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COMPARISON BETWEEN BELOW KNEE AMPUTATION IN DIABETIC PATIENTS WITH AND WITHOUT TOURNIQUET

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Abstract

Objectives: *To evaluate blood loss after below knee amputation surgery performed with and without tourniquet, in patients suffering from diabetic foot infection.*

Study Design: *Quasi-experimental pilot study.*

Place and Duration of Study: *Department of General, Thoracic & Paediatric Surgery at a Tertiary Care Hospital in Kharian, Pakistan from 10th April 2024 to 9th October 2024.*

Methodology: *Fifty patients suffering from diabetic foot infection were stratified after utilising a non probability with a subtype of consecutive sampling technique into two groups. 25 patients were allotted in group-A for the application of pneumatic torniquet during below knee amputation operation. Rest 25 patients were placed in group-B as a control group for no application of pneumatic torniquet. Difference in pre-operative and post-operative hemoglobin was evaluated to find out the effect of tourniquet on the outcome of operation.*

Results: *Post-operative hemoglobin fall was 1.54 ±1.59 g/dl in group-A and 3.46 ± 1.92 g/dl in group-B. Post-operative blood transfusion requirement was in 8% of the patients in group-A and 72% of the patients in group-B. Median hospital stay of group-A was 3 (1) days and was 5 (1) days for group-B patients. The above-mentioned differences were significant with p-value less than 0.001.*

Conclusion: *We concluded that pneumatic tourniquet facilitates below knee amputation effectively with respect to peri-operative hemorrhage, post-operative blood transfusion and hospital stay.*

INTRODUCTION

Across the world, more than half a billion people are diagnosed to have diabetes mellitus.[1] Microvascular complications are potentially lethal outcome of longstanding and uncontrolled diabetes mellitus, often forming diabetic ulcers and irreversible gangrene necessitating amputation. 33.7% people die of non-trauma-related major lower limb amputations every year.[2] Peripheral vascular disease remains under-diagnosed in diabetics during routine medical visits at primary

and secondary healthcare levels, affecting 20-30% diabetics worldwide.[1] Non-healing ulcers over extremities, limb amputation and lasting disablement are calamitous outcome. Atheromatous occlusive angiopathy of the extremities affects over 200 million people worldwide and 8.5 million people in the United States.[3] In the developed world, 50-70% of diabetic patients reporting with foot ulcers have underlying peripheral vascular disease.[4] Disease affects 32 to 43% of Pakistani population who are already suffering from type-2 diabetes mellitus.[5] Application of pneumatic tourniquet during amputation has always been an operator's choice, and the decision has remained crucial, debatable and sometimes bewildering. Theoretical risks while applying tourniquet during below knee amputation (BKA) in diabetics, have always left the operator surrounded by controversy. Evidence-based regional data on this controversy is sparse. In such unwarranted situations, hemorrhage control has always led to mitigated peri-operative morbidity and mortality by enhancing clarity of view to the surgeon and reducing operation time. Concurrently, possible failure to re-perfuse the amputated limb after use of tourniquet has remained a great concern thus dividing the views on the practice.

The research paper delves into the surgical realm of BKA in diabetic patients, highlighting benefits and drawbacks of applying tourniquet during amputation. The aim is to provide an insight into optimal approach for the operating surgeon while performing BKA in diabetic patients. This research will provide a local database on the subject which can later be incorporated into a national level metanalysis.

METHODOLOGY:

This quasi-experimental (*pilot*) research was conducted at the Department of General, Thoracic and Paediatric Surgery at a tertiary care hospital in Kharian Pakistan from 10th April 2024 till 9th October 2024, following a formal approval from institutional review board of the hospital (reference is made to letter number: A/24/32 dated, 11th March 2024). We adopted a non-probability, purposive consecutive sampling mechanism.

Inclusion criteria: 50 patients above 50 years of age, suffering from the diabetic foot infection, who officially consented for their trans-tibial BKA operation and utilization of their data for the research purpose at our surgical center underwent operation and were included.

Exclusion criteria: Patients upon whom amputation was conducted for reasons other than diabetic foot infection were excluded from the study.

