

# **Tunnelled haemodialysis catheters in central Free State: Epidemiology and complications.**

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Submitted in fulfillment of the requirements in respect of the Master's Degree M.Med in the Department of Clinical Imaging Sciences in the Faculty of Health Sciences at the University of the Free State.

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### **Author declaration**

I, John Edward Fox, declare that the coursework Master's Degree mini-dissertation that I herewith submit as a published article for the Master's degree M.Med Diagnostic Radiology, at the University of the Free State is my independent work and that I have not previously submitted it for a qualification at another institution of higher education.

### **Authors' contributions:**

- John Fox was the principal investigator who designed the study, conducted the literature review, obtained ethical clearance and statistical input, captured and processed the data and wrote the final manuscript.
- Dr E Loggenberg was the study leader who conceptualized the study, assisted with literature review, critically analyzed the manuscript and approved the final version.
- Prof G Joubert assisted with the study protocol, provided statistical analysis of the data and critical analysis of the manuscript.

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- None.

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## **Abstract:**

**Background:** End stage renal disease (ESRD) is a disease with profound impact on the patient, health system and economy. Tunnelled haemodialysis catheters (TDC) are amongst the most common dialysis methods. It has been established internationally that certain demographic descriptors and aetiologies carry an increased risk of complications. There is a dearth of epidemiological profiling of ESRD patients with TDC in South Africa.

**Objective:** To establish the epidemiological profile of patients who received TDC and to establish the complication rate, with the goal of demonstrating associations between the epidemiological profiles and complications.

**Method:** This was a retrospective study of all patients who received TDC in an Academic Hospital Interventional Radiological Suite over a period of 60 months between 01 March 2011 and 29 February 2016.

**Results:** A total of 179 patients received 231 catheters. The majority of patients were male (58.7%) and 35.8% of the patients resided in Mangaung. The leading aetiologies of ESRD included hypertensive nephropathy (43.6%), primary glomerular disease (17.3%) and HIV associated nephropathy (6.1%). Procedural complications occurred in 7/224 (3.1%) insertions, whilst 37/185 (20.0%) developed catheter related infection and 54/185 (29.2%) developed dysfunctional catheters. There were no deaths due to catheter related complications.

**Conclusion:** Our patients' demographic profile, ESRD aetiology, complication rate for procedural complications and catheter related infections are roughly on par with international studies, however, the catheter dysfunction rate is higher than in the aforementioned studies. This possibly reflects the difficulty of accessing specialist care for our patients, the majority of whom reside outside the Mangaung district. Further studies with larger patient numbers are required to demonstrate statistically relevant associations.

**Keywords:** end stage renal disease, tunneled haemodialysis catheters, epidemiological profile, complication rate.

## **Introduction:**

End stage renal disease (ESRD) is an increasing health care concern across the world with a high mortality rate and associated economic implications, particularly in Southern Africa, where it affects a younger demographic than in developed countries.<sup>1,2</sup> An effective screening program would assist in early nephrologist/renal centre referral which is shown to have an impact on decreasing the morbidity and mortality of these patients.<sup>3,4</sup>

In state healthcare, 44.1% of the dialysis population are managed with haemodialysis, and at our institution a large portion of the dialysis population undergo tunnelled haemodialysis catheter insertion either for temporary vascular access (whilst grafts or fistulae mature or the peritoneum recovers) or when other vascular access routes are exhausted.<sup>5</sup> Tunnelled haemodialysis catheters (TDC) do offer some advantages, including immediate dialysis and no repeated venepuncture. However, they are associated with an increased risk of complications and significant mortality when compared to other types of vascular access, with a 1-year survival of patients on TDC of 75%.<sup>3,6</sup>

Based on studies in China and Croatia, multiple risk factors have been demonstrated to carry an increased risk of complications.<sup>3, 7</sup> However, no local study has assessed our complication rate and investigated epidemiological risk factors. Filling this void would assist in the implementation of focused and effective screening programs.

The goal of this study was multifactorial. We aimed to establish the epidemiological profile of patients at an Academic Hospital who received TDC at the Interventional Radiological unit over a 60-month period, to establish the complication rate within that population group and to determine if associations between the risk factors, epidemiological data and complications could be established.

## **Research methods and design:**

### **Study design and setting:**

This was a retrospective, analytic study conducted at an Academic Hospital Interventional Radiology unit, which serves the population of the Free State province as well as occasional out of province and private patients.

### **Study population and sampling strategy:**

The study population consisted of all state patients who received TDCs at an Academic Hospital Interventional Radiology unit during the period of 01 March 2011 to 29 February 2016. All patients aged 18 years and older, who received their catheter at the interventional suite, were included.

### **Catheter Insertion:**

Catheters were inserted by an experienced interventional radiologist in the Interventional unit via percutaneous access. The procedure was performed under sterile theatre conditions with ultrasound guided venous access. All TDCs inserted in our centre are cuffed. The catheter is tunnelled subcutaneously for approximately 9-10cm from the venous access site. The catheter is then placed under fluoroscopic control with tip positioning in the right atrium. Cutaneous

fixation is created with sutures until cuff adhesion – approximately 8-12 weeks. Initial patency and positioning are confirmed during the procedure. The catheter is then locked with heparin (1000u/ml)

The primary goal for access was the internal jugular vein. However, in patients with previous access and complications, other sites were used. Subclavian access was used when no other access site was available.

### **Secondary intervention:**

In patients where the catheter is unable to maintain adequate extracorporeal blood flow and thrombolytic therapy (alteplase) has been ineffective, brushing is performed in the Interventional unit under fluoroscopic guidance and sterile conditions to displace and remove the fibrin sheath (a composite of cells and debris that forms a biofilm around catheters that can obstruct the lumen, acting as a valve) or thrombus by using a Terumo guidewire to sound the catheter lumen and rinse the lumen with saline. The catheter is then locked with heparin, 1000u/ml. If brushing fails to restore patency, then snaring is employed - vascular access is gained from another site and mechanical stripping of the catheter tip is performed via a snare.

### **Data collection:**

Patients were identified using the procedural register and further information was gathered from existing electronic medical records. A comprehensive data sheet was completed. Details captured included date of birth, age at catheter insertion and residence. Aetiology was grouped into diabetes, primary glomerular disease (including nephrotic syndrome, acute glomerulonephritis, rapidly progressive glomerulonephritis), hypertensive nephropathy, acute renal failure, obstructive uropathy, renal tubular interstitial diseases (including acute tubular necrosis, tubulointerstitial nephritis, contrast nephropathy, reflux nephropathy and myeloma), Human Immune deficiency virus associated nephropathy (HIVAN), drug induced nephropathy, polycystic kidney disease and unknown.

For ease of analysis, complications were grouped into procedural complications (air embolism, bleeding and pneumothorax), catheter related infection and catheter dysfunction (malposition, thrombosis, fibrin sheath, central vein stenosis, loosening or catheter breakage)

Further details recorded included whether the catheters underwent repair or brushing and if they were removed due to complications, fistula maturation or peritoneal dialysis catheter use. In the cases of patient demise, it was noted whether this was due to catheter related complications or other causes.

