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Original Research Article.

Tunnelled Cuffed Catheters for Hemodialysis, Placed By Nephrologists: Success Rate, Efficacy & Complications

Rudramani Swami[1], Swapnil Jadhav[2], Kalpana S. Mehta[3*], Gajanan Pilgulwar[4], Sunil Jawale[5], Atim Pajai[6]

[1]M.D [General Medicine], D.M [Nephrology],
Assistant Professor in Nephrology, T. N. Medical College & BYL Nair Ch Hospital, Mumbai, Maharashtra, India.
[2]M.D [Medicine], D.M [Nephrology],
Senior Registrar in Nephrology, T. N. Medical College & BYL Nair Ch Hospital, Mumbai, Maharashtra, India.
[3]M.D [General Medicine], D.N.B. [Nephrology],
Professor & Head Nephrology, T. N. Medical College & BYL Nair Ch Hospital, Mumbai, Maharashtra, India.
[4]M.D [Paediatrics],
Senior Registrar in Nephrology, T. N. Medical College & BYL Nair Ch Hospital, Mumbai, Maharashtra, India.
[5]M.D [Medicine], D.M [Nephrology], Consultant Nephrologist, Jahangir Hospital, Pune, Maharashtra, India.
[6]M.D.[General Medicine], [DNB] Nephrology,
Assistant Professor in Nephrology, Seth GSMC and KEM Hospital, Mumbai, Maharashtra, India.

ABSTRACT

Introduction: A large majority of tunnelled cuffed catheters (TCC) are placed by interventional radiologist using fluoroscopy. As fluoroscopy is not always available to meet the great demand that some hospitals require, modified traditional placement of tunnelled catheter can be done under Ultrasound guidance.

Methods: All patients were chronic kidney disease, dialysis dependent [CKD-VD].USG Doppler of bilateral neck veins was done to look for patency of neck veins & location of vein prior to puncture. Post TCC placement X ray chest was done in all. Patient demographics, technical complications, and Catheter flow rates, patency, catheter survival, and catheter related infections, reasons for catheter removal were recorded.

Results: Total 131 TCC were placed in 131 CKD (VD) patients. 72 were male and 59 were female. Majority of patients had chronic glomerulonephritis (41.98%) as primary disease followed by Diabetic kidney disease (36.64%) and hypertension (12.21%) respectively. Technical success rate was 98.5%. Patency duration was Longest 585 days & shortest 14 days. Right Internal Jugular vein was preferred (83.2%) site. 80.9% patients had no complications. Catheter related blood stream infections (CRBSI) were observed in 16%. Two patients (1.5%) had blockage of catheter. One patient each had oozing from tract due to extrusion of cuff and right femoral deep vein thrombosis. 35.9% are still ongoing catheters. 32.8% TCC were removed due to maturation of Arteriovenous fistula followed by 10.7% due to CRBSI.

Conclusion: In our study, we observed that placement of TCC by Nephrologist, with the help of USG Doppler & post placement X ray chest was a safe procedure.

Key words: Hemodialysis (HD), Tunnelled Cuffed Catheters (TCC), Success Rate, Efficacy, Complications.

***Correspondence to:**

Dr. Kalpana S. Mehta,
3D/504, Vaishali Nagar,
K. K. Marg,
Mahalaxmi East, Mumbai 4000 11.

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INTRODUCTION

The number of patients suffering from chronic kidney disease (CKD) who require renal replacement therapy (RRT) is increasing in India. Vascular access plays a big role in patients on hemodialysis (HD). Although autogenous arteriovenous fistulas (AVFs) are the first choice as the permanent vascular access, a period of at least six weeks is recommended to pass after the formation of AVF, to be used.[1,2] Additional time may be necessary for interventional or surgical operation on the AVF to mature it. Prosthetic arteriovenous (AV) grafts can be cannulated within 2-3 weeks from the implantation, although they are not preferred as the primary vascular access. Additionally, AVF may not be appropriate for patients with serious heart failure or chronic

respiratory failure or for those with steal syndrome which causes pain and peripheral ischemia.[3,4] Hence, temporary and permanent tunneled cuffed catheters [TCC] should be used in these patients and those who need acute HD.[5,6] TCC have decreased the rates of malfunction, infection, and thrombosis significantly when compared to temporary catheters, and should be preferred if the patient would need this access for more than 1 month.[7] Placements of central venous catheters are high risk vascular procedures and require strict aseptic conditions. HD catheters are not only associated with higher risks of long-term complications like central venous stenosis, thrombosis, and infections, but also early interventional complications like arterial puncture, haematoma, and pneumothorax. These patients should have a TCC placement while they wait for a definitive vascular access. A large majority of TCC are placed by interventional radiologist using fluoroscopy. As fluoroscopy is not always available to meet the great demand that some hospitals require, modified traditional placement of tunnelled catheter can be done under Ultrasound guidance. In this study, we assessed the success rate, efficacy & complication of putting TCC for dialysis without using fluoroscopy.

