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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 where 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 ± 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 ± 3% (minimal standard deviation: ± 0.2 mmol/L) within the haematocrit range of 35–50% and ± 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 ± 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 ± 4.4 kg/m^2 and for the SRT group 31.7 ± 3.9 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