Primary and secondary patency was calculated. Primary patency is regarded as the time duration of catheter patency until the first intervention required to maintain patency whilst secondary patency is regarded as the length of time from insertion until catheter removal due to complication/catheter failure. <sup>8</sup>

### **Data analysis:**

The primary researcher entered all the data onto an Excel data sheet, which was then submitted for statistical analysis by the Department of Biostatistics at the University. Results were summarised as frequencies and percentages (categorical variables) and means, standard

deviations and percentiles (numerical variables). Associations were investigated using appropriate hypothesis testing with  $p < 0.05$  considered statistically significant.

### **Results:**

A total of 179 patients received TDC during the study period and qualified for the study. A hundred and five of the patients were male (58.7%) and 64 of the patients (35.8%) resided in the Mangaung district. The mean age at insertion was 40.4 years with a standard deviation of 12.05. The 4 leading aetiologies were hypertensive nephropathy, primary glomerular disease, HIVAN and unknown aetiology; see Table 1 for more information.

The patients received 231 catheters. A hundred and fifty-eight patients had catheters inserted for the first time. The majority of patients (141, 77.3%) received one catheter, 25 patients (14.0%) received two, 10 patients (5.6%) received three, one patient (0.6%) received four and one patient (0.6%) received 5 catheters during the study period. Of the 231 catheters inserted, 224 (97.0%) had information regarding insertion and 185 (80.1%) had information regarding follow up. The majority of lines were inserted in the right internal jugular vein, with the left internal jugular vein insertion being the second as per Table 2.

Procedural complications occurred in 3.1% of insertions whilst 20.0% developed catheter related infections and 29.2% developed complications related to dysfunction. See Table 3 for further breakdown.

The mean age at insertion varied between the complication groups: in the catheter related infection group the mean age was 37.5 years; the procedural complication group mean age was 40.2 years; and the catheter dysfunction group mean age was 39.8 years. Table 4 summarises the patient characteristics, complications recorded and the associations between them.

Out of the 231 catheters, 45 catheters (19.5%) had incomplete follow up. Of the catheters with adequate follow up, 4.3% went on to receive catheter repair, 17.7% required a single brushing, 5.4% received 2 brushings, 3.2% received 3 brushings, with a primary patency rate of 98 days. Complications resulted in 27.9% of the catheters being removed whilst 32.3% were removed due to fistulas and 18.8% due to peritoneal dialysis being initiated or resumed. No patients demised due to catheter related complications, whilst 10.2% of the patients demised due to other causes. Secondary patency rate was 87.0% at 6 months and 76.1% at 12 months.

### **Discussion:**

The high financial burden of ESRD has a considerable impact on the limited resources of the South African health system. Therefore, it would be of benefit if there was earlier diagnosis and efficient management of renal disease preventing or delaying the progression to end stage renal disease. The Academic Hospital Interventional Radiology unit assists with TDC insertion for a large percentage of the Free State dialysis population as can be demonstrated by considering that in 2016 the Free State had 235 patients on dialysis; our study population over the five year period numbered 179 patients.<sup>5</sup> Despite the increased risk of infection and mortality compared to fistulae or grafts, TDCs remain an important part of dialysis patient care.<sup>9,10,11</sup>

The epidemiological analysis of the study population revealed that the patient's age (mean of 40.4 years) was in keeping with a local South African study on ESRD, but younger than studies from other African countries and developed countries where renal failure is predominantly a diagnosis of the middle aged and elderly.<sup>1,2</sup> Male patients formed 58.7% of the sample; this corresponds to previously reported rates in Africa of 61-63% male gender in renal failure patients.<sup>1</sup> The female proportion of the study population experienced the majority of the complications, however, the gender discrepancy was not found to be statistically significant, which is also in keeping with an international study which indicated that patient gender did not impact catheter survival.<sup>12</sup>

A significant percentage (64.2%) of the study population resided outside the Mangaung district with implications in terms of ease of access to specialised medical services and further management of the TDC and the patient. The patients outside the Mangaung district experienced the majority of the complications (57-68%) across all three complication groups although the discrepancies were not statistically significant.

ESRD aetiology was similar to other studies in Africa with hypertension being the most commonly recorded in 43.6% of patients versus 34.6% (Sudan) and 30.9% (Cameroon). Further common causes in our study included primary glomerular disease and HIVAN. In Cameroon other aetiologies included glomerulonephritis (15.8%), diabetes (15.9%), HIVAN (6.6%) and unknown (14.7%).<sup>13</sup> In a Sudanese study the causes included chronic glomerulonephritis (17.6%), diabetes (12.8%) obstructive uropathy (9.6%) and in 10.7% no cause was identified.<sup>1</sup>

Hypertension as an aetiology constituted a larger percentage of this study population than international studies, although it is difficult to determine whether this was primary hypertension or secondary to chronic kidney disease. Additionally, this study had a high percentage of patients with an unknown cause. These findings could be a reflection on the lack of efficient primary health care with many patients presenting late in the course of the disease and not receiving renal biopsies.

The majority of catheters were inserted in the right jugular vein with no statistically significant discrepancy between site of insertion and procedural or dysfunctional complication rate, however, there was a statistically significant correlation between catheter related infection and insertion of the catheter in either femoral site. In a study by Dewelter et al, it was demonstrated that right jugular insertion confers significantly improved outcome as compared to other sites of insertion.<sup>14</sup>

This study, as compared to a study in Pakistan, had a decreased incidence of procedure related complications (3.2% versus 5.6%) but an increased rate of catheter related infection (20% versus 17.3%) as well as dysfunction related complications (29.2% versus 16%)<sup>15</sup> The increased incidence of catheter related infection and complications causing dysfunction reflect perhaps the difficulty for our patients in accessing specialist care after the procedure, particularly if they reside in another district. In light of the above, it might be of value to consider a chronic low dose of aspirin to maintain tunneled CVC patency.<sup>16</sup>

Catheter related infections remain a significant problem within the dialysis population with implications for cost of care and patient quality of life, as patients with catheter related infections have an average hospital stay of 6.5 days, undergo several tests and receive treatment during the hospital stay.<sup>17</sup> Considering the incidence of catheter related infections, future

studies could analyze the benefit of antimicrobial barrier caps in reducing this rate, as per KODQI guidelines.<sup>16</sup>

The secondary patency rate is better than a study in India at 6 months (87.0% compared to 55%) and the 12 month catheter survival rate falls within the wide range found in a previous review article of 2007 (between 25-75%)<sup>8,18</sup> A high percentage of the catheters were removed due to initiating or resuming peritoneal dialysis or use of fistulae. This is perhaps due to the increased number of patients in state health care who are on peritoneal dialysis compared to private health care (27.8% versus 6%).<sup>5</sup> There were no deaths in our study due to catheter related complications.

The aetiology in the study population on average did not have a statistically significant impact on the complication rate although other studies have shown that diabetes conveys increased risk and that age can have an influence additionally.<sup>7</sup> Polycystic kidney disease was shown to have an increased risk of catheter dysfunction related complications. The reason for this is unknown and merits further investigation.

