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ORIGINAL ARTICLE

Stent graft deployment in haemodialysis fistula: patency rates in partially thrombosed aneurysm and residual thrombi

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ABSTRACT

Background. Current evidence is insufficient to determine the contribution of stent grafts as treatment in partially thrombosed aneurysms or residual wall-adherent thrombi in arteriovenous fistulae (AVFs) for haemodialysis. The overall purpose of this study was to analyse patency rates of post-interventional covered stent deployment in those cases. We also assessed if patency rates differed when fistulas were punctured through the stent during dialysis sessions.

Methods. We conducted a retrospective study between 2006 and 2014 analysing post-intervention primary patency rates using the Kaplan–Meier log-rank test. Multivariate Cox proportional regression models were performed to determine if cannulation within the stent graft area was a potential risk factor for occlusion, by adjusted hazard ratio (HR).

Results. A total of 27 procedures were included in the study. Primary patency rates (%) after stent deployment at 3, 6, 12, 24, 36 and 72 months were, respectively: total 59, 32, 32, 21, 11 and 5; stent puncture 53, 21, 21, 16, 5 and 0; and no stent puncture 80, 80, 80, 40, 40 and 40. Cannulation through the stent graft was not significantly associated with increased risk of obstruction in multivariate analysis ($HR = 3.01$; $P = 0.286$).

Conclusion. Stent graft treatment may be a feasible procedure in partially thrombosed aneurysms and residual thrombi in AVF. Although fistulas punctured through the stent presented lower patency rates, this practice was not associated with a higher risk of obstruction. Giving the impossibility of comparing with similar approaches, further studies are needed to confirm or refute the advantages of this procedure.

Keywords: aneurysm, arteriovenous fistula, renal dialysis, stents, thrombosis, vascular patency

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INTRODUCTION

A well-functioning vascular access (VA) is essential for optimal haemodialysis sessions. Arteriovenous fistulae (AVFs) are the preferred option for VA; however, they are not free of complications [1–3]. Aneurysms, defined as a dilatation of all three layers in any segment of the vein with a diameter >18 mm [4–6], may complicate all types of AVF by increasing bleeding risk and compromising an adequate blood flow [5]. While there is a consensus to not treat asymptomatic cases, different treatment options have been developed for symptomatic aneurysms, which are commonly managed with surgical techniques (e.g. aneurysmorrhaphy) or even with endovascular interventions [5, 7, 8]. Percutaneous deployment of stent graft has been used as an alternative treatment for AVF aneurysms to restore patency in selected cases [5, 8, 9].

Aneurysms are commonly accompanied by large thrombi [8, 10]. Endovascular methods can easily treat non-wall-adherent thrombi; however, wall-adherent thrombi are resistant to repeated catheter aspiration manoeuvres, causing compromised flow or anatomical failure [11]. The remaining clot may act in a ball valve fashion to incite re-thrombosis. In other instances, it serves as a nidus for rapid re-thrombosis [12]. Stent grafts theoretically provide a combination of endoluminal support to maintain vessel wall patency and a biocompatible barrier to prevent cellular ingrowth [13], and could be useful to avoid clot migration and re-thrombosis [14]. Partially thrombosed aneurysms or residual wall-adherent thrombi in AVF are not included as indications for use of stent graft [8, 15]. However, there are insufficient clinical data at present to determine the contribution of this percutaneous technique in these case scenarios.

To address this gap, we described the use of stent grafts to trap residual thrombi in partially thrombosed aneurysms and residual thrombi in AVF for haemodialysis. We assessed patency rates after stent graft deployment and, additionally, examined if these patency rates differed when the stent grafts were punctured with needles during the dialysis sessions.

MATERIALS AND METHODS

Study design and AVF selection

This is a retrospective cohort study designed to evaluate patients with end-stage renal disease undergoing percutaneous treatment with a stent graft in their AVF between January 2004 and December 2016. Patients with symptoms or functional AVF problems, including aneurysm of the outflow vein, were evaluated in our Vascular Radiology Unit (VRU) with duplex ultrasound scans. Patients with total or partial endoluminal thrombosed fistula were referred directly for percutaneous thrombectomy and for angioplasty when needed. In cases in which thrombectomy and angioplasty were unsuccessful, shown by ultrasound (persistent thrombus, or fistula unsalvageable with a high chance of fistula dysfunction recurrence or inability to achieve optimal flow), a stent graft was placed to salvage the fistula.

