The timing of tourniquet release: its influence on blood loss and possible complications after total knee arthroplasty. A prospective multicenter study

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Purpose. We conducted a prospective multicenter study with alternate selection methodology in order to evaluate postoperative blood loss further to primary knee replacement at the time of tourniquet release, with or without hemostasis, as well as possible local and systemic complications.
Materials and methods. We studied 194 patients (194 knees) divided into two similar groups. Group I (Hemostasis - H) - the tourniquet was deflated intraoperatively after implantation of the metal components and hemostasis was achieved prior to wound closure. Group II (No Hemostasis - NH) - the tourniquet was released after the wound was closed and a compressive bandage applied.
Results. Mean bleeding was 721ml (30-1540) for group I and 625 ml (60-1540) for group II. No statistically significant differences were found (p = 0.3). No significant differences were found between the groups as regards general or local complications.
Conclusions. Postoperative blood loss is not related directly with the time of tourniquet release further to TKR. Our findings cast certain doubts on the efficacy of tourniquet release, which means that intraoperative hemostasis may not be necessary.

Key words: *intraoperative hemostasis, ischemia, tourniquet, total knee replacement, complications.*

Cuándo aflojar el manguito neumático de isquemia: su influencia sobre las pérdidas hemáticas y posibles complicaciones en la prótesis total de rodilla. Estudio prospectivo multicéntrico

Objetivo. Realizar un estudio prospectivo multicéntrico de selección alternante para valorar las pérdidas hemáticas postoperatorias de la prótesis total de rodilla en relación con el momento de soltar la isquemia, realizando o no hemostasia, y las posibles complicaciones locales y generales.
Material y método. Se analizan 194 pacientes (194 rodillas) distribuidos en dos grupos homogéneos:
1. Grupo I hemostasia (H): se libera el torniquete de isquemia después de la colocación de los implantes metálicos, realizando la hemostasia previa al cierre de la herida quirúrgica.
2. Grupo II no hemostasia (NH): se coloca la prótesis, se realiza el cierre de la herida quirúrgica, se coloca vendaje compresivo y en este momento se afloja el manguito neumático.
Resultados. El sangrado promedio total del grupo I (H) fue de 721cc. (30-2210) y el del grupo II (NH) fue de 625cc. (60-1540), no existiendo diferencias significativas entre ambos grupos (p = 0,3). No se encuentran tampoco diferencias significativas entre ambos grupos con respecto a las complicaciones locales o generales.
Conclusión. Las pérdidas hemáticas postoperatorias no se relacionan directamente con el momento de soltar la isquemia durante las prótesis totales de rodilla.

Palabras clave: *hemostasia intraoperatoria, isquemia, torniquete, prótesis total de rodilla, complicaciones.*

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Hemorrhage, tourniquet use and hemostasis in prosthetic knee surgery remain controversial topics. All of them have their pros and cons, with some authors fervently against them[1-4] and others defending their use almost systematically[5-8], given that not using them leads to greater blood loss and few postoperative advantages.

In exceptional situations, such as peripheral vascular disease, rheumatoid arthritis and some of its corticoid-dependent variants, previous thromboembolism, active tumoral pathology and multiple eschars on the leg, among the most usual ones, it could be indicated not to induce ischemia or use a tourniquet.

Nevertheless, in this regard there is no consensus in the scientific literature as to the advantages of performing hemostasis following placement of a total knee prosthesis before closing the surgical wound[1,8-15]; apparently such a maneuver could be beneficial to reduce postoperative pain, enhance the performance of the quadriceps muscle, decrease inflammation, permit better wound healing and reduce postoperative bleeding[16].

The question in point is whether it is really useful or advisable to release the ischemia cuff to carry out hemostasis of the bleeding vessels before closing the surgical wound, with a view to reducing post-operative blood loss and, consequently, the need for transfusion. If vessel coagulation decreases the number of general and local complications, especially as regards postoperative pain, the presence of hematomas and surgical wound healing, then tourniquet release might be considered a valid option.

In order to address the issues above, we have drawn up this paper, which reports the results of a prospective multicenter study with alternating selection methodology that includes data from 5 participating hospitals, all of them with experience of knee prosthesis.

In a recent paper, Wright[17] defends the need to carry out prospective multicenter studies as a way to advance scientific research and he encourages the transfer of the results obtained to clinical practice.

MATERIALS AND METHODS

Our analysis comprised 194 patients from 5 hospitals of whom full details were available; 6 patients were excluded either because the data was insufficient or because they were referred to another hospital. The patients selected for the study were alternately distributed into the following groups:

1. Group I: hemostasis (H). After placing the metal implants and before placing the polyethylene component the ischemia cuff is released and the bleeding vessels coagulated.

