Short Term Outcome of Bare Metal Stent vs Covered Stent in Treatment of Symptomatic Central Venous Occlusion in Association with Functioning upper Limb Arterio-Venous Access

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Aim: To assess the primary patency of the central veins of the upper limb after percutaneous transluminal balloon angioplasty (PTA) with bare metal stent Vs covered stent.

Patients and methods: 26 patients having venous hypertension of the upper limb on regular hemodialysis at Ain Shams University Hospitals dialysis units and Menia University were included in the study from June 2016 till June 2017. Collected data were followed up till December 2018. Patients were divided randomly into two groups, Group A: 13 Patients who underwent balloon dilatation of completely occluded or more than 50% stenosed central veins with bare metal stent and Group B: 13 Patients who underwent balloon dilatation of completely occluded or more than 50% stenosed central veins with covered stent . The primary patency, assisted primary patency and secondary patency of these procedures were assessed in a period of 18 months.

Results: The technical success rate was 100% (n=26), 1ry stenting was done in 100% (n=26) of cases. The patency rate at 18 months after intervention was 69.2% primary assisted patency and 92.3% secondary patency in bare metal stent group while it was 100% both primary assisted and secondary patency at 18 months in covered stent group.

Conclusion: Percutaneous transluminal angioplasty with covered stent carries a higher patency rate in short term follow up. But more cases should have longer follow up time in multi centers.

Keywords: Venous hypertension, bare metal stent, covered stent, central veins, primary stenting of central veins, Chronic renal failure.

Introduction

Central venous occlusive disease associated with functioning upper limb arteriovenous access is a significant problem facing hemodialysis patients with incidence of 2%-40%.[1] Its clinical presentation ranges from upper limb, facial, or breast swelling up to compromised dialysis and possibility of loss of dialysis access or it can be asymptomatic.[1]

The etiology of such problem is thought to be either repeated percutaneous central venous catheter placement or turbulent high flow through central veins due to functioning access.[2]

Intervention is needed in 12%-13% of symptomatic central venous occlusive disease patients.[3] Due to associated morbidity to surgical approach which has prolonged patency, endovascular solutions are the first line treatment reserving the surgical options for failed percutaneous procedures.[4,5] Unfortunately, the immediate results of balloon angioplasty of occlusive lesions showed immediate elastic recoil in 50% of cases and bare metal stents have no advantage over balloon angioplasty as regard long term patency.[6,7]

Recently, stent graft placement has encouraging results in treatment of recurrent cephalic arch stenosis and arteriovenous graft venous end anastomosis stenosis due to combined benefits of such graft as regard being a barrier for intimal hyperplasia in addition to mechanical advantages of bare metal stent as well as safe and effective role of controlling bleeding.[1,8-10]

Patients and methods

This study was conducted on patients on regular haemodialysis at dialysis units of Ain Shams University hospitals and Menia Uneversity Hospitals. This is a prospective randomized study that was conducted upon patients on regular haemodialysis through an arteriovenous vascular access from June 2016 till June 2017. Collected data were followed up till December 2018.

Patients were divided randomly into two groups, **Group A:** 13 Patients who underwent balloon dilatation of completely occluded or more than

50% stenosed central veins with bare metal stent and **Group B:** 13 Patients who underwent balloon dilatation of completely occluded or more than 50% stenosed central veins with covered stent. The primary patency, assisted primary patency and secondary patency of these procedures were assessed in a period of 18 months.

The inclusion criteria of these patients were:

1. All patients aging > 18 years.
2. Patients on haemodialysis for more than 3 months.
3. Increase of venous pressure resistance during haemodialysis (measured by the dialysis machine pressure transducer at the beginning of hemodialysis using 15 gauge needles at a blood flow of 200 ml/min, measurements > 150 mmHg are considered abnormal).
4. Persistent or progressing entire limb swelling after creation of arterio-venous access.
5. Appearance of dilated chest veins after creation of arterio-venous access.
6. All included patients must have central venous occlusion or > 50 stenosis on the ipsilateral upper limb of functioning arteriovenous access.
7. Patient's approval to be included in the study.

The exclusion criteria were:

1. Patients below 18 years .
2. Patients on haemodialysis for less than 3 months.
3. History of Upper limb DVT prior to AV access creation.
4. Presence of non central venous lesion.
5. Non Functioning arterio-venous access.

Method of randomization:

Every patient was given a number reflecting his order for intervention odd numbers in group A and even numbers in group B

Every patient was subjected to:

1. History taking with especial attention to previous central venous catheterization.
2. Clinical examination with recording of the upper limb size (circumference).
3. Duplex Scanning and or CT angiography, if not feasible or inconclusive intraoperative direct angiography was done.

