

## Role Of Hydrostatic Outflow Vein Segment Dilatation In Av Fistula Maturation And Patency: An Intervention Cohort Study

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### ABSTRACT

**Introduction:** Hemodialysis becomes pertinent for a major fraction of patients suffering from Chronic Renal Failure, in order to maintain homeostasis. Surgical Arteriovenous Fistula creation is an attempt to form an anastomotic site between a good-caliber artery and vein, maturing over time, offering a dilated aneurysmal site that can be easily cannulated to facilitate dialysis. Several surgical techniques have been put forth to improve the outcomes for such patients. The present study was done to assess the role of manual hydrostatic dilatation of outflow vein segment (draining vein) while creating AVF in its maturation and longevity of fistula patency.

**Material and methods:** It was an intervention cohort study using convenience sampling recruiting 97 patients to undergo AVF creation in a tertiary healthcare setup. Subjects were randomized into two groups, 'test' group, who underwent AVF creation with manual hydrostatic dilatation of outflow venous segment, and controls where AVF was made using conventional surgical technique.

**Result:** The primary outcome of immediate functioning of fistula was achieved in 90% of the test and in 96% of the control group. (p value = 0.251). In the test group, most participants had their first cannulation of AVF between 5<sup>th</sup> and 7<sup>th</sup> weeks. In contrast, the control group predominantly experienced their first cannulation later (6<sup>th</sup> to 8<sup>th</sup> week). The difference was found to be statistically significant (p value <0.001) and this highlighted the role of hydrostatic dilatation in achieving maturity of AVF early.

**Discussion & Conclusion:** AVF lies at the heart of HD for CRF patients. Attempts have been made to cater needs for such patients for an ideal vascular access. Hydrostatic dilatation while during the AVF creation is a promising technique in order to achieve an early maturity of a well patent functioning fistula.

**Keywords:** AVF, Fistula, HD, Hemodialysis, CKD, CRF, Hydrostatic dilatation

### 1. INTRODUCTION

A compromised renal function for more than three months classifies as chronic renal failure (CRF), more often than not necessitating the use of renal replacement therapy. Patients with CRF can be subjected to renal transplant if a suitable donor is available. In settings when a suitable donor is not available, hemodialysis (HD) becomes pertinent for such patients in order to maintain homeostasis, where toxins are removed and fluid and electrolytes maintained using an artificial dialyzer through a vascular access. Various modalities to achieve vascular access at the patient's end have been used and evolved ever since; catheterization of femoral or central veins, subcutaneous tunneled catheter placed in the deep venous system, and creation of arteriovenous fistulas (AVF) [1]. Artificially induced channels like femoral or central venous catheters are prone to get blocked with time and usage and require recannulation of the sites [2]. This highlights the role of surgically created AVF, which remains functional and serves as a near-permanent vascular access for patients on maintenance HD. A manmade AVF is an attempt to create an anastomotic site between a good-caliber artery and vein, maturing over time, offering a dilated aneurysmal site that can be easily cannulated to facilitate HD [3]. AVF is the lifeline of patients requiring repeated HD.

Autogenous fistula is always preferred over fistula with prosthetic graft. Attempts have been made to create autogenous arteriovenous fistula between the radial artery and cephalic vein in the distal forearm, autogenous brachial artery and cephalic vein fistula in the elbow region, and arteriovenous fistula created between the brachial artery and basilic vein with superficialization of the basilic vein at the time of surgery or superficialization later [4]. The anastomosis is created at the most distal site available in the nondominant upper limb, to alleviate late complications due to repeated cannulations, if any occur. Radio-cephalic AVF is the most preferred, except in the elderly [5]. Creation of a radio-cephalic AVF comes with its own challenges. Small caliber of radial artery, unsure availability of a patent vein with fair size near to artery without arborization of the venous bed (straight segment of vein draining into the cephalic vein) are a few to name. A venous diameter of 2 mm and an arterial diameter of 2 mm have been proposed as critical for the creation of radio-cephalic AVF [6].

