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" Balloon management of Dysfunctional Arteriovenous Fistula for Hemodialysis with Ligation of Competitive Veins "

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Abstract:

Introduction: Arteriovenous fistula (AVF) is the recommended access for patients in need for long term hemodialysis (HD). The primary dysfunction of AVF because of stenosis is a surgical problem and need to manage it. The aim of the study is to salvage AVFs by balloon angioplasty. **Methods:** a prospective clinical study was done from July 2019 to November 2022, including 42 dysfunctional native AVFs, and recommended for endovascular salvage. Follow up of patency of AVF along duration of the study (12 months) post-intervention using fistula-gram to estimate the success and patency rate with preserving function. **Results**: the study was done on 42 end stage renal disease (ESRD) patients. 42 AVFs, aged 45.6 ± 14.2 years, 27 (64.3%) were males, 15 (35.7%) were females, 3 (7.1%) patients were smokers, 33 (78.6%) of the patients were diabetics, 32 (76.2%) patients were hypertensive and 27 (64.3%) patients have ischemic heart disease. The stenotic lesions were detected in AVA in 4 (16.7%) patients, Juxta-anastomotic in 3 (12.5%) patients, Proximal venous outflow in 6 (25%), distal venous outflow in 7 (29.2%) and lesion in central venous in 2 (8.3%) patients. Success rate was recorded in 30 (71.4%) patients. **Conclusion:** Endovascular approach for treatment of non-functioning AVF is safe and efficient for maturation of the AVF and make it useful for hemodialysis.

Keywords: Arteriovenous fistula, Balloon angioplasty, hemodialysis, Stenosis.

Introduction

Autogenous (AVFs) still the most recommended type of dialysis access in (ESRD) patients, on regular (HD). In comparing of arteriovenous grafts (AVGs) with permanent venous catheters. AVFs are considered longer patency, lower failure rate and less liability of infection. [1,2] nevertheless, failure of maturation of AVFs still the common disadvantage in up to 65% of patients. [3–9]

The perfect size of the functioning AVFs that could be cannulated when the vein $\geq$ 6 mm in diameter, depth < 6 mm, the flow rate > 600 mL/min and adequate subcutaneous tissue to avoid leakage and extravasation at puncture site. [10]

Competing branches (collaterals) are considered a resisting factor for AVF maturation because, when plenty, they could steal the blood flow from intended main fistula vein, affecting the recommended dilation. [11]

The maturation of AVF is affected by demographic risk factors in addition to anatomical distribution resistance, classified into three parts: The inflow tract (arterial stenosis by atherosclerosis/occlusion or juxta-

anastomotic stenosis) or outflow tract (venous stenosis and/or collateral veins). [12]

The failure of AVFs could be related to, the juxta arterio-venous anastomotic vein segment (JAV) does not reach to the recommended luminal diameter for the sake of regional hemodynamics purpose. Otherwise, in case of extensive calcific (atherosclerosis) vessels, causing blood inflow deficiency to the fistula even with appropriate vein diameter. [13, 14]

Other factors affecting maturity of AVFs and will result in failure of using it in dialysis include hereditary causes, low shear stress, increases in intraluminal pressure, turbulence, variations in wall resistance in arteries versus veins, and vascular trauma during mobilization leading to intimal hyperplasia affecting vascular remodeling. [15]

For that, by time, the increment rate of patients with functionless AVFs on account of failure of maturation in recent decades. [16]

These collected data could be resulting of alteration of patient demographics, with old age, diabetes mellitus, and renal diseases up to ESRD. As increase the chance of arterial calcification and vein sclerosis could be the leading cause of vessel readjustment, resulting in deficient blood flow low through the anastomosis. [17]

The important Forecasts for failure AVF maturation could be female gender, peripheral arterial disease, cerebrovascular disease, and narrowed cephalic vein < 2.5 mm. [18] Non-matured AVF could be defined practically by imperfect arterialization of the vein one month after creation, difficulties to get the access, or impossibility to reach flow > 300 mL/min, for possibility of successful dialysis. Also, could be defined non-mature fistula for cannulation and dialysis after overtaking 8 weeks of it. [19,20]