Fistula dysfunction was defined as the failure to attain or maintain an extracorporeal blood flow >300 mL/min at a pre-pump arterial pressure more negative than −250 mmHg or failure to maintain an extracorporeal blood flow sufficient to perform adequate haemodialysis without significantly lengthening the haemodialysis treatment [1]. Indications for fistula dysfunction treated with a stent graft included recurrent stenoses, thrombosis and aneurysms. Significant stenosis was diagnosed in the presence of ≥70% decrease in lumen area associated with decreased flow, elevated venous pressures or an abnormal physical examination (reduced thrill or pulsatile flow) [8]. Total thrombosis was considered when clinical examination showed complete absence of thrill and ultrasonographic study confirmed clots in the entire trajectory of the vein. Partial thrombosis, which developed in still running fistulas, did not totally occlude fistula lumen, and presented with a variety of clinical signs such as puncture difficulties, clot extraction and recirculation, and ultrasonographic study confirmed the presence of thrombus [16]. Aneurysm consisted of a dilatation of all three layers in any segment of the vein with a diameter >18 mm [4–6]. Symptomatic AVF aneurysm was considered in the presence of bleeding risk with an inadequate flow [5]. Wall-adherent thrombus was defined as thrombus that is resistant to repeated catheter aspiration manoeuvres causing compromised flow or anatomical failure [11]. Then, the two eligible procedures evaluated in this study were stent graft deployment due to: (i) aneurysmal fistula with residual wall-adherent thrombus or (ii) a fistula with wall irregularities and residual wall-adherent thrombus. Data were recorded during the endovascular procedure and included the general characteristics of the patients, AVF information and endovascular interventions.

Endovascular procedures

Patient preparation. Patients underwent a duplex ultrasonography to delineate the extension of the thrombus, and the zones of stenosis were marked. Then, the stent procedure was performed as an outpatient procedure in all cases. The upper extremity was prepared and draped in the usual sterile manner. Patients were monitored with electrocardiography, pulse oximetry and blood pressure measurement. Midazolam was used for conscious sedation during interventions. Digital subtraction angiography was performed with iodixanol contrast material. Blood flow fistula was measured before and after the intervention.

Thrombectomy and percutaneous transluminal angioplasty. The technique used for total or partial thrombectomy has been detailed by Turmel-Rodrigues [17] and modified [16]. Declotting was performed by ultrasound-guided manual catheter-directed thromboaspiration [16] without previous urokinase infusion in all cases. Stenoses were crossed with a 0.035-inch curved tip glide wire and were dilated under ultrasound and/or angiographic control, using high-pressure balloons. The diameter of the balloon was chosen to match the diameter of the normal vessel immediately upstream or downstream (measurements were done with duplex ultrasound imaging).

Stent deployment procedure. Patients were treated with a self-expanding nitinol skeleton encapsulated within two ultrathin layers of expanded polytetrafluoroethylene (PTFE) (Fluency Plus Stent Graft, Bard Peripheral Vascular, Inc., Tempe, AZ, USA). The stent diameters used ranged from 8 to 12 mm with lengths of 40–80 mm. Overlapping stents were required in some cases to sufficiently cover the length of the aneurysms (Figure 1). In all cases, a modified purse-string suture technique that included a miniature ‘tourniquet’ was used at the end of the procedure to achieve haemostasis [18]. Heparin was administered at doses

