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Original Article

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Tesio-Caths provide effective and safe long-term vascular access

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Abstract

Background. Vascular access is judged on its ability to provide good dialysis adequacy, its durability and complication rates. Formation of a functional arteriovenous fistula is desirable but difficult to achieve in a significant proportion of patients. We report the large-scale use of Tesio-Caths, a twin-line single-lumen central venous catheter, to maximize dialysis adequacy where formation of an arteriovenous fistula was not possible.

Methods. All patients who had Tesio-Caths inserted between 1 January 1999 and 1 October 2002 were studied.

Results. Six hundred and twenty-three Tesio-Caths were inserted from 1 January 1999 to 1 October 2002 in 435 patients, generating 7464 patient months of follow-up. Five hundred and ninety-four out of 623 (95.3%) Tesio-Caths were immediately functional. Mean dialysis adequacy measured by single-pool Kt/V was 1.5 ± 0.3 for all Tesio-Caths for the entire period of study, with 68% of Tesio-Caths delivering a Kt/V >1.4. Cumulative functional Tesio-Cath survival to final failure was 77.8 and 44% at 1 and 3 years, respectively. Cumulative patient survival was 84.7, 71.4 and 63% at 1, 2 and 3 years, respectively. Access-related infection accounted for 0.28 admissions/1000 catheter days, and the death rate from access-related sepsis was 9.6 deaths/1000 patient years at risk. The admission rate for access dysfunction was 0.33/1000 patient years at risk.

Conclusion. Tesio-Caths provide good dialysis adequacy for patients in whom an arteriovenous fistula cannot be formed. Patient and functional access survival for this group was comparable with current European data irrespective of vascular access type. Complication rates were acceptably low.

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Introduction

Adequate dialysis influences patient survival and morbidity. Vascular access is judged on its ability to provide good dialysis adequacy (with high blood flow rates and minimal re-circulation), its durability and its associated complications (low rates of infection, mechanical dysfunction and vascular stenosis). The supremacy of the native arteriovenous fistula (AVF) is well established, and their use is advocated where possible [1]. However, in spite of practice guidelines, it is widely recognized that it is difficult to achieve this form of dialysis access in a significant proportion of the dialysis population. This is demonstrated by the DOPPS study of patterns of vascular access use in the USA and Europe, where only 24% of prevalent patients in the USA and 67% in the UK had an AVF [2], and, at the time of our study, 27% of patients prevalent on dialysis at our centre were dependent on an AVF. Successful formation of an AVF is hampered by poor vasculature commonly encountered in the ageing dialysis population, with individuals who have increasingly difficult access histories and highly calcified vessels as a result of diabetes and hyperparathyroidism. It is very difficult to predict the functional success of AVF formation, and attempts to meet the targets set by national guidelines result in a high rate of primary failure to the disadvantage of the patient [3].

An alternative is to make long-term use of central venous catheters (CVCs). Until recently, this form of vascular access has been deprecated on the basis of evidence showing increased mortality rates, short-term function, dialysis inadequacy and high infection rates when compared with AVFs [1]. In spite of this, CVCs are still used as permanent access for 17% of prevalent patients in the USA and 22% in the UK [2]. They are

easy to insert, have immediate use and do not require needling, thus fostering support from physicians and patients alike.

Tesio-Caths consist of two 10F Bio-Flex polyurethane lines, each with a single cuff and side holes, arranged in a spiral pattern at the tip, and their use was first described a decade ago [4]. Our single-centre study examines the long-term use of Tesio-Caths in terms of effective dialysis delivery and complication rates for a large number of patients in whom the creation of an AVF was not possible or had failed.

Subjects and methods

Patients

This retrospective study identified all patients who had a Tesio-Cath inserted between 1 January 1999 and 1 October 2002 at our centre, which acts as the admission unit for three satellite units. The indication for Tesio-Cath placement in incident patients was a lack of suitable vessels for AVF creation, and the indication for prevalent patients was inadequate or failed haemodialysis access via an existing CVC, AVF or arteriovenous graft (AVG). The protocol for care outlined below was consistently adhered to.