Simple creation of AVF doesn't guarantee its functioning. The time taken by AVF post-surgery to attain its functional capacity is defined as its maturation, generally taking several weeks [7]. Maturation of an AVF depends on several parameters, such as procedural (the skill of the operating surgeon, technique of the procedure, sterility of the procedure, post-operative care), and patient-based (built of the patient, AVF handling by the subject, exercising of the operated limb to ensure adequate blood flow, and maintaining hygiene of the body and AVF site) [8]. Old age and history of diabetes mellitus have been found to be major factors negatively affecting early fistula functioning. Early cannulation of AVF may result in its disruption and nonfunctioning, rendering all efforts futile. Selection of a suitable vessel, its caliber, vessel's course, and identification and addressing of other associated vascular lesions are also helpful in procuring a well-functioning fistula [9]. A few studies attribute some role of venous diameter in AVF maturation. In contrast, few authors demonstrated importance of distensibility of vein rather than absolute size of vein in maturation of AVF. The primary failure rate is around 70% and besides this, substantial proportion of these fistulae fail to mature after creation. [6]

AVF remain functional for a good number of years offering assistance in HD till life in a few cases if no unforeseen complications occur. The AVF lifespan is different varying across CRF populations, due to a number of factors, like late procedural complications, sterility of instrument and cannulation at every step of the way in procuring HD sessions, the frequency of HD sessions a patient partake, handling of AVF by the technicians before, during, and after HD, & in general nutritional status, built and hygiene of the subject. Many other factors and complications, sometimes inevitable, can affect fistula longevity.

The present study was done to assess the role of manual hydrostatic dilatation of outflow vein segment (draining vein) while creating AVF in its maturation and longevity of fistula patency in comparison to the control group.

## 2. MATERIAL AND METHODS

**Study setting & design:** It was an intervention cohort study using convenience sampling recruiting 97 patients to undergo AVF creation. The study was carried out in the settings of a tertiary health care setup located in urban area of north India, with trained nephrologist and surgeons team, alongside experts in other super specialities, well-equipped operation theatres, round the clock dialysis centre, advanced intensive care units for management of complications, daily out patient and emergency services, and other facilities. Patients of more than 18 years of age who were diagnosed with CRF stage 5, in need of future maintenance HD were included in the study. All patients were screened for viral markers including Hepatitis B, Hepatitis C, and HIV-1,2 using rapid card tests in hospital's laboratory services. Only viral markers negative individuals were included in the study.

**Test & control groups:** Subjects were randomly allocated in two groups, controls who later underwent radio-cephalic arteriovenous fistula creation without any dilatation of venous out channel with minimal handling, and cases, who were later subjected to manual hydrostatic dilatation while during the procedure of Radio-Cephalic AVF creation. Written consent was obtained from all the subjects, ensuring their willful participation after explaining the purpose of the present study, and known complications of the AVF procedure.

**Pre-requisites and Procedure:** Physical examination of peripheral arteries and veins was done. Clinical assessment of arterial function of the left upper limb was done using Allen's test. Doppler ultrasonography to ensure patency and caliber of the artery and vein of interest, and rule out any local vascular or stenotic lesion was carried out in all the patients. Venous diameter cut-off of 2 mm and arterial diameter of 2 mm were used. Condition of central neck veins was assessed by doppler study to rule out stenosis or thrombosis. All patients underwent routine lab investigations and pre-anesthesia checkup by experts in field as per Indian Society of Anaesthesiologists (ISA) to assess their fitness to undergo vascular access surgery. Patients were included only after obtaining clearance by Cardiologist in order to assess the likelihood of withstanding the impact of hemodynamic changes after creation of AVF.

The vascular access procedure was carried by the in-house team of trained surgeon and staff under all aseptic conditions in local anesthesia. All standard procedure and precautions were followed before and while during the surgery.

**Hydrostatic dilatation of venous outflow segment during the surgery:** In test group, during the surgery of AVF creation, after dissecting out venous segment, gentle venous dilatation of venous drainage channel was done with stiff vein dilator followed with hydrostatic dilatation of vein with 5F infant feeding tube attached to 20 cc syringe containing

heparinized solution. The assembly was introduced into venous channel, and cut end of vein pinched with thumb and index finger by the in-lead surgeon. Assistant then applied external compression to the vein with thumb around 10-15 cm proximal to the cut end site of vein. Dilatation of segment was done by distending the vein with syringe, approximately up to one and half times of original vein size. Side to end arteriovenous anastomosis was then ensured with 7-0/8-0 prolene suture. (Fig. 1 & 2)