We recorded baseline demographic details of each patient and obtained meticulous evidence about comorbidities including medical history of diabetes and smoking, medication for ischemic heart disease, peripheral vascular disease, chronic kidney disease (CKD) and end-stage renal disease (ESRD), pre-operative hemoglobin, and American Society of Anesthesiologists (ASA) scoring. Further stratification was performed randomly into two groups, group-A and group-B (Figure 1).

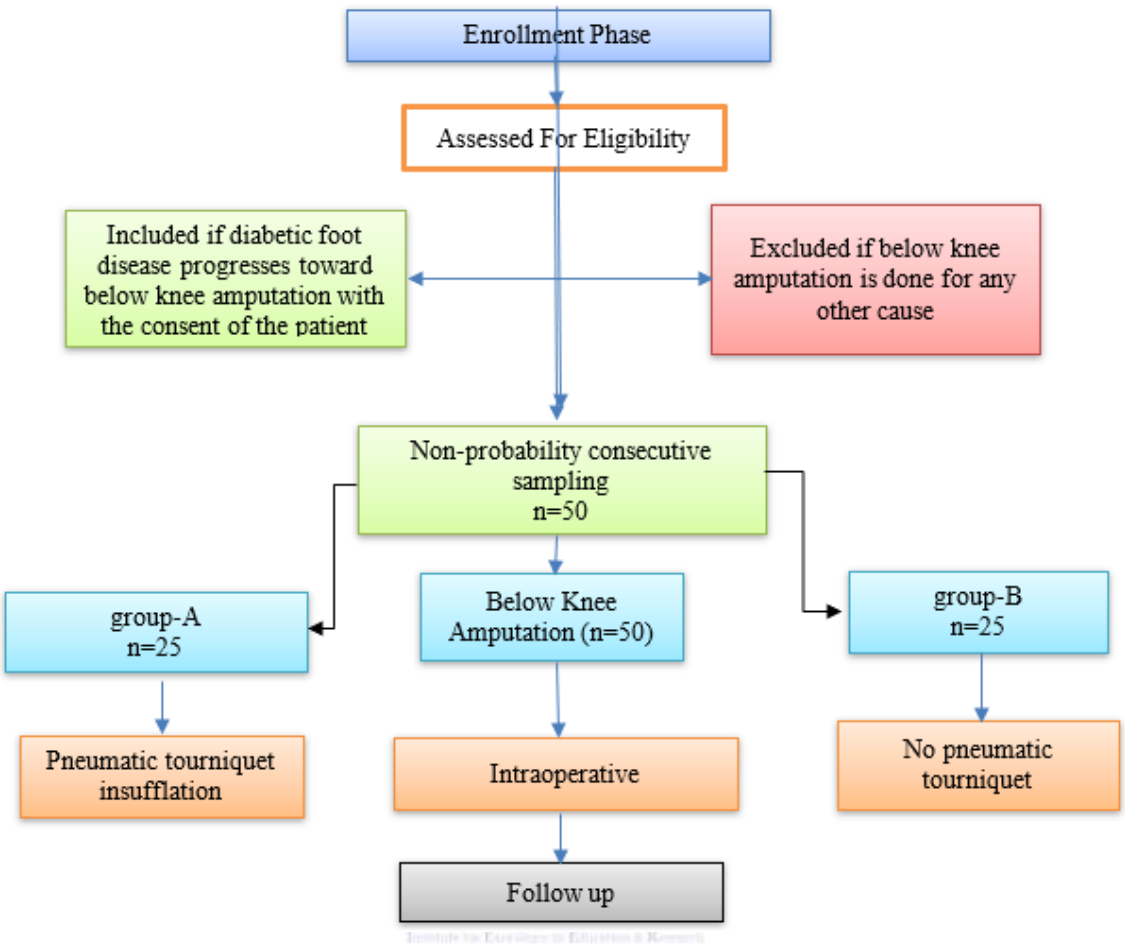


Figure 1: Patient Flow Diagram n=50

Patients falling into group-A were subjected to standard trans-tibial amputation operation approximately 10cm below tibial tuberosity after inflating a pneumatic tourniquet to 250 mmHg above the systolic blood pressure before making an incision. We removed the tourniquet at the completion of the operation after ensuring necessary hemostasis by ligation of blood vessels, galvanic coagulation and stump closure. Similar operative procedure was completed in all patients falling into group-B, without applying a pneumatic tourniquet at any point of time in the operation. All surgical procedures were conducted by the same team of surgeons. Post-operative hemoglobin of each patient was determined 4 hours following the operation and was quantified in Siemens automated hematology analyzer.

