Twitter Thread by Aisha Shaikh



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■ 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

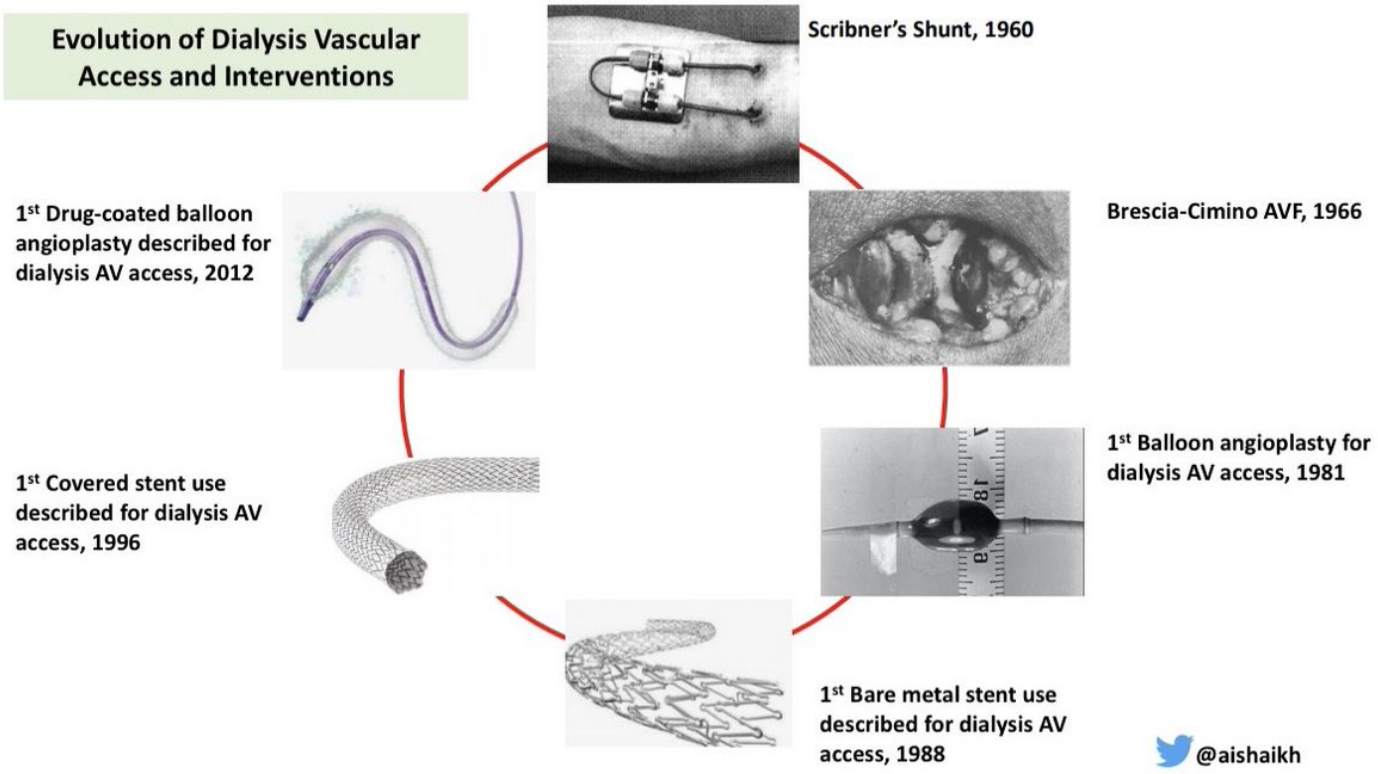
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@ASDINNews
#VascularAccessPearls

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

■■Most AV access associated complications are due to vascular stenosis■■
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■■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
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■■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■■

