

Original Research Article

Lower tourniquet cuff pressure reduces postoperative thigh pain in obese patients undergoing total knee arthroplasty

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ABSTRACT

Background: The use of high tourniquet pressures in obese patients undergoing total knee arthroplasty increases the risk of postoperative thromboembolic events and skin complications. Measurement of limb occlusion pressure (LOP) before surgery may lead to the use of lower tourniquet cuff pressure during surgery and thereby reduce the risk of postoperative pain and complications.

Methods: Eighty-six obese patients scheduled for total knee arthroplasty were randomized to a control group (n=43) with tourniquet pressures at 300 mmHg or the LOP group (n=43) where a recommended tourniquet pressure was determined based on the patient's limb occlusion pressure. The primary outcome measure was postoperative thigh pain; the secondary outcome measures were the quality of bloodless field, postoperative drop in haemoglobin, postoperative complications and Oxford knee scores.

Results: The tourniquet cuff pressure was significantly lower in the LOP group than in the control group ($p<0.001$). Patients in the LOP group showed significantly lower postoperative thigh pain scores till postoperative day 3. Our study did not show any difference in intraoperative quality of bloodless field ($p<0.103$), postoperative complications and Oxford knee scores ($p<0.775$) at six months after surgery.

Conclusions: Our results show that the use of limb occlusion pressure method results in decreased postoperative thigh pain without reducing the quality of the bloodless field. We believe that this method in tourniquet application is safe and beneficial for the subset of obese patients undergoing total knee arthroplasty.

Keywords: Tourniquet, Limb occlusion pressure, Obesity, Thigh pain, Total knee arthroplasty

INTRODUCTION

The pneumatic tourniquet was introduced in 1904 by Harvey Cushing as an aid to total knee replacement (TKR) surgery by improving visualization by preventing intra-operative blood loss.¹ A survey in 2010 found that 95% of surgeons in the USA use a tourniquet for total knee replacement (TKR) surgery.² However, majority of orthopaedic surgeons inflate the tourniquet to fixed pressures without considering the baseline blood pressure of the patient on whom the tourniquets are being applied. Tourniquet inflation leads to local effects due to

compression with tourniquet pain being one of the most intriguing pains for the anesthesiologists and also a cause of concern for orthopaedic surgeons.

The effects and complications of tourniquet use are amplified when operating on obese patients. More than a third of patients undergoing total knee arthroplasty (TKA) have a body mass index (BMI) in the obese range.³ Application of a pneumatic tourniquet to maintain a blood-free surgical field in this group of patients may pose as a challenge. The problems include the need for larger and wider cuffs thereby dangerously decreasing the

distance from the distal edge of the tourniquet to the incision; tourniquets tend to slide distally when inflated due to the taper of the thigh; occlusion of arterial flow in the obese patient requires higher pressures, thereby causing more tissue compression (crush injury) and skin damage.⁴

Measuring the limb occlusion pressure (LOP) just before surgery by means of an automated photo-plethysmographic sensor connected to a tourniquet apparatus takes into account such variables as the patient's blood pressure, the type and width of the cuff, the tightness of cuff application, the fit of the cuff to the limb, and the properties of the patient's soft tissues and vessels.⁵ It has therefore been suggested to result in a more optimal and possibly lower tourniquet cuff pressure.

The use of an automated measurement of limb occlusion pressure for TKR surgery and its outcomes has been investigated in only few clinical studies.^{6,7} However, there are concerns as to whether the lower tourniquet pressures would lead problems such as increased intra-operative bleeding and hence post-operative complications. This has thus far not been investigated in any study in the unique group of obese patients. The obese thigh is typically very wide, acutely tapered, and relatively soft. The loose skin makes this sliding even easier with a tendency to pull some skin folds along.⁸ The rheology of the obese tissues is another factor that must be considered, namely the compressibility of the adipose tissue is such that higher pressures are needed in order to transmit the pressure from the skin surface beneath the tourniquet to the vicinity of the blood vessel. It is unknown the effects of the limb occlusion pressure method of tourniquet on this subset of patients.