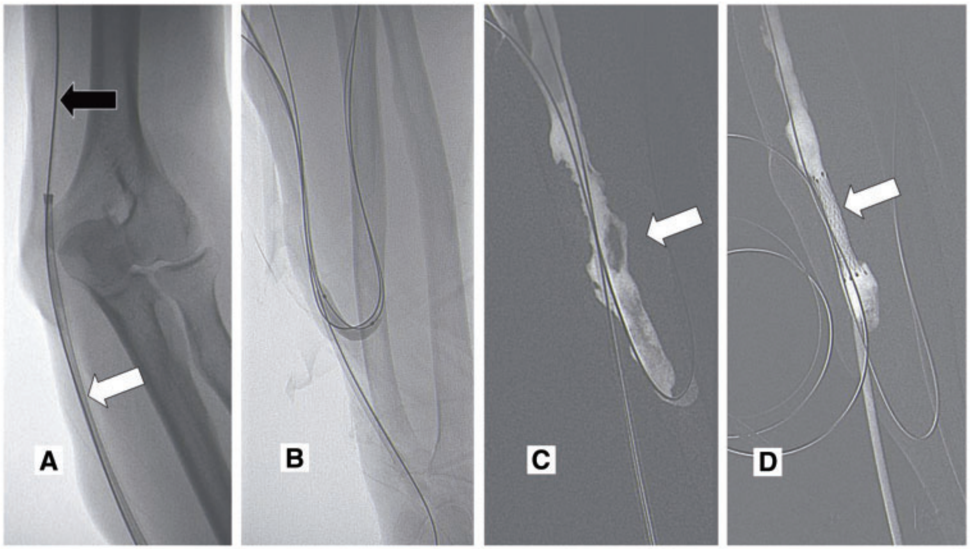

FIGURE 1: Manual thromboaspiration in an ulnar AVF. (A) Catheter (white arrow) and security wire (black arrow). (B) An anastomotic stenosis was dilated. (C) Residual parietal thrombus in basilic vein (white arrow). (D) Stent graft (Fluency, Bard) was implanted (white arrow).

ranging between 3 and 5000 IU. Antibiotics (cefazolin) were routinely administered for prophylaxis.

Follow-up and patency endpoints

Post-intervention patency follow-up was retrospectively reviewed. Data were collected from electronic medical records and additionally by phone calls to nephrologists when data were incomplete or not available (mainly explained by patients who underwent dialysis therapy in hospitals and haemodialysis units other than our VRU). Surveillance and monitoring after vascular radiology treatments were the responsibility of the nephrologists who initially referred the patients. A new endovascular treatment was performed when a recurrence appeared.

Primary patency of AVF after radiologic treatment was defined in accordance with recommended standards [19]. Post-intervention primary patency was defined as the interval from stent deployment to thrombosis, repeat intervention anywhere in the access circuit or the time of measurement of patency.

All patients underwent haemodialysis sessions after stent graft procedure. Dialysis nurses were instructed to avoid puncturing the stent grafts for 2–3 weeks after stent placement to allow for healing and ingrowth except in those cases in which it was necessary to canalize immediately due to lack of other feasible options.

Statistical analysis

Patients and VA characteristics were described using mean ± SD for quantitative variables, and absolute and relative frequency measurements for qualitative variables.

Survival tests using Kaplan–Meier method were performed to calculate primary patency rates and standard error (SE) at 3, 6, 12, 24, 36, 48 and 72 months, and median survival [±95% confidence interval (CI)]. Censored data were lost due to follow-up, study end and withdraw because of death, switch to peritoneal dialysis and renal transplantation. Log-rank test was used to compare patency rate differences according to general and clinical AVF characteristics, including post-interventional stent puncture. For the log-rank analysis, continuous variables were split according to median value. Multivariate Cox proportional hazards regression models were used to assess potential risk of obstruction and patency loss according to post-interventional stent puncture by adjusted hazard ratio (HR) with 95% CI. Enter method was performed to obtain final models. Factors included were post-interventional stent puncture and variables with $P < 0.1$ in log-rank test.

All tests were two-tailed and the level of statistical significance was <0.05. Analyses were performed with the statistical software IBM SPSS v.21 (IBM Corporation, Armonk, NY, USA).

