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Comparison of Outcome between Transradial and Transvenous Percutaneous Angioplasty for Stenosed Hemodialysis Access Fistula

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ABSTRACT:

Background*:* The outcomes of enhancing vascular access remain an ongoing challenge for vascular surgery. Mature fistulas have better longevity and require fewer interventions. The major obstacle to increasing fistula approach is the higher rate of failure due to the maturity of newly created fistulas. Hemodialysis access fistulas are the lifeline of an end stage renal disease patient on hemodialysis. With the raise in the rate of development of end stage renal disease, the creation of arteriovenous fistula has become the most frequent performing procedure in a vascular surgery outpatient department.

Aim of The Study*:* The purpose of this study was to compare the early and long-term outcomes of trans venous and trans radial fistuloplasty in a single surgeon's practice and to provide information on treatment strategies for patients with end-stage renal disease.

Material & Methods*:* This prospective study was carried out in vascular care center in Ibn Sina hospital, Dhanmondi, Dhaka, Bangladesh from 2017 to 2019. A total number of 50 patients who needed endovascular interventions for non-functioning fistula, were selected for the study. The inclusion criteria were thrombotic or fibrous stenosis of >50% of luminal area and flow volume <600ml/min on Doppler ultrasound study. The exclusion criteria were-primary failure of AV fistula, critical stenosis *(*>90% reduction in luminal diameter*)*, long segment venous stenosis *(*>2.5cms*)*, stenosis that were associated with the presence of a small or calcified or stenotic feeding artery due to progressive atherosclerosis.

Results*:* The mean age of patients was 54.14±7.05 and 50.3±8.65 years. Male were 18*(*51.4*%)* & 17*(*48.6*%)* and female 9*(*60*%)* & 6*(*40*%)* in group A and group B. Three types of intervention offered *(*thrombolysis 6*%*, balloon dilatation 74*%* and stenting 20*%)*. Follow up after 6 months, 80*%* fistula were functional and 20*%* non-functional.

Conclusion*:* Conventional trans venous fistuloplasty, is an effective way of dealing with a non-functioning haemodialysis fistula. In the past, this technique was employed for maintaining access for hemodialysis. Transradial approach is relatively safer, as it has fewer chances of distal

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embolization. The identification of AV anastomosis is easier and the whole procedure can be performed safely with less fluoroscopic exposure.

Keywords*:* Fistula, stenosis, vascular, access, hemodialysis

INTRODUCTION:

Hemodialysis access fistulas are the lifeline of an end stage renal disease patient on hemodialysis. With the raise in the rate of development of end stage renal disease, the creation of arteriovenous fistula has become the most frequent performing procedure in a vascular surgery outpatient department.[1] Due to the limited sites available for the creation of fistula, maintenance of its patency demands an aggressive approach.[2]Location and type (anatomic, extra anatomic, autologous and graft) of a hemodialysis fistula depends on a number of patient variables like the adequacy of venous and arterial anatomy. Autologous anatomical fistula is the choice because of their higher patency rate and longer usability for hemodialysis access.[3-5]There are several different types of autogenous arteriovenous fistulas. The most common type in the forearm is the Brescia-Cimino/radio cephalic fistula, which is built at the wrist between the radial artery and the cephalic vein, usually end-to-side, or the proximal radial artery anastomosed with the median antebrachial vein side-to-side.[6] Another method is to use an end-to-side anastomosis of the brachial artery and the cephalic vein at the cubital fossa. These fistulas are typically formed in the non-dominant forearm, unless there is an unfavorable anatomy.[1]Two factors are essential for an arteriovenous fistula to be usable for hemodialysis- the adequate blood flow and a caliber sufficient to allow cannulation.[7] Failure of an autogenous fistula results from a variety of causes and leads to different form of stenosis or occlusion. Inflow stenosis results from neointimal hyperplasia at juxtra anastomotic site, presence of an anatomically small vessel and atherosclerotic disease due to the co-existence of comorbidities like hypertension and diabetes.[6,7] Venous outflow stenosis on the other hand, is usually caused by thrombosis due to reduced blood flow resulting from a stenotic vein from pre-existing anomalies such as anatomical small vein and fibrotic segments developed due to previous puncture site.[7]Intervention of a non/poorly functioning fistulae is indicated when there is stenosis of >50% of luminal area and fistulae flow volume is <600ml/min on Doppler ultrasound study.[7,8]Both surgical and endovascular management are established modalities for the repair of a non/ poorly functioning fistula.Due to the advancement of endovascular technique, it is now regarded as the first line treatment than conventional surgery. Endovascular techniques are less invasive, preserved native tissue better and the access can continue to be used after 24 hours. Trans venous andtrans radialendovascular approachesare commonly deployedfor intervention of stenotic or occluded fistulas. Both the two approaches have their own merits and demerits. The access vein is usually dilated (in mature fistulas) and rarely spasms in standard transvenous access. Large diameter angioplasty balloons and stents can also be accommodated. The major disadvantages of this access are the difficulty in identifying AV anastomosis, the possibility of distal embolization, and puncture site occlusion due to compression after the procedure. With a single puncture, transradial access allows for the evaluation and treatment of an entire fistula from the afferent artery to the central veins.It also has minimum risk of embolization and post procedure hemostasis (radial artery) is easily achieved due to its superficial location. However, puncture of radial artery is technically demanding and the narrow caliber may hinder the passage of wide sheaths for further procedure. Multiple puncture over the radial artery, sometimes, may lead to occlusion.[9] The aim of thisstudy