Pre-operative preparation

Both a nephrologist and a surgeon made a clinical assessment of each patient, and those who were deemed unfit for successful AVF formations were put forward for CVC insertion. It has not been our local practice to form AVGs. Prospective mapping of the central veins by venography was only performed for patients with clinical signs suggestive of central venous stenosis, or with a history of multiple uncuffed or cuffed CVC insertions. If dialysis was required before a CVC could be inserted, an uncuffed temporary venous catheter was inserted via the femoral vein only. Temporary access was never present for more than a few days as there were thrice weekly access lists.

Both incident and prevalent dialysis patients were screened for MRSA (methicillin-resistant *Staphylococcus aureus*) carriage with swabs from nose, throat and axilla. Bactroban ointment (mupirocin 2%) was applied nasally to those with MRSA, and naseptin cream (chlorhexidine hydrochloride 0.1%/neomycin sulfate 3250 U/g) was applied nasally to all other patients. The nasal agents were continued for 1 week after Tesio-Cath insertion.

Single oral doses of both clarithromycin 250 mg orally and ciprofloxacin 250 mg orally were used on the day of insertion prior to the procedure, since these anti-microbial agents offered good tissue penetration and broad anti-bacterial cover to both Gram-positive bacteria (including methicillin-sensitive and some methicillin-resistant *S.aureus*) and Gram-negative bacteria (including *Pseudomonas*). If the patient was MRSA positive on screening, a single dose of vancomycin 500 mg intravenously was substituted for clarithromycin.

Tesio-Cath insertion

Tesio-Caths were inserted on a day-case basis by four experienced operators under sterile conditions, either surgically or radiologically, on designated access lists three times a week. X-ray fluoroscopy and ultrasound were used to guide correct Tesio-Cath placement via the internal jugular vein in all cases. The insertion point into the internal jugular vein was between the sternal and clavicular heads of the sternocleidomastoid muscle. Lines were inserted percutaneously and there was no dissection to the vein. The surgeons employed a one-puncture, two-guide wire technique, whilst the radiologists performed a two-puncture, two-guide wire technique. The tip of the 'venous' line was placed ~3 cm beyond the right atrial margin visible on X-ray. The tip of the 'arterial' line was maintained 3 cm cephalic to the tip of the 'venous' line. The cuffs were then individually tunnelled from the point of percutaneous puncture to lie within the tunnel 3 cm from its snug-fitting exit site. Care was taken to maintain an oblique angle between the intravenous part of the line and the tunnel to avoid kinking. The tunnels and exit sites for venous and arterial lines were separated by at least 1 cm. A post-operative erect chest X-ray was performed to exclude complications and assess Tesio-Cath tip position.

Tesio-Cath care

Tesio-Caths were locked between dialysis sessions with heparin 5000 U/ml according to the dead space of each line. Antibiotic locks were not used. The exit site was cleaned at each dialysis session with sterile normal saline followed by chlorhexidine solution 4%, and allowed to air-dry before application of a bio-occlusive dressing. Routine systemic anti-platelet or anticoagulant agents were not used to improve blood flow rate.

Tesio-Cath infection

Dialysis patients with a pyrexia (tympanic temperature of >38°C) with or without a systemic inflammatory response (SIRS) were investigated for a Tesio-Cath-related source of infection with exit site swabs and blood cultures taken prior to starting antibiotics. Antibiotic starts were pre-emptive and followed an initial protocol of intravenous vancomycin 500 mg post-dialysis for Gram-positive cover and intravenous ceftazidime 2 g post-dialysis for Gram-negative cover (or oral ciprofloxacin 250 mg twice daily if penicillin allergic). Antibiotics were then continued according to culture and antibiotic sensitivity for at least 4 weeks. The dose of vancomycin was tailored to maintain trough levels of >10 mg/l.