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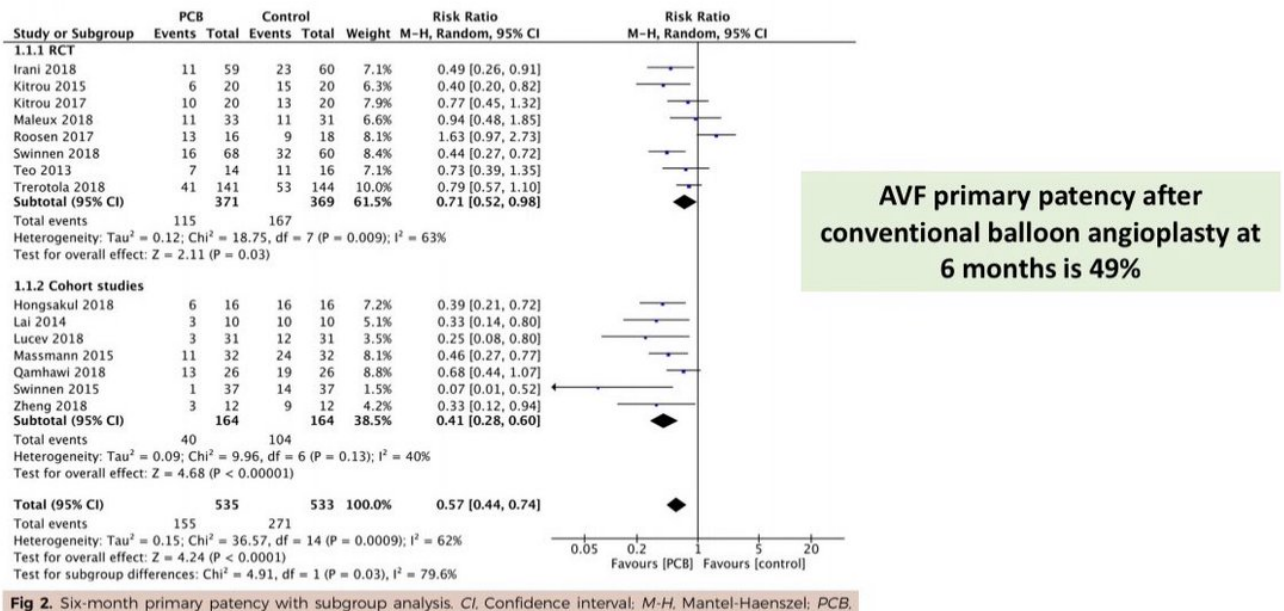


Fig 2. Six-month primary patency with subgroup analysis. *CI*, Confidence interval; *M-H*, Mantel-Haenszel; *PCB*, paclitaxel-coated balloon; *RCT*, randomized controlled trial.