RESULTS

A total of 2943 treatment procedures were identified within 12 years. Out of these, 27 procedures (0.9%) corresponding to 24 patients met the eligibility criteria. Three patients had two eligible procedures and 21 had one eligible procedure. The mean (SD) age of the patients was 70.8 (6.9) years, 51.9% were male, mostly non-smokers (88.9%) and with arterial hypertension (88.9%). The mean (SD) age of AVF until stent deployment was 1143.1 (809.8) days (Table 1). The mean time with dysfunction was 3.8 days, total thrombosis was present in 37.0% of interventions and the indications of stent placement were wall-adherent thrombus in aneurysm ($n = 13$) and residual wall-adherent thrombi ($n = 14$). Eighteen procedures were additionally treated with thrombectomy and 23 with percutaneous transluminal angioplasty.

All fistulas were located in the upper limb, mostly left-sided (74.1%). The main AVF location was in the upper arm (77.8%) (Table 1). Of these, the most frequent type of access was brachial–cephalic (20 access), and only one AVF was brachial–basilic. No perioperative complications that occurred were associated with stent graft deployment. In relation to haemodialysis sessions after stent graft procedure, a total of 19 AVF were punctured through the stent, while 8 patients were punctured in a different AVF area.

Post-interventional primary patency rates (SE) (%) at 3, 6, 12, 24, 36, 48 and 72 months were 59 (10), 32 (10), 32 (10), 21 (9), 11 (7), 5 (5) and 5 (5), respectively (Table 2). When we evaluated stent puncture as a risk factor in relation to post-interventional

Table 1. General and clinical characteristics of 27 AVFs

Characteristic	Total	P-value[b]
Patient age (years)		0.214
Mean (SD)	70.8 (6.9)	
≤70[a]	15 (55.6)	
Female	13 (48.1)	0.596
Smoking	3 (11.1)	0.091
Diabetes	11 (40.7)	0.416
Arterial hypertension	24 (88.9)	0.452
Dyslipidaemia	10 (37.0)	0.212
Cardiovascular disease	14 (51.9)	0.664
Time of haemodialysis (days)		0.372
Mean (SD)	1628.0 (1118.6)	
≤1544.0[a]	14 (51.9)	
AVF location		0.954
Forearm		
Radial-cephalic	5 (18.5)	
Ulnar-basilic	1 (3.7)	
Upper arm		
Brachial-cephalic	20 (74.1)	
Brachial-basilic	1 (3.7)	
Right side AVF	7 (25.9)	0.570
AVF age (days)		0.315
Mean (SD)	1143.1 (809.8)	
≤737.0[a]	14 (51.9)	
Previous procedures	18 (66.7)	0.267
Previous stent	4 (14.8)	0.368
Time of dysfunction (days)		0.399
Mean (SD)	3.8 (4.7)	
≤3.0[a]	15 (55.6)	
Total thrombosis	10 (37.0)	0.785
Thrombectomy	18 (66.7)	0.350
Percutaneous transluminal angioplasty	23 (85.2)	0.134
Stent indication		0.566
Partially thrombosed aneurysm	13 (48.1)	
Residual thrombi	14 (51.9)	
Stent puncture	19 (70.4)	0.039

Values presented are absolute frequency (percentage) unless otherwise indicated.

[a]Dichotomized variable using the median value as cut-off.

[b]Log-rank test P-values for comparison between subgroups.

patency loss, the post-stent deployment primary patency rates were higher in those AVF that were not punctured through the stent area (Table 2). Statistically significant difference was observed between both groups (Kaplan–Meier log-rank test; P = 0.039); however, stent puncture was unrelated to risk of obstruction in an adjusted model (HR = 3.01, 95% CI 0.40–22.75; P = 0.286; Figure 2). We additionally evaluated patency rates according to stent indication (partially thrombosed aneurysm versus residual thrombi; Supplementary data, Table S1). No statistically significant differences were found either in log-rank test (P = 0.566; Table 1) or in multivariate model (HR = 1.10, 95% CI 0.43–2.65; P = 0.884) (data not shown).