**Fig 1. 5F infant feeding tube and 20 cc syringe assembly used for AVF Hydrostatic dilatation**

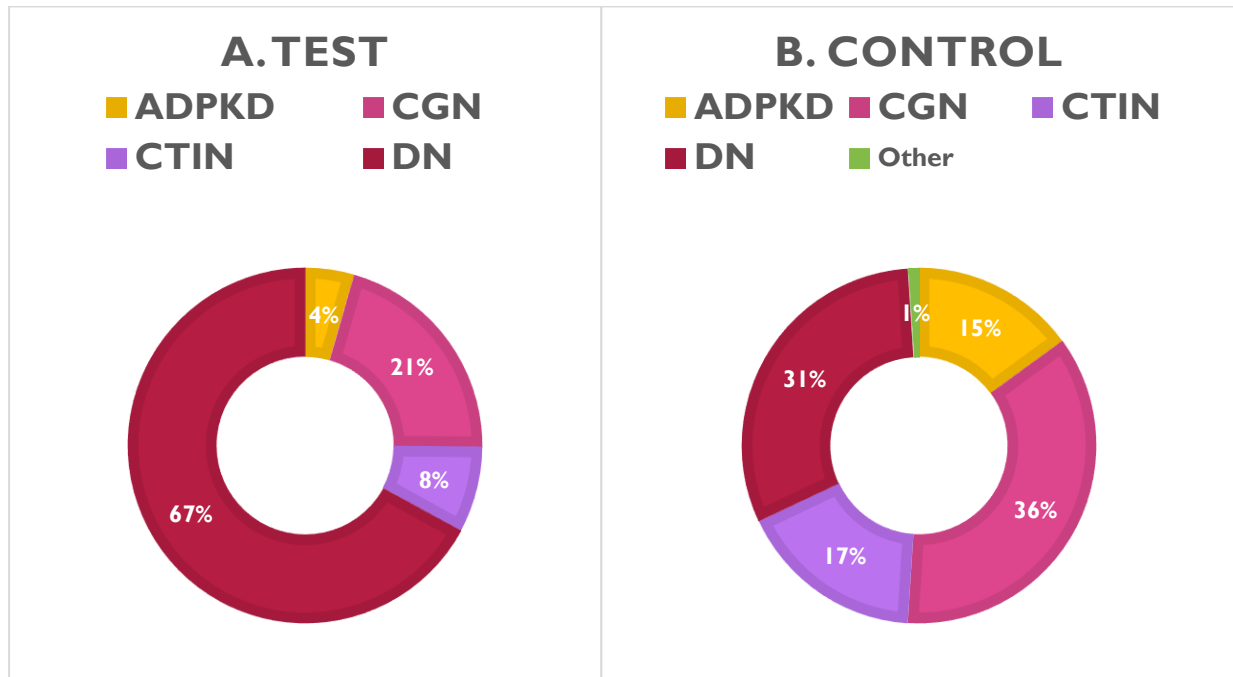


**Fig 2. Intraoperative picture post AVF creation & hydrostatic dilatation.**

**Post procedure & Follow up:** Quality post-operative care and antibiotics was ensured to all the subjects. The primary outcome was defined as the immediate functioning of the fistula, assessed as a palpable thrill by the patient. Both groups were instructed about the standard precautions and measures for fistula care. Participants of both the groups were encouraged for active finger movements and exercise with a handheld soft ball after 48 hours of fistula creation and blood pressure monitoring at home. Patients were advised for regular HD sessions and nephrology & surgery out-patient visits. Each participant was followed up for a period of 6 month since the day of procedure. The data was collected, tabulated, and analyzed using SPSS Statistics for Windows, version 18.0 (SPSS Inc., Chicago, IL, USA).

### 3. RESULTS

Individuals were randomly allocated in the test and control groups. The male and female distribution in the two groups was fairly balanced. 59% males and 41% females accounted for test population, and were equally distributed in halves in the control group. The mean age for subjects in test group was 48.45 ( $\pm 7.82$ ) years, and 47.73 ( $\pm 8.16$ ) years for control group. Most of the cases of CRF in both the groups were attributed to Chronic Glomerulonephritis (CGN) and diabetic nephropathy (DN). Cases of Autosomal Dominant Polycystic Kidney Disease (ADPKD) and Chronic Tubulointerstitial Nephritis (CTN) were similar in distribution in the two groups.



**Fig.1. Causes of CRF found in test (A.) and control (B.) groups. CGN- Chronic Glomerulonephritis, DN- Diabetic Nephropathy, ADPKD- Autosomal Dominant Polycystic Kidney Disease, CTN- Chronic Tubulointerstitial Nephritis**

**Table 1. Patient characteristics and measurements before AVF creation.**

Patient Characteristics	Test Group (n= 49)	Control Group (n = 48)
Age (years)	48.45 $\pm$ 7.82	47.73 $\pm$ 8.16
BMI (kg/m <sup>2</sup> )	22.32 $\pm$ 1.68	21.88 $\pm$ 1.82
Arterial diameter (mm)	3.32 $\pm$ 0.62	3.16 $\pm$ 0.72
Venous diameter (mm)	2.78 $\pm$ 0.32	2.83 $\pm$ 0.28
Vein distance from skin surface (mm)	4.86 $\pm$ 1.44	5.02 $\pm$ 1.25

