Prospective, randomized study of tunneled cuffed hemodialysis catheter removal and delayed insertion, versus guidewire exchange to treat catheter related blood stream infection. Interim results of first 100 cases.

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Abstract: Background: Among the various approaches to management of CRBSI, removal and delayed insertion, or catheter exchange over a guidewire. The aim of this trial was to compare the clinical outcomes of these two approaches. **Methods:** We prospectively analyzed the outcomes of all cases of tunneled dialysis CRBSI during a 5-year period. The infection-free survival time of the subsequent catheter was evaluated in two groups of patients.**Results:** The infection-free survival time of the replacement catheter was similar for the two groups (P = 0.69).**Conclusions:** Exchange of the infected tunneled cuffed hemodialysis catheter over a guidewire is equally effective to catheter removal and delayed insertion in treatment of CRBSI, in addition to saving veins for future access.

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1. Introduction

Tunneled cuffed hemodialysis catheters are commonly used in end stage renal disease patients as a temporary vascular access until arteriovenous fistula maturation or graft is ready to use or as a permanent vascular access in patients who have exhausted all options for creation of a fistula or graft.[1-3]Central venous catheter-related blood stream infection (CRBSI) is a major cause of morbidity and mortality in patients with end-stage renal disease treated with chronic hemodialysis. Among the various approaches to management of CRBSI, catheter removal (CR) and delayed insertion or guidewire exchange (GE) of the catheter. [4-8]The aim of this study was to compare the clinical outcomes of CRBSI treated with two different strategies: Guidewire exchange (GE) of the infected catheter with a new one *versus* catheter removal with delayed insertion.

2. Methods

The study was performed at King Salman Hospital. The study protocol was approved by our institutional review board and written informed consent was obtained from all patients.

Study design. Patients with tunneled- cuffed hemodialysis CRBSI were prospectively randomized (by a sealed envelope randomization service[7]) to undergo GE of the infected catheter with a new one (GE group) two to three days after antibiotic therapy, or removal of the infected catheter followed by insertion of a new catheter 3 to 10 days later (CR group). In the interim, these patients were dialyzed with a femoral dialysis catheter. All procedures were done by vascular surgeons. Method of catheter replacement over guidewire is seen in (fig. 1-4).

Inclusion criteria

All patients with end stage renal disease on hemodialysis from tunneled cuffed dialysis catheters with suspected catheter-related bloodstream infection with no identifiable infection source except the catheter were included.

Exclusion criteria

Exclusion criteria are listed in Table I.

Table I. Exclusion criteria

Septic shock (CRBSI + hemodynamic instability)
Metastatic infection
Patients with an identifiable infection source other than the dialysis catheter.
Patients in whom the catheter was not replaced within 10 days (due to having a permanent access ready to use, persistent fever after catheter removal, or patient death)
Catheter colonization in the absence of clinical signs of infection
Negative catheter tip culture

Management of catheter-related bloodstream infection

Infection was suspected whenever patients with a dialysis catheter developed fever, chills & leukocytosis, in the absence of an alternative source of infection. Treatment with empiric broad spectrum antibiotics (vancomycin and gentamicin) was initiated immediately after obtaining blood cultures from the catheter and peripheral blood (first culture). A definitive diagnosis of catheter-related bacteremia can be made when blood cultures obtained from both the catheter lumen and a peripheral blood (in patients with clinical symptoms of sepsis in the absence of any other noticeable source of infection) grow the same organism. Then after catheter removal the distal 5 cm of the catheter (containing the tip) sent for culture (second culture). Patients in both groups received three weeks of systemic antibiotic according to culture sensitivity.

A repeat blood culture was obtained 7 to 10 d after completion of antibiotic therapy (third culture).

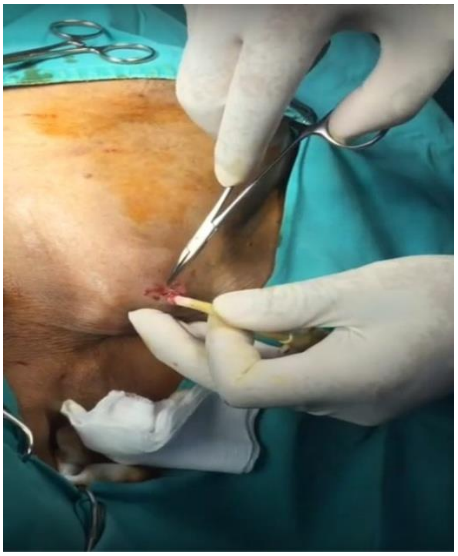

Figure 1: Dissection of the Dacron cuff

Figure 2: Removal of infected catheter

Definition of Treatment Results

Cure: defined as a 45-day symptom-free interval after completion of antibiotics in addition tonegative blood culture at least 1 week after completion of antibiotic therapy. Treatment failure: Any bacteremia involving the original organism that occurred within 45 d of initial treatment. Indeterminate result: If the patient died, the catheter was removed for an unrelated reason before the end of the 45-d period, or if the recurrence of infection was with a different organism.

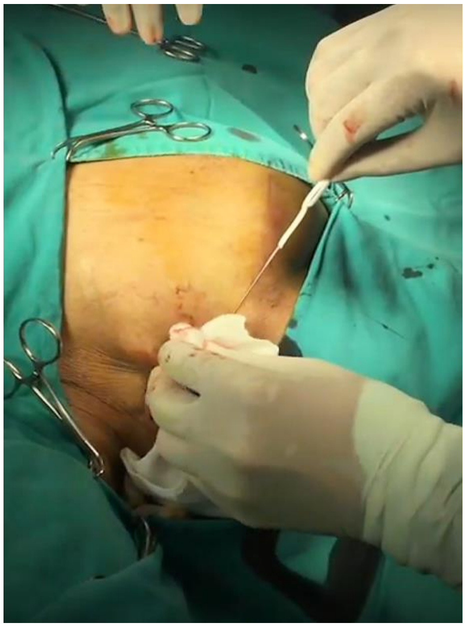

Figure 3: New catheter insertion over guidewire

Figure 4: New catheter inserted

Data collection

Dialysis access coordinators maintained a computerized record of all procedures performed. The following demographic and clinical information was collected for each patient: age, sex, diabetic status, and the organism grown from the blood cultures. Finally, each patient is followed up for serious complications associated with catheter-related bloodstream infection. The indication for catheter removal was categorized as infection or elective (permanent vascular access ready to use).

Statistical analysis

Descriptive statistics were used to summarize the sample data. The infection-free survival time of the replacement catheter (GE or CR) was calculated. Survival analysis was used to model infection-free survival time. Univariate Cox proportional hazard models were fit. Multivariable Cox proportional hazard models allowed for the evaluation of the significance of several independent variables in the presence of each other. Hazard ratios and the associated 95% confidence intervals were computed. The catheter infection-free survival was assessed by Kaplan-Meier analysis. P values <.05 were considered statistically significant.

3. