Blood Loss in Total Knee Arthroplasty

Background

Patients undergoing Total Knee Arthroplasty (TKA) have expected blood loss during and after surgery. The morbidity associated with blood loss and the burden of blood transfusions in adult arthroplasty necessitates pre-operative optimisation as routine practice. Current literature remains inconclusive on which TKA surgical instrumentation techniques are effective in minimising peri-operative blood loss, and consequently lower transfusion rates. The primary objective of this retrospective review, of a prospective randomized cohort study, was to compare surgical and patient factors, and their influence on blood loss and transfusions rates, between one type of Patient Specific Instrumentation (PSI), Navigated Computer-Assisted Surgery (CAS) and Conventional TKA surgical techniques.

Methods

A cohort of 128 matched patients (38 PSI, 44 CAS, 46 Conventional surgeries) were compared. Pre-operative factors analysed included; age, gender, Body Mass Index (BMI), pre-operative hemoglobin (Hb) (g/L), International Normalized Ratio (INR), use of anticoagulants and co-morbid bleeding diathesis. Maximal Hb drop and transfusion requirements were compared on Day 1 to 3. Peri-operative factors collected included; surgical time, tourniquet time, drain output, insitu drain time, order of tibia or femoral cut and intra-operative loss from suction.

Results

The 3 groups did not differ on the pre-operative patient demographics examined. The difference between pre-operative Hb and the lowest post-operative Hb readings did not differ between study groups (p=0.39).

Conclusion

There are no statistically significant differences in blood loss when comparing PSI vs. CAS vs. Conventional TKA. Although emerging evidence on PSI is encouraging, the PSI technique for TKA does not result in reduced blood loss.

Registration: ClinicalTrials.gov: NCT01145157

Key Words: Blood Loss; Surgical Technique; Total Knee Arthroplasty; Patient Specific Instrumentation (PSI); Transfusion.

1. Introduction

Peri-operative blood loss and the requirement for blood product transfusion after joint replacement have been extensively studied. Total Knee Arthroplasty (TKA) results in substantial blood loss and patients undergoing total joint replacement are at increased risk for transfusion. Following TKA, transfusion rates have been reported as high as 39%.[1] There has been a paradigm shift to reduce the need for post-operative transfusion by improving peri-operative blood management and positively impact early and long-term outcomes.

The current literature includes many studies assessing the potential benefit of navigated Computer-Assisted Surgery (CAS) TKA against Conventional TKA, producing mixed findings. CAS TKA was proposed to allow reduced blood loss due to the avoidance of the medullary cavity.[2] Findings from previous studies support this concept, reporting reductions in blood loss, lower Hemoglobin (Hb) drop and the risk of post-operative transfusion.[2,3] Schnurr et al. (2010) also reported reduced blood loss in patients implanted via CAS, resulting in a 50.0 % reduction in transfusion rate in comparison to patients having received Conventional TKA.[4] Similarly, findings from a randomized controlled trial reported less drained blood, however no statistically significant difference in average Hb drop and allogenic transfusion rate.[5]

Recent literature has demonstrated no significant difference in blood loss[6], post-operative Hb or the need for transfusion between Conventional and CAS TKA.[7,8] Similarly to CAS TKA, Patient Specific Instrumentation (PSI) assisted TKA does not breach the medullary canals, potentially resulting in reduced blood loss and a lower risk of transfusion.[9] A comprehensive search of the literature produced one study that considered PSI and the effect on blood loss. Theinpont et al.

(2014) reported no statistically significant difference between calculated blood loss, Hb drop and transfusion rate between PSI-assisted and conventional minimally invasive surgical techniques.[9]

Current literature examines CAS vs Conventional and PSI vs Conventional, but no paper exists comparing all 3 techniques in 1 matched cohort. This retrospective review of a prospective randomized cohort aims to compare these 3 surgical techniques (PSI, CAS, and Conventional TKA) to determine which technique, if any, results in reduced blood loss and therefore a lower risk of transfusion. Our hypothesis was that use of the PSI technique would lead to reduced blood loss and post-operative Hb drop.

2. Materials and Methods

This retrospective review was approved by the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC 300.14, June 2014) and the prospective cohort study was registered on a Clinical Trials registry (ClinicalTrials.gov: NCT01145157).

2.1 Study Selection

All TKA patients listed on our institution's routine elective arthroplasty clinic were screened for study eligibility. Patients meeting study selection criteria were invited to participate in the trial.

