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Use of a Tourniquet in Lower Limb Amputations: Evaluating Blood Loss in Peripheral Arterial Disease Patients -A Systematic Review

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Abstract

Background: Tourniquets have become an inseparable part of many different types of intricate and major surgeries, including amputation. Tourniquets create a bloodless environment, which is thought to facilitate surgery and reduce time, potential errors and subsequent complications.

Objectives: To investigate the effectiveness of using a pneumatic tourniquet as an adjunct in lower limbs amputation in peripheral arterial disease to reduce blood loss and requirement for blood transfusions. Stump revision rate, complication and mortality will be assessed as secondary objectives.

Method: For this systematic review, a search was performed using the keywords phrases, "peripheral arterial disease", "lower limb amputation" and "tourniquet" in PubMed, Medline, Embase and Google scholar, this work has been reported in line with PRISMA and AMSTAR guidelines.

Results: Based on univariate analysis, to determine the relationship between risk factors and blood loss, the study demonstrated the use of tourniquet significantly reduces the amount of blood loss during lower limb amputation (LLA), F (21.01), P=0.044. An independent t -test demonstrated that there was a statistically significant difference in mean blood loss between tourniquet and non-tourniquet studies, (T=-2.588, P=0.049). In this review the mean blood loss was 251.67±2.89 and 462.5±137.69ml for tourniquet and non-tourniquet studies respectively.

Conclusion: Using a tourniquet is a technically feasible approach to LLA, and effectively reduces the amount of blood loss and requirements of blood transfusion. No change in revision rates were noted.

Keywords: Tourniquet; Blood loss; Revision; Amputation; Lower limb; Pain

Abbreviations: PRISMA-P: Preferred Reporting Items for Systematic Reviews and Meta- analysis for Protocol; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; AMSTAR: Assessing the Methodological Quality of Systematic Reviews; RCTs: Randomized Controlled Trials; PAD: Peripheral Arterial Disease; DM: Diabetes Mellitus; LLA: Lower Limb Amputation

Background and Aim

Major limb amputation is a common surgical operation for patients with diabetic foot sepsis and critical limb ischemia who failed or are not candidates for revascularization. These patients often have significant co morbidities and outcomes are generally guarded. Post-operative hemorrhage is a common complication that can occur after any surgical procedure. A tourniquet is a device that prevents blood flow in the limbs and has the advantage of improving the surgical field and decreasing the blood loss Its usage is universal, but many controversies remain about it and with passage of time some principles have changed. In general, there are two types of tourniquets, namely surgical and emergency. Surgical tourniquets are used in orthopedic and plastic surgeries for creation of a bloodless field, greater safety, better precision, and convenience for the surgeon. Another use of the tourniquet is as an adjunct for regional anesthetic. Emergency tourniquets are used out of hospital to control traumatic bleeding in limbs. A tourniquet can be either pneumatic or elastic (Esmarch). In recent times, most tourniquets are of the pneumatic design. Currently

the use of a tourniquet during amputation is not universally practiced, mostly due to surgical anecdote. With this review we aim to evaluate the current literature on the use of a tourniquet to prevent blood loss during amputation.

Methods

Protocol and Registration

The study is reported according to the Preferred Reporting Items for Systematic Reviews and Meta- analysis for Protocol (PRISMA-P) [1]. The work has been reported in line with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) with Registration number: CRD42021231657 and AMSTAR (Assessing the Methodological Quality of Systematic Reviews) Guidelines.

Statement of Human Rights and Ethics

This is a systematic review and does not involve patients directly. The protocol has been approved by the local institutional ethic committee (HREC/ REF/512/2020).

Eligibility Criteria

Randomized controlled trials (RCTs) and retrospective studies comparing tourniquet with non-tourniquet amputations of the lower limb, for patients aged 18 and above, with peripheral arterial disease (PAD), with the following risk factors, diabetes mellitus (DM), HPT, smoking, hyperlipidemia, and HIV.

Information Sources

Two review authors searched the PubMed, Cochrane, Google Scholar Library and EmBase databases for all results.

Search

A simple, but exhaustive keyword search was performed using the keyword "tourniquet" in EmBase and as a MeSH term in PubMed. Other keywords used were amputations with tourniquet, peripheral arterial disease (PAD), blood loss, Amputation.

Study Selection Criteria

The search results were captured on an online data repository. Two review authors independently reviewed all results, based on the study inclusion and exclusion criteria. Any discrepancies for each step were resolved before proceeding to the next step. Extracted articles were first evaluated for the title, abstract and the complete manuscript to assess eligibility as per PRISMA flow diagram. Non-English articles were excluded.

Data Collection Process

All data collected will be put on a separate sheet under the last name of the first author, year, size of population, median age, country, and type of operation. One author developed the data capture repository, while the other author extracted the relevant data.

Data Items

Primary data extraction concerned only patients with peripheral arterial disease (PAD), who underwent lower limb amputation (LLA), with tourniquet. Secondary data extraction concerned lower limb amputation outcomes such as blood loss, revision rate, operative time, complication, and mortality. Other variables collected were country of study, study design, number of participants and characteristics of study participants (age, sex, fracture type and length of stay in hospital) and operation characteristics (data on the use of a tourniquet and surgery duration).

Summary Measures

Primary outcomes, blood loss, revision rate, operative time, number of complications and mortality were reported across the studies. A p-value < 0.05 was considered statistically significant. Statistical analysis was performed using the SPSS version 26 software.

Study Selection

The study selection process is outlined in the Preferred Reporting Items for Systematic Reviews (PRISMA) diagram (Figure 1). A total of 75 articles were identified during the initial search. After removal of six duplicate records remaining with 69. A further review of the 69 abstracts resulted in the removal of 11 citations that were not related to the research, giving 58 full manuscripts that were related to the research question. Screening the remaining 58 manuscripts based on the minimum eligibility criteria excluded 43 articles that did not meet the minimum eligibility criteria. A total of 15 full manuscripts met the minimum eligibility criteria.

Results Synthesis

Fifteen studies met the minimum inclusion criteria and were included in this systematic review as shown in Table 1. The number of participants ranged from 42 to 138 and except for one study [2] there was a surplus of males included. Amputations among men were higher compared to women, 11 studies showed (92%) amputations among men were above 50% and five studies (42%) amputations were above 60% compared to women. Prevalence of DM varied between 35% and 58% for the 15 studies.

In this systematic review, one article reported on re-operation after lower limb amputation in PAD patients [1], three articles [3-5] on the role of diabetes in increasing the risk of LLA in PAD patients, two articles on application of tourniquets to reduce blood loss in LLA in PAD patients [6,7], two articles on mortality rate after LLA for PAD patients [8,9] and three articles on trends in LLA for PAD patients [2,10,11]. A detailed analysis of profile of patients in the studies and complications associated with LLA surgery is given in Table 2 & Table 3 respectively. By using univariate analysis to determine the relationship between risk factors and blood loss, the

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study demonstrated the use of a tourniquet significantly reduces the amount of blood loss during lower limb amputation, F = 21.01, P = 0.044 (Table 4). An independent t -test, demonstrated that there was a statistically significant difference in mean blood loss between tourniquet and non-tourniquet studies, (T= -2.588, P= 0.049). The mean blood loss was 251.67±2.89 and 462.5±137.69 milliliter for tourniquet and non-tourniquet studies respectively.