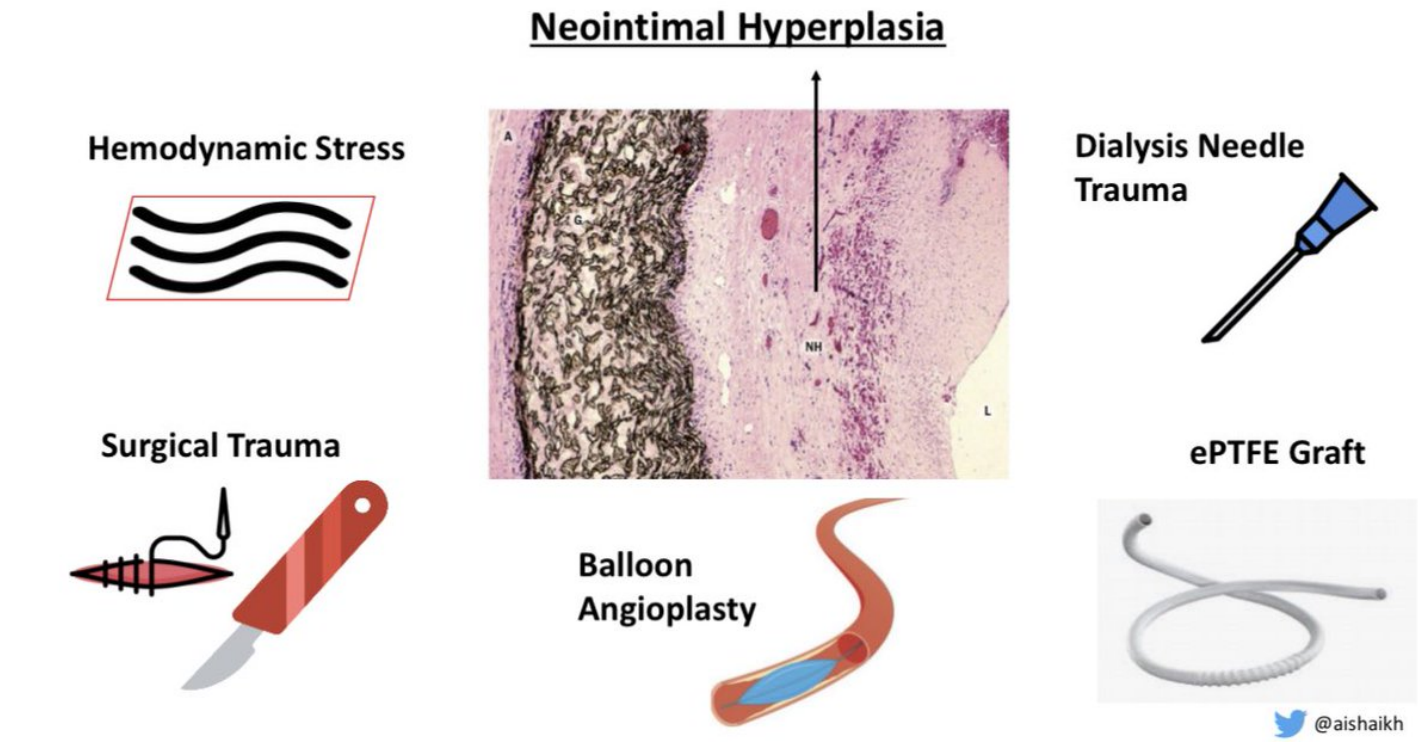
Wee et al. J Vasc Surg 2019;70:970-9

AVF primary patency after conventional balloon angioplasty at 6 months is 49%

■■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■■
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■■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
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■■Types of Stents:

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

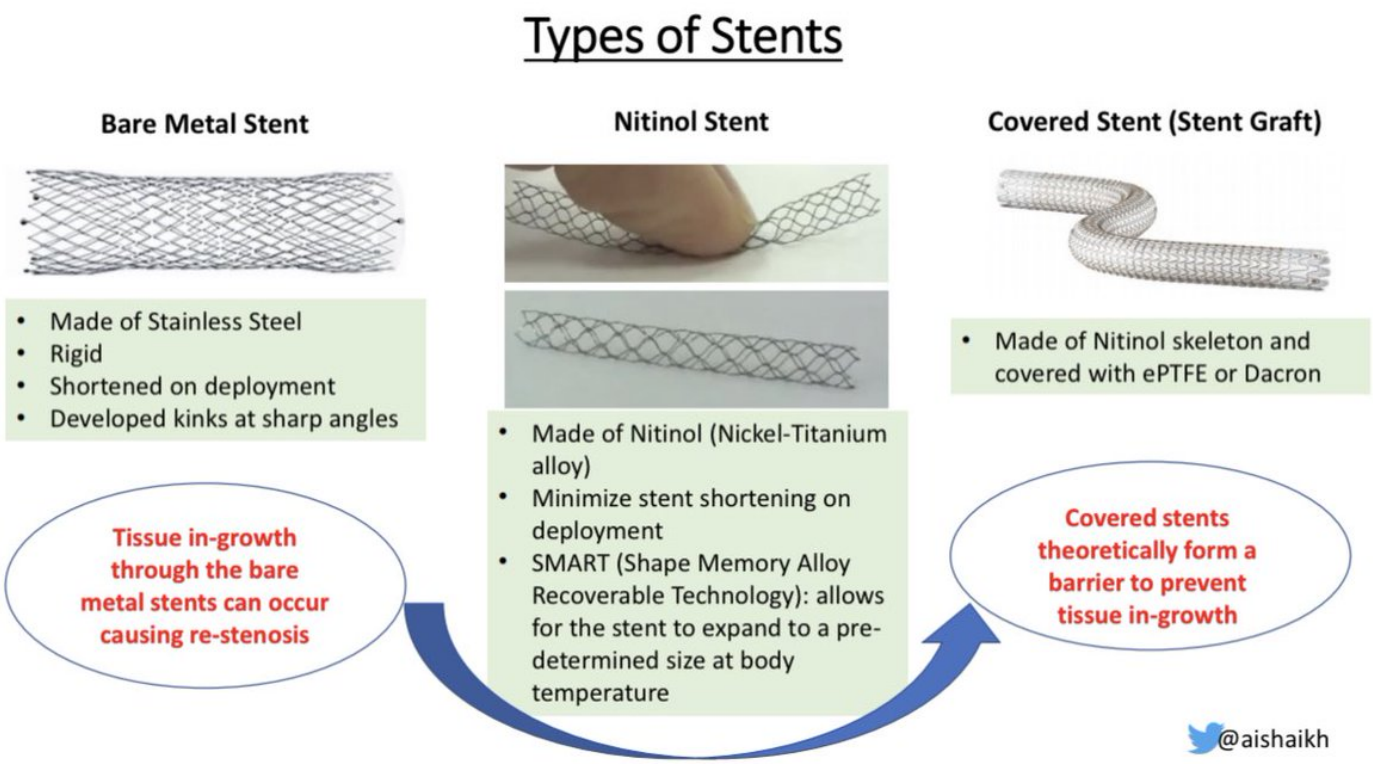
-Next generation of metal stents were Nitinol Stents made of nickel-titanium alloy