2.1.1 *Inclusion criteria*

Patients were of legal age and skeletal maturity, and required primary TKA due to non-inflammatory degenerative joint disease (e.g. osteoarthritis, traumatic arthritis, avascular necrosis, and dysplasia/DDH) or inflammatory joint disease (e.g. Rheumatoid Arthritis). Patients met an acceptable pre-operative medical clearance and were free from, or treated for, cardiac, pulmonary, hematological or similar conditions that posed excessive operative risk. Patients were required to be willing and able to provide written informed consent to participate in the length of the study.

2.1.2 *Exclusion criteria*

Patients were excluded from study participation if they had history of active infection or sepsis (treated or untreated), vascular insufficiency, muscular atrophy, or neuromuscular disease at a severity to compromise implant stability or post-operative recovery. Restrictions were also placed for patients with inadequate bone stock to support the device (e.g., severe osteopenia or family history of

94 severe osteoporosis), known moderate to severe renal insufficiency or metal sensitivity, a history of
95 previous knee surgery (except arthroscopy and/or open meniscectomy) on the affected knee, or a
96 Body Mass Index (BMI) > 40. Further exclusions were immunocompromised patients or those
97 receiving high doses of corticosteroids, as well as patients with an emotional or neurological
98 condition that pre-empted their ability or willingness to participate in the study, including mental
99 illness, intellectual disability, drug or alcohol abuse or a contraindication to MRI (metal artifacts in
100 soft tissue, claustrophobia, body mass). Female patients of child-bearing age not taking contraceptive
101 precautions were ineligible for study participation.
102
103 Eligible patients were consented by research staff following a comprehensive explanation of the
104 study process. Participants were then randomized into 1 of the 3 study arms, PSI, CAS or
105 Conventional TKA. Information relating to functional scores, radiographic evaluations, operative
106 details, discharge details, end of study and missed/unplanned visits were captured. A 1:1:1 block
107 randomization was used in the study. The assignments were predetermined through a schedule
108 generated using randomly permuted blocks with random block sizes method. Randomization plan
109 generator available on the randomization.com website was used. During post-operative reviews,
110 radiologists were blinded to the assignments until individual randomization assignments were
111 requested.
112
113 A total of 5 consultant Orthopedic Surgeons were the primary surgeons for this cohort. All surgeons
114 were experienced with the 3 techniques and underwent industry training for the Signature^{TM} system.
115 Patients randomized to the PSI Personalised Patient Care arm had an MRI 6 weeks pre-operatively.
116 The MRI image was used to build surgical instruments customised for a patient's unique knee
117 anatomy. Cutting positioning guides were produced to match the outer shape of the individual's

distal femur and proximal tibia. Consultants on the study team reviewed the pre-operative plans before the final guides were manufactured.

This was a single centre study with 150 patient enrolled. A number of participants (22) were excluded due to the following reasons; inability to undergo pre-operative MRI, voluntary withdrawal, PSI template molds not available at time of surgery and computer-assisted navigation abandoned due to software/instrument issue. A number of participants were withdrawn from the PSI group (13) and the CAS group (9) as they were converted to undergo Conventional TKA. Therefore, in this study, 128 patients were available for comparison comprising the PSI (Signature, Biomet, Warsaw, USA), CAS and Conventional TKA, using the Vanguard Knee System. A total of 38 patients were randomized to PSI, 44 to CAS and 46 to Conventional implants.

2.2 Pre-Operative factors

Pre-operative factors were collected to assess homogeneity between the 3 groups. Baseline demographics included (Table 1); age, gender, BMI, pre-operative Hb (g/L), International Normalized Ratio (INR), use of anticoagulants, determining if held prior to surgery and co-morbid bleeding diathesis. Routinely, all medications that had an influence on bleeding were ceased (including nutraceuticals i.e. Fish Oil). Exceptions were Aspirin or Clopidogrel, which were continued in cases of ischemic heart, or valvular disease as directed by Peri-Operative Physicians. Complete blood count, biochemistry and coagulation bloods tests were performed as routine pre-operatively.

2.3 Intra-operative factors

Length of surgical time, tourniquet time, order of tibia or femoral cut and intra-operative loss from suction including estimated blood loss from weighed packs were collected at time of surgery.