Although our study was unable to establish a statistically significant association between demographics, aetiology and complications in the majority of cases, we were, however, able to demonstrate an association between femoral site catheter insertion and the risk of catheter related infection; and between patients with polycystic kidney disease and increased risk of catheter dysfunction. Studies have shown that associations exist between several patient characteristics (male gender, increased age, diabetic nephropathy, hypertensive nephropathy and glomerulonephritis) and their risk of complications.<sup>3,7</sup>

#### Study limitations:

Many patients who had their catheter inserted and were then managed further in other centers were lost to follow up, resulting in incomplete information particularly with regards to catheter related infection and dysfunctional catheter complications. A further challenge was the relative paucity of renal biopsies to confirm the ESRD aetiology.

#### **Conclusion:**

Our demographics, aetiology of ESRD and complication profile largely correspond to other studies except for an increased complication incidence in females, an increased percentage of hypertension as the cause for ESRD and an increased percentage of catheter dysfunction complications. These findings are perhaps a reflection on the challenges our primary health care system faces and the difficulty for these patients to access specialist care in the periphery. Due to the limited number of patients and complications, this study was unable to establish statistically significant correlations between complications and epidemiological factors in many of the measured characteristics.

In our setting, given pre-existing research that has demonstrated a decreased risk of complications with early referral to specialist care and dialysis initiation with other vascular access options (besides TDC),<sup>4</sup> it would be optimal to create a screening program for high risk patients (HT, DM)<sup>2</sup> If a South African multicentre study with a larger study population was able to confirm local risk factors for complications, then appropriate care centers could implement protocols for increased vigilance and screening for complications in the vulnerable population groups. This could also lead to and assist with the formation of local guidelines for

the management of dialysis such as the KODQI 2018 guidelines.<sup>16</sup> Together, these could assist in early identification of patients at risk of developing ESRD and lead to earlier referral to specialist care which has been shown to have positive effect on patient outcome <sup>4,18,19,20</sup>

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Table 1. Aetiology per patients (n=179)

Aetiology	n, %
Diabetes	7; 3.9%
Primary glomerular disease	31; 17.3%
Hypertensive nephropathy	78; 43.6%
Vasculitis	5; 3.0%
Acute renal failure	1; 0.6%
Obstructive uropathy	5; 3.0%
Renal tubular interstitial diseases	3; 1.7%
HIVAN	11; 6.1%
Drug induced	5; 3.0%
Polycystic kidney disease	8; 4.5%
Unknown	34; 19.0%
Other:	
HELLP	1; 0.6%
Lupus Nephritis	2; 1.1%
Nephrectomy due to malignancy	1; 0.6%
Oligomegaphronia	1; 0.6%
Oncocytoma	1; 0.6%

Table 2. Site of Insertion (n=224)

Site of insertion	n; %
Left internal jugular	22; 9.8%
Left common femoral	13; 5.8%
Left subclavian	2; 0.9%
Right internal jugular	165; 73.6%
Right femoral	14; 6.2%
Right subclavian	8; 3.6%
*Sites of insertion were recorded for 224 of the 231 catheters inserted.	

Table 3. Complications and incidence

Complications	Number, %
<b>Procedural</b>	
Air embolism	1/224; 0.4%
Bleeding	7/224; 3.1%
Pneumothorax	0/224; 0%
<b>Catheter dysfunction</b>	
Thrombosis	25/185; 13.5%
Fibrin sheath	20/185; 10.8%
Central vein stenosis	5/185; 2.7%
Catheter loosened	9/185; 4.9%
Dysfunction due to malpositioning	4/185; 2.2%
<b>Catheter related infection</b>	
Catheter related infection	37/185; 20%
* Denominators are procedures. Procedural complication was recorded during initial catheter insertion and admission and thus has a larger denominator than catheter related infection and dysfunctional complications which were recorded in patients who returned for follow up. More than one complication could occur per insertion.	

Table 4. Complications and Associations per catheters

Characteristic	Procedural complications n catheters: 7/224	P value	Catheter related infection n catheters: 37/185	P value	Dysfunctional complications n catheters: 54/185	P value
Gender						
Male	3/126; 2.4%	0.7	16/99; 16.2%	0.16	26/99; 26.3%	0.35
Female	4/98; 4.1%		21/86; 24.4%		28/86; 32.6%	
Residing		0.69		0.65		0.74
-Mangaung	3/77; 2.7%		12/66; 18.2%		18/66; 27.3%	
-Outside district	4/127; 3.9%		25/119; 21%		36/119; 30.3%	
<b>Aetiology</b>						
Diabetes	0/9		1/7; 14.3%		2/7; 28.6%	
Primary glomerular disease	1/39; 2.6%		11/33; 33.3%		7/33; 21.2%	
Hypertensive nephropathy	4/94; 4.3%		10/77; 12.9%		21/77; 27.3%	
Renal tubular interstitial disease	0/6		2/6; 33.3%		1/6; 16.7%	
HIVAN	0/12		3/9; 33.3%		2/9; 22.2%	
Polycystic kidney	0/12		2/10; 20%		7/10; 70%	
<b>Site of insertion</b>						
Left femoral	1/13; 7.7%	0.38	4/11; 36.4%	0.01	5/11; 45.5%	0.38
Left subclavian	0/2		1/2; 50%		1/2; 50%	

Table 4. Complications and Associations per catheters

Characteristic	Procedural complications n catheters: 7/224	P value	Catheter related infection n catheters: 37/185	P value	Dysfunctional complications n catheters: 54/185	P value
Left internal jugular	1/22; 4.6%		4/22; 18.2%		9/22; 40.9%	
Right femoral	1/14; 7.1%		7/12; 58.3%		4/12; 33.3%	
Right internal jugular	4/165; 2.4%		20/132; 15.2%		34/132; 25.8%	
Right subclavian	0/8		1/6; 16.7%		1/6; 16.7%	
<p>* Procedural complications were recorded during initial catheter insertion and admission and thus consist of a larger pool than catheter related infection and dysfunctional complications which were recorded in patients who returned for follow up.</p> <p>* Only aetiologies with 5 patients or more were included in this table.</p>						

### **List of Appendices:**

- A. UFS Health Sciences Research Ethics Committee Approval
- B. Free State Department of Health Ethics Approval.
- C. Approval to do research project from head of department.
- D. Approval to use Universitas patient record system.
- E. Research protocol.
- F. Electronic data form used for data capturing.
- G. Plagiarism certificate (Turnitin).
- H. South African Journal of Radiology – Author guidelines.
- I. Published Article.

IRB nr 00006240  
REC Reference nr 230408-011  
IORG0005187  
FWA00012784

30 August 2017

DR JOHN E FOX  
DEPT OF CLINICAL IMAGING SCIENCES  
FACULTY OF HEALTH SCIENCES  
UFS


Dear Dr John E Fox

**HSREC 62/2017 (UFS-HSD2017/0478)**  
**PRINCIPAL INVESTIGATOR: DR JOHN E FOX**  
**SUPERVISOR: LOGGENBERG EUGENE**  
**PROJECT TITLE: OUTCOME OF HAEMODIALYSIS TUNNELED CATHETER INSERTION AND ASSOCIATIONS WITH PATIENTS' EPIDEMIOLOGICAL PROFILE AND UNDERLYING RENAL FAILURE AETIOLOGY**

**APPROVED**

1. You are hereby kindly informed that, at the meeting held on 29 August 2017, the Health Sciences Research Ethics Committee (HSREC) approved this protocol after all conditions were met.
2. The Committee must be informed of any serious adverse event and/or termination of the study.
3. Any amendment, extension or other modifications to the protocol must be submitted to the HSREC for approval.
4. A progress report should be submitted within one year of approval and annually for long term studies.
5. A final report should be submitted at the completion of the study.
6. Kindly use the **HSREC NR** as reference in correspondence to the HSREC Secretariat.
7. The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

