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Parameters to predict functional maturation and outcomes of arteriovenous fistula in end stage renal disease patients: A single centre study

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ABSTRACT

Background: The 'gold standard' vascular access for haemodialysis is an endogenously created arteriovenous fistula (AVF). AVF is the most preferred mode of vascular access because this mode is mostly devoid of infection, gives a high blood flow rate, and has least chances of clot formation. The main purpose of thisstudy is to predict the factors affectingAVF maturation and outcomes in patients with end stage renal disease.

Methods: This is aprospective observational study conducted from July 1, 2017 to December 31, 2018. Out of 150 patients consented for surgery, 5 patients died during the follow up period and 2 patients were lost to follow up so these patients were not included in final data analysis. As per the outcome, patients were divided into AVF functional group that included 81.8% (n=117) patients and AVF failure group (18.2%, n=26). All patients were followed at 2 weeks, 4 weeks, 6 weeks and at 12 months.

Results: Male sex had more AVF failure ratethan female sex. Patients having associated comorbidities had comparable risk of non-maturation of AVF (18.0%, p= 0.87). Smoking had a predictive relationship with non-maturation of AVF (p value - 0.004). Diabetic nephropathy (50.3%) followed by hypertensive nephrosclerosis (37.8%) were most common causes of ESRD. RCF had the best patency rate as compared to BCF and BBF (p= 0.28). Vein as well as artery diameter was not found to be a significant factor for AVF maturation (p value > 0.05).Most common cause of AVF failure was found to be thrombosis (11.9%) followed by stenosis (3.5%), infection (2.1%), pseudoaneurysm (0.7%).

Conclusion: Neither gender nor vessel, vein as well as artery, diameters affected patency rates of AVF. Smoking had a predictive relationship with non-maturation of AVF (p value - 0.004). RCF had the best patency rateas compared to BCF and BBF.There was no significant statistical relationship between types of AVF, surgeons experience, site, associated comorbidity and AVF patency rate. Duplex vein mapping should be done for all the cases of AVF surgery to obtain better patency rates.

Keywords – Arteriovenous fistula, chronic kidney disease, haemodialysis, duplex ultrasound, arteriovenous graft

I. INTRODUCTION

Chronic kidney disease (CKD) is a widespread problem both in developed and developing countries. In India, majority of patients are not able to get proper treatment because of the high cost. CKD is emerging as an important chronic disease in the world because the incidence of diabetes and hypertension is continuously increasing with time. The upgoing incidence of CKD in India because of increasing population which likely leads to major concern for both healthcare and the economy in coming time. In India, the age adjusted incidence rate of ESRD is 229 per million population and >100,000 new cases are registered in renal replacement programs per year.[1] Diabetes and hypertension are the two major diseases which accounts for 40–60% cases of CKD in India.[2]

Maintenance haemodialysis has become the most important form of renal replacement therapy (RRT). Different types of vascular access are -1) Arteriovenous fistula (AVF) 2) Arteriovenous grafts (AVG), and 3) Central venous catheters.AVF is the most preferred mode of vascular access because it is mostly devoid of infection, has high blood flow rate, and has least chances of clot formation. AVGs have higher infection rate than AVFs.[3]The 'gold standard' vascular access for haemodialysis is AVF that has good survival rate and lesser complication rate as compared to AVG and central venous catheters. The recent guidelines suggest that a minimum of 1 month and maximum of 2–3 months are required

for maturation of AVF before it can be used for adialysis access.[4]Arteriovenous grafts may have a good patency rate than AVF in the short term but as the AVF last longer than grafts, the cumulative patency is better than arteriovenous grafts. When AVF is fully matured and functional, it requires lesser intervention procedures like angioplasty, balloon dilatation, stenting and thrombectomy.[5] Studies shows that AVFs are also at risk of early failure and there are 20–60% chances of these not providing enough flow for a good hemodialysis.[6]

The 2006 updated NKF-KDOQI guidelines recommend that AVF prevalence should be more than equal to 65% for the patients who are on haemodialysis. Recent study has shown the prevelance of AVF in dialysis patients to be around 80% in Europe and 60% in United States but there is no such data is available in India.[7]First priority for endogenous AVF should be radiocephalic fistula (RCF) at wrist, followed by brachiocephalic fistula (BCF) at elbow, and thirdly is either a brachiobasilic fistula (BBF) or an arteriovenous graft (AVG) at forearm.