**Table 2. Comparison of gender and major surgical outcomes of AVF creation procedure in test and control groups.**

Variable		Test Group (n= 49)	Control Group (n = 48)	Statistical test and p value
Gender	Male	29 (59.0%)	24 (50.0%)	X <sup>2</sup> = 0.82 P value = 0.37
	Female	20 (41.0%)	24 (50.0%)	
Primary Outcome	Yes	44 (90.0%)	46 (96.0%)	X <sup>2</sup> = 1.32



<b>Achieved?</b>	No	5 (10.0%)	2 (4.0%)	p value = 0.251
<b>Time of first cannulation day</b>	0 weeks	0 (0.0%)	0 (0.0%)	t-value = -3.63 p value <0.001**
	2 weeks	0 (0.0%)	0 (0.0%)	
	3 weeks	0 (0.0%)	1 (2.0%)	
	4 weeks	5 (10.0%)	1 (2.0%)	
	5 weeks	14 (29.0%)	2 (4.0%)	
	6 weeks	17 (34.0%)	17 (35.0%)	
	7 weeks	10 (20.0%)	15 (31.0%)	
	8 weeks	1 (2.0%)	8 (17.0%)	
	9 weeks	1 (2.0%)	2 (4.0%)	
	N/A	1 (2.0%)	2 (4.0%)	
<b>Day of critical outcome (i.e. development of any surgical complication)</b>	0 weeks	4 (8.0%)	0 (0.0%)	t-value = -1.16 p value = 0.14
	6 weeks	1 (2.0%)	0 (0.0%)	
	9 weeks	1 (2.0%)	0 (0.0%)	
	10 weeks	0 (0.0%)	1 (2.0%)	
	13 weeks	0 (0.0%)	1 (2.0%)	
	15 weeks	2 (4.0%)	0 (0.0%)	
	N/A	1 (2.0%)	2 (4.0%)	
	NIL	40 (80.0%)	44 (92.0%)	
<b>Fistula Salvaged</b>	N/A	41 (80.0%)	46 (96.0%)	-
	YES	5 (10.0%)	2(4.0%)	
	NO	4 (8.0%)	0(0.0%)	
<b>Fistula patency at 3 months</b>	N/A	1 (2.0%)	2 (4.0%)	X <sup>2</sup> = 0.457 p value = 0.498
	YES	43 (86.0%)	43 (90.0%)	
	NO	5 (10.0%)	3 (6.0%)	
<b>Fistula patency at 6 months</b>	N/A	1 (2.0%)	2 (4.0%)	X <sup>2</sup> = 0.899 p value = 0.342
	YES	37 (74.0%)	39 (81.0%)	
	NO	11 (22.0%)	7 (15.0%)	

Diameters of vessels of interest were measured before AVF creation. Arterial diameter for test group was 3.32 ( $\pm 0.62$ ) mm and 3.16 ( $\pm 0.72$ ) for control group. Venous diameters were also comparable (2.78  $\pm 0.32$  mm for test group, and 2.83  $\pm 0.28$  mm for control group). Individuals enrolled in test group were subjected to hydrostatic dilatation of venous outflow segment, and the step skipped in control group. The main primary outcome of AVF creation procedure was defined as immediate functioning of fistula appreciated by the patient as a palpable thrill. Majority of the patients achieved the outcome (90% in test and 96% in control group). Any difference was not significant and was simply due to by chance. (p value = 0.251) Patients requiring maintenance HD were given by femoral or central catheter routes till the time AVF matured. Best judged

clinically, AVF was decided to be used for subsequent HD sessions post maturation. In the test group, most participants had their first cannulation of AVF between 5<sup>th</sup> and 7<sup>th</sup> weeks, with the highest proportion (34.0%) occurring in the 6<sup>th</sup> week. In contrast, the control group predominantly experienced their first cannulation later (6<sup>th</sup> to 8<sup>th</sup> week), with the highest proportion (35.0%) in the 6<sup>th</sup> week and another significant portion (31.0%) in the 7<sup>th</sup> week. The difference was found to be statistically significant ( $p$  value  $<0.001$ ) and this highlighted the role of hydrostatic dilatation in achieving maturity of AVF early. One individual in test group, and two in control group succumbed to death even before their first cannulation could be achieved.