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was to evaluate the difference of earlyand long-term outcomes following trans venous and trans radialfistuloplasty in a single surgeon's practice and toprovide details regarding treatment strategies forpatients having end stage renal disease.

MATERIALS & METHODS:

Between the years 2017-2019, this prospective study was carried out in vascular care center in Ibn Sina hospital, Dhanmondi, Dhaka. A total number of fifty (50) patients who needed endovascular interventions for non functioning fistula, were selected for the study. The same vascular surgeon performed both trans venous (Group A) and trans radial (Group B) interventions. The inclusion criteria for intervention were thrombotic or fibrous stenosis of >50% of luminal area and flow volume <600ml/min on Doppler ultrasound study.[10] The access point (trans venous/trans radial) for PTA were decided on the basis of physical examination, anatomicpattern, suspected type, review of relevant imaging and operator preferences.The exclusion criteria for this intervention were-primary failure of AV fistula, critical stenosis (>90% reduction in luminal diameter), long segment venous stenosis (>2.5cms), stenosis that were associated with the presence of a small or calcified or stenotic feeding artery due to progressive atherosclerosis.[11,12]Procedural details: Preoperatively, all the patients were clinically examined with Allen's test. Immediately prior toAVF intervention, Fentanyl Citrate and Midazolam Hydrochloride were administered intravenously for conscious sedation. During the whole procedural period the patient was monitored using pulse oximetry, automated blood pressure measurement and continuous electrocardiography using continuous monitoring system. The puncture site was infiltrated with 02% Lidocaine and systemic heparinization were done. For transvenous access, under duplex guidance, puncture was made using 21G needle. A hydrophilic guidewire was passed; vascular sheath of 5-6F was introduced over the guidewire. For thrombolysis a 5F catheter were advanced into the superior vena cava. The catheter was slowly withdrawn, while contrast material was injected under fluoroscopy to clarify the location and extent of thrombosis. De-clotting was attempted using urokinase/t-PA. The venous outflow was de-clotted prior to arterial inflow to minimize systemic embolization. For stenotic lesion appropriate balloon catheterof different size (Mustang, Boston, USA) were introduced over the guidewire. After proper placement of the balloon, it was inflated up to 20-25atmuntil the disappearance of the waist for 2 minutes. The diameter of the balloon was determined by measuring the non-stenotic portions of the vessel above and below the stenosis. On completion, fistulogramwas performed and haemostasis was ensured using local compression.

