



## Orthopaedics

## A PROSPECTIVE RANDOMISED CONTROLLED STUDY FOR ASSESSMENT OF USE OF PNEUMATIC TOURNIQUET IN ABOVE KNEE AMPUTATION OF ISCHEMIC LIMB IN PERIPHERAL VASCULAR DISEASE.

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**ABSTRACT** This is a prospective randomised controlled study for assessment of use of pneumatic tourniquet in above knee amputation of ischemic limb in peripheral vascular disease. The use of tourniquet is said to be a contraindication during surgeries involving amputations in peripheral vascular disease as they might injure the already compromised arteries above the planned level of amputation. Taking into consideration the promising results from some previously done studies, we assumed that the use of a pneumatic tourniquet has potential to improve the outcome following trans-femoral amputation without jeopardizing the healing of surgical stump wound. We selected forty patients for our study. All of them with non salvageable limb due to peripheral vascular disease. They were further randomized to either tourniquet or no tourniquet (control) group. Various parameters noted were intra-operative loss of blood ( $P < 0.0001$ ), post-operative need of transfusions ( $P < 0.037$ ), post-operative fall in haemoglobin ( $P < 0.0001$ ), wound healing, wound dehiscence/ breakdown and revision of amputation. Results of the trial showed that the use of a tourniquet during above knee amputation in peripheral vascular disease significantly reduces intra operative blood loss consequently reducing fall in post operative Haemoglobin and need for blood transfusion.

### KEYWORDS :

#### INTRODUCTION

Pneumatic tourniquets have been used widely in orthopaedics and trauma. They provide some surgical and medical benefits by limiting blood loss during operative procedure (Guest *et al.*, 2005) and prove to be more economical in terms of cost (Guest *et al.*, 2005). These clinical advantages become more important and valuable when dealing with the elderly patients with associated co-morbidities. Historically, the use of tourniquets has been shown to reduce blood loss during various surgical procedures like varicose vein surgery (Sykes *et al.*, 2000; Robinson *et al.*, 2000). But the use of tourniquet in patients with peripheral vascular disease (PVD) has long been debated and the studies pertaining to this field of application are limited.

The time-honored view is that the use of tourniquets is said to be a contraindication during surgery involving amputations in peripheral vascular disease as they might injure the already compromised arteries above the planned level of amputation. Bruce *et al.* (2002) studied the use of tourniquet during surgery in patients with clinically absent foot pulses or claudication if the femoral pulse is palpable and there is no active ulceration or rest pain. The study concluded that it is safe to use tourniquet during surgery (Bruce *et al.*, 2002). Due to nutritional and many other causes our population setup has baseline haemoglobin level on lower side and the subset of patients we usually receive tend to have low haemoglobin. Besides, due to various social and cultural norms the blood donation often becomes a matter of contention for the kith and kin of patients. The magnitude of the problem is also compounded at times due to unavailability of a needed blood group match in the emergency scenario. So we are only left with the option of limiting intra-operative blood loss to a minimum in anaemic patients with gangrenous limbs. A study done by Wolthuis *et al.* (2006) concluded that the use of a pneumatic tourniquet improves the outcome following trans-tibial amputation. Taking cue from these promising results we were prompted to study the use of a pneumatic tourniquet possibly improving the outcome in a population of elderly patients with peripheral vascular disease following trans-femoral amputation, without compromising stump wound healing.

#### MATERIALS AND METHODS

Our study design was based on Forty patients with severe peripheral vascular disease. These patients had either rest pain, skin ulceration or gangrene and had been chosen for above knee amputation. Any patient requiring above knee amputation was taken in this study provided the intended level of amputation was distal enough (Distal 3<sup>rd</sup> or Supracondylar Level) to allow tourniquet application without hampering the fashioning of amputation stump flaps. All these patients had ischemic limbs which were not salvageable as evidenced by pre operative Ultrasound color Doppler and CT angiograms.