2. Group II: no hemostasis (NH). The pneumatic cuff is released after placement of the prosthesis, closing of the surgical wound and application of the compressive bandage.

Table 1. Variables studied in the present study

Age, sex, side, previous surgery (ligament arthroscopy or osteosynthesis)
Hypotensive or antiaggregating medication prior to surgery
Type of prosthesis: resurfacing or syabilized with stems
Cemented, uncemented or hybrid
Toruniquet time and surgical wound closing time
Drains at 24 and 48 hours and total bleeding
Post-operative regime with low molecular weight heparin or another alternative
Prophylactic regime with antibiotics: cephalosporin or other
Transfusion needs with reinfusion, allogeneic transfusion or not required.
Post-operative pain assessed on the visual analog scale18 at 24 and 72 hours.
Inflammation/hematoma: 0 no inflammation; 1 slight; 2 moderate; 3 severe; 4 very severe; 5 requires evacuation
Appearance of the wound at 7 days from surgery: 0 well healed; 1 slight necrosis /dehiscence; 3 requires dressing; 4 requires surgery
Hemoglobin and hematocrit analytical data (pre-op, post-op, at 24 hours and on discharge).
Complications such as thrombophlebitis/ thromboembolism, infection, stiffness, vascular lesion, nerve lesion or death.

Subsequently the variables shown in table 1 were introduced in an Excel spreadsheet. All of this data was analyzed using the SPSS statistical software, using Student's t test for independent samples.

All of these data were analyzed with the SPSS statistical software. Student's "t" test was used for independent samples. Results were significant when the p value was lower than 0.05.

RESULTS

Our 194 patients were distributed into 2 equal groups of 97 patients each. Each Group had 19 men and 78 women. In group I (H) 49 prostheses were implanted on the right side and 48 on the left side, and in group II (NH) 53 were implanted on the right side and 44 on the left side. Mean patient age at the time of surgery was 69.1 years (42-85) in group I (H) and 73.2 years (32-86) in group II (NH). Twenty-four patients in both groups took anticoagulants preoperatively and 56 patients in group I (H) and 59 in group II (NH) used hypotensors. Fifteen subjects in group I (H) and 17 in group II (NH) took both medications. Ninety-five patients in group I (H) and 93 in group II (NH) were on prophylaxis with low molecular weight heparin, while 2 patients in group I and 4 in group II took fractionated heparin. Antibiotic therapy consisted of cephalosporin in 93 patients in group I and 94 in group II; the 7 remaining patients used other regimes due to allergy. Previous surgeries are reflected in table 2; 81 subjects in group I and 83 in group had not undergone previous surgery. In both groups bleeding was greater and statistically significant in

Table 2. Surgical procedures carried out prior to total knee arthroplasty

	Hemostasis	No hemostasis
Prior surgery		
Osteosynthesis	2	2
Arthroscopy	8	6
Ligaments	2	–
Osteotomy	4	6
No surgery	81	83

Table 3. Degree of inflammation further to total knee arthroplasty

	Hemostasis	No hemostasis
Inflammation		
None	25	26
Mild	45	46
Moderate	22	19
Severe	5	5
Very severe	0	1

patients with a history of bone surgery and osteosynthesis; p = 0.04.

Prostheses used were as follows: 93 resurfacing implants in both groups; 46 posterior cruciate ligament retaining and 47 posterior stabilized in group I; 43 posterior cruciate retaining and 50 posterior stabilized in group II. Four rotational stabilized total prostheses were also implanted in both groups.

All components were cemented, except for 11 prostheses in both groups that were hybrid, (the tibial component was cemented and the femoral component left uncemented) and 3 uncemented prostheses in group II (NH).

Tourniquet time was 77 minutes (44-130) and surgical wound closing time was 89 minutes (55-135) in group I. Tourniquet time was 80 minutes (60-140) and surgical wound closing time 78 minutes (50-135) in group II.

As regards preoperative bleeding, in group I (H) it was 562 cc (25-1940) at 24 hours, which accounts for nearly 78% of the overall blood loss figure for the group [721 cc (30-2210)]. In group II (NH) bleeding at 24 hours was 488 cc (60-1180), which accounts for 78% of the overall blood loss figure for the group [625 cc (60-1540)]. The data obtained are not statistically significant; p = 0.3.

