The secondary patency after patch venoplasty versus balloon venoplasty in management of neointimal hyperplasia of the venous anastomosis of thrombosed arteriovenous grafts for hemodialysis

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Background
The pathogenesis of neointimal hyperplasia associated with hemodialysis arteriovenous (AV) grafts is complex and likely involves surgical manipulation of the tissues, material biocompatibility, and mechanical factors. Both surgical and radiological interventions for stenosed and thrombosed AV graft have been described aiming at the optimal restoration of morphology and function.
Aim
To compare the secondary patency after patch venoplasty and balloon venoplasty in management of neointimal hyperplasia of the venous anastomosis of AV graft for dialysis.
Patients and methods
This is a double-armed randomized prospective study that was carried out at Ain Shams University hospitals for 2 years. A total of 20 patients with thrombosed synthetic AV graft were enrolled in this study. The first group (10 patients) was treated with patch venoplasty, and the second group (10 patients) with balloon venoplasty adjunctive after surgical thrombectomy.
Results
Graft patency at 6-month and 12-month follow-up was 90 and 70% for the balloon angioplasty group versus 60 and 40% for the surgical patch venoplasty group (P=0.3 and 0.37, respectively).
Conclusion
In the present study, the outcome of balloon venoplasty was better than and patch venoplasty for thrombosed AV grafts. In addition to better graft patency, balloon venoplasty offers the advantage of shorter operative time and lower morbidity. Further studies with a large sample size and multicentric cooperation are required to confirm the present findings.

Keywords:
balloon venoplasty, neointimal hyperplasia, patch venoplasty, thrombosed arteriovenous graft

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Introduction

The three major forms of vascular access used for chronic hemodialysis are the native arteriovenous (AV) fistula, the synthetic AV graft, which is usually made of expanded polytetrafluoroethylene (ePTFE), and the cuffed, tunneled double-lumen central venous catheter [1].

AV grafts are used in patients with end-stage renal disease who are not candidates for autologous AV fistula creation owing to lower patency rates. Graft neointimal hyperplasia (NH) at the anastomotic site leads to graft thrombosis and failure. There are two theories when it comes to the initiating factors that lead to venous intimal hyperplasia at the graft vein anastomosis site. The widely accepted theory is that low shear stress caused by turbulence and compliance mismatch alters smooth muscle cells, leading to venous hyperplasia at the anastomotic site [2].

NH tends to form in the 'shoulder' region within the lumen of the graft and in the 'cushion' region of the native vessel. Stenotic tissues obtained from the graft–venous anastomosis of human AV ePTFE grafts showed an abundance of smooth muscle cells and/or myofibroblasts, accumulation of extracellular matrix, neovasculature within the NH and adventitia, and the presence of a macrophage layer lining the PTFE graft material [3].

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Balloon angioplasty is the standard percutaneous treatment for NH stenoses involving native arteries, native veins, and vascular anastomoses. The ease and speed of an angioplasty procedure, for both patient and physician, contributes to the continuing popularity of the procedure. However, balloon angioplasty does not remove the neointimal tissue that causes the obstructive stenosis. Its mechanism of action is forceful intraluminal expansion creating deep fractures into the neointimal tissue thereby, enlarging luminal cross-sectional area and improving blood flow. NH stenoses are dense, fibrotic lesions that are often resistant to dilatation requiring balloon inflation pressure of 15–20 atmospheres [4].

Open surgical revision has remained the gold standard for the treatment of stenoses in grafts. Surgical options include vein patch angioplasty, interposition grafting, and jump grafting. Patch angioplasty has been shown to be especially effective in the treatment of focal lesions [5].

Aim

We aim to compare the secondary patency after patch venoplasty and balloon venoplasty in management of NH of the venous anastomosis of AV graft for dialysis.

Patients and methods

This is a double-armed randomized prospective study at Ain Shams University hospitals from December 2017 to December 2019. This research was performed at the Department of Vascular Surgery, Ain Shams University Hospitals. Ethical Committee approval and written, informed consent were obtained from all participants. A total of 20 patients with thrombosed synthetic AV graft were enrolled in this study (10 per group). The first group was treated with patch venoplasty and the second group with balloon venoplasty as an adjunctive therapy to surgical thrombectomy by Fogarty catheter for removal of graft thrombus.

