Original Article

Silicone ring tourniquet versus pneumatic cuff tourniquet in total knee arthroplasty surgery: A randomised comparative study

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ABSTRACT

Introduction: The aim of the present study was to compare a silicone ring tourniquet (SRT) and a classic pneumatic cuff tourniquet (PT) in patients undergoing total knee replacement. We have compared the impact on the glycolytic activity caused by the ischaemia applied to the limb during the surgery.

Material and methods: 140 patients that underwent total knee arthroplasty (TKA) were randomised in two groups. Serum lactate determination was made by reactive strips of enzymatic-amperometric detection, 5 min before tourniquet application and 5 min after tourniquet removal.

Results: The mean tourniquet time was similar for both groups ($p = 0.13$). Postoperative serum lactate levels were higher with statistical significance than the preoperative levels and with a positive Pearson's correlation in the overall cases. The postoperative serum lactate levels were higher in the PT group (4.097 ± 2.248 mmol/L) than the SRT group (3.499 ± 1.566 mmol/L). There was no significant difference ($p = 0.07$) to be able to affirm that there was a difference of the anaerobic metabolism according to the tourniquet system used.

Discussion: Ischaemia applied to the lower extremity during knee replacement surgery can produce tissue injury. Serum lactate determination allows comparison of the ischaemic changes during TKA surgery caused by two different tourniquet systems.

Conclusions: SRT may be not disadvantageous compared to the classic PT from the impact on the glycolytic activity caused by the ischaemia.

Level of evidence II.

1. Introduction

Currently, pneumatic tourniquet has been widely used in orthopaedic surgery due to its multiple advantages, but remains controversial during total knee arthroplasty (TKA).^{1,2} Documented advantages of the use of tourniquet are a bloodless operative field, less intra-operative blood loss, and a better cement penetration.^{3,4} However, the use of pneumatic tourniquet may be also associated with potential complications, such as more postoperative blood loss, a greater occurrence of venous thrombosis, neuromuscular or cutaneous damage, and delayed rehabilitation. Tourniquet time over 120 min increases the risk of complications after knee arthroplasty surgery and special attention is advocated to reduce the tourniquet time,^{5,6} although there is no sufficient evidence to absolutely contraindicate prolonging the ischaemia time until 3 h.

Tolerance to ischaemia is variable, depending on the different

tissues. Different critical ischaemia times (maximum ischaemia time at ambient temperature that each tissue can tolerate, remaining viable after reperfusion) have been established. In the extremities, the muscular tissue is the most sensitive and presents a critical ischaemia time of 4 h. Other tissues present longer critical ischaemia times, for example the peripheral nerve (8 h), fat (13 h), skin (24 h) or the bone tissue (4 days).⁷ On the other hand, satisfactory outcomes have been observed after TKA implanted without tourniquet.⁸

Use of a silicone ring tourniquet (SRT) was introduced into clinical practice as an alternative to the standard pneumatic tourniquet.⁹ This novel device (marketed as the S-MART® or HemaClear®, OHK Medical Devices, Haifa, Israel) consists of a silicone ring wrapped within an elastic sleeve (stockinet) and two straps attached to pull handles, and has been designed for exsanguination and occlusion of the blood flow to the limb. The entire device is sterile and comes in different sizes. There are three tension models for the medium and large sizes (systolic blood

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pressure ≤ 130 mmHg < 160 mmHg and < 190 mmHg), and the appropriate model is selected for each patient according to the systolic blood pressure measured in the operating room before the placement of the device. 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. This device has been compared to the pneumatic tourniquet in healthy volunteers and in clinical studies of patients that underwent upper extremity operations.^{10, 11} This device has the advantage of being applied in sterile conditions and being able to be located at a greater distance from the surgical field than conventional tourniquets.

The aim of our study was to compare the SRT and the conventional PT in patients undergoing total knee replacement. We have compared the impact on the glycolytic activity caused by the ischaemia applied to the limb during the surgery.

2. Material and methods

The study was monocentric and prospective. The study group involved 140 patients operated between January 2013 and June 2015 that underwent TKA. Patients were randomly assigned using a random number online generator. Our study followed the ethical standards of the World Medical Association Declaration of Helsinki, as revised in 2013, and was accepted by the institutional ethical committee. All patients gave their informed consent for the study.