A total of 20 (74.1%) fistulas developed complications after endovascular procedure during follow-up. Post-operative early complications (<30 days) occurred in three fistulas (11 cases, 1%), which consisted of one stenosis and two thrombosis. Long-term complications (≥30 days) were due to stenosis (11 cases, 40.7%) and thrombosis (6 cases, 22.2%). No episodes of symptomatic arterial embolization of thrombus, clinical signs of pulmonary embolism or clinical signs of fistula infection occurred in the follow-up period (data not shown).

Table 2. Post-interventional stent deployment primary patency rates and median time of AVF, in total and according to stent puncture groups

Time Months	Total Rate[a] (SE) (%)	Stent puncture Rate[a] (SE) (%)	No stent puncture Rate[a] (SE) (%)
3	59 (10)	53 (11)	80 (18)
6	32 (10)	21 (9)	80 (18)
12	32 (10)	21 (9)	80 (18)
24	21 (9)	16 (8)	40 (30)
36	11 (7)	5 (5)	40 (30)
48	5 (5)	0	40 (30)
72	5 (5)	0	40 (30)
Me (95% CI) (days)	138.0 (70.7–205.3)	131.0 (75.5–186.5)	512.0 (0.0–1145.8)

[a]Estimated percentage patency.

Me, median survival; SE, standard error.

DISCUSSION

In this retrospective cohort study, we examined the risk of obstruction of the stent graft deployment procedure for treating partially thrombosed aneurysm and residual thrombi in AVF. Post-interventional primary patency rates were >50% at 3 months and less than one-third of the fistulas remained patent at 6 and 12 months. We also found that fistulas cannulated through the stent had lower patency rates compared with avoiding the stent area during dialysis; however, this factor was unrelated to the risk of fistula occlusion.

To our knowledge, this is the first published study with the largest experience in stent graft implantation in partially thrombosed aneurysm and residual thrombi. Compared with previous works using stent grafts, the homogeneity of treatment indication in this study allowed us to report specific patency rates in these cases. Bent *et al.* [9] reported Fluency stent graft implantation in 17 patients, 6 cases with persistent thrombus within an aneurysmal venous segment with inability to achieve optimal flow, obtaining total primary patency rates of 94.1% at 3 months and 88.2% at 6 and 12 months. Gupta *et al.* [20] implanted four stent grafts in four cases: two patients had covered stents placed after multiple failed angioplasties, pseudoaneurysm formation and non-occlusive thrombus formation with multiple interventions, and another two had covered stent placement after attempted thrombectomy of fully occluded fistula in which the clot could not be completely evacuated and continued to limit flow. Other papers showed the experience in thrombosed aneurysms with the use of other devices. Ahn *et al.* [21] reported 16 patients who had a thrombosed AVF complicated with an aneurysm. Recanalization procedures were performed by mechanical thrombectomy using the Arrow-Trerotola percutaneous thrombectomy device and adjunctive treatments. In this study, the primary patency rates at 3, 6 and 12 months were 70.5, 54.8 and 31.3%, respectively. The reasons for the differences from our results may be due to a younger average age of participants (63.2 years versus 70.8 years), and other characteristics (e.g. diabetic or not) that were not accounted for.

Surgical works have described their experience with aneurysmorrhaphy, a mainly used technique for the aneurysm of AVF [8]. Rokošný *et al.* [7] reported a total of 62 patients (median age of 60 years) in >5 years using reinforced aneurysmorrhaphy with PTFE mesh in autogenous access. Of them, one case had a