A fistula is said to be matured when it is fully patent and cannulation can be done for dialysis which is based on adequate blood flow through the vascular access and the adequate vein dilation with respects to length (>10 cm segment), depth (<6 mm), and diameter (>6 mm), should also deliver a minimum blood flow rate of 300 mL/min and should have minimum of 3 consecutive successful cycles of haemodialysis.[8]Dember et al[9] defined AVF functional maturation as the ability to sustain a good blood flow rates of ≥ 300 mL/min during 8 of 12 haemodialysis cycles. According to recently given NKF K/DOQI guidelines a “fistula maturation” is defined as “the process by which a fistula becomes suitable for cannulation”. The major complications encountered with AVF creation is the high chances of primary failure because of high incidence of thrombosis, infections, stenosis or failure to mature. In some of the studies primary failure rate of an AVF found to be upto 40%.[10,11]

Recent studies suggest that the patient factors, namely elderly age, diabetes mellitus, smoking habits, atherosclerosis, hypotension prior to dialysis, and vessels characteristicshave direct effects on patency rates of AVFs. In vessels having small diameter (<2 mm) and calibre or which have decreased distensibility, there are lesser chances of a functional AVF. According to recent evidence, there is no significant relation between gender or high body mass index (>35 kg/m^2) and fistula patency rate. The factors like early referral for AVF, vessel mapping by duplex USG preoperatively, vascular clips use and blood flow measurements intraoperatively affects patency rates of AVF in different ways.[12]

Conte MS et al[13] found that diabetic patients had significantly lower patency rates in the 24 weeks of the follow-up period. Similarly, Salmela et al[14] reported that diabetes, female sex and thrombophilia were all associated with decreased primary fistula patency rates. Conversely, Sedlacek et al[15] in study of 195 patients reported that diabetes was not associated with AVF maturation (67% matured in the diabetic group vs. 62% in non-diabetic group). More recently, Allon et al[16] found that both age and diabetes were not associated with increased non-maturation rates. However, there is no good data available from Indian population regarding the maturation of AVF.

This study was conducted to assess theoutcomes and factors affectingsuccessful arteriovenous fistula maturation in patients with end stage renaldisease.Primary end point was either completion of six weeks of follow up, successful cannulation or failure of AVF in the form of AVF thrombosis or patient death.

II. MATERIALS AND METHODS

This is aprospective observational study donefrom July 1, 2017 to December 31, 2018.150consecutive patients with end stage renal disease were consented for arteriovenous fistula formation.All ESRD patients consenting to native vessel AVF were included. Those who did not gave consent for the study, active substance abusers (alcohol or other),having persistent non adherence with medications, dialysis treatment or medicalrecommendations,severe restrictive or obstructive pulmonary disease,systemic infection, untreated or uncontrolled psychiatric disorders that would affect the ability to care for self were excluded.

Status of veins and arteries,type of AVF, duplex USG findings such as vessels characteristics like calibre, course, diameters,surgeon’s experience, type of anastomosis, complications associated with procedure were noted. All patients were followed for a period of 12 months and both duplex USG and clinical examination were performedfor functional maturation, non-maturation and dialysis frequency. Patients were divided into two groups. **AVF functional group** in which AVF was considered functionally matured and dialysis was started. **AVF failure group** in which AVF failed to matured and dialysis was not started.All the assimilated data was compiled in

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Microsoft Excel spread sheet at the end of study period and subjected to statistical analysis. Statistical analysis was done by linear aggression analysis andcompared means. Frequency distribution and two-way tables were used to summarize the data and Chi-square test or Fishers Exact Test were used to determine the association between categorical and continuous variables, p value of < 0.05 was considered significant.

