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Tourniquet in knee surgery

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Abstract

Introduction: The tourniquet is a surgical device composed of a round pneumatic cuff in which air at high pressure can be inflated with an automatic programmable pump to avoid bleeding and technical impediment.

Sources of data: Comprehensive searches of Medline, Cochrane and Google Scholar databases were performed for studies regarding tourniquet application in arthroscopic and open surgery of the knee. The methodological quality of each study was evaluated using the Coleman methodology score (CMS).

Areas of agreement: The use of a tourniquet does not lead to significant increase in the risk of major complications, and there is no difference in clinical outcome in the medium term. The inflated cuff does prevent intraoperative blood loss, but hidden blood loss is not avoided completely. There is a statistically significantly higher occurrence of deep vein thrombosis in patients who undergo surgery with tourniquet, but the clinical relevance of this finding is uncertain.

Areas of controversy: The heterogeneity in terms of inflating pressure and duration of application of tourniquet in the single studies makes it very difficult to compare the outcomes of different investigations to draw definitive conclusions.

Growing points: Standardization of pressure and application time of the cuff could allow a comparison of the data reported by the trials. Better study methodology should be also implemented since the mean CMS considering all the reviewed articles was 57.6 of 100.

Research: More and better designed studies are needed to produce clear guidelines to standardize the use of tourniquet in knee procedures.

Key words: tourniquet, knee arthroscopy, knee open surgery, total knee replacement, Coleman methodology score, systematic review

Introduction

A tourniquet is commonly used during arthroscopic and open knee surgical procedures to avoid bleeding and technical impediment.[1] The tourniquet is a surgical device composed of a round pneumatic cuff in which air at high pressure can be inflated with a programmable pump. Its function is to produce a transient ischemia of the operated region during open or arthroscopic surgical procedures on the upper and lower limb. This provides surgeons with a clearer view of the structures to treat, given the bloodless surgical field, helping to better identify anatomic structures. A tourniquet can also be used in cases of excessive bleeding, given its hemostatic function. Nevertheless, this device can produce complications such as muscular dysfunctions, postoperative pain, subsequent blood loss, venous thrombosis and pulmonary embolism.

In knee surgery, the cuff is positioned at the root of the thigh.[2] Elevation of the limb, the use of an elasticated band to apply in a distal-to-proximal direction or the use of the Rhys-Davies exsanguinator[3] allows the surgeon to remove blood from limb vessels, and then air is progressively inflated into the cuff to reach a pressure based on the value of limb occlusion pressure (LOP), which represents the minimum pressure needed to efficiently oppose the peripheral arterial circulation. LOP can be found, with the patient anesthetized and after blood pressure has stabilized, by inflating the cuff and observing at which pressure the distal pulse is absent.[4] No standard protocols yet have been established for the use of this device,[1] but several authors investigated the safe use of tourniquet in terms of pressures and timings for the different interventions on the knee.

Given the present lack of consensus, this systematic review analyzes the role of tourniquet in both open and arthroscopic knee surgery procedures, presenting available data on clinical outcomes following the use of this device and focusing on the complications reported. Finally, we also evaluated the methodological quality of the studies published on the subject to assess the reliability of the evidences proposed.

Materials and methods

Study selection and data extraction

Online databases were searched for studies regarding tourniquet application in arthroscopic and open surgery of the knee. Medline (http://www.ncbi.nlm.nih.gov/pubmed), Cochrane (http://www.thecochranelibrary.com/view/0/index.html) and Google Scholar (http://scholar.google.it/) databases were accessed on 25 March 2014, obtaining results for >500 relevant studies using combination or isolated key words such as [Tourniquet AND knee], [Tourniquet AND arthroscopy], [Tourniquet AND total knee replacement], [Tourniquet AND total knee arthroplasty], [Tourniquet AND knee replacement], [Tourniquet AND knee arthroplasty], [Tourniquet AND TKA], [Tourniquet AND TKR], [Tourniquet AND anterior cruciate ligament (ACL) reconstruction], [Tourniquet AND PCL reconstruction], [Tourniquet AND knee osteotomy], [Tourniquet AND meniscectomy], [Tourniquet AND ligament] and [Tourniquet AND complications]. No peer-reviewed journal was excluded and no time interval limit was set. Given our language capabilities, we limited research to paper in English, French, Spanish and Italian. We then proceeded to exclude studies that did not deal with our research topic based on their titles. After consulting the abstract of each article not excluded in the first step, we took into consideration only studies investigating clinical outcomes and complications after tourniquet use for open or arthroscopic knee procedures, and which compared patients in whom a tourniquet had been used with patients in whom it had not. Only trials on human subjects

were considered. Once an article was identified as likely to be included, full-text versions were obtained to evaluate the exact content of the study. The reference lists of the selected articles were then examined by hand to identify articles not identified at the electronic search. All journals were considered, and all relevant articles were retrieved (Fig. 1).