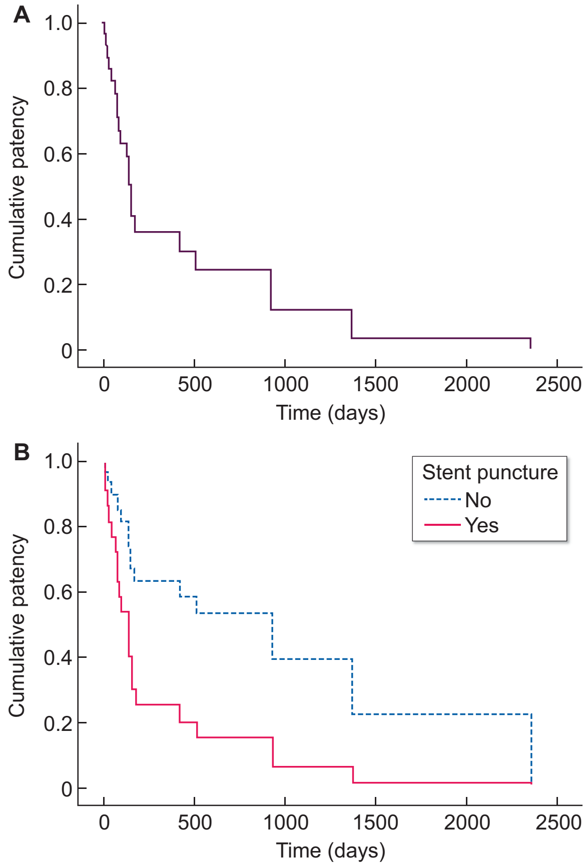

FIGURE 2: Multivariate Cox regression models evaluating patency rates of post-interventional covered stent deployment in wall-adherent thrombus aneurysm or residual wall-adherent thrombus in AVF for haemodialysis. Post-interventional primary patency rates for total cohort (A) and according to stent puncture (B) ($P \geq 0.05$).

thrombosed aneurysm as the surgical indication. Primary patency rates achieved 93, 86 and 79% at 3, 6 and 12 months, respectively. Wang and Wang [22] described their experience with 185 aneurysmal AVF (patients aged 60.1 years on average) using partial aneurysmectomy and repair. There were 24 organized thrombi complicating the aneurysm, and total primary patency rates resulted in 59% and 45% at 6 and 12 months, respectively.

In relation to stent grafts that were punctured with needles during the dialysis sessions, no statistically significant differences have been observed in patency loss when compared with those AVF punctured avoiding the stent. The safety of repeatedly cannulating a stent graft has not been conclusively established [23, 24]. Schürmann *et al.* [25] compared nitinol stents and Wallstents placed in a carotid–jugular shunt in a sheep model and reported that intimal hyperplasia was more pronounced in punctured when compared with non-punctured stents. The outward bulge of the vascular layers over the stent struts was greater with nitinol stents compared with Wallstents. Zaleski *et al.* [26] and Turmel-Rodrigues *et al.* [27] also confirmed the feasibility of stent puncture in VA outflow veins. Rhodes and Silas [28] suggest that a Wallgraft-covered stent can withstand routine venepuncture at dialysis without flow-limiting stent distortion.

Several limitations should be discussed. First, there was no comparison between stent graft implantation in aneurysms with residual thrombi and aneurysmal surgical resection because of the impossibility of making this randomization in our working environment. Secondly, some important information such as flow, vessel diameter and lesion size was not available in our study; therefore, we could not rule out the possibility of residual confounding in the adjusted analysis. Thirdly, although procedures were performed by two expert interventional radiologists from a single centre, data were retrospectively reviewed and operators were not blinded to the study. Fourthly, this work has been focused on fistulas with partially thrombosed aneurysm and residual thrombi, which may have increased the internal validity; however, it may limit the generalizability to other stent graft indications. Finally, although this is the largest study reported to date and represents the standard clinical practice in our VRU, the sample size was small and could lead to a lack of statistical significance. Randomized controlled trials with higher sample size are definitely needed to confirm our findings and to allow comparability between different techniques in terms of patency and safety results.

In conclusion, this is the first study reporting on the use of stent grafts as a feasible procedure in partially thrombosed aneurysms and residual thrombi for haemodialysis fistulas. The results of this procedure showed low patency rates, decreasing in fistulas that were punctured through the stent during dialysis. However, this practice was unrelated to higher risk of obstruction. Given the impossibility of comparison with similar approaches, further prospective studies with higher sample sizes are needed to confirm the advantages of this technique.

SUPPLEMENTARY DATA

Supplementary data are available at ckj online.

CONFLICT OF INTEREST STATEMENT

None declared. The results presented in this article have not been published previously in whole or part, except in abstract format.

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