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

■■But before we get to the trials, let's discuss the basic indications for Stent use:

■■Rupture of the vessel

■■Recoil (Residual stenosis)

■■Restenosis

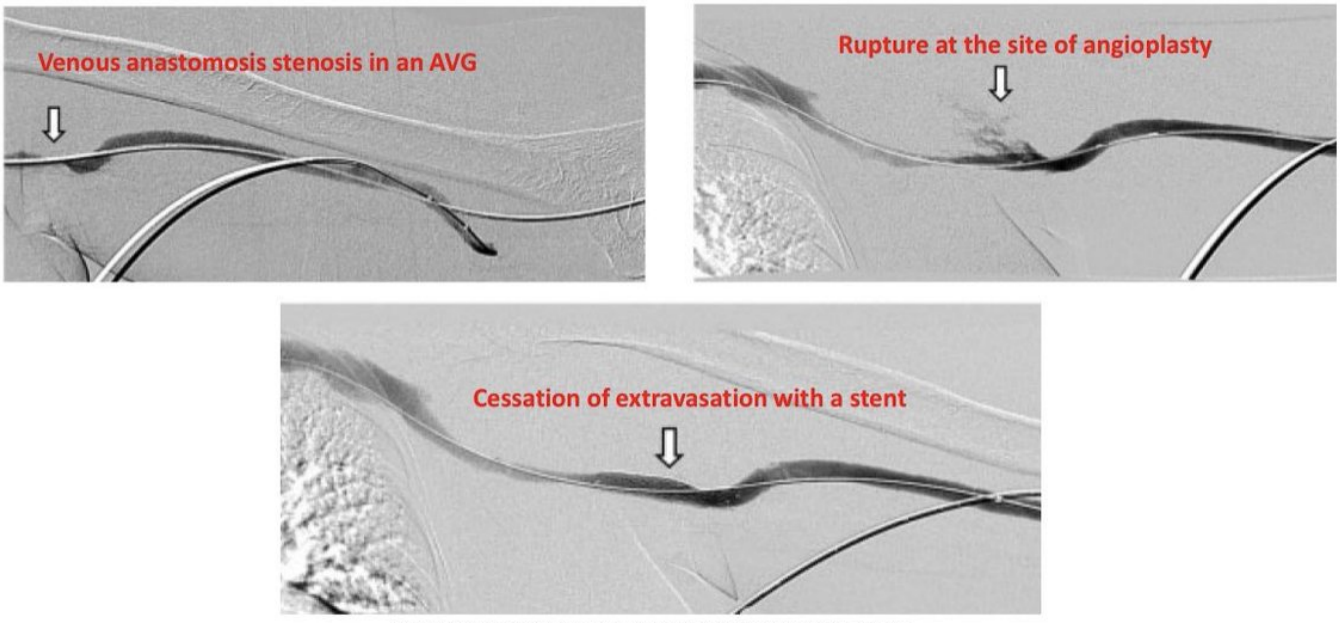
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Indications for Stent Use in Dialysis Vascular Access



