A PROSPECTIVE CASE CONTROL STUDY ON THE EFFECTIVENESS OF FOGARTY CATHETER THROMBECTOMY IN ISCHEMIC LIMBS UNDERGOING ABOVE KNEE AMPUTATION

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ABSTRACT

BACKGROUND

Lower extremity amputation is one of the commonest procedures done in any surgical hospital. The ageing of our population and the persistent trend for delayed and inconsistent referral to vascular surgery are major reasons for large number of amputations in developing countries. Despite advances in lower extremity revascularisation, with widespread use of alternative vein conduit and bypass to tibial /pedal targets, there has been no remarkable reduction in major lower extremity amputation in our country. Compounding the problem, amputations are rarely considered by anaesthesiologist and/ or surgeons as a case of the same magnitude as a major vascular reconstruction or cardiac case. Surgical site infections, flap necrosis, wound gaping, stump pain etc., are some of the night mares of an amputee.

MATERIALS AND METHODS

The study was conducted for a period of one year starting from January 2009 to December 2009 at Dept. of Surgery, Govt. Medical College, Kottayam. Twenty-five cases were taken as control group. Twenty-five were enrolled into study group and in these patients, Fogarty catheter thrombectomy was done. Post surgery complications like flap necrosis, surgical site infection and mean hospital stay were studied in both groups.

RESULTS

Major postoperative complications were compared between the two groups. Flap necrosis was reported in 4% of cases in study group while that in control group was 24% with exact one tailed P (Chi square test) value being 0.049. Surgical wound infection was 20% and 38.9% respectively in both groups with P value being 0.5 is not statistically significant. Average hospital stay after surgery is 8.92 for case and 10.36 for control with a P value of 0.052.

CONCLUSION

Fogarty catheter thrombectomy is a very easily performed procedure which helps in establishing better circulation to the stump. It thus reduces postoperative complications like flap necrosis, rate of surgical site infections and also mean hospital stay.

KEYWORDS

Above Knee Amputation, Fogarty Catheter, Flap Necrosis, Surgical Site Infection.

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BACKGROUND

Lower extremity amputation is one of the most common surgical procedures done in any surgical hospital. Amputation is performed on patients with advanced critical limb ischaemia, in patients who cannot be treated with reconstructive vascular surgery or in whom vascular surgery has failed, for patients with diabetic foot infections, or following major trauma.[1] 85-90% of lower limb amputations in the developed countries are done for peripheral vascular disease.

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The ageing of our population and the persistant trend for delayed and inconsistent referral to vascular surgery are major reasons for large number of amputations in developing countries. Despite advances in lower extremity re vascularisation with widespread use of alternative vein conduit and bypass to tibial /pedal targets, there has been no remarkable reduction in major lower extremity amputation in our country. Compounding the problem amputations are rarely considered by anaesthesiologist and or surgeons as a case of the same magnitude as a major vascular reconstruction or cardiac case.

Surgical site infections, Flap necrosis, wound gaping, stump pain etc., are some of the night mares of an amputee. Avoiding repeated amputations and nonhealing operative sites is critical for the recovery of the patient and optimal functional rehabilitation or palliation.

Objective

Primary Objective is to assess the effectiveness of Fogarty catheter thrombectomy in improving morbidity, of patients

with ischaemic limb disease undergoing above knee amputation.

MATERIALS AND METHODS

A Prospective case control study was conducted on fifty patients posted for above knee amputation for ischemic limb, satisfying exclusive and inclusive criteria were enrolled into the study. Informed consent for the study was taken. They were then allotted to case and control group randomly.

Inclusion Criteria

Above knee amputation cases done for gangrene due to peripheral occlusive arterial diseases.

Exclusion Criteria

1. Above knee amputation for malignancies.
2. Above knee amputation for trauma
3. Above knee amputation for infective gangrene without vascular compromise.
4. Cases in which gangrene/ infection extended above the knee joint
5. Guillotine above knee amputation
6. Cases in which insertion of Fogarty was a failure due to heavily calcified vessel.

At the time of presentation detailed history and clinical examination including peripheral pulses and condition of the vessel were noted. The length in centimetres from the proposed level of amputation to umbilicus of the patient was noted and that much length of an appropriately sized Fogarty catheter (no; 5 or no; 6) was inserted through the cut end of femoral artery and proximal thrombectomy was done. Post op follow up was done till day of discharge and then on the first review in the outpatient department, then studied the rate of surgical site infection, flap necrosis, wound healing and duration of hospital stay.

