

Peripheral vascular thrombo-embolism and the role of various fogarty arterial thrombo-embolism catheters: A comparative prospective study and its result

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ABSTRACT

Introduction: Acute embolism and thrombosis are the commonest cause of peripheral vascular occlusion. Acute ischemic rest pain is the common mode of presentation in an emergency department. Majority of vascular thromboembolism are presented in late stage. Usage of Fogarty arterial embolectomy catheter results in incomplete thromboembolism and the poor chance of revascularization. It leads to a greater chance of amputation and mortality. Usage of Fogarty adherent clot catheter with Fogarty arterial embolectomy catheter has an advantage. It does not only improve the rate of better revascularization but also salvage the limbs and reduces the mortality.

Materials and methods: It is randomized prospective study, includes 200 patients from December 2015 to January 2018. 100 patients each in group A and group B. Fogarty arterial embolectomy catheter used alone in Group A and Fogarty arterial embolectomy catheter with Fogarty adherent clot catheter used in Group B.

Results: It is proven that usage of Fogarty adherent clot catheter along with Fogarty arterial embolectomy catheter in thromboembolism, results in better peripheral limb revascularization.

Conclusion: Regardless of the time of the presentation, use of Fogarty adherent clot catheter with Fogarty arterial embolectomy catheter has the better outcome.

Key Words: Embolism; Thrombosis; Fogarty catheter; Artery; Amputation

INTRODUCTION

Thrombo-embolism is the commonest cause of critical limb ischemia worldwide. They are responsible for the major disabilities and death due to septic gangrene. Acute vascular embolism and thrombosis have different underlying pathophysiology, treatment and outcome. The result of treatment depends on the time of presentation and conditions of the organs affected (1).

Majority of the source of embolism is due to the atrial fibrillation caused by ischemic heart disease and rheumatic heart disease (2,3). The *in-situ* thrombosis caused by ulcerated atherosclerotic plaque, hypercoagulable state, vascular stenosis, dehydration, trauma and previous vascular bypass surgery (4).

The lower limb vessels frequently affected compared to upper limbs. Thromboembolism of brain, mesenteric and renal arteries are rare and life-threatening. Cardiac source of emboli inflicts multiple organs with variable severity.

Manifestation depends on the limbs, bowel, renal and cerebral ischemia. Ultimate outcome correlates with organ involved, time of presentation and collaterals. The symptomatic thrombo-embolism needs aggressive assessment and intervention compared to asymptomatic thrombosis (5).

Historically open incomplete thromboembolism was associated with higher incidence of amputation and deaths. The invention of Balloon Fogarty catheter and its further modification lead to a decreased incidence of amputation and deaths (6). No single device offers complete extraction of primary and secondary embolus to achieve total revascularization. Catheters selection is based on cause, source and composition of the thrombus. The rate of revascularization dictated by the type of catheters due to the varied tensile strength of balloons and wires to extract thrombo-embolus (7).

MATERIALS AND METHODS

It is a prospective study comprising 200 patients, suffering from limb ischemia due to vascular thromboembolism.

Patients with limb ischemia due to thromboembolism, who were symptomatic for 3 months or less included in the study. They have been evaluated for the causes, co-morbidities and conditions of the limb at the time of presentation. The severity of the limb ischemia assessed as per Rutherford classification (8). Diagnosis confirmed by vascular Doppler study and C T angiogram. Patients who were asymptomatic, thrombosis over 3 months, vascular trauma, peripheral vascular disease and critically ill excluded from the study.

Group A (n-100) underwent thromboembolism with Fogarty arterial embolectomy catheter (Figure 1). Group B (n-100) underwent thromboembolism with the help of both Fogarty adherent clot catheter and Fogarty arterial embolectomy catheter (Figure 2).

Groups A and B evaluated to compare device efficiency based on the complete extraction of thrombus, revascularization, relief of pain, limb salvage, mortality and the complications.

Majority of the procedure was done under local anaesthesia. Injection heparin 5000 IU, bolus dose given, 3 minutes before clamping vessels. The



Figure 1) Group A: Fogarty arterial embolectomy catheter

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technique of thromboembolectomy followed based on the group. Post-op patients put on injection Heparin infusion, 20 units per kg body weight per hour, till PT/INR optimised by oral anticoagulants. Activated clotting time (ACT) done twice a day, to maintain between 180 to 250. The peripheral pulse recorded by a palpatory method and Doppler probe.

Patients were assessed by vascular Doppler study of the operated limb to evaluate the extent of the revascularization.

RESULTS

In our study, 65 in group A (65%) and 59 in group B (59%) were male patients (Figure 3). Majority of patients were between 40 to 70 years in both groups (Figure 4).

