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COMPARATIVE STUDY OF THE CLINICAL OUTCOMES OF FUNCTIONAL SIDE TO SIDE ANASTOMOSIS AND TRADITIONAL END TO SIDE ANASTOMOSIS IN RADIO CEPHALIC FISTULA FOR DIALYSIS ACCESS

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ABSTRACT **Background :** End stage renal disease is a major public health problem, incidence of which is increasing every year. The significant mortality and morbidity associated with end stage renal disease is directly related to vascular access for hemodialysis. Hence, in this study we attempt to compare the outcomes of functional side to side anastomosis and traditional end to side anastomosis in radio cephalic AVF. Methods : Totally 60 patients with CKD receiving radial artery-cephalic vein arteriovenous shunt for hemodialysis were randomly divided into 2 groups, namely, the functional side-side anastomosis and the traditional end-side anastomosis. All parameters related to success rate and patency rate of the two methods were compared and analyzed. **Results :** Comparative analysis of mean cephalic vein diameter at 2nd and 6th week between ETS and STS groups showed statistically significant difference(p value <0.0001). But, at 12th week, mean diameter was not statistically significant. Flow rate across anastomosis in both groups were kept on increasing, but was less in STS than ETS. The short-term patency rates are similar between haemodialysis patients undergoing functional and traditional end-to-side anastomosis for radial artery-cephalic vein arteriovenous fistula. **Conclusion :** Although not all the results of the study were statistically conclusive but the parameters of Flow rate across anastomosis and cephalic vein diameter across anastomosis in the Functional STS group show statistically significant results thus fulfilling two important criteria for fistula maturation in accordance with —The Rule of Sixe. The Functional side-to-side technique can be definitely applied for initiating renal replacement therapy with some advantages over end-to-side technique, and without increasing the risk of primary failure of the fistula.

KEYWORDS : AV fistula; Dialysis; Functional side to side AVF

1. Introduction

End stage renal disease is a major public health problem, the incidence of which is increasing every year [1]. The introduction of hemodialysis as a treatment for renal failure represents one of the significant medical developments of the twentieth century. The significant mortality and morbidity associated with end stage renal disease is directly related to vascular access [2]. It was Dr Appel a surgeon working at the Bronx VA hospital in the year 1966, developed the idea of a surgically created arterio venous access for dialysis. His nephrology colleagues, Dr Brescio and Cimino received this idea with enthusiasm [3].

For successful construction of an AV fistula, a prerequisite is that of a suitable artery and vein located in proximity to each other [4]. The most common limiting factor is the absence of an adequate caliber vein [5]. The solution to this problem was to interpose an autologous or synthetic tube graft between an artery and vein. This access type has provided excellent function for chronic dialysis, but its complication rates and the cost of maintenance is higher in comparison to of an autogenous AV fistula [6].

A well-functioning vascular access is an important prerequisite for hemodialysis providing a repeated access to circulation with trivial complications [7]. The major limiting factor for dialysis is the high rate of primary failure (primary nonfunctioning before puncture). This high primary failure rate and maturation issues still enforce the search for better solutions [8]. The most common locations are radio cephalic (wrist), brachiocephalic (elbow) or brachiobasilic transpositions [9]. The most common types of AVF anastomosis used in uremic patients are vein end to arterial side (ETS). Other described techniques are vein side to arterial side (STS), vein end to arterial end (ETE) and vein side to arterial side (STE) [10]. In clinical practice, ETS anastomosis is the most common type because of higher proximal venous flow, longer fistula survival and lesser long-term complications like limb edema, steal phenomenon associated with conventional side to side fistulas [11]. In recent years, some scholars reported a modified AVF anastomosis, which had a good result. This modified AVF anastomosis was named functional STS anastomosis using side to side anastomosis with distal vein ligation, which achieved similar effects as those with ETS [12]. This article compares the clinical outcomes of functional side to side anastomosis and traditional end to side anastomosis in radio cephalic AVF for dialysis access and To compare the clinical outcomes of traditional end to side and functional side to side anastomosis in radio cephalic AVF for dialysis access.