2.1. Patient population

There were 110 women (78.6%) and 30 men (21.4%), with a mean age of 74 years (± 6) and a mean BMI of 32.1 kg/m^2 (± 4.2). According to the ASA physical status classification system, updated in 2014 by the American Society of Anaesthesiologists, 4 patients (2.9%) have been considered by the Anaesthesiology and Reanimation Service of our Centre, ASA I, 109 patients (77.8%) ASA II and 27 patients (19.3%) ASA III. Additional demographic information is presented in Table 1.

Patients were randomised in two groups (a standard PT was used in 70 patients and a SRT in the other 70). Inclusion criterion was implantation of a TKA for knee osteoarthritis with intraoperative use of tourniquet. Exclusion criteria included the presence of a contraindication to the use of tourniquet, severe hypertension, recent traumatic history, rheumatoid arthritis, diabetes, other conditions that could produce hypoxia of the tissues, acid-base imbalances or disorders or increased lactate production, patients undergoing anaesthesia other than spinal anaesthesia, prior knee surgery and bilateral TKA procedures in one time.

Table 1

Patients characteristics in the two study groups. F: female, M: male, BMI: Body Mass Index, ASA: American Society of Anaesthesiologists. (ASA I - normal healthy patient, ASA II - patient with mild systemic disease and ASA III - patient with severe systemic disease). Quantitative variables were expressed as the mean $\pm$ standard deviation, while qualitative variables were expressed as frequencies (and percentages).

	Standard Pneumatic Tourniquet	Silicone Ring Tourniquet
Gender	53 F (75.7%) - 17 M (24.3%)	57 F (81.4%) - 13 M (18.6%)
Age (years)	73.6 ± 5.9	74.4 ± 6.6
BMI (kg/m^2)	32.4 ± 4.4	31.7 ± 3.9
ASA Classification	ASA I 1 (1.4%) ASA II 55 (78.6%) ASA III 14 (20%)	ASA I 3 (4.3%) ASA II 54 (77.1%) ASA III 13 (18.6%)

2.2. Intervention

In all the cases, the TKA surgery was performed using a CT-based patient-specific cutting block technique (MyKnee®, Medacta International S.A., Castel San Pietro, Switzerland) with the same type of cemented fixed bearing knee prosthesis (GMK®, Medacta International S.A., Castel San Pietro, Switzerland). All patients were operated by the same knee surgery staff, integrated by two senior surgeons.

An inferior limb tourniquet was applied in all the cases. A standard PT was used in 70 patients. We have employed the A.T.S. 3000 (Automatic Tourniquet System by Zimmer) with a standard 76-by-10-centimetre cuff and a standard pressure of 350 mmHg. The standard PT was applied by the operating nurse around the upper thigh before draping. Exsanguination was performed by the surgical team employing a sterile Esmarch elastic bandage and the tourniquet was inflated just prior to skin incision. The tourniquet was deflated after completely dressing application. An SRT, the S-MART™ or HemaClear® system (OHK Medical Devices, Haifa, Israel) was used in the other 70 patients. In all the cases, size L or XL was used according to the circumference of the thigh of the limb to be operated (with a pressure provided by the manufacturer of 286 ± 54 mmHg for size L and 321 ± 21 mmHg for size XL). The SRT was applied by the operating team after draping, just prior to skin incision. The ring was sectioned after completely dressing application. All patients followed the same regimen of preoperative, intraoperative and postoperative drugs.

Serum lactate determination was made by reactive strips of enzymatic-amperometric detection, 5 min before tourniquet application and 5 min after tourniquet removal. The Lactate Scout + analyser (SensLab GmbH, Leipzig, Germany) was used. The measuring range of this device is estimated from 0.5 to 25.0 mmol/L and it requires a volume of blood 0.2 microlitres for its analytical process. According to the manufacturer's specifications, the Lactate Scout + has a coefficient of variation of $\pm 3\%$ (minimal standard deviation: ± 0.2 mmol/L) within the haematocrit range of 35–50% and $\pm 4\%$ (minimal standard deviation: ± 0.3 mmol/L) within the extended haematocrit range. Similar results have been published by independent authors.¹²

2.3. Statistical plan

Statistical analysis of the data was performed using the Statistical Package for the Social Sciences (SPSS), version 24 for Windows (SPSS, Inc., Chicago, IL, USA). All quantitative variables were expressed as the mean $\pm$ standard deviation, while qualitative variables were expressed as frequencies (and percentages). The normality of the quantitative variables was tested with the Kolmogorov-Smirnov test. The Student's *t*-test for paired and independent samples was used. Bivariate correlations have been used with the Pearson's correlation coefficient as a measure of linear association between two variables. Statistical significance was considered for *p* values of less than 0.05.