Exit site swabs were performed if there were exudates or crust with or without pain, redness or induration at the exit site. Infection limited to the exit site was treated initially with oral clarithromycin 250 mg twice daily and oral ciprofloxacin 250 mg twice daily, and adjustment was made according to response and culture results for a minimum of 2 weeks.

Tunnel infections were defined by pain, redness or induration along the subcutaneous course of the line with or without exudates at the exit site. Tunnel infections were treated from the onset with the aforementioned empirical intravenous antibiotics, and these were adjusted when culture results were available, with the addition of a second appropriate oral antibiotic for a minimum of 4 weeks.

Patients with pyrexia exhibiting SIRS, relative hypotension (determined from the individual patient's usual range for blood pressure) or persistent tunnel infection were admitted

solely to our centre. Bacteraemia alone did not qualify the patient for admission. If access-related infection resulted in septic shock, a persistent bacteraemia or tunnel infection for >3 days, the Tesio-Cath was removed and a new line was sited in the opposite internal jugular vein. The over-the-wire technique was not employed in cases of sepsis to avoid contaminating the new line by insertion through or in proximity to the site of the existing infected line. The bloodstream was cleared of infection for at least 48 h prior to the insertion of the new line.

The hospital admission rate for Tesio-Cath-related sepsis and line replacement for infection were chosen as robust end-points of infective complications in this study. Bacteraemia rates have not been reported because we were unable to identify the specific cause of bacteraemic episodes retrospectively.

Tesio-Cath dysfunction

The target blood flow for Tesio-Caths was ≥350 ml/min. A blood flow of consistently <250 ml/min and declining dialysis adequacy (a falling trend in Kt/V confirmed on three sequential measurements) were used as markers for Tesio-Cath dysfunction. Line displacement or kinking was excluded by a chest X-ray. Every patient then had 5000 U of urokinase locked into each line of the Tesio-Cath for 2 h and dialysis was re-attempted on an out-patient basis. If this strategy failed, patients were admitted to the ward for a 12 h intraluminal infusion of urokinase (12 500 U) into each line of the Tesio-Cath as previously described in the literature [5]. If this final strategy was unsuccessful, the Tesio-Cath was removed and replaced. The over-the-wire technique was not employed to avoid the risk of inserting the new line into an old fibrin sheath.

The hospital admission rates for urokinase infusion and line replacement for mechanical failure were robust end-points of Tesio-Cath dysfunction and are reported in this study.

Dialysis and assessment of dialysis adequacy

Patients were dialysed thrice weekly using COBE Centrisystem C3 dialysis machines and Kimal BioWet polyethylene glycol-substituted cellulose membranes. Measurement of single-pool Kt/V [6] using the slow flow method was made during the first week of the month for each patient. The mean Kt/V for the life of each Tesio-Cath was derived from all these monthly measurements. During the period 1999–2002, our Kt/V target was ≥1.4. In those patients failing to achieve this target, the following steps were taken to improve Kt/V: haemodialyser size was maximized, blood flows were increased to ≥350 ml/min, dialysate flow rates adjusted to ≥500 ml/min and access recirculation was excluded by a urea-based method. Finally, dialysis hours were increased if necessary to a maximum of 5 h.

Patient and access survival

Kaplan–Meier survival curves for patient survival and Tesio-Cath survival from creation until first and final failures were obtained. Log rank tests were performed to assess the importance of diabetic status, with significance taken as a $P < 0.05$.

Statistics

Data are presented as mean ± 1 SD unless otherwise stated. Statistical analysis was made using Statview for Windows (Version 5.0, SAS Institute).