The Time of treatment is an important factor for saving AVFs. In most of cases, stenotic segment within the circuit in the beginning will propagate to complete vessel occlusion and thrombosis, resulting in regress in the chance of salvage of AVFs. Also, in case of early immature, the liability of regional complications during using it. [21]

In order to make AVFs back to work, endovascular treatment, by balloon angioplasty, has been considered as most recommended technique. [22-24] in addition to angioplasty, ligation any accessory vein will facilitate the rapid growth of AVFs. [25, 26]

Methods:

A prospective interventional study during the period from July 2019 to November 2022, and was done for 42 AVFs in ESRD patients on regular dialysis, after exclusion of 6 ESRD patients during follow up period post intervention. The study was done in El-Rahma specialized hospital, Omar Ibn El-Khattab specialized hospital, Lotus specialized hospital in Port Said and El-Safwa specialized hospital, Giza, Egypt.

The patients attended complaining of failure of AVFs maturation, after creation for at least 8 weeks, without success for cannulation during hemodialysis (HD).

This is included (**A**) Never used AVFs for HD because of immaturity. (**B**) First trial fistulas failure for cannulation and ignored; (**C**) Cannulated AVFs, but functionless because of deficient flow rate at the anastomosis (defined by KDOQI guidelines) [(6)] with Reduced thrill of vascular access by elevated venous tension (venous pressure of more than 150 mmHg) or diminished arterial inflow (access flow less than 600 ml/min, or less than 1000 ml/min with a more than 25% decrease nest 4 month post-operative; and (**D**) Virgin thrombosed AVFs before trial of HD. (**E**) Stenosis detected by duplex ultrasound. The excluded cases were Patients presented with thrombosed AVF, infection of AVFs, old DVT of the limb, patients presented with dye allergic reaction and in case of AVFs that became suitable for HD before intervention and after data collection.

All patients were consented and accepted participation in the study. This study was confirmed by faculty of medicine, port-said university Ethics Committee, and got ERN: MED (5/10/2022) s. no (62) SPS/VSC_005.

Technique of the procedure:

The pre-operative evaluation by duplex ultrasound (DUS) was done pre-operative for all patients to assess the arterial inflow, the anastomosis and the venous outflow drainage. Assess the flow rate of the fistula. A remarkable stenosis (≥ 50% of vein diameter) was significant.

The sites of Stenosis will be classified into: inflow arterial stenosis, juxta anastomosis arterial stenosis, at the anastomosis stenosis, juxta anastomosis venous outflow stenosis (4 cm from the anastomotic point), at the puncture point for access entrance.

The interventions were done in angio-suite, using local / regional anesthesia. Although, general anesthesia could be needed for mental, disturbed or alert patients. There were different accesses for entrance through the fistula to reach the lesion, as:

Radial artery*:* Most of cases in the study were used the radial artery access as easy entered percutaneous, good access for management of all lesions proximal or distal to the anastomosis. The entrance will be distal to the anastomosis, and not affect the blood stream through the managed fistula and less rate of post-operative complications.

Cephalic vein*:* It was used in case of difficult radial entrance, less recommended approach, on condition patent distal to anastomosis venous flow, (Figure 1, 2).

Trans brachial*:* It was less commonly used.

Fistulogram will be done first to assess the AVF, after injection 5000 IU heparin. Manipulate hydrophilic guide wire (0.035") (terumo) to cross the lesion. In case of resistance, we will use stiffer (0.018") to have more push power and smaller to deal with challenging lesions. The 5F vertebral catheter will be used to support the manipulation of the wire and facilitate crossing the lesions.

Insertion of the 6 mm / diameter balloon over the wire for dilatation of the out-flow vein, and 4 mm for anastomotic stenosis. The duration of balloon inflation will be up to 2-3 Min. in 12-14 atm. We use recurrent balloon inflation in severe or hard lesions till draining, and might require prolonged time for sustained dilatation of the tight segment. Immediate post-intervention fistulogram will be done for assessment of the flow stream through the fistula, (Figure 3).