Quality assessment

The methodological quality of each study was evaluated using the Coleman methodology score (CMS).[5] The features of each article were separately assessed by two reviewers (R.P. and G.T.). The scores range from 0 to 100 points (100 points score represents a perfect well-designed study with no influence of bias, chance and confounding factors) based on the sum of the partial values for each of the 10 criteria analyzed by this scale. The two investigators discussed scores where more than a two-point difference was evident until consensus was reached.

Results

We identified 30 studies: 28 clinical randomized trials and 2 retrospective studies. Of these, 13 discussed about arthroscopic-assisted procedures,[6–18] while the remaining 17 studies were about open surgery procedures.[19–35] All these studies were designed to evaluate whether patients undergoing knee surgery could benefit from the use of tourniquet compared with the same surgical procedures without this device. Tourniquet application details were summarized in Table 1. The mean CMS (Table 2) considering all the reviewed article was 57.6 (ranging from 33[12] to 80[17]), showing a suboptimal methodological quality.

Arthroscopic surgical procedures

Type of surgery

Studies concerning arthroscopic-assisted surgery report ~935 procedures. We retrieved 214 ACL reconstructions,[7,9–11] 51 partial meniscectomies,[8,12] 2 arthroscopic loose body removals[12] and 28 washout procedures.[13] The specific type of procedure was not reported in the remnant 640 cases.

Number and type of studies

Of these, 12 are randomized controlled trials and 1[10] is a retrospective study.

Preoperative features

The mean age at surgery was 36 years (the average of the single studies ranged from 24[9] to 46[15]). One

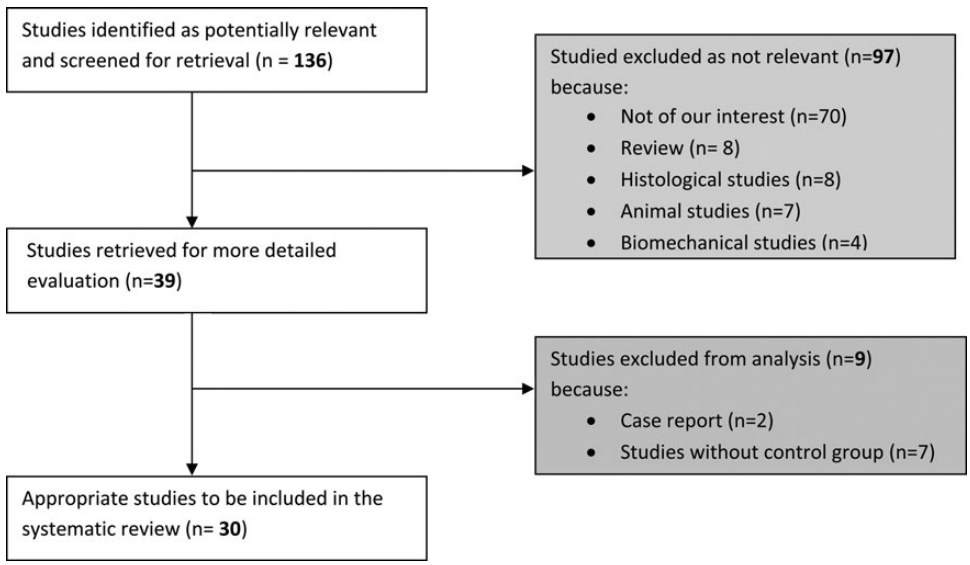

Fig. 1 Flow diagram of the studies included in the present investigation.

