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CLINICAL & BASIC RESEARCH

Safety and Complications of Double-*Lumen* Tunnelled Cuffed Central Venous Dialysis Catheters

Clinical and radiological perspective from a tertiary centre in Oman

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سلامة ومضاعفات القساطير الوريدية المركزية النفقية المكممة الخاصة بالديلزة الدموية

منظور سريري وشعاعي من مركز واحد في عمان

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ABSTRACT: ***Objectives:*** This study aimed to assess the technical success, safety and immediate and delayed complications of double-*lumen* tunnelled cuffed central venous catheters (TVCs) at the Sultan Qaboos University Hospital (SQUH), Muscat, Oman. ***Methods:*** This retrospective study took place between January 2012 and October 2013. The clinical records and radiological data of all patients who underwent ultrasound- and fluoroscopy-guided TVC placement at SQUH during the study period were reviewed. Demographic data and information regarding catheter placement, technical success and peri- and post-procedure complications (such as catheter-related infections or thrombosis) were collected. ***Results:*** A total of 204 TVCs were placed in 161 patients. Of these, 68 were female (42.2%) and 93 were male (57.8%). The mean age of the patients was 54.4 ± 17.3 years. The most common reason for catheter placement was the initiation of dialysis (63.4%). A total of 203 procedures were technically successful (99.5%). The right internal jugular vein was the most common site of catheter placement (74.9%). Mild haemorrhage which resolved spontaneously occurred in 11 cases (5.4%). No other complications were observed. Subsequent follow-up data was available for 132 catheters (65.0%); of these, thrombosis-related catheter malfunction was observed in 22 cases (16.7%) and catheter-related infection in 29 cases (22.0%). ***Conclusion:*** Radiological-guided placement of tunnelled haemodialysis catheters can be performed safely with excellent technical success. The success rate of catheter insertion at SQUH was favourable in comparison with other studies reported in the literature.

Keywords: Central Venous Catheters; Interventional Radiology; Thrombosis; Catheter-Related Infections; Renal Dialysis; Oman.

الملخص: الهدف: هدفت هذه الدراسة إلى تقييم النجاح التقني وعنصر السلامة والمضاعفات الآنية والمتأخرة للقساطير الوريدية المركزية ثنائية الجوف النفقية المكممة (القساطير الوريدية) في مستشفى جامعة السلطان قابوس في مسقط في عمان. **الطريقة:** هذه الدراسة الاستعراضية الاستعادية أجريت ما بين شهر 2012 و شهر اكتوبر 2013. من خلال مراجعة السجلات السريرية والبيانات الشعاعية لجميع المرضى الذين تم وضع قساطير قساطير وريدية لهم بتوجيه من جهاز الفحص بالامواج فوق الصوتية (السونار) والتنظير الشعاعي (الفلوروسكوبي) في مستشفى جامعة قابوس في فترة الدراسة. تم جمع ومراجعه كافه البيانات الديموغرافية والمعلومات الخاصة بادخال القساطير والنجاح التقني ومضاعفات مابعد العملية (مثل الانتانات المتعلقة بالقسطار، والتخثر). **النتائج:** خلال فترة الدراسة تم ادخال 204 قسطارا وريديا في 161 مريضا. من بين هؤلاء المرضى كان عدد الإناث 68 بنسبة (42.2%) والذكور 93 بنسبة (57.8%). معدل أعمار المرضى كان يتروح مابين 17.3 ± 54.4 سنة. من خلال هذه الدراسة وجدنا أن السبب الأكثر شيوعا لإدخال القسطار كان لغرض ابتداء الديلزة الدموية بنسبه (63.4%). 203 حالة (99.5%) أجريت بتقنية ناجحة. الوريد الوداجي الداخلي الأيمن كان الموضع الأكثر شيوعا لإدخال القسطار بنسبة (74.9%). حدوث نزف بسيط مع التوقف التلقائي سجلت في 11 حالة و بنسبة (5.4%). لم تشاهد أي مضاعفات أخرى، معلومات عن المتابعة للمضاعفات المتأخرة كانت متوفرة من 132 قسطارا (65.0%)، من بينها 22 حالة (16.7%) عطل في عمل القسطار ناتج عن التخثر، وإنتانات متعلقة بالقسطار في 29 حالة (22.0%). **الخلاصة:** وضع قساطير الديلزة الدموية النفقية بالتوجيه الشعاعي يمكن إجراؤه بأمان و بنجاح تقني ممتاز. معدل النجاح في إدخال القساطير في مستشفى جامعة السلطان قابوس كان مرضيا مقارنة بالدراسات الأخرى المسجلة والمنشورة.