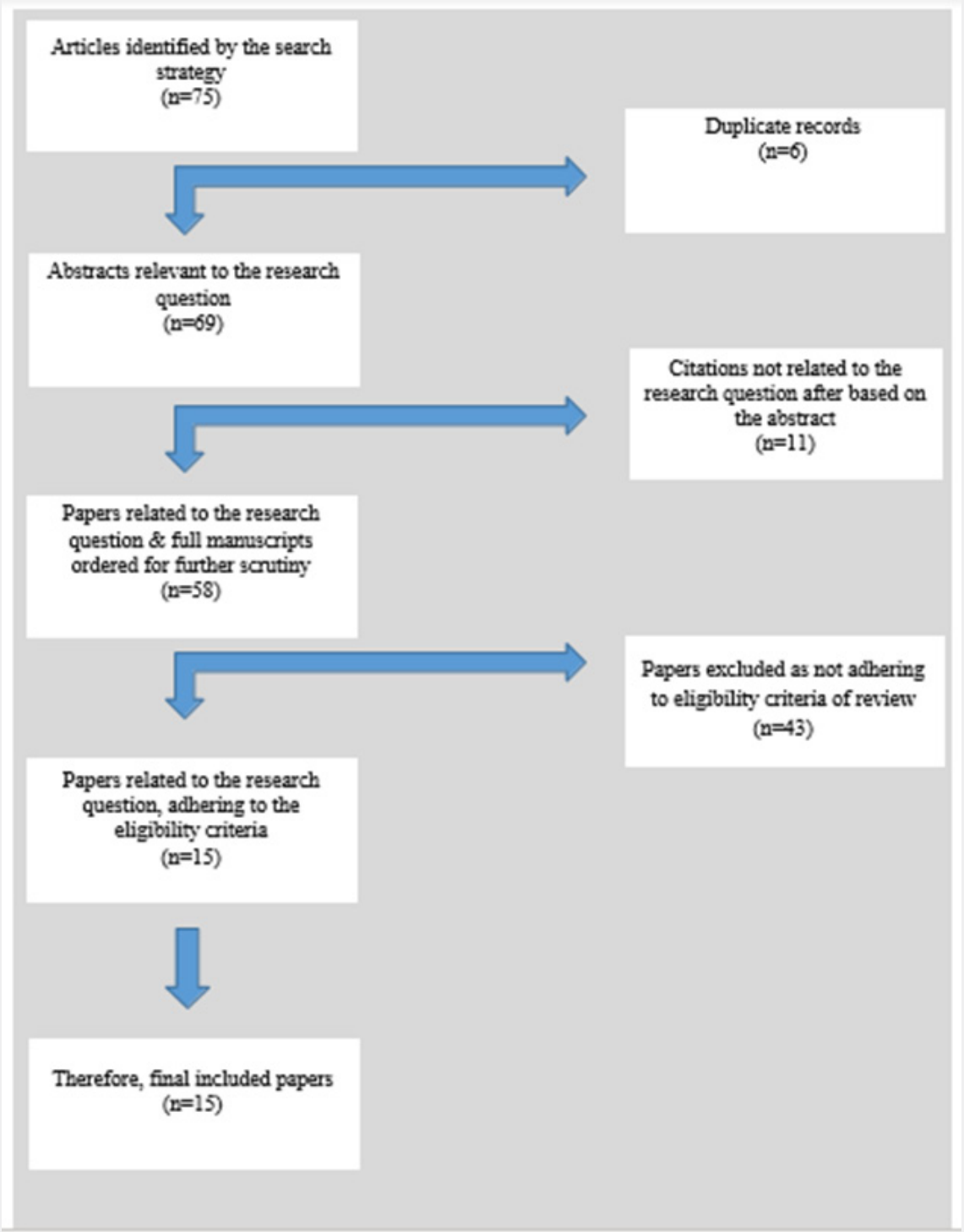

Figure 1: PRISMA flow diagram of the screening process.

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Table 1: Study characteristics of the included studies.