This is the only study to date examining the outcomes of the use of the LOP technique in tourniquet application on the subset of obese patients undergoing TKR surgery. Any system that can result in the use of a lower tourniquet pressure during surgery without any detrimental side effects would be especially beneficial to this group of patients. The primary aim of this study was to investigate if the LOP method of tourniquet application on the subset of obese patients undergoing TKR surgery leads to reduced tourniquet pressures and if this leads to decreased postoperative thigh pain. The secondary aim was to investigate whether there were any differences in the quality of bloodless field, postoperative drop in haemoglobin, transfusion requirements, postoperative complications and Oxford knee scores.

METHODS

This was a prospective randomized study performed from January 2017 to January 2018 on patients who underwent primary unilateral total knee arthroplasty (TKA) by a single surgeon at Singapore General Hospital. The hospital's medical ethics committee audited and approved the study protocol (CRIB: 2017/2743/D) The study was

performed in accordance with the consolidated standards of reporting trials (CONSORT) and the ethical standards laid down in the 1964 Declaration of Helsinki, and a written informed consent was obtained from all the patients recruited.

Patient selection

Patients with a BMI of >30.0 and who were eighty years of age or younger were considered eligible for inclusion. Patients who had a systolic blood pressure of >200 mmHg, were on anticoagulation medication (including, had significant peripheral vascular disease rendering tourniquet use undesirable, or evidence of chronic or recent deep vein thrombosis in the index limb were excluded from the study.

Categorization

The patients were randomized into 2 groups: whether they had a tourniquet with the LOP system applied (Group 1) or whether there was a fixed tourniquet pressure of 300 mmHg (Group 2). Randomization was carried out at a pre-operative clinic using opaque sealed envelopes.

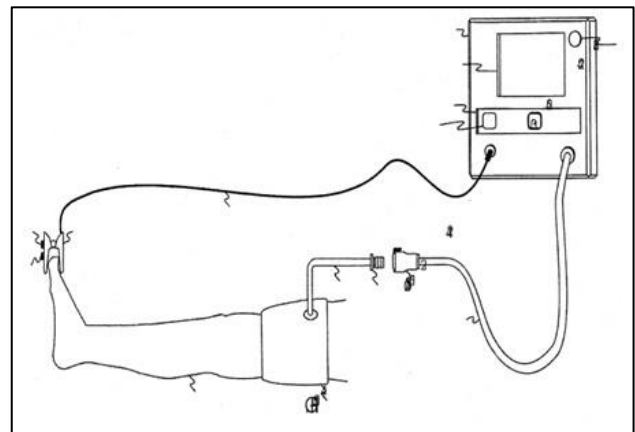


Figure 1: Set up displaying how the limb occlusion pressure is measured by the Zimmer A.T.S 3000 automatic tourniquet system.

In both groups, the limb underneath the tourniquet cuff was protected by layers of autobahn. The operating room nurse then applied a standard 140-mm wide contour thigh cuff for all patients. In the LOP group (Group 1), the cuffs were connected to a Zimmer ATS 3000 tourniquet instrument (Zimmer Orthopaedic Surgical Products). The Zimmer A.T.S 3000 automatic tourniquet system has an automated plethysmographic system built into the tourniquet that measures limb occlusion pressure at the beginning of an operation. The tourniquet cuff is applied to the patient's operative limb prior to surgical prep, the LOP sensor is applied to the big toe or second toe on the operative limb in which the tourniquet cuff has been applied (Figure 1). Once the LOP has been determined, the tourniquet system will automatically calculate the

patient's specific recommended tourniquet pressure (RTP). The RTP is determined by a programmed algorithm which is derived from a combination of the pressure margin and the LOP measurement. In the control group (Group 2), the tourniquet pressure was fixed at 300

mmHg. The surgeon was blinded to the randomization and was not told which tourniquet pressure was applied. For both groups, tourniquet inflation time was noted, as was blood pressure at the time of cuff inflation and deflation.