Yours faithfully



DR SM LE GRANGE  
CHAIR: HEALTH SCIENCES RESEARCH ETHICS COMMITTEE





health

Department of  
Health  
FREE STATE PROVINCE

21 July 2017

Dr JE Fox  
Dept. of Clinical Imaging Sciences  
Faculty of Health Sciences  
UFS

Dear Dr. JE Fox

**Subject: Outcome of haemodialysis tunnelled catheter insertion and associations with patients' epidemiological profile and underlying renal failure aetiology.**

- Please ensure that you read the whole document, Permission is hereby granted for the above – mentioned research on the following conditions:
- This letter replaces that letter dated **11 July 2017** and should be considered the only approval letter.
- Serious Adverse events to be reported to the Free State department of health and/ or termination of the study
- Ascertain that your data collection exercise neither interferes with the day to day running of the Universitas Hospital nor the performance of duties by the respondents or health care workers.
- Confidentiality of information will be ensured and please do not obtain information regarding the identity of the participants.
- **Research results and a complete report should be made available to the Free State Department of Health on completion of the study (a hard copy plus a soft copy).**
- Progress report must be presented not later than one year after approval of the project to the Ethics Committee of the University of Free State and to Free State Department of Health.
- Any amendments, extension or other modifications to the protocol or investigators must be submitted to the Ethics Committee of the University of Free State and to Free State Department of Health.
- **Conditions stated in your Ethical Approval letter should be adhered to and a final copy of the Ethics Clearance Certificate should be submitted to [sebecelats@fshealth.gov.za](mailto:sebecelats@fshealth.gov.za) before you commence with the study**
- No financial liability will be placed on the Free State Department of Health
- Please discuss your study with the institution manager/CEOs on commencement for logistical arrangements
- Department of Health to be fully indemnified from any harm that participants and staff experiences in the study
- Researchers will be required to enter in to a formal agreement with the Free State department of health regulating and formalizing the research relationship (document will follow)
- You are encouraged to present your study findings/results at the Free State Provincial health research day
- Future research will only be granted permission if correct procedures are followed see <http://nhrd.hst.org.za>

Trust you find the above in order.

Kind Regards

Dr D Motau

HEAD: HEALTH

Date: 28/07/2017

---

28 March 2017

Dear Professor De Vries,


I would hereby like to apply for permission to conduct my research for my MMed project.

The research title is: Outcome of haemodialysis tunneled catheter insertion and associations with patients' epidemiological profile and underlying renal failure aetiology.

My study leader is Dr E Loggenberg.

Kind regards

Dr J Fox

 *Sappard*  
Prof C. De Vries.



health

Department of  
Health  
FREE STATE PROVINCE

Dr J E Fox  
Department of Clinical Imaging Science  
Faculty of Health Science  
University of Free State

Dear Dr Fox

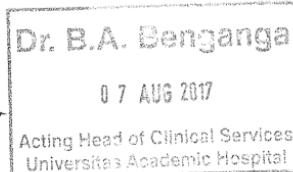
**OUTCOME OF HAEMODIALYSIS TUNNELLED CATHETER INSERTION AND ASSOCIATIONS WITH PATIENT'S EPIDEMIOLOGICAL PROFILE AND UNDERLYING RENAL FAILURE AETIOLOGY**

Universitas Academic Hospital will only grant permission when the following criteria have been met:

- ✓ that you obtain Ethical Clearance from the Human Research Ethics Committee of the relevant University;
- ✓ that the Hospital incurs no cost in the course of your research;
- ✓ that access to the staff and patients at Universitas Academic Hospital will not interrupt the daily provision of services; and
- ✓ that prior to conducting the research you will liaise with the supervisors of the relevant sections and introduce yourself with permission letter and to make arrangements with them in a manner that is convenient to the sections.

Yours sincerely

**DR B A BENGANGA**  
**ACTING HEAD: CLINICAL SERVICES**



**UNIVERSITAS ACADEMIC HOSPITAL**

Private Bag X20660, Bloemfontein, 9300  
Clinical Services, First Floor, Logeman Street, Universitas, Bloemfontein, 9301  
Tel: (051) 405 3496 Fax: (051) 405 3500  
E-mail address: bengangaba@universitas.fs.gov.za

**Title:**

Outcome of haemodialysis tunneled catheter insertion and associations with patients' epidemiological profile and underlying renal failure aetiology.

Researchers: Dr JE Fox, MBCHB (Pretoria)

Study Leader: Dr E Loggenberg

**Introduction**

According to the South African Renal Registry Annual Report of 2014 71.8% of the total South African dialysis population (including private and state patients) were on haemodialysis, in state health care 47,7% of 3280 patients were receiving haemodialysis. <sup>1</sup>

Arteriovenous fistula are the goal vascular access for chronic haemodialysis patients, however tunneled dialysis catheters are widely used whilst awaiting fistula formation or maturation. <sup>2</sup> In reviewing the importance of tunneled haemodialysis catheters it should be considered that in these ill patients the likelihood of reaching a mature AVF might be reduced, according to a study by Barker in 2005 which found that 6 months after starting tunneled dialysis only 53% and by 1 years only 80% were on permanent access (ie AVF). <sup>3</sup> Also in some groups of patients an AVF is not practical due to the increased cardiovascular demands of the AVF. AVFs have also been found to predispose patients to myocardial infarction, and pulmonary hypertension occurs rapidly after AVF creation. <sup>4</sup>

Catheter related infections are a major mortality cause (second highest) in patients with end stage renal disease - haemodialysis catheters account for the majority of vascular access infections with a 12-26% mortality rate.<sup>5</sup> Other studies reported a baseline of 0.9-2 incidents per patient per year.<sup>6</sup> Thus catheter related infection is particularly a major concern. A large multicentre study performed in China found that many different factors, including epidemiological, were associated with risk of catheter infection; catheter dysfunction and central vein stenosis. This study found that in their study population of 875 dialysis patients the catheter infection incidence was 38,61%, catheter dysfunction affected 56,65% and central vein stenosis affected 8,79%. <sup>6</sup>

There is a dearth of epidemiological profiling of our end stage renal disease haemodialysis population and shortage of data regarding our local complication rate.

In our dialysis unit approximately 28 patients are dialysed weekly of whom 8 are on haemodialysis, further from our interventional radiology suite approximately 80 patients per annum receive tunelled dialysis catheter insertion, and 8-10 per annum receive brushing of the catheters.

### **Research Aim and Objectives:**

**Aim:** Establish epidemiological profile and outcome of patients who received tunneled haemodialysis catheter insertion at Universitas Academic Hospital and determine if any association can be demonstrated.

### **Objectives:**

Determine epidemiological profile of our patient population who received haemodialysis tunneled catheter.

Determine complication rate as regards catheter infection, catheter dysfunction, central vein stenosis.

Determine association between epidemiological data and complication incidence.

### **Methodology:**

**Study design:** retrospective analytic study using existent medical records for tunneled dialysis lines inserted between March 2011 to February 2016

**Study population:** Approximately 80 patients per annum receive haemodialysis tunneled catheter insertion at our centre, some of these are dialysed in the periphery and will not form part of this study if inadequate data is available.