79 group A (79%) and 64 group B (64%) were smokers (Figure 5). 58 group A (58%) and 53 group B (53%) had a history of hypertension (Figure 6). Diabetes mellitus found in 42 group A (42%) and 54 group B (54%) (Figure 7).

In 8 group A (8%) and 7 group B (7%) cases had pre-gangrene at the time of presentation (Figure 8).

Group A involved, 34 femoral arteries (34%), 36 popliteal arteries (36%), four infrarenal aortae (4%), 12 iliac arteries (12%), ten axillary arteries

(10%), four subclavian arteries (4%). In group B, 37 femoral arteries (37%), 39 popliteal arteries (39%), three infrarenal aortae (3%), nine iliac arteries (9%), six subclavian arteries (6%), six axillary arteries (6%) were involved.

In group A 56 right limbs (56%), 36 left limbs (36%) and 8 bilateral limbs (8%). in group B, 52 right limbs (52%), 38 left limbs (38%), 10 bilateral limbs (10%) involved.

As per Rutherford classification, in group A 40 class I (40%), 31 class II a (31%), 28 class II b (28%) and one class III (1%). in group B 34 class I (34%), 42 class II a (42%), 22 Class II b (22%) and two Class III (2%) were present (Figure 9).

Minor device-related complications found. Group A had two dissections (2%), one haematoma (1%), and one embolization of ruptured bit of balloon (1%). In group B one perforation (1%), three haematoma (3%) and one vascular avulsion (1%).

Postoperatively, eight group A (8%) and two group B (2%) cases had to undergo re-embolctomy for persisting pain and thrombosis of vessels. Post

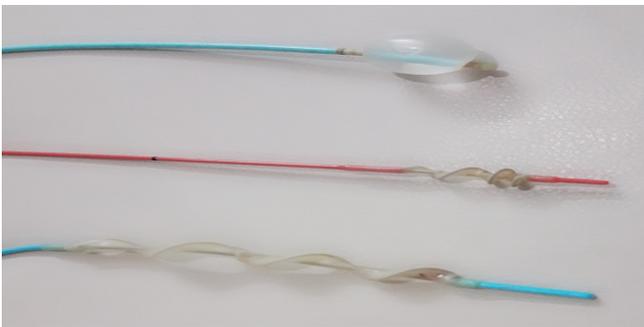


Figure 2) GroupB: Fogarty arterial embolectomy catheter and fogarty adherent clot catheter