Demographic data is shown in Table 1. After Randomization, the randomization details were placed in sealed envelopes which were opened in the operating theatre just prior to start of the operation. All patients were given a prophylactic antibiotic dose of cefuroxime (1.5 gm) intravenously within 30 minutes of commencement of surgery. All patients were operated under spinal anaesthesia. In tourniquet group limb was elevated for about 5 minutes before inflating the tourniquet. The tourniquet was guarded from slipping distally by fastening it to a Steinman pin (4.5 mm) fixed into iliac crest. Standard Orthopaedic pneumatic tourniquet was used with Inflation pressure twice the systolic blood pressure. In all patients above knee amputation was done and myocutaneous flaps of equal length were fashioned. After femoral bone transaction and ligation of major vessels, the tourniquet was released to see and coagulate any bleeder before suturing of skin flaps. A 16F suction drain was kept in place and a non-rigid dressing was used.

**Table 1. Demographics**

Patient Characteristics	Control Group	Tourniquet Group
Number	20	20
Age in years (median)	64	65
Sex Ratio (M/F)	12/8	15/5
Diabetes	12(60%)	11(55%)

The amount of blood lost intra-operatively was quantified from suction and swabs. Post-operative hemoglobin, transfusion requirements, wound condition and other complications were recorded. Blood was transfused post operatively if the hemoglobin level dropped to below 8 gm/dl. Follow up was performed at 1<sup>st</sup>, 3<sup>rd</sup>, and 6<sup>th</sup> week. Non-parametric data were analyzed using the Mann-Whitney test. Categorical data were compared using the Chi squared test

#### RESULTS

This study was done on Forty patients with half of them randomized for tourniquet use (Table 2).

The patients median age was 65 years (range 50-75) in the tourniquet group and 64 years (range 50-70) in the control group. All patients had advanced peripheral vascular disease which was non reconstructable or had failed reconstruction. Mean and median intra-operative blood loss for the control group was 600 ml (350-700ml) and 600 ml respectively. For the tourniquet group mean blood loss was 300 ml (200-400 ml) and median blood loss was 250 ml ( $P < 0.0001$ ). Mean Pre-operative haemoglobin concentration was 9.5 gm/dl in tourniquet group and 9.7 gm/dl in control group. The mean post operative haemoglobin fall was 0.82 gm/dl and 1.72 gm/dl in tourniquet and non tourniquet groups respectively ( $P < 0.0001$ ). The mean post operative

haemoglobin concentration was 8.12 gm/dl and 8.92 gm/dl in control and tourniquet group respectively.

Two patients (10%) required transfusion with one unit of blood in tourniquet group. Whereas in the control group twelve patients (60%) needed blood transfusion with two patients requiring more than one blood transfusion.

In tourniquet group three patients (15%) had wound breakdown which required serial debridement and later on secondary closure was done. In control group six patients (30%) had wound breakdown. Revision amputation was required in two patients (10%) among the tourniquet group and in control group five patients (25%) ended up with revision amputation with one patient ended up in hip disarticulation.

**Table 2. Results**

Parameters	Control Group	Torniquet Grroup	P Value
Blood loss (median)	600 ml	250 ml	<0.0001
Drop in Heamoglobin (mean)	1.72 gm/dl	0.82 gm/dl	<0.0001
Total number of Blood units Transfused	14	2	0.037
Wound Breakdown (number of patients)	6	3	Not significant
Revision of amputation (number of patients)	5	2	Not significant

## DISCUSSION

Our results confirm that use of a tourniquet during above knee amputation significantly reduces intra- operative blood loss. Since loss of blood during surgery is an important predictor of mortality (Law *et al.*, 2004) and our patients have preoperative haemoglobin level on lower side this will lead to clinical benefits. It seems that the previous fears about arterial damage from tourniquets is unfounded. Our results are broadly similar to those reported by Wolthius *et al.* (2006) In their study, blood loss was not measured directly, but the inference was made from the drop in haemoglobin concentration and a reduction in transfusion requirements. Like Wolthius we also observed a lower fall in hemoglobin level and a lower requirement of blood transfusion in tourniquet group. Wolthius *et al.* observed a beneficial effect on stump revision rate in the tourniquet group. We did not observe this effect significantly.

Our results confirm that the use of an tourniquet during above knee amputation in ischemic limbs m reduces blood loss intra-operatively, reduces fall in post operative hemoglobin and reduces the need for bood transfusion without potential complications.

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