Study	Country	Amputation	Follow-up	Tourniquet			No tourniquet		
				n	Mean age (SD)	M/F %	n	Mean age (SD)	M/F %
Berli et al. [16]	Switzerland	BKA, AKA	814 days	182	66.5 (31-93)	69/31	-	-	-
Carmona et al. [8]	Switzerland	BKA, AKA	9–32 months	40	52 (6.4)	83/17	198	78 (7.5)	56/45
Choksy et al. [17]	UK	BKA	1-6 weeks	25	69 (60-75)	84/16	29	69 (63-77)	86/14
Fortington et. al [19]	Netherlands	BKA, AKA	24 months	-	-	-	299	74.1 (11.2)	60/40
Hsu et. al [13]	Netherlands	BKA, AKA	5.7 years	-	-	-	69332	62.6 (13)	49/51
Jain et. al [15]	USA	BKA, AKA	-	-	-	-	14012860	69±12.3	49/51
Kolossvary et. al [10]	Hungary	BKA, AKA	-	-	-	-	32 084	63.9 (11.5)	65/35
Malyar et. al [14]	German	BKA, AKA	4 years	-	-	-	24687	72.1±10.3	52/48
Rowe et. al [12]	German	BKA, AKA	-	-	-	-	48293	72.1±27	52/48
Scott et. al [18]	UK	BKA, AKA	12 months	-	-	-	339	73(162-79)	69/31
Spoden et. al [11]	German	BKA, AKA	-	-	-	-	55595	74 (64-81)	69/31
Wolthuis et. al [2]	UK	BKA, AKA	-	42	76	60/40	47	72	53/47
Wied et.al (2017a) [21]	Denmark	TTA	30 days	38	71±9.8	71/29	36	73±12	61/39
Wied et.al (2017b) [9]	Denmark	AKA	-				81	77±11	48/52
Mohd et. al [7]	India	AKA	1, 3, 6 weeks	20	65	75/25	20	64	60/40

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Table 2: Showing profile of patients included in this study.

Paper	Sample	Mean age (SD)	Gender		Diabetes	Revision/ Reamputation	Mortality/ year	Hypertension	Obesity	Dyslipidemia	Smoking	Myocardial Infarction	Ischemic stroke	Sepsis
			F	M										
Spoden et al [11]	55595	74 (64-81%)	17234 (31%)	38361	26686 (48%)	5646 (10%)	4276 (7.7%)							
Malyar et al [14]	24687 (61.8%)	72.1±10.3	11742 (47.6%)	12945 (52.4%)	8652 (35%)			15955 (64.6%)	1186 (4.8%)	7471 (30.3%)	3418 (13.8%)	149 (0.6%)	62 (0.3%)	1870 (7.6%)
Carmona et al [8]	209		93 (44.5%)	116 (55.5%)	101 (48.3%)	23 (11%)	80 (38.3%)	100 (47.8%)	87(41.2%)		47 (22.5%)		17 (8.1%)	
Jain et al [15]	14 012 860	69±12.3	6 067568 (43.3%)	7 945 29 2(56.7%)			434 39 (3.1%)	10 467 606 (74.7%)		6 249 736 (44.6%)	3 349 07 4 (23.9%)			
Berli et al [16]	180	66.5 (31-93)	55 (31%)	125 (69%)	104 (57.8%)	54(30%)	34 (18.9%)							
Hsu et al [13]	69332	62.6±13	35359 (51%)	33973 (49%)			13850 (20%)	51028 (73.6%)				1444 (4.5%)	3754 (11.7%)	
Kolossvary et al [10]	38084	63.9±11.5	11229 (35%)	11229 (35%)	16170 (50.4%)							1444 (4.5%)	3754 (11.7%)	
Rowe et al [12]	48293	72.1±27	23084 (48%)	25209 (52%)										
Choksy et al [17]	25	69 (60-75%)	4 (16%)	21 (84)	13 (52%)									7 (28%)
Wolthuis et al [2]	42	76	14 (33%)	14 (33%)	19 (45.2%)	6 (14.3%)	3 (7.1%)	25 (59.5%)						
Scott et al [18]	339	73 (26-92%)			131 (39%)	5 (15%)	121 (35.7%)							
Fortington et al [19]	229	74.1±11.2	121 (40%)	178 (60)	150 (50.2%)		231 (77%)				228 (76%)			
Wied et al [9]	40	72.3±11.0	25 (34%)	49 (66%)	39 (53%)		6 (8.1%)							
Wied et al [20]	81	6 (8.1%)	42 (52%)	39 (48%)	22 (27%)		11 (13%)							
Mohd et. al [7]	40	65 (50-75%)	13 (33%)	27 (67%)	23 (58%)	7 (18%)								

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Table 3: Detailed analysis of complications.