Procedure:

1. The procedure was done under local infiltration anesthesia with puncture of the arterlized vein or PTFE graft at mid arm of the affected site while the patient was in the supine position, some cases we need also retrograde femoral axis.
2. Seldinger technique was used with introduction of a 8 -10 F (Prelude®, MeritMedical or Cordis®) sheath, Diagnostic angiogram was done to select the area for intervention using non ionic contrast media.
3. A 0.035 J shaped guide wire (Terumo®, Terumo corporation) was manipulated to cross the lesion as much as possible distal to the lesion, this negotiation with the lesion was done by a combination of 5F guiding catheter(Performa®, MeritMedical).
4. After crossing the lesion, the balloon was introduced. Balloons were from 12-16 mm in diameter with length of 40 mm. The balloon catheter was advanced into position over the guide wire using fluoroscopy. The balloon was slowly inflated by diluted contrast solution under fluoroscopy, using an inflation device, or hand inflation.
5. Completion angiography was done for evaluation of angioplasty results. Followed by insertion of bare metal stent at the site of total occlusion in group A, and covered stent in group B.
6. Technical success was defined as improvement of luminal diameter of more than 50% or less than 30% residual stenosis **(Figure 1)**.
7. Manual compression of the puncture site: immediately after removal of the sheath for 15 to 20 minutes (it was done immediately after the procedure).
8. Follow up was done every 3 months interval postoperatively till 18 months, in the form of clinical examination to assess improvement of symptoms.

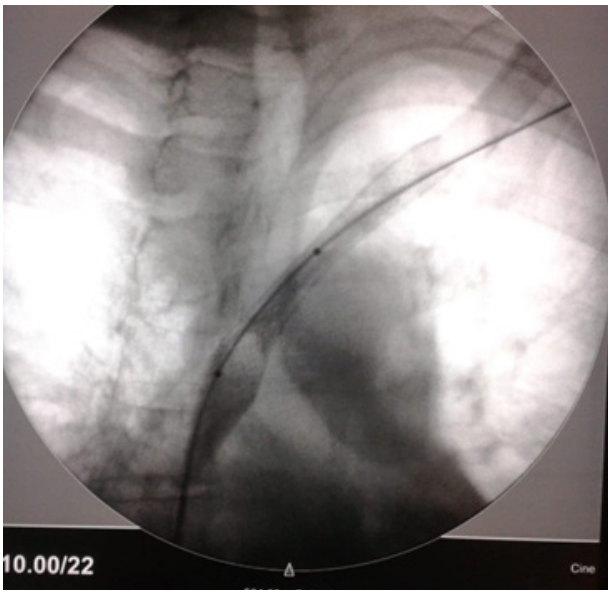

Fig 1: Left innominate baremetal stent.

Results

This study was conducted on 26 patients undergoing regular hemodialysis sessions at Ain Shams University Hospitals dialysis units and Menia university hospitals in the period from June 2016 till June 2017, collected data were followed up till

December 2018.

The patients included in the study were 11 males versus 15 females with a percentage of 42.3% and 57.7 % respectively. The mean age of patients was 61.23±13.276years other demographic data are shown in **(Table 1)**.

Table 1: The following table shows patients' demographic data

		Stent type		P-value
		Bare metal stent	**Covered stent**	
Gender	Male	5 45.5%	6 54.5%	0.69*
	Female	8 53.3%	7 46.7%	
Smoking	No	10 45.5%	12 54.5%	0.27**
	Yes	3 75.0%	1 25.0%	
Obesity	No	10 50.0%	10 50.0%	1**
	Yes	3 50.0%	3 50.0%	
DM	No	5 41.7%	7 58.3%	0.43*
	Yes	8 57.1%	6 42.9%	
HTN	No	3 27.3%	8 72.7%	0.047*
	Yes	10 66.7%	5 33.3%	
ISHD	No	5 45.5%	6 54.5%	0.69*
	Yes	8 53.3%	7 46.7%	
Renal Insufficiency	Yes	13 50.0%	13 50.0%	-

Of the studied group, most of patients had previous history of central venous catheterization, all have thrill over the fistulae and all have dilated chest veins, the following **(Table 2)** demonstrate the clinical data between both groups.