With provision of regular out-patient visits in nephrology and surgery department and round the clock emergency services, follow-up was ensured for 6 months after the day of procedure. Any complication related to the surgical procedure, including thrombosis of fistula or inability to provide adequate flow for HD, resulting in a nonfunctional/ failing AVF was referred as the day of critical outcome. The distribution of critical outcome days between the Test and Control groups did not show any statistically significant difference ( $p = 0.231$ ). In the Test Group, approximately 8% of cases experienced a critical outcome at 0 weeks, which may be indicative of increased injury due to hydrostatic dilatation, while no such cases were observed in the Control Group. Other critical outcomes in the Test Group were scattered across different weeks, whereas the Control Group had isolated occurrences at 10 and 13 weeks. The majority of participants in both groups had no critical outcome (80% in the Test Group, 92% in the Control Group).

The patients that developed complications in the test ( $n = 8$ ) and control group ( $n = 4$ ) were subjected to measures to salvage AVF. Fistula was salvaged in 50% of the cases of test group that developed complications ( $n=4$ ), and in all of the cases developing complications in control group ( $n=4$ ). Majority of the individuals did not require any measures for salvaging the fistula. Any variation in fistula salvage rates between the two groups was attributed to chance rather than a true effect.

The patency rates at 3 months show similar outcomes between the Test and Control groups. Majority of patients in both the groups maintained AVF patency (86.0% in the Test Group vs. 90.0% in the Control Group). The patency rates at 6 months also remain comparable between the two groups (74.0% in the Test Group vs. 81.0% in the Control Group). No significant difference was found in the patency outcomes at 3 months or 6 months of follow up in between the two groups.

#### 4. DISCUSSION

Vascular access procedures in CRF patients are highly beneficial when established early in the treatment course. Some authors have reported that an early autologous primary access through AVF is considered better than creating an AV fistula in patients already subjected to central venous catheter access, which delays the procedure [7]. AVF remains the gold standard for vascular access in patients with CRF requiring repeated HD. The selection of vascular access should be patient-centered, as some studies have questioned the necessity of HD initiation in elderly CRF populations [8]. The choice of vascular access must cater to the patient's needs, considering various factors such as financial status, family responsibilities, work roles, and other practical circumstances [9]. The present study enrolled 98 CRF patients requiring repeated HD, best determined through clinical judgment and supported by laboratory evidence.

Autologous AVF creation between an artery and an adjacent vein remains the gold standard, ideally positioned as distally as possible in the non-dominant upper extremity [4]. Besides the timing of the procedure, the AVF site is equally important. The artery and vein size also significantly influence AVF longevity and patency, as demonstrated in previous studies [5]. Some literature also suggests that fistula maturation is dependent on venous caliber but not on arterial size [6]. Certain authors have emphasized the role of pre-existing intimal hyperplasia as a crucial predictor of AVF outcome, while others have highlighted the significance of medial hyperplasia [7]. Variable cutoffs for venous diameters have been proposed, and in this study, a venous diameter of 1.9 mm was considered critical for radio-cephalic AVF creation [8].

Changes in flow dynamics following AVF creation lead to intimal hyperplasia, influencing AVF lifespan, longevity, and maturation [9]. Laminar shear forces favor endothelial stabilization, preventing adverse vascular remodeling and minimizing endothelial hyperplasia [3]. The present study highlights the significance of manual hydrostatic dilatation of the venous outflow channel during AVF creation (in the test group) in achieving early maturation. A statistically significant difference was observed in maturation rates, with the test group achieving early first AVF cannulation compared to the control group [5]. In the test group, the first cannulation was mostly achieved between 2 to 5 weeks, whereas in the control group, it occurred between 6 to 8 weeks [6].

The primary outcome, i.e. patent AVF immediately after surgery, was not achieved in 5 individuals of test group in comparison to only 2 individuals in control group, but had no statistical significance. Incidence of critical outcome and proportion of associated fistulas which could be salvaged were also similar across the two group. The groups also showed no significant disparity in patency rates at 3 months and 6 months follow-up. A long-term functioning fistula is dependent on variable factors, also associated with fistula care which differs from patient to patient. The assessment of fistula longevity even with best efforts to address these issues is a challenge to face.

## 5. CONCLUSION

AVF lies at the heart of HD for CRF patients. Attempts have been made to cater needs for such patients for an ideal vascular access. An autologous radio-cephalic AVF placed as distally as possible in the nondominant upper extremity has been the standard of care requiring long term HD. Advent in surgical approaches to improve the surgical outcomes are ever emerging. Hydrostatic dilatation while during the AVF creation is a promising technique in order to achieve an early maturity of a well patent functioning fistula. Further studies and randomized controlled trials recruiting a larger number of patients and a longer follow up are needed. High mortality in CRF, unforeseen clinical scenarios mandating HD termination, and different patient situations are challenges that ever remain.

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