

Metallic dilator use for intraoperative outflow vein dilatation to improve dialysis arteriovenous fistula maturation and accelerate cannulation

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Abstract

Objective: A well-planned and meticulously constructed AVF should mature in 4 to 8 weeks. Creation of a rapidly maturing fistula provides a potential way to diminish the current dependence on central catheter placement.

Aim of the work: To evaluate effect of intraoperative dilatation for small veins using metal dilators on the initial autogenous hemodialysis accesses patency, maturation and cannulation.

Patients and methods: Sixty adult patients with end-stage kidney disease who were scheduled to undergo radiocephalic (RCAVF) or brachiocephalic arteriovenous (BCAVF) dialysis fistula surgery during the period from August 2010 through August 2011. The primary outcomes of the study were fistula maturation and time of successful first cannulation. Vein diameter was assessed intraoperatively by inserting metal dilator heads to measure the approximate diameter. The relationship between vein diameter after metallic dilators passage and maturation, short-term patency rate and time to first cannulation were assessed.

Results: The patients' age (mean) was 65.9 15 years, range 18-85 years. Preoperative duplex was performed in only 15 (25%) of the cases. Mean duplex cephalic vein diameter was 2.23 ± 0.17 mm in successful RCAVF patients and 3.44 ± 0.18 mm in BCAVF. Cumulative primary patency at 6 months in RCAVF patients was 75% (30/40 fistulae) and 85% (17/20 fistulae) for BCAVF. Matured Fistulas were 49 (81.67%). Eleven fistulas (18.33%) failed to mature; five underwent revision, mostly for failure to mature. Assisted functional maturity was 52/60 (86.67%). Overall mean times for fistula maturation and first cannulation were 32 ± 1.29 days ($n=49$) and 40 ± 9.6 days respectively. The more increased vein diameters after mechanical dilatation; the more likely for the fistula to mature and the lesser mean time for maturation and cannulation.

Conclusion: Early fistula patency rate was better than that in several reports. We recommend careful preoperative patient evaluation as well as careful anastomosis technique, which includes mechanical dilatation for small veins.

Key words: Arteriovenous fistula, vein dilatation, maturation, cannulation.

Introduction:

Native arteriovenous fistula (AVF) is preferred than synthetic grafts for hemodialysis vascular access due to lower rates of thrombosis, infection, and longer patency.^{1,2} The National Kidney Foundation Kidney Disease Outcome Initiative (NKF K/DOQI) guidelines recommended that a wrist

(radiocephalic) fistula is the first choice for native AVF, second is an elbow (brachiocephalic) fistula, and third is either a transposed brachiocephalic vein fistula or a forearm arteriovenous graft.³ However, 20-60% of fistulas fail to mature sufficiently to support dialysis.^{4,5} Thus, the high rate of maturation failure is a major unresolved

problem. Dilatation of the anastomosed artery and vein are key steps in fistula maturation.⁶

The clinical data suggest that a well-planned and meticulously constructed AVF should mature in 4 to 8 weeks.⁵ Creation of a rapidly maturing fistula provides a potential way to diminish the current dependence on central catheter placement. A hemodialysis fistula comprises inflow artery, outflow vein and a venous segment suitable for cannulation. All of these components contribute to the maturation and proper functioning of a fistula. For the fistula to be functionally mature it should provide the following: blood flow >600 mL/min through the fistula, a single straight vein >10 cm in length or two straight segments at least 4 cm in length, the vein diameter should be >6 mm, and located <6 mm under the skin surface. This permits easy placement of two needles with their tips far enough apart to prevent recirculation.⁷

Venous outflow lesions are the most common lesions found in fistulae that fail to mature. Venous outflow lesions, including the central veins, may be due to preexisting anomalies, such as anatomically small veins, fibrotic or stenotic veins, or sites of prior puncture or catheter placement.⁸ The treatment of these lesions concentrates on post-operative management of fistula non-maturation through various techniques of surgical and endovascular modalities, these treatment methods are in part costly in time and expenses as well as have not gained much acceptance especially in countries with limited resources and late patient referral for hemodialysis like Egypt where most of patients cannot wait 3-6 months for maturation and cannulation of his fistula.