■■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■■
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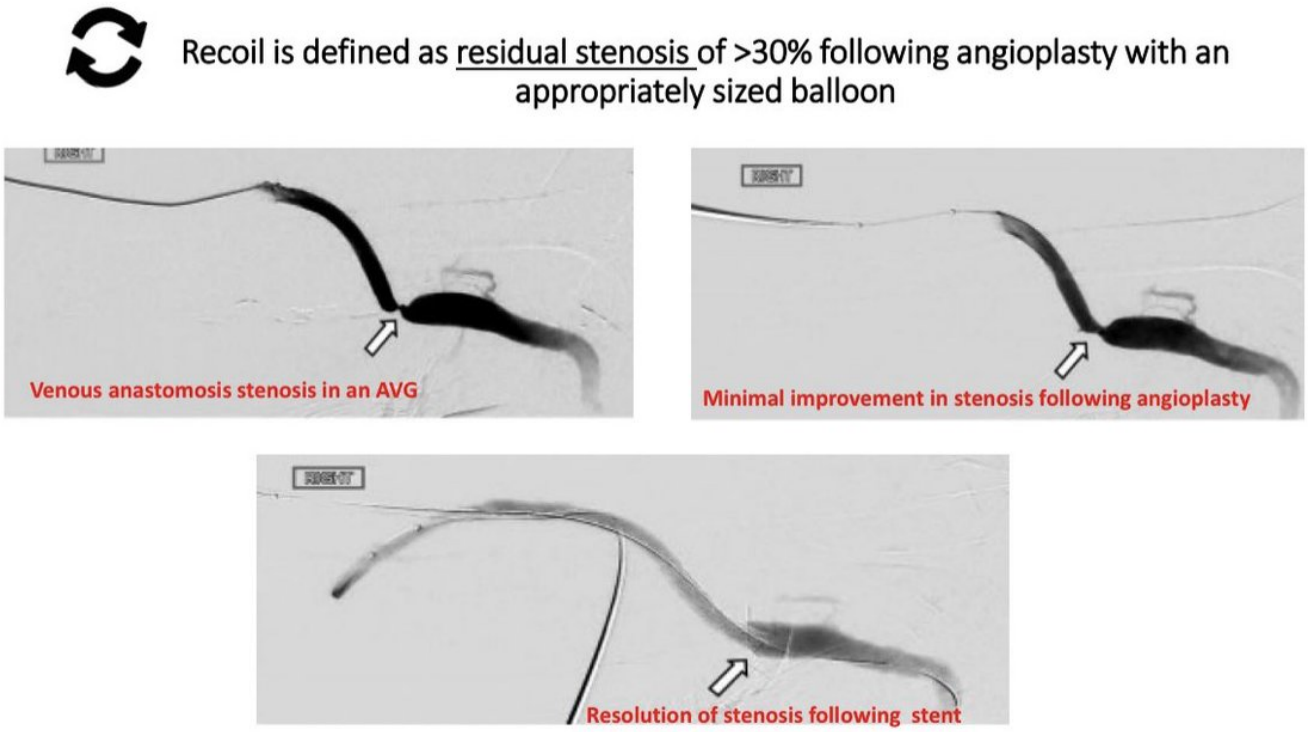


Ginsburg et al. Seminars in Interventional Radiology Vol. 32 No. 2/2015

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

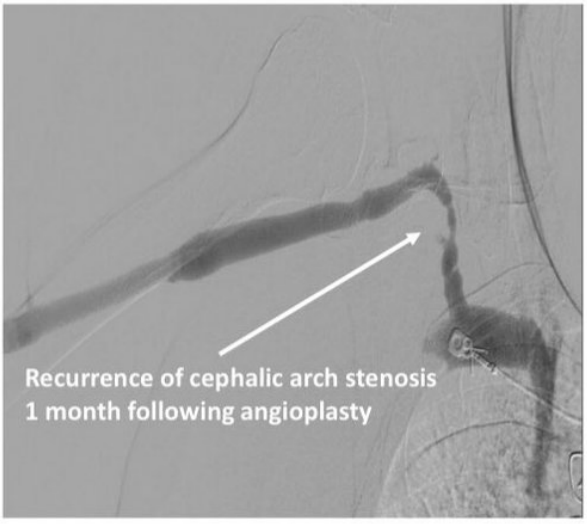
■■Restenosis is the most common indication for stent use■■

■■AVG patency post-angioplasty is very poor■■

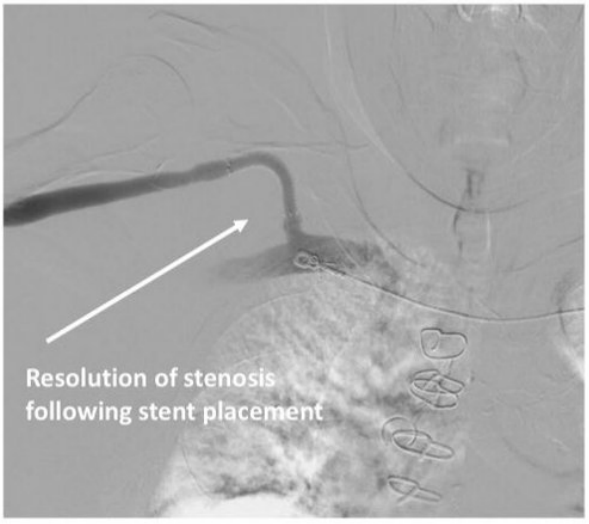
■■Most common site for AVG stenosis is at the graft-vein anastomosis, therefore recent clinical trials have tested the Stent-grafts at this site■■
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Restenosis: Rapid recurrence of stenosis following conventional angioplasty

Pre-angioplasty



Post-angioplasty and stent



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

■■Flair PIVOTAL Trial: Flair SG vs. PTA for AVG
■■REVISE 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■■
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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.