If we correlate bleeding to the patients' gender, we observe that in both groups men have bled more than women [954 cc (240-2210) vs. 598 cc (30-1800)]. These data are statistically significant; p = 0.001. The pain score according to the Visual Analog Scale was 4.1 (0-10) in the first 24 hours and 2.5 (0-7) at 72 hours for group I. For group II the pain score at 24 hours was 3.8 (0-9) and at 72 hours 2.4 (0-8). These data are not statistically significant.

Table 4. Appearance of the surgical wound and wound healing

	Hemostasis	No hemostasis
Healing	90 Correct	82 Correct
Slight necrosis	5	14
Necrosis-disinfection	2	1

Table 5. Transfusion needs

	Hemostasis	No hemostasis
Transfusion	17	20
Reinfusion	39	34
No transfusion	37	40
Both	4	3

Table 6. Hemoglobin/ hematocrit decrease

	Hemostasis	No hemostasis
Pre-surgical hemoglobin	14.1 (12.5-16.3)	13.8 (11.1-15.6)
Hemoglobin at 24 hours	< 3.8 g (2.4-5.5)	< 3,3 g (1.1-5.2)
Pre-surgical hematocrit	42.4 (37.4-49)	40.6 (34.2-46.8)
Hematocrit at 24 hours	< 13.9 (8-29.2)	< 17.5 (3.8-16.4)

If we correlate hemostasis induction with the presence of inflammation in the operated knee (table 3), we can see that there are no significant differences. However, if we correlate hemostasis with the appearance of the surgical wound and with the rate of wound healing (table 4), even if data are not statistically significant there is a significant trend for patients in group II (NH) to present with more wound healing problems.

Complications in group I have been one patient with stiffness and one thrombophlebitis; and for group II, 4 patients had stiffness, one thrombophlebitis and another pulmonary thromboembolism. No large vessel vascular complications or nervous complications were recorded. Transfusion needs in both groups are reflected in table 5; they are similar and lack statistical significance.

Table 6 shows hemoglobin and hematocrit decrease at 24 hours for both groups; a decrease of over 3 g was recorded for hemoglobin, which was not related to whether the patient had received a transfusion, a reinfusion, both or neither. In any event, there were no significant differences between both groups.

DISCUSSION

Groups are homogeneous as regards age, gender and operated side; likewise the prosthetic models used are similar in both groups, without significant differences.

As regards prophylaxis with heparin and antibiotic therapy, it has been used in all 5 hospitals with minimal (not statistically significant) variations.

Differences between both groups concerning tourniquet time and wound closing time are extremely slight and devoid of statistical significance.

When analyzing postoperative bleeding, it is interesting to see that hemorrhage levels are similar in both groups, regardless of whether intra-operative hemostasis was induced following tourniquet release; these findings are in line with those of some publications[8,11-15] and contradict the claims of others[10,16].

The amount of blood collected when the drainages are withdrawn can sometimes be significant, exceeding 2 l, and on other occasions scarce and even negligible. These variations seem to indicate that there are numerous factors that may influence the amount of bleeding such as drain malpositioning, unusual and therefore unknown alterations in the coagulation factors and injuries to the (especially lateral) middle genicular artery, among other causes.

Bleeding in group I is higher even in absolute terms, although without statistical significance. These data are in line with those found by Christodoulou[19] and Jorn[11]; who found that patients with intra-operative hemostasis bled significantly more than those without hemostasis. They claim that if the tourniquet is not released until after the compressive bandage is applied, there is better control of fibrinolytic activity and a better activation of coagulation factors.

In this study we did not record data on intra-operative bleeding following tourniquet release in patients in group In this connection, H. Mylod[20] states that intra-operative blood loss is mainly due to the continuous bleeding of the cancellous bone exposed during surgery; unfortunately coagulation with the electrocautery is not possible in these cases.

Lotke[5] carried out a prospective study of 4 different groups, with ischemia induced in all of them, where the variables were the use (or nonuse) of hemostasis and the mobilization of the knee immediately post-operatively or after 3 days. He concluded that the main factor regarding postoperative bleeding was continuous passive motion, since the sooner it begins the more bleeding is observed in operated knees.

The amount of blood drained at 24 hours was 78% in both groups, i.e. drains can be withdrawn between 24 and 48 hours, since the blood collected thereafter is not significant.

Another clearly interesting finding was that, in both groups, men bled more than women; this is also reflected in the literature[21,22].

Figures for postoperative pain are striking since this is a usually painful surgery. The pain-related patient figures reflected on the Visual Analog Scale are rather low, both at 24 and at 72 hours; they are also very similar in both groups. Mention should be made in this regard to post-operative analgesic measures, especially the use of analgesia pumps, which tend to be placed for no less than 48 hours and modify the perception of pain. On the other hand, there are significant individual variations since pain is highly subjective, with the personal and emotional components related to pain tolerance could modify the data.