2.4 Post-operative factors

At the study institution it is standard practice for all patients to have a blood sample taken on post-operative Day 1. Thereafter, blood sampling is determined on an individual patient basis depending on their clinical circumstances. The minimum and maximum post-operative time that elapsed before a valid Hb measurement was taken and included for analysis was 6 hours and 72 hours, respectively. The protocol for the study institution was to transfuse if Hb < 80 or if the patient is symptomatic of anemia (e.g. tachycardia or hypotensive). It is presumed study patients did not receive tranexamic acid, as the use of this drug was not standard practice in the department at the time in which the study was conducted.

The thromboprophylaxis protocol at study institution standardizes mechanical prophylaxis for all patients in the form of compression stockings and sequential pneumatic pumps. Pharmacological prophylaxis is stratified according to individual patient risk profile. High-risk patients (usually on warfarin pre-operatively) are commenced on bridging enoxaparin and warfarin post-operatively. Enoxaparin is ceased when INR values stabilize in the therapeutic range and then warfarin is continued for 3 months duration. Low-risk patients are commenced on Aspirin 150mg daily for 6 weeks post-operatively.

The use of a drain was determined by surgeon preference. In patients with drains, the total output at time of removal was recorded in medical records and fluid balance charts by nursing or medical staff.

2.5 Statistical analysis

All analyses were conducted with IBM SPSS Statistical software package. Differences in age, gender, BMI, tourniquet time, pre-operative INR, pre-operative anticoagulation medication, between groups were determined using the Chi-squared or Fisher's exact test. Additionally, differences in requirement for wound drains and post-operative drain insertion time were compared between groups using the Kruskall-Wallis test. For all association tests, a P-value (*p)* of less than 0.05 was considered statistically significant.

3. Results

A total of 128 patients comprised the study cohort, representative of 44 CAS, 46 conventional and 38 PSI. Demographic information is summarised in Table 1 and displays no significant difference in age, gender or BMI between the 3 groups. A significant difference in tourniquet time was identified, and routine pre-operative baseline blood tests demonstrated comparable pre-operative Hb levels across the 3 groups (p=0.23).

Pre-surgery factors appeared comparable, with no significant differences seen between the 3 groups. Patient demographics that were matched included; age, BMI, pre-operative Hb, INR and anticoagulant use.

3.1 Anticoagulant use/ holding pre-operatively

A total of 16 patients had raised INR pre-operatively and were spread as follows; 4 (PSI group), 4 (CAS group) and 8 (Conventional group). In the PSI group, 2 of the 4 patients were on warfarin which was held pre-operatively for 7 days. INR results for these 2 patients were 1.1 and 1.4. The remaining 2 patients were not on warfarin and both had an INR of 1.1.

No patients in the CAS group were taking warfarin and all had an INR of <1.2. The 4 patients with INR of 1.1 or 1.2 are not representative of a higher bleeding potential. INR was developed to specifically monitor warfarin therapy and may not be used as an assay for bleeding potential in patients not taking warfarin [10]. In the Conventional group, 2 of the 8 patients were on warfarin and this was held pre-operatively for 7 days. INR results were 1.2 and 1.3, respectively. The remaining 6

patients were not on warfarin and their INR levels were ≤1.2. The study authors did not consider raised INR levels on non-warfarin patients to be a contributing factor to bleeding risk.

The PSI group had a single patient who was continued on Celebrex despite instructions. However, this patient was not excluded as this was discovered post-operatively, and blood loss in this patient was within normal range. All anticoagulants were withheld in the CAS group. A total of 3 patients were continued on Aspirin in the Conventional group due to cardiac or valvular co-morbidities.

3.2 Surgical Factors

Surgical factors are summarised in Table 2. A significant difference was found between surgical times across the 3 groups, with the CAS group displaying the longest surgical time (Fig. 1). The difference in tourniquet time between the 3 groups was also significant (Fig. 1). The CAS group had the longest time with a mean of 78 minutes in contrast to the shortest mean time of 61 minutes in the PSI group. The tourniquet was routinely inflated prior to first skin incision in all cases except 5 cases. The 5 cases used short tourniquet time for the cementing process only and cases were evenly spread across the three groups (Conventional (2), CAS (2) and PSI (1)). Length of surgery over time for the PSI group is displayed in Fig. 2.

A significant association was observed between use of drains and surgical treatment group. The frequency of drain use appeared greater in the Conventional group (54.35%) compared to the other 2 groups. The use of drains was due to surgeon preference. The difference in Length of Stay in Hospital (LOS) was not significant, with a mean LOS of 5 days across all 3 groups. No significant association was observed between groups and whether the tibia or femoral component was cut and implanted first.