**Inclusion criteria:** Patients receiving tunneled haemodialysis catheter insertion who are followed up at Universitas Academic Hospital from March 2011-March 2016.

**Exclusion criteria:** Patients with complications from lines inserted in peripheral hospitals will not be included initially however further tunneled dialysis catheter insertions at our unit will be recorded.

**Sample selection:** Consecutive sampling. All patients who received tunneled haemodialysis line at Universitas Interventional Radiology Vascular laboratory from March 2011 to March 2016.

**Measurement:**

Retrospective data collection from Interventional Radiology Vascular laboratory records and electronic hospital clinical notes.

Data sheet to record: age at insertion, gender, registered residential address, primary disease and cause for renal failure, date of catheter insertion, site of insertion, complications arising during insertion, longer term complications, line revision/brushing and the date thereof.

If further catheters inserted these will be recorded under the same patient study number but as separate incidences.

**Methodological and measurement errors:** Potential problems include poor patient record keeping; patients lost to follow up, patient demising due to underlying disease process or other causes.

**Pilot study:** Pilot study of one months patients will be done to determine if data sheet adequate, after ethical approval has been granted, using the data from March 2011.

**Analysis:**

Researcher to enter data into Excel data sheet.

Statistical analysis by Department of Biostatistics at University of Free State.

Results will be summarised by frequencies and percentages (categorical variables) and means, standard deviations and percentiles (numerical variables). Associations will be investigated using appropriate hypothesis testing with relative risks and 95% confidence intervals. Data will be presented as tables and graphs.

**Implementation:** Hoping to determine from the study our complication rate and outcomes, also then to determine associations between co-morbidities and epidemiological factors in these patients outcomes.

**Time schedule:** Ethical committee submission March 2017. 6 months data collection (May-October 2017, 2 months statistical analysis.

**Budget:** R500 self for paper and data costs

**Ethical Aspects:** Ethical approval to be obtained from Health Sciences Research Ethics Committee of the University of the Free State and the Free State Department of Health. Ethical concerns are maintaining patient confidentiality. This will be done by anonymizing data sheets and all data collected and reported, will be handled confidentially. As data will be collected retrospectively and anonymized no informed consent required.

No conflict of interest.

## **References**

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Appendices: Data sheet.

Outcome of haemodialysis tunneled catheter insertion and associations with patients' epidemiological profile and underlying renal failure aetiology.

Dr J E Fox.

Patient identifier			
Patient age at line insertion			
Gender			
Rural		Yes	No
Urban		Yes	No
<b>Comorbidities</b>			
Diabetes		Yes	No
Hypertension		Yes	No
HIV		Yes	No
Connective tissue disease		Yes	No
<b>Renal failure aetiology</b>			
Diabetes		Yes	No
Primary Nephropathy		Yes	No
Hypertensive Nephropathy		Yes	No
Acute Renal Failure		Yes	No
Obstructive Uropathy		Yes	No
Renal tubular interstitial diseases		Yes	No
HIV Nephropathy		Yes	No
Drug induced Renal damage		Yes	No
Myeloma		Yes	No
Idiopathic		Yes	No
Other			
<b>Catheterization details</b>			
Date catheter inserted			
Previous tunneled catheter		Yes	No
Site of previous catheter			
How long before new catheter in months			

<b>Complications arising during insertion</b>			
Air embolism		Yes	No
Bleeding/Haematoma formation		Yes	No
Pneumothorax		Yes	No
<b>Further complications</b>			
Catheter related infection		Yes	No
Dysfunction related to malpositioning		Yes	No
Thrombosis		Yes	No
Fibrin shell		Yes	No
Central vein stenosis		Yes	No
<b>Further catheter related details</b>			
Line repositioning		Yes	No
Interval in months			
Line brushing		Yes	No
Interval in months			
Second line brushing		Yes	No
Interval in months			
Line removal due to complication		Yes	No
Interval in months			
Line removal due to AV fistula		Yes	No
Interval in months			
Patient demised due to line complications		Yes	No
Patient demised due to other causes			
Further tunneled dialysis catheter insertion		Yes	No

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**Title:** The article's full title should contain a maximum of 95 characters (including spaces).

**Abstract:** The abstract, written in English, should be no longer than 250 words and must be written in the past tense. The abstract should give a succinct account of the objectives, methods, results and significance of the matter. The structured abstract for an Original Research article should consist of five paragraphs labelled Background, Objectives, Method, Results and Conclusion.

**Background:** Why do we care about the problem? State the context and purpose of the study. (What practical, scientific or theoretical gap is your research filling?)

**Objectives:** What problem are you trying to solve? What is the scope of your work (e.g. is it a generalised approach or for a specific situation)? Be careful not to use too much jargon.

**Method:** How did you go about solving or making progress on the problem? State how the study was performed and which statistical tests were used. (What did you actually do to get the results?)

Clearly express the basic design of the study; name or briefly describe the basic methodology used without going into excessive detail. Be sure to indicate the key techniques used.

**Results:** What is the answer? Present the main findings (that is, as a result of completing the procedure or study, state what you have learnt, invented or created). Identify trends, relative change or differences on answers to questions.

**Conclusion:** What are the implications of your answer? Briefly summarise any potential implications. (What are the larger implications of your findings, especially for the problem or gap identified in your motivation?)

Do not cite references and do not use abbreviations excessively in the abstract.

**Introduction:** The introduction must contain your argument for the social and scientific value of the study, as well as the aim and objectives:

**Social value:** The first part of the introduction should make a clear and logical argument for the importance or relevance of the study. Your argument should be supported by use of evidence from the literature.

**Scientific value:** The second part of the introduction should make a clear and logical argument for the originality of the study. This should include a summary of what is already known about the research question or specific topic, and should clarify the knowledge gap that this study will address. Your argument should be supported by use of evidence from the literature.

**Conceptual framework:** In some research articles it will also be important to describe the underlying theoretical basis for the research and how these theories are linked together in a conceptual framework. The theoretical evidence used to construct the conceptual framework should be referenced from the literature.

**Aim and objectives:** The introduction should conclude with a clear summary of the aim and objectives of this study.

**Research methods and design:** This must address the following:

**Study design:** An outline of the type of study design.

**Setting:** A description of the setting for the study; for example, the type of community from which the participants came or the nature of the health system and services in which the study is conducted.

**Study population and sampling strategy:** Describe the study population and any inclusion or exclusion criteria. Describe the intended sample size and your sample size calculation or justification. Describe the sampling strategy used. Describe in practical terms how this was implemented.

**Intervention (if appropriate):** If there were intervention and comparison groups, describe the intervention in detail and what happened to the comparison groups.

**Data collection:** Define the data collection tools that were used and their validity. Describe in practical terms how data were collected and any key issues involved, e.g. language barriers.

**Data analysis:** Describe how data were captured, checked and cleaned. Describe the analysis process, for example, the statistical tests used or steps followed in qualitative data analysis.

**Ethical considerations:** Approval must have been obtained for all studies from the author's institution or other relevant ethics committee and the institution's name and permit numbers should be stated here.