Results

Patient demographics

Six hundred and twenty-three Tesio-Cath insertion procedures were made in 435 patients during the period of study. A large proportion were male, >70 years old, diabetic and had been established on dialysis long term (Table 1). There were a total of 7464 patient months follow-up, with a mean follow-up of 12.6 months (range 0.3–44.8). Three hundred and sixty-one Tesio-Cath procedures were surgical (58%) and the remainder were radiological. In 29 cases, we initially were unable to insert Tesio-Caths (4.7%); 19 of these technical failures were surgical and 10 were radiological. All patients who had technical failures had Tesio-Caths successfully sited at a subsequent procedure. There was one death (0.2%) during a radiological insertion in a 55-year-old woman with ischaemic cardiomyopathy. This patient had an asystolic arrest shortly after cannulation of the left internal jugular vein. The serum potassium was normal (3.6 mmol/l). A subsequent pericardiocentesis was negative, and injection of contrast into the central vein via the catheter showed it to be correctly sited in the vein with no apparent leak.

Dialysis adequacy, patient and Tesio-Cath survival

The mean dialysis adequacy was Kt/V 1.5 ± 0.3 for all Tesio-Caths over the entire period of study; 88% of Tesio-Caths delivered a mean Kt/V ≥1.2 and 68% of Tesio-Caths delivered a mean Kt/V ≥1.4.

The cumulative patient survival was 84.7% at 1 year, 71.4% at 2 years and 63.0% at 3 years by Kaplan–Meier analysis (censoring for change in modality of renal replacement and transfer to another renal unit) (Figure 1). The presence or absence of diabetes had no statistical significance (logrank $\chi^2 = 0.32$, $P = 0.11$).

The cumulative functional Tesio-Cath survival to first failure was 71.9% at 1 year and 37.9% at 3 years by Kaplan–Meier analysis (censoring for death with

Table 1. Patient demographics

Male:female	308:127
Mean age (years)	59.3 (15.4–89.5)
>70 years (%)	29
Diabetics (%)	26
Incident: prevalent haemodialysis patients	191:244
Mean haemodialysis duration for prevalent patients (months)	49 (3–273)

Ranges are given in parentheses.

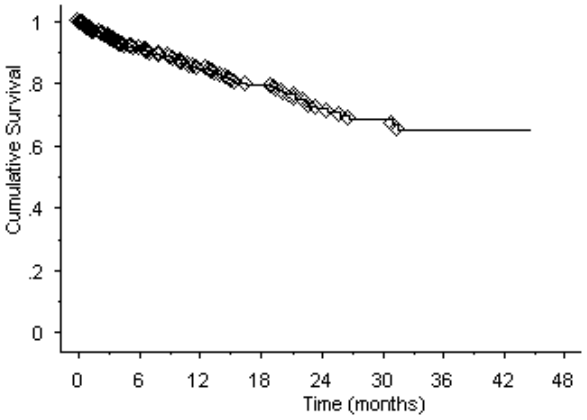

Fig. 1. Patient survival by Kaplan–Meier analysis (censored for change in modality of renal replacement and transfer to another renal unit).

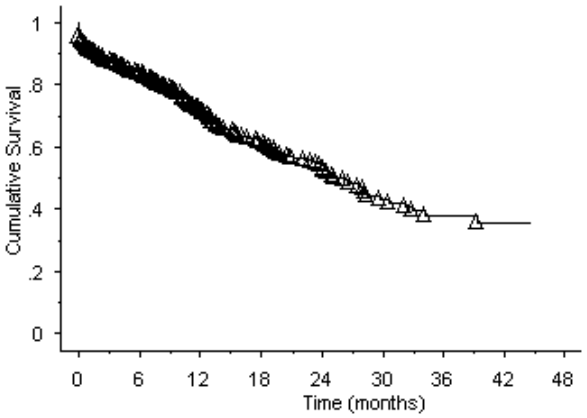

Fig. 2. Tesio-Cath survival to first line failure by Kaplan–Meier analysis (censored for death with a functioning Tesio-Cath, change in modality of renal replacement and transfer to another renal unit).

a functioning Tesio-Cath, change in modality of renal replacement and transfer to another renal unit) (Figure 2), and was similar to the cumulative functional Tesio-Cath survival to final failure which was 77.8% at 1 year and 44.0% at 3 years by Kaplan–Meier analysis (censoring for death with a functioning Tesio-Cath, change in modality of renal replacement and transfer to another renal unit) (Figure 3). The diabetic status of the patient was not a statistically significant influence on survival to final failure (log rank $\chi^2 = 0.31$, $P = 0.58$).