The difference in intra-operative blood loss between the 3 groups was also not significant. The observed blood loss was recorded at the time of surgery, with PSI and Conventional both recording a mean observed loss of 100ml while CAS recorded 150ml.

As displayed in Table 3, no significant difference between the mean pre- and post-op Hb levels was present between the 3 groups. However, a significant difference was observed with respect to Day 1 Hb. The difference between Pre-Op Hb and the lowest of the Post-Op Hb readings did not differ between the 3 groups (Fig. 3). In this study, 4 patients required transfusion due to either Hb <80g/l or clinically symptomatic. These 4 patients were all from the Conventional TKR group.

Drains were used in 3 of the 4 cases in the Conventional group that required transfusion. Total drain output for these patients were 550ml, 700ml and 1000ml, with time in situ for these drains being 24 hours, 20 hours and 28 hours, respectively.

The study captured a 3-day post-operative period in which two complications were reported. One patient experienced a dislocation of the operative knee, while the second had a pulmonary embolism 2 days post TKA. Both patients were in the PSI group and complications were resolved. In an extended review of complications reported as part of the prospective cohort study an additional 5 significant surgical, bleeding and thromboembolic complications were identified. A further 2 patients from the PSI group reported complications including a wound haematoma 10 days post-operatively and a manipulation under anesthesia procedure. Complications reported from patients in the conventional group included a pulmonary embolism 19 days post-operatively and a knee haemarthrosis. A single patient from the CAS group experienced failure of the polyethylene device

locking clip which was resolved via revision of the polyethylene component.

4. Discussion

This study sought to investigate blood loss between 3 surgical techniques for TKA. The PSI and CAS groups do not perforate the intramedullary cavity [9,11] and thereby reducing intra-operative systemic emboli.[12] The current literature is inconclusive on if the PSI or navigation offer increased accuracy in component placement.[9,11] Reduced complications, Length of Stay (LOS) and transfusion requirements through a more accurate and less disruptive method is desirable. However, in this study the most important finding was no significant difference between blood loss across the 3 groups.

Across all 3 study groups BMI ranged from 21.2 to 44.1 with an average of 31. A BMI of 31 is classified as 'Moderately Obese' according to the WHO criteria.[13] In a recent systematic review of morbidity and TKR, complications were significantly higher in morbidly obese patients (BMI < 40). Complications higher in the BMI > 40 group included superficial and deep infections, deep vein thrombosis and avulsion of the medial collateral ligament.[14]

The sugical time was signficantly different between the 3 groups. The navigation group had the highest average surgical time (110 min) and longest mean tourniquet time. Longer tourniquet time and total surgical time has been reported previously in the literature for patients undergoing CAS knee arthroplasty.[2,15,16] Increased tourniquet time is associated with increased wound infection, tissue ischemia, DVT and anesthetic risk.[15] Rama et al. (2007) found that early tourniquet release increased both the calculated blood loss and the total measured blood loss but not the post-operative blood loss.[17] This indicates that early release of tourniquet may contribute to increased total blood loss at the intra-operative stage.[17] In this study, the timing of release of tourniquet was at the surgeon's preference and not routinely deflated before or after wound closure. The use of diathermy to ensure haemostasis prior to wound closure was anecdotally the most frequently used technique, however

some surgeons may have relied on local compressive or tamponade effects to stem bleeding when releasing tourniquet after wound closure. The risk of a complication requiring additional surgery is significantly increased when the tourniquet was left inflated until wound closure was complete.[17] The data on timing of tourniquet release was not recorded prospectively, or available retrospectively. This is a limitation of this study, as release of tourniquet can occur at any stage of the operation at surgeon's discretion. Our data suggests that the intra-operative blood loss observed from suction was not significantly different between the 3 groups, hence the timing of tourniquet release was not considered a major factor in recording post-operative losses.

The learning curve associated with the new Signature™ PSI system was evaluated using the surgical length of time as a surrogate marker of experience and skill with the system. Figure 2. depicts a varying surgical time over the 4 year study period and no definite trend line exists in this group to suggest decrease in surgical time over the study period.