Inclusion criteria

The following were the inclusion criteria:

(1) Only PTFE brachioaxillary grafts were included.
(2) Thrombosed AV grafts implanted at least 3 months earlier diagnosed by failure of dialysis, loss of thrill, and confirmed by duplex ultrasound.
(3) Duration of graft thrombosis of 10 days or less.

Exclusion criteria

The following were the exclusion criteria:

(1) Hypotensive patients.
(2) Patients with signs of graft infection or systemic sepsis.
(3) Manifestations of central venous occlusion clinically and by venous duplex or computed tomography venography.
(4) Graft failure owing to arterial side stenosis by duplex.
(5) Puncture site pseudoaneurysm.

Technique

The balloon venoplasty group

All procedures were performed under local infiltration anesthesia. A short incision was made over the middle part of the graft, and the graft was exposed and controlled. A small graftotomy was made and thrombectomy followed, using a 5-F Fogarty balloon at venous side and 4 F Fogarty balloon at arterial side. A 6-F or 8-F, 11-cm-long introducer sheath was placed, and a venogram was performed to identify the cause of the graft thrombosis. Venous anastomotic stenosis or occlusion was crossed with a 0.035-inch guide wire terumo followed by gradual balloon dilatation to 6–8-mm diameter, using high-pressure mustang balloons (Boston Scientific, Natick, Massachusetts, USA) (Fig. 1).

The patch venoplasty group

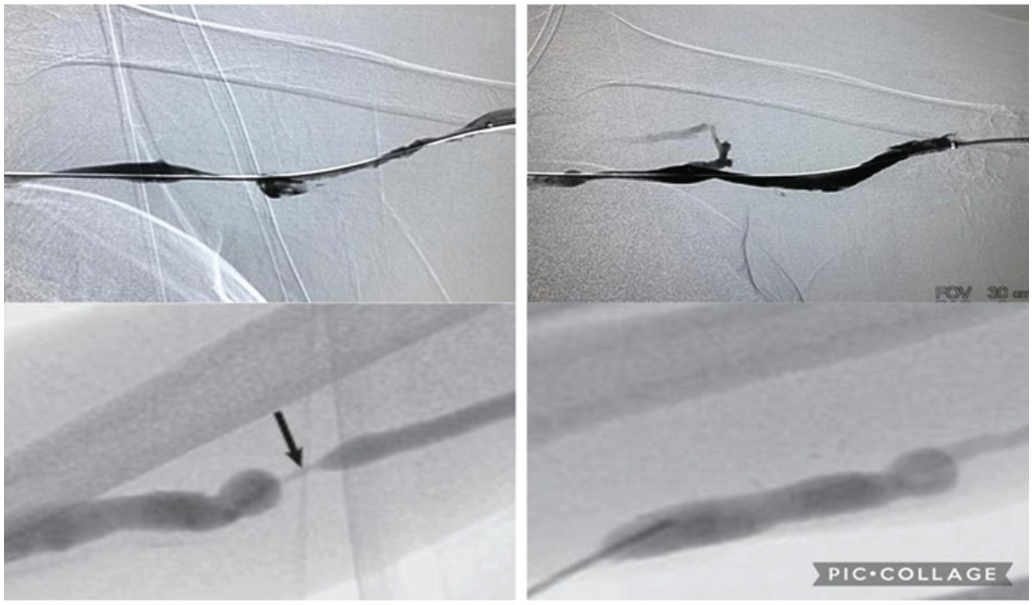
Procedures were performed under local infiltration anesthesia, supraclavicular block, or general anesthesia. After graft exposure at the venous end, a small longitudinal incision at venous end of the graft about 5 and extended on to the native vein. Mechanical thrombectomy was performed using a 5-F Fogarty catheter on the venous limb first and then 4-F Fogarty catheter on the arterial limb. The graft and the vein were closed by a PTFE patch using 5-0 prolene (Fig. 2).

Follow-up: dialysis was resumed after removal of stitches 7–10 days postoperatively. Follow-up was carried out at 6 and 12 months for patency and complications. Patency was assessed clinically and by duplex ultrasound.

