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Comparative analysis of pain in patients who underwent total knee replacement regarding the tourniquet pressure ☆

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ABSTRACT

Objectives: To evaluate through the visual analog scale (VAS) the pain in patients undergoing total knee replacement (TKR) with different pressures of the pneumatic tourniquet.

Methods: An observational, randomized, descriptive study on an analytical basis, with 60 patients who underwent TKR, divided into two groups, which were matched: a group where TKR was performed with tourniquet pressures of 350 mmHg (standard) and the other with systolic blood pressure plus 100 mmHg (P + 100). These patients had their pain assessed by VAS at 48 h, and at the 5th and 15th days after procedure. Secondarily, the following were also measured: range of motion (ROM), complications, and blood drainage volume in each group; the data were subjected to statistical analysis.

Results: After data analysis, there was no statistical difference regarding the incidence of complications ($p = 0.612$), ROM ($p = 0.202$), bleeding after 24 and 48 h ($p = 0.432$ and $p = 0.254$) or in relation to VAS. No correlation was observed between time of ischemia compared to VAS and bleeding.

Conclusions: The use of the pneumatic tourniquet pressure at 350 mmHg or systolic blood pressure plus 100 mmHg did not influence the pain, blood loss, ROM, and complications. Therefore the pressures at these levels are safe and do not change the surgery outcomes; the time of ischemia must be closely observed to avoid major complications.

Análise comparativa da dor em pacientes submetidos à artroplastia total do joelho em relação aos níveis pressóricos do torniquete pneumático

R E S U M O

Palavras-chave:
Artroplastia do joelho
Medição da dor
Torniquetes

Objetivos: Avaliar, por meio da escala visual analógica (EVA), a dor em pacientes submetidos à artroplastia total do joelho (ATJ) com diferentes pressões do torniquete pneumático.

Métodos: Foi feito um estudo observacional, descritivo, de caráter analítico, prospectivo, randomizado, no qual 60 pacientes foram submetidos à ATJ, divididos em dois grupos, os quais foram comparados entre si: um grupo no qual a ATJ foi feita com pressão do torniquete de 350 mmHg (Padrão) e outro com 100 mmHg acima da pressão arterial sistólica (P + 100). Esses pacientes tiveram sua dor aferida pela EVA após 48 horas, no quinto e no 15° dias após o procedimento cirúrgico. Secundariamente, foram medidos também a amplitude de movimento (ADM), o sangramento via dreno suctor e as complicações em cada um dos grupos estudados; os dados foram submetidos à análise estatística.

Resultados: Após a análise dos dados, não foi constatada diferença estatisticamente significante em nível de 5% de significância da pressão em relação à incidência de complicações (p = 0,612), ADM (p = 0,202), ao sangramento após 24 e 48 h (p = 0,432 e p = 0,254) e à EVA. Também não foi constatada correlação do tempo de isquemia em relação a EVA e ao sangramento.

Conclusões: As pressões usadas do torniquete pneumático, 350 mmHg ou pressão arterial sistólica + 100 mmHg, não tiveram influência sobre a dor, a perda sanguínea, a amplitude de movimento e as complicações, são pressões seguras que não alteram o resultado final, desde que respeitados o tempo da isquemia e individualizados os casos.

Introduction

The role of the pneumatic tourniquet is still controversial. However, it is widely used by orthopedic surgeons. It is believed that its use is effective in reducing intraoperative blood loss and creating a bloodless field, which would theoretically facilitate surgery and the cementation technique. The use of the tourniquet is almost indispensable in orthopedic practice.