III. RESULTS

A total of 150 patientswho underwent surgery for creation of AVF were enrolled but final data analysis was done for 143 patients as 5 patients died during the follow up period and 2 patients were lost to follow up. As per the outcome, patients were divided into AVF functional group (81.8%, n=117) and AVF failure group that included 18.2% (n=26) patients.

The mean age of patients found to be50.74 ± 14.57 years in AVF functional group and 46.88 ± 13.39 years in AVF failure group (P-value was > 0.05).AVF functional group included 76 were male patients (65%) and 41female patients (35%). Male sex had a higher failure rate as compared to female sex. Chi square test was 0.629 and p - value was 0.42. This suggest that although males had high failure rate than females, this was statistically insignificant and sex was not a predictable factor for non-maturation of AVF. Patients having associated comorbidities (Diabetes mellitus and Hypertension) had comparable risk of non-maturation of AVF (18.0%) as those who did not have comorbidities (20.0%, p value - 0.87).Smoking was found to be statistically significant factor as smokers had more risk of AVF failure (34.3%) as compared to non-smokers (13%). Chi square test was 8.079, p- value was 0.004.Diabetes mellitus was the most common cause (50.3%) leading to end stage renal failure followed by hypertension which accounts for 37.8% and chronic glomerulonephritis/unknown accounts for 11.9% cases.**(Table 1)**

Demographics		AVF functional group	AVF failure group	p -value
Age (years)		50.74 ± 14.57	46.88 ± 13.39	0.20
Gender	Male	76 (65%)	19 (73.1%)	0.42
	Female	41 (35%)	7 (26.9%)	
Comorbidity	Yes	109 (93.2%)	24 (92.3%)	0.87
	No	8 (6.8%)	2 (7.7%)	
Smoking	Yes	23 (19.7%)	12 (46.2%)	**0.004**
	No	94 (80.3%)	14 (53.8%)	
Alcohol	Yes	6 (5.1%)	1 (3.8%)	0.78
	No	111 (94.9%)	25 (96.2%)	
Basic disease	Diabetes	61 (52%)	11 (42.3%)	0.20
	Hypertension	42 (35.9%)	12 (46.2%)	
	CGN/Unknown	14 (12%)	3 (11.5%)	

Table 1: Showing the demographics variables

RCF was made in 48.3% patients, BCFsin 44.1% and BBFs in 7.7% patients. It was found that RCF has the best patency rate (87%) as compared to BCF (77.8%) and BBF (72.7%)(p value - 0.283).AVF failure rate was 16.7% when surgeon had experience of less than 2 years as compared to 18.4% surgeons who had more than 2 years of surgical experience which was comparable.The narrow calibre vein has higher fistula failure rate as compared to good calibre vein (p value- 0.49). Patients having venous stenosis had higher fistula failure rate as compared to those who do not have stenosis(p= 0.72).

RCF having cephalic vein diameter of 3 mm or less, fistula failure rate was 12.7% as compared to cephalic vein having diameter of more than 3 mm (14.3%) which was comparable. BCF and BBF having cephalic vein diameter of 4 mm or

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less than 4 mm, fistula failure rate was 22.2% and 27.3% respectively (p value -0.20).RCF having radial artery diameter of 2 mm or less than 2 mm have comparable risk of fistula failure (11.4%) as compared to those having diameter of more than 2 mm (16%). BCF having brachial artery diameter of more than 3 mm were having more failure rate (25%) as compared to those having diameter of 3 mm or less (17.4%). Arterial diameter was not directly associated with AVF failure (P value > 0.05).Arteries having atherosclerotic and calcified wall were at higher risk (40%) of AVF failure as compared to healthy and pulsatile wall (17.4%). Type of anastomosis does not have any direct correlation with AVF failure rate**(Table 2 and 3).**

VARIABLES			AVF functional group	AVF failure group	p -value
AVF		RCF	60 (51.3%)	9 (34.6%)	0.208
		BCF	49 (41.9%)	14 (53.8%)	
		BBF	8 (6.8%)	3 (11.5%)	
Surgeon experience		>2 years	102 (87.2%)	23 (88.5%)	0.85
		<2 years	15 (12.8%)	3 (11.5%)	
Venous factors	Course	Straight	117.(100%)	25 (96.2%)	**0.03**
		Tortuous	0.0%	1(3.8) %	
	Caliber	Good	115 (98.3%)	25 (96.2%)	0.49
		Narrow	2 (1.7%)	1 (3.8%)	
Vein diameter		RCF	2.9 ± 0.46 mm	2.8 ± 0.23mm	0.804
		BCF	3.52 ± 0.57 mm	3.50 ± 0.59mm	0.921
		BBF	2.62 ± 0.23 mm	3.26 ± 0.61mm	0.206