2. Materials and Methods

The study was conducted in the Department of Burns, Plastic and Maxillofacial Department, Safdarjung Hospital, New Delhi. Patients with chronic kidney disease referred to the department for vascular access creation for dialysis. Total of 50 patients, 25 in each group (To maintain statistical significance and to minimize statistical error the sample size were taken as 30 in each group) and followed up for 18 months. Patients with CKD visiting the OPD for vascular access creation satisfying the following criteria were included in the study: Age (18-60 years), Visible cephalic vein, Cephalic vein courses superficially, Easily palpable radial artery, Patent palmar arch (assessed by Allen's test). Patient with either of the following conditions were excluded from the study: severe cardiac insufficiency, patient with bleeding disorders, patients in anticoagulants, veins which had previously been used for iv cannulation/hemodialysis/sampling.

Venous assessment using a tourniquet done, thereby assessing the calibre and course of cephalic vein at the level of wrist, mid and distal fore arm. The patient was then sent for duplex sonography. The imaging was done by a single experienced sonologist. Following variables were estimated: Cephalic vein diameter (at two representative sites at the wrist and mid fore arm), Radial artery diameter (at two representative sites at the wrist and mid fore arm) and Pre-operative radial artery flow rate at the wrist.

A single microvascular surgeon operated on all the cases. Patient was operated under local anaesthesia. The procedure was performed on the left wrist. If the left side was found unfavourable or if the patient is found to be left dominant then the procedure was done on the right wrist. The patient was allocated to either of the groups (ETS and STS) using a prior formulated randomized allocation technique. The fistula was then evaluated for thrill and complications like hematoma formation. Additional parameters recorded was operative time. After the suture removal between post-operative days 10-14 the patient was sent for duplex sonography on the 14th day, then at 6th and 12th weeks. The parameters assessed were: Cephalic vein diameter at the anastomosis, Flow rates across the fistula, Depth of vein from skin surface at anastomotic site, Complications like hematoma/abscess at operative site and thrombosis of cephalic vein across the fistula.

The clinical outcomes were measured in terms of maturation post-operative flow rates, patency and complications. The working definition of a mature fistula was that which satisfies either of the following criteria: Ability of access to withstand 3 consecutive dialysis sessions, Ability to provide a minimum flow of 600ml/min, Minimum diameter of the cephalic vein >/= 6mm, Depth of the fistula not more than 6mm from skin surface.

3. Results

3.1. pre operative assessment :

Pre operative assessment of patients in both groups states that maximum i.e. 23 (76.7%) patients in both groups(total = 46,76.6%) had cephalic vein diameter at wrist was 2-2.5, while 7 patients (23.7%) in both groups (total = 14, 23.4%) had CV diameter at wrist was >2.5. While maximum i.e. 39 patients (65%) (19 in STS, 20 in ETS) cephalic vein diameter at forearm was 2-2.5, while 21 patients (35%) in both groups had cephalic vein diameter at forearm was>2.5. But it had no statistical significance [Table 1]. 38 (63.4%) patients in both groups(19 in both groups) had radial artery diameter at wrist was 2-2.5, while 22 patients(36.6%) in both groups (11 in both groups) had radial artery diameter at wrist was >2.5. while 37 patients(61.6%) (18 in STS, 19 in ETS) radial artery diameter at forearm was 2.5-3, while 23patients (36.7%) in both groups had radial artery diameter at forearm was >3. It has no statistical significance. Mean RA flow at wrist in STS and ETS group was 60.5±7.9.Table 1.

Table 1: Comparision of pre operative assessment STS and ETS groups

VARIABLES FOR PRE OPERATIVE ASSESSMENT	VALUE	STS	ETS	TOTAL	P VALUE
CV DIAMETER					P VALUE-0.99
AT WRIST	2-2.5	23,50%	23,50%	46	
	>2.5	7,50%	7,50%	14	
	MEAN	2.3±0.24	2.3±0.24		
AT FOREARM	2-2.5	19,48.7 %	20, 52.3%	39	
	>2.5	11,52.3 %	10, 47.7%	21	
	MEAN	2.5±0.19	2.49±0.2		
RA DIAMETER					
AT WRIST	2-2.5	19,50%	19,50%	38	P VALUE - 0.98
	>2.5	11, 50%	11,50%	22	
	MEAN	2.62±0.28	3.05±0.23		
AT FOREARM	2.5-3	18,52.3 %	19,48.7 %	37	
	>3	12, 52.3%	11, 48.7%	23	
	MEAN	2.62±0.28	3.04±0.25		
RA FLOW AT WRIST	MEAN	60.5±7.9	60.5±7.9		P VALUE - 0.98

3.2. Comparison of intra operative assessment in STS and ETS groups: Intra operative assessment of patients in both groups states that mean operative time in both group was 50.6±17.9 minutes. All patients in both groups had pulsation across vein and thrill during intervention. Table 2.