The purpose of this study is to evaluate effect of intraoperative dilatation for small veins using metal dilators on the initial autogenous hemodialysis accesses patency, maturation and cannulation.

Patients and methods:

a) Study design:

We enrolled 60 adult patients with end-stage kidney disease who were scheduled to undergo radiocephalic or brachiocephalic arteriovenous dialysis fistula surgery during the period from August 2010 through August

2011. Operations were performed in Vascular Surgery Unit, General Surgery department of Tanta University Hospitals and a private dialysis center. Only patients with first time permanent native hemodialysis access were included in the analysis. Patients who received synthetic vascular access, prior constructed AV access, brachio basilic fistulae were excluded from the study. The presence of a temporary dialysis catheter was not an exclusion criterion. All patients gave written informed consent including relevant details of the procedure and the expected post-operative complications. On the day of surgery, patients underwent preoperative measurement of arterial blood pressure.

- The same vascular surgeons created all fistulas and took all diameter measurements. Pre-anastomosis artery and vein diameters were measured with intraluminal probes during surgery. Dialysis staff and physicians who managed the fistulas and made cannulation decisions were blinded to diameter measurements.

b) Study endpoints:

The primary outcomes of the study were fistula maturation and time of successful first cannulation. We defined maturation as successful and adequate dialysis through at least three consecutive sessions within 6 months of surgery.

c) Data and statistical analysis:

Variables were compared by using Fisher's exact test, and unpaired t tests where appropriate. Data were analyzed by Graphpad prism 5TM; a p-value of <0.05 was considered significant.

- Outcome variables included the patients' demographic data, site and type of AV fistula, medical risk factors as smoking, diabetes mellitus, hypertension, ischemic heart disease, and liver insufficiency. Etiology of renal failure was noted as well as history of prior and recent central catheter placement especially ipsilateral to the planned site of fistula. Vein diameter was assessed intraoperatively by inserting metal dilator heads to measure the approximate diameter. Intra- and post-operative complications were recorded such as vein perforation, thrombosis, failure of dilator passage or false passage, absence of palpable

thrill, wound hematoma, hemorrhage and infection. The relationship between vein diameter after metallic dilators passage and maturation, short-term patency rate and time to first cannulation were assessed. Patients were followed up for a mean of 6 months (Range 2-11).

d) Patient assessment:

Both upper limbs were assessed for arteries and veins. Arterial assessments included whole limb pulses and blood pressure examination with comparison of both sides, and Allen's test for continuity of the palmar arch. Venous assessments were done with and without tourniquet placed at about the anterior axillary fold. Duplex ultrasonography (DUS) of arteries and veins was an adjunct to physical examination only in patients with uncertain quality and anatomy of the examined vessels. Duplex venous assessments included diameter, compressibility, depth, and continuity. Duplex arterial assessment was for diameter, waveform and flow velocities.

e) Definitions:

Fistula maturation is defined by the determination of both vascular surgeon and nephrologist that an access is patent and ready for cannulation based on adequacy of blood flow through the fistula and the adequacy of vein dilation with respects to length (>10cm segment), depth (<6mm), and diameter (>6mm).⁹ Functional maturation is defined as successful cannulation of the fistula with the ability of the access to deliver a flow rate of 350 to 400 ml/min and maintain dialysis for 4 hours or less.¹⁰ Inadequate maturation is defined as insufficient access flow to maintain dialysis or the unavailability to cannulate an AVF, if required, at 6 weeks after surgery. Primary fistula failure is defined as fistula abandonment prior to cannulation regardless of patency status. This definition includes (1) inadequate maturation, (2) early thrombosis, (3) failure of first cannulation, and (4) other complications such as ischemia or infection.¹¹

Primary patency rate is defined as the time between the initial operation and failure or the need for reintervention. Assisted primary patency rate is defined as the total life span of the AVF after the initial operation, regardless of whether reintervention was required before

or after initial maturation. Secondary patency rate refers to the life span of an AVF that had become completely occluded but was successfully reopened by means of thrombectomy.¹²