Statistical analysis

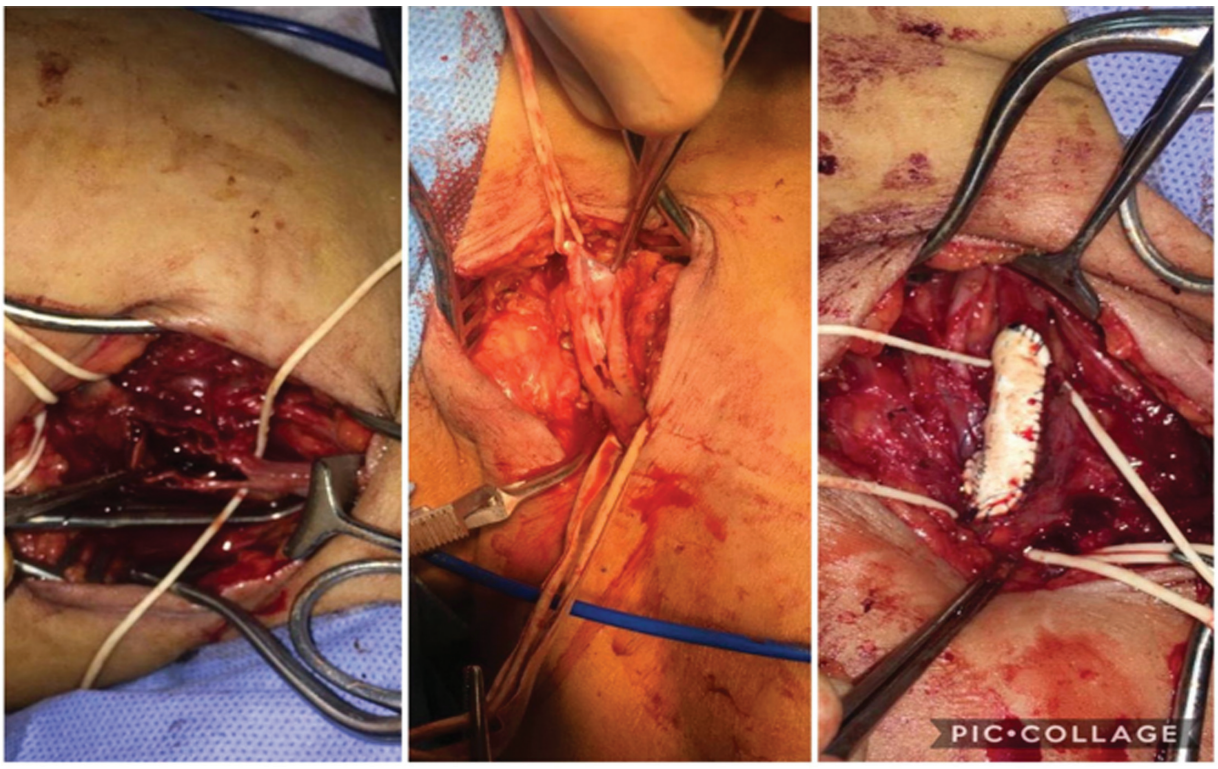
The statistical results were calculated in intention to treat from prospective data. The continuous variables were presented in the form of mean and SD. The categorical variables were presented as percentages. The demographic data and the comorbidities of the patients were related to the number of patients, whereas the patency data were calculated according to the number of limbs.

Figure 1



(a) Occluded venous anastomotic site of AV graft, (b) post-balloon venoplasty of the venous anastomosis site. AV, arteriovenous.

Figure 2



(a) Thrombosis of the venous anastomotic site of AV graft, (b) Neointimal hyperplasia of the venous anastomotic site after removal of thrombosis, (c) the PTFE patch placed at the venous site of AV graft. AV, arteriovenous; PTFE, polytetrafluoroethylene.

Table 1 Demographics and risk factors for the two groups

	Group I (patch venoplasty)		Group II (balloon venoplasty)		*t**	*P* value
	Mean	SD	Mean	SD		
Age	49.20	13.92	55.20	12.66	1.01	0.33 NS
	n (%)		*n* (%)		χ^{2**}	*P* value
Sex	Male (6)		60.0% (4)		0.80	0.37 NS
	Female (4)		40.0% (6)			
ESRD duration (years)	5.80 (2.78)		4.65 (3.38)		0.83	0.42 NS
Current smoking	10 (100.0)		10 (100.0)		–	–
Ex-smoker	0		1 (10.0)		1.05	1.00 NS
Obesity	2 (20.0)		3 (30.0)		0.27	1.00 NS
Diabetes	2 (20.0)		6 (60.0)		3.33	0.17 NS
Hypertension	2 (20.0)		4 (40.0)		0.95	0.63 NS
Hypercholesterolemia	2 (20.0)		5 (50.0)		1.98	0.35 NS
Ischemic heart disease	0		2 (20.0)		2.22	0.47 NS
ASA grade						
2.00	10 (100.0)		8 (80.0)		2.22	0.47 NS
3.00	0		2 (20.0)			

Determine that no significant differences between both group.