Table 2: Comparison of intra operative assessment in STS and ETS groups

VARIABLES FOR PRE OPERATIVE ASSESSMENT	VALUE	STS	ETS	TOTAL
OPERATIVE TIME (MINUTE)	MEAN	50.6±17.9	50.6±17.9	
PULSATION ACROSS VEIN	YES	30	30	60
	NO	0	0	0
	TOTAL	30	30	60
THRILL	YES	30	30	60
	NO	0	0	0
	TOTAL	30	30	60

3.3. Comparative distribution of cephalic vein diameter at anastomosis at 2nd, 6th and 12th week :

Comparative analysis of cephalic vein diameter at the anastomosis shows that the mean cephalic vein diameter at 14th day in the ETS group is 2.92 and the STS group is 3.64. There is statistically significant difference in the cephalic vein diameter between the two groups at the 6 th week with a mean value of 3.43 in the ETS group and 3.84 in the STS group. The mean diameter at the 12 th week is 3.88 in the ETS group and 4.01 in the STS group which is not statistically significant. Table 3.

Table 3: Comparative distribution of cephalic vein diameter at anastomosis at 2nd, 6th and 12th week

CV DIAMETER AT ANASTOM	GROUP				P value
	ETS		STS		
	Mean	Standard Deviation	Mean	Standard Deviion	
14TH DAY	2.92	0.20	3.64	0.25	<0.0001
6TH WEEK	3.43	0.27	3.84	0.16	<0.0001
12TH WEEK	3.88	0.23	4.01	0.15	0.024

3.4. Comparative distribution of depth of cephalic vein from skin at anastomosis at 2nd / 6th / 12th weeks :

Comparative analysis of depth of cephalic vein from skin at anastomosis at the 2nd week showed a mean of 4.50 in the ETS group & 4.60 in the STS group. At the 6th week a mean of 3.36 in the ETS group and 3.38 in the STS group and at the 12th week a mean of 1.82 in the ETS group and 1.79 in the STS group. Table 4.

Table 4 : Comparative distribution of depth of cephalic vein from skin at anastomosis at 2nd / 6th / 12th weeks

DEPTH OF CV FROM SKIN AT ANASTOMOSIS	GROUP				P value
	ETS		STS		
	Mean	Standard Deviation	Mean	Standard Deviation	
14TH DAY	4.50	0.60	4.60	0.50	0.535
6TH WEEK	3.36	0.49	3.38	0.49	0.938
12TH WEEK	1.82	0.39	1.79	0.41	0.826

3.5. Comparative distribution of flow rate across the anastomosis at 2nd / 6th / 12th weeks :

Comparative analysis of the flow rate across the anastomosis at 2nd week / 6th week / 12th week is shown in the table. At the 2nd week the ETS group shows a mean flow rate of 782ml/min and the STS group 794.52ml/min. In the 6th week ETS group shows a mean flowrate of 811.23 ml/min and STS group 980.50 ml/min with a statistically significant difference (p value <0.0001) Table 5.

Table 5: Comparative distribution of flow rate across the anastomosis at 2nd / 6th / 12th weeks :

FR ACROSS ANASTOMOSIS	GROUP				P value
	ETS				
	Mean	Standard Deviation	Mean	Standard Deviation	
14TH DAY	782.00	74.34	794.52	77.88	0.577
6TH WEEK	811.23	52.43	980.50	54.31	<0.0001
12TH WEEK	976.14	63.32	1011.75	43.46	0.030

3.6. Comparative distribution of thrombosis across the anastomosis at 2nd / 6ht / 12th week :

Comparative analysis of the presence of thrombosis across the anastomosis in both the ETS and STS group showed no statistically significant difference in the incidence of thrombosis between both groups. The p value at 2nd week was 0.519, at the 6th week 1.00 and at the 12th week was 1.000.