All essential data was compiled and we used Statistical Package for Social Sciences (SPSS) version 23 for statistical analysis. Initially, normality of the variables was checked by using the Kolmogorov-Smirnov test. Variables like pre-operative hemoglobin, post-operative hemoglobin, drop in hemoglobin, age, pre-operative fasting glucose, diabetic years, serum LDL and total cholesterol were normally distributed and represented by mean ± standard deviation (SD) . But variables such as pre-operative HbA1c, smoking years, serum triglycerides and hospital stay were not normally distributed and they were represented with median (interquartile range). As the wound infection rate was recorded as zero at 30 days, so its normality was not checked. Moreover, ASA was 3 in all the patients, and no statistics could be inferred, so its normality was not checked. Qualitative data such as gender, number of

patients who required transfusion, anticoagulants used, and comorbidities, were represented with frequency and percentage. Chi-square test was used for qualitative variables, t-test was utilised for normally distributed quantitative variables, and Mann-Whitney U test was used for not normally distributed variables. The level of statistical significance (p) was kept at 0.05.

RESULTS:

After final inclusion and exclusion application, 50 patients were divided into two groups with 25 in each group. Mean age of all the patients was 59.66 ± 4.95 years with Group-A mean age of 59.24 ± 4.99 years and that of group-B was 60.08 ± 4.99 years. In gender distribution, group-A constituted of 15 (60%) males and 10 (40%) females. Group-B had 11 (44%) males and 14 (56%) females (Table I). Our patients had a mean pre-operative fasting venous plasma glucose at 253.12 ± 82.35 mg/dl and median glycosylated hemoglobin (HbA1c) at 7.9 (1.26) % in study group-A. Whereas patients belonging to study group-B had a mean fasting venous plasma glucose level at 252.28 ± 82.69 mg/dl and median glycosylated hemoglobin (HbA1c) at 7.97 (1.7) % (Table IV). Many of the patients belonging to study group-A had a mean rank cigarette smoking history of 24.32 pack years with median of 0 and interquartile range of 39 pack years, while patients in group-B had a mean rank cigarette smoking account of 26.68 pack years with median of 0 and interquartile range of 35 (Table IV). Hypertension, as the only comorbid, was the most frequent pre-existing finding in both groups (52% [n=13] in group-A vs 68% [n=17] in group-B). 8% (n=2) in group-A were already receiving medical treatment for hypertension as well as ischemic heart disease vs 12% (n=3) in group-B (TableIII). None of the patients had kidney disease or pre-existing peripheral vascular disease. In both groups, salicylate was prescribed to all the hypertensive patients. But clopidogrel was prescribed to only 8% (n=2) in group-A and 12% (n=3) in group-B (Table III). These medications were temporarily withheld 5 days prior to the date of operation, in consultation with the consultant physician. We commenced all once the coagulation screen of every patient was ensured to be in the normal range. In group-A, pre-operative lipid profile of our patients was recorded as mean serum low density lipoproteins at 150.10 ± 6.91 mg/dl, median serum triglyceride 168.9 (17.05) mg/dl and mean total cholesterol 217.36 ± 11.72 mg/dl. The recordings corresponded to mean serum low density lipoproteins 146.18 ± 7.216 mg/dl, median serum triglycerides 172.3 (26) mg/dl and mean serum total cholesterol at 218.29 ± 11.40 mg/dl in study group-B.

Mean hemoglobin levels recorded before and after the operation are depicted in Table-II. It showed a significant drop in mean hemoglobin levels in non-tourniquet group-B compared to tourniquet group-A, i.e.; 1.54 ± 1.59 g/dl in group-A vs 3.46 ± 1.92 g/dl in group-B (Table-II). Median hospital stay of group-A subjects after the operation remained 3 (1) days, and was 5 (1) days, in group-B patients ($p<0.001$) (Table-IV). Post-operative transfusion data is reflected as 8 percent (n=2) required transfusion in group-A which was comparable to 72% (n= 18) in group-B ($p<0.001$) (Table III). Wound site morbidity after discharge (in terms of hemorrhage or post-procedural 30 days infection) warranting return to hospital and/or re-admission was accounted for none in both groups. In both group-A and group-B, ASA score was 3.