**Results:** Present the results of your study in a logical sequence that addresses the aim and objectives of your study. Use tables and figures as required to present your findings. Use quotations as required to establish your interpretation of qualitative data. All units should conform to the SI convention and be abbreviated accordingly. Metric units and their international symbols are used throughout, as is the decimal point (not the decimal comma).

**Discussion:** The discussion section should address the following four elements:

**Key findings:** Summarise the key findings without reiterating details of the results.

**Discussion of key findings:** Explain how the key findings relate to previous research or to existing knowledge, practice or policy.

**Strengths and limitations:** Describe the strengths and limitations of your methods and what the reader should take into account when interpreting your results.

**Implications or recommendations:** State the implications of your study or recommendations for future research (questions that remain unanswered), policy or practice. Make sure that the recommendations flow directly from your findings.

**Conclusion:** Provide a brief conclusion that summarises the results and their meaning or significance in relation to each objective of the study.

**Acknowledgements:** Those who contributed to the work but do not meet our authorship criteria should be listed in the Acknowledgments with a description of the contribution. Authors are responsible for ensuring that anyone named in the Acknowledgments agrees to be named. Also provide the following, each under their own heading:

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
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# Tunnelled haemodialysis catheters in central Free State: Epidemiology and complications

**Authors:**

John Fox<sup>1</sup>   
Gina Joubert<sup>2</sup>   
Eugene Loggenberg<sup>1</sup> 

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**Background:** End-stage renal disease (ESRD) is a disease with profound impact on the patient, health system and economy. Tunnelled haemodialysis catheters (TDC) are amongst the most common dialysis methods. It has been established internationally that certain demographic descriptors and aetiologies carry an increased risk of complications. There is a dearth of epidemiological profiling of ESRD patients with TDC in South Africa.

**Objective:** To establish the epidemiological profile of patients who received TDC and to establish the complication rate, with the goal of demonstrating associations between the epidemiological profiles and complications.

**Method:** This was a retrospective study of all patients who received TDC in an Academic Hospital Interventional Radiological Suite over a period of 60 months between 01 March 2011 and 29 February 2016.

**Results:** A total of 179 patients received 231 catheters. The majority of patients were male (58.7%) and 35.8% of the patients resided in Mangaung. The leading aetiologies of ESRD included hypertensive nephropathy (43.6%), primary glomerular disease (17.3%) and HIV-associated nephropathy (6.1%). Procedural complications occurred in 7/224 (3.1%) insertions, whilst 37/185 (20.0%) developed catheter-related infection and 54/185 (29.2%) developed dysfunctional catheters. There were no deaths linked to catheter-related complications.

**Conclusion:** Our patients' demographic profile, ESRD aetiology, complication rate for procedural complications and catheter-related infections are roughly on par with international studies; however, the catheter dysfunction rate is higher than in the aforementioned studies. This possibly reflects the difficulty of accessing specialist care for our patients, the majority of whom reside outside the Mangaung district. Further studies with larger sample sizes are required to demonstrate statistically relevant associations.

**Keywords:** End-stage renal disease; tunnelled haemodialysis catheters; epidemiological profile; complication rate.

## Introduction

End-stage renal disease (ESRD) is an increasing healthcare concern across the world with a high mortality rate and associated economic implications, particularly in Southern Africa, where it affects a younger demographic than in developed countries.<sup>1,2</sup> An effective screening programme would assist in early nephrologist or renal centre referral which is shown to have an impact on decreasing the morbidity and mortality of these patients.<sup>3,4</sup>

In state healthcare, 44.1% of the dialysis population is managed with haemodialysis and at our institution a large portion of the dialysis population undergo tunnelled haemodialysis catheter insertion either for temporary vascular access (whilst grafts or fistulae mature or the peritoneum recovers) or when other vascular access routes are exhausted.<sup>5</sup> Tunnelled haemodialysis catheters (TDC) do offer some advantages, including immediate dialysis and no repeated venepuncture. However, they are associated with an increased risk of complications and significant mortality when compared with other types of vascular access, with a 1-year survival of patients on TDC of 75%.<sup>3,6</sup>

Based on studies in China and Croatia, multiple risk factors have been demonstrated to carry an increased risk of complications.<sup>3,7</sup> However, no local study has assessed our complication rate and investigated epidemiological risk factors. Filling this void would assist in the implementation of focused and effective screening programmes.

The goal of this study was multifactorial. We aimed to establish the epidemiological profile of patients at an academic hospital, who received TDCs at the Interventional Radiological Unit over a

60-month period, to establish the complication rate within that population group and to determine if associations between the risk factors, epidemiological data and complications could be established.

## Research methods and design

### Study design and setting

This was a retrospective, analytic study conducted at an Academic Hospital Interventional Radiology Unit, which serves the population of the Free State province, as well as occasional out of province and private patients.

### Study population and sampling strategy

The study population consisted of all state patients who received TDCs at an Academic Hospital Interventional Radiology Unit during the period of 01 March 2011 to 29 February 2016. All patients aged 18 years and older, who received their catheter at the interventional suite, were included.

### Catheter insertion

Catheters were inserted by an experienced interventional radiologist in the Interventional Unit via percutaneous access. The procedure was performed under sterile theatre conditions with ultrasound guided venous access. All TDCs inserted in our centre are cuffed. The catheter is tunneled subcutaneously for approximately 9 cm – 10 cm from the venous access site. The catheter is then placed under fluoroscopic control with tip positioning in the right atrium. Cutaneous fixation is created with sutures until cuff adhesion – approximately 8–12 weeks. Initial patency and positioning are confirmed during the procedure. The catheter is then locked with heparin (1000  $\mu$ /mL)

The primary goal for access was the internal jugular vein. However, in patients with previous access and complications, other sites were used. Subclavian access was used when no other access site was available.

### Secondary intervention

In patients where the catheter is unable to maintain adequate extracorporeal blood flow and thrombolytic therapy (alteplase) has been ineffective, brushing is performed in the Interventional Unit under fluoroscopic guidance and sterile conditions to displace and remove the fibrin sheath (a composite of cells and debris that forms a biofilm around catheters that can obstruct the lumen, acting as a valve) or thrombus by using a Terumo guidewire to sound the catheter lumen and rinse the lumen with saline. The catheter is then locked with heparin, 1000  $\mu$ /mL. If brushing fails to restore patency, then snaring is employed – vascular access is gained from another site and mechanical stripping of the catheter tip is performed via a snare.

### Data collection

Patients were identified using the procedural register and further information was gathered from existing electronic

medical records. A comprehensive data sheet was completed. Details captured included date of birth, age at catheter insertion and residence. Aetiology was grouped into diabetes, primary glomerular disease (including nephrotic syndrome, acute glomerulonephritis and rapidly progressive glomerulonephritis), hypertensive nephropathy, acute renal failure, obstructive uropathy, renal tubular interstitial diseases (including acute tubular necrosis, tubulointerstitial nephritis, contrast nephropathy, reflux nephropathy and myeloma), Human Immunodeficiency Virus Associated Nephropathy (HIVAN), drug induced nephropathy, polycystic kidney disease and unknown.

For ease of analysis, complications were grouped into procedural complications (air embolism, bleeding and pneumothorax), catheter-related infection and catheter dysfunction (malposition, thrombosis, fibrin sheath, central vein stenosis and loosening or catheter breakage).