Table 1 Tourniquet application details

	Type of surgery	Tourniquet application details		
		Location	Pressure (mmHg)	Duration (min)
Arciero *et al.*[9]	Arthroscopic-assisted ACL reconstruction	Thigh	269	64–105
Daniel *et al.*[10]	Arthroscopic-assisted ACL reconstruction	Thigh	250–300	40–186
Graf *et al.*[8]	Partial meniscectomy	Thigh	225–400	49
Hoogeslag *et al.*[6]	Knee arthroscopy	Thigh	350	13.9
Hooper *et al.*[11]	Arthroscopic-assisted ACL reconstruction	Thigh	300	51–70
Jarrett *et al.*[12]	Knee arthroscopy (partial meniscectomy, diagnostic arthroscopy, loose body removal)	Thigh	250	20.2
Johnson *et al.*[13]	Knee arthroscopy	Thigh	SBP + 100	10–83
Kirkley *et al.*[14]	Knee arthroscopy	Thigh	N/A	N/A
Nakayama and Yoshiya[7]	Arthroscopic-assisted ACL reconstruction	Thigh	300	9.7–14.3
Thorblad *et al.*[16]	Meniscus lesions procedures	Thigh	450	26
Tibrewal[15]	Knee arthroscopy			35
Tsarouhas *et al.*[17]	Meniscectomy	Thigh	320	27.5
Wakai *et al.*[18]	Knee arthroscopy	N/A	N/A	18–34
Abdel-Salam and Eyres[21]	TKR	Thigh	Twice SBP	60–105
Aglietti *et al.*[22]	TKR	Thigh	N/A	72–107
Clarke *et al.*[23]	TKR	N/A	225 T + 1, 350 T + 2	N/A
Fukuda *et al.*[24]	TKR	Thigh	350	N/A
Harvey *et al.*[25]	TKR	N/A	N/A	163 T + c, 133 T +
Katsumata *et al.*[27]	TKR	N/A	N/A	55–75
Ledin *et al.*[26]	TKR	N/A	275	85
Matziolis *et al.* 2004[28]	TKR	Thigh	400	65–115
Molt *et al.*[35]	TKR	N/A	300	48–68
Motycka *et al.*[20]	Tibial osteotomy	Thigh	300	N/A
Nishiguchi *et al.*[29]	Unilateral and bilateral TKR	N/A	N/A	N/A
Tai *et al.*[30]	TKR	N/A	SBP + 100	42–62
Tetro and Rudan[31]	TKR	Thigh	SBP + 125–150 (tot max 300)	83
Vandenbussche *et al.*[32]	TKR	N/A	350	100–240
Wakankar *et al.*[33]	TKR	N/A	N/A	N/A
Wauke *et al.*[34]	TKR	Thigh	SBP + 100	45–100
Yavarikia *et al.*[19]	TKR	Thigh	220–275	55–100

SBP, systolic blood pressure.

study does not report this detail.[12] Demographic data are reported in Table 3.

Study population

The total of patient operated amounted to 935. Of these, 433 were males and 340 were females (the sex was not specified in some of the studies). The average reported follow-up length was 4.4 months. The mean CMS was 57.1 (ranging from 33[12] to 80[17]).

Year of publication

A low association between CMS (Table 2) and the publication year was evidenced using Pearson's test ($r = 0.21$).

Table 2 Coleman methodology score

	Study size	Mean follow-up	Number of different procedures	Type of study	Diagnostic certainty	Description of surgical procedure	Description of postoperative rehabilitation	Outcome criteria	Procedures for assessing outcomes	Description of subject selection process	Total
Arciero *et al.*[9]	4	2	0	15	5	5	10	10	4	10	65
Daniel *et al.*[10]	10	2	10	0	5	5	10	10	4	13	69
Graf *et al.*[8]	4	0	10	15	5	0	0	10	4	0	48
Hoogeslag *et al.*[6]	10	0	0	15	0	5	0	0	0	5	35
Hooper *et al.*[11]	4	0	10	15	0	0	0	7	12	10	58
Jarrett *et al.*[12]	4	0	0	15	3	5	0	2	4	0	33
Johnson *et al.*[13]	10	0	0	15	5	3	0	8	12	5	58
Kirkley *et al.*[14]	10	0	10	15	5	3	0	10	15	10	78
Nakayama and Yoshiya[7]	7	0	10	15	5	5	5	8	4	0	59
Thorblad *et al.*[16]	0	0	7	15	5	5	10	10	0	0	52
Tibrewal[15]	7	0	10	15	0	0	0	4	0	5	41
Tsarouhas *et al.*[17]	10	0	10	15	5	5	10	10	7	8	80
Wakai *et al.*[18]	4	0	10	15	5	0	0	10	0	0	44
Abdel-Salam and Eyres[21]	10	2	10	15	5	5	5	10	8	0	70
Aglietti *et al.*[22]	4	0	10	15	5	5	0	10	4	5	58
Clarke *et al.*[23]	4	0	10	15	5	5	0	8	4	5	56
Fukuda *et al.*[24]	7	0	10	15	5	5	5	10	4	5	66
Harvey *et al.*[25]	10	0	0	0	5	5	0	10	0	5	35
Katsumata *et al.*[27]	7	0	10	15	5	3	0	10	0	0	50
Ledin *et al.*[26]	7	2	10	15	5	5	5	10	5	0	64
Matziolis *etal.*[28]	4	0	10	15	5	3	0	10	0	5	52
Molt *et al.*[35]	7	4	10	10	5	5	0	10	5	8	64
Motycka *et al.*[20]	10	0	10	15	5	5	0	10	0	5	60