Table-I: Gender and Age-wise stratification of patients (n= 50)

Variables		Total (n= 50)	Groups		p-value
			Group-A (n=25)	Group-B (n= 25)	
Age (years)		59.66 ± 4.95	59.24 ± 4.99	60.08 ± 4.99	0.554
Gender	Male	26 (52%)	15 (60%)	11 (44%)	0.258
	Female	24 (48%)	10 (40 %)	14 (56%)	

Table-II: Pre-op & post-op hemoglobin along with hemoglobin drop in both groups (n= 50)

	Group-A (n=25)	Group-B (n=25)	p-value
Pre-operative Hemoglobin (g/dl)	12.54 ± 1.12	12.308 ± 1.38	0.510
Post-operative Hemoglobin (g/dl)	11.01 ±1.13	8.85 ±1.25	<0.001
Drop in Hemoglobin (g/dl)	1.54 ± 1.59	3.46 ± 1.92	<0.001

Table-III: Transfusion needed in the number of patients, anticoagulants usage and comorbidities in both groups (n= 50)

		Total (n=50)	Group-A (n=25)	Group-B (n=25)	p-value
Transfusion Needed	Yes	9 (18%)	2 (8%)	18 (72%)	<0.001
	No	41 (82%)	23 (92%)	7 (28%)	
Anticoagulants	ASA (75mg) + Clopidogrel (75mg)	5 (10%)	2 (8%)	3 (12%)	0.086
	ASA (75mg)	33 (66%)	14 (56%)	19 (76%)	
	No	12 (24%)	9 (36%)	3 (12%)	
Comorbidities	Htn	30 (60%)	13 (52%)	17 (68%)	0.138
	IHD	4 (8%)	1 (4%)	3 (12%)	
	Htn + IHD	5 (10%)	2 (8%)	3 (12%)	
	No	11 (22%)	9 (36%)	2 (8%)	

ASA means Acetylsalicylate
Htn means Hypertension
IHD means Ischemic Heart Disease

Table-IV Preoperative HbA1c, Smoking years and hospital stay postoperatively in both groups (n=50)

	Group-A (n=25)	Group-B (n=25)	p-value
Preoperative HbA1c (%)	7.9 (1.26)	7.97 (1.7)	0.923
Smoking Years	0 (39)	0(35)	0.523
Hospital Stay (days)	3 (1)	5 (1)	<0.001

% is the unit of HbA1c being used in Pakistan

DISCUSSION:

Diabetes mellitus is a chronic illness in which microangiopathy may precipitate critical limb ischemia and gangrene necessitating prompt and meticulous intervention. Use of tourniquet in perspective of trans-tibial below knee amputation has always remained a subject of debate.

From simple leather bands tied around bleeding limbs in the battleground to the modern day versatile digitally operable tourniquets used in operating rooms, the device has undergone momentous evolution over decades. Great names in operative surgery like Hildanus, Lister and Cushing have popularized the use of tourniquet in limb surgery. However, based upon experience, this stance kept changing over the decades afterwards. From proponents standpoint, applying pneumatic tourniquet during surgical procedures remains a standard practice to minimize blood loss and provide a clear operative field.[6] Mishwani and coworkers have emphasized on role of tourniquet in trauma to the limb vessels in the field.[7] However, apprehensions had remained high regarding the potential adverse effects of tourniquet use, particularly in diabetic patients who often present with compromised vascular health. Proponents argue that a tourniquet can enhance the surgeon's precision by reducing bleeding, facilitating a more controlled procedure, as it was found that perioperative blood loss is different between both groups in Ron Gurel and other colleague work, where blood loss was 0.24 g/dl and 0.72 g/dl between the both tourniquet and non-tourniquet groups, although the difference was declared non-significant. But the difference was 1.54 g/dl and 3.46 g/dl in our study, and it was with statistical significance. This could be explained by the different techniques being used in both settings, upon which we can not comment in detail due to lack of every little piece of technique information in Ron's work. The median length of stay was 3 (1) days and 5 (1) days in our setup, however, in Ron's setup it was 11(6) days and 17(15) days postoperatively for below knee amputation with and without tourniquet, respectively.[8] The median overall hospital stay in our setting after below knee amputation for both group was 3 (1) days but in the Danish national patient registry data, Anna Trier Heiberg and colleagues found that the mean duration of stay to be 11 (12) days postoperatively from 2010 to 2021. This might be hinting towards different way of patient management where in one setting the wound healing happens to be dependent upon daily home based dressings while in other setting the patient isn't discharged till the wound fully heals, moreover rehabilitation does not take place, which we do not have in our setup.[9] It is quite interesting that we utilized the 'present at time of surgery (PATOS)' due to which surgical site infection rate was lower as compared to 13.8% to 17.5% for tourniquet and non-tourniquet reported by Ron Gurel and the colleagues. In the same work of Ron Gurel, the transfusion rate for tourniquet vs non-tourniquet were 27.6% and 40 % which happens to be 8% and 72% in our study for the respective groups.[8]