MATERIALS & METHODS

It is an observational prospective study, done at our tertiary care centre, over a period from 1st August 2014 to 1st August 2016, to assess efficacy & complications of tunneled HD catheters, TCC, placed by Nephrologists, without fluoroscopy guidance but with the use of Doppler Sonography.

The main objectives were

1) To study the success rate
2) To study patency duration
3) To study complications

A written informed consent, explaining procedure, necessity, all complications and risks, was taken from patient &/or relatives, before enrolling them in the study. A patient information sheet in vernacular language was given to the patient.

Inclusion Criteria

- CKD stage VD patients waiting for AVF OR
- CKD stage VD patients with AVF failure.

Exclusion Criteria

- All patients with matured and working AVF

Details of Catheter

The TCC by Covidien MAHURKAR, were used for insertion. TCC length as per site used for insertion is given as per table 1. Two makes used were: Permacath & Palindrome

Permacath TCC (Figure 1)

- Made of soft silicone rubber (15Fr)
- 2.5cm separation between arterial lumen and venous tip
- May be implanted in the jugular, subclavian or femoral vein

Palindrome TCC (Figure 2 & 3)

- Palindrome™ Symmetric Tip Dual Lumen Catheter (14.5fr)
- Unique symmetric tip and laser-cut side slots minimize recirculation and likelihood of positional occlusion, as well as reduce clot formation by decreasing debris attachment.

Definitions

a. Ongoing catheter: Catheter still in use and flow>250ml/min
b. Catheter dysfunction: Catheters with flow <250ml/min
c. Technical success: Dialysis following placement of TCC provides flow >250ml/min.
d. Failure: Catheter kink

Table 1: Tunnelled cuffed catheters site and length used

Site	Implant Length	Actual Length
Right IJV	19 cm	36 cm
Left IJV	23 cm	40 cm
Right Subclavian	19 cm	36 cm
Left Subclavian	19 cm	36 cm
Femoral	33 cm	50 cm

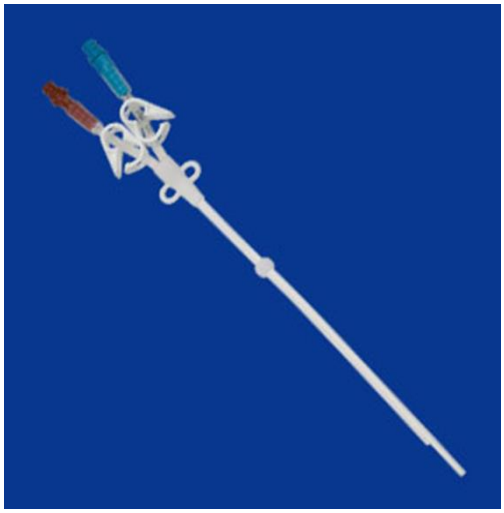

Figure 1: Permacath Tunelled Cuffed Catheter

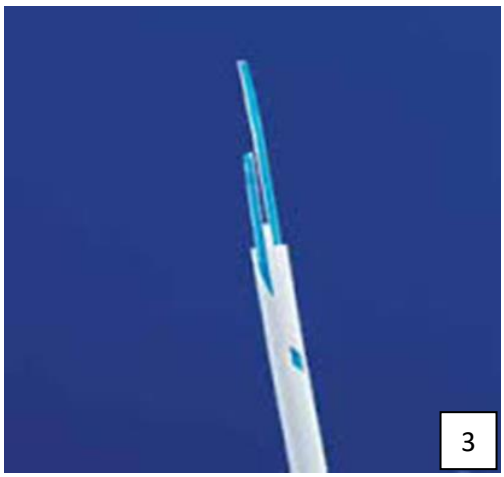

Figure 2 & 3: Palindrome Tunnelled Cuffed Catheter with Unique symmetric tip and laser-cut side slots

Prerequisite for the Procedure

Before insertion of the catheter, all patients had their complete blood count, prothrombin time, and partial thromboplastin time checked.

