Navigation-Assisted Total Knee Arthroplasty with Normal Pressure Drainage Reduces Blood Loss – A Prospective Comparative Study of Three Modalities

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Abstract: Several modalities have been developed to reduce perioperative blood loss during total knee arthroplasty (TKA) and a navigation system has been successfully introduced in TKA. This study compared the blood loss of navigation-assisted TKA and conventional TKA in the presence of negative or normal pressure drainage. Patients were separated into 3 groups. We enrolled 60 patients undergoing conventional TKA with negative pressure drainage in Group A, and those undergoing navigation-assisted TKA with negative or normal pressure drainage were enrolled in Group B (64 patients) and C (66 patients), respectively. Haemovac drainage volume, reduction of haemoglobin, estimated total blood loss, range of motion at 3 months after surgery, number of blood transfusions and hospitalisation days were all recorded. There were no differences in the demographic data of these 3 groups. Patients in Group B had significantly decreased total drainage volume, estimated total blood loss and blood transfusion rate than those in Group A. The significant reduction of total drainage volume, estimated total blood loss and blood transfusion rate were also noted in Group C when compared with Group B. Patients in Group C had a significantly reduction in haemoglobin, heaemovac drainage volume, estimated total blood loss, blood transfusion rate and hospitalisation days when compared with Group A. Navigation-assisted TKA with normal pressure drainage is a potential modality for the reduction of the haemovac drainage volume, perioperative blood loss and transfusion rate without compromising range of motion at 3 months after surgery.
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1. Introduction

Total knee arthroplasty (TKA) is a well-developed technique with a highly satisfactory success rate for treating knee disorders. Post-TKA complications are significant concerns to knee surgeons. Excessive perioperative blood loss leading to unstable hemodynamic status is a concern. Haemolytic and allergic reactions and viral infection are the concerns following blood transfusion. Several modalities have been developed to reduce perioperative blood loss, including hypotension anesthesia [1], drain clamp [2-4], fibrin tissue adhesive [5], compression bandage, cryotherapy [6], tranexamic acid injection [7, 8] and sealing of the femoral canal using an autologous bone block.

A navigation system has been successfully introduced to assist in TKA. This system is reportedly beneficial in improvement of alignment and accuracy, in complex cases, and in sparing the intramedullary canal [9, 10]. Reduced blood loss during navigation-assisted TKA was reported by Kalairajah et al. [11]. However, details for the combination of drainage modification and the navigation system have not been reported. A prospective study was carried out to compare the blood loss among patients after conventional TKA with negative pressure drainage, navigation-assisted TKA with negative pressure drainage, and navigation-assisted TKA with normal pressure drainage. We hypothesized that navigation-assisted TKA with normal pressure drainage would further improve the perioperative blood loss.

2. Material and Methods

We conducted a prospective, comparative study between January 2005 and September 2009 to evaluate the perioperative blood loss and postoperative range of motion among patients by conventional TKA with negative pressure drainage (Group A), by navigation-assisted TKA with negative pressure drainage (Group B) and by navigation-assisted TKA with normal pressure drainage (Group C). Indications for TKA included advanced osteoarthritis, rheumatoid arthritis and traumatic arthrosis. Contraindications included knee sepsis with previous osteomyelitis, a remote source of ongoing infection, extensor mechanism dysfunction, severe vascular disease and recurvatum deformity secondary to muscular weakness. This study received approval from the institutional review board of the hospital and informed consent was obtained from all patients.

We enrolled 60,64 and 66 patients into Group A, B and C, respectively. The patients were separated into 3 groups according to their own wishes and financial concerns when the surgery was scheduled. The use of acetylsalicylic acid was stopped 1 week before the surgery and continued on the next day after the surgery. Other nonsteroidal anti-inflammatory drugs were not restricted before or after surgery. No antithrombus medications were given perioperatively. All surgeries were conducted under general anesthesia and were performed by or under the direct supervision of the senior orthopedic surgeon. Conventional TKA was performed in a bloodless field using a pneumatic tourniquet at a pressure of 300 mm Hg after a single injection of antibiotic (cefazolin sodium 1 g). A midvastus approach was used through a midline skin incision of 10-12cm. The femur and tibia bone cuts were adjusted via an intramedullary guide. The prosthesis (Advantim Knee System, posterior stabilizing type; Wright Medical Technology, Arlington, TN, USA) was implanted with cement fixation. A 1/8 inch haemovac(Zimmer Haemovac; Zimmer, Warsaw, IN, USA) was inserted as a closed drainage system and was maintained at a negative pressure (700 mm Hg). The haemovac was removed 72 hours after TKA or when the drainage volume was less than 50 ml in the preceding 8 hours.