Table 2: Showing types of AVFs and effect of venous factors

International Journal Dental and Medical Sciences Research
Volume 6, Issue 2, Mar - Apr 2024 pp 147-155 www.ijdmsrjournal.com ISSN: 2582-6018

Artery diameter	RCF	2.15 ± 0.37 mm	2.16 ± 0.35mm	0.941
	BCF	3.43 ± 0.68 mm	3.49 ± 0.58mm	0.759
	BBF	3.07 ± 0.10 mm	3.46 ± 0.23mm	0.089
Post op thrill, bruit and pulsation	Good	116(82.25%)	24(17.14%)	**0.001**
	Weak	1(33.3%)	2(66.7%)	
Duplex USG at 6 weeks	Volume flow (ml/min)	556.12 ± 64.91	205.0 ±35.35	**0.003**

Table 3: Showing effect of arterial factors and post op thrill, pulsation and duplex USG findings

27 patients had post operative complications in form of thrombosis in 17 cases (11.9%), stenosis in 5 cases (3.5%), infection in 3 cases (2.1%), pseudoaneurysm in 1 case (0.7%) and lymphocele in1 case (0.7%) as shown in **figure 1**. All AVF having these complications were not able to matured except AVF who had lymphocele which was aspirated post operatively and fistula becomes functional. Patients who had weak thrill and bruit after surgery had higher chances (66.7%) of early fistula failure **(p value was 0.001)**. Volume flow was measured by duplex USG at 6-8 weekspost procedure and it was found that the mean volume flow was 550.22 ± 78.8 ml/min.

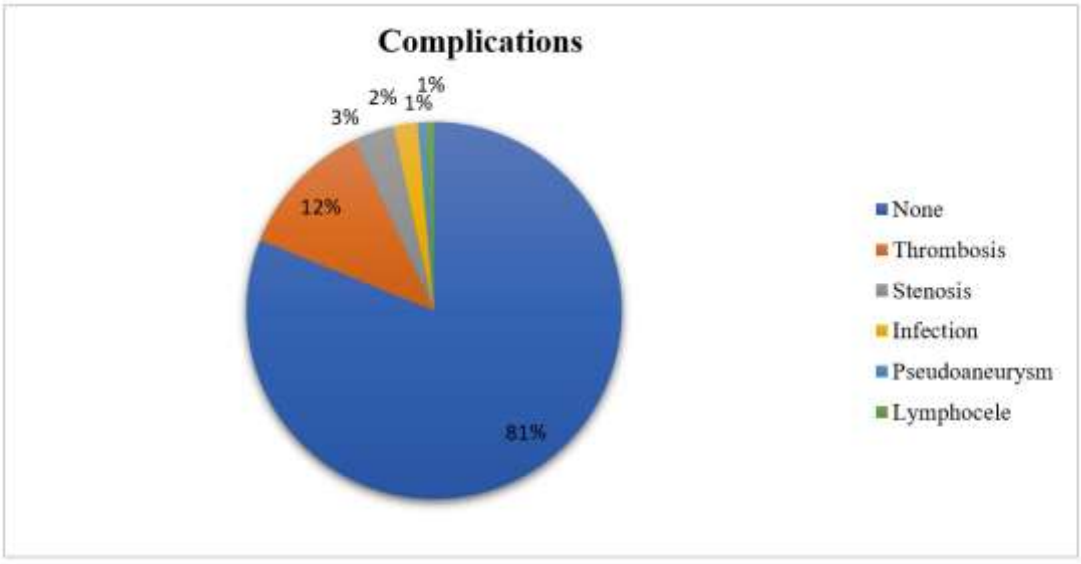

Figure 1: Shows the complications associated with AVFs surgery

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IV. DISCUSSION

It has been established that a functional AVF access is the least likely to be associated with thrombosis, infection, hospital admissions, secondary interventions to maintain patency and death[17,18]. However, the process of AVF maturation is complex and remains poorly understood despite numerous studies looking into the pathophysiology of the process and biomechanical factors associated with maturation.

