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ORIGINAL PAPER

Silicone ring tourniquet or pneumatic cuff tourniquet for total knee arthroplasty

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Abstract
Purpose The goal of the present study was to evaluate the potential advantages of a silicon ring tourniquet in comparison to the conventional pneumatic cuff tourniquet. The tested hypothesis was that the calculated blood loss will be decreased after use of the silicone ring tourniquet.
Methods The study was monocentric and mixed retrospective and prospective evaluation of prospectively collected data. Inclusion criterion was implantation of a total knee arthroplasty. The retrospective control group involved 39 patients operated on with a pneumatic cuff tourniquet. The prospective study group involved 33 patients operated on with a silicone ring tourniquet. All patients were followed for three months. Primary criterion was the calculated blood loss (OSTHEO formula). Secondary criteria were pain on third post-op day, need for allogenic transfusion, haemoglobin drop, delay of discharge, and occurrence of complications.
Results The mean calculated blood loss was 901 ml in the study group and 989 ml in the control group (NS). There was no significant difference in pain evaluation and haemoglobin drop between the two groups. There was a non significant decrease of allogeneic transfusion and length of stay in the study group. There was a significant decrease of complication rate in the study group, and especially for skin complications.
Conclusions The tested hypothesis was not confirmed: there was no significant change in the calculated blood loss. No bias was identified in complication analysis. The decreased rate of skin complication might be a positive influence of the silicone ring tourniquet.

Keywords Calculated blood loss · Silicone ring tourniquet · Tourniquet · Total knee arthroplasty

Introduction

Use of a tourniquet remains controversial during total knee arthroplasty (TKA) [1–3]. Satisfactory outcomes have been observed after TKA implanted without tourniquet [4]. Documented advantages are a bloodless operative field [5], less intra-operative blood loss [6], and a better cement penetration [7]. However, disadvantages may be more post-operative blood loss [2], a greater occurrence of venous thrombosis [3], neuromuscular [8] or cutaneous [9] damage, and delayed rehabilitation [10]. Especially, tourniquet time over 100 minutes increases the risk of complications after TKA, and special attention should be given to reduce the tourniquet time [11]. Consequently, alternate procedures have been suggested. The half-course tourniquet strategy [12] could decrease the total peri-operative blood loss in primary TKA, and may be beneficial in helping patients to achieve earlier functional recovery by improving the pain experience and limb swelling early in the post-operative period.

Use of a silicone ring tourniquet (SRT) (Hemaclear ®, Provin Medical, Lyon, France) has been suggested [13]. It is postulated that this tourniquet will decrease blood loss through a better exsanguination, and will decrease soft tissue damage through a smaller compression area [14]. The goal of the present study was to evaluate advantages and disadvantages of this new tourniquet for TKA. The tested hypothesis was that the calculated total blood loss after TKA will be decreased with

Level of evidence: Level III – retrospective comparative study

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use of the SRT in comparison to a conventional pneumatic cuff tourniquet (PCT).

Material and methods

The study followed the ethical standards of the Helsinki declaration of 1975 as revised in 2000, and was accepted by the institutional ethical committee. It was a monocentric evaluation which mixed retrospective and prospective analysis of prospectively collected data. Inclusion criterion was implantation of a TKA for end-stage knee osteoarthritis. Exclusion criteria were a contra-indication to the intra-operative use of a tourniquet and bilateral procedures.

Seventy two patients were selected after having given their informed consent. The retrospective control group involved 39 patients operated on with a PCT between May 2014 and December 2014. The prospective study group involved 33 patients operated on with a SRT between January 2015 and June 2015. There were 24 men and 48 women, with a mean age of 67 years (±10) and a mean body mass index (BMI) of 32.9 kg/m^2 (±8.9). All patients received a cemented TKA (e.motion ® TKA, Aesculap, Tuttlingen, FRG) implanted by one single surgeon (JYJ) under control of a navigation system (OrthoPilot ®, Aesculap, Tuttlingen, FRG). Hemostasis was performed during the whole procedure with electrocautery according to the surgeon's judgment. No drainage was left, either in the joint or in the soft tissue.

In the control group, the PCT was applied by the operating nurse around the upper thigh before draping. Exsanguination was performed by gravity by lifting the foot for five minutes, and the tourniquet was inflated just prior to skin incision. The tourniquet was deflated after dressing application.

In the study group, the SRT was applied by the operating surgeon after draping just prior to skin incision. The ring was sectioned after dressing application.

All patients followed the same regimen of pre-operative, intra-operative and post-operative drugs, including the intra-operative use of 1 g of tranexamic acid (Exacyl ®, Sanofi-Aventis, Paris, France), and a six week post-operative deep venous thrombosis (DVT) prophylaxis by enoxaparin (Lovenox ® 4000 UI/d, Sanofi-Aventis, Paris, France). All patients followed the same accelerated rehabilitation process, with immediate full weight bearing and unrestricted knee range of motion [15].

All patients were evaluated after three months. Primary criterion was the calculated blood loss (CBL) according to the OSTHEO formula [16]. Secondary criteria were duration of tourniquet inflation, pain on third post-operative day measured by a visual analogic scale (VAS), need for allogeneic transfusion, hemoglobin drop, delay of discharge, and occurrence of complications. All criteria were compared between both groups with the appropriate statistical tests at a 0.05 level of significance. The sample size was calculated to detect a difference of 200 ml in the CBL with a power of 0.80.

Results

There was no significant difference between both groups for pre-operative items. Especially, the mean pre-operative hemoglobin level was 13.5 g/dL (±1.5) in the control group and 13.7 g/dL (±1.2) in the study group (NS).