A uniform size threshold for acceptable vein diameter was not used during the study period.

f) Operative technique:

All operations were performed in the operating room under local anesthesia. After venous dissection and venotomy, heparinized saline was instilled into the vein to prevent thrombosis with the forthcoming manipulations. Venous diameter of cephalic vein in forearm or arm was measured by gently inserting the tip of metallic vascular dilator (23 cm length and 1.5-6 mm caliber), without much distending the vein wall. Vein dilatation began by gently passing the dilator that approximately mimics the vein internal lumen diameter with successively and gradually increasing dilator diameters. Overstretching was avoided, it is known when a force is needed to introduce dilator tip with increased wall transparency. In cases of radiocephalic fistula we dilate the whole forearm cephalic vein till about the elbow crease, in cases of arm brachiocephalic fistulas we dilate the whole arm cephalic vein with the aim of approaching or reaching the cephalic arch with the long dilator as this is a very common area of venous stenosis however, this was done with utmost care and caution as this area is prone for rupture.

Passage at ease during insertion and withdrawal of the dilator is a must for completion of dilatation process, then heparinized saline instillation and mild hydropneumatic dilatation was done in order not to overstretch the vein wall. All anastomoses were performed using monofilament non-absorbable polypropylene running sutures. Patients were then seen routinely 7 to 14 days postoperatively and then 4 to 6 weeks thereafter to assess for adequate maturation.

Results:

Demographic data and co-morbidities: The relevant demographic and clinical characteristics of the patients for whom fistula adequacy could be determined are summarized

in **Table(1)**. The patients' age (mean) was 65.9 15 years and ranged between 18 and 85 years. Thirty percent of the fistulas were created in patients 65 years of age or older. Approximately 63.33% of the fistulas were constructed in men (38 patients) and 36.67% in women (22 patients). Diabetes was present in 25 (41.67%) of the patients, hypertension was highly prevalent in patients with either upper or forearm fistulae 46 (76.67%); Nine patients (15%) were identified as having ischemic heart disease, impairment of liver function in 10

(16.67), pulmonary disease in 3 (5%), history of previous cerebral stroke in 5 (8.33%) and 7 patients (11.67%) were currently smokers. Approximately (11.67%) of the patients were overweight (BMI ≥ 27 kg/m²). Patients who were receiving dialysis at the time of their operation were the majority 54 (90%), and those having ipsilateral central venous catheter were 9 (15%). Forty forearm radiocephalic and 20 brachiocephalic fistulas constructed around the elbow region.

Table (1): Demographic data, co-morbidities and type of AV access.

Demographic data	Number	%
Age (Years) Mean \pm SD	65 \pm 15 (18-85yrs)	
Sex		
Male	38	63.33
Female	22	36.67
Current dialysis	54	90.00
Medical comorbidities		
DM	25	41.67
Hypertension	46	76.67
Ischemic heart disease	9	15.00
Liver impairment	10	16.67
Pulmonary disease	3	5.00
Smoking	7	11.67
Obesity	7	11.67
Previous stroke	5	8.33
Ipsilateral central cath.	9	15.00
Site and type of AV Fistula		
Radiocephalic	40	66.67
Brachiocephalic	20	33.33

Results of preoperative duplex examination:

Preoperative duplex examination was performed in only 15 (25%) of the cases. In the RC AVF group, mean duplex forearm cephalic vein diameter was 2.23 \pm 0.17mm in the successful fistula patients, and 1.8 \pm 0.19 mm in patients with primary fistula failure (P=0.15). In the BC AVF patients, mean antecubital cephalic vein diameter was 3.44 \pm 0.18 mm.