The data collected was analysed using appropriate statistical method, EPI info software for chi square test & Microsoft excel for T test.

Procedure

The patients enrolled to case group underwent thrombectomy using Forgarty catheter. The instrument was threaded into the femoral artery and passed either through the thrombus or between the thrombus and the vessel wall. It is virtually impossible to push an embolus and its associated thrombus with a deflated catheter.

Although the pliability of the catheter tip is designed to facilitate safe proximal or distal passage, forceful probing at sites of non-embolic obstruction can lead to vessel wall injury and resultant arterial occlusion. Embolic material and associated thrombus do not in themselves offer resistance to catheter advancement. If there is resistance during the introduction of the catheter gentle probing usually allows the instrument to pass.

When the approximately sized catheter has gently been advanced as far as possible the balloon is progressively inflated while the catheter is being slowly with- drawn. The surgeon who withdraws the catheter should also control the balloon size because the feel the surgeon gains in this manner is an important factor in ensuring complete clot retrieval and preventing vessel damage. When traction on the catheter appears excessive, it is imperative to allow sufficient balloon deflation to permit smooth passage across segments of atherosclerotic luminal narrowing. As catheter withdrawal continues additional fluid should be added as needed to maintain gentle wall contact. The increased resistance offered by hard atherosclerotic plaque causes displacement of fluid to the un-inflated portion of the balloon allowing catheter to glide across areas of mild constriction without causing trauma to wall.

Figure 1 Femoral Artery Cut Open to Reveal the Thrombosed Lumen and Absolutely No Bleeding from the Cut End

Figure 2. Introducing Fogarty Catheter

Figure 3. A Portion of Thrombus Removed Original Lumen

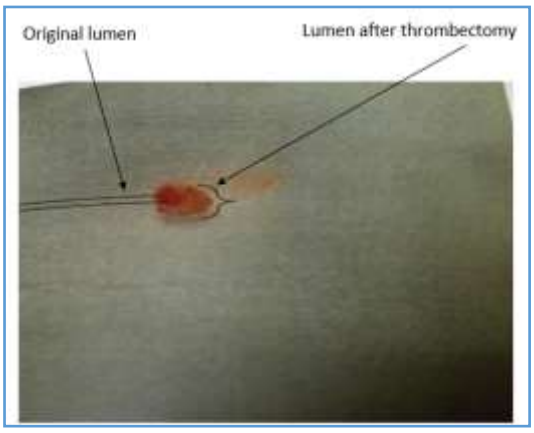

Figure 4. Vessel Lumen Prior to and after Thrombectomy

Figure 5. The Establishment of Blood Flow after Thrombectomy

RESULTS

A total of 50 patients were enrolled. The patients were randomly divided into cases and controls.

Demographics

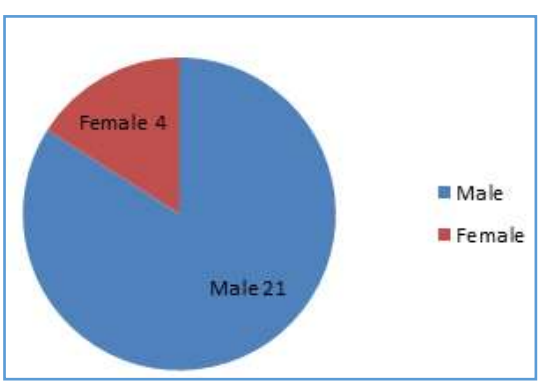

Figure 6. Sex Ratio of Cases

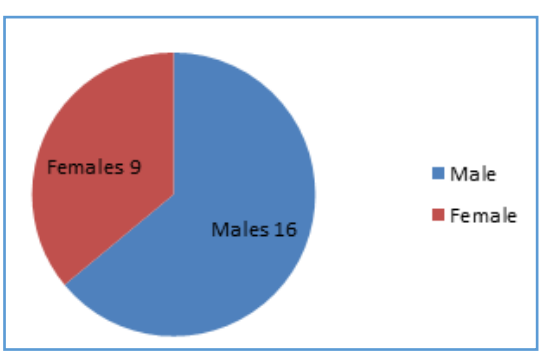

Figure 7. Sex Ratio of Controls

Comorbidity	Cases	Control
Diabetes	20	19
Hypertension	11	8
Renal Failure	2	3
Jaundice	1	1
Anaemia	6	5

Table 1. Co Morbidities of both the Groups

None of the patients had a palpable dorsalis pedis or posterior tibial pulsation but all had a palpable femoral pulsation.