A navigation-assisted TKA was performed on the Group B patients with a similar midvastus approach through a midline skin incision. The synovium was partially removed to enable precise registration. An infrared camera was equipped to track two fixed references with marker spheres that were fixed to the distal femur (4 mm pins) and the proximal tibia (3 mm pins) using two bi-cortical half-pins inserted via separate 0.5cm incision. A CT-free Navigation System (Vector Vision; Brain LAB, Heimstetten, Germany) with anatomical mapping of the knee and kinematics analysis was employed to generate a working model of the patient's knee. The centre of the femoral head, ankle landmarks and mapping of the distal femur and proximal tibia were registered. The femoral component was referenced parallel to the anterior cortex of the distal femur. A multiple referencing method using the epicondylar line, Whiteside line and posterior condylar line was adapted for the rotation of the femoral component. The rotation of the tibial component was adjusted to that of the femoral component and was parallel to the axis between the medial third of the tibial tuberosity and the center of the tibial plateau. An additional extramedullary guiding rod was used as a reference for the midpoint of the anterior ankle joint to assist with the determination of the rotation of tibial component. Osseous cut was achieved without intramedullary violation and the prosthesis (LPS-Flex system, Nexgen; Zimmer, Warsaw, IN, USA) was implanted with cement fixation. The ideal mechanical axis of within a 1.0° deviation was obtained after soft tissue balancing with the aid of a real-time computer screen. The tourniquet was released when the wound was closed. A 1/8 inch haemovac was also inserted as a closed drainage system and was maintained at a negative pressure (700 mm Hg). The haemovac was removed 72 hours after TKA or when the drainage volume was less than 50 ml in the preceding 8 hours.

Patients in Group C were operated on using the same navigation-assisted procedure as Group B. However, the tourniquet was released when the joint was closed and a 1/8 inch haemovac was inserted as a close drainage system and maintained at a normal pressure (760 mmHg) without compressing the haemovac to a negative pressure. The drainage was removed 24 hours after surgery.

Intraoperative blood loss for all patients was less then 30 ml due to the application of the tourniquet. Body fluid supplements were administrated with 0.9% normal saline or 0.9% NaCl with 5% glucose to stabilize the vital signs and urine output perioperatively. Blood transfusion with packed red blood cells was indicated when the haemoglobin (Hb) concentration was less than 8 mg/dl or 8-9 mg/dl with unstable vital signs. All patients started continuous passive motion after the removal of the drain. Bedside exercise for active flexion-extension, quadriceps training and walker-aided ambulation were conducted under the assistance of a physical therapist. All patients were discharged when the range of motion of the knee was greater than 90°, the wound was clean and dry and the patient's general condition was stable. We recorded the perioperative complications and range of motion 3 months after surgery to compare the effect of the navigation technique or drainage management on the knee motion.

Estimation of total blood loss

Patient blood volume (PBV) was calculated according to the formula [12]:

PBV (in litres) = k1 × height $(m)^3$ + k2 × weight (kg) + k3

Where: k1 = 0.3669, k2 = 0.03219, k3 = 0.6041 for males;

k1 = 0.3561, k2 = 0.03308, k3 = 0.1833 for females.

The loss of Hb (Hbloss) was calculated according to the formula [8]:

Hbloss = PBV × (Hbi - Hbe)

Where: Hbloss (in g) is the amount of Hb loss, Hbi (in g/l) is the Hb concentration before surgery and Hbe is the Hb concentration at 24 h after the surgery. Finally, the estimated blood loss of the first postoperative day (in ml) was calculated by using the following formula [1]:

Estimated blood loss = Hbloss/Hbi

The estimated total blood loss was the sum of the haemovac drainage volume of the following days and the estimated blood loss.