Tesio-Cath-related sepsis

There were 66 episodes of Tesio-Cath-related infection requiring admission (0.28/1000 catheter days at risk), with a median duration of admission of 4 days (range 1–84) (Table 2). The results of blood cultures for these episodes are outlined (Table 3). Six (9%) of these episodes resulted in deaths (9.6 deaths per 1000 patient years at risk); four from septicaemia, one from MRSA endocarditis, and one with subsequent withdrawal of dialysis on compassionate grounds in an 82-year-old patient. In 17 of the 66 episodes, Tesio-Caths (26%) were removed and replaced as a result of sepsis. The remaining 43 episodes (65%) were treated successfully with antibiotics. Only one patient with a Tesio-Cath that was salvaged from septicaemia with *Pseudomonas aeruginosa* had a second admission for access-related infection, which was 2 months later. *Pseudomonas aeruginosa* was not re-isolated and the Tesio-Cath was removed and replaced on the second admission.

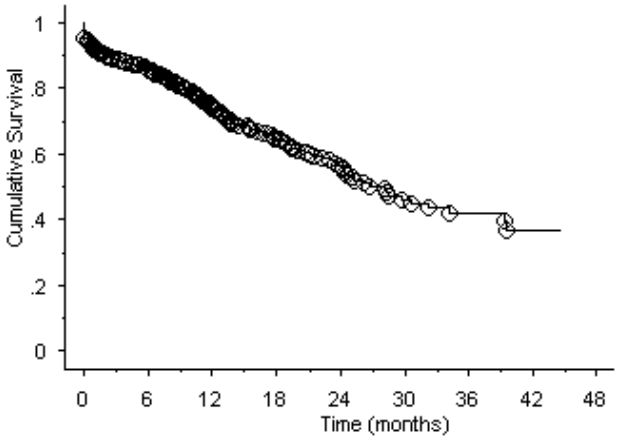

Fig. 3. Tesio-Cath survival to final line failure by Kaplan–Meier analysis (censored for death with a functioning Tesio-Cath, change in modality of renal replacement and transfer to another renal unit).

Table 2. Tesio-Cath-related infection

Hospital admission for access-related infection/ 1000 catheter days	0.28
Deaths due to access-related infection/1000 patient years	9.6
Success rate of salvage antibiotic therapy (%)	72

Table 3. Blood culture results for patients admitted with access-related infection

Blood culture result	No. of admissions	Median duration of admission (days)	Patient deaths from access-related infection	Tesio-Caths salvaged successfully
No growth	29	3 (1–47)	0	23
MSSA	13	5 (1–13)	1	6
MRSA	13	9 (3–84)	4	5
Staphylococcus epidermidis	4	10 (5–14)	0	3
Streptococcus mitis	1	3	0	1
Gram-negatives	6	4 (2–10)	1	5

MRSA = methicillin-resistant *S.aureus*, MSSA = methicillin-sensitive *S.aureus*.

Table 4. Tesio-Cath-related dysfunction

Hospital admission for access dysfunction/1000 catheter days	0.33
Thrombosis/1000 catheter days	0.28
Success rate of salvage thrombolytic therapy (%)	52
Dislodgement/1000 catheter days	0.03
Line cracks/1000 catheter days	0.01

Tesio-Cath dysfunction

Seventy-six admissions were for Tesio-Cath dysfunction (incidence 0.33/1000 catheter days at risk) and mean duration 5.7 days (range 1–20) (Table 4). Sixty-five of these 76 admissions were for suboptimal blood flow rates (<250 ml/min) requiring treatment with urokinase. This was successful in 34 out of 65, while in 31 out of 65, the Tesio-Cath had to be removed and replaced. Repeated treatment with urokinase was required for six Tesio-Caths (mean duration of patency 308 days, range 11–729); four of these were successfully salvaged, and two subsequently were removed and replaced.