Further details recorded included whether the catheters underwent repair or brushing and if they were removed because of complications, fistula maturation or peritoneal dialysis catheter use. In the cases of patient demise, it was noted whether this was a result of catheter-related complications or other causes.

Primary and secondary patency was calculated. Primary patency is regarded as the time duration of catheter patency until the first intervention required to maintain patency whilst secondary patency is regarded as the length of time from insertion until catheter removal because of complication or catheter failure.<sup>8</sup>

### Data analysis

The primary researcher entered all the data onto an Excel data sheet, which was then submitted for statistical analysis by the Department of Biostatistics at the University. Results were summarised as frequencies and percentages (categorical variables) and means, standard deviations and percentiles (numerical variables). Associations were investigated using appropriate hypothesis testing with  $p < 0.05$  considered statistically significant.

### Ethical considerations

Ethical clearance was obtained from the Health Sciences Research Ethics Committee of University of Free State (HSREC 62/2017) and Free State Department of Health (UFS-HSD2017/0478).

## Results

A total of 179 patients received TDCs during the study period and qualified for the study. In the study sample, 105 were male (58.7%) and 64 (35.8%) resided in Mangaung district. The mean age at insertion was 40.4 years with a standard deviation of 12.05. The four leading aetiologies were hypertensive nephropathy, primary glomerular disease, HIVAN and unknown aetiology (see Table 1 for more information).

The patients received 231 catheters. A hundred and fifty-eight patients had catheters inserted for the first time. The majority of patients (141, 77.3%) received one catheter, 25 patients (14.0%) received two, 10 patients (5.6%) received three, 1 patient (0.6%) received four and 1 patient (0.6%) received five catheters during the study period. Of the 231 catheters inserted, 224 (97.0%) had information regarding insertion and 185 (80.1%) had information regarding follow up. The majority of lines were inserted in the right internal jugular vein, with the left internal jugular vein insertion being the second as per Table 2.

Procedural complications occurred in 3.1% of insertions whilst 20.0% developed catheter-related infections and 29.2% developed complications related to dysfunction (see Table 3 for further breakdown).

The mean age at insertion varied between the complication groups: in the catheter-related infection group, the mean age was 37.5 years; in the procedural complication group, mean age was 40.2 years; and in the catheter dysfunction group, mean age was 39.8 years. Table 4 summarises the patient characteristics, complications recorded and the associations between them.

Out of the 231 catheters, 45 catheters (19.5%) had incomplete follow up. Of the catheters with adequate follow up, 4.3% went on to receive catheter repair, 17.7% required a single brushing, 5.4% received two brushings and 3.2% received three brushings, with a primary patency rate of 98 days.

**TABLE 1:** Aetiology per patients ( $n = 179$ ).

Aetiology	<i>n</i>	%
Diabetes	7	3.9
Primary glomerular disease	31	17.3
Hypertensive nephropathy	78	43.6
Vasculitis	5	3.0
Acute renal failure	1	0.6
Obstructive uropathy	5	3.0
Renal tubular interstitial diseases	3	1.7
HIVAN	11	6.1
Drug induced	5	3.0
Polycystic kidney disease	8	4.5
Unknown	34	19.0
<b>Other</b>		
HELLP	1	0.6
Lupus nephritis	2	1.1
Nephrectomy due to malignancy	1	0.6
Oligomegaphronia	1	0.6
Oncocytoma	1	0.6

HELLP, haemolysis, elevated liver enzymes, low platelet count syndrome.

**TABLE 2:** Site of insertion ( $n = 224$ ).

Site of insertion	<i>n</i>	%
Left internal jugular	22	9.8
Left common femoral	13	5.8
Left subclavian	2	0.9
Right internal jugular	165	73.6
Right femoral	14	6.2
Right subclavian	8	3.6

Note: Sites of insertion were recorded for 224 of the 231 catheters inserted.

Complications resulted in 27.9% of the catheters being removed whilst 32.3% were removed because of fistulas and 18.8% because of peritoneal dialysis being initiated or resumed. No patients demised because of catheter-related complications, whilst 10.2% of the patients demised because of other causes. Secondary patency rate was 87.0% at 6 months and 76.1% at 12 months.

## Discussion

The high financial burden of ESRD has a considerable impact on the limited resources of the South African health system. Therefore, it would be of benefit if there was earlier diagnosis and efficient management of renal disease, preventing or delaying the progression to ESRD. The Academic Hospital Interventional Radiology Unit assists with TDC insertion for a large percentage of the Free State dialysis population as it can be demonstrated by considering that in 2016 the Free State had 235 patients on dialysis; our study population over the five year period numbered 179 patients.<sup>5</sup> Despite the increased risk of infection and mortality compared with fistulae or grafts, TDCs remain an important part of dialysis patient care.<sup>9,10,11</sup>

The epidemiological analysis of the study population revealed that the patient's age (mean of 40.4 years) was in keeping with a local South African study on ESRD, but younger than studies from other African countries and developed countries where renal failure is predominantly a diagnosis of the middle aged and the elderly.<sup>1,2</sup> Male patients formed 58.7% of the sample; this corresponds to previously reported rates in Africa of 61% – 63% male gender in renal failure patients.<sup>1</sup> The female proportion of the study population experienced the majority of the complications, however, the gender discrepancy was not found to be statistically significant, which is also in keeping with an international study which indicated that patient gender did not impact catheter survival.<sup>12</sup>

A significant percentage (64.2%) of the study population resided outside the Mangaung district with implications in terms of ease of access to specialised medical services and

**TABLE 3:** Complications and incidence.

Complications	<i>n</i> †	%
<b>Procedural (N = 224)</b>		
Air embolism	1	0.4
Bleeding	7	3.1
Pneumothorax	0	0
<b>Catheter dysfunction (N = 185)</b>		
Thrombosis	25	13.5
Fibrin sheath	20	10.8
Central vein stenosis	5	2.7
Catheter loosened	9	4.9
Dysfunction due to malpositioning	4	2.2
<b>Catheter-related infection (N = 185)</b>		
Catheter-related infection	37	20.0

Note: Procedural complication was recorded during initial catheter insertion and admission and thus has a larger denominator than catheter-related infection and dysfunctional complications which were recorded in patients who returned for follow up. More than one complication could occur per insertion.

†, Denominators are procedures.