Patient was adequately dialysed 1 day prior to procedure. Prophylactic antibiotic (Vancomycin 1000 mg OR 15mg per Kg) was given routinely to all patients pre-procedure. Xray chest was done in all patients prior to procedure.

Doppler sonography of neck veins was done to look for patency of neck veins. Follow-up included the period from catheter insertion to removal, but in the case of persistent patency it continued up to the end of the study, on August 1st 2016.

Reasons for catheter removal included elective removal (fistula creation, transfer of therapy modality, recovery of renal function, or kidney transplant), death, infection, dysfunction (blood flow less than 250 ml/min) and accidental removal.

Procedure

The procedures were done under strict sterile conditions, in a specific room and according to standard practices. The procedure was initiated in the traditional manner[8,9], using ultrasound in all cases to guide initial cannulation.[10] The non-tunnelled catheters which were < 2 weeks old, were directly converted to TCC by using right or left internal jugular venotomy sites. Conversion from non-tunneled to TCC was done only when the blood cultures were negative. We prefer not to cut the catheter to thread the guidewire, as some physicians have proposed. All were monitored for oxygen saturation [with pulse oximeter], Blood pressure & ECG during the procedure

- Surface marking was done with Arterial tip of the catheter at the angle of Luwis & exit site marked in such a way that no obvious kinking is seen.
- Fresh puncture of the central vein was taken with the help of USG guided markings.
- A guidewire was advanced through the fresh prick.
- A subcutaneous tunnel was created from the right or left exit site to the venotomy site
- A catheter passed through the tunnel using the tunneler provided with the catheter kit.
- After this, a peel away sheath/dilator combination was placed over the guidewire.
- The dilator and guide wire were removed and the catheter inserted centrally through the sheath. The sheath was peeled away. Flow through both ports checked.
- Both ports blocked with inj Heparin 5000u/ml.
- Chest X-ray was performed to check for the correct placement of the catheter tip and postprocedure complications.
- The patient was kept for observation for 24 hours

Complications within 180 days of the procedure, were labelled as early whereas long term complications after 180 days were labelled as late complications.

After TCC placement, and control of uremic manifestations, these patients are referred to outside dialysis centres to continue maintenance HD, with detailed note about care of TCC. These patients were asked to follow up regularly. At the end of follow-up, all catheters providing adequate venous access were classified as ongoing.

Being Public Health Institute, our workload of dialysis & turnover is extremely high.

Statistical Analysis

Data for continuous variables are presented as mean ± standard deviation. Qualitative variables are expressed as percentages. For survival analysis, the Kaplan-Meier model was applied and Cox hazards ratios calculated. For multivariate analysis, Cox proportional hazard models were used. Only factors identified as predictors in the uni-variate analysis ($p<0.20$) were included in the multivariate analysis. When there were not pre-established cut-off scores, the median was used instead. The Statistical Package for the Social Sciences for Windows, version 10.0, and software package GraphPad Prism, Version 3.00 for Windows (GraphPad Software, Inc., San Diego, USA) were used for statistical analysis. Statistical significance was defined as a p value less than 0.05.

Table 2: Etiology of CKD

Diagnosis	n	%
CGN	55	41.98
DKD	48	36.64
HTN	16	12.21
Obstructive kidney disease	8	6.11
Allograft dysfunction	4	3.06
Total	131	100

Table 3: Distribution of tunnelled catheter sites:

Tunneled catheter site	n	%
Right IJV	109	83.2%
Left IJV	6	4.6%
Right subclavian	5	3.8%
Right EJV	5	3.8%
Left subclavian	3	2.3%
Right & Left IJV Attempted	2	1.5%
Right Femoral	1	0.8%
TOTAL	131	100.0%

Table 4: Duration of TCC

Duration of Catheter	n	%
< 3MONTHS	87	66.4%
3-6 MONTHS	28	21.4%
> 6MONTHS	16	12.2%
Total	131	100.0%

Table 5: Complications related to Tunnelled Cuffed Catheter

COMPLICATIONS	n	%
No complications	106	80.9%
CRBSI	21	16.0%
Catheter blocked	2	1.5%
Oozing from Tract due to cuff extrusion	1	0.8%
Right Femoral vein DVT	1	0.8%
TOTAL	131	100.0%

RESULTS

Total 131 catheters were placed. Out of 131 patients, 72 (55%) were male and 59 (45%) were female. Majority of patients had chronic glomerulonephritis (41.98%) as primary disease followed by Diabetic kidney disease (36.64%) and hypertension (12.21%) respectively [Table 2].