Figure: **I Ballon used in Fistuloplasty with guidewire**

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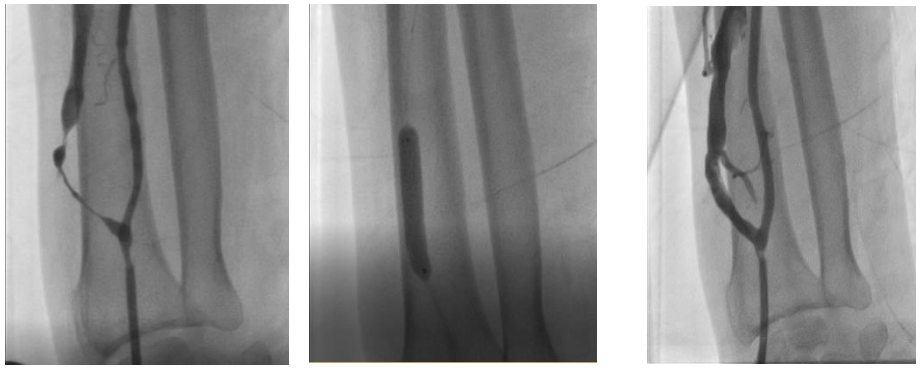

Figure*:* **IITransradial Approach**

Fig*:* **III Sheath**

Fig*:* **IV Catheter**

Fig*:* **V Puncture Needle**

For trans radial access, the wrist was kept hyperextended at ≥60° while supported from the back with a rolled towel. Under duplex guidance puncture was done using 21G puncture needle 2to 3 centimeters distal to anastomosis. A 0.018-inch guidewire was then passed. A 5-6 F sheath can usually be passed through the radial artery over the guidewire proximal to anastomosis. The sheath was then gradually removed (keeping the guidewire in situ), while injecting contrast to visualize the condition of the non-functioning fistulae. Once transradial access is established de-clotting and/or angioplasty can be carried out safely. For thrombolysis or de-clotting urokinase/t-PA is used via a 5F catheter inserted into the proximal part of occluded fistulae. Further dilatation and mobilization of thrombus is performed using 4-5mm PTA balloon with low-pressure hand inflation. For recurrent stenosis, self-expandable metallic stents 7-8mm of diameter with variable lengths were deployed in some cases. On completion, fistulogram was performed and haemostasis was ensured during local compression.Study endpoint and follow up: The primary end-point of the study was the diameter and flow rate of fistula at 6 months' Doppler study. The secondary end-point was the comparison of outcome and level of compliance during hemodialysis after the intervention. During the study period, all patients were followed up on OPD basis and necessary data was recorded in preformed data collection sheet for further analysis. SPSS version 24 was used for all statistical analyses. Continuous variables were

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expressed as mean(SD), and categorical variables as percentages. Pearson's chi-square test was used to compare categorical variables.

RESULTS

Different parameters of demographic profile between group A and group B were statistically insignificant (p >0.05). The mean age of patients was 54.14±7.05 and 50.3±8.65 years in groups A and B respectively (p=0.90). Male patients were 18(51.4%) and 17(48.6%)and female patients were 9(60%) and 6(40%) in group A and group B respectively (p=0.577). The difference of mean BMI (24.44±3.73 in groupA and 24.6±3.9 in group B) was also not significant statistically (p=0.86). In terms of the presence of one or more co-morbidity (hypertension, diabetes or both) in patients, both the groups have statistically insignificant characteristics (p= 0.35, 0.82, 1.00 respectively.Patient underwent PTA for non-functioning fistula and 3 types of intervention were offered to them (thrombolysis 6%, balloon dilatation 74% and stenting 20%). At follow up after 6 months, 80% fistula were functional and 20% non-functional.

Table 1: **Demographic profile**:

	Group A (Trans venousApproach) n=27	Group B (TransracialApproach) n=23	p Value
[a]Age	54.14±7.05	50.3±8.65	0.90^{ns}
[b]Sex			0.577^{ns}
Male	18 (51.4%)	17 (48.6%)	
Female	9 (60%)	6 (40%)	
[a]BMI	24.44±3.73	24.6±3.90	0.86^{ns}
[c]Diabetes	10 (66.7%)	5 (33.3%)	0.35^{ns}
[b]Hypertension	9 (56.3%)	7 (43.8%)	0.82^{ns}
[c]MultipleComorbidity	4 (57.1%)	3 (42.9%)	1.00^{ns}

Qualitative data were analyzed using Chi Square test/ Fisher's Exact test. Quantitative data were analyzed using independent t test. P value ≤0.05 were considered significant

*a= independent t test,

*b= Chi square test,

*c= Fishers exact test,

*ns=non-significant, *s= significant.