The modern pneumatic tourniquet has its roots in Roman times (199 BC to 500 AD), when bronze and leather devices (Fig. 1) were used to control bleeding in limb amputations during battles. The term tourniquet was coined by Jean Louis Petit, being a derivation of the French verb *tourner* (rotate). With the advent of general anesthesia, in 1864 Joseph Lister was the first to use a tourniquet to create a bloodless surgical field. In 1904, Harvey Cushing introduced the first inflatable (pneumatic) cuff, thus allowing the pressure of the tourniquet to be monitored and controlled manually.[1]

A disadvantage of the tourniquet is the morbidity that comes from its use, especially in neuromuscular injuries secondary to neural and muscle tissues ischemia and to nerve-compressing direct injury. Furthermore, the hemodynamic changes that accompany inflation and deflation may depress cardiac function in the perioperative period.[2] The duration and pressure for safe tourniquet use remain controversial, and no strict guidelines have been established. A safe limit of 1–3 h has been described.[3] The use of the tourniquet over 2 h and pressures greater than 350 mmHg on the lower limbs

Fig. 1 – Tourniquet used by the Romans. The tourniquet is made of bronze and is covered with leather to help protect the thigh of the patient and reduce pain.
Source: **Printed with permission of the Science and Society Picture Library: http://www.scienceandsociety.co.uk/.**

and greater than 250 mmHg on the upper limbs increase the risk of compression and neuropraxia.[4]

The most common way to assess pain is through the visual analog scale (VAS), an instrument that attempts to measure a characteristic or attitude that is believed to vary over a continuum of values and that cannot be directly measured easily. For example, the amount of pain the patient feels may range from no pain (0) to extreme pain (10).[5]

The aim of this study was to assess, through VAS, the pain in patients undergoing TKA. Two groups of patients were compared: in the first group, TKA was performed with
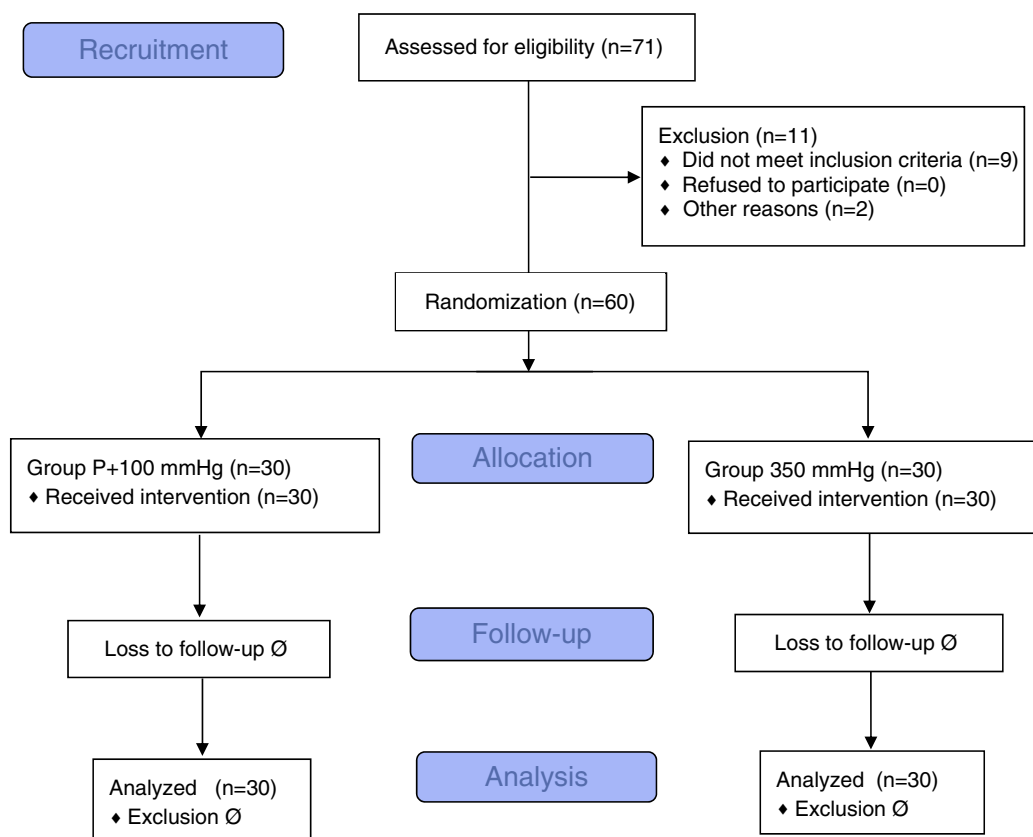
Fig. 2 – CONSORT flowchart.

tourniquet pressures of 350 mmHg, and in the other group, with 100 mmHg above systolic blood pressure (SBP). Secondarily, blood loss, surgical wound complications, and the range of motion (ROM) of the operated knee were assessed. Thereafter, the safer and more advantageous method for the patients was determined.