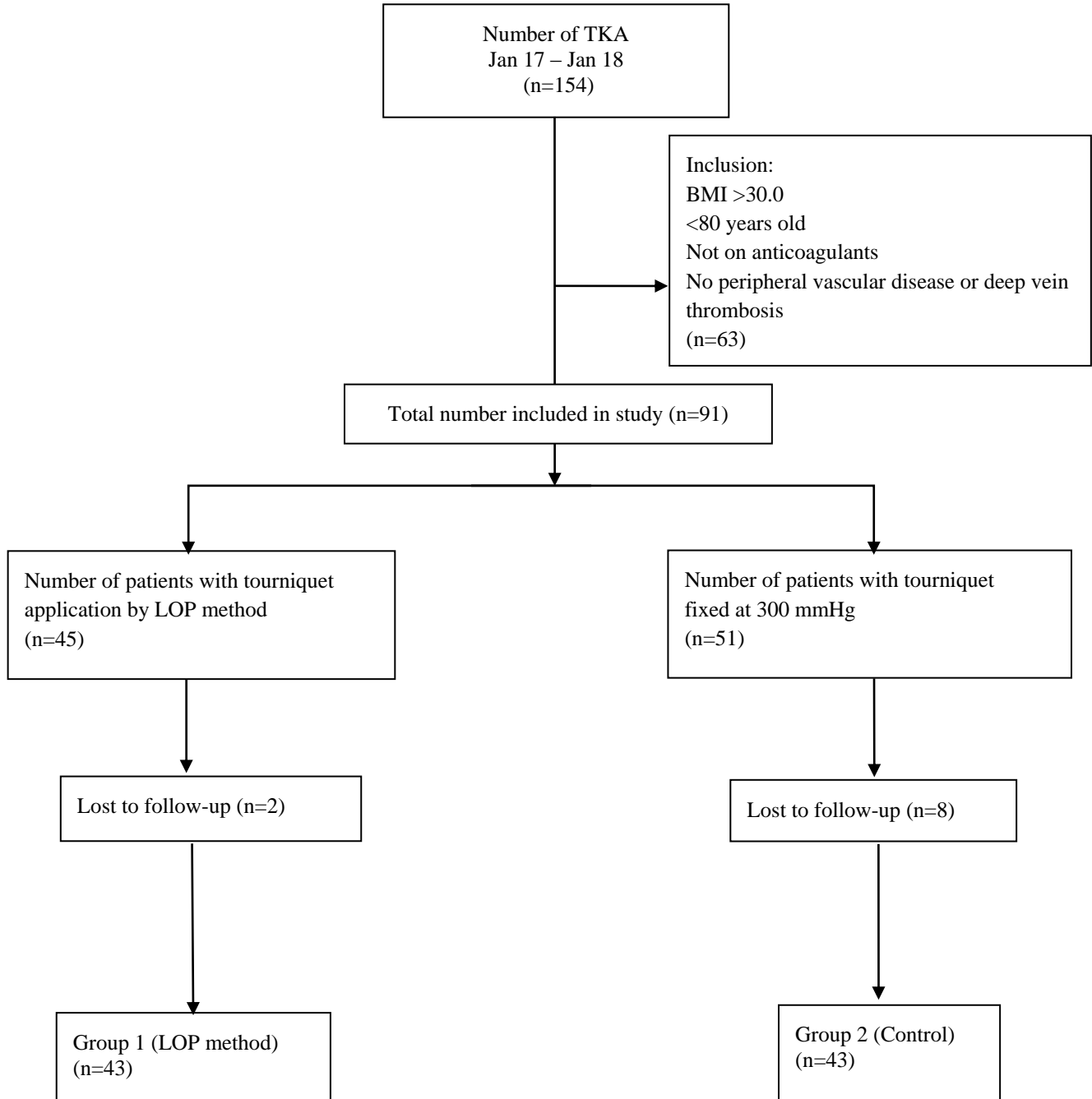


Figure 2: Consolidated standards of reporting trials (CONSORT) flow diagram for the study.