Procedure related complications:

The forearm cephalic vein was perforated by false passage of the metallic dilator in one patient; fortunately this was near its presumed site of anastomosis and was managed by elongating the skin incision and more proximal dissection of the vein excluding the perforated segment. In another case of RCAVF, the dilator (No. 2) passed gently and smoothly but (No. 2.5) stopped midway in spite of good diameter of vein (3mm); mostly due to outflow stenosis,

we did not try violent attempts for dilator passage and completed the procedure but this patient had no post-operative palpable thrill and fistula deemed failed to mature. Three fistulas had intra-operative thrombosis that were managed by thrombectomy, that resulted in salvage of 2 fistulas and regain of pulsatile flow without thrill in the third one due to small diameter radial artery and weak inflow. One out of the 2 salvaged fistulas were affected by post-operative thrombosis due to hypotension during dialysis.

Mild post-operative complications that were not associated with primary fistula failure are summarized in **Table(2)**; all were managed conservatively except one case of BCAVF that developed large wound hematoma then became infected with thrombosis and hemorrhage necessitating fistula ligation.

Causes of primary fistula failure:

Primary AVF failure occurred in 13 patients

(21.67%). Early thrombosis was diagnosed in 6 patients (10%) **Table(2)**, two of these patients had small veins that failed to dilate intra- and post-operatively, one had intra-operative thrombosis and thrombectomy was done but again thrombosis ensued postoperatively mostly due to hypotension during dialysis, one had infection, hemorrhage and thrombosis necessitating ligation and 2 had undergone successful thrombectomy and became mature later on. Inadequate maturation was the underlying problem in 11.67% of the cases (n=7), two of which as a result of accessory vein(s) that were revised later on and became mature. Three out of seven had no palpable thrill either due to small and weak inflow radial artery, or outflow vein stenosis and 2/7 failed to be cannulated one for small sized vein and the other vein was too deep and underwent superficialization and was successfully cannulated later on.

Table (2): Intra- and post-operative complications.

Complications	Number	%
Intraoperative		
Vein perforation	1	1.67
Failure of dilator passage	1	1.67
Thrombosis	3	5.00
Absence of palpable thrill	3	5.00
Postoperative Causes of primary fistula failure		
Inadequate maturation	7	11.67
Thrombosis	6	10.00
Infection	1	1.67
Hemorrhage	1	1.67
Mild complications		
Wound hematoma	4 (3 mild)	6.67
Steal syndrome	1	1.67
Venous hypertension	2	3.33

Maturation, functional maturation and primary fistula failure rates:

Of 60 access procedures the total number of fistulas that were judged to be matured was 49 (81.67%). Eleven (18.33%) fistulas were deemed not mature and were either not used, or abandoned at last follow up **Table(3)**. The total number of fistulas deemed “mature” that actually became functionally mature at first time cannulation was 47 out of 49 (95.9%). A total of 5 fistulas underwent revision, mostly for failure to mature. Two of the fistulas in which the vein failed to dilate sufficiently for cannulation underwent accessory vein ligation, 2 had successful thrombectomy, and one was too deep for cannulation and underwent transposition. Thus, after secondary procedures fistulas achieving assisted functional maturity became 52/60 (86.67%). Overall mean time to fistula maturation was 32 ± 1.29 days ($n=49$). For RCAVF mean maturation time was 33.63 ± 4.8 days, while that for BCAVF was

30.5 ± 4.3 days. Overall mean time from fistula creation to first time cannulation was 40 ± 9.6 days. It was longer in patients with RCAVF (43.22 ± 4.7) days than in patients having BCAVF (38.9 ± 3.6) days **Table(4)**. The more increased vein diameters after mechanical dilatation; the more likely for the fistula to mature and the lesser mean time for maturation and cannulation.

Access patency:

Cumulative primary patency was reduced in forearm fistulae compared with upper arm fistulae, with RCAVF having only 75% primary patency at 6 months (30/40 fistulae), compared with 85% at 6 months (17/20 fistulae) for BCAVF; Similarly, cumulative assisted primary patency was also reduced in RCAVF fistulae compared with BCAVF; assisted primary patency was 90% at 6 months in BCAVF (18/20 fistulae) compared with 85% at 6 months (34/40 fistulae) in the RCAVF ($p=0.036$).

Table (3): Vein diameter and its relation to fistula maturation.