Continued

Table 2 Continued

	Study size	Mean follow-up	Number of different procedures	Type of study	Diagnostic certainty	Description of surgical procedure	Description of postoperative rehabilitation	Outcome criteria	Procedures for assessing outcomes	Description of subject selection process	Total
Nishiguchi *et al.*[29]	10	0	0	15	5	5	0	10	0	5	50
Tai *et al.*[30]	10	0	10	15	5	5	10	10	5	5	75
Tetro and Rudan[31]	10	0	10	10	5	5	0	10	0	5	55
Vandenbussche *et al.*[32]	10	0	10	15	5	3	5	10	4	8	70
Wakankar *et al.*[33]	10	0	10	15	5	5	10	10	0	5	70
Wauke *et al.*[34]	4	0	10	15	5	5	0	10	0	0	49
Yavarikia *et al.*[19]	10	0	10	15	5	3	5	10	0	5	63

Subject selection

Three studies[9,10,14] described the subject selection criteria. In three,[13,15,17] the description of inclusion criteria was poor, while in four other studies[8,12,16,18] the selection process was not described at all.

Surgical description and postoperative rehabilitation

Most studies give a description of surgical procedure, and 5 of 10 scored the highest in this field of CMS. The description was generally addressed to describe the details of the application of tourniquet. Three studies scored 0 in this field. Regarding the rehabilitation protocol, only four studies described it exhaustively, all the others scored 0.

Outcome measures

Several scores were used to assess postoperative pain, such as a verbal pain score[11] and the visual analog scale (VAS).[7,13–15,17] The WOMAC score[14] and the Lysholm knee score[9,17] were used to assess the general condition of the patient preoperatively. Other scores evaluated motor function of the limbs, of these, the main were the single-leg hop tests,[9,10] range of motion (ROM)[17] and international knee documentation committee (IKDC)[17] (Fig. 2).

Main clinical outcomes

Most of the studies evaluated the postoperative function of the quadriceps and hamstrings through isokinetic testing. Arciero *et al.*[9] at 1 month showed electromyography changes in both groups (6 vs. 2 in control, $P = 0.08$), and a higher degree of atrophy of the thigh in the group with tourniquet (thigh girth at 1 month of 40.75 vs. 41.74 cm, $P = 0.07$). No significant difference was evident 1 year after surgery (41.1 vs. 41.3 cm, $P = 0.77$). Daniel *et al.*[10] retrospectively evaluated the strength of the quadriceps and hamstrings at 1 year after ACL reconstruction. Lower values of the patients in a tourniquet group were found at 6, 12 and 24 weeks, but the difference leveled at 1 year (quadriceps index at 1 year: 74 vs. 77%). Kirkley *et al.*[14] assessed isokinetic strength at

Table 3 Demographic data

Study	Level of evidence	Number of patients operated	Mean age	No. of males	No. of females	Type of surgery	Mean follow-up	Coleman score
Arciero *et al.*[9]	1	40	24	10	30	Arthroscopy	12 months	65
Daniel *et al.*[10]	3	94	26	68	26	Arthroscopy	12 months	69
Graf *et al.*[8]	1	34	39	29	5	Arthroscopy	1 months	48
Hoogeslag *et al.*[6]	1	245	41	98	147	Arthroscopy	N/A	
Hooper *et al.*[11]	1	29	35.5	15	14	Arthroscopy	5 h	58
Jarrett *et al.*[12]	1	32	N/A	25	7	Arthroscopy	N/A	33
Johnson *et al.*[13]	1	109	36	72	37	Arthroscopy	2.5 months	58
Kirkley *et al.*[14]	1	120	43.5	86	34	Arthroscopy	0.5 months	78
Nakayama and Yoshiya[7]	1	51	26.3	27	24	Arthroscopy	3 months	59
Thorblad *et al.*[16]	1	19	40	3	16	Arthroscopy	24 h	52
Tibrewal[15]	1	56	46	N/A	N/A	Arthroscopy	1 month	41
Tsarouhas *et al.*[17]	1	80	33.3	N/A	N/A	Arthroscopy	N/A	80
Wakai *et al.*[18]	1	26	30.5	N/A	N/A	Arthroscopy	N/A	44
Abdel-Salam and Eyres[21]	1	80	73	32	48	TKR	24 months	70
Aglietti *et al.*[22]	1	20	69	7	13	TKR	1 h	58
Clarke *et al.*[23]	1	31	N/A	N/A	N/A	TKR	1 week	56
Fukuda *et al.*[24]	1	48	72	7	41	TKR	5 days	66
Harvey *et al.*[25]	3	78	70.5	N/A	N/A	TKR	N/A	35
Katsumata *et al.*[27]	1	50	66	10	40	TKR	0.75 months	50
Ledin *et al.*[26]	1	50	70.5	20	30	TKR	24 months	64
Matziolis *et al.*[28]	1	20	74.5	5	15	TKR	24 h	52
Molt *et al.*[35]	1	30	69	32	28	TKR	2 years	64
Motycka *et al.*[20]	1	65	61	30	35	Osteotomy	2.2 months	60
Nishiguchi *et al.*[29]	1	86	72	12	74	TKR	24 h	50
Tai *et al.*[30]	1	72	71.7	17	57	TKR	4 days	75
Tetro and Rudan[31]	1	63	70	26	37	TKR	36 h	55
Vandenbussche *et al.*[32]	1	80	70.5	25	55	TKR	3 months	70
Wakankar *et al.*[33]	1	77	72.5	25	52	TKR	4 months	70
Wauke *et al.*[34]	1	37	62	N/A	37	TKR	3 days	49
Yavarikia *et al.*[19]	1	84	66	22	62	TKR	24 h	63

