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# Twitter Thread by Aisha Shaikh





## ■ Role of Stents in Dialysis Vascular Access - Tweetorial

■Indications for Stent Use

■■Recent Clinical Trials of Stents in Dialysis Vascular Access

## ■■Complications associated with Stent Use

## 1/

@ASDINNews #VascularAccessPearls

Arterio-venous (AV) Access causes significant morbidity & mortality in patients on hemodialysis

Most AV access associated complications are due to vascular stenosis

■■Vascular Access care has evolved over the past 60 years:

-Scribner's Shunt in 1960 → -Brescia-Cimino AVF in 1966 → -1st Balloon Angioplasty in 1981 → -1st Bare Metal Stent in 1988 → -1st Covered Stent in 1996 → -DCB use in 2012 3/



Despite these innovations, AV access stenosis remains a big problem

-Percutaneous Balloon Angioplasty (PTA) remains the 1st line therapy for stenosis but it is NOT very effective

-AVF patency after PTA is only 50% at 6-months & it is worse for AVGs

	PC	в	Contr	ol		Risk Ratio	Risk Ratio	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% Cl	
1.1.1 RCT								
Irani 2018	11	59	23	60	7.1%	0.49 [0.26, 0.91]		
Kitrou 2015	6	20	15	20	6.3%	0.40 [0.20, 0.82]		
Kitrou 2017	10	20	13	20	7.9%	0.77 [0.45, 1.32]		
Maleux 2018	11	33	11	31	6.6%	0.94 [0.48, 1.85]		
Roosen 2017	13	16	9	18	8.1%	1.63 [0.97, 2.73]		
Swinnen 2018	16	68	32	60	8.4%	0.44 [0.27, 0.72]		
Teo 2013	7	14	11	16	7.1%	0.73 [0.39, 1.35]		
Trerotola 2018 Subtotal (95% CI)	41	141 371	53	144 369	10.0% 61.5%	0.79 [0.57, 1.10] 0.71 [0.52, 0.98]	<b></b>	AVF primary patency after
Total events	115		167					
Heterogeneity: Tau <sup>2</sup> =	0.12; C	$hi^2 = 18$	8.75, df =	= 7 (P =	= 0.009);	$l^2 = 63\%$		conventional balloon angioplasty at
Test for overall effect	: Z = 2.1	1 (P = 0)	0.03)					6 months is 49%
1.1.2 Cohort studies								
Hongsakul 2018	6	16	16	16	7.2%	0.39 [0.21, 0.72]		
Lai 2014	3	10	10	10	5.1%	0.33 [0.14, 0.80]		
Lucev 2018	3	31	12	31	3.5%	0.25 [0.08, 0.80]		
Massmann 2015	11	32	24	32	8.1%	0.46 [0.27, 0.77]		
Qamhawi 2018	13	26	19	26	8.8%	0.68 [0.44, 1.07]		
Swinnen 2015	1	37	14	37	1.5%	0.07 [0.01, 0.52]	·	
Zheng 2018	3	12	9	12	4.2%	0.33 [0.12, 0.94]		
Subtotal (95% CI)		164		164	38.5%	0.41 [0.28, 0.60]	•	
Total events Heterogeneity: Tau <sup>2</sup> = Test for overall effect	40 = 0.09; C : Z = 4.6	hi <sup>2</sup> = 9. 8 (P < 0	104 96, df = 0.00001)	6 (P =	0.13); I <sup>2</sup>	= 40%		
Total (95% CI)		535		533	100.0%	0.57 [0.44, 0.74]	•	
Total events	155		271					
Heterogeneity: Tau <sup>2</sup> = Test for overall effect Test for subgroup diff	= 0.15; C : Z = 4.2 ferences:	$hi^2 = 36$ 4 (P < 0 Chi <sup>2</sup> =	5.57, df = 0.0001) 4.91, df	= 14 (P = 1 (P	= 0.0009 = 0.03),	9); $I^2 = 62\%$ $I^2 = 79.6\%$	0.05 0.2 1 5 Favours [PCB] Favours [control]	20
Fig 2. Six-month paclitaxel-coated	priman balloon	, pate RCT,	ncy wit randor	h sub nized	ogroup contro	analysis. <i>Cl</i> , Confider lled trial.	nce interval: <i>M-H</i> , Mantel-Haensze	I: PCB.