Materials and methods

This was a randomized clinical study; the main investigator was blinded to the pressure that would be used in the tourniquet. This study was conducted from September 2014 to September 2015, including 60 patients undergoing TKA. The study followed the rules set forth by the Consolidated Standards of Testing Reports (CONSORT, which was developed by an international group of clinical, statisticians, epidemiologists, and biomedical journals publishers in order to improve the recording of randomized clinical trials and thus allow readers to understand the study design, behavior analysis, and interpretation through full transparency) (Fig. 2).[6,7]

A protocol was created for the study. Patients who met eligibility criteria for TKA in this study were randomly assigned, regardless of age, sex, and deformity, into two groups, through simple drawing by one of the authors, who did not participate in surgery. In the first group, Standard, tourniquet pressure on the thigh root was 350 mmHg; in the second group, P + 100, utilizing tourniquet pressures 100 mmHg above

the last SBP measured before entering the operating room (process done in the recovery room). The groups were randomized as follows: 60 Post-it®(3 M do Brasil, Sumaré, SP) sheets, 101 mm × 101 mm, of the same color, were used. On 30 of them, the word "Standard" was written; on the other 30, "P + 100." The sheets were twice folded and placed into a cloth bag. Then, sheets were drawn as the patients were operated; if the surgery was suspended for any reason, sheets would be returned to the bag. Thus, the Standard group consisted of 30 patients, seven males and 23 females, mean 65.4 years, standard deviation (SD) ± 8.6 years. In the group P + 100, 30 patients were included, eight male and 22 female, with a mean age of 66 years (SD ± 7 years). Varus deformity was present in 83.3% of cases; valgus deformity was observed in 16.7% of all patients.

The study included patients regularly registered in the institution where the study was performed, who met the classical indication for TKR, namely: medial or lateral impingement with obliteration of the joint space; varus femorotibial alignment greater than 15°; valgus femorotibial alignment greater than 10°; tibiofemoral subluxation in the frontal plane greater than 10 mm; anteriorization of the tibia relative to the femur in the profile X-ray; severe impairment of two of the three joint compartments of the knee (medial tibiofemoral, lateral tibiofemoral, or patellofemoral),[8] and failed conservative treatment for at least three months when these criteria were not met. Although the consensus states that the preferable age for this surgery is above 60 years,

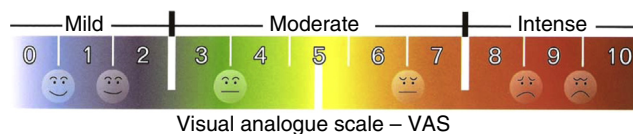**Table 1 – Bruner's ten rules for the safe use of the tourniquet (as recommended by Kutty and McElwain).[11]**

Application	Only in healthy limbs, or with caution in involved limbs.
Size of the tourniquet	Arm 10 cm; thigh 15 cm or larger in larger thighs.
Application site	Proximal arm; proximal thigh.
Padding	At least two layers of orthopedic cotton.
Skin preparation	Avoid soaking the cotton (the tourniquet should be occluded).
Pressure	50–100 mmHg above systolic for the arm; double systolic for the thigh; or 200–250 mmHg on the arm; 250–350 mmHg on the thigh.
Time (duration)	Maximum 3 h (recovers in 5–7 days); generally, do not exceed 3 h.
Temperature	Avoid heating; cold if feasible; the surgical field should be kept moist.
Documentation	Duration and pressure.
Calibration	At least weekly, with a mercury manometer.
Maintenance	Quarterly.