3. Results

There was no statistical significant difference in patient demographics between both study groups: mean age for the PT group 73.6 ± 5.9 years and for the SRT group 74.4 ± 6.6 years (*p* 0.47). Mean BMI for the PT group $32.4 \pm 4.4 \text{ kg/m}^2$ and for the SRT group $31.7 \pm 3.9 \text{ kg/m}^2$ (*p* 0.32). The mean tourniquet time was similar for both groups: PT group 98.16 ± 16.5 min and SRT group 102.5 ± 17.3 min (*p* 0.13). Also the surgical time (skin-to-skin time) was similar for both groups: PT group 79.64 ± 12.2 min and SRT group 77.12 ± 10.6 min. Postoperative serum lactate levels (3.798 ± 1.954 mmol/L) were higher with statistical significance (*p* 0.009) than the preoperative levels (2.316 ± 1.043 mmol/L) and with a weak positive linear correlation in the overall cases (Pearson's correlation coefficient 0.220, *p*-value 0.01). We also observed pre- and postoperative weak positive linear correlation in the PT group

(preoperative 2.254 ± 1.177 mmol/L and postoperative 4.097 ± 2.248 mmol/L, Pearson's correlation coefficient 0.246, *p*-value 0.05), but not in the SRT group (preoperative 2.377 ± 0.894 mmol/L and postoperative 3.499 ± 1.566 mmol/L, Pearson's correlation coefficient 0.209). The postoperative serum lactate levels were higher in the PT group (4.097 ± 2.248 mmol/L) than the SRT group (3.499 ± 1.566 mmol/L). There was no significant difference (*p*-value 0.07) to be able to affirm that there was a difference of the anaerobic metabolism according to the tourniquet system used.

4. Discussion

Ischaemia applied to the lower extremity during knee replacement surgery can produce tissue injury through a triple mechanism: mechanical injury due to the compression exerted by the tourniquet applied to maintain the ischaemia, anoxia injury and the inflammatory and oxidative lesion of the tissues after the reperfusion.^{5,7} During ischaemia, the cell's energy stores are depleted in an attempt to maintain homeostatic functions. Long periods of ischaemia lead to the decrease in the capacity to regenerate adenosine triphosphate through the aerobic systems. As a consequence, skeletal muscle cells must alter from oxidative phosphorylation to anaerobic glycolysis for energy production, causing a rise in lactic acid production. In our study we have used serum lactate levels as a marker of the increase of anaerobic glycolysis secondary to ischaemia. Jawhar et al¹³ found in a randomised, controlled, monocentric trial of muscle biopsies obtained from vastus medialis immediately after performing the surgical approach and exactly 60 min later, that tourniquet application did not affect the free/conjugated ubiquitin as well as total ubiquitin-protein ligase activity significantly. The proteasome-dependent peptidase activities were significantly upregulated during tourniquet application, suggesting an increase in protein degradation, which in turn might explain the skeletal muscle atrophy occurring after TKA.

Ejaz et al¹⁴ observed, using microdialysis, that performing TKA with tourniquet is associated with increased ischaemia. This affects all metabolites (including the lactate levels) but the changes are normalised after 5 h. Previously, Östman et al¹⁵ evaluated microdialysis as an *in vivo* method to characterise the time-course and relative kinetics of pyruvate, glucose, lactate, glycerol, hypoxanthine, uric acid, and urea, in skeletal muscles, exposed to prolonged ischaemia and 2 h of reperfusion, in patients having elective arthroscopic assisted anterior cruciate ligament reconstruction. To our knowledge, our study is the first to assess, without an invasive technique, the ischaemic changes during TKA surgery caused by two different tourniquet systems in a randomised setup.

Only few papers have been published about SRT. Drosos et al⁹ reported the use of SRT in 362 elective operations and 174 trauma cases. Pereira et al¹⁶ reported no clinically significant advantage in a retrospective comparison of carpal tunnel syndrome cases operated using a SRT versus a PT. However, Drosos et al¹¹ in a prospective randomised study of carpal tunnel syndrome cases, observed a significant decrease in pain evaluation, suggesting less soft tissue damage. To our knowledge, previous to our study, only two evaluations of the SRT during TKA have been reported. Brin et al¹⁷ observed that patients operated with SRT had a smaller decrease in haemoglobin on postoperative days one and three, and the amount of blood collected from drains at 24 h was significantly lower, in comparison with the patients operated with conventional pneumatic tourniquet. In the opposite way, Jenny et al¹⁸ reported that the calculated blood loss and the need for allogeneic transfusion were not significantly decreased by the use of SRT and it cannot be considered as an advantage of this device. These authors postulate however, that a significant decrease in operating time and a significant decrease in complication rate warrants further investigation.