Table 3. Treatment Success and Patency End Points in the Intention-to-Treat Population, According to Treatment Group.*

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

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

FLAIR® Pivotal Trial

1st RCT to compare the efficacy of FLAIR Stent-graft 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)

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

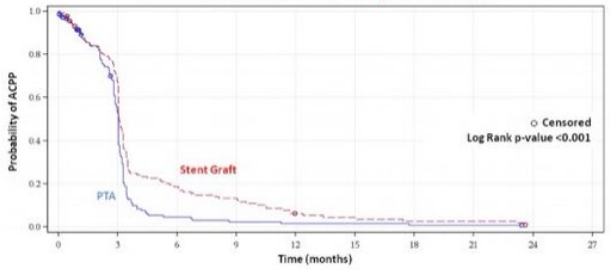
■■RESCUE Trial: Fluency SG vs PTA for In-stent restenosis in both AVF & AVG

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

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

Access Circuit Primary Patency



Time	Stent Graft Group				PTA Group			
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

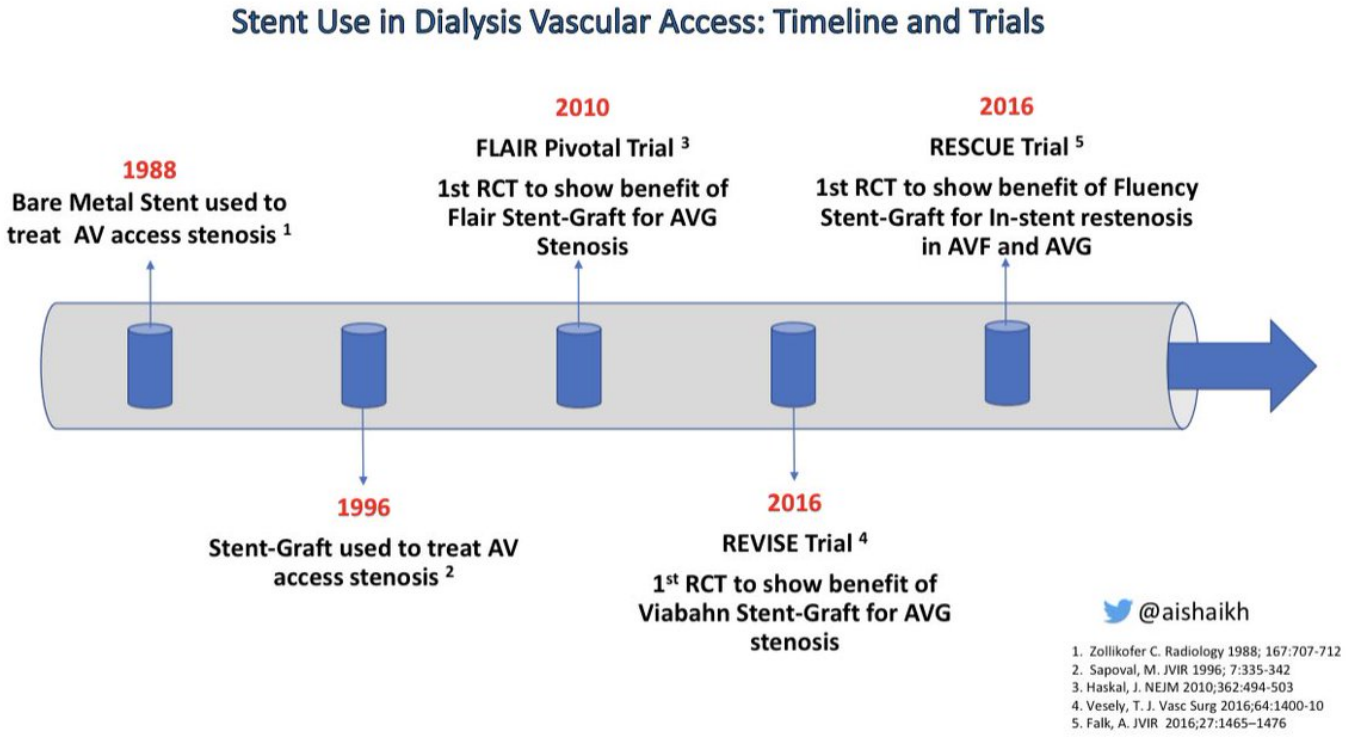
Falk, A. JVIR 2016;27:1465–1476

RESCUE Trial

1st RCT that compared the Fluency Stent-graft 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)