Wee et al. J Vasc Surg 2019;70:970-9

■■Neointimal Hyperplasia (NIH) causes vascular stenosis & it is due to:

-Hemodynamic stress

- -Surgical trauma
- -Cannulation needle trauma
- -AVG

■■But balloon angioplasty, the treatment for stenosis, can itself induce NIH & cause restenosis■■ 5/



■■Therefore, Endovascular Stents have been used to treat the vascular stenosis

#### ■■What are Endovascular Stents?

They are scaffolds that provide mechanical endoluminal support to the vessel wall to maintain patency 6/

■■Types of Stents:

-1st generation stents were Bare-Metal Stents made of stainless steel

-Next generation of metal stents were Nitinol Stents made of nickel-titanium alloy

- Covered-Stents (Stent-Grafts) are Nitinol stents covered w/ ePTFE or Dacron

■Bare Metal Stents & Nitinol Stents have problems because the tissue in-growth through the bare metal causes restenosis

Covered Stents (Stent-Grafts) theoretically form a barrier, & prevent tissue in-growth through the stent & cause less restenosis

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Recent clinical trials have tested the efficacy of Stent-Grafts for AV access stenosisBut before we get to the trials, let's discuss the basic indications for Stent use:

- Rupture of the vessel
- Recoil (Residual stenosis)
- Restenosis
- 9/

## Indications for Stent Use in Dialysis Vascular Access



🔰 @aishaikh

■■Rupture of the vessel can occur during angioplasty of a severely stenotic lesion

In most cases, extravasation can be controlled w/ manual compression or balloon tamponade but if bleeding persists then stents can be used to control the bleeding



■Another indication for Stent use is Recoil

Recoil is defined as residual stenosis of > 30% following angioplasty & is thought to occur due to elastic recoil of the vessel wall

Recoil is associated w/ poor AV access survival 11/



Recoil is defined as <u>residual stenosis</u> of >30% following angioplasty with an appropriately sized balloon







Ginsburg et al. Seminars in Interventional Radiology Vol. 32 No. 2/2015

■Restenosis is the most common indication for stent use■

■AVG patency post-angioplasty is very poor

Most common site for AVG stenosis is at the graft-vein anastomosis, therefore recent clinical trials have tested the Stent-grafts at this site



# Restenosis: Rapid recurrence of stenosis following conventional angioplasty

#### Pre-angioplasty

Post-angioplasty and stent



■Stent-Graft (SG)Trials in Dialysis Vascular Access

Flair PIVOTAL Trial: Flair SG vs. PTA for AVGREVISE Trial: Viabahn SG vs PTA for AVG

Both trials showed better 6-month patency with SG use compared to PTA for graft-vein anastomosis stenosis 13/

#### Stent Graft versus Balloon Angioplasty for Failing Dialysis-Access Grafts

Ziv J. Haskal, M.D., Scott Trerotola, M.D., Bart Dolmatch, M.D., Earl Schuman, M.D., Sanford Altman, M.D., Samuel Mietling, M.D., Scott Berman, M.D., Gordon McLennan, M.D., Clayton Trimmer, D.O., John Ross, M.D., and Thomas Vesely, M.D.

End Point	Stent Graft	Balloon Angioplasty	P Value		
	no. of patients/total no. (%)				
Anatomical success	91/97 (94)	68/93 (73)	< 0.001		
Hemodynamic success	97/97 (100)	93/93 (100)			
Clinical success	85/97 (88)	78/93 (84)	0.49		
Procedural success	91/97 (94)	68/93 (73)	<0.001		
Primary patency of treatment area					
2 mo	77/96 (80)	71/92 (77)	0.72		
6 mo	46/91 (51)	20/86 (23)	<0.001		
Primary patency of access circuit					
2 mo	76/96 (79)	71/92 (77)	0.86		
6 mo	35/92 (38)	17/86 (20)	0.008		

FLAIR<sup>®</sup> Pivotal Trial

1st RCT to compare the efficacy of <u>FLAIR Stent-graft</u> versus PTA for AVG venous anastomosis stenosis

At 6-months, the primary patency of the target lesion was significantly better in the stent graft group 51% vs 23% (p = <0.001)

Haskal, J. NEJM 2010;362:494-503

■Stent-Grafts (SG) have also been tested for In-stent restenosis

■ RESCUE Trial: Fluency SG vs PTA for In-stent restenosis in both AVF & AVG

■ RESCUE Trial showed better 6-month patency with SG compared to PTA ■ 14/

A Prospective, Randomized Study of an Expanded Polytetrafluoroethylene Stent Graft versus Balloon Angioplasty for In-Stent Restenosis in Arteriovenous Grafts and Fistulae: Two-Year Results of the RESCUE Study

Abigail Falk, MD, Ivan D. Maya, MD, and Alexander S. Yevzlin, MD, for the RESCUE Investigators

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Months	Survival	Patients with Events	Censored Patients	Patients at Risk	Survival	Patients with Events	Censored Patients	Patients at Risk
0	100%	0	0	132	99.3%	1	0	142
3	66.7%	43	3	86	52.6%	64	9	70
6	18.6%	105	3	24	4.5%	128	9	6
12	6.2%	121	4	7	1.5%	132	9	2
18	2.7%	125	4	3	0.8%	133	9	1
24	0.9%	127	5	0	0.8%	133	10	0

#### **RESCUE Trial**

1st RCT that compared the <u>Fluency Stent-graft</u> versus PTA for in-stent restenosis in AVGs and AVFs