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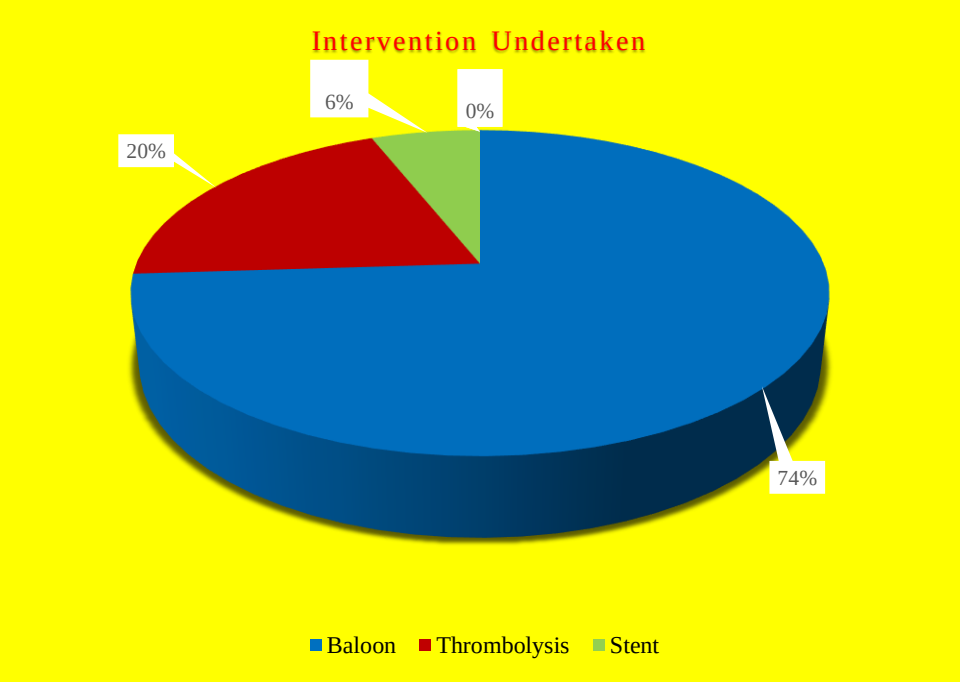

Figure: **VI Pie chart showing interventions undertaken for non-functions fistulas**