**TABLE 4:** Complications and associations per catheters.

Characteristic	Procedural complications <sup>†</sup> and catheters: 7/224		<i>p</i>	Catheter-related infection and catheters: 37/185		<i>p</i>	Dysfunctional complications and catheters: 54/185		<i>p</i>
	<i>n</i>	%		<i>n</i>	%		<i>n</i>	%	
<b>Gender</b>	-	-	0.7	-	-	0.16	-	-	0.35
Male	3/126	2.4		16/99	16.2		26/99	26.3	-
Female	4/98	4.1		21/86	24.4		28/86	32.6	-
<b>Residing</b>	-	-	0.69	-	-	0.65	-	-	0.74
Mangaung	3/77	2.7		12/66	18.2		18/66	27.3	-
Outside district	4/127	3.9		25/119	0		36/119	30.3	-
<b>Aetiology<sup>‡</sup></b>	-	-	-	-	-	-	-	-	-
Diabetes	0/9	-		43/72	14.3		43/503	28.6	-
Primary glomerular disease	1/39	2.6		11/33	33.3		7/33	21.2	-
Hypertensive nephropathy	4/94	4.3		10/77	12.9		21/77	27.3	-
Renal tubular interstitial disease	0/6	-		2/6	33.3		1/6	16.7	-
HIVAN	0/12	-		3/9	33.3		2/9	22.2	-
Polycystic kidney	0/12	-		2/10	20.0		7/10	70.0	-
<b>Site of insertion</b>	-	-	0.38	-	-	0.01	-	-	0.38
Left femoral	1/13	7.7		4/11	36.4		5/11	45.5	-
Left subclavian	0/2	-		1/2	50.0		1/2	50.0	-
Left internal jugular	1/22	4.6		4/22	18.2		9/22	40.9	-
Right femoral	1/14	7.1		7/12	58.3		4/12	33.3	-
Right internal jugular	4/165	2.4		20/132	15.2		34/132	25.8	-
Right subclavian	0/8	-		1/6	16.7		1/6	16.7	-

<sup>†</sup>, Procedural complications were recorded during initial catheter insertion and admission and thus consist of a larger pool than catheter-related infection and dysfunctional complications which were recorded in patients who returned for follow up; <sup>‡</sup>, Only aetiologies with five patients or more were included in this table.

further management of the TDC and the patient. The patients outside the Mangaung district experienced the majority of the complications (57% – 68%) across all three complication groups although the discrepancies were not statistically significant.

End-stage renal disease aetiology was similar to other studies in Africa with hypertension being the most commonly recorded cause in 43.6% of patients versus 34.6% (Sudan) and 30.9% (Cameroon). Further common causes in our study included primary glomerular disease and HIVAN. In Cameroon, other aetiologies included glomerulonephritis (15.8%), diabetes (15.9%), HIVAN (6.6%) and unknown (14.7%).<sup>13</sup> In a Sudanese study the causes included chronic glomerulonephritis (17.6%), diabetes (12.8%) obstructive uropathy (9.6%) and in 10.7% no cause was identified.<sup>1</sup>

Hypertension as an aetiology constituted a larger percentage of this study population than international studies although it is difficult to determine whether this was primary hypertension or secondary to chronic kidney disease. Additionally, this study had a high percentage of patients with an unknown cause. These findings could be a reflection on the lack of efficient primary healthcare with many patients presenting late in the course of the disease and not receiving renal biopsies.

The majority of catheters were inserted in the right jugular vein, with no statistically significant discrepancy between site of insertion and procedural or dysfunctional complication rate, however, there was a statistically significant correlation between catheter-related infection and insertion of the catheter in either femoral site. In a study by Dewelter et al, it was demonstrated that right jugular insertion confers a

significantly improved outcome as compared with other sites of insertion.<sup>14</sup>

This study, as compared with a study in Pakistan, had a decreased incidence of procedure-related complications (3.2% vs. 5.6%) but an increased rate of catheter-related infection (20% vs. 17.3%) as well as dysfunction-related complications (29.2% vs. 16%).<sup>15</sup> The increased incidence of catheter-related infection and complications causing dysfunction reflect perhaps the difficulty for our patients in accessing specialist care after the procedure, particularly if they reside in another district. In light of the above, it might be of value to consider a chronic low dose of aspirin to maintain tunnelled central venous catheter (CVC) patency.<sup>16</sup>

Catheter-related infections remain a significant problem within the dialysis population with implications for cost of care and patient quality of life, as patients with catheter-related infections have an average hospital stay of 6.5 days, undergo several tests and receive treatment during the hospital stay.<sup>17</sup> Considering the incidence of catheter-related infections, future studies could analyse the benefit of antimicrobial barrier caps in reducing this rate, as per the Kidney Disease Outcomes quality Initiative (KDOQI) guidelines from the National Kidney Foundation.<sup>16</sup>

The secondary patency rate is better than a study in India at 6 months (87.0% compared with 55%) and the 12-month catheter survival rate falls within the wide range found in a previous review article of 2007 (between 25% – 75%).<sup>8,18</sup> A high percentage of the catheters were removed because of initiating or resuming peritoneal dialysis or use of fistulae. This is perhaps because of the increased number of patients

in state healthcare who are on peritoneal dialysis compared with private healthcare (27.8% vs. 6%).<sup>5</sup> There were no deaths in our study because of catheter-related complications.

The aetiology in the study population, on average, did not have a statistically significant impact on the complication rate although other studies have shown that diabetes conveys increased risk and that age can have an influence additionally.<sup>7</sup> Polycystic kidney disease was shown to have an increased risk of catheter-dysfunction-related complications. The reason for this is unknown and merits further investigation.

Although our study was unable to establish a statistically significant association between demographics, aetiology and complications in the majority of cases, we were, however, able to demonstrate an association between femoral site catheter insertion and the risk of catheter-related infection; and between patients with polycystic kidney disease and an increased risk of catheter dysfunction. Studies have shown that associations exist between several patient characteristics (male gender, increased age, diabetic nephropathy, hypertensive nephropathy and glomerulonephritis) and their risk of complications.<sup>3,7</sup>

## Study limitations

Many patients who had their catheter inserted and were then managed further in other centres were lost to follow up, resulting in incomplete information, particularly with regards to catheter-related infection and dysfunctional catheter complications. A further challenge was the relative paucity of renal biopsies to confirm the ESRD aetiology.

## Conclusion

Our demographics, aetiology of ESRD and complication profile largely correspond to other studies except for an increased complication incidence in females, an increased percentage of hypertension as the cause for ESRD and an increased percentage of catheter dysfunction complications. These findings are perhaps a reflection on the challenges our primary healthcare system faces and the difficulty for these patients to access specialist care in the periphery. Because of the limited number of patients and complications, this study was unable to establish statistically significant correlations between complications and epidemiological factors in many of the measured characteristics.

In our setting, given pre-existing research that has demonstrated a decreased risk of complications with early referral to specialist care and dialysis initiation with other vascular access options (besides TDC),<sup>4</sup> it would be optimal to create a screening programme for high risk patients (HT, DM).<sup>2</sup> If a South African multicentre study with a larger study population was able to confirm local risk factors for complications, then appropriate care centres could implement protocols for increased vigilance and screening for complications in the vulnerable population groups. This could also lead to and assist with the formation of local

guidelines for the management of dialysis such as the KODQI 2018 guidelines.<sup>16</sup> Together, these could assist in early identification of patients at risk of developing ESRD and lead to earlier referral to specialist care which has been shown to have a positive effect on patient outcome.<sup>4,18,19,20</sup>

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### Competing interests

The authors have declared that no competing interests exist.

### Authors' contributions

J.F. was the principal investigator who designed the study, conducted the literature review, obtained ethical clearance and statistical input, captured the data, processed the data and wrote the final manuscript; E.L. was the study leader, who conceptualised the study, assisted with literature review, critically analysed the manuscript and approved the final version; G.J. was the third author who assisted with the study protocol, provided statistical analysis of the data and critical analysis of the manuscript.

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### Data availability statement

Data sharing is not applicable to this article as no new data were created or analysed in this study.

### Disclaimer

Any opinions and views expressed in this article are the authors' own and do not necessarily reflect the official policy or position of any affiliated agency of the authors.

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