Table 2: The clinical data for both groups

		Stent type		P-value
		Bare metal stent	Covered stent	
Thrill over AVF	Yes	13 50.0%	13 50.0%	-
Oedema	Mild	2 66.7%	1 33.3%	0.49
	Moderate	5 38.5%	8 61.5%	
	Severe	6 60.0%	4 40.0%	
Side of oedema	Left upper limb	6 54.5%	5 45.5%	0.69*
	Right upper limb	7 46.7%	8 53.3%	
Pain grade	Mild	2 50.0%	2 50.0%	0.29**
	Moderate	7 41.2%	10 58.8%	
	Severe	4 80.0%	1 20.0%	
Ability to use access for dialysis	Cannot be used	4 50.0%	4 50.0%	0.49**
	Can be used with difficulty	8 47.1%	9 52.9%	
	Can be used	1 100.0%	0 0.0%	
Ulcer	No	12 48.0%	13 52.0%	0.23*
	Yes	1 100.0%	0 0.0%	
Gangerene	No	12 48.0%	13 52.0%	0.23*
	Yes	1 100.0%	0 0.0%	
Distal pulse	Palpable	10 45.5%	12 54.5%	0.268**
	Impalpable	3 75.0%	1 25.0%	
Upper limb DVT	No	13 50.0%	13 50.0%	-
Dilated chest veins	Yes	13 50.0%	13 50.0%	-
History of central venous catheterization	No	1 50.0%	1 50.0%	1**
	Yes	12 50.0%	12 50.0%	

All patients were subjected to either duplex examination, CT venography or intaraoperative venogram to determine the location and degree of the lesion. The following **(Table 3)** describes these data and the endovascular details as wire type, balloon type and site of stenting.

Table 3: Demographics of the endovascular procedure

Degree of stenosis	Total occlusion	11 47.8%	12 52.2%	0.546**
	>50% stenosis	2 66.7%	1 33.3%	
Site of stenosis	Subclavian	2 66.7%	1 33.3%	0.486**
	Innominate	5 38.5%	8 61.5%	
	Innominate and Subclavian	6 60.0%	4 40.0%	
Access site	Trans-access	12 52.2%	11 47.8%	0.536**
	both access and femoral vein	1 33.3%	2 66.7%	
Guidewire character	Standard 0.035 hydrophilic guidewire	8 50.0%	8 50.0%	0.422**
	Stiff 0.035 hydrophilic guidewire	4 66.7%	2 33.3%	
	Standard 0.018 guidewire	1 25.0%	3 75.0%	
Balloon type	High pressure	13 50.0%	13 50.0%	-
Site of Stent	Subclavian	2 66.7%	1 33.3%	0.486**
	Innominate	5 38.5%	8 61.5%	
	Innominate and Subclavian	6 60.0%	4 40.0%	

Technical and procedural success were obtained with intact thrill, and decreased oedema and dilated chest veins **(Table 4)** and **(Figure 2)**.

Table 4: Postoperative outcomes between 2 groups

Postoperative thrill over AVF	Yes	13 50.0%	13 50.0%	-
Postoperative oedema	Mild	2 50.0%	2 50.0%	0.424**
	Moderate	5 38.5%	8 61.5%	
	Severe	6 66.7%	3 33.3%	
Technical success	Yes	13 50.0%	13 50.0%	-
Procedural success	Yes	13 50.0%	13 50.0%	-
Postoperative distal pulse	No	10 45.5%	12 54.5%	0.268**
	Yes	3 75.0%	1 25.0%	
Postop dilated chest veins	Disappeared	11 55.0%	9 45.0%	0.348**
	Mild	2 33.3%	4 66.7%	