Vein diameter (mm)	Number (%)		Maturation No. (%)		P-value
	RCAVF	BCAVF	RCAVF	BCAVF	
1.5-2	10(25%)	-	6(60%)	-	-
$\geq 2-3$	19(47.5%)	7(35%)	15(78.9%)	5(71.4%)	0.6465
$\geq 3-4$	10(25%)	10(50%)	8(80%)	9(90%)	1.000
$\geq 4-5$	1(2.5%)	3(15%)	1(100%)	3(100%)	-
Total	40(100%)	20(100%)	30(75%)	17(85%)	0.5128
Overall	60		47		

Table (4): Vein diameter and its relation to maturation and cannulation times.

Vein diameter (mm)	Maturation Time (days)		P-value	First cannulation time (days)		P-value
	RCAVF	BCAVF		RCAVF	BCAVF	
1.5-2	41.3 ± 8.8	-	-	50.4 ± 7.6	-	-
$\geq 2-3$	36.2 ± 6.7	36.3 ± 9.1	0.6702	47.3 ± 4.2	44.2 ± 6.3	0.0282*
$\geq 3-4$	30.8 ± 2.3	28.7 ± 1.5	0.0783	38.6 ± 3.4	40.3 ± 2.2	0.3043
$\geq 4-5$	25	24.3 ± 1.2	0.3739	31	30 ± 2	0.2879
Mean for the type (days)	33.63 ± 4.8	30.5 ± 4.3	$< 0.0001^*$	43.22 ± 4.7	38.9 ± 3.6	0.0021*
Overall (days)	32 ± 1.92			40 ± 9.6		

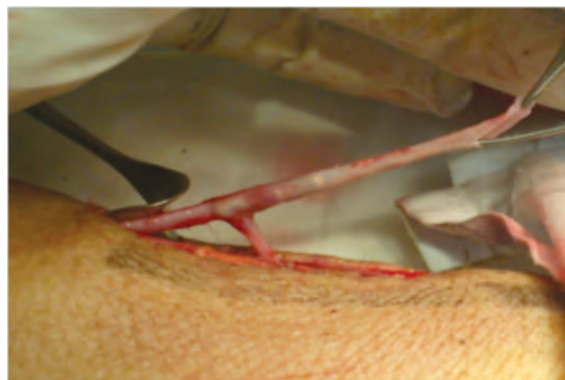


Figure (1): Cephalic vein before dilatation and dilator inside the vein.



Figure (2): Cephalic vein after dilatation and finished fistula.



Figure (3): Dilator in cephalic vein and finished anastomosis.



Figure (4): Cephalic vein before and after dilatation.

Discussion:

In order for a fistula to mature properly, the inflow artery and outflow vein should be unrestricted and free from disease. The diameter of these vessels is important since the resistance to flow through a cylindrical vessel is inversely proportional to the vessel radius.¹³ Vein size logically seems to be a major predictor of fistula maturation if we base functional maturity on flow. As Pouseuille's law dictates, flow (Q) is proportional to the product of change in pressure gradient (ΔP) and the fourth power of the vessel radius (r) divided by the viscosity (η) of blood ($Q \propto \Delta P \times r^4 / \eta$). Hence, larger veins (radius) mean larger flow. However, this does not take into account the arterial factors and normal pulsatile blood flow. Furthermore, venous compliance after fistula creation should be considered.³

In a study by Lauvao et al,³ the mean age was 58 ± 1.29 , our patient population was of slightly higher age (65 ± 15) years, and the prevalence of diabetes was higher than ours (62% vs. 41.67%). Hypertension, however, was found in 94% (148/158) of patients in their study compared with 76.67% (46/60) in our study population. Smokers were 16% similar to our data. Of special importance that our study patients were mostly on current dialysis (90%) in contrast to most other studies in USA and Europe where the guidelines recommend and implement planning for dialysis at least 6 months before the presumed date.