Ryan Laloo and colleagues showed that tourniquet can be safely used in both diabetics and those who are suffering from peripheral vascular disease.[10] On the other hand, critics point to the risks of ischemia-reperfusion injury and compromised wound healing associated with tourniquet use. Safe and effective use of tourniquet incorporates clear indication/contraindication; pre-operative planning basing on patient's medical history, physical condition and duration of operation; risk assessment; system check and cuff selection; proper cuff placing; skin protection; cuff re-positioning; tourniquet inflation pressure setting; monitoring

of potential complications during operation; deflation coordination and post-torniquet evaluation. A record of events and training of staff always ensures good outcome.[11] As cited by Tian et al, Mathru and coworkers concluded tourniquet-induced exsanguination for limb surgery is responsible for toxic free oxygen radical H2O2 production during the ischemia-reperfusion event.[12] Stump closure before releasing tourniquet causes occlusion of arteries resulting in hypoxia and as a result cell response to restoration is inhibited along with process of angiogenesis and macrophages and fibroblasts migration. Mace et al pointed out persisting vasospasm observed on post-operative computed tomographic angiogram (CTA) following tourniquet application.[13] Arai et al highlighted that a tourniquet inflated for longer duration and with excessive pressure is likely to induce a sympathetic efferent response leading to hypertension.[14] Atherosclerotic calcification in vessel wall has been attributed to tourniquet failure in elderly, eventuating into massive hemorrhage. Post operative transfusion to correct blood loss in such elderly frail patients with concomitant cardio-pulmonary ailments heralds larger morbidity.[15] Such hemodynamic alterations can lead to hypertension,hypotension, bradycardia and asystole. Compartment syndrome is a common fallout of acute limb ischemia due to the rupture of atherosclerotic plaque in the large vessel wall at time of manipulation with the tourniquet.[13] Fatal pulmonary embolism has also been reported after tourniquet deflation owing to its faulty placing in a patient being operated upon lower extremity.[16] Foregoing in view, where benefits of applying pneumatic tourniquet outweigh its risks, studies examining below knee amputation in diabetic patients with the use of a tourniquet underscore the importance of maintaining adequate blood flow throughout the procedure.[17] It is crucial to acknowledge heterogeneity among diabetic patients, considering variations in vascular status, comorbidities, and overall health.[18] Individualized approaches to below knee amputation, taking into account the patient's specific conditions, may provide better insights into the optimal use or avoidance of tourniquets.[19]

Limitation of the study: A limitation of our research is its smaller sample size, which calls for recruiting a larger number of patients, diversifying the study parameters, and true randomization in order to generate high-quality evidence.

CONCLUSION:

Transtibial amputation in unsalvageable or gangrenous diabetic foot infection, especially in compromised patients aims at preventing further tissue loss, yet involves immense potential morbidity and at times mortality. Multidisciplinary approach encompassing general surgeon, vascular surgeon, endocrinologist, rehabilitation consultant and pathologist; optimizing glycemic status; individualizing surgical technique; meticulous wound management, early mobilization and rehabilitation point toward promising outcome. Best practices comprise of situation-specific and targeted selection of procedure, aiming at hemorrhage control during surgical operation. Controlled application and close monitoring ensure advantages of tourniquet in below knee amputation.

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MI & YSK: Conception, study design, drafting the manuscript, approval of the final version to be published.

AR & ASM: Data acquisition, data analysis, data interpretation, critical review, approval of the final version to be published.

MHA & RQA: Conception, data acquisition,

drafting the manuscript, approval of the final version to be published.
Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated an

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