Smoking

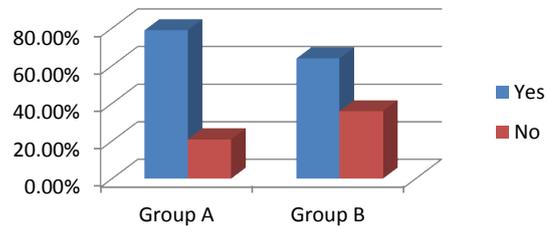


Figure 5) Smoking

Hypertension

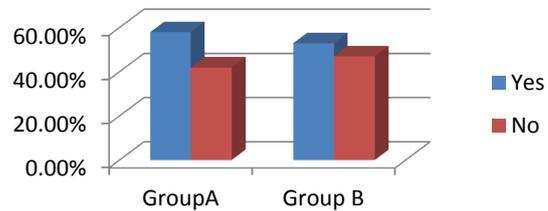


Figure 6) Hypertension

Diabetes

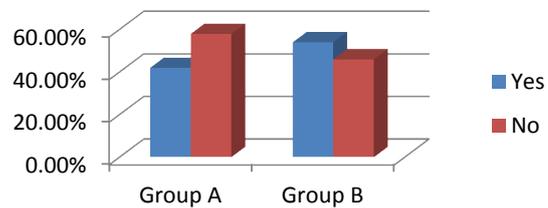


Figure 7) Diabetes mellitus

Pre-op Gangrene

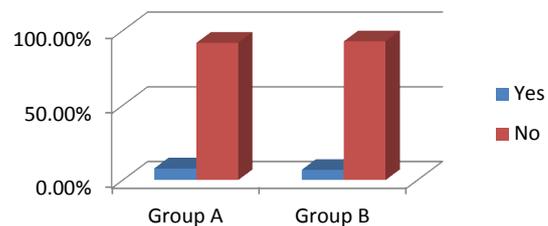


Figure 8) Preop gangrene

Gender

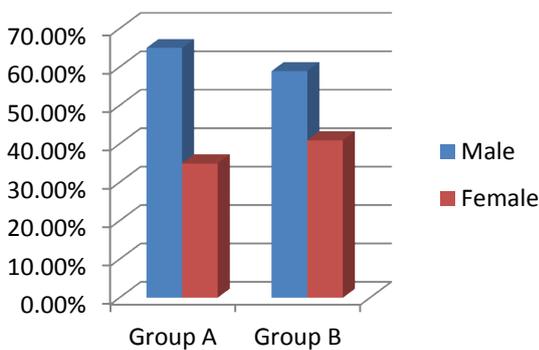


Figure 3) Gender distribution

Age Group

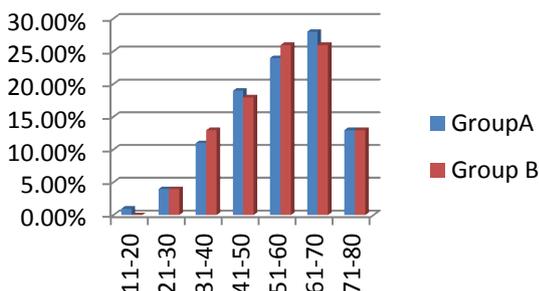


Figure 4) Age distribution

thromboembolism, in group A, four below knee amputation (4%), four forefoot amputation (4%) and two toe disarticulations (2%) compared to group B, one below knee amputation (1%) and two toe disarticulation (2%) done, which is a significant finding (p-value 0.05). Three group A (3%) and one group B (1%) patient died due to progressive septicaemia.

Postoperative Doppler study evidently showed, in group A 20 monophasic flow (20%), 50 biphasic flow (50%) and 30 triphasic flow (30%) compared to group B ten monophasic flow (10%), 40 biphasic flow (40%) and 50 triphasic flow (50%) found, which is significant finding (p-value 0.009) (Figure 10).

DISCUSSION

Cardiac source of embolism and vascular in situ thrombosis are the commonest cause of ischemia leading to disability and mortality. Thromboembolism frequently found in peripheral limbs. The incidence of upper limb ischemia and gangrene less compared to lower limbs due to collaterals (9). Extent and severity of ischemia dictate the outcome of treatment. The high rate of mortality found in acute arterial ischemia due to the release of toxins from the affected limb (10). The goal of intervention to re-establish circulation, restoring pulses, pain relief and salvage the limb.

The incidence of chronic arterial thromboembolism unusual but not rare. Early detection and appropriate management either thromboembolism or bypass surgery salvage the limbs (11). *In-situ* thrombosis due to prothrombotic endothelium caused by hyperhomocysteinaemia or ulcerated atherosclerotic plaque (12). Ulcerative plaque can induce blue toe syndrome due to the shower of crystal cholesterol microembolization. It can also put life and limbs in danger in case of larger embolization. Proximal major vessel embolectomy required to save the life of patients and distal vessel embolectomy required to save limbs (13).

Options for treatment of the thromboembolism based on cause, time of presentation and severity of limb ischemia. Treatment with Intravenous anticoagulation, catheter-directed thrombolysis, thromboembolism by Fogarty catheters and bypass surgery used (14,15).

In selected patients, thrombolysis has a successful role (16). Emergency dissolving thromboembolism guarantees the limb salvage and prevents mortality (17). Catheter-directed thrombolysis has been tried in various studies. It showed, dissolution of embolus in 70%, 80% symptoms free and 80% limbs salvaged. Infusion of thrombolytic agent for 24 hours or more showed better results. The major drawback is the significant incidence of cerebral haemorrhage and embolic stroke (18).

Pre Fogarty arterial embolectomy catheter era, Procedure of thromboembolism was cumbersome and time-consuming. Majority of the cases were needed multiple arteriotomies in multiple sites of vessel walls. High incidence of incomplete thromboembolism with progressive

ischemia terminated into either amputation or death. Innovating newer techniques and devices for thromboembolism worked in few and most remained unsuccessful (19-21).

Dr Thomas Fogarty invented Fogarty arterial embolectomy catheter in 1963 and presented a paper in 1965, about his experience. Fogarty catheter embolectomy becomes minimally invasive, the fast technique does complete or near complete embolectomy, re-establishing the circulation. It leads to dramatic reduction in the incidence of amputation and death (22). Recent studies have shown, simple Fogarty arterial embolectomy catheter, useful in the selective group of patients. Successful in less 50% of cases and remaining 50% of cases would require other forms of percutaneous catheter intervention or bypass surgery (23). Simple embolectomy enables extraction of the thromboembolic load if presented at an early stage as long as vessels are not diseased (24). The option of delayed thromboembolism has a definitive role in establishing vascularisation with gratifying results. This avoids surgical bypass and related complications (25).

The incidence of *in-situ* thrombosis has been increased in native vessels and prosthetic grafts. The technique of percutaneous aspiration of thrombus useful in selective patients (26). Primary success of aspiration is about 60% and secondary technical success is 96% (27).