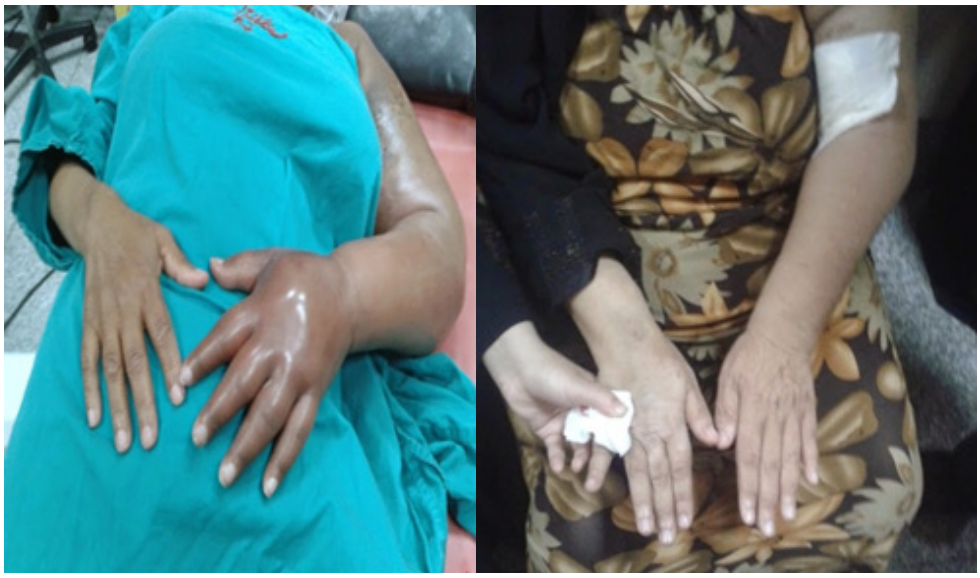

Fig 2: Left upper limb oedema pre and post-procedure (oedema subsides gradually within few days).

Follow up of these patients was done depending upon recurrence of symptoms including recurrence of upper limb swelling, presence of veins on anterior chest wall, and/or follow up duplex.

Primary patency rates were found to be 100% in the first 3months in both groups then decreased to be 84.6%, 61.5%, 23.1% and 23.1% at 6,9,12 and 18 months respectively in the group of bare-metal stents ,while in the group of covered stents primary patency was 100 %, 92.3 %,76.9 % and 69.2% at 6,9,12 and 18 months respectively **(Figure 3).**

Primary assisted patency was found to be much lower in bare-metal stent group being 100% 100%, 76.9% and 69.2% at 6,9,12 and 18 months respectively if compared by the group of covered stent which was 100 % till 18 months **(Figure 4).**

The secondary patency was also lower in bare-metal stent group being 100 % ,92.3 % and 92.3% at 9, 12 and 18 months respectively compared to 100 % patency at 18 months in the covered stent group **(Table 5)**.

Table 5: Patency of Covered and Bare-metal stent groups

		Frequency (Percent)	P-value
Primary patency at 3 months	Covered	13 100.0%	
	Bare-metal	13 100.0%	
Primary patency at 6 months	Covered	13 100.0%	0.08**
	Bare-metal	11 84.6%	
Assisted primary patency at 6 months	Covered	13 100.0%	
	Bare-metal	13 100.0%	
Secondary patency at 6 months	covered	--- ---	
	Bare-metal	--- ---	
Primary patency at 9 months	Covered	12 92.3%	0.05**
	Bare-metal	8 61.5%	
Assisted primary patency at 9 months	Covered	13 100.0%	
	Bare-metal	13 100.0%	
Secondary patency at 9 months	Covered	--- ---	
	Bare-metal	13 100.0%	
Primary patency at 12 months	Covered	10 76.9%	0.006*
	Bare-metal	3 23.1%	
Assisted primary patency at 12 months	Covered	13 100.0%	0.03**
	Bare-metal	10 76.9%	
Secondary patency at 12 months	Covered	13 100.0%	0.23**
	Bare-metal	12 92.3%	
Primary patency at 18 months	Covered	9 69.2%	0.018*
	Bare-metal	3 23.1%	
Assisted primary patency at 18 months	Covered	13 100.0%	0.12**
	Bare-metal	9 69.2%	
Secondary patency at 18 months	Covered	13 100.0%	0.3**
	Bare-metal	12 92.3%	

