodilution as part of their blood-saving strategy. They reported

that none of their JW patients needed ABT. Since the mean follow-up period was 5 ± 0.4 years in this study, the researchers had the chance to present their patients' postoperative Harris hip scores and implant survival in addition to other parameters, such as complication and mortality rates. As per this analysis, they concluded that their approach led to excellent clinical outcomes in terms of these parameters with a mean postoperative Harris hip score of 86 points, implant survivorship of 97%, and minor complication rate of 9%. In addition to this, they encountered no major complications and mortality.

Despite the fact that Harwin et al.^[5] presented favorable short-term and long-term outcomes associated with their protocol, which included intraoperative use of cell saver, there are contradictory findings in the literature concerning its use in THR surgeries.^[9,11-14] Schneider et al.^[9] used cell saver to reduce the rate of ABT in 227 THR patients and reported that this approach was not beneficial. Gargaro and Walls^[14] compared the ABT rates among patients who underwent THR with (n=32) and without (n=32) intraoperative use of cell saver. In line with Schneider et al.,^[9] they did not find a significant difference between these patient groups.^[14] In contrast, Guerra and Cuckler^[11] stated that the use of cell saver during primary THR surgeries led to a 40% decrease in the rate of ABTs. In accordance with this finding, Ernst et al.^[12] reported that intraoperative cell saver use significantly reduced the ABT requirement. Their comparison regarding ABT rates among 18 patients who underwent THR with a cell saver and 17 patients who had the same procedure without a cell saver revealed that the ABT rate in the former group was 50%, while it was 99.9% in the latter. Elawad et al.^[13] prospectively reviewed the data of 40 patients who underwent primary THR and compared the ABT requirement between the patients who were treated with (n=20) and without (n=20) cell saver. They concluded that cell saver was safe to use and significantly reduced the ABT rate. McMurray et al.^[15] performed primary (n=49) or revision (n=57) THR on 106 patients and compared the cases during which cell saver was used (n=58) with the ones performed without this system (n=48). These authors reported that cell-saver use significantly reduced ABT not only in primary THR cases but also in revision THR procedures, during which there is a higher risk of bleeding compared with primary cases.

The results suggest that there was no significant difference between the non-JW patients and JW

patients who were treated by cell saver during primary THR procedures in terms of ABT requirement. This finding seems to suggest that intraoperative cell saver use does not reduce the need for ABT. However, it should be considered that the rate of ABT requirement was very low in our non-JW patients, and our study had a small sample size. A significant amount of blood loss occurs during the operation; however, bleeding continues after the operation into the intra-articular space and between the tissue planes. The increase in EBL between the first day and the third day is an indicator of hidden blood loss from the intravascular space.

In addition to the small sample size, our study has some other limitations that need to be considered. First, it is a retrospective study that can be affected by all inherent weaknesses stemming from its retrospective design. Second, our follow-up period was short; it was limited to the discharge day of our inpatients. Therefore, it was not possible to analyze late complications and implant survival data. This was not the primary aim of this study. We also did not include a cost-effectiveness analysis.

In conclusion, a combination of intravenous administration of 1 g of TXA, meticulous hemostasis, and intraoperative use of cell saver constitutes a reasonable strategy for achieving the goal of transfusion-free primary THR. However, orthopedic surgery teams should adopt certain preoperative criteria, including a specific baseline Hgb level as a threshold, before proceeding with the primary THR procedure for patients who do not accept ABT. It should be considered that these patients need close postoperative monitoring since alternative methods should be readily implemented in the case that they require ABT.

Ethics Committee Approval: The study protocol was approved by the Local Ethics Committee (date: 6.5.2017, no: 069/20). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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