3 months: extension was 87.06° in the tourniquet-up group vs. 86.00° in the controls, and flexion was 94.64 vs. 113.82°, respectively. On the other hand, Graf *et al.*[8] did not found any significant differences between the study and control groups at 1 and 4 weeks after partial meniscectomy, in terms of strength of the leg affected compared with the uninvolved leg (quadriceps strength decrease at 4 weeks: 85–72% and hamstrings strength decrease at 4 weeks: 90–80%. Also, Tsarouhas *et al.*[17] reached the same conclusions, with no evidence of superiority of the tourniquet-assisted procedures in terms of IKDC score (44.6 ± 12.2 vs. 48.8 ± 16.1), VAS (0.7 ± 0.6 vs. 0.6 ± 1.26 at 15 days postoperatively) and ROM ($142° \pm 7.5$ vs. $139.3° \pm 11.4$, $P = 0.22$). Furthermore, Nakayama and Yoshiya[7] did not show any significant difference in terms of functional recovery.

Jarrett *et al.*[12] assessed the occurrence of deep vein thrombosis (DVT) in different types of knee

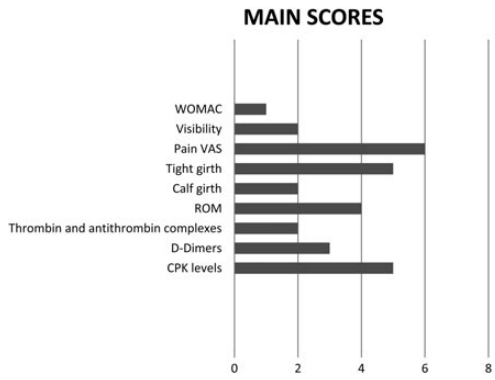

Fig. 2 Main outcome scores and evaluated parameters.

arthroscopy performed with tourniquet vs. a control group. Detection through transesophageal ultrasound assessment was positive in 72% (23 of 32) of patients, with a greater incidence in the tourniquet group (78 vs. 64%, $P = 0.45$), but no clinical significant or alarming symptom or sign was observed.

Arthroscopic visibility has been largely examined by Hoogeslag *et al.*[6] who study reported significant difference between groups in terms of clear view of the surgical field ($P < 0.001$); in 11 of the 16 cases in which visibility was expressed as 'poor', the surgeon failed to inflate tourniquet during the procedure. Johnson *et al.*[13] showed that in 89% (97 of 109) of the patients operated with the tourniquet, visibility was judged as 'Excellent'. Hooper *et al.*[11] assessed the difference in arthroscopic visibility for surgery which was considered poorer when the tourniquet was not applied. Surgeons reported 'impaired visibility' in 10 controls ($P < 0.0001$) compared with experimental group.

Biochemical evidence of inflammation has been the focus of two studies. Thorblad *et al.*[16] found no biochemical alteration achieved pathological levels after meniscectomy: creatine kinase rose over normal serum levels (2.6 kat/l) only in two subjects and one control. Wakai *et al.*[18] monitored monocyte activation state, neutrophil activation, transendothelial migration and concentration changes in cytokines [interleukin (IL)-1b, IL-10 and tumor necrosis factor alpha]. The main measurement was at 15 min after reperfusion, with a significant increase of these markers (IL-1, monocyte and polymorphonuclear leukocyte activation) in patients in whom a tourniquet had been used when compared with controls.

Open knee surgery

Type of surgery

Unilateral total knee replacement (TKR) was performed in almost all studies, except for the study by Nishiguchi *et al.*,[29] where 47 of the 86 patients underwent bilateral TKR, and for the study by Motycka *et al.*,[20] where proximal tibial osteotomy was performed. The total of the open knee surgeries reported by the studies included in this review amounts to 1018, of these, 486 were performed with a tourniquet applied.

Number and type of studies

Seventeen studies concerning knee replacement surgery were analyzed in this review.[19–35] Of these, 16 are randomized controlled trials and 1[25] is a retrospective study.

Preoperative features

The mean age at surgery was 68 years (the average of the single studies ranged from 62[34] to 74.5[28]). Only one study did not report the mean age.[23] Demographic data are given in Table 3.

Study population

The total of patient operated amounted to 971. Of these, 270 were males and 624 were females, but 2 studies[23,25] did not report data concerning sex of the patients. Reported follow-up lengths averaged 19.4 weeks. The mean CMS (Table 2) was 58.8 (ranging from 35[25] to 75[30]). The lowest average scores were achieved in 'Mean follow-up' and 'Description of postoperative rehabilitation' categories.

Year of publication

Pearson's test showed a low association between CMS and the publication year ($r = 0.26$).

Subject selection

In all studies, the subject selection process description was very poor, and no study reached high scores in this field of CMS, with four studies lacking this information,[21,26,27,34] therefore scoring 0.

Surgical description and postoperative rehabilitation

The surgical procedure was well described in all studies, with 12 of 17 studies scoring 5/5. Three studies scored 3 in this field, lacking some details. Postoperative rehabilitation was not described in most of the studies, even though two studies scored high in this field.

Outcomes measures

To evaluate the general condition of the patients, the most often utilized score was hospital for special services (HSS) score,[21] the VAS pain score was utilized in more than one study[26,30] (Tai *et al.*[30] utilized two separate score for thigh and knee pain) and ROM was assessed in two studies to evaluate knee function[26,28] (Fig. 2).

Main clinical outcomes

All the studies concern monolateral TKR, except where it was otherwise specified.

Blood loss has been the focus of several studies. Abdel-Salam and Eyres[21] observed higher intraoperative blood loss in the tourniquet-off group, but the overall blood loss was comparable between groups (800 vs. 805 ml in controls).

Harvey *et al.*[25] divided their study population into three groups, on the basis of tourniquet usage (no tourniquet, tourniquet until tibial tray cementing and tourniquet for the entire procedure), assessing higher blood loss in the first group (1493 vs. 1157 vs. 709 ml) and positive correlation with tourniquet time and operative time ($P = 0.0001$ and $P = 0.0135$, respectively). Tai *et al.*[30] reported greater blood loss, hemoglobin and hematocrit drops in the control group (Hb: 2.6 ± 0.9 vs. 3.7 ± 1.3, $P < 0.001$ and Ht: 7.6 vs. 10.4, $P = 0.005$). In a Tetro and Rudan[31] study, intraoperative blood loss and total measured blood loss were higher in the control group (IBL: 148 vs. 295 ml, $P < 0.0001$ and TMBL: 654 vs. 742 ml $P > 0.25$), even though the total calculated blood loss was higher in the tourniquet-up group (1792 vs. 1499 ml, $P = 0.02$). Vandenbussche *et al.*[32] showed that the calculated overall blood loss was higher in the control group (1234.9 vs. 1557.4 ml, $P = 0.0165$). Comparable results between groups (692.50 ml ± 360.25 vs. 582.77 ml ± 240.37) were reported by Katsumata *et al.*[27] Furthermore, Yavarikia *et al.*[19] found no statistical differences among groups for mean blood loss ($P = 0.062$), Hb value ($P = 0.132$) and Hematocrit value ($P = 0.454$).

DVT assessment has been studied.[22] One hour after surgery, significant difference in levels (higher in control group) were observed for prothrombin fragment 1 + 2 (7.2 vs. 9.7 nmol/l, $P = 0.03$), thrombin–antithrombin complexes (TAT) (73.0 vs. 117.0 nmol/l, $P = 0.03$), while D-D (D-dimer) was highly increased in the tourniquet group (1241.0 vs. 751 ng/ml). Fukuda *et al.*[24] diagnosed ultrasonographically DVT in 39 patients (21 in the group with tourniquet and 18 in controls, 81.3% of the total cohort), but in only two patients (one from each group, 1.7% of the total) a symptomatic pulmonary embolism became evident, with no fatal consequence. Harvey *et al.*[25] detected DVT in 27.5% of patients, independent from tourniquet application ($P = 0.671$). Katsumata *et al.*[27] reported that TAT ($P < 0.05$), D-Dimer ($P < 0.05$) and neutrophil elastase($P < 0.05$) levels increased significantly more in the tourniquet group. Motycka *et al.*[20] studied the incidence of thrombosis in high tibial osteotomies in two groups of patients (with and without the use of a tourniquet). Eleven patients in the study group and three patient in the control group resulted positive at D-Dimer test, but a diagnosis of DVT was confirmed only in six (five operated with tourniquet) patients after venogram. There was no statistically significant difference of the incidence of DVT ($P = 0.18$) between the study and control groups. Venography confirmed femoral thrombosis in four subjects in the study by Abdel-Salam and Eyres,[21] out of a total of 80 patients (40 subjects and 40 controls).

Nishiguchi *et al.*[29] divided their cohort into four groups: bilateral TKR with tourniquet inflated, bilateral TKR without tourniquet, unilateral TKR

with tourniquet and unilateral TKR without tourniquet. The trial aimed at evaluating pulmonary thromboembolism (PTE) occurrence, after deflation of tourniquet, through monitoring of O_2 saturation (PTE was suspected if O_2 saturation fell <95%) and lung scintigraphy. Hypoxemia was observed in 8 of 83 patients (9.3%), and scintigraphy confirmed PTE in 6 of these (2 of the first group, 3 of the second one and 1 of the third one). Also Wauke *et al.*[34] evaluated PTE occurrence through transesophageal echocardiography. The findings revealed a Grade 2 or 3 emboli in 23 of 37 patients (19 in the tourniquet-up group and 4 in controls); PTE was confirmed in one patient and DVT in two patients, all in the tourniquet group.

A singular though relevant trial was carried out by Clarke *et al.*[23] who evaluated the possible hypoxia of wound flaps through oxygenation electrodes, dividing their cohort into three groups: subjects undergoing surgery with tourniquet inflated to 225 mmHg (low-pressure tourniquet, LT), a second group undergoing surgery with tourniquet inflated to 350 mmHg (high-pressure tourniquet, HT) and a control group (NT). Concerning the medial wound flap, in the HT group, a significant oxygenation drop was observed compared with the LT at 6 days postoperatively ($P = 0.038$) and to the NT at 2 days from surgery ($P < 0.042$). The lateral flap had significant lower oxygenation in HT, compared with NT and LT, throughout the whole postoperative period ($P < 0.017$).

Recovery of motor function was also the focus of most studies. Abdel-Salam and Eyres[21] reported that full knee extension was achieved by all patient, but a faster straight-leg rising was observed in the control group (2.4 vs. 4.6 days; $P < 0.05$). In the study by Ledin *et al.*,[26] the control group showed better outcomes compared with the tourniquet group in terms of pain, VAS and ROM (at 2-year ROM was 11° better: 113° in the tourniquet group vs. 124° in controls, $P = 0.01$). Wakankar *et al.*[33] observed a mean change in knee flexion at 1-week significantly improved in the control group (−41.76° vs. −32.28° in controls, $P = 0.03$), with no differences at 4 months (−4.51° vs. −1.03°, $P = 0.37$).

Ledin *et al.*[26] and Molt *et al.*[35] evaluated prosthesis fixation, through a radiostereometric analysis of the migration. In the first study,[26] migration differed by 0.01 mm between the groups: the clinical relevance of such finding is dubious. In the second study,[35] no statistical significance was reported along or around any of the axes ($P > 0.05$).

Discussion

The present review compared the outcomes of several studies regarding open and arthroscopic knee surgeries, all collecting data from two groups of patients: a group who underwent tourniquet-assisted surgery and a control group in whom a tourniquet had not been used to evaluate the beneficial or negative effects of this device. We used the CMS to assess the methodology of the selected studies. This score has been validated for methodology evaluation of the studies in orthopedic surgery, assessing a variety of criteria.[5]

Even though numerous studies[36–38] and meta-analyses[39] have been published on this topic, a generally agreed opinion is not available yet. The studies generally conclude that is up to the surgeon to discuss the possible application of a tourniquet, on a case-by-case basis.

The real problem consists of a not clear balance between the complications and the benefits that the tourniquet can offer. Although it is true that cuff inflation prevents excessive intraoperative blood loss, providing a clearer view to the surgeon and simplifying the surgical procedure, local and systemic events (caused by ischemia–reperfusion processes) could represent the cause of various complications. Many papers focused on tourniquet-induced complications. Since 1970s, clinical or animal studies evaluated nervous complications[40–45] and muscular tissue metabolism alterations:[46–50] most reported that the prolonged use of tourniquet increases the risk of soft tissue injury. Some studies compared the expected prevention of an excessive blood loss and the actual blood loss,[51–55] observing that in tourniquet-assisted procedures the intraoperative blood loss was lower, but the postoperative blood loss was slightly higher compared with the control group, since hidden blood loss cannot be avoided. DVT is a most important consequence of ischemia–reperfusion conditions,

and therefore it can be considered the main major complication which can occur following the activation of the coagulation pathway. Three studies[22,27,34] reported a significantly different activation of the coagulation pathway between subjects and controls, while in three others[20,24,25] the results did not achieve statistical significance. Hirota *et al.*[56,57] studied the incidence of DVT after tourniquet release, and all these investigations showed that this complication mostly occurs during or after the application of a tourniquet.