A total of 154 patients underwent primary unilateral total knee arthroplasty between January 2017 and January 2018. 91 patients met the inclusion criteria for the study. Patients with missing pre or postoperative outcome data

were eventually excluded. In total, 86 patients who underwent primary unilateral TKA with a BMI >30.0 who were included in the study 43 in the LOP group and 43 in the control group (Figure 2).

Operative technique and data collection

Total knee arthroplasty surgery was performed according to the routine at our department. All surgeries were performed by a senior surgeon and operative techniques were standardized across both groups. The patient's lower limb was elevated while tourniquet was being inflated. All patients received perioperative antibiotics (IV Cephazolin 2g). All surgeries were performed using the standard medial para-patellar quadriceps splitting approach with the patella everted. The distal femur was prepared using an intra-medullary rod. The proximal tibia was prepared using an extra-medullary jig. All patients had cemented implants from DePuy Synthes PFC@ Sigma® Knee System (Warsaw, IN, USA) All patients also received a local infiltration analgesic (300 mg of ropivacaine/0.5 mg of epinephrine/30 mg of ketorolac) at the end of the surgery by infiltration into the fascia, muscles, and subcutaneous tissue, regardless of whether they had had spinal or general anesthesia. The tourniquet was released after cementation of implants and hemostasis of visible bleeders was performed with a diathermy for all patients. Before closure of the retinaculum, all patients received topical tranxanemic acid intra-operatively. Surgical drains were not used. Postoperatively, a standard thromboembolic prophylaxis protocol was followed. Pneumatic calf pumps were given until ambulation. Subcutaneous Clexane 40 mg once daily (Sanofi, Paris, France) was given to all patients on the first post-operative day and continued until discharge from hospital.

Immediately after the surgical procedure, the surgeon rated the quality of the bloodless field on a visual analog scale (VAS), with 1 indicating the worst possible rating and 10, the most optimal. Other intra-operative data collected included operative time and tourniquet time.

Post operatively, patients rated their thigh pain score using the VAS index with 1 indicating minimal pain and 10, the worst possible pain. The VAS index is a self-administered but conducted by the surgical team immediately post op when the patient is reviewed in the ward, and subsequently on post-operative day one to four during the morning surgical rounds. The skin underneath the tourniquet was also inspected immediately after the surgery and on postoperative day one to four for any skin

or wound related complications. Further parameters measured post operatively included the decrease in haemoglobin and haematocrit, and transfusion requirements.

All patients were followed up at the orthopaedic diagnostic centre at one month, two months and six months postoperatively with inspection of the wound and detected of any postoperative complications noted at each visit. Knee function assessments using the Oxford knee scores (OKS) were also performed at 6 months follow-up.

Statistical analysis

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 21 (SPSS, Inc, an IBM Company, Chiago, IL). For normally distributed continuous variables, Student's t-test was used. For continuous variables that are not normally distributed, Mann Whitney U-test was used. Pearson chi-square test was used to analyze categorical variables. All comparison were two-tailed and a $p < 0.05$ was considered statistically significant.

RESULTS

Data was collected for 154 patients who underwent primary unilateral total knee arthroplasty between January 2017 and January 2018. After applying the inclusion criteria, complete data was available for 86 patients, with 43 patients who underwent TKA with a tourniquet pressure applied with the LOP technique (Group 1) and 43 patients who had a tourniquet pressure of 300 mmHg (Group 2).

The differences found in patient demographics such as sex, age, thigh girth and body mass index (BMI) were not statistically significant between the two groups. Systolic blood pressure, measured on the arm routinely at the start of surgery, was a mean (and SD) of 130 ± 20 mmHg in the control group compared with 128 ± 19 mmHg in the LOP group (difference not significant). Total duration of operation and tourniquet application time were also both found to be not statistically significant between both groups (Table 1).