Success Rate & Patency Duration

Technical success rate was 98.5% (n=129). Patency duration was 585 days in longest catheter survival & shortest was 14 days. All deaths were unrelated to TCC placement.

TCC Sites

Right Internal Jugular vein is preferred site 83.2% (n=109) followed by Left internal jugular 4.6% (n=6) and right External jugular vein 3.8% (n=5) (Table 3). Right and left subclavian vein were used in 6.1% (n=8) due to thrombosed jugular veins followed by femoral vein 0.8% (n=1)

TCC Duration Used

66.4% (n=87) of TCC were used for Less than 3 months (Table 4) followed by 21.4% (n=28) for 3 to 6 months, 12.2% (n=16) for more than 6 months respectively.

Complications

80.9% (n=106) patients had no complications (Table 5). Catheter related blood stream infection was observed in 16.03% (n=21). 1.5% (n=2) patients had blockage of catheter. One patient, each, had oozing from tract due to cuff extrusion and right femoral deep vein thrombosis.

Table 6: Complications related to Tunnelled Cuffed Catheter, in less than 6months

Complication <6 months	n
Catheter blocked	2
CRBSI	19
Right Femoral vein DVT	1

Table 7: Complications related to Tunnelled cuffed catheter after 6months

Complication >6 months	n
CRBSI	2
Oozing from Tract due to cuff extrusion	1

Table 8: Indication for catheter removal

INDICATION FOR REMOVAL	n	%
Ongoing catheter	47	35.9%
AVF Matured	43	32.8%
Expired	16	12.2%
CRBSI	14	10.7%
Live Related kidney Transplant	3	2.3%
Technique Failure	2	1.5%
Renal recovery	2	1.5%
Catheter Blockage	2	1.5%
DVT	1	0.8%
Improved	1	0.8%
Total	131	100.0%

Catheter related blood stream infection were observed more in early period i.e. less than 6 months in 14.5% (n=19) (table 6, 7), than in later period [1.52%, n=2]

Indications for Removal of TCC

Ongoing TCC ie still in use with flow > 250 ml/min were 35.9 %, while 32.8% TCC were removed due to maturation of Arteriovenous fistula (Table 8). 10.7% TCC were removed due to catheter related blood stream infection. Live related kidney transplantation & renal recovery were the reasons for withdrawal of TCC in 2.3%. TCC block & brachiocephalic block were seen in 1.5% cases each. Deep vein thrombosis was seen in 0.8%.

DISCUSSION

India has one of the largest population of advanced CKD. Creation and utilization of AVF is not without hurdles. Reliance on the limited local vascular surgical expertise results in significant primary failure rate of AVF. Most often patients present themselves in advanced uremia for the first time to the nephrologists without a functioning AVF. Extremely high rates of bacteremia are encountered within 2-4 weeks in nontunnelled catheters.[11] Tunnelled catheters play an important role by providing a viable dialysis access for maintenance hemodialysis. Dialysis Outcomes and Practice Patterns Study (DOPPS) analysis showed that catheters as a primary vascular access were used in 23%-73% of incident dialysis patients in several countries.[12]

Ours being a tertiary care public hospital with increased load of end stage renal disease, in time AVF construction in every patient is not feasible .So TCC insertion became the need of hour especially in elderly, diabetic, female patients, in whom technical success of AVF construction is less with delayed AVF maturation. Also, majority of our CKD –VD population presents without permanent vascular access & maintaining on HD with non-tunnelled catheters exposes this group to very high risk of CRBSI. Blind percutaneous jugular venous cannulation is technically more difficult because landmarks are less prominent than in subclavian vein cannulation[13], especially in obese patients or in those patients who may not be able to lie flat because of pulmonary congestion in ESRD. Anatomical variations of the internal jugular vein occur in about 5% of patients, making it difficult to locate the vein using landmarks alone.[14] Puncture- related complication occur in up to 11% of the series in the literature[15] and some of these complications have been fatal.