Fig. 3 – Visual analog scale (VAS).

age was not taken into account, but rather the real damage to the knee joint: patients had to have a diagnosis of moderate or more severe arthrosis (Ählback modified by Keys ≥ III).[9,10]

Exclusion criteria comprised patients with decompensated diabetes mellitus (fasting blood glucose > 140 mg/dL), uncontrolled hypertension (SBP > 200 mmHg), peripheral vascular disease, previous thromboembolism, active neoplasia, infection, rheumatoid arthritis, obese with a body mass index greater than 35 kg/m^2, or those with a high surgical risk (American Society of Anesthesiologists [ASA] score > III); those who evolved with severe complications; and those who refused to sign or did not understand the informed consent form.

For the application of tourniquet, Bruner's ten rules for the safe use of the tourniquet (a recommended by Kutty and McElwain), shown in Table 1, were followed.[11] The tourniquet used in all patients was a 12.5-cm wide Scandmed Electronic Tourniquet 600-20® (Scandmed AB, Stockholm, Sweden).

Patients underwent spinal anesthesia according to the protocols of the anesthesiology service of the institution (anesthesiologists were blinded to the purpose of the study). After anesthesia, the pneumatic tourniquet was applied on the thigh root of the limb to be operated over a layer of orthopedic cotton, in order to protect the skin. Surgical technique used was the standard for TKR, with joint access via the classic trans-quadriceps approach and patellar eversion. The routine in the service is the use of intramedullary guides for femoral cuts and extramedullary guides for tibial cuts. The decision of whether or not to spare the posterior cruciate ligament (PCL) was made in accordance with the intraoperative findings, deformities, and soft tissue balance. Patellar resurfacing after local denervation and synovectomy is a routine practice in this service in order to avoid clunk syndrome; the cases in which the patella was not resurfaced were due to the thickness (<18 mm), but these were eburnated, neurotized, and a lateral facetectomy was performed. The prosthesis used was the Modular III® (MDT, Rio Claro, SP, Brazil), either PCL-sparing or not. Portovac suction drains of 3.2-mm diameter were used, allocated intraarticularly and deeply into the subcutaneous

tissue; after the sutures, an inguinal-malleolar compressive occlusive Robert Jones dressing was made. If surgery lasted over two hours, the tourniquet was deflated; subsequently, hemostasis was assessed, and a process similar to the previous was performed (drains and dressings). Mean time of ischemia was 118.5 min in group P + 100 mmHg and 110 min in the Standard group. Surgeries were always performed by the principal investigator or under his direct assistance.

At 24 and 48 h postoperatively, the outputs of the suction drains were assessed; dressings were changed and drains were removed 48 h after the procedure by the author who did not draw the groups. Subsequently, pain was assessed using the VAS (Fig. 3) with no joint manipulation; passive ROM and the surgical wound were assessed. According to their clinical conditions, patients received the same analgesia protocol (tenoxicam 20 mg every 12 h, tramadol 50 mg IV every 8 h, dipyrone 1 g IV every 6 h), and rehabilitation. On the fifth day, patients were assessed again for pain, ROM, and surgical wound appearance; they were discharged as tolerated and referred to the physiotherapy service. On the 15th day, these standards were re-assessed in an outpatient consultation and recorded in the protocol. All patients received thromboprophylaxis with dabigatran at a dose adjusted to age and renal function for 15 days (220 mg or 15 mg/day). All patients received prophylaxis for surgical site infection with cefazolin sodium at a dose of 1 g every 8 h for five days.

The data were presented in graphs and tables, in which the simple and relative absolute frequencies were calculated for categorical data. In the analysis of quantitative data, the mean, standard deviation (SD), and 95% confidence intervals (95% CI) were calculated. However, when the assumption of data normality was rejected by the Shapiro–Wilk test at a significance level of 5% ($p < 0.05$), it was decided to calculate the median and quartiles (Qi). When comparing the means for the parametric data, Student's t-test was used. In the median analysis, the nonparametric Mann–Whitney test was used. The significance level was set at 5%.

Epi-Info software, version 7.4 for Windows, was used for statistical analysis.

All patients read and signed the informed consent form; the study was submitted to the Research Ethics Committee (REC) of the institution, with a Certificate of Presentation for Ethical Assessment (CAAE): 36658014.2.0000.0007, and received REC opinion No. 869.472.