■■Summary of Stent Trials in Dialysis Vascular Access■■



■■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

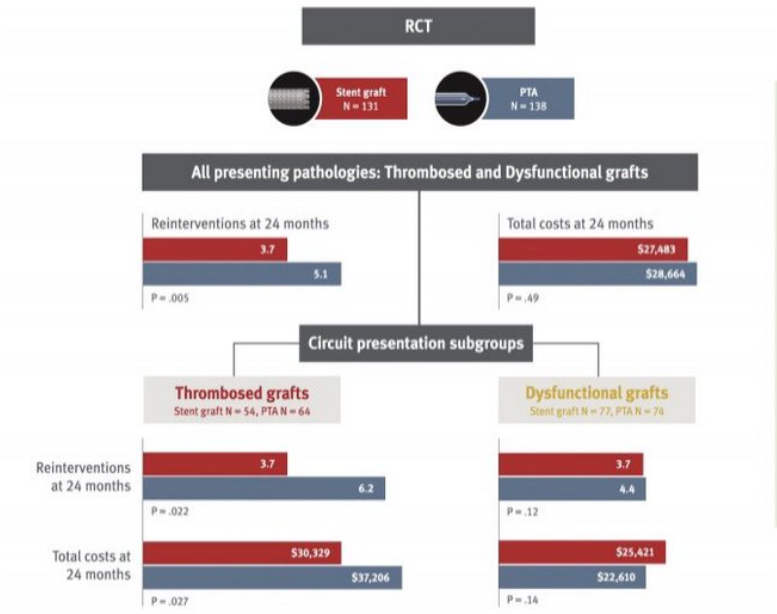
- Recurrent clinically significant graft-vein anastomotic stenosis in AVG
- Recurrent graft-vein anastomotic thrombosis in AVG
- In-stent re-stenosis in AVF and AVG
- Treatment of ruptured venous stenotic segment of AVF and AVG
- Treatment of highly select AV access aneurysm/pseudoaneurysm (see AV access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

AJKD Vol 75 | Iss 4 | Suppl 2 | April 2020

■■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



Stent-graft is more expensive than PTA

BUT

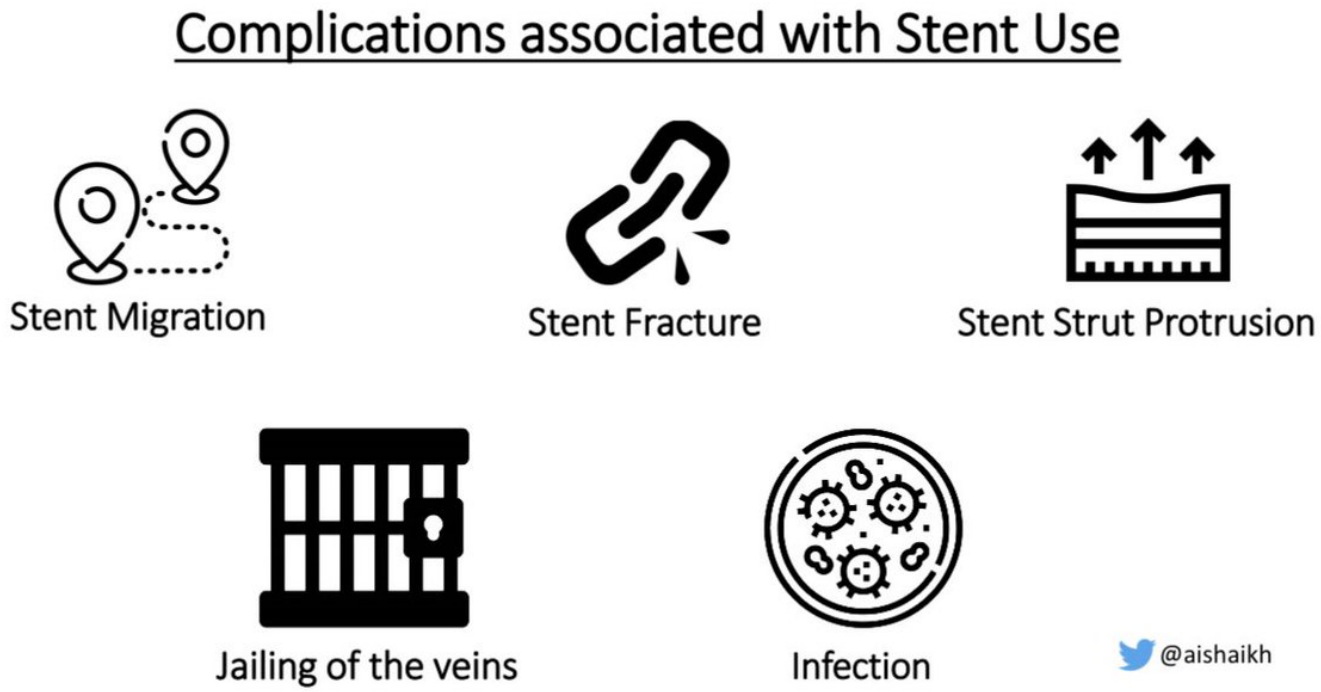
At 24-months following the stent placement, the total overall costs were similar in the 2 groups ($27,483 vs $28,664, $p = 0.49$)