In the present study, the mean tourniquet time was similar for both groups. In our study, we found no statistical significant difference in postoperative serum lactate levels between the patients operated with

standard PT and the patients operated with SRT, although postoperative serum lactate levels were discreetly higher in the PT group than the SRT group. We cannot affirm that there was a difference of the anaerobic metabolism according to the tourniquet system used. Therefore, it seems that SRT may be not disadvantageous compared to the classic pneumatic tourniquet from the impact on the glycolytic activity caused by the ischaemia.

The present study has several limitations. We do not have a serum lactate baseline determination of the patients, but the aim of our experience was not to demonstrate an increase in lactate values compared to basal lactate, but to target the increase from the moment just before the application of ischemia to the moment just after release. It should be noted that the patients in our study presented abnormally high values of serum lactate, also preoperatively. We think this elevation just before the intervention may be due to the metabolic alteration as a response to the patient's stress before the operation. In addition, there is no consensus regarding the validity of capillary lactate measurements using enzymatic-amperometric reactive strips. Bouzat et al¹⁹ conducted a prospective observational study in one level I trauma centre and tested the agreement between capillary lactate and blood lactate concentrations using Bland and Altman analysis. Although a significant association between point of care lactate concentration and transfusion requirements was found, the diagnostic performance of capillary lactate measurements was poor. Due to large disagreement between capillary lactate and blood lactate, the authors think that capillary lactate cannot be considered in the clinical setting. In the opposite direction, Purcarea et al²⁰ analysed in a prospective, observational, monocentric study point of care measurements of baseline capillary and venous lactate levels and compared them with the blood samples that were analysed in the central laboratory. They conclude that capillary lactate levels could be a more sensitive method than the classical lactate measurement for predicting the outcomes of acute conditions, especially infections. Recently, Baig et al²¹ examined the accuracy and timesaving effect of a handheld point of care lactate device for the measurement of fingertip and whole blood lactate and compared it with the reference laboratory blood testing in a sample of adult emergency department patients and conclude that fingertip point of care lactate measurement is an accurate method to determine lactate levels in septic adult emergency department patients. On the other hand, no portable device is absolutely accurate for the analysis of serum lactate levels, but it has been estimated that such devices are reliable enough for the determination of serum lactate levels.^{12,22}

5. Conclusion

In this randomised trial, the SRT may be not disadvantageous compared to the classic PT from the point of view of the glycolytic activity caused by the ischaemia. The results of this evaluation have led the authors towards a systematic use of the silicone ring tourniquet in primary TKA, since this device offers the advantage of being applied in sterile conditions and being able to be located at a greater distance from the surgical field than conventional tourniquets. Further studies are required to continue explorations in this direction and/or strengthen our conclusions.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Conflict of interest

None of the other authors have any conflict of interest or any financial or non-financial competing interests to declare with regard to this paper. No benefits or funds were received in support of the study.

Authors' contributions

VL made substantial contributions to the conception and the design of the work, to the analysis and interpretation of data for the work, performed the statistical analysis and drafted the manuscript. AL participated in the design of the study, helped to draft the manuscript and revised it critically for important intellectual content. CH participated in the design of the study, revised critically the manuscript and made substantial contributions to the analysis and interpretation of data for the work. ML conceived of the study and participated in its design and coordination, helped to draft the manuscript, revised critically the manuscript and made substantial contributions to the analysis and interpretation of data and performed the statistical analysis. All authors read and approved the final manuscript and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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VL, AL and CH are specialists in Orthopaedic Surgery and Musculoskeletal Traumatology. VL and AL constitute the staff of the Knee Surgery Service of the Department of Orthopaedic Surgery and Traumatology. ML is specialist in Computer Engineering in the field of information and communications technology.

Ethical guidelines

The Institutional Review Board of Hospital General Universitario José María Morales Meseguer (of which the Hospital de la Vega Lorenzo Guirao is dependent) approved the study.

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