مفتاح الكلمات: قسطار وريدي مركزي؛ علم الاشعة التداخلية؛ تخثر؛ إنتانات متعلقة بالقسطار؛ ديلزة دموية؛ عمان.

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Advances in Knowledge

- *To the best of the authors' knowledge, this study provides the first local data from Oman regarding the clinical safety of interventional radiological placement of double-lumen tunnelled cuffed central venous catheters (TVCs). This study presents the initial experience of this procedure at a tertiary care hospital.*

Application to Patient Care

- *As the number of patients requiring dialysis continues to grow, the creation and maintenance of haemodialysis access remains a vital healthcare issue worldwide.*
- *This retrospective study assessed the safety and performance of TVCs at a tertiary care hospital in Oman to identify the nature and frequency of problems related to catheter insertion and usage. This will aid catheter placement and handling practices and ultimately improve patient care.*

The provision of adequate haemodialysis depends on reliable access to large blood vessels capable of providing rapid blood flow.[1] Currently, the three forms of long-term access most commonly used are the native arteriovenous (AV) *fistula*, synthetic graft and double-*lumen* tunnelled cuffed central venous catheter (TVC).[2] First developed in 1987, these catheters are radio-opaque and made of soft silicone or polyurethane and are widely used to either provide bridging access before the creation and maturation of a high-flow AV *fistula*/graft or permanent access when a creation of a *fistula*/graft is not possible.[3,4]

At the Sultan Qaboos University Hospital (SQUH) in Muscat, Oman, TVCs are available in 12.5–14.5 French catheter sizes. They are placed in the distal superior *vena cava* and right atrium, usually using an internal jugular vein puncture after the creation of a subcutaneous tunnel superior to the breast along the lateral chest wall. Compared to a temporary dialysis catheter, TVCs have a softer polymer and therefore carry a reduced risk of subsequent vessel injury or erosion.[5] Additionally, the larger diameter of the *lumen* allows increased blood flow during dialysis.[5] They have a special antimicrobial cuff which serves to anchor the catheter in its tunnel using the in-growth of fibrous tissue. These catheters are normally placed by nephrologists or surgeons depending on local expertise. However, there is an increasing global trend for these catheters to be placed by interventional radiologists with very low incidences of procedure-related complications.[2] Nevertheless, late complications—particularly infection and thrombosis—remain problematic and can lead to catheter dysfunction and significant morbidity.[6–8] To the best of the authors' knowledge, no local data yet exist from Oman regarding the safety of radiological catheter placement and the prevalence of catheter-related complications. This study therefore aimed to assess the technical success, safety and immediate and delayed complications of ultrasound- and fluoroscopy-guided TVCs at SQUH.

Methods

This retrospective study was carried out between January 2012 and October 2013 at the Departments of Radiology & Molecular Imaging and Medicine at SQUH. All patients who underwent TVC placement during this 22-month period were included in the study. Demographic data for all patients were recorded on a structured form along with information about catheter placement, technical success, complications of the catheter placement procedure and the development of any subsequent complications, such as catheter-related infections or thrombosis.

All catheters were inserted by an interventional radiologist while the patient was in a supine position and under local anaesthesia. Coagulation parameters were checked before the procedure, including the prothrombin time, partial thromboplastin time and platelet count. A platelet count of ≥100 x 10^9/L and an international normalised ratio of <1.5 were considered acceptable. The procedures were performed using ultrasound and fluoroscopic guidance in the interventional radiology suite using a sterile technique. Ultrasonography was used to verify the patency of the internal jugular or femoral veins and to mark an appropriate puncture site. The vein was accessed with an 18-gauge needle with real-time ultrasound guidance and a 0.038-inch J-shaped flexible wire. Subsequently, a peel-away sheath was introduced over the guide wire following serial dilatation. After the patient had received lidocaine injected into either the upper chest or thigh (according to the puncture site), a subcutaneous tract was created using a tunnelling trocar. The catheter was attached to the threaded end of the trocar and pulled through the tunnel and out via the exit site. The TVC was then introduced through the peel-away sheath under fluoroscopy. The catheter hubs were flushed with heparinised saline solution and sterile caps were attached. A chest or pelvic radiograph was taken at the end of the procedure to confirm the position of the catheter tip. When required, the catheter was removed using a sterile technique. Using