Statistical Analysis:

Haemovac drainage volume, Hb level on the first postoperative day, reduction in Hb level, estimated total blood loss, range of motion 3 months after surgery, and days of hospitalisation were all recorded and statistically analyzed using ANOVA and Scheffé's method. The blood transfusion rate was compared using Pearson's chi-square test. A p value of less than 0.05 was regarded as statistically significant.

3. Results

There were no statistical differences in the demographic data of the patients in the 3 groups (Table 1). Patients in Group B had significantly lower haemovac drainage volume ($p < 0.01$), blood transfusion rate ($p < 0.01$), estimated total blood loss ($p < 0.01$) and better range of motion 3 months after surgery ($p < 0.01$) than the patients in Group A, although Hb loss (g) or Hb reduction did not significantly differ between the two groups. Patients in Group C had also significant reduction in the haemovac drainage volume ($p < 0.01$), blood transfusion rate ($p < 0.01$) and estimated total blood loss ($p < 0.001$) than the patients in Group B (Table 2).

In the comparison between Groups A and C, we observed that patients in Group C showed significant reductions in haemovac drainage volume ($p < 0.01$), Hb reduction($p = 0.03$), estimated total blood loss ($p<0.01$), blood transfusion rate ($p < 0.01$), hospitalisation days ($p < 0.01$) and better range of motion 3 months after surgery ($p < 0.01$) when compared to Group A (Table 2).

Major complications, such as symptomatic deep venous thrombosis, thromboembolic disorders, major organ failure and deep infections were all reviewed. One patient in Group A was diagnosed perioperatively with an acute infarction of the right corona radiata. A significant reduction of Hb (14.5 mg/dl drop to 8.8 mg/dl) and haemovac drainage volume (2270 ml) was found at 24 hours after surgery. The estimated total blood loss was 2745 ml and this may have contributed to the cerebrovascular accident. Otherwise, no other major complications were encountered within the 3 groups.

The navigation groups (B and C) had better range of motion 3 months after surgery when compared with Group A and there was no significant difference between Group B and C ($119.5 \pm 9.3°$ vs $115.8 \pm 12.4°$, respectively, $p = 0.213$). Therefore, the improvement in the range of motion was significant in the navigation groups compared to conventional TKA, and there was no difference between the use of negative pressure or normal pressure drainage in patients who underwent navigation-assisted TKA.

4. Discussion

In this prospective comparative study, reduced blood loss was achieved after navigation-assisted TKA with normal pressure drainage compared to navigation-assisted TKA with negative pressure drainage and conventional TKA with negative pressure drainage. The blood transfusion rate was also lower than observed in previous reports [13, 14] (Table 3).

Some modalities have been proposed to reduce blood loss during TKA and hence to decrease blood transfusion and associated complications. These include a modified drainage system [2-4], tranexamic acid administration [7,8], minimal incision surgery [14], and computer-assisted surgery [9, 11]. It is conceded that skillful surgery is an important strategy for reducing blood loss. Minimal -incision TKA has been suggested to reduce blood loss and decrease the transfusion rate from 24.5% to 10.1% [14]. A navigation-system has been introduced to TKA with the advantages of improved alignment and accuracy and sparing the intramedullary canal [10]. Previous reports also demonstrated that computer-assisted TKA is associated with lesser blood loss than conventional techniques [11,15]. In our study, Hb reduction was significant in Group A compared to Group C, but not in the comparison between Groups A and B or Groups B and C (Table 2). The Hb level reflects the concentration of Hb in the PBV and it was obviously affected by body size. Due to the limited number of cases, the reduction and loss of Hb was not statistically significant although the mean value was less in Group B when compared with Group A. The reduction in Hb does not precisely represent the actual blood loss during the procedure. Therefore we identified the actual blood loss and analyzed the differences among each group by calculating the estimated total blood loss. When we compared Group A with Group C, the Hb reduction, haemovac drainage volume and estimated total blood loss were significantly less in Group C. These results imply that normal pressure drainage would further enhance the reduction in perioperative blood loss in addition to avoidance of medullary violation through the navigation technique and neither wound complications nor ROM deficit were encountered postoperatively. In addition, different brands of posterior stabilizing prosthesis would not change the amount of blood loss because of the same approach and osseous resection. To our knowledge, we provide the first evidence indicating that navigation-assisted TKA with normal pressure drainage is beneficial for the improvement of the perioperative blood loss, and blood transfusion rate when compared with the conventional procedures. The mean estimated total blood loss was 639.3 ± 212.8ml in Group C, which was the lowest compared with previous studies [13, 16](Table 3).