Out of 143 patients, AVF was found matured and functional in 81.8% and failed to mature in 18.2% cases. AVF failure rate of 18.2% was below as observed by Ravani et al [10] (40%) and Palder et al [19] (28-53%). In another study done by Carrie A et al [20] primary failure rate was 37%. One probable explanation for this lesser failure rate in comparison to these studies was that the duration of follow up was only 6 weeks as mandated by study protocol constraints. After following patients for longer duration of time (3 months), the patency rate of AVFs was decreased significantly (81.8% to 55.33%) and failure rate was increased (18.2% to 21.9%).

Age, gender, associated comorbidities, surgeon experience, type of anastomosis was not found to be directly associated with AVF maturation. In a study conducted by Funda Sari et al[21] in 2016, it was shown that demographic data of patients - elderly age and female gender both were negative risk factors for AVF maturation. In the Haemodialysis (HEMO) Study [22], female sex was identified as a significant risk factor of graft failure rather than AVF use, but there is little evidence that patency of AVF was affected by both male and female sexes.

It of interest to note that our study drew conclusions which appear to be against conventional wisdom and published literature namely that radiocephalic AVFs had better patency rates than brachial artery fistulas, and that neither gender nor vessel diameters were a significant factor in AVF maturation rates. It is pertinent to mention that all AVF at our centre were taken for surgery only after ultrasound mapping of the complete vascular tree. In this setting, on the one hand, radiocephalic fistulas are likely to be undertaken only when the surgeon is assured of a high likelihood of success.

Smoking was found to be statistically significant factor as smokers had more risk of AVF failure (34.3%) as compared to non-smokers (13%). Chi square test was 8.079, p- value was 0.004**.** This finding in agreement with the other published literature indicating that smokers were more likely to have AVF failure probably because smoking induces calcification, plaque formation and subsequently atherosclerosis in arteries that can lead to AVF failure. The direct association with non-maturation of AVF was first suggested by Wetzig et al [23], who found that the incidence of early and late fistula failure significantly higher in patients who were cigarette smokers.

Similarly, it is surprising that neither gender nor vessel, vein as well as artery, diameters affected patency rates. The use of ultrasound mapping to exclude patients with likelihood of AVF failure based on vein diameters and the use of a conservative limit to differentiate the vessel diameters can be a plausible explanation for the unexpected findings regarding gender and vessel diameter effects on AVF maturation. It appears that as long as the vein and arterial diameters are above a certain minimum, as has been suggested by other literature (Silva et al [24] -2.5 mm for vein and 2.0 mm for artery), the technical failure is low. A finding which supports the above hypothesis is the relatively high patency rate reported at 6 weeks of 81.8%. Caplin et al[25] showed that arterial and venous diameters were not significantly different between men and women. Subsequent meta-analysis data suggest that women have similar maturation and 1-year patency rates as men for radio-cephalic AVFs.[26]

Non-maturation in study by Feldman et al [27], was associated with a history of stroke, transient ischemic attack, age and dependence on dialysis when the fistula was created. However, a study by Lee et al [28] reported that age, race, diabetes, gender and peripheral vascular disease did not show significant association with access survival. Monroy-Cuadros et al [29] estimated that age, smoking, diabetes and site fistula did not alter the success rate.Diehm et al [30] observed that female gender and diabetes were the significant risk factors in maturation of AVF and their patency rate.

Of interest is the data collected before final compilation which reveals that 15.3% of patients died, 14% of AVFs became thrombosed, 5.3% of patients had persistent stenosis, only 53.3% of AVFs were being used and only 5.9% of patients underwent transplantation as shown in **figure 2**. Although this study group is unlikely to represent the ESRD population in the country being selected as they were by referral to a large tertiary care centre with a robust nephrology service, this final bit of data probably a reflection of the unmet need for healthcare in the ESRD population.