Table 1: Indications for double-*lumen* tunnelled cuffed central venous dialysis catheter insertion among patients at the Sultan Qaboos University Hospital, Muscat, Oman (N =161)

Indication	n (%)
Dialysis initiation	102 (63.4)
Replacement of temporary catheter	34 (21.1)
Failed AV *fistula*/graft	17 (10.6)
Failed transplant	4 (2.5)
Replacement of blocked TVC	3 (1.9)
Not available in records	1 (0.6)
Total	**161 (100.0)**

AV = arteriovenous; TVC = tunnelled cuffed central venous catheter.

meticulous blunt dissection, the cuff was freed and the catheter was gently pulled out.

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS), Version 20.0 (IBM Corp., Chicago, Illinois, USA). Ethical permission for this study was obtained from the Medical Research & Ethics Committee of the College of Medicine & Health Sciences at Sultan Qaboos University, Muscat, Oman (MREC #840).

Results

A total of 161 patients were referred to SQUH for TVC insertion during the study period. Of these, 68 were female (42.2%) and 93 were male (57.8%). The mean age of the patients was 54.39 ± 17.3 years (range: 13–90 years old). In total, 204 catheter placement procedures were performed on these patients; four patients had between 3–8 catheters inserted, 26 patients had two catheters inserted and 131 patients had one catheter inserted. The most common indication for catheter placement was the initiation of dialysis in newly diagnosed patients (63.4%) [Table 1]. Catheter placement procedures were successful in 203 cases (99.5%). Only one procedure failed; the catheter could not be placed due to bilateral internal jugular vein *stenosis*. The patient was restless and had respiratory distress due to pulmonary oedema. However, after his condition had stabilised, he returned the next day and a TVC was successfully placed in the right femoral vein.

Of the successfully-placed catheters, 201 (99.0%) were placed during the first puncture. In the remaining two cases, the first puncture was unsuccessful and the catheters were placed during a second puncture within the same session. The right internal jugular vein was accessed in 152 cases (74.9%) while 32 catheters were placed through the left internal jugular vein (15.8%), 15

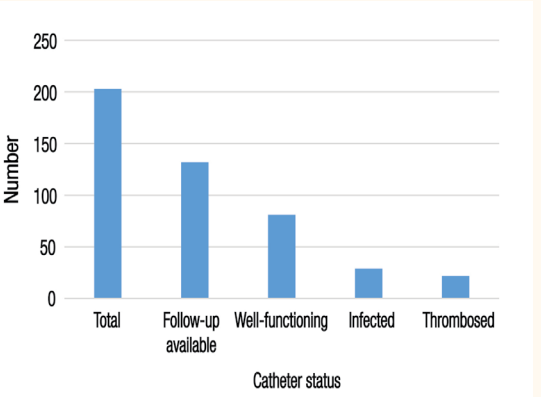

Figure 1: Catheter status at follow-up of double-*lumen* tunnelled cuffed central venous dialysis catheter catheters inserted among 161 patients at the Sultan Qaboos University Hospital, Muscat, Oman (N = 204). Follow-up information was only available for 132 catheters placed in 100 patients. Blood-borne and exit site infections were observed at follow-up in 29 catheters (22.0%) placed in 22 patients. Thrombosis-related catheter malfunctions were observed in 22 cases (16.6%) leading to subsequent problems during dialysis.

catheters were placed through the right femoral vein (7.4%) and four catheters were placed through the left femoral vein (2.0%). A total of 193 catheters (95.1%) were inserted in a satisfactory position with optimal placement and without any kinks in the catheter *lumen* and 10 catheters (4.9%) had suboptimal placement with kinks, malposition or both.