Study	Tourniquet Complications n (%)		Non-tourniquet complications n (%)	
Berli et. Al [16]	Skin necrosis	1		
	Soft tissue infection	1		
	Delayed wound healing	2		
	Necrotizing fasciitis	1		
Choksy et al [17]	Wound breakdown	0 (0)	Wound breakdown	9 (3)
	Revision of amputation stump	1 (4)	Revision of amputation stump	9 (3)
	Wound healing	57 (14)	Wound healing	59 (17)
	Myocardial infarction	4 (1)	Myocardial infarction	7 (2)
	Cardiac arrhythmias	12 (3)	Cardiac arrhythmias	10 (3)
	Pulmonary edema	8 (2)	Pulmonary edema	3 (1)
	Intraoperative blood loss (OBL)	255 (155-572.5)	Intraoperative blood loss (OBL)	550 (255-1058)
	Hemoglobin concentration	1.0 g/dl (0.6–2.4)	Hemoglobin concentration	1.8 g/dl (0–1.2)
Malyar et. Al [14]	Myocardial infarction Ischemic stroke Infections Sepsis		Acute renal failure	218 (0.9)
			149 (0.6)	
			62 (0.3)	
			1870 (7.6)	
			398 (1.6)	
			Deaths	579 (2.3)
Wolthuis et. Al [2]	Pulmonary edema	1	Pulmonary edema	
	Pulmonary embolism	1	Pulmonary embolism	
	Clostridium difficile diarrhea	2	Clostridium difficile diarrhea	1
	Acute myocardial infarction	1	Acute myocardial infarction	
	Urinary tract infection		Urinary tract infection	1
	Cerebrovascular accident		Cerebrovascular accident	1
	Post-operative death	1	Post-operative death	2
	Death after revision procedure	1	Death after revision procedure	1
	Disseminated ovarian cancer	1	Disseminated ovarian cancer	
	Drop in hemoglobin	5.60%	Drop in hemoglobin	14.30%
	Revision rate	14.30%	Revision rate	38.30%
	Mortality	7.10%	Mortality	6.40%
Brien et. Al [21]	30-day mortality Wound complications Non-wound complications Post-operative hospitalization		Early amputation failure	1130 (13%)
			626 (7.1%)	
			805 (9.1%)	
			1903 (21.4%)	
			6 (4.7%)	
Bourke et. al. [22]	Soft tissue pathology Infection Pain (neuroma) Pain (other)		Bone pathology	13 (18.3%)
			22 (31%)	
			22 (31%)	
			10 (14.1%)	
			5.60%	

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Iannuzzi et. Al [23]	Venous thromboembolism Renal Neurologic Cardiac Graft/Prosthesis Post-operative bleeding Minor complications Wound disruption Incisional infection	Respiratory complication	910 (8.2%)
		190 (1.7%)	
		259 (2.3%)	
		124 (1.1%)	
		14 (3.5%)	
		59 (0.5%)	
		620 (5.6%)	
		1380 (12.5%)	
		182 (1.6%)	
		924 (8.4%)	
Wied et. al (2017 a) [9]	Seepage of blood from wound due to damaged vessels by tourniquet	More Intraoperative blood loss (OBL)	
	Late onsets drop in Hemoglobin (Hgb)	More blood transfusions	
	Increased postoperative bleeding		
	Exsanguinated limbs swell by 10% after removal of tourniquet		
	Total Blood loss (TBL) 773 (336-1218) ml	Total Blood loss 859 (383-	
	Intraoperative Blood loss (OBL) 250 (150-500) ml	Intraoperative blood loss (OBL) 300 (225-600) ml	
Wied et. al. (2017 b) [20]	52 amputations due to atherosclerotic complications Blood loss (median) 964 mL (IQR 443-1558) Intraoperative blood loss (OBL) 400ml	22 amputations due to diabetes-related	9 (41%) post-operative complications
		16 (31%) post- operative	
		complications	
Mohd et. Al [27]	1x1l Transfusion 2 (10%)	1x1l Transfusion 12 (60%)	
	Wound break down 3 (15%)	Wound break-down 6 (30%)	
	Revision amputation 2 (10%)	Revision amputation 5 (25%)	
		Hip disarticulation 1 (5%)	
	Blood loss (median) 250ml	Blood loss (median) 600ml	
	Drop in hemoglobin (mean) 0.82gm/dl	Drop in hemoglobin (mean) 1.72gm/dl	