Table 6: Comparative distribution of thrombosis across the anastomosis at 2nd / 6ht / 12th week

THROMBOSIS	GROUP				P
	ETS		STS		
	Count	Column N %	Count	Column N %	

14TH DAY	NO	23	76.7%	25	83.3%	0.519
	YES	7	23.3%	5	16.7%	
6TH WEEK	NO	24	80.0%	24	80.0%	1.000
	YES	6	20.0%	6	20.0%	
12TH WEEK	NO	24	80.0%	24	80.0%	1.000
	YES	6	20.0%	6	20.0%	

4. Discussion

End Stage Renal Disease patients depend on life-long renal replacement therapy either through dialysis or renal transplant to sustain their lives. Therefore, the most fundamental and crucial factor in haemodialysis treatment is securing vascular access for sufficient blood flow. The end cephalic vein-to-side radial artery arteriovenous fistula remains the ―gold standard procedure for primary haemodialysis access but it is associated with high rates of primary failure.

Brescia et al introduced internal AVF between the radial artery and the cephalic vein, also called the Brescia-Cimino procedure, which has been recognized as the most common surgical technique for internal AVF construction. Cascardo et al described the side-to-side brachiocephalic fistula in 1970 and Gracz et al introduced perforating vein AVF in 1977. Mehigan and McAlexander suggested procedures for the creation of AVF at the snuffbox for proximal vascular preservation in 1982 [14]. The ideal AVF provides adequate blood flow without any complications in the long term. However, repeated vessel punctures during prolonged haemodialysis lead to the development of vessel injuries, which in turn lead to thrombosis or obstruction [15]. Therefore, additional AVF construction is essential. The duration of use of the AVF is profoundly corelated to the lifespan of patients with CRF. The most commonly reported techniques of AVF anastomosis are ETE, STE, ETS and STS.ETE and STE anastomosis has the low fistula flowrate, which are used less in clinical practice STE anastomosis also has the greatest risk of venous hypertension .ETS anastomosis is a highly recommended anastomosis type because it has a high fistula flow and the low risk of venous hypertension of the hand . But in the fifty years since the original description of a radial-cephalic AVF, this technique is now known to have the worst patency of any primary fistulas [16]. In up to 77% of forearm fistulas, the primary cause of maturation failure at present is juxta-anastomotic stenosis. Two main hypotheses exist as to why the traditional AVF is susceptible to such a high percentage of neointimal hyperplasia.

First, disturbed hemodynamic forces, such as turbulent flow, may be accountable for endothelial activation, leading to neointimal hyperplasia. Altered hemodynamic forces are likely to be the result of the technique's geometry, including the angle of the venous segment with the artery, the length of the mobilized segment, and torsion of the mobilized vein, in addition to mechanical vibrations.

Second, mobilization of a large segment of vein divides the vasa vasorum, potentially creating relative ischemia as well as ischemia-reperfusion injury. Thus, a high rate of juxta- anastomotic stenosis is likely to be a significant factor in the surgical manipulation necessary to create the traditional end vein-to-side artery anastomosis [17].

On the basis of these hypotheses, various approaches have been tried, including use of anastomosis aids to reduce endothelial activation, alteration of the AVF's geometry and anastomosis style, and using drugs to impede neointimal hyperplasia. In addition, no-touch techniques for venous dissection have been tested, even though they did not significantly improve the results, which suggests that the principal reason for juxta-anastomotic stenosis is the geometry and manipulation in traditional technique. Hence there is a need for an alternative technique which can circumvent the problems of juxta-anastomotic stenosis.

STS anastomosis is the easiest construct technique and used commonly, which has the highest fistula flow. However, STS anastomosis has the highest risk of venous hypertension. The most effective solution of venous hypertension is ligation of the distal venous arm. The procedure of functional ETS anastomosis is STS anastomosis followed by distal cephalic vein ligation or distal cephalic vein ligation followed by STS anastomosis. It has a similar effect of traditional ETS anastomosis and has advantages of STS anastomosis at the same time.

In the present study we have compared two techniques to create an arteriovenous fistula (AVF): Traditional End to Side radio cephalic technique and Functional Side to Side anastomosis technique. This was a prospective observational study done on 60 patients of whom 30 underwent the traditional ETS radio cephalic AVF creation and 30 underwent the Functional Side to side technique.