The majority of the successful procedures (n = 193; 95.1%) were completed uneventfully without any complications. Mild bleeding at the skin entry site in the chest wall occurred during 11 procedures (5.4%); all of these resolved following manual compression for 10–15 minutes. These patients did not require any blood transfusions and were placed under observation to ensure their haemodynamic stability. There were no instances of haemo/pneumothorax, air embolisms or any other complications. After catheter placement, 114 patients (70.8%) continued dialysis outside of SQUH at other governmental facilities. The remaining 47 patients (29.2%) continued receiving dialysis at SQUH.

Clinical follow-up information regarding catheter status was only available for 132 catheters placed in 100 patients [Figure 1]. The remaining 61 patients were lost to follow-up and no clinical records were therefore available for the remaining 71 catheters (35.0%). Of the patients who were lost to follow-up, 52 patients (85.3%) were receiving dialysis at other governmental facilities and nine patients (14.7%) had had their initial dialysis session at SQUH but did not return after being discharged. Out of the 132 catheters with follow-up data, 10 (7.6%) were accidentally pulled out after placement and three (2.3%) were found to have cuts.

Table 2: Thrombosis-related malfunctions of double-*lumen* tunnelled cuffed central venous dialysis catheter procedures among patients at the Sultan Qaboos University Hospital, Muscat, Oman (N =15)

Catheters placed per patient	Thrombosed catheters per patient
8	6
6	3
2	1
2	1
2	1
1	1
1	1
1	1
1	1
1	1
1	1
1	1
1	1
1	1
1	1

All of these catheters were not suitable for reuse and had to be replaced.

Of the 132 catheters placed in the patients who were not lost to follow-up, thrombosis-related malfunctions were observed in 22 catheters (16.6%) leading to subsequent problems during dialysis. These 22 catheters were placed in 15 patients [Table 2]. The highest frequency of catheter-related thrombosis was seen in two patients. One of these patients had thrombosis in six out of eight catheters placed during the study period. As a result, this patient had multiple access problems, bilateral central venous *stenosis* and a thrombosed *fistula*. A routine thrombophilic screening test was negative. For the other patient, thrombosis was observed in three out of six catheters placed. This patient was in a hypercoagulable state and had a previous history of deep venous thrombosis of the lower limbs. He also had protein C and protein S deficiencies and there were pre-existing venous stenoses in the right internal jugular vein and the veins of right lower limb which were believed to be responsible for the recurrent thrombosis. The stenoses in the lower limb veins were treated by angioplasty. Among the thrombosed catheters, the patency of five catheters was successfully restored via the injection of thrombolytic agents into the catheter lumen. However, 17 catheters were still non-functioning after this treatment and were removed.

Table 3: Catheter-related infections of double-*lumen* tunnelled cuffed central venous dialysis catheter procedures among patients at the Sultan Qaboos University Hospital, Muscat, Oman (N = 22)

Catheters placed per patient	Infected catheters per patient	Route of infection	Causative organism
6	2	Blood-borne	*Staphylococcus aureus*
		Exit site	*Staphylococcus aureus*
4	3	Blood-borne	*Pseudomonas*
		Blood-borne	*Enterobacter*
		Blood-borne	*Enterobacter*
2	2	Blood-borne	*Staphylococcus aureus*
		Blood-borne	*Pseudomonas*
2	2	Blood-borne	*Acinetobacter*
		Blood-borne	*No growth*
2	2	Blood-borne	*Staphylococcus aureus*
		Both routes	*Staphylococcus aureus*
2	2	Both routes	*Staphylococcus aureus*
		Both routes	*Staphylococcus aureus*
2	1	Blood-borne	*Pseudomonas*
2	1	Both routes	*Acinetobacter*
2	1	Blood-borne	*Staphylococcus aureus*
1	1	Exit site	*Staphylococcus aureus*
1	1	Blood-borne	*Staphylococcus aureus*
1	1	Exit site	*Staphylococcus aureus*
1	1	Blood-borne	*Acinetobacter*
1	1	Blood-borne	*Staphylococcus aureus*
1	1	Blood-borne	*Staphylococcus aureus*
1	1	Both routes	*Klebsiella*
1	1	Both routes	*Proteus mirabilis*
1	1	Blood-borne	*Enterococcus*
1	1	Blood-borne	*Staphylococcus aureus*
1	1	Both routes	*Staphylococcus aureus*
1	1	Blood-borne	*Staphylococcus epidermidis*
1	1	Exit site	*Staphylococcus aureus*