Table 4: Univariable analysis with linear regression of association between risk factors for the total blood loss.

Dependent variable- Blood loss		
Variable	F-value	P-value
Intercept	351.7	0.003
Age (Years)	16.6	0.055
Tourniquet (Y/N)	21.01	0.044
Sex (M/F)	0.5	0.553

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Discussion

In this systematic review, there were studies suggesting that PAD stage was not predictive of the need for revision surgery [1]. In a study by Carmona in Geneva between the year 1990 and 1999, the rate of amputation for PAD patients increased from 1.8 to 11.4/10 000 patients/year and the increase was observed to be associated with age and male gender of patients [3]. In addition, this group demonstrated that diabetes was present in 48% of patients, conferring a 10 times risk of lower limb amputation (LLA). In the same cohort it was demonstrated that major lower limb amputation has a poor prognosis, characterized by 40% mortality in a two-year period. Another study by Scott, similarly, showed that major lower limb amputation is a high-risk procedure with a high 30-day mortality of 12.4% and that an increase in age was associated with an increase in the risk of mortality following LLA for PAD patients [12]. Rowe et al reported that there was an association between increased application of endovascular technology and reduced rates of amputation in patients with PAD [13].

Jain [14] demonstrated that individuals with PAD and DM1 are more likely to be amputated compared to PAD and DM2 (17.7% vs 10.6%). However, PAD and DM2 patients were observed to be older than PAD and DM1. Kolossvary reported that 50.4% of LLA for PAD had diabetes [2]. In a study by Wolthuis [2] the drop in hemoglobin following surgery was higher among non-tourniquet patients (14.8%) compared to tourniquet patients (5.6%), with a higher need for transfusion in the non-tourniquet group. The revision rate was 14.3% in the tourniquet group and significantly higher in the non-tourniquet group (38.3%) [7]. Interestingly, according to this work, mortality was higher among tourniquet (7.1%) than non-tourniquet patients (6.4%), however the difference in mortality was not statistically significant, P = 0. 895. According to Choksy intraoperative blood loss was higher among non-tourniquet patients; 550 (255-1058) ml compared to tourniquet patients 255 (155-572.5) ml [6]. In addition, there was a significantly greater drop in hemoglobin concentration (median and IQR) in non-tourniquet compared to the tourniquet group (1.8 g/dl (0–1.2) vs1.0 g/dl (0.6–2.4) and the difference was statistically significant, P = 0.035. Therefore, the requirement for blood transfusion was lower in the tourniquet group. The rate of wound healing, breakdown and revision were similar in the tourniquet and non-tourniquet groups, respectively (59 vs 57%, 0 vs 9%, 14 vs 9%) [15-26].

Conclusion

The study provides valuable insight into the differences between tourniquet and non-tourniquet for lower limb amputations, with respect to outcomes such as blood loss (both intraoperative blood loss and total blood loss), revision rate, operation time, complications and mortality. However, not all the studies provide the entire list of outcomes. The weakness of the study is that there is a paucity of randomized control studies (RCTs) investigating tourniquet use in lower limbs amputation in PAD patients. We recommend doing more prospective investigation for lower limb amputations.

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