Table 1: Patient's demographics.

Charcateristics	Group 1 (LOP) (n=43)	Group 2 (n=43)	P value
Age (years)(SD)	66 (7)	66 (7.5)	0.564
Gender (male:female)	15:28	11:32	0.481
BMI (kg/m ²)(SD)	29.1 (2.6)	29.4 (3.2)	0.685
Thigh girth (cm)(SD)	58 (4)	58 (5)	0.752
Operation duration (minutes) (SD)	110 (15)	105 (10)	0.302
Tourniquet application time (minutes) (SD)	70(10)	71.7 (15)	0.783

Table 2: Intra-operative quality of bloodless field rating and patient outcomes.

Outcomes	Group 1 (LOP) (n=43)	Group 2 (n=43)	P value
Mean VAS score (SD) for quality of bloodless field	8.2 (1.2)	8.9 (1.7)	0.335
Drop in haemoglobin (SD)	2.5 (0.7)	1.9 (1.3)	0.035
Difference in haematocrit (SD)	7.6 (2.5)	6.5 (3.7)	0.009
Need for transfusion (Number)	4	3	0.685
Oxford knee score (6 months) (SD)	18.5 (5.3)	18.0 (3.5)	0.775

The mean cuff pressure in the LOP group was 272.4±15 mmHg and this was found to be significantly lower ($p<0.001$) than the control group which had tourniquet pressures set at 300 mmHg (Figure 3). No significant difference between the groups could be detected regarding the quality of the bloodless field as judged by the surgeon (Table 2). Quality of the surgical field was noted to be acceptable in all cases and there were no incidents of breakthrough bleeding that required an increase in cuff pressure during the surgical procedure.

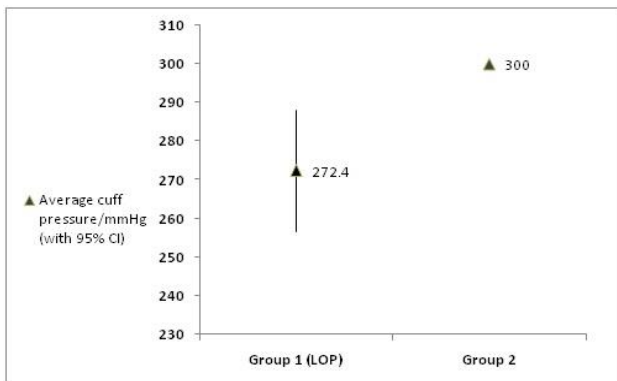


Figure 3: Average tourniquet cuff pressure was significantly lower in the group in which LOP was measured, in comparison with the control group (300 mmHg).

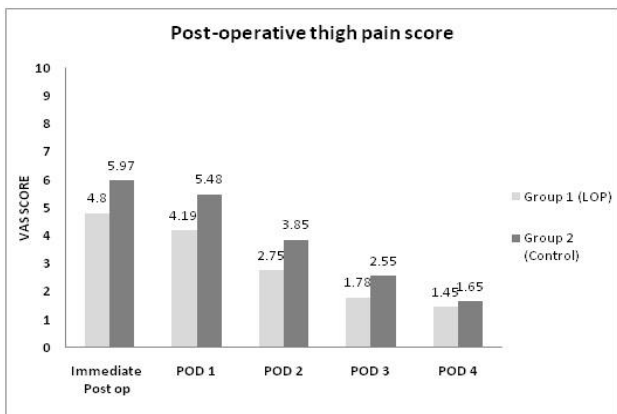


Figure 4: Average VAS pain scores for the first 4 days post operatively in the LOP and control groups (demonstrating significantly lower pain scores in the LOP group till postoperative day 3).