Pre operative assessment of patients in both groups states that maximum i.e. 23 (76.7%) patients in both groups (total=46,76.6%) had CV diameter at wrist was 2-2.5, while 7 patients (23.7%) in both groups (total=14, 23.4%) had CV diameter at wrist was >2.5. while maximum i.e. 39 patients (65%) (19 in STS, 20 in ETS) CV diameter at forearm was 2-2.5, while 21patients (35%) in both groups had CV diameter at forearm was >2.5. 38 (63.4%) patients in both groups (19 in both groups) had RA diameter at wrist was 2-2.5, while 22 patients(36.6%) in both groups (11 in both groups) had RA diameter at wrist was >2.5. while 37 patients (61.6%) (18 in STS, 19 in ETS) RA diameter at forearm was 2.5-3, while 23patients (36.7%) in both groups had RA diameter at forearm was >3. There was no statistically significant difference in the cephalic vein diameter and radial artery diameter between the ETS and STS study groups. Mean RA flow at wrist in STS and ETS group was 60.5±7.9 and the difference was not statistically significant.

In a study done by bojakowski et al differences in the radial artery diameter between individuals with a patent fistula (2.59 +/- 0.47 mm) and patients with abnormal function vascular access (2.41 +/- 0.44) were not statistically significant. Preoperative diameter of radial vein, measured in the peripheral part of the forearm with a properly vascular access, amounted to 2.7 +/- 0.65mm and was statistically significantly higher diameter of the malfunctioning fistulas – 2.35 +/- 0.48 mm. preoperatively, peak velocity measured at rest in the peripheral part of the radial artery was significantly higher (44.0 +/- 15.45 cm/s) in patients with properly functioning fistulas patients with abnormalities in the fistular function (33.25±18.46) ($P<0.05$) [18].

Intra operative assessment of patients in both groups states that mean operative time in both group was 50.6±17.9 minutes. All patients in both groups had pulsation across vein and thrill during intervention. On the contrary in study of Sheng Guan et al the mean operation time periods for functional and traditional end-side anastomosis were (20.4±5.6) min and (26.2±5.2) min, respectively ($P<0.05$).

Flow rate across anastomosis infers that in STS group post op flow rate kept on increasing i.e. from 794.52(on 14th day) to 1011.75 (on 12th week). Similarly in ETS group post op flow rate kept on increasing i.e. from 782 (on 14th day) to 976.13 (on 12th week) but it was less than STS group. Comparative analysis of the flow rate across the anastomosis at 2nd week/6th week /12th week was done. At the 2nd week the ETS group shows a mean flow rate of 782ml/min and the STS group 794.52ml/mi. In the 6th week ETS group shows a mean flowrate of 811.23 ml/min and STS group 980.50 ml/min with a statistically significant difference (p value <0.0001). Since STS fistula achieves higher flow rate earlier than ETS fistula, it is better in terms of faster maturation. Similar results were also reported by a meta- analysis by Weigang et al average maturation time in functional ETS anastomosis was shorter than in traditional ETS anastomosis and 1-month patency rate in functional ETS anastomosis was higher than in traditional ETS anastomosis [19].

Comparative analysis of cephalic vein diameter at the anastomosis shows that the mean cephalic vein diameter at 14th day in the ETS group is 2.92 and the STS group is 3.64.The p value is <0.0001 is statistically significant. There is a statistically significant difference in the cephalic vein diameter between the two groups at the 6 th week with a mean value of 3.43 in the ETS group and 3.84 in the STS group and a p value of <0.001.The mean diameter at the 12 th week is 3.88 in the ETS group and 4.01 in the STS group which is not statistically significant with a p value of 0.024.A study done by EL Kassaby et al the mean dilatation of cephalic vein was found to be higher in the ETS group but they found no difference in patency rates of the fistula between the two groups [12].

Comparative analysis of depth of cephalic vein from skin at anastomosis at the 2nd week showed a mean of 4.50 in the ETS group,4.60 in the STS group with a p value of 0.535. At the 6th week a mean of 3.36 in the ETS group and 3.38 in the STS group with a p value of 0.938. And at the 12 th week a mean of 1.82 in the ETS group and 1.79 in the STS group with a p value of 0.826. There was no statistically significant differences in both groups in terms of cephalic vein depth

from skin. In a study done by crystal A Farrington et al primary AVF patency was not associated with postoperative AVF measurements, including blood flow, depth, or stenosis. Finally, using a multivariable model, the only factor associated with post maturation intervention was AVF diameter [20].