Of the remaining 11 admissions, eight Tesio-Caths were dislodged (incidence 0.03/1000 catheter days at risk), two developed cracks in a line necessitating replacement (incidence 0.01/1000 catheter days at risk), and one patient chose to convert to peritoneal dialysis and the Tesio-Cath was removed.

Discussion

This large retrospective study demonstrates that Tesio-Caths provide effective and safe access for the challenging group of haemodialysis patients who are unsuitable for AVF formation. The demographics of the study group were comparable to European dialysis populations in terms of age, sex and proportion of diabetics [7], making the outcomes and conclusions widely relevant.

Dialysis adequacy

Good dialysis adequacy was achieved in our study. The mean Kt/V was 1.5 ± 0.3 for all Tesio-Caths across the entire study period, 88% of Tesio-Caths delivered a Kt/V $\geq$1.2 (the UK Renal Association minimum standard), and 68% of Tesio-Caths delivered a Kt/V $\geq$1.4 (our local standard). Long-term dialysis adequacy delivered by Tesio-Caths in our study was at least as good as that reported in the other studies to date [4,8]. Tesio-Caths were the only catheter in use at our centre, but previous studies have made favourable comparison with other catheter types: there were no significant differences in blood flow rates, hydraulic resistance or catheter survival demonstrated between Tesio-Caths and Opti-Flow, Ash Split and Mahurkar catheters [9,10]. One prospective randomized study has demonstrated that Tesio-Caths provide reliable and superior dialysis adequacy when compared with VasCath Soft Cell catheters (mean Kt/V 1.44 *vs* 1.19, respectively) [11]. It has been accepted previously that CVCs are inferior to arteriovenous access in terms of blood flow and reliability; however, the difference in achieved dialysis adequacy may not be so marked. In a study of 42 incident dialysis patients, where the 12 month use of a permanent twin-line CVC similar to the Tesio-Cath was compared with a subsequent 12 month use of arteriovenous access in the same patients [12], the permanent twin-line CVC provided sustained dialysis adequacy at a level only 5–6% lower than for the subsequent arteriovenous access.

Access survival

In terms of durability, functional Tesio-Cath survival to final failure in our study was 77.8% at 1 year and 44% at 3 years, and compared well with the results reported by Canaud *et al.* in their long-term observational study of permanent twin-line CVCs [13]. Access survival rates to first failure in our study at 1 year (71.9%) were similar to access survival for AVFs at 1 year in Europe and the USA (83 and 68%, respectively) [2]. AVGs are advocated before the use of tunnelled CVCs in the USA when an AVF cannot be formed [1], but AVGs are not widely used in the UK (58% USA prevalent patients *vs* 9% UK) [2]. It has not been our local policy to form AVGs, and we cannot therefore make a direct comparison with Tesio-Caths; however, access survival to first failure for Tesio-Caths in our study at 1 year is better than the reported 49% survival of AVGs at 1 year in the USA [2]. We believe that the use of CVCs should not be rejected on grounds of unreliability in favour of AVGs. Rates of access dysfunction for Tesio-Caths in this study were acceptably low and may be attributed to catheter design, care in placement to avoid kinking and the use of 12 h intraluminal infusions of urokinase. A prospective assessment of central venous stenosis rates is needed.

Patient survival

Our data suggest that when an elective decision is made to use Tesio-Caths as long-term access in patients who have poor vasculature, patient survival is good. Patient survival of 74.1% at 2 years in our study compared favourably with ERA-EDTA for incident dialysis patients from 90 days, showing an adjusted survival probability of 75% at 2 years in their population that was similarly matched for age [7].