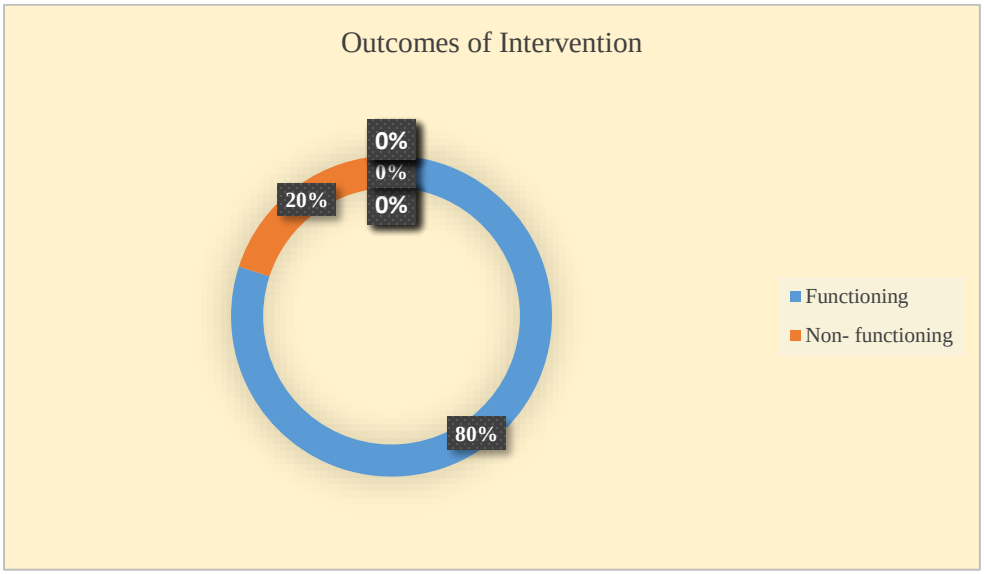

Figure: **VII Pie chart showing outcome of intervention**

Non-functioning fistula were significantly higher in patients with multiple co-morbidity due to re-stenosis, however it had no effect on the incidence of re-thrombosis & infection.

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Table 2: **effect on outcome of multiple and single comorbidity**

	Multiple Comorbidity (n=7)	Single Comorbidity (n=43)	p Value
Failure	6	4	<0.001[s]
Re-stenosis	4	1	0.001[s]
Re-thrombosis	1	1	0.263[ns]
Infection	2	0	1.00[ns]

Data were analyzed using Fisher's Exact test. p value ≤ 0.05 were considered significant. **ns=non-significant, *s= significant*

Evaluation of duplex parameters after six months of intervention, proves no statistically significant difference of mean flow rate, re-thrombosis, re-stenosis and infection (p=0.825, 1.0, 1.0 and 0.49 respectively) between patients undergoing PTA either by transvenous or transradial access. The occurrence of distal embolization, however, was statistically higher in transvenous PTA for non-functioning fistula (p=0.05).

Table 3: **Outcome of intervention**:

	Trans venousAccess (n=27)	TransracialAccess (n=23)	p value
[a]Mean Flow rate	544.7±155	553.82±129.9	0.825[ns]
[c]Thrombosis	1 (3.7%)	1 (4.3%)	1.00 [ns]
[c]Stenosis	3 (11.3%)	2 (8.7%)	1.00 [ns]
[c]Infection	2(7.4%)	0 (0%)	0.49 [ns]
[c]Embolization	5 (18.5%)	0 (0%)	0.05 [s]

Qualitative data were analyzed using Fisher's Exact test. Quantitative data were analyzed using independent t test. P value ≤ 0.05 were considered significant.

*a= independent t test,
*b= Chi square test,
*c= Fishers exact test,
*ns=non-significant, *s= significant.

DISCUSSION:

Patients undergoing PTA for nonfunctioning fistula were grouped (A=transvenous, B=transradial) according to approach through which they were dealt with. The demographic characteristics of the patients the groups, in terms of age, sex, BMI were uniform with statistically insignificant variation. Presence of one (diabetes, hypertension) or more (Patients with both hypertension and diabetes) co morbidity was also similar in both groups.Majority of

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patients of both groups needed balloon dilation (74%) and only 10% of patient needed stent placement. Thrombolysis was done in 3 cases (6%), due to fact that the procedure is technically demanding and very expensive to carry out in our center. Outcome of evaluation of PTA done for non-functioning fistula, were evaluated after 6months using Doppler ultrasonography. The success rate of PTA intervention in our center was 80%, which is similar to a previous study carried out at Sweden.[13]There is also a statistically significant relationship of post PTA failure due to stenosis and presence of multiple co-morbidity (p=0.001), which is in par with a previous study.[14]Variation of approach to conduct PTA for non-functioning fistula, did not result in any statistically significant difference in post procedure complications like re-thrombosis, re-stenosis and infection (p>0.5).However, the rate of distal embolization was significantly higher in transvenous approach (p=0.05). Embolization following PTA using transvenous access is a recognized complication and have been reported in many studies.[9]

CONCLUSION:

Conventional transvenousfistuloplasty, is an effective way of dealing with a non-functioning haemodialysis fistula. In the past, this technique was employed for maintaining access for hemodialysis. Because of the recent technological development, newer techniques like transradial PTA, are being used more frequently. Transradial approach is relatively safer, as it has fewer chances of distal embolization. The identification of AV anastomosis is easier and the whole procedure can be performed safely with less fluoroscopic exposure.

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CONFLICT OF INTERESTS

The authors of the manuscript have no potential conflict of interests.

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