The use of drains in TKA is controversial. Literature supports no statistically significant difference in post-operative Hb levels or allogenic blood transfusion requirement between patients with no drain, closed drain or reinfusion drain.[18,19] In our study a drain was used for 33% in PSI, 15% in CAS and 54% in the Conventional group. This difference in drain use was statistically significant, however, literature supports the authors' view that drain use does not represent a confounding factor in our results. A limitation of this study was that the recordings of drain time removal and total blood collected at time of removal was reliant on recording of fluid balance chart/documentation in nursing notes in medical records. The element of human error and lack of documentation is apparent in retrospective chart reviews.[20]

Mean LOS in hospital was 5 days across the 3 study groups. LOS is important for reduction of healthcare costs, hospital efficiency and management of patient expectations.[21] The use of hospital stay time as a surrogate marker for post-operative recovery and hospital efficiency has seen the mean LOS decrease from 7.9 days in 1991 to 3.5 days in 2010.[22] There was no significant difference between LOS across the 3 arthroplasty groups in our study, reflecting similar co-morbidities and adequate assistance at home.

Blood loss in total knee replacement is a well published entity and a known complication in arthroplasty. Calculations have been used in previous studies to assess factors such as hemodilation from crystalloids and blood volume to determine a cumulative blood loss.[23,24] This study sought to assess each variable individually. The testing of hematocrit was not routinely performed after day 1 post – surgery, as compared with other studies, which relied on hematocrit in combination with Hb to determine blood loss.

We followed the paper by Thienpont et al.[9] in their method comparison of pre-operative Hb and lowest post-operative to gauge the maximal drop. Measured blood loss after TKA is generally an underestimation and can be only 50% of the "true" blood loss, as calculated with several methods.[25,26] This finding suggests that the available methods of measuring intra-operative blood loss are inefficient.

The mean Hb pre-operative was 140 for PSI, 135 for CAS and 139 for conventional. The mean post-operative Hb was 111 for PSI, 104 for CAS and 107 for conventional. Thereby calculating that the mean percentage drop was 21%, 23% and 23%, respectively. No significant difference was found between mean pre- and post-operative Hb levels.

The difference between pre-op and Day 1 post-op Hb levels was not significant ($p = 0.05$). The timing of day 1 levels was not uniform. In some patients the Day 1 blood test occurred in the

afternoon on same day of surgery, for others it was the following morning. In addition, the hematocrit was not taken to assess for hemodilation as a contributing factor.

The authors prefer pre-op and lowest post-op as a method of analysing Hb drop data. The lowest post – operative sample may have occurred on Day 1, Day 2 or Day 3. The latter 2 would have allowed for fluid balance homeostasis, however, further blood tests were at the discretion of the treating team and not routinely performed.

Despite these limitations, Anesthesia and post-operative care were standard across all groups in the same conditions. DVT prophylaxis protocol was uniformly used in all patients and no patients were found to have DVT and commenced on therapeutic anticoagulation during first 3 days post-surgery. The decision to transfuse or not was deemed in accordance with the institution protocol (Hb <80 or symptomatic of anemia).

The strength of this study is that blood values were obtained at regular post-operative times with daily phlebotomy rounds. In addition, pre-operative pharmacist and anesthetic consultations documented the recordings of anticoagulant use. The patient demographics and accountability of randomization was also a strength.

The 4 patients who required transfusion from the Conventional group all recorded Hb levels below 90. Of these, 1 patient had a recorded 1 liter intra-operative blood loss and was transfused in the immediate post-operative period.

5. Conclusions

It was hypothesized that performing TKA surgery using PSI technology would lead to lower intra-operative blood loss and a reduced drop in post-operative Hb. The technique does not require the use

of intramedullary alignment rods and the soft tissue dissection is less extensive than in the other techniques.

Our results demonstrate that surgical technique did not influence post-operative blood loss when comparing PSI, CAS and Conventional TKA. This is the first article to compare all 3 knee arthroplasty systems in a matched patient series. The surgeon's preference of drain use did not appear to influence post-operative blood loss.

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Figures:

Figure 1. Mean Surgical and Tourniquet Time

Blue Columns: Mean Surgical Time (minutes) per surgical technique

Green Columns: Mean Tourniquet time (minutes) per surgical technique

Figure 2. Surgical time over the study period for the Patient – Specific Instrumentation (PSI) Group

Figure 3. Hemoglobin Drop – Mean Pre – Op, Post – Op and Maximal Hb Drop

Error Bars: 95% Confidence Interval (CI)

Blue Columns: Pre-operative Hb

Green Columns: Post-operative Hb

Grey Columns: Peri-operative Differential Hb*