In extensive thrombosis (fibrosis) in dysfunctional AVF, merged procedure with open thrombectomy will be done away of the site needle puncture for dialysis. This was done throw a small oblique incision on distal intact venous segment, using Fogarty catheter (5-6 Fr.) simply with gentle handling of the vein and extracting of the thrombus. Fistulogram will be repeated till gain the recommended outcomes. Competitive vein elimination will be done by surgical ligation after marking guided DUS (coils can’t be afforded for financial reasons).

Assessment of ESRD patients post intervention, for the blood flow through the AVF and presence of good thrill. The patients could start HD

immediately after improving and healed wound if present. With follow up of flow rate and if present restenosis less than 30% consider accepted.

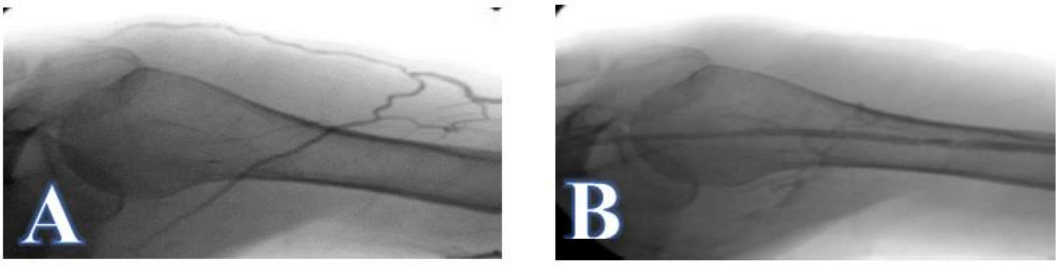

Figure (1): Fistulogram of LT. brachio-cephalic fistula (BCF), **A**) cephalic vein stenosis till the shoulder. **B**) post-dilatation of the cephalic vein with functioning AVF.

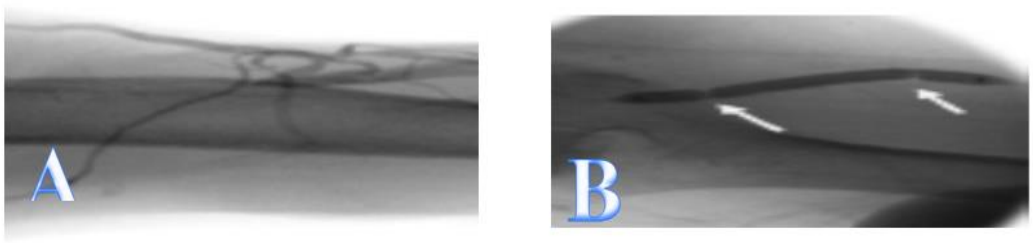

Figure (2): Fistulogram on LT. BCF with **A**) Narrowing of cephalic vein till the shoulder. **B**) Maturation of BCF by balloon angioplasty to LT. cephalic vein.

Statistical Analysis:

Chi-square test will be utilized to deal with different variables, and assess their significant, and affect the study success SPSS v26 (IBM, Chicago, IL, USA) was used for statistical analysis using the Shapiro-Wilks test and histograms. Parametric quantitative data were presented as mean and standard deviation (SD) and compared using unpaired student t-test. Kaplan-Meier curve will be used for assess the primary and secondary patency of the AVFs in relation to different factors. The statistical significance will be when P value <0.05. We performed the statistical analysis with SPSS 16.0 software.