There was no statistically significant difference in the distribution of confounding variables between either group.

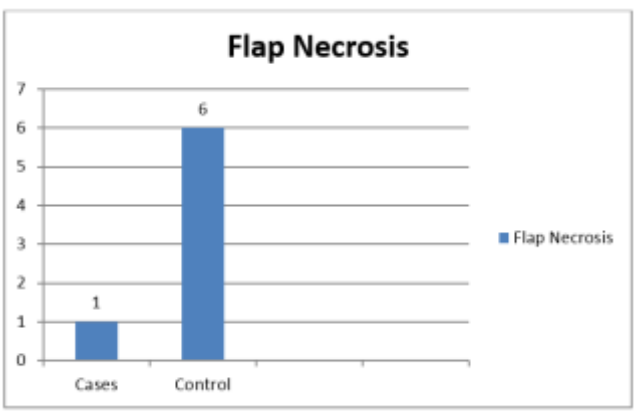

Figure 8. Showing the Flap Necrosis of both the Groups

Flap necrosis is the blackish discoloration of the flap due to tissue necrosis as a result of ischemia.

Out of the 25 cases only 1 patient developed Flap necrosis i.e. 4%.

Out of the 25 controls 6 patients developed Flap necrosis i.e. 24%.

The Fisher Exact P (Chi square test) value is 0.049.

	Popliteal Artery Pulsation +	Popliteal Artery Pulsation -	HTN	DM	Renal Failure	Jaundice
Case (1)	**nil**	**1**	**-**	**-**	**-**	**-**
Control (6)	**2**	**4**	**5**	**3**	**-**	**-**

Table 3. Details of Cases which had Flap Necrosis

Surgical Site Infection

Surgical site infection may be superficial incisional or deep incisional.

A) Superficial Incisional

- Infection less than 30 days after surgery
- Involves skin and subcutaneous tissue only plus any one or more of the following
  1. Purulent discharge.
  2. Diagnosis of superficial surgical site infection by a surgeon.
  3. Symptoms of erythema, pain, local edema.

B) Deep Incisional

Infection of less than 30 days after surgery with no implant and soft tissue involvement.

Infection less than 1 year after surgery with an implant; involves deep soft tissue (fascia and muscle), plus one of the following;

- Purulent drainage from the deep space but no extension to organ space.
- Abscess found in the deep space on direct or radiological examination or on re operation
- Diagnosis of a deep space surgical site infection by the surgeon.
- Symptoms of fever, pain, and tenderness leading to dehiscence of the wound or opening by a surgeon.

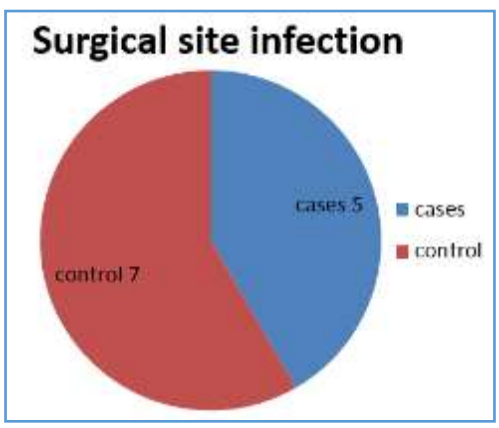

Figure 9. Showing the Surgical Site Infection of Both the Groups

Surgical site Infection was 20% in cases and 38.9% in controls.

P value being 0.5 and is not significant.