Results

Of the 60 patients operated, 45 were female and 25 male. The right side was operated in 53.3% of cases; the left side, 46.7%. There was a predominance of varus deformity, with 50 patients; only ten patients had valgus deformity. There was one complication on group P + 100 mmHg and three in the

Table 2 – Summary of patient assessments.

| Variables ($n = 60$) | Tourniquet pressure (mmHg) | | | | Total | p |
| | P + 100 | | 350 | | | |
	f_i	%	f_i	%		
Sex						0.766[a]
Female	22	48.9	23	51.1	45	
Male	8	53.3	7	46.7	15	
Age (years)						0.794[b]
Mean ± SD	66.0 ± 7.0		65.4 ± 8.6			
Complications						0.612[c]
Yes	1	3.3	3	10.0	4	
No	29	96.7	27	90	56	
VAS 2nd POD						0.625[d]
Median	2.0		2.0			
Q_1–Q_3	0.5–3.0		0.5–4.0			
VAS 5th POD						0.571[d]
Median	2.0		1.0			
Q_1–Q_3	1.5–3.0		0.5–3.0			
VAS 15th POD						0.195[d]
Median	2.0		3.0			
Q_1–Q_3	1.0–3.0		1.5–5.0			
Bleeding 24 h						0.432[d]
Median	525.0		590.0			
Q_1–Q_3	380–760		450–900			
Bleeding 48 h						0.254[d]
Median	170.0		120.0			
Q_1–Q_3	105–240		55–180			

f_i, simple absolute frequency; SD: standard deviation; Q_i, quartile; VAS, visual analog scale; TKA, total knee arthroplasty.

[a] Pearson's chi-squared test.
[b] Student's t-test.
[c] Fisher's exact test.
[d] Mann–Whitney test.

Standard group, with no statistically significant difference ($p = 0.612$). The VAS in the second, fifth, and 15th postoperative days (POD) also showed no statistically significant differences ($p = 0.625$; 0.571; 0.195; respectively). Bleeding through the suction drain at 24 and 48 h also showed no statistically significant differences in both groups, as calculated by the Mann–Whitney test (Table 2). The VAS and bleeding results are better represented in the box plots in Figs. 4 and 5, respectively. ROM was not significantly different in both groups (Table 3). No correlation was observed between ischemia time

and the following variables: VAS on the second, fifth, and 15th POD, and bleeding at 24 and 48 h (Table 4), showing no statistical significance.

Discussion

The history of a surgical specialty is largely written around the records of its technical advances. Compared with other paraphernalia in the modern surgical arsenal, the pneumatic

Table 3 – Distribution according to the median of flexion, extension, and ROM regarding tourniquet pressure in patients undergoing TKA.

| Variables ($n = 60$) | Tourniquet pressure | | | | | | |
| | P + 100 mmHg | | | 350 mmHg | | | |
	Q_1	Median	Q_3	Q_1	Median	Q_3	p[a]
Flexion pre-	100.0	110.0	120.0	100.0	110.0	120.0	0.375
Flexion post-	90.0	95.0	100.0	90.0	97.5	130.0	0.664
Extension pre-	0.0	2.5	10.0	0.0	0.0	10.0	0.980
Extension post-	0.0	0.0	0.0	0.0	5.0	10.0	**<0.001**
ROM pre-	95.0	107.5	120.0	90.0	100.0	120.0	0.398
ROM post	90.0	95.0	100.0	80.0	90.0	100.0	0.202

p-Value in bold italics indicates statistical difference of the medians at 5% significance level.
f_i, simple absolute frequency; Q_i, quartile; ROM, range of motion; TKA, total knee arthroplasty.