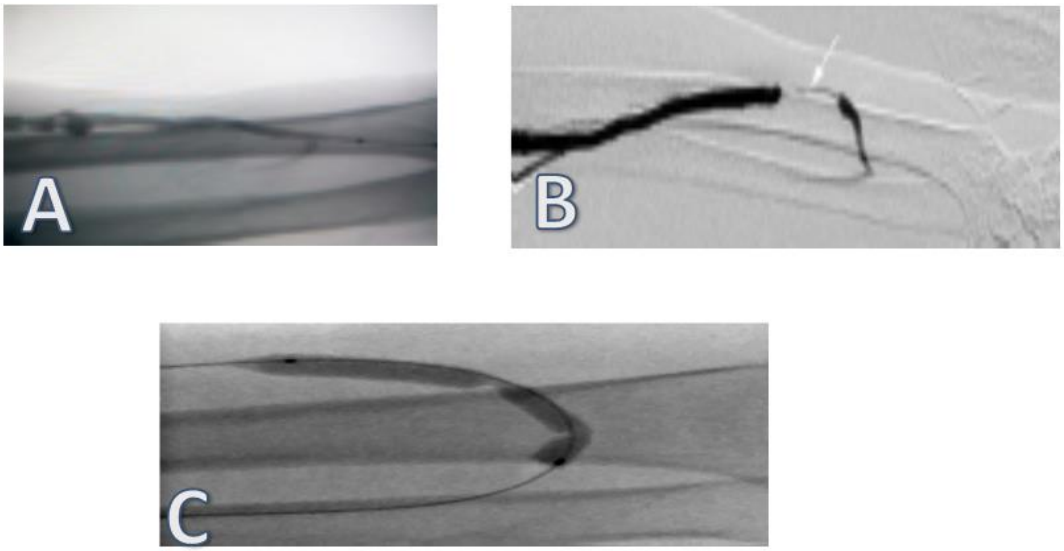

Figure (3): Fistulogram on LT. radio-cephalic fistula **A**) Narrowing at beginning and along course of cephalic vein. **B**) Occluded proximal part of the LT. cephalic vein. **C**) Balloon angioplasty of the proximal part of cephalic vein.

Results:

Through the study, 42 AVFs were involved in. Aged 45.6 ± 14.2 years (range 37-68 years), 3 (7.1%) patients were smokers, 27 (64.3%) were males, 15 (35.7%) were females. 33 (78.6%) of the patients were diabetics, 32 (76.2%) patients were hypertensive, 6 (14.2%) patients were hypotensive, 27 (64.3%) patients have ischemic heart disease, and 30 (71.4%) patients have hypercholesterolemia.

The condition the non-functioning fistula was because of significant stenosis in 24 (57%) patients and immaturity in 18 (42.9%) patients. The immaturity was because of narrowing of the anastomosis in one patient (5.6%) and non-arterialization of the vein in 17 patients (94.4%).

The noticed clinical manifestation of dysfunctional AVF were weakness of thrill 37 (8.1%) patients and resistant limb edema because of venous HTN 5 (11.9%) patients, **Table (1).**

Table (1): characters of the participants involved in the study.

Character		**Number (%) (N=42)**
Age	< 55 yrs	18 (42.9%)
	> 55 yrs	24 (57.1%)
Gender	Male	27 (64.3%)
	Female	15 (35.7%)
Risk factors	Smoking	3 (7.1%)
	D	33 (78.6%)
	HTN	32 (76.2%)
	HYPO	6 (14.2%)
	IHD	27 (64.3%)
	Hypercholesterolemia	30 (71.4%)
Condition of AVF	Stenosis	24 (57%)
	Immature	18 (42.9%)
Clinical picture	weakness of thrill	37 (88.1%)
	resistant limb edema	5 (11.9%)

Note: yrs.: years, D: diabetic, HTN: hypertension, HYPO: hypotensive and IHD: ischemic heart disease and AVF: arteriovenous fistulas

Most of dysfunction AVFs was on the LT upper limb 33 (78.6%) patients. Radio-cephalic fistula was in 19 (45.2%) patients, brachial-cephalic in 16 (38.1%) patients and Brachial-basilic in 7 (16.6%) patients. Two different accesses were used for entrance, and reach the target lesion, Trans-

venous in 11 patients (26.2%) and trans-arterial access was used in 31 patients (73.8%). Trans- brachial in 21 (67.7%) patients, Trans- radial in 9 (29%) patients and trans-femoral in 1 (3.3%) patient because of difficult access to reach the target lesion through ante-grade approach, Table (2).