Ratings of postoperative pain were measured by the visual analogue pain score. Figure 4 displays the average pain scores for the first 4 days for the two groups. The difference in pain scores were statistically significant immediately post-operative till postoperative day 3 with the patients in the LOP group reporting lower thigh pain scores. There was no difference in thigh pain score postoperative day 4. There was a larger drop in haemoglobin and haematocrit count (taken at post-operative day 1) in the LOP group as compared to the control group. But this did not translate to a higher need for transfusion in the LOP group with 4 patients in that group requiring blood transfusion compared to 3 in the control group ($p=0.685$). Oxford knee scores and range of motion were not significantly different between both groups at follow up points up to 12 months (Table 2).

None of the patients reported any post op complications such as deep vein thrombosis, nerve injury, post-operative wound infection or post-operative wound dehiscence during their inpatient hospitalization and at follow up at 6 months. 5 patients in the control group developed minor blistering or other pressure-related injuries such as mild ecchymosis under the tourniquet cuff application site as compared to 3 patients from the LOP group. 7 patients in the control group had some oozing from the wound site as compared to 9 patients from the LOP group. These complications were however all not found to be significantly different between the LOP and control groups.

DISCUSSION

This is the first study known in literature that analyses the effects of the use of limb occlusion pressure method in tourniquet application on a subset of obese patients undergoing total knee arthroplasty. Our results show that the limb occlusion pressure measuring technique reduces the tourniquet cuff pressures in these patients undergoing total knee arthroplasty, and this in turn demonstrated a significant decrease in post-operative thigh pain. The generally lower tourniquet pressure in the LOP group still maintained a good quality of bloodless field with no difference as compared to the control group, and did not have any impact on the risk of developing postoperative wound complications nor did it affect postoperative knee scores.

Surgeons may tend to typically use higher cuff pressures when operating on obese patients with the intent to obtain a satisfactory bloodless surgical field. The ability to expel the blood from the operated limb prior to tourniquet inflation is difficult in the obese patient, time consuming and tedious and often suboptimal, leaving substantial volume of blood in the vessels. Other published studies have set similar high cuff pressures of 300-350mmHg for their control group.^{5,9,10} However, our study has validated that significantly lower tourniquet cuff pressures (272±15 mmHg) based on LOP measurement technique and application can be used effectively in this group of obese patients undergoing total knee arthroplasty without compromising the quality of the surgical field. Some studies have reported otherwise that under pressurization may result in blood in the surgical field and passive congestion of the limb.^{5,11} Tai et al found that the use of a tourniquet was effective in reducing blood loss.¹² However, similar to our results, Reilly et al and Olivecrona et al in their studies showed that quality of surgical field was acceptable in their LOP group and had no significant difference when compared to a control group with higher tourniquet setting.^{7,13}

Our study showed that the use of a higher tourniquet pressure does have a detrimental effect on the patient's recovery following TKA, in particular with respect to the patient's postoperative thigh pain. Pain scores were higher in the control group and reached statistical significance immediately post-operatively, and till day 3 post-operatively. The tourniquet, therefore, appears to be a significant source of post-operative thigh pain. Previous studies comparing the effect of different tourniquet pressures on postoperative thigh pain have reported mixed conclusions. Ledin et al found significantly less pain and better range of motion at 2 years in his no tourniquet group.¹⁴ Likewise, Liu et al found that his no tourniquet group had significantly less pain in the early post-operative period as compared to the tourniquet group, and quadriceps function, measured by surface ECG, was compromised for the first six months post-surgery by tourniquet use.¹⁵ However, Olivecrona et al in a randomized study demonstrated no advantage was found in the LOP group with regards post-operative pain, knee range of motion or complications.⁷ The authors explained that as a routine in their department, all patients received local infiltration analgesia at the end of surgery, and most of them received it the next day as well. The fact that postoperative pain treatment was good in all patients could be one of the reasons why their study could not demonstrate any differences in postoperative pain between both groups.