At 6-months, the Access Circuit Primary Patency was better in the stent graft group versus the PTA group **18.6% versus 4.5% (p= < 0.001)** 

Falk, A. JVIR 2016;27:1465-1476

■Summary of Stent Trials in Dialysis Vascular Access■

#### Stent Use in Dialysis Vascular Access: Timeline and Trials



■Based on this data, KDOQI 2019 guidelines recommend Stent-Graft use for:

■Recurrent graft-vein anastomosis stenosis in AVG

■In-stent restenosis in AVF & AVG■■

## KDOQI 2019 Recommendations

Table 15.2. Indications for Stent-Graft Use in AV Access

- · Recurrent clinically significant graft-vein anastomotic stenosis in AVG
- Recurrent graft-vein anastomotic thrombosis in AVG
- In-stent re-stenosis in AVF and AVG
- Treatment of ruptured venous stenotic segment of AVF and AVG
- Treatment of highly select AV access aneurysm/pseudoaneurysm (see AV access aneurysms section)

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■■Cost analysis of Stent-Grafts (SG) show that even though the initial cost of the SG is higher than the cost of balloon angioplasty, the overall cost was similar in the 2 groups at 24-months because the re-intervention rate was lower in the SG group■■

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#### Cost Analysis of the use of Stent-graft in the REVISE Trial at 24-months

■■Complications associated with Stent use:

Stent Migration
Stent Fracture
Stent Strut Protrusion
Jailing of the veins
Infection
18/



EStent Migration can cause downstream vein occlusion/stenosis & can impact future AV access options

Stent fracture & protrusion can occur due to repeated cannulation thru the stent

■Stent fracture can occur if stent is placed across a joint■



The stent has migrated into the right pulmonary artery



- Stent migration can be immediate or delayed
- It can cause downstream venous occlusion or stenosis
- Impact future AV access options
- Therefore, it is critical to follow the stent device instructions and to accurately size the stent before it is deployed

Sharma et al., Nephrol Dial Transplant (2002) 17: 511

■Jailing of the Veins is a complication of stent placement & this can impact future AV access options

Hence, the operator must be very careful during stent deployment in order to avoid this complication



Patel et al. CVIR Endovascular (2020) 3:7



# Jailing of the veins

- Stent placement in a venous outflow segment can potentially cause 'jailing' of other veins
- This can limit the option of surgical revision of the AV access and also impact the option of creating a new AV access in the future

Table 3. Graft Infection Based on Location and Indicationfor the 178 Unique Stent-Treated AV Graft Circuits on aPer-Graft Basis

Location/Indication	Infection	P Value
Covered stent for pseudoaneurysm		<.001
No	15/144 (10.4)	
Yes	14/34 (41.2)	
Intragraft stent		<.001
No	5/91 (5.5)	
Yes	24/87 (27.6)	
Covered stent for		.029
pseudoaneurysm		
No	10/53 (18.9)	
Yes	14/34 (41.2)	
All locations/indications	29/178 (16.3)	

Note. — Values in parentheses are percentages. AV = arteriovenous.

Kim et al., JVIR. 2012; 23:69-74



16.3% of the stent-implanted AV grafts were surgically excised due to AVG infection

Stents used to treat an intra-graft pseudoaneurysm were more commonly associated with graft infection compared with stents deployed for other reasons 42.1% versus 18.2% (p = 0.011)

Stents deployed in an intra-graft location were also associated with a higher incidence of graft infection compared with those deployed at the venous anastomosis or outflow vein 26.9% versus 6.9% (p = 0.001)

Stent placement must be avoided in pseudo-aneurysms & in the cannulation zone due to high risk of infection & risk of stent fracture from needle trauma

■KDOQI Guidelines state that stent placement for pseudo-aneurysm only be used as a 'last resort'■■ 22/

17.10 KDOQI considers it reasonable that open surgical treatment should be deemed the definitive treatment for AV access aneurysms/pseudoaneurysms with the specific approach determined based on local expertise. (Expert Opinion)

Note: The approach may include a plan for staged repair of multiple aneurysms to avoid bridging CVCs in the perioperative period.

- 17.11 KDOQI considers it reasonable to use covered intraluminal stents (stent-grafts) as an alternative to open surgical repair of AV access aneurysms/ pseudoaneurysms <u>only in the special circum-</u> <u>stances such as patient contraindication to sur-</u> <u>gery or lack of surgical option, due to the</u> <u>associated risk of infection in this scenario.</u> (Expert Opinion)
  - 17.12 **KDOQI considers it reasonable that, should a stent** graft be used to treat AV access aneurysms/pseudoaneurysm, cannulation over the stent-graft segment be avoided when possible. (Expert Opinion) Note: The use of stent grafts to manage aneurysms/pseudoaneurysms is not an FDA-approved indication.

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■Summary

EStent-Grafts are a viable therapeutic option for AV access stenosis but it's use must be guided by scientific evidence

Balloon angioplasty remains the 1st line therapy for the majority of the AV access stenotic lesions

End/