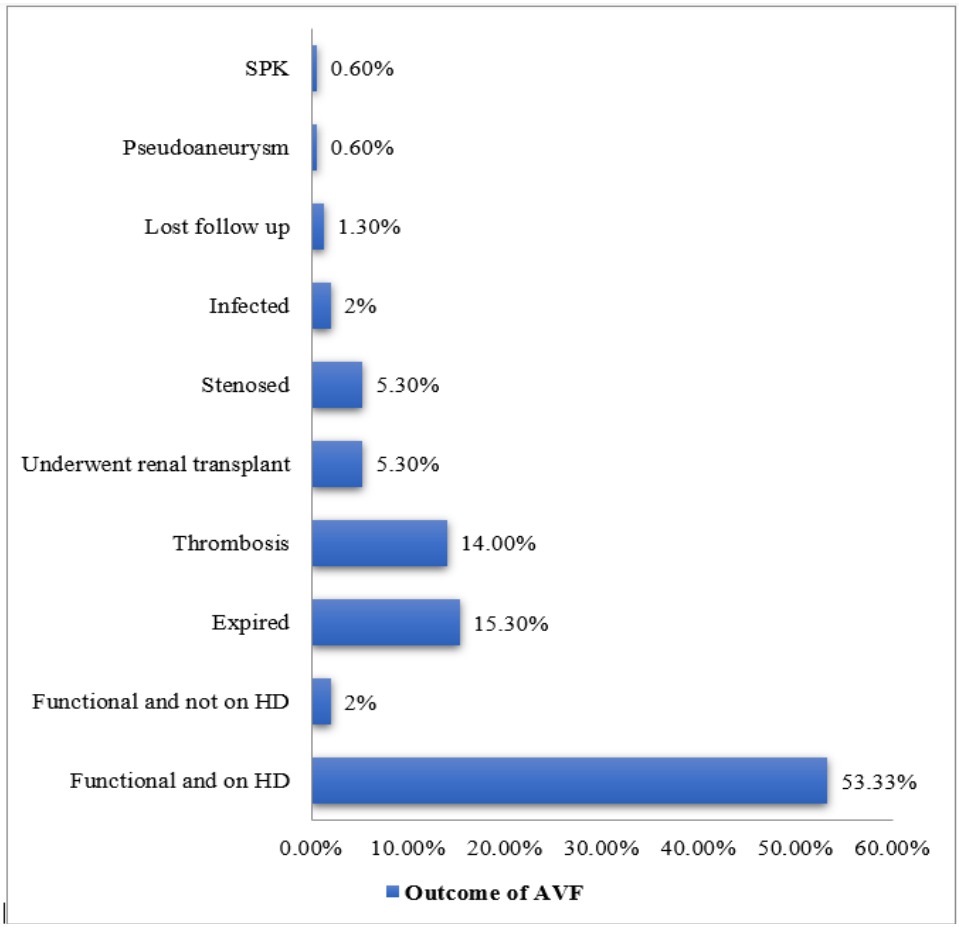

Figure 2 – Showing outcomes of AVF.

V. LIMITATIONS

Longer follow up duration is required to demonstrate the true outcomes of AVFs. It is acknowledged that only a limited set of data on patient's blood flow during dialysis through the created AVF was collected as they were not followed for a longer time and that the appropriate measure of AVF success is the ability to support optimal dialysis flow.

VI. CONCLUSION

Arteriovenous fistula maturation is a complex process with multiple factors involved. Neither gender nor vessel, vein as well as artery, diameters affected patency rates of AVF as long as the vessel diameter used were above 1.6 mm for artery and 2 mm for vein respectively.There was no significant statistical relationship between types of AVF, surgeons experience, associated comorbidity and AVF patency rate.Duplex vein mapping should be done for all the cases of AVF surgery to obtain better patency rates.

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

Ethical approval
The study had been approved by the ethical committee of the participating hospitals. All subjects signed informed consent by each patient. All clinical investigations had been conducted according to the principles expressed in the Declaration of Helsinki.

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