Our study reported that there was a significant decrease in post-operative haemoglobin and haematocrit levels in the LOP group. An increase pooling of blood in vessels in lower tourniquet pressures or an increase in local fibrinolysis postoperatively after tourniquet deflation, secondary to release of fibrinolytic factors from the surgical site, may explain the increased risk of bleeding

post-operatively into the joint or drains.¹⁶⁻¹⁸ However importantly, this decrease in haemoglobin levels did not translate to higher frequency of transfusion in the LOP group. Smith et al in his meta-analysis reported that there is an initial increase in blood loss in groups without tourniquet use, but no difference in total blood loss or transfusion in comparison with patients in whom a tourniquet was used.¹⁹ In randomized studies, tourniquet use during knee replacement surgery does not reduce total blood loss.^{20,21} We acknowledge many patient factors determine transfusion need both intra-operatively and post-operatively but we were unable to analyze and account for all of them.

Our study did not demonstrate any differences in Oxford knee scores and knee motion between both groups at follow up point of 6 months post surgery. Both groups showed an improvement in Oxford knee scores and knee range of motion post op. Some studies comparing knee or ankle surgery with and without tourniquet have shown significantly better knee flexion after surgery without a tourniquet. The authors suggested that this could be due to swelling of the limb after use of a tourniquet, with an immediate 10% increase in limb girth, up to 50% over the first post-operative day.^{22,23}

A number of different tourniquet-related injuries have been reported in literature related including muscle weakness, compression injuries, nerve injuries and even extremity paralysis.²⁴⁻²⁷ Wound hypoxia during lower limb orthopaedic surgery is also greater with tourniquet use than without.²⁸ This may be relevant to wound healing and infection. Prolonged tourniquet inflation time is also known to be a risk factor for infectious complications.²⁹ The risk of deep vein thrombosis has been proven to be significantly increased with a tourniquet time of more than 60 mins.³⁰ The formation deep vein thrombosis begins during tourniquet inflation and continues after deflation due to an increase in circulating markers of thrombosis.^{31,32} Guss et al postulated that under-pressurization can lead to a substantial volume of blood being left behind in the vessels, this blood can clot over course of the period of tourniquet inflation, and can be released into the circulation when the tourniquet is deflated.³³ Our study did not any report of major complications such as deep vein thrombosis, superficial or deep wound infections or wound dehiscence. This could be because we excluded patients with high risk factors such as previous deep vein thrombosis, diabetes or significant peripheral vascular disease from the study. We did have a few patients with some minor complications such as post op blistering and oozing from the wound site. But this was not found to be significantly different between both groups.

The strength of this study is that it was a prospective study on a randomized controlled population. A limitation of this study relates to the subjective rating of post-operative thigh pain and quality of intra-operative bloodless surgical field. Previous studies have similarly

used the VAS as a method of assessing post-operative thigh pain.¹³ Visual analog scales are commonly used to assess subjective clinical outcomes such as pain; however, it has not previously been validated to assess the quality of bloodless surgical fields. Other studies have assessed the level of blood in surgical fields into groups such as poor, fair, good or excellent or simply just adequate or inadequate.^{5,34} In an effort to increase accuracy and consistency, one single surgeon blinded to randomization of the groups ranked the quality of the visual field.

CONCLUSION

Tourniquet use, although widespread in TKA surgery, is not without complications. Careful patient assessment, knowledge of the principles of tourniquet use and an understanding of the pathophysiological changes that occur are essential in minimizing the morbidity of this often ritually used piece of equipment. The problems with tourniquets in the obese patient have led to a framework of strict procedures and protocols with the application of tourniquets. The concept of measuring limb occlusion pressure prior to inflation of a surgical tourniquet establishes a basis for setting the optimal tourniquet pressure for each patient. Our study has shown that the use of the LOP method in tourniquet application in TKA can lead to lower tourniquet pressures being used and results in decreased postoperative thigh pain. In the future, to further tourniquet safety, efficacy and reliability, safer tourniquet systems which monitor physiologic variations and estimates dynamic limb occlusion pressures intra-operatively may be developed. This study serves as a pilot for future studies in the development and evaluation of surgical tourniquets.

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