The studies included in our work compared the advantages that the device provides and the complications it may induce. Significant difference in outcomes has been assessed in those studies which evaluated postoperative motor function recovery.[9,10,14,15,17,21] These studies demonstrated that the patients undergoing surgery with the tourniquet inflated have a slower recovery of motor function, but full recovery was achieved by the subjects at latest follow-up, without any difference compared with the control group. Pain score was assessed in six studies,[11,13,17,18,21] with no difference between the patients undergoing surgery with the tourniquet and controls. One study[18] assessed the activation of the inflammatory response, which increased in the tourniquet group. The studies which showed superiority in surgical technique parameters for the group using the tourniquet demonstrated a significant difference in visibility in two cases.[11,14] Blood loss was lower only in the intraoperative period,[25,31] while total blood loss was similar among the different groups.[19,27] All in all, no major complications are reported. Furthermore, there was lack of statistical significance of complication rate or of other parameters between the groups.

Regarding clinical outcomes in arthroscopic-assisted procedures, there is no clear evidence of the beneficial or negative effect of tourniquet use for this type of surgery. Although some complications can occur,[9,12] even in the medium term all the patients seem to be healthy and free of any tourniquet-induced consequence. Moreover, arthroscopic vision was better with the tourniquet.[11,13] Hence, the main issue to solve is whether the opportunity to achieve better visibility (therefore, an easier to perform and faster procedure) can be traded off with the possibility of early minor complication: this can only be decided by the operating surgeon. For TKR surgery, the main focus in the literature has been the assessment of the incidence of DVT. Seven studies evaluated this topic, and four[24,25,32,33] suggest that the use of a tourniquet does not exert a significantly negative influence on the occurrence of DVT. Studies assessing biochemical parameters, such as coagulation pathway activation[22,27] or inflammation markers,[28,30] observed an increased soft tissue inflammatory response and injury in the tourniquet group, indicating that its use induces a possibly negative systemic response, but this appears to be transitory and of uncertain clinical relevance.

Yavarikia *et al.*[19] demonstrated that the use of tourniquet allows a shorter operating time in TKR surgery compared with the control group. Furthermore, Clarke *et al.*[23] showed significant differences between the groups in terms of oxygenation of the wound, depending on different pressure the tourniquet is applied at. However, there is a lack of consensus about timing and pressure at which the tourniquet should be applied. Most studies reported very different pressure and time of release, which did not allow a comparison of the results. In the literature,[1] the effect of excessive pressure is recognized as deleterious on tissues which undergo ischemia–reperfusion, with a threshold of 2.5 h.[1] Therefore, time and pressure are strictly connected, although none of the studies included focused on these features. In our review, only the study by Vandenbussche *et al.*[32] broke the threshold of 2.5 h, without any significant consequence. Therefore, a time of use <2 h (which is reported in most of the studies) allows a relatively safe use of the tourniquet.

Concerning the pressure of inflation, several formulae to calculate the more suitable inflation pressure have been proposed,[1] but no guidelines have been developed yet. Because these parameters seem to be the main features affecting complications, we do think that further focused research should be undertaken on this particular aspect of tourniquet use.

Regarding the CMS of articles included, the mean score was 57.6/100. This relatively low average demonstrates only an acceptable quality of the clinical studies. A major issue is that no study analyzes together all the main outcomes concerning the use

of tourniquet (blood loss measurement, DVT assessment, pain scores, recovery of motor function, nervous and vascular injuries), comparing all these clinical and functional parameters with a control group.

Conclusion

The current literature lacks well-designed trials about this topic, and the methodological quality is relatively poor. The heterogeneity in terms of inflation pressure and duration of application makes it very difficult to compare the outcomes of different investigations to draw definitive conclusions.

Clear surgical advantages achievable from the use of a tourniquet in knee procedures concern blood loss control, arthroscopic visibility and better surgical field management. Moreover, there is also no evidence of dramatic systemic or local complication with the use of a tourniquet, except for some early complication and some cases of DVT. Therefore, a tourniquet can be utilized safely, provided that the inflation pressure is not excessive and that it is inflated for <2 h. However, each surgeon should evaluate each case individually to prevent complications. More and better designed studies are needed to produce clear guidelines to standardize the use of tourniquet in knee surgery.

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