Table (2): types of AVFs and site of the lesions.

Characters			Number (%)
Side	RT side		9 (21.4%)
	LT side		33 (78.6%)
Type of the AVFs	RC		19 (45.2%)
	BC		16 (38.1%)
	BB		7 (16.6%)
Access of entrance	Trans-arterial (**31** patients)	Trans-brachial	21 (67.7%)
		Trans-radial	9 (29%)
		Trans-femoral	1 (3.3%)
	Trans-venous		11 (26.2%)

Note: RT.: right, LT.: left, AVFs: arteriovenous fistulas, RC: Radio-cephalic, BC: Brachial-cephalic and BB: Brachial-basilic.

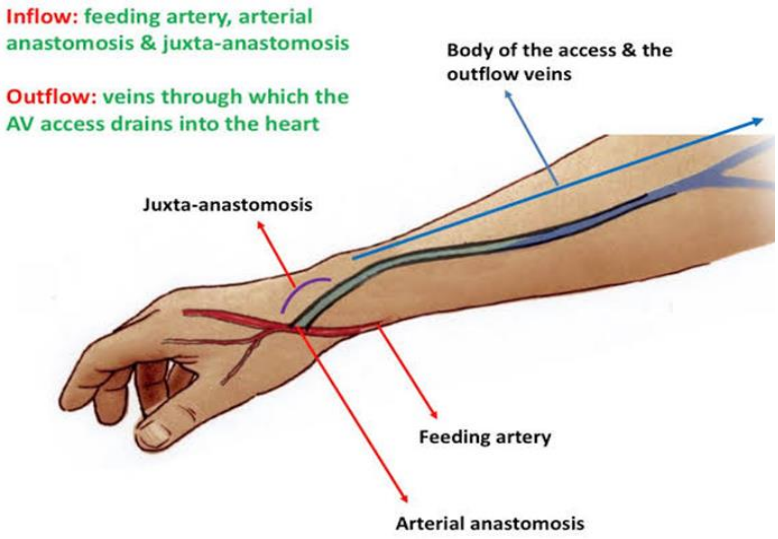

Figure (4): a drawing shows different sites of stenosis in AVF.

It was noticed that 2 (8.3%) patients had attended with a significant arterial stenosis (> 50%), stenotic lesions in AVA in 4 (16.7%) patients, in Juxta-anastomotic in 3 (12.5%) patients, Proximal venous outflow in 6 (25%), distal venous outflow in 7 (29.2%) and lesion in central venous in 2 (8.3%) patients, Table (3).

Table (3): Frequency and distribution of stenotic lesions.

location	Number (n=24)	%
Artery	2	8.3%
AVA	4	16.7%
Juxta-anastomotic	3	12.5%
Proximal venous outflow	6	25%
Distal venous outflow	7	29.2%
Central venous	2	8.3%

Notes: AVA: Arteriovenous anastomosis

During the study along the scheduled time for follow up (12 months), it was noticed only one case failed immediately post angioplasty. 3 patients failed and re-occluded after 3 months. Another 3 patients re-occluded after the period of 6 months and 5 patients after the recommended period of follow up (12 months).

It was recorded that the failure cases were highly significant in association with older age (> 55 years) than others (60.5 ± 4.72 vs 51.85 ± 6.24 years respectively)) and also associated with IHD patients 48% than Non-IHD patients 14%.

All smokers' patients failed the procedure along the follow up duration. Other factors were not significantly related to failure. Post-procedure complications were summarized in Puncture site hematoma in 3 (7.1%) patients and managed conservatively by light compression and using Thrombex cream after hot fomentation and resolved. Local inflammation was noticed in one patient, and resolved by systemic and local antibiotics.

Table (4): the AVFs clinical patency rate along the period of the study.