We also studied the appearance of the operated limb and, specifically, the knee inflammation / hematoma, where values were similar for both groups; over half the patients presented with slight inflammation in the knee and in around one-fourth the inflammation was moderate. None of the hematomas required surgical evacuation. Group II (NH) patients could have been expected to have more significant hematomas, but this was not confirmed by our study.

Another interesting aspect is the appearance of the surgical wound; the data collected indicate that wound healing is usually uneventful, although in some patients it is necessary to disinfect the wound because of the appearance of slight necrosis on the edges. The statistical analysis of these findings indicates that there is a (non significant) trend for patients in group II (NH) to present with more wound healing problems, albeit slight ones; these could be related to tissue distension caused by the edema and the postoperative hematoma. Complications have been scarce in both groups, and with no vital risk.

Finally, the last data analyzed are related to the need for allogeneic transfusion or reinfusion of the patient's own filtered blood, and variations concerning hemoglobin/hematocrit. Both groups had similar blood requirements with no significant differences; nearly half of the patients did not require a transfusion and it seems that when a transfusion is needed a allogeneic transfusion is losing ground to reinfusion[23,24].

With respect to the hemoglobin/ hematocrit parameters, the most significant finding is the decrease of hemoglobin by over 3 g 24 hours post-op; this figure is similar for both groups but without statistical significance; the fact that the patient has required transfusion does not modify these values.

The limitations of the present work are partly due to individual patient variations that were not evaluated, such as obesity, diabetes, etc., and some surgical technique-dependent factors like the opening of the lateral patellar retinaculum.

It should also be mentioned that different hospitals used different types of anesthesia: general, spinal, variant and complementary; post-operative analgesia regimes should also be mentioned since the time during which analgesia pumps are applied could lead to changes in pain patterns, especially during the first 24 hours.

There are also variations concerning the assessment of the hematoma and the appearance of the surgical wound. Even if there are guidelines to make this assessment, the subjective criterion of the specialist could modify inclusion of a patient into one group rather than another.

I think one of the strengths of this paper is that it is by far the largest study published in terms of the number of patients included in a prospective protocol to assess post-operative blood loss in relation with hemostasis in knee arthroplasty. We have not found any paper that sets forth a prospective multicenter study like ours.

Finally, an important factor that cannot be assessed but which must be reckoned with in all operated knees is occult blood loss, which can sometimes be significant and affects knees in both groups.

Analyzing the study as a whole may give the impression that there are numerous factors that may influence postoperative bleeding, but hemostasis does not seem to be an essential factor; the difficulty lies in the fact that it is difficult to *ex ante* predict which knees will bleed more than others, although our study provides some revealing findings in this connection.

Release of the intra-operative tourniquet before wound closure would have an absolute indication if at a certain moment in the procedure the surgeon suspects a more serious vascular injury, an occurrence that is fortunately rate. Lotke et al[5] have not had any injury to the popliteal artery after 1,500 prosthetic procedures.

To conclude, clinical parameters for pain and inflammation are not influenced by hemostasis, but there is a trend towards poorer wound healing in the group with no hemostasis. Postoperative bleeding is not influenced by hypotensive or antiggregating medication. There are significant bleeding differences in both groups if patients have undergone previous bone surgery with osteosynthesis. Men bleed more than women in both groups of patients, with highly significant differences.

Bleeding patterns do not change as a function of the type of prosthesis used and there are no significant differences in the transfusion needs of both groups. Postoperative blood loss is not directly related to intra-operative hemostasis, for which reason intra-operative hemostasis does not seem indispensable or even necessary.