In STS group post operative thrombosis was seen in 23.4 patients on 14th day, then seen in 20% patients on 6th week and 12th week. While in ETS group post operative thrombosis was seen in 26.7% patients on 14th day, then it was seen in 20% patients on 6th week and 12th week. Comparative analysis of the presence of thrombosis across the anastomosis in both the ETS & STS group showed no statistically significant difference in the incidence of thrombosis between both groups. The p value at 2nd week was 0.519, the 6th week 1.00 and at the 12th week was 1.000. In a study done by Sung Yung et al the patency rates for the first and the second years were compared with those of previous studies conducted domestically. Fistula failure occurred in 13 patients during the follow-up. The most common cause of fistula failure was thrombotic occlusion (7 patients), followed by venous hypertension (3 patients), cephalic vein stenosis (2 patients), and poor function (1 patient).

Similar data about complications were reported in four articles of Guan S et al, Xu H et al, Chen JZ et al and Sun YB et al. Incidences of haemorrhage (1.40%, 2/143), infection (1.40%, 2/143), hand swelling (0.55%, 1/183), early thrombosis (1.00%, 1/101),thrombosis (2.11%, 3/142), venous stenosis (0%, 0/110) in the functional ETS group were all lower than incidences of haemorrhage (6.99%, 10/143), infection (6.29%, 9/143), hand swelling (1.09%, 2/183),early thrombosis (10.10%, 10/99), thrombosis (11.27%, 16/142), venous stenosis (3.96%, 4/101) in the traditional ETS group. The total incidence of complications were 8/246 (3.3%) for the functional ETS group and 39/244 (15.9%) for the traditional ETS group. The heterogeneity among these studies was not substantial (P=0.95, I2=0%), so the fixed-effects model was used for the meta-analysis. Complications of the functional ETS group were fewer than the traditional ETS group (OR 0.18, 95% CI 0.08–0.39, P <0.01.

In a study done by Mohammed EL Kassaby et al he reported that complications rates were more or less the same in the functional STS and traditional ETS group although the incidence of hematoma was almost significantly higher in the STS group (P 1⁄4 0.058). This he attributed to the extra dissection of tissues required to bring the vein into closer proximity to the artery. [12].

Juxta anastomosis stricture was seen in 6.7% of ETS group on 6th week and 12th week. While it was absent in STS group. Juxta anastomotic vein segment is described as the vein segment between 2-5 cm from the anastomosis. Stenosis in this segment is a reported complicated of the traditional end to side technique of anastomosis. This because of the altered hemodynamic forces are likely to be the result of the technique's geometry, including the angle of the venous segment with the artery, the length of the mobilized segment, and torsion of the mobilized vein, in addition to mechanical vibrations.(30,31) .In a study conducted by Keith Bertram et al fistula failure rate was 31% in traditional radio cephalic fistulas .The overall incidence of early juxta anastomotic stenosis was 7.5% and late 12.6%. [21,22].

There was no significant difference between the two groups with regards to primary patency as shown in the study. Although a fistula might remain patent for a long time, it might not be functioning to achieve adequate dialysis. Similarly in study of Sheng Guan et al the 1-month, 6-month, and 12-month patency rates were 93.6%, 87.3%, and 76.2%, in the functional end-side anastomosis group, and 95.1% (P>0.05), 82.0%(P>0.05), 72.1%(P>0.05) in the traditional end-side anastomosis group, respectively, with no significant differences found in the three rates between the two groups [19].

5. Conclusions

Although not all the results of the study may be statistically conclusive but the parameters of Flow rate across anastomosis and cephalic vein diameter across anastomosis in the Functional STS group show statistically significant results thus fulfilling two important criteria for fistula maturation in accordance with ―The Rule of Sixes .The Functional side-to-side technique can be definitely applied for initiating renal replacement therapy with some advantages over end-to-side technique, and without compromising efficacy and without increasing the risk of primary failure of the fistula.

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