[a] Mann–Whitney test.
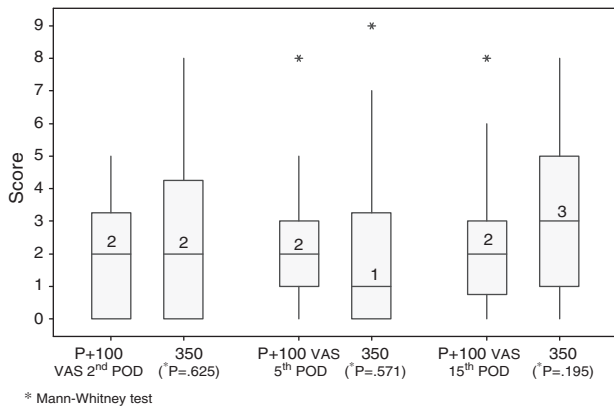
* Mann–Whitney test

Fig. 4 – Box plot of the median VAS in relation to tourniquet pressure in patients undergoing TKA. VAS, visual analog scale; TKA, total knee arthroplasty; POD, postoperative day.
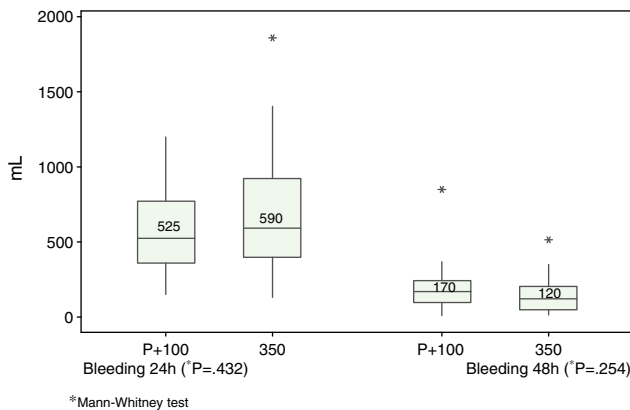

*Mann-Whitney test

Fig. 5 – Box plot of the median bleeding (24 and 48 h) in relation to tourniquet pressure in patients undergoing TKA. TKA, total knee arthroplasty.

tourniquet is a simple instrument. However, it has played an important role in improving the accuracy of orthopedic surgery. Despite being a relatively simple device, the tourniquet leads to many potential dangers and its application should be entrusted only to experienced professionals.[12]

In 1995, Abdel-Salam and Eyres[13] stated that the complications rate in TKAs without the use of a tourniquet was lower

Table 4 – Correlation of ischemia and VAS 2nd POD, VAS 5th POD, VAS 15th POD, and bleeding.

Variables (n = 60)	Ischemia time	
	R	p[a]
VAS 2nd POD	−0.18	0.174
VAS 5th POD	0.21	0.102
VAS 15th POD	0.13	0.318
Bleeding 24 h	−0.02	0.882
Bleeding 48 h	−0.08	0.558

R, correlation coefficient; VAS, visual analog scale; POD, postoperative day.

[a] t-Test for correlation.

than when surgery utilized ischemia, in which there was a significant reduction in postoperative pain and faster knee recovery. The non-use of a tourniquet in TKA showed no benefit, except a slightly faster recovery from postoperative pain.

When using a tourniquet in this surgery, surgeons should carefully consider its efficacy and safety. Inflating the tourniquet only during cementation or for a limited time might be an option. Further well-designed randomized controlled trials are needed to clarify the roles and compare the effects of different methods of tourniquet application in TKAs.[14]

Worland et al.[15] reached similar conclusions, but with a different method than that of the present study; those authors recommended the use of the tourniquet with a pressure of 100 mmHg above the systolic blood pressure for TKA, which was suitable for creating a bloodless surgical field and resulted in less post-operative pain, data that are supported by the present study.

In 2012, Tai et al.,[16] in a prospective, randomized, well-controlled study, concluded that the use of the tourniquet in TKA reduces surgical time and blood loss; it also prevents inflammation and excessive muscle damage.

The great current controversy is about whether or not to use the tourniquet. In a recent meta-analysis, Nikolaou et al.[17] concluded that the answer to this dilemma is still difficult, despite the extensive research on the subject. Clearly, several issues concerning the use of a tourniquet arise; they relate, for example, the best time to release the pressure and the optimal phases of the surgery for its inflation. In a meta-analysis, Zhang et al.[18] showed that the non-use of a tourniquet in TKA improved clinical outcomes regarding the incidence of complications and ROM in the immediate postoperative period. In the present study, there was no significant difference between groups regarding the actual blood loss. Therefore, the efficacy and safety of use of the tourniquet in TKA needs to be considered, and surgeons should use it prudently. However, the data assessed in the present study did not disclose differences regarding blood loss.