There is much discrepancy between time of maturation in various reports. For example, the median time to first fistula cannulation differed between countries, ranging from 28 days in Japan and Italy to 96 and 98 days in transplantation in UK and US, respectively.¹⁴ In Lauvao et al³ study, among 158 accesses constructed, 47 (29.74%) fistulas were deemed not mature and were either not used, or abandoned. Maturation rate was 111/158 (70%). Functional maturity was 101 out of 111 (91%). Overall mean time to fistula maturation was 82 ± 1.29 days. Mean time from fistula creation to first time cannulation was 147 ± 19.6 days. Only 80 patients (51%) were already on dialysis. Clearly different results were observed in our study where 11 (18.33%) fistulas were

deemed not mature and were either not used, or abandoned. Overall maturation rate was 49 (81.67%) and functional maturity was 47 out of 49 (95.9%). Assisted functional maturity after a secondary intervention was 52/60 (86.67%). Overall mean time to fistula maturation was 32 ± 1.29 days ($n=49$). Overall mean time from fistula creation to first time cannulation was 40 ± 9.6 days. Nearly similar mean maturation time was observed in Zadeh et al study while it was 38.60 days ($SD=42.13$).¹⁵ The Dialysis Outcomes and Practice Patterns Study (DOPPS) reported a mean cannulation time of 98 days in the United States.¹⁶ Fitzgerald et al¹² reported that overall, 80% fistulas matured, with 23% requiring an intervention to achieve maturity. The mean time to maturation was 3.8 months.

Several studies have provided insight into the problem of inadequate maturation however, there is relatively limited understanding of why fistulas fail. Roy-Chaudhury et al¹⁷ summarized the pathophysiology of early fistula failure. Genetic predisposition, turbulence, low shear stress, increases in transmural pressure, differences in compliance between arteries and veins, and injury to vasa vasorum of mobilized vein segment all lead to neointimal hyperplasia and harmful vascular remodeling. Failure due to early thrombosis is usually secondary to technical errors, judgment error regarding vessel adequacy, or a period of hypotension.¹⁸ A wide range of early primary fistula failure rates have been reported in the literature. Da Silva et al¹⁹ reported a 15% early failure rate, and Ozkoleli et al 18.8%.²⁰ A range of 12%-29% have been observed in other studies.^{21,22} In our study, primary AVF failure occurred in 13 patients (21.67%). Early thrombosis was diagnosed in 6 patients (10%). Overall primary patency was 47/60 (78.33) at 6 months. Also, Ekici et al²³ reported a 12% early thrombosis rate. Fitzgerald et al¹² reported overall primary patency and assisted primary patency rates at 12 months of 50% and 74%, respectively they observed that 2% of early thrombosis occurred after first use of the AVF.

A recent study by Iyem²⁴ reported an early thrombosis rate (5.98%) lower than that reported in the literature. The author attributed this to the use of mechanical dilatation with a

probe for relieving spasm of both the arteries and veins, and to the use of topical papaverine. He suggested that a proportion of early failure can be attributed to technical inadequacy, which can be avoided through this maneuver. He concluded that mechanical dilatation of the artery and vein, before starting the anastomosis, as well as the use of vasodilatory agents, could decrease early thrombosis of the fistula, and this method has very high early patency. We think that the aim of mechanical dilatation is to dilate the whole length of the small vein in order to promote maturation and hence cannulation, to relieve any spasm due to manipulation, to dilate any invisible stenotic or fibrotic areas which would be more evident after vein distension by blood flow causing outflow stenosis and to decrease resistance to blood flow in outflow vein through increasing the radius. As Corpataux et al²⁵ found in RCAVF, vein luminal size can increase by 86% in one week. However, distensibility (compliance) and not size was reported by van der Linden et al to be predictive of fistula maturation.²⁶

Conclusion:

In this study, the early fistula patency rate was better than that in several reports, the possible reasons for this may be: careful preoperative evaluation of the patients as well as careful anastomosis technique, which included mechanical dilatation for the vein in each patient and the artery in some cases. Gentle mechanical dilatation of the artery and vein, before starting the anastomosis can decrease the risk of early thrombosis of the fistula. Smooth non-violent passage of the dilator is a must to get benefit instead of harm from this procedure. Studies are still mandated to elucidate vein characteristics (early post-operative flow, vein size, or compliance) to increase fistula suitability for dialysis.

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