Outcomes		Number (%)
Direct post-operative	**succeeded**	41(97.6%)
	failed	1(2.4%)
After 3 months	**succeeded**	38(90.5%)
	failed	3(7.1%)
After 6 months	**succeeded**	35(83.3%)
	failed	3(7.1%)
After 12 months	**succeeded**	30 (71.4%)
	Failed	5(11.9%)
All after follow up	**Succeeded for dialysis**	30 (71.4%)
	Failed	12(28.6%)
Post procedures complications	**Puncture site hematoma**	3 (7.1%)
	Local site inflammation	1 (2.4%)

DISCUSSION

Previously, the usual next step post failure of AVF was plan for a new one. Subsequently, consuming of the available options for AVF formation and reflect on patient life expectancy. [(27)]

The maturity of AVFs occurs by the vessel wall remodeling and arterialization of the out-flow vein due to high arterial pressure and increased drainage blood flow. [(28)]

Failure or immaturity of designed native AVF is considered a great element of trouble for the ESRD patients. It could be detected by ‘insufficient flow through the fistula for accessibility of maintaining hemodialysis (HD).

In our research, we discussed the evaluation of role of endovascular approach using balloon angioplasty with ligation of the accessory veins for higher rate of salvaging of these immature AVFs.

Previous data has been mentioned about the endovascular approach for salvaging AVFs with contradictory results. [(29, 30, 31, 32)] So, still discussed that the maturation of AVFs by the assisted endovascular approach may demand recurrent intervention to keep the fistula patent. [(33, 34)] The Kidney Disease Outcomes and Quality Initiative (KDOQI) guidelines recommended that all

new virgin AVFs should be evaluated for maturation within 4-5 months post creation, and if doubtful noticed, immediate prepare the patient for endovascular intervention for dilatation. [35]

The failure of maturity of the AVFs usually related to stenosis, out-flow venous occlusion or neointimal hyperplasia. [36]

Through the study, the primary and secondary patency rates were 71.4% and 77% during follow up, respectively. These results are relatively related to other studies of 50% to 72 % primary patency and 68% to 79 % secondary patency, with minimal and controlled complication rate. [37-41]

It was recommended that the results could be affected by factors as the condition of the blood vessel (artery or vein): diameter, condition the wall and condition of distal out-flow, age, blood pressure and diabetes control that affect clinical out-comes and maturation of AVF. [42, 43]