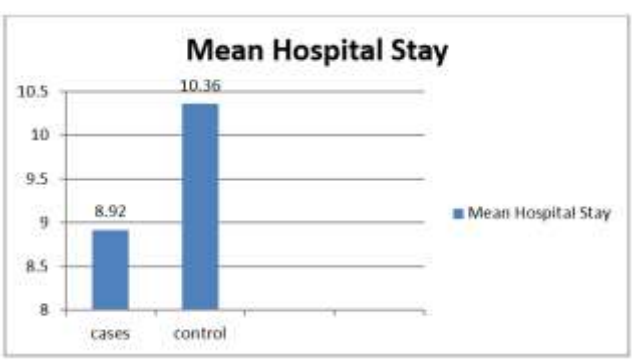

Figure 10. Comparison of Mean days of Hospital Stay among Cases and Control

P value being 0.052 and is not statistically significant.

	Case	Control
Flap necrosis	1	1
SSI	-	1
Wound gaping	1	2
Lost to follow up	6	8

Table 4. Showing the Followup Visit of both the Groups

Follow up visit after 2 weeks did not show any statistical significance in flap necrosis among the case and control group.

DISCUSSION

Major lower extremity amputation continues to be a part of all vascular practices despite aggressive attempts in limb salvage. Majority of patients undergoing amputation of the lower limb have peripheral vascular disease, often resulting in significant morbidity and mortality. Although often viewed as failure of treatment major amputation should be embraced as an important definitive treatment option. Complications in AKA patients included haemorrhage or hematoma, wound infection and failure to heal requiring further operative intervention.[2] A 30 day mortality rate of 16.5% was noted in a previous study.[3] Survival probabilities for below- and above-knee amputees were 77% and 59% at 1 year in case series studied by Bernadette Aulivola et al,[3] The mortality rate is higher in Above knee amputation than in below knee amputation and the reason may be advanced degree of ischemia.[4,5,6]

Major amputation continues to result in significant peri-operative morbidity and mortality in the patient population with peripheral vascular disease. In another study the 30-day mortality rate of 8.6% has been reported previously.[7,8]

The mortality rates are high due to the fact that most of the patients undergoing amputation have co morbidities like Diabetics, Hyper tension Renal failure etc.,

In our study population of 50 patients, 39 patients had diabetes, 19 had hypertension and 5 had renal failure. Previous studies show that the survival rate is less in patients with DM and End stage renal diseases.

In our study population none of the patients reported with haemorrhage from wound site.

Less arterial inflow and oxygenation of the healing stump can potentiate hypoxia at the surgical site, increase free-radical formation, and lead to tissue damage and eschar formation.[9,10,11] Early detection of relative stump mal-perfusion in at risk diabetic patients can help inform the post-operative surveillance time-line and anticipated wound care needs.

Post amputation ischemia of the above-knee stump is a common and lethal complication of above knee amputation. It has not been addressed much in the literature. Failure of the stump to heal is usually attributed to ischemia. Broad spectrum bacterial infection can soon supervene, and this adds to the ischemic disease in producing further necrosis. The necrosis in turn produces a culture medium for additional bacterial proliferation, further invasion of marginally viable tissue by the various toxic by-products of bacterial proliferation, and can finally lead to sepsis. In our study of 50 cases, Flap necrosis was found in 7 patients. Among these, flap necrosis was only 4% in patients who underwent Fogarty catheter thrombectomy, while the controls who were not subjected to thrombectomy the incidence of flap necrosis was 24%. Our study also showed that flap necrosis was more in patients with absent popliteal artery pulsation, and also in patients with co morbidities.

Dr. Thomas Fogarty invented Fogarty arterial embolectomy catheter in 1963 and presented a paper in 1965. Fogarty catheter embolectomy is a minimally invasive and fast technique and it does complete or near complete embolectomy, re-establishing the circulation. The design of the Fogarty catheter includes a small inflatable balloon at the tip of the catheter. Once the catheter has been inserted and the placement has been confirmed the balloon can be inflated with air or a sterile fluid. The filled balloon hold the catheter in place. It is available in graduated sizes from No 2 to 7 French.