Cannulation is best performed under ultrasound guidance. Anatomical variations of the jugular veins are present in 5–18% of patients and ultrasound guided placement results in significantly lesser incidence of failed attempts and arterial puncture.[14,16,17] The advantages of TCCs include short learning period for the nephrologist who is already well versed with placement of central venous catheters, availability of multiple sites for catheter insertion, immediate availability of an access providing high blood flow rates of 250-300 ml/minute, no hemodynamic consequences unlike AVF, its longevity and the low rates of catheter infection.[11]

In our case series all TCC were inserted by only the nephrologist in the dedicated room for catheter insertion close to intensive renal care unit under ultrasound guidance and Monitoring of Blood pressure, ECG, pulse oximetry .

In our study, Technical success rate was 98.5% (n=129). Patency duration was 585 days in longest catheter survival & shortest was 14 days. All deaths were unrelated to TCC placement.

As per the study published by Sampathkumar et al, all catheters were inserted by only the nephrologist either in the interventional nephrology suite or in the fluoroscopy unit.[11] Fry AC et a from UK had three types of insertion. In 358 cases, the TCCs were inserted in an operating theatre setting by a surgeon almost exclusively using fluoroscopic guidance. In other 454 cases a dedicated procedures room on the acute nephrology ward, with monitoring (blood pressure, pulse oximetry, and electrocardiography) but no fluoroscopic guidance. In the remaining cases the catheters were inserted under fluoroscopic guidance by a physician in the radiology angiographic suite.[18] Subclavian veins are not routinely used any more due to risk of central venous stenosis.[19] We used subclavian veins only in 8 (6.1%) patients due to thrombosis of the other veins. The published complications of hemothorax, pneumothorax, venous rupture, and atrial perforation were not seen in our series. In few cases oozing at the tunnel site entry was encountered which resolved on conservative management.

Survival rate of catheters is not uniform and varies from centre to centre. Maya et al. described catheter survival rates of 43% and 81% at 60 days, 33% and 78% at 90 days, and 14% and 67% at 180 days for femoral and internal jugular veins respectively.[20] Similarly, Sampathkumar et al. showed survival rates of 80% and 55% for 3 months and 6 months respectively.[11] While Study done by Abdur Raheem et al, 89%, 77% and 64% for 60, 90 and 180 days respectively.[21] However Our study shows catheter survival rate of 66.4%, 21.4%, 12.2% at 3 months, 3-6months and more than 6 months respectively.

Catheter related blood stream infection was most common among all complication seen in our study. We had observed 21 episodes of bacteremia while 6 episodes had been seen in study by Sampathkumar et al.[11] This is proabaly because of different policy of catheter care at different centers providing dialysis & our patients, after TCC placement & initial HD sessions were on Maintainance HD at outside centres. Prophylactic antibiotic use in routine central line placement may not be recommended by some authors.[22,23] However, we believe that antibiotic use is warranted when exchanging temporary catheters for TCC, as the procedure represents high risks for infection.

In our Study 35.9% (n=47) had ongoing catheter with blood flow > 250 ml/min. 32.8% (n=43) of TCC were removed due to maturation of AV Fistula followed by 12.2% (n=16), 10.7% (n=14), 2.3% (n=3), 1.5% (n=2) Death, Bacteremia, Renal transplant, Catheter block respectively. None of the deaths were related to TCC placement.

The K/DOQI recommendation makes it difficult for nephrologists to perform this procedure without access to fluoroscopy, mainly in developing countries. Fluoroscopy is ideal but not every hospital has facility. However, we would certainly not suggest that fluoroscopic assistance is unnecessary, rather, fluoroscopic guidance is desirable in more 'complicated TCC insertions and for all left-sided TCC placements, where risk of incorrect placement is high .We had technique failure in two patient while putting in left IJV and transferred to other centre for insertion under fluoroscopy guidance. As mentioned in other studies, Naive Right IJV (83.2%, n=109) is most preferred site in our study also. The technique of TCC placement without fluoroscopy has been tested previously, concluding that there was no difference in major or minor complications between the Modified TCC placement and the fluoroscopy guided group.[18,24]

CONCLUSION

Combination of ultrasound Doppler with monitoring (ECG, pulse oxymetry, Blood pressure) and post procedure x ray chest can be used for TCC insertion when fluoroscopy is not available. With this technique, in our study, Technical success rate was 98.5% (n=129). Patency duration was 585 days in longest catheter survival & shortest was 14 days. No complications were seen in 80.9%. All deaths were unrelated to TCC placement.

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