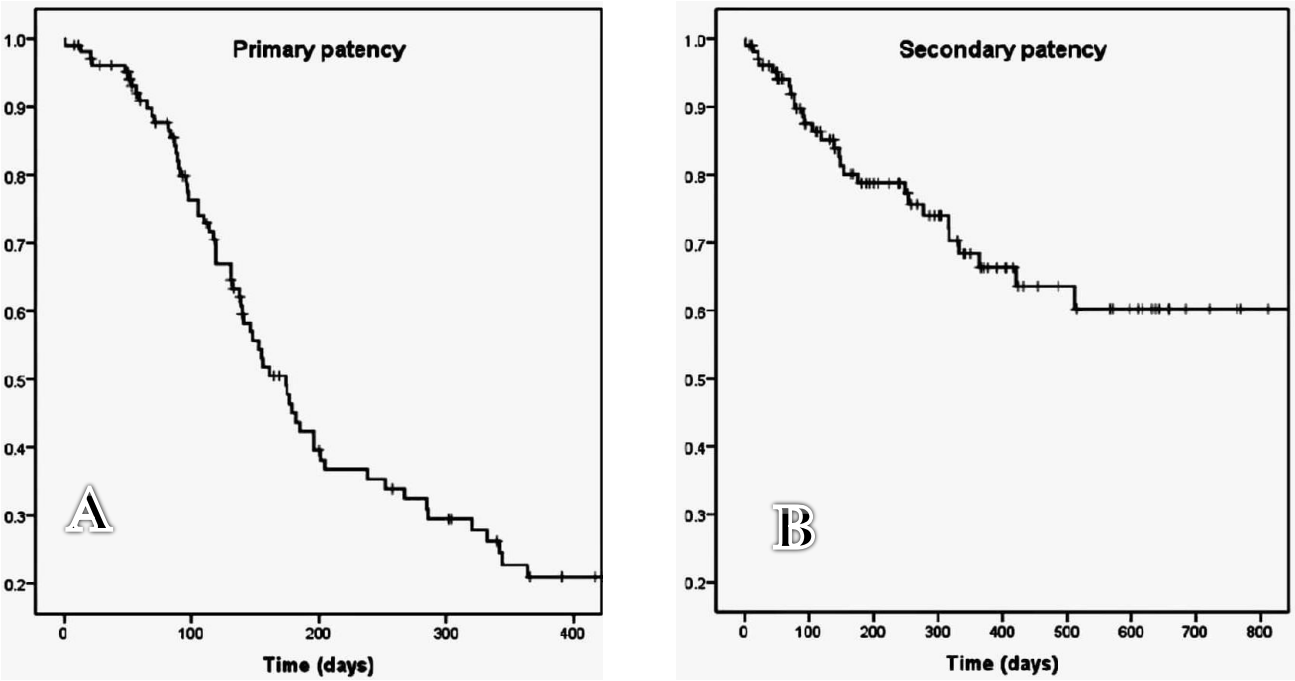

Figure (5): Assessment of the primary and secondary patency of the AVFs using the Kaplan-Meier curve . The statistical significance will be when P value <0.05.

Ascher et al. [44], Gallagher et al. [45], DerDerian et al. [46] and Rizvi et al. [47] had mentioned that, for increasing rate of maturity of AVFs when kept un-mature for more than 5 weeks post-operative using balloon

angioplasty after doing US or angiography for assessment the cause of immaturity, and recorded success of intervention between 55% to 89%.

DerDerian et al. [48] mentioned that, the recorded complications were ecchymosis (40%), leaking extravasation (9%), entrance site hematoma (4%), and thrombosis (2%). In our research, the puncture site hematoma was recorded in 7.1% of patients and local inflammation in one patient and resolved conservatively.

Barone et al. [49] worked on 43 patients with immature AVFs. The evaluation post endovascular surgery with disconnection of accessory veins for increasing the flow rate and maturation of fistulae with success rate 85%. Minimal recorded complications post angioplasty as puncture site hematoma and local inflammation with mild edema, which resolved by conservative measures.

Beathard et al. [50] included patients with immature AVFs that were classified into stenosis in 78 %. balloon angioplasty was done and success in 98 %. during the study follow up, 84% of the patients were succeeded within 3 months, 72 % at 6 months, and 68 % at 12 months. The recorded complications through the study were in 4%.

Shah and Agarwal et al. [51] had mentioned the evaluation of newly operated AVF within 4-6 weeks post-surgery to detect patients with early immature AVF (non-functioning). Once discovered by clinical assessment and DUS for the flow rate of the AVF. For these patients, should underwent balloon angioplasty and ligation of competitive veins. So, they concluded that, most of early diagnosed immature fistula could be saved.

Jeon et al. [52] worked on 59 patients with immature AVFs post 5 weeks of intervention. Endovascular intervention for maturation of the fistulae with clinical success 90% and primary patency 71%, which go with our clinical results of the study.

Nikam et al. [53] declared in the study which had been done on 41 patients with failed or immature AVFs. Post angioplasty, the success rate was 76% with primary patency 78%. The outcomes were average with our study results.

We should confess that, the role of endovascular procedure in saving immature or failed AVFs does not cancel the importance of another surgery for new access formation in some failed or re-stenotic situations. However, considering of endovascular management should be thought first before

surgery for new access. Because of the advantage of the endovascular procedure resulted in higher success rates, less in complication and higher rate of patency.

CONCLUSION:

The success of endovascular management for dysfunction AVFs immediately with higher patency depended on the site of lesion and relation to the anastomosis. Percutaneous angioplasty is considering the most recommended for immature AVFs as has more advantages like simplicity, less invasive, shorter duration, encourage rapid dialysis, less rate of infection, and prolonged patient's life by preservation of the veins.

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-Conflicts of interest: There are no conflicts of interest.

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