Table 2 Preoperative clinical data

	Group I (patch venoplasty)		Group II (balloon venoplasty)		*t**	*P* value
	Mean	SD	Mean	SD		
Duration of AVG (months)	11.30	6.95	13.90	8.69	0.74	0.47 NS
Duration of thrombosis (days)	5.00	1.83	5.20	2.10	0.23	0.82 NS
SBP	116.00	9.66	115.00	8.50	0.25	0.81 NS
DBP	70.00	8.16	71.50	6.69	0.45	0.66 NS
	n (%)		*n* (%)		χ^{2**}	*P* value
Site of AVG						
Right UL	4 (40.0)		3 (30.0)		0.22	1.00 NS
Left UL	6 (60.0)		7 (70.0)			

AVG, arteriovenous graft; DBP, diastolic blood pressure; SBP, systolic blood pressure; UL, upper limb. *Student *t* test. **Fisher exact test.

Results

A total of 20 patients were enrolled in this study (10 per group): the first group was treated with patch venoplasty and the second group with balloon venoplasty.

The two groups were well matched regarding age, sex, duration of dialysis, and risk factors (Table 1).

Preoperative laboratory findings including hemoglobin, HbA1c, creatinine level, and albumin levels were similar in both groups (Table 2).

The duration of procedure showed no-significant difference between the two groups in favor of the balloon venoplasty group (Fig. 3).

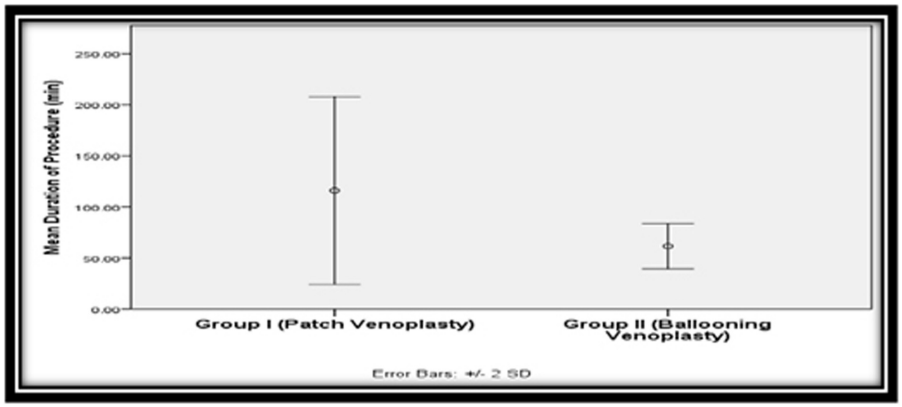
At 6 and 12 months, there was no statistically significant difference in patency rate between the two groups in favor of the balloon venoplasty group (90 and 70% vs. 60 and 40% patency rate of the patch venoplasty group), with *P* values of 0.3 and 0.37, respectively (Figs 4–6).

Discussion

Results of management of AV graft thrombosis have generally been unsatisfactory with a 1-year primary patency of ~50%. Open surgical revision, by patch venoplasty, interposition grafting, or jump grafting, has remained the gold standard for the treatment of anastomotic graft stenosis for a long time. More recent literature has shown promising results with balloon angioplasty for management of such cases [6].

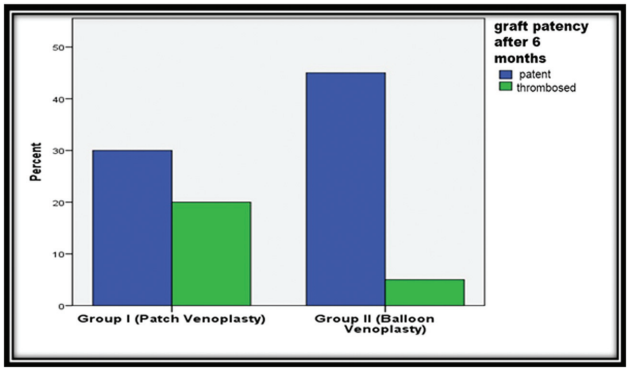
Tordoir *et al.* [7] analyzed the evidence to see whether endovascular or surgical treatment has the best outcome in terms of primary success rate and long-term patency. The authors performed a systematic literature search of endovascular and surgical repair of thrombosed hemodialysis vascular access. One meta-analysis and eight randomized studies on the