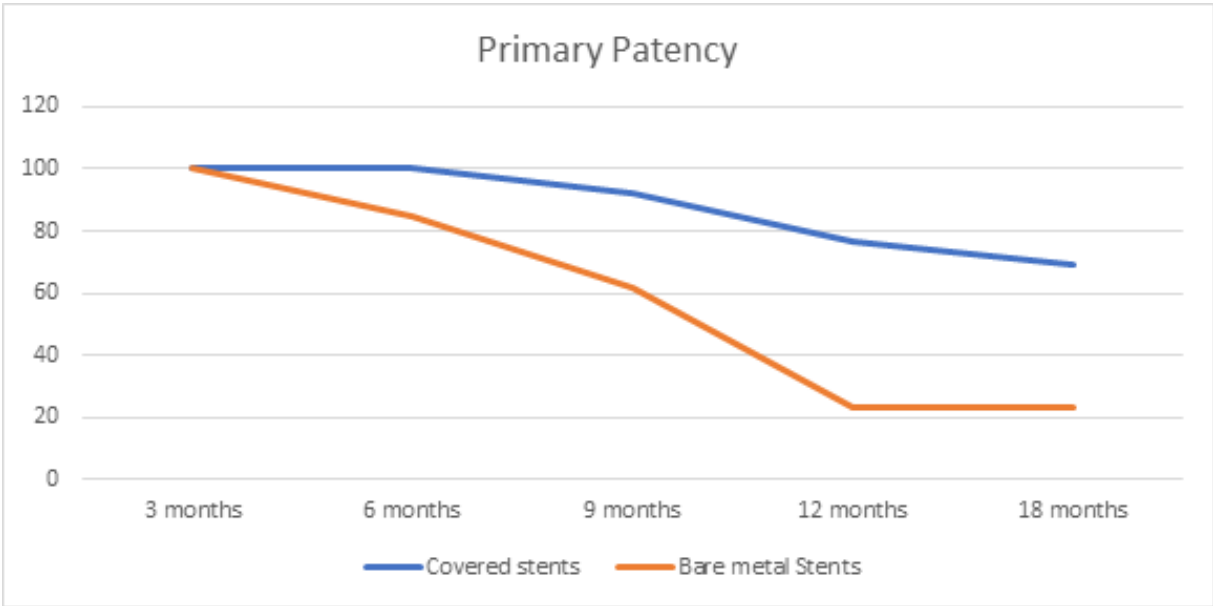

Fig 3: Primary patency of both groups.

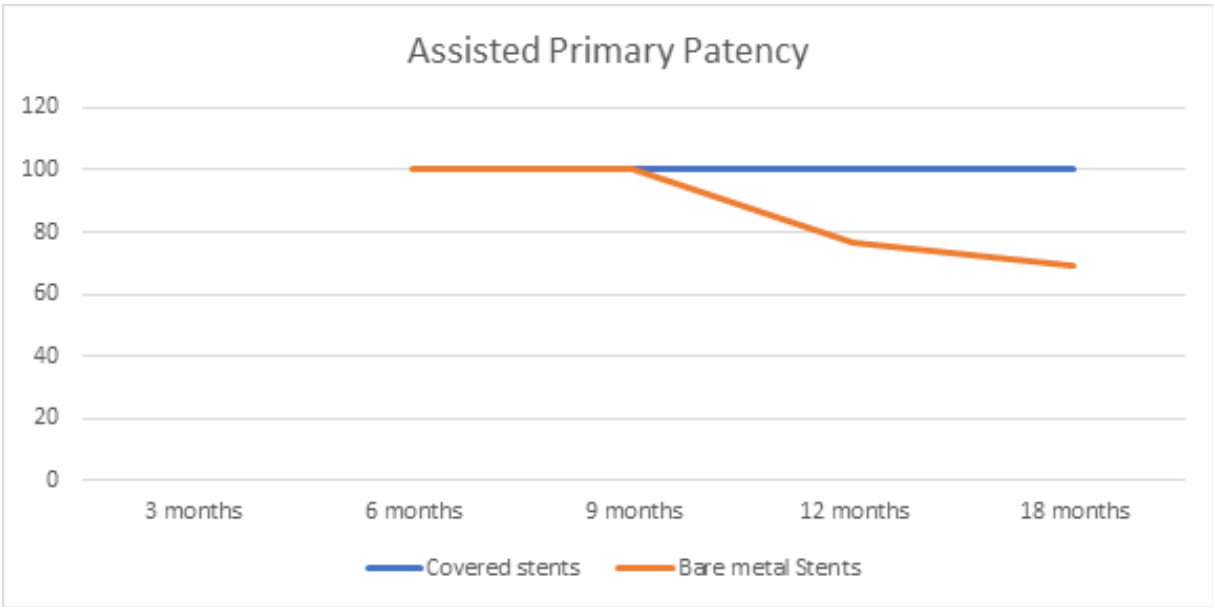

Fig 4: Assisted primary patency of both groups.

Discussion

The central venous occlusive disease carries a lot of access morbidities which necessitate active management in form of balloon angioplasty but the ideal treatment of occlusive lesion is currently under evaluation.

Recurrence after balloon angioplasty due to intimal hyperplasia or recoil is common with primary patency rates at 3, 6, 12 months are 58%, 23%-63%, 43% respectively.[4,11,12] Bare metal stent placement is subjected to in-stent stenosis because of intimal hyperplasia through fenestrations which does not improve patency rates.[7,12] On the other hand, stent graft placement carries better patency rates at 9 months up to 100% based on few non randomized studies.[13]

In our study, results demonstrate better short term outcome with longer patency rates as the patency rate at 18 months after intervention was 69.2% primary assisted patency and 92.3% secondary patency in bare metal stent group while it was 100% both primary assisted and secondary patency at 18 months in covered stent group which suggest its use in occlusive type of lesions waiting for long term results that recommend stent graft placement.

Conclusion

Percutaneous transluminal angioplasty with covered stent carry a higher patency rate in short term follow up. But more cases should have longer follow up time in multi centers.

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