Complications have always been present with the use of tourniquets. Odinsson and Finsen[19] observed a complication rate similar to that of the 1970s. Castropil et al.[20] reported a case of femoral nerve injury in which the pressure of the tourniquet was within the indicated range, and it had not been re-inflated. This demonstrates that even when all the inflation parameters described as suitable for knee surgery are followed, there is still a risk for complications. Numerically, the group in which the pressure of the tourniquet was 350 mmHg presented more complications, but without statistical significance (p = 0.612).

Olivecrona et al.[21] used a technique called "occlusion pressure of the limb" and standard pressure, which may help surgeons to individualize the cuff pressures, often lower. They concluded that, even in the group of patients in which the "occlusion pressure of the limb" was used, which was generally lower, no reduction in postoperative pain or other results was observed. However, patients undergoing TKA with a tourniquet pressure ≤225 mmHg had a lower rate of surgical wound complications, such as delayed healing and infection, findings that were reproduced in the present study, as no differences were observed in the patterns of pain, bleeding, and complications between the groups.

Noordin et al.[1] and Sharma and Salhotra[4] gave an excellent explanation about the use of tourniquets, with future guidelines, and summarized that higher pressures on the tourniquet are associated with a higher associated risk of nerve damage. Ishii and Matsuda[22] recommended a pressure of 100 mmHg above systolic pressure, instead of the conventional 350 mmHg, in order to obtain a sufficiently bloodless surgical field and minimize potential complications, facts that were observed in the study, in which surgery was perfectly feasible with lower pressures and there was a general perception of faster recovery with no evidence of major bleeding.

Souza Leão et al.,[23] in a national publication, assessed only the blood loss with the release of the tourniquet after cementation or preparation of dressings, without taking into account the insufflation pressure. They concluded that there were no statistically significant differences regarding hematimetric levels and blood loss from the suction drain; when different cuff pressures were compared, there was no difference in blood loss, as demonstrated in the present study.

Wakankar et al.[24] concluded that the use of the tourniquet is safe and that the practice can be maintained. There was no significant difference in operative time, postoperative pain, need for analgesia, volume collected in the drains, postoperative edema, and incidence of wound complications or deep vein thrombosis; similar results in the evaluated parameters were observed in the present study. It is surgical skill that considerably reduces surgical time and consequently the tourniquet use; furthermore, lower complication rates are observed.

Unver et al.[25] showed that the application of the tourniquet with lower inflation pressure can minimize the complications of its use and that patients regain functional mobility faster. Their data was corroborated by Papalia et al.,[26] who indicated that the use of the tourniquet does not lead to a significant increase in the risk of major complications, but with no clinical difference in the medium-term results.

The VAS is a valid instrument for measuring pain at a specific point in time. However, pain in VAS is not linear, and receptivity can vary depending on the peculiarities of pain. Consequently, minimally important clinical differences either alter the scores in general or overestimate the true change.[27]

Limiting factors of the present study include the short patient follow-up after surgery, even to assess other complications such as deep vein thrombosis, which usually appears within 30 days, but the patients were no longer entered in the study protocol; and the absence of muscle strength tests, as assessing the real damage caused by the tourniquet, joint function, and the result of the surgery through specific scores for this purpose were not among the study objectives. Finally, it may be occasionally difficult to assess pain using the VAS, as patients may have difficulty understanding where to locate themselves in order to quantify their pain.

Conclusions

With the present data, no differences were observed in the groups studied regarding level of pain by VAS, the volume of bleeding through the suction drain, and knee ROM; it was also not possible to correlate these variables with the

ischemia time. The complication rate was numerically higher in the group in which the pressure of the pneumatic tourniquet was 350 mmHg, but without statistical significance. Thus, pressures of up to 350 mmHg in the tourniquet are safe; if the surgeon chooses to use lower pressures, these will not hinder the surgery nor generate any major bleeding. Pressures should be individualized for patients; complications are much more related to surgeon's experience than to the tourniquet pressures used, as long as the appropriate parameters are followed.

Conflicts of interest

The authors declare no conflicts of interest.

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