REFERENCES

1. Abdel-Salam A, Eyres KS. Effects of tourniquet during total knee arthroplaty. A prospective randomised study. J Bone Joint Surg Br. 1995;77:250-3.
2. Eyres KS, Sharpe I, Abdel-Salam A. The tourniquet in total knee arthroplasty. J Bone Joint Surg Br. 1999;81B:932.
3. Tetro AM, Rudan JK. The effects of a pneumatic tourniquet on blood lose in total knee arthroplasty. Can J Surg. 2001;44:33-8.
4. Iorio R, Healy WL. Tourniquet use during total knee arthroplasty did not reduce total blood loss. J Bone Joint Surg Am. 2001;83A:1282.
5. Lotke PA, Faralli VJ, Orenstein EM, Ecker ML. Blood loss after total knee replacement. Effects of tourniquet release and continuous passive motion. J Bone Jont Surg Am. 1991;73A: 1037-40.
6. Vandenbussche E, Duranthon LD, Couturier M, Pidhorz L, Augereau B. The effect of tourniquet use in total knee arthroplasty. Int Ortop. 2002;26:306-9.
7. Wakankar HM, Nicholl JE, Koka R, D'Arcy JC. The tourniquet in total knee arthroplasty. A prospective randomised study. J Bone Joint Surg Br. 1999;81B:30-3.
8. Mencia-Barrio R, Sánchez-Herráez S, Alonso-Barrio JA, Sánchez-Lázaro J, Betegón-Nicolás JC, Fernández-Hernández O. Eficacia de la hemostasia tras retirada del torniquete en la artroplastria de rodilla. Rev Ortop Traumatol. 2005;49:341-5.
9. Gutiérrez-Alamo J, Barco-Laakslo J, Ordóñez Parra M, Ortega Andreu. Isquemia y hemostasia en la artroplastia total de rodilla. Revista Digital de la Sociedad Española de la rodilla. serod@serod.org. 2000;12(9).
10. Sanguesa Nebot MJ, Cabanes Soriano F, Villanueva Garcia E, Fernández Sabaté E. Estudio comparativo de las pérdidas sanguíneas en cirugía protésica primaria de rodilla con diferentes pautas de drenaje. Rev Ortop Traumatol. 2004; 75 Supl 2:160.
11. Jorn LP, Lindstrand A, Toksvig-Larsen S. Tourniquet release increase bleeding. A randomized study of 77 knee repalcements. Acta Orthop Scand. 1999;70:265-70.
12. Widman J, Isacson J. Surgical hemostasis after tourniquet release does not reduce blood loss in knee replacement. A prospective randomized study of 81 patients. Acta Orthop Scand. 1999;70:268-70.
13. Hersekli MA, Akpinare S, Ozkoc G, Ozalay M, Uysal M, Cesur N, et al. The timing of tourniquet release and its influence on blood loss after total knee arthroplasty. Int Orthop. 2004;28:138-41.
14. Burkart BC, Bourne RB, Rorabeck CH, Kirk PG, Nott L. The efficacy of tourniquet release in blood conservation after total knee artrhoplasty. Clin Orthop. 1994;299:147-52.
15. Garriga Santamaría M, Fernández JJ, Cardona JM, Saló JC, Más J, Dealbert A. Sangrado Postquirúrgico en la artroplastia total de rodilla según el uso de manguito de isquemia arterial. Comunicación Oral 24 Congreso SEROD. Andorra. Mayo de 2005.
16. Barwell J, Anderson G, Hasssan A, Rawling I, Barwell NJ. The effects of early tourniquet release during total knee arthroplasty: a prospective randomized double –blind study. J Bone Joint Surg Br. 1997;79:265-8.
17. Wright JG, Gebhardt MC. Multicenter clinical trials in Orthopaedics: time for muskuloskeletal specialty societies to take action. J Bone Joint Surg Am. 2005;87A:214-7.
18. Huskisson EC. Measurement of pain. Lancet. 1974;304:1127-31.
19. Christodoulou AG, Ploumis AL, Terzidis IP, Chantzidis P, Metsovitis SR, Nikiforos DG. The role of timing of tourniquet release and cementing on perioperative blood loss in total knee replacement. Knee. 2004;11:313-7.
20. Mylod AG Jr, France MP, Muser DE, Parson JR. Perioperative blood loss associated with total knee arthroplasty. A comparison of procedures performed with and without cementing. J Bone Joint Surg Am. 1990;72:1010-2.
21. Claus A, Ashe G, Brade J, Bosing-Schwenkglenks M, Horchler H, Muller-Farber J, et al. Risk profiling of postoperative complications in 17.644 total knee replacements. Unfallchirurg. 2006;109:5-12.
22. Prasad N, Padmanabhan V, Mullaji A. Blood loss in total knee arthroplasty: an analysis of risk factors. Inter Orthop. 2007;31:39-44.

23. Faris PM, Ritter MA, Keating EM, Valeri CR. Unawashed filtered shed blood collected after knee and hip arthroplasties. J Bone Joint Surg Am. 1991;73A:1169-78.
24. Newman JH, Bowers M, Murphy J. The clinical advantages of autologous transfusion. A randomised controlled study after knee replacement. J Bone Joint Surg Br. 1997;79B:630-2.

Conflict of interests

The authors have declared to have no conflict of interests.