A prospective, comparative study in 90 patients who underwent TKA, observed no benefits using the postoperative drainage systems [17]. Another prospective study reported no advantages for the postoperative drainage systems, including the incidences of swelling or persistent drainage, and range of motion [18-20]. However, excessive haematoma is a concern in patients without drainage and may become the source of infection. Therefore drainage is still preferred by most orthopaedic surgeons in TKA. The efficacy of a drainage clamp for reducing blood loss is still controversial in patients with TKA. Drain clamping for 30 min with an intra-articular injection of saline and adrenaline has been reported to be an effective method for reducing blood loss during TKA [21]; however, patients with drain clamping for 24 hours after TKA reportedly have more complications than those with clamping for 1 hour [4]. No significant differences in blood loss or postoperative Hb levels were reported between a 2-hour clamp group and a control group [2].

A negative pressure produced by the drainage system can evacuate a haematoma from the joint, but it can also breakdown the intra-articular pressure caused by the haematoma and joint capsule tension, and leads to more perioperative blood loss. Therefore, we suggested a closed system with normal pressure drainage. The intra-articular blood can be drained out under balanced pressure without inducing further blood loss. In this study, the mean drainage volume was 130.5 ± 87.2 ml, which was lower than observed for the conventional TKA, the navigation-assisted group with negative pressure drainage and with previous reports (Table 3). Also, the retained blood clot within the knee joint did not compromise the range of motion after the surgery (Table 2) or resulted in major complications.

The use of tranexamic acid is an alternative approach for the reduction of blood loss. Plasmin binds to fibrinogen or fibrin structures to induce fibrinolysis. Tranexamic acid blocks the lysine-binding site of plasminogen that inhibits the conversion of plasmin. Tranexamic acid reportedly reduces the drainage volume by 50% [7, 8], but it does not significantly reduce the hidden blood loss caused by the extravasation of red blood cells just after tourniquet release [13].

The limitation of this study was the randomization of the patients. Due to the extra-cost of the navigation system, patients` decision to undergo conventional or navigation TKA was based on their own wishes that would make blind randomization incapable. However, the preoperative demographic data showed no statistical differences among these 3 groups.

Table 1 Demographic data for the Groups A, B and C

Variables	Group A (n = 60)	Group B (n = 64)	Group C (n = 66)	p
Age (years)	66.0 ± 7.5 (48 - 77)	64.1 ± 11.8 (27 - 86)	64.9 ± 5.6 (50 - 77)	0.488
Male/female	11/49	8/56	8/58	-
OA/RA /trauma	53/6/1	56 / 7 / 1	62 / 4 / 0	-
Body weight (kg)	66.8 ± 12.8 (42 - 107.2)	68.0 ± 13.9 (47 – 109)	68.4± 9.6 (52 – 111)	0.745
Body height (m)	1.53 ± 0.07 (1.43-1.73)	1.54 ± 0.08 (1.4 –1.75)	1.54 ± 0.05 (1.44 – 1.66)	0.750
Patient blood volume(ml)	3752.6± 583.5 (2614.0-5083.0)	3780.7 ± 671.3 (2869.2-5658.4)	3799.6 ± 424.9 (2989.1-5181.3)	0.897
Preoperative Hb (mg/dl)	13.12±1.31 (9.8 - 15.6)	12.87 ± 1.46 (9.2 - 6.7)	13.09 ± 1.28 (9.2 - 16.7)	0.538

Group A: Conventional TKA with negative pressure drainage
Group B: Computer-assisted TKA with negative pressure drainage
Group C: Computer-assisted TKA with normal pressure drainage
OA: Osteoarthritis; RA: Rheumatoid arthritis;
Hb: Haemoglobin
ANOVA $p < 0.05$ is considered significant difference