The mechanical thromboembolism catheters have been modified to suit to remove organised adherent thrombus and prosthetic graft thrombus. Endovascular catheters have been developed and utilized as per suitability for underlying disease and time of presentation (28).

The hydrodynamic device is made and used for fragmentation of the thrombus followed by aspiration in selective patients (29). The hydrodynamic catheter has two lumens, can be used to shred the thrombotic material and aspirated by venturi effect simultaneously (30). Mechanical devices can also be used for complete or partial recanalisation of vessels (31). Amplatz device is one such a promising option. It helps faster and safe recanalisation of peripheral chronic thromboembolic occlusion of arteries (32).

Surgical thromboembolism is a blind procedure. It is difficult to assess on the table about the completion of thromboembolism. To overcome this shortfall, studies have been done to improve technique and to assess completeness of thromboembolism (33). It is found that fluoroscopically assisted thromboembolism (FATE) greatly improves the results of the treatment. It helps to negotiate the catheter, gives the idea of completion of embolectomy and decreases the catheter-related complications (34).

Nature of consistency of embolus and thrombus varied with an underlying cause and duration of occlusion (35). Mere usage of Fogarty balloon arterial embolectomy catheter remains inadequate in a majority of the cases, who presents after 72 hours. Such embolus gradually get organised with the intima of a vessel as primary embolus with neo secondary embolus formed proximal and distal to it due to stasis of blood. It is difficult to extract organised thromboembolism with simple Fogarty arterial embolectomy catheter. This is true and evidently seen on our postoperative Doppler study. Secondary embolus remains fragile and unstable, it's likely chances of migration into the distal smaller vessels are very high. Its clearance by antegrade and retrograde embolectomy dictates completeness of revascularization.

Fogarty arterial embolectomy balloon catheters, inflation volume and pull force has its limitations. Beyond a limit, likely chance of rupture of the balloon is high, if tried for an adherent or organized thromboembolism. It is advocated for simple embolectomy in acute embolism preferably lesser than 72 hours. It should not be used for fibrous or adherent thrombus (36). Acute embolism and presentation of such cases within 72 hours, rare in the Indian scenario. Majority of symptomatic cases presented to us after week or more.

Fogarty adherent clot catheter flexible, made of polyvinyl chloride surrounding stainless steel spring body. It has a handle to modulate spiral cable diameter as per requirement. Device easy to negotiate through organised, even sometimes calcified thrombus and able to clear occlusion. It enhances results of complete revascularization (37). This unique characteristic of adherent clot catheter helped us to extract maximum embolism and got better revascularisation results. It has reduced number of amputations and deaths.

All types of Fogarty thromboembolism catheters and its modified percutaneous devices are an indispensable collection in the armamentarium of thromboembolism. Catheters are simple, safe and easy to use. Immensely helped to salvaged millions of limbs and life. Device-related

Rutherford Classification

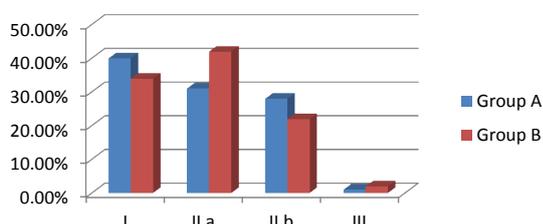


Figure 9) Rutherford classification

Post Op Doppler Report

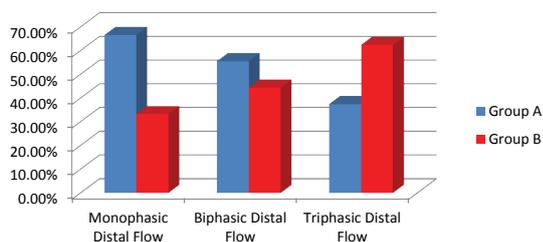


Figure 10) Post op doppler study

complications were minor and rare. Complications in the form of vessel dissection, perforation, haematoma, rupture and avulsion of vessels found (38). Majority of the complications treated conservatively. In one of the cases, popliteal artery got avulsed, during usage of adherent clot catheter. Reanastomose of the vessel done uneventfully. Amount of traction and recoiling diameter of adherent clot catheter has to be controlled, based on the quality and diameter of the vessels.

CONCLUSION

Complete extraction of primary and secondary thrombo-embolus is the mainstay for re-establishing peripheral circulation. Using Fogarty adherent clot catheter with Fogarty arterial embolectomy catheter has the greater advantage in achieving the purpose. Fogarty adherent clot Catheter usage evidently reduced the incidence of amputations and mortality.

It's safe and easy to use Fogarty adherent clot catheter with the minimum learning curve. No serious complications found if used with appropriate precautions.

DECLARATION OF CONFLICTING INTERESTS

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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