The mean CBL was 989 mL (±505) in the control group and 901 mL (±488) in the study group (NS). The mean duration of tourniquet inflation was 95 minutes (±18) in the control group and 86 minutes (±18) in the study group ($p = 0.04$). The mean pain evaluation on third post-operative day was 2.9 (±1.7) in the control group and 3.2 (±1.3) in the study group (NS). The mean haemoglobin drop was 2.2 g/dL (±1.0) in the control group and 1.8 g/dL (±0.8) in the study group (NS). There was a non significant, but clinical relevant decrease of allogeneic transfusion in the study group (one case, 4 units) in comparison to the control group (five cases, 10 units). There was a significant decrease in the delay for discharge in the study group (3.8 ± 1.9 d) in comparison to the control group (5.4 ± 2.8 d) ($p = 0.05$). There was a significant decrease of complication rate in the study group (one case of skin dehiscence) in comparison to the control group (four cases of skin dehiscence, three cases of delayed rehabilitation with prolonged stay, one case of symptomatic DVT, and one case of fracture after a fall) ($p = 0.02$).

Discussion

Few papers have been published about SRT. The results are controversial for carpal tunnel syndrome. Pereira et al. [17] reported no clinically significant advantage in a retrospective comparative study. However, Drosos et al. [13], in a prospective randomized study, observed a significant decrease in pain evaluation, suggesting less soft tissue damage. Only one evaluation during TKA has been reported [14]. Patients with SRT had a smaller decrease in haemoglobin on post-operative days one and three, and the amount of blood collected from drains at 24 h was significantly lower.

The primary hypothesis of the present study was not confirmed: the decrease in CBL observed in the study group was not statistically significant. This statement was confirmed by the absence of significant difference in the haemoglobin drop and the need for allogeneic transfusion between both groups. The theoretical positive impact on blood loss due to the SRT was not confirmed. The difference with a previous study [14] is probably due to a lack of power of the present study with fewer patients included (72 versus 311), as the absolute figures were similar for blood loss and haemoglobin drop. The

decreased need for allogeneic transfusion was felt to be clinically relevant. Furthermore, the operating surgeon had the subjective feeling that the operative field, and especially the osteotomized bone areas were drier in the study group than in the control group; but this statement could not be documented. The SRT cannot currently be considered as a blood preserving technique, and alternate techniques should be used, such as pre-operative haemoglobin optimization, femoral canal obturation, limited incision and release, peri- and intra-articular use of saline with adrenalin, tourniquet release after skin closure, and tranexamic acid [18].

Some significant differences were still observed.

The decrease in operating time was nine minutes in the study group. This might be due:

- To a less frequent need for haemostasis during surgery, in correlation with the subjective feeling of drier operative field;
- To a faster drying of the bone areas before cementing: pulsed lavage was frequently considered unnecessary by the operating surgeon.

The rate of complication was significantly decreased in the study group. Especially, the occurrence of skin necrosis was dramatically lower. This might be due to a decreased pressure trauma by the SRT. The smaller area of compression decreases the amount of soft tissue deformation under the ring in comparison to the cuff. It has been demonstrated that the seric enzymes elevation was lower in an experimental setting on rabbits [19]. The significant decrease in tourniquet time may be theoretically favorable to decrease the risk of tourniquet induced complications [11]. Furthermore, an electromyographic study showed that wider cuffs resulted in more severe changes in the nerve [20]: the SRT with its narrower compression may be beneficial.

An earlier discharge was also observed in the study group, but the detailed analysis showed that this change was clearly correlated to the treatment of complications.

No cost analysis was performed during this study. However, one can postulate that the extra-cost of the SRT (50€ in France), might be compensated:

- by a decreased operating time. It has been estimated recently that one minute operating time in France has a cost of 10.8 € [21];
- by a decreased need for allogeneic transfusion: one blood unit cost in France was about 180 € in 2015;
- by an earlier discharge: hospital charge for a TKA in France was about 5000 € in 2015 whatever the length of stay.

However, this medico-economic evaluation should be performed in a separate study to provide reliable results.

The present study has several limitations. Its retrospective design and the absence of randomization may induce uncontrolled biases. However, the comparability of both groups was controlled retrospectively, and no change in the operating technique or post-operative care occurred during the whole study. The study was powered to analyze the impact of the SRT on calculated blood loss; the significant differences observed in the secondary criteria must be considered with caution, and a further study is mandatory to confirm these differences. The potential benefit of using a sterile tourniquet instead of an off the shelf one for bacterial contamination [22] was not addressed. Finally, no actual cost analysis was performed, and the cost-effectiveness ratio could not be retrieved from the collected data.

However, the present study has some strength. This is the first evaluation of the SRT in TKA. Patient inclusion was consecutive, and no patient was lost of follow-up. No data in the retrospective control group was missing, and data collection in the study group was prospective. Sample size was calculated to be able to detect a clinically significant difference in CBL.

The CBL and the need for allogeneic transfusion were not significantly decreased by the use of SRT and cannot be considered as an advantage of this device. However, the significant decrease in operating time and the significant decrease in complication rate warrants further investigation. If these results are confirmed, the cost-effectiveness of the SRT might be positive.

Compliance with ethical standards

Conflict of Interest JYJ receives royalties from B-Braun Aesculap and is a paid consultant for B-Braun Aesculap, FH Orthopedics, Exactech. DB has nothing to disclose. No conflict interferes with the present paper.

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