Figure 3



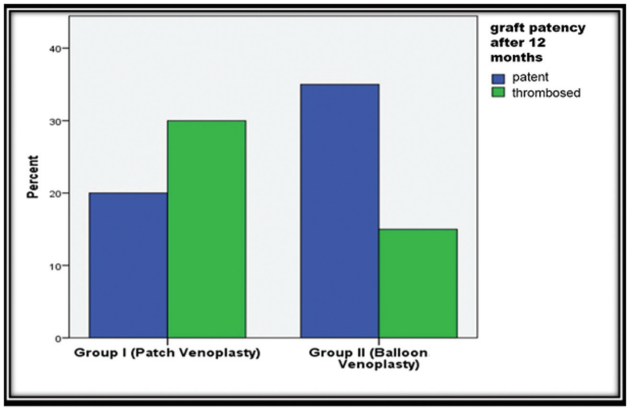
Duration of procedure for the two groups.

Figure 4



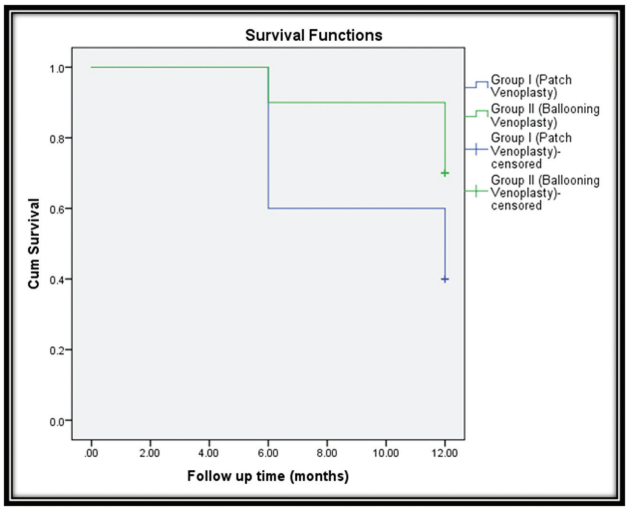
Graft patency at 6 months.

Figure 5



Graft patency at 12 months.

Figure 6



Kaplan–Meier survival curve for secondary patency of patch angioplasty versus balloon angioplasty.

treatment of AV graft thrombosis were identified. There were no statistically significant differences between both techniques in terms of procedural success and subsequent graft patency [7].

Our 1-year graft patency rate was significantly higher for balloon venoplasty compared with patch venoplasty (70 vs. 40%). Allam *et al.* [8] evaluated mid-term outcomes of surgical thrombectomy of clotted AV graft with adjunctive venous outflow procedures mainly patch angioplasty versus balloon dilatation to restore their function regarding patency and safety. They showed a graft patency at 6, 9, 12, and 18 months of 86.4, 100, 88.6, and 77.3%, respectively, for balloon angioplasty versus 72.1, 90.7, 79.1, and 69.8%, respectively, for patch venoplasty, with no statistically significant difference [8].

Likewise, Kao *et al.* [9] retrospectively reviewed patients who received dialysis graft thrombectomy to compare the effectiveness of two different methods. A total of 289 dialysis graft thrombectomy procedures performed were reviewed. The results of 163 cases in balloon angioplasty group were compared with those of 129 patients who underwent outlet revision. There was

no difference between two groups regarding graft patency [9].Furthermore, Liu *et al*. [10] investigated the long-term outcome of dialysis graft thrombectomy. Surgical outcomes of 590 consecutive dialysis graft thrombectomies performed between 2001 and 2003 were retrospectively reviewed. No statistically significant difference between balloon venoplasty and patch venoplasty was observed [10].

Conclusion

Balloon venoplasty offers an equivalent and probably more superior option over patch venoplasty for thrombosed AV graft. In addition to graft patency, balloon venoplasty offers advantage over patch venoplasty in terms of shorter operative time. Further studies with a large sample size and multiregional cooperation are required to establish such results.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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