This is because the SG use reduced the number of reinterventions in the access circuit by 27% (3.7 in the stent-graft group vs 5.1 in the PTA group, $p = 0.005$)

Mohr et al. JVIR. 2019; 30:203–211

■■Complications associated with Stent use:

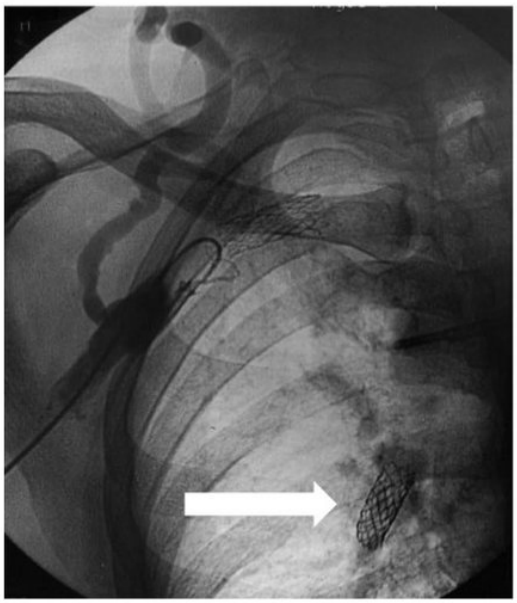
■■Stent Migration
■■Stent Fracture
■■Stent Strut Protrusion
■■Jailing of the veins
■■Infection
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■■Stent Migration can cause downstream vein occlusion/stenosis & can impact future AV access options

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

■■Stent fracture can occur if stent is placed across a joint■■
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The stent has migrated into the right pulmonary artery

Stent Migration

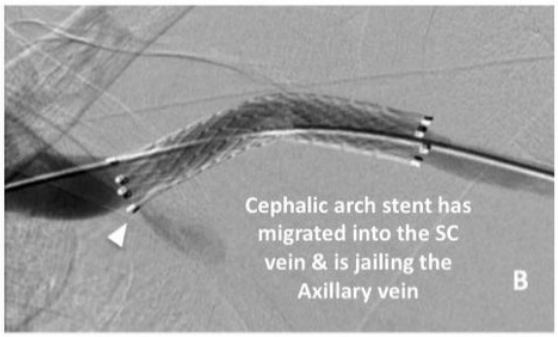
- Stent migration can be immediate or delayed
- It can cause downstream venous occlusion or stenosis
- Impact future AV access options
- Therefore, it is critical to follow the stent device instructions and to accurately size the stent before it is deployed

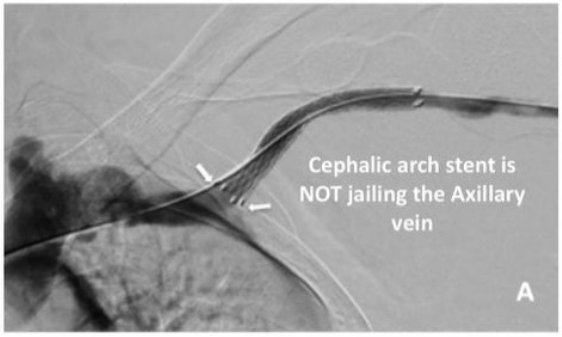
Sharma et al., Nephrol Dial Transplant (2002) 17: 511

■■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■■

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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

■■Stent associated infection is a serious complication & may require AV access excision

■■Stent associated AV access infections are more common when the stents are placed in the Pseudo-aneurysms ■■
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Table 3. Graft Infection Based on Location and Indication for the 178 Unique Stent-Treated AV Graft Circuits on a Per-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 pseudoaneurysm		.029
No	10/53 (18.9)	
Yes	14/34 (41.2)	
All locations/indications	29/178 (16.3)	

Note.—Values in parentheses are percentages. AV = arterio-venous.

Kim et al., JVIR. 2012; 23:69–74



Infection

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’■■
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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 only in the special circumstances such as patient contraindication to surgery or lack of surgical option, due to the associated risk of infection in this scenario. (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.

■Summary

■■Stent-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/