Table 2 Comparative perioperative data of Group A,B and C

Variables	Group A (n = 60)	Group B (n = 64)	Group C (n = 66)	ANOVA p	Scheffe p Group A vs B	Scheffe p Group B vs C	Scheffe p Group A vs C
Hb loss (gm)	8.07 ± 4.25 (0.32 – 23.93)	7.53 ± 3.09 (1.87 – 16.98)	6.64 ± 2.57 (0.69 – 12.21)	0.056	-	-	-
Hb reduction (mg/dl)	2.14 ± 1.05 (0.1 – 5.7)	1.98 ± 0.70 (0.5 – 3.6)	1.75 ± 0.66 (0.2 – 3.2)	0.03	0.56	0.29	0.03
Haemovac drainage amount (ml)	582.7 ± 393.2 (125–2745)	336.6 ± 222.7 (5 – 1090)	130.5 ± 87.2 (0 – 460)	<0.01	<0.01	<0.01	<0.01
Estimated total blood loss (ml	1190.4 ± 562.0 (329.1–4395.0)	918.4 ± 338.5 (146.0-2106.5)	639.3 ± 212.8 (89.8 – 1090.4)	<0.01	<0.01	<0.01	<0.01
Hospitalisation days	8.7 ± 2 (5 – 20)	7.9 ± 2.2 (5–17)	6.9 ± 2.2 (3 – 14)	< 0.01	0.119	0.072	<0.01
ROM (degree)	105.4 ± 22.3 (80-130)	119.5 ± 9.3 (90- 135)	115.8 ± 12.4 (70 - 150)	<0.01	<0.01	0.21	<0.01
Blood transfusion (%)ǂ	28.3	9.4	0	< 0.01			

Group A: Conventional TKA with negative pressure drainage
Group B: Computer-assisted TKA with negative pressure drainage
Group C: Computer-assisted TKA with normal pressure drainage
ROM : Range of motion 3 months after surgery ;
Hb: Haemoglobin
p value of less than 0.05 was regarded as statistically significant.
ǂ Blood transfusion rate was compared using Pearson's chi-square test

Table 3 Series of perioperative blood loss, Hb reduction and transfusion rate

Authors	Numbers of TKA	Drain volume (ml)	Hb reduction (mg/dl)	Estimated blood loss (ml)	Transfusion rate (%)
Dae et al. [15]	50 (CATKA)	464.9	2.59	–	–
Good et al. [13]	27 (TCTKA) 24 (placebo)	385 845	2.8 2.8	1045 1426	11.1 58.3
Kalairajah et al.[11]	30 (CTKA) 30 (CATKA)	1747 1351	5.3 3.6	– –	– –
Sehat et al. [16]	101 (CTKA)	733	3.0	1498	–
Tenholder et al. [14]	69 (MIS) 49 (CTKA)	– –	3.2 3.8	– –	10.1 24.5
Tsumara et al.[19]	106 (CTKA)	662	2.4	–	–
Present series	60(CTKAN) 64 (CATKAN) 66 (CATKAP)	582.7 ± 393.2 336.6 ± 222.7 130.5 ± 87.2	2.14± 1.05 1.98± 0.7 1.75± 0.66	1190.4 ± 562.0 918.4 ± 338.5 639.3 ± 212.8	26.6 9.4 0

(CTKA) : Conventional TKA
(CTKAN) : Conventional TKA with negative pressure drainage
(CATKAN): Computer-Assisted TKA with negative pressure drainage
(CATKAP) : Computer-Assisted TKA with normal pressure drainage
(TCTKA): Tranexamic acid administration following conventional TKA
(MIS): Minimal incision TKA; Hb: Haemoglobin

In this study, navigation-assisted TKA with normal pressure drainage was proven to be the most effective at reducing perioperative blood loss, transfusion rate and hospitalisation days. Navigation-assisted TKA affords a technical advance in reducing blood loss by the avoidance of an intramedullary violation. Normal pressure drainage avoids excessive blood loss while evacuating intra-articular haematomas. This drainage strategy is simple and easy and no additional equipment or nursing care is required.

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