The results for patient survival in our study contrast with those of two large retrospective studies of mortality and access type, which relate high mortality from sepsis and cardiovascular disease with the use of CVCs when compared with native AVF [14,15]. Both of these studies recognized a patient selection bias that may explain the difference in results. In these studies, patients with the highest levels of co-morbidity had CVCs inserted rather than AVFs formed. What is more, in the USRDS-based study, there was not

only a large reliance on temporary uncuffed CVCs over permanent cuffed CVCs, but the CVC group also achieved a low Kt/V [14]. The disparity with our results may also have arisen due to differences in the UK dialysis population when compared with the US dialysis population, which is older and has a higher proportion of diabetic patients [16].

The data comparing the mortality associated with CVCs and AVGs are at present ambivalent. Pastan *et al*. have reported a higher mortality rate for CVCs compared with AVGs [15], while the USRDS-based study did not show increased mortality for CVCs (with the exception of cardiovascular deaths in non-diabetic patients) [14].

Sepsis

Vascular access infection is the source of septicaemia for the majority of haemodialysis patients. The long-term use of CVCs carries a relative risk of access-related bacteraemia of 7.6 when compared with AVFs [17]. However, the incidence of CVC-related bacteraemia is highly variable between centres, quoted at 0.7–5.5/1000 access days [18], which may reflect use of different CVC types and care practices. We cannot make direct comparison with the CVC-related bacteraemia rate reported by these studies, but the hospital admission rate for CVC-related infection reported in our study equating to 106 per 1000 patient years at risk can be compared with the USRDS adjusted admission rates for vascular access infection approaching 150 per 1000 patient years at risk in 2001 [16]. Infection is well recognized as a major cause of mortality in haemodialysis patients, exceeding the death rate for acute myocardial infarction [16]. Six of the admissions in our study resulted in death, with a rate of 9.6 deaths per 1000 patient years at risk. The mortality rate in our study is below the mortality rate from septicaemia in the USRDS of 26.4 deaths per 1000 patient years at risk [16].

The type of bacteria subsequently isolated from blood cultures from hospital admissions in our study were as anticipated from other studies of vascular access infection [18]. The catheter was less likely to be salvaged where *S.aureus* was identified. The number of negative culture episodes may have been the result of antibiotic treatment pre-empting venesection for blood culture. One of the deaths in our study was the result of MRSA endocarditis, the only metastatic complication of access-related infection that was encountered. In a recent review of 25 cases of infective endocarditis in dialysis patients with access-related infection [19], 48% of patients were reliant upon tunnelled CVCs, but 32% had AVFs and 12% had AVGs. Notably, mortality was higher for patients with an AVF or an AVG.

Tesio-Caths were removed and replaced in only 17 out of 60 patients surviving sepsis, and there were no serious consequences as a result of attempted salvage. The fact that the line was saved in 43 out of 60 patients was an advantage given the limited future access options for these patients. Our data therefore demonstrate that a more conservative approach with prolonged intravenous antibiotic therapy can be successful. This is in contrast to a previous study that had suggested that CVC removal was necessary in the majority of cases to clear CVC-related bacteraemia [20], and this may be related to inter-study differences in patient immunocompetence, single-lumen *vs* dual-lumen catheters and catheter care and antibiotic treatment. There is no room for complacency, however, as the major complication of CVC access remains one of infection, and the USRDS adjusted admission rates for vascular access infection have risen linearly since 1993 [16]. Meticulous aseptic technique is essential; dialysis adequacy, eradication of nasal carriage of MRSA, clinical vigilance and prompt intravenous antibiotic treatment are also likely to have contributed to low rates of admission with access-related infection in our study.

Our study demonstrates that Tesio-Caths are an effective, durable and safe form of vascular access. Tesio-Caths are a pragmatic alternative for patients in whom a native AVF cannot be formed and who have limited vascular access options. Further studies are warranted to refine the use of this valuable approach and to determine the long-term outcomes prospectively.

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Conflict of interest statement. None declared.

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