Figure 11. Fogarty Catheter

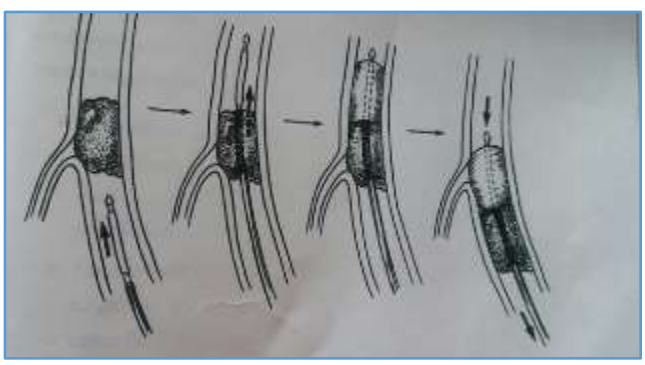

Figure 12. Showing the Technique of Fogarty Catheter Embolectomy with Catheter Insertion in the Distal Vessel

Fogarty embolectomy via a femoral or popliteal approach ia a quick approach in cases of circumscribed thrombi and embolic disease and has stood the test of time. In older thrombi wall adhesion of the occluding clots may become severe which might make Fogarty thrombectomy difficult. To meet this need two new tools have been designed: an adherent clot catheter (ACC) and a graft thrombectomy catheter (GTC).

Inflow revascularization cannot be delayed until recognition of the developing ascending gangrene after amputation.[12] Attempting major inflow procedures in patients with sepsis is analogous to "emergency" amputations, as here the mortality rate is recognized as ranging from 20% to 50% or to "emergency" revascularization/thrombectomy to control acute embolic/thrombotic phenomena with ischemic limbs were the mortality rate ranges from 10% to 25%.[13]

Wound infection is one of the major complications of amputation. In a retrospective review of lower extremity amputations for peripheral vascular disease by Aulivola et al,[3] he found that wound infections occurred in 5.5% of below-knee amputation limbs and 6.7% of above-knee amputation limbs. Data from the Surgical Site Infection Surveillance Service in England[14] reveals that the highest rate of surgical site infection was reported in association with lower limb amputations. This may be because many patients undergo amputation for grossly infected limb ulceration. The authors of the report explain that high infection rates are likely to be related to underlying risk factors that affect wound healing and vulnerability to infection, like poor limb perfusion and diabetes. Patients with diabetes are approximately five times more likely to have a post-surgical wound infection than non-diabetics.[15]

In our study Surgical site infections occurred in 12 patients accounting for 24% of all the cases enrolled. In the control group were thrombectomy was not done an infection rate of 38.9% was reported and in the case group were Fogarty thrombectomy was done the infection rate at surgical site occurred only in 20%.

The mean hospital stay was also increased in patients who did not undergo thrombectomy before amputation. The mean hospital stay was 10.36 days in the control group. The mean hospital stay in the case group were thrombectomy using Fogarty catheter was done was 8.92 days.

CONCLUSION

Despite aggressive attempts at limb salvage, major lower extremity amputation continues to be part of all vascular practices. With the escalation of risk factors like diabetes, hypertension. hypercholesterolemia, smoking and paucity of effective preventive measures, the prevalence of peripheral vascular diseases are increasing in the community. In developing countries like ours, the asses to vascular intervention centers are less when compared to the west, and this coupled with the delay in referring patients to higher centers makes amputation of the lower extremity, the only option at the time of presentation.

The technical simplicity of major amputations stands in contrast to the clinical complexity of the patients requiring them. Surgeons performing amputations should accord them the same attention to detail as complex extremity arterial reconstruction.

The goal of amputation is to remove all infected, gangrenous and ischemic tissue and to provide the patient with the greatest length of functional limb.

Avoiding repeated amputations and non-healing operative sites is critical for the recovery of the patient and optimal functional rehabilitation and palliation.

Fogarty catheter thrombectomy is a very easily performed procedure which takes very little extra time, needs no extra expense, needs no extra equipment apart from the catheter, has no morbidity associated with the procedure while establishing better circulation to the stump as evidenced by a statistically significant reduction in flap necrosis rate.

Reduction in surgical site infection and average hospital stay post-op was not statistically significant in our study. A study with a larger sample size may throw new light into this.

This study demonstrates the technical feasibility of performing Fogarty catheter thrombectomy in above knee amputation patients and demonstrates its ability to reduce the occurrence of flap necrosis. This may offer surgeons opportunity to improve stump healing and avoiding revising an amputation to a higher level. Most people consider amputation as an end point, but for the patient it is the beginning of a new life, a healthy amputation stump makes that life comfortable and happier.

Limitations

We acknowledge the following limitations to our study.

- Ours is a single-center cohort study.
- Another limitation is the small sample size, which can introduce bias into the statistical evaluation of the cohort.

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