Infection was observed at follow-up in 29 catheters (22.0%) placed in 22 patients [Table 3]. Two of the patients with infected catheters also had thrombosis but it was not possible to determine which condition occurred first. Of the infections, there were 18 cases of blood-borne infections (62.1%), four cases (13.8%) of exit site infections in the skin of the chest and seven cases (24.1%) of both blood-borne and exit site infections. One elderly male patient had blood-borne infections which occurred in three out of four catheters placed during the study period. He was diabetic and hypertensive and had coronary artery disease. His dialysis sessions were held at another facility outside of SQUH. Four patients had catheters placed twice during the study period, with all of these catheters developing infections. Culture results indicated that the most common bacteria causing infections was *Staphylococcus aureus* in 16 cases (55.2%), followed by bacteria of the *Acinetobacter* and *Pseudomonas* genera which were each seen in three cases (10.3% each). Infections in five catheters (17.2%) were successfully treated with antibiotics while 24 infections (82.8%) did not respond well to antibiotics and persisted, leading to the catheters being removed.

Discussion

Dialysis as a modality of renal replacement therapy is generally required in patients with acute kidney injury or end-stage renal disease. Haemodialysis accounts for 89% of all patients who receive dialysis, with the rest receiving peritoneal dialysis.[9] Although the AV *fistula* is the preferred mode of access for haemodialysis, TVCs can help patients awaiting maturation of an AV *fistula* or those for whom an AV *fistula* is not possible.

The success rate of catheter insertion in the current study was favourable in comparison with other studies reported in the literature.[10,11] This may be because all of the procedures were performed using ultrasound and fluoroscopic guidance, which is known to increase the success rate of insertion.[11,12] Additionally, the procedure was very safe for the majority of patients with a very low procedure-related immediate complication rate. All of the immediate complications were related to local bleeding and could be controlled by manual compression. None of the patients required additional procedures for management and there were no cases of haemo/pneumothorax or air embolism detected. These findings are similar to those reported elsewhere.[10,11]

Catheter-related thrombosis in the form of a fibrin sheath or a *thrombus* in the catheter is a frequent complication of indwelling catheters and accounts for up to 40.0% of catheter failures.[2] In the present study, the rate of *thrombus*-related catheter malfunctions (16.7%) was lower than those reported in the literature.[2,4] In particular, one patient had eight catheters inserted of which six thrombosed and an AV *fistula* which also thrombosed without ever being used for dialysis. Although a routine thrombophilic screen was negative, it is likely that the patient was suffering from an unknown thrombophilic disorder. Another patient had a previous history of deep venous thrombosis and protein C and protein S deficiencies which probably contributed to the multiple catheter failures. However, although the overall thrombosis-related catheter failure rate was lower than previously reported, and several affected catheters were salvaged by intracatheter thrombolysis, the majority of the affected catheters had to be removed.

Another serious complication with significant morbidity and mortality in patients undergoing haemodialysis is catheter-related infection. The risk of bacteraemia with a cuffed tunnelled catheter is nearly 10 times that of an AV *fistula*.[13] The overall infection rate in the current study (21.9%) was much lower than that reported in the literature; catheter-related infection rates of 54.0% have been reported, with up to two-thirds of catheters requiring removal.[2,3] Despite the low catheter-related infection rate, the majority of infected catheters in the current study required removal and very few infections were cleared satisfactorily with antibiotics.

Cuffed tunnelled catheters provide a temporary alternative to AV *fistulae* for haemodialysis patients. Nevertheless, while patient acceptance is particularly high with catheters as no needles are required for the purposes of the dialysis, significant complications and failure rates remain higher than for AV *fistulae*.[14] Further research into catheter materials and construction is needed to reduce the rates of these complications and prolong the useful life span of catheters.

Conclusion

Radiology-guided placement of tunnelled haemodialysis catheters at SQUH was performed safely with excellent technical success (99.5%). Mild haemorrhage which resolved spontaneously was the only procedure-related immediate complication (5.4%). Additionally, low rates of subsequent thrombosis-related catheter malfunction (16.7%) and catheter-related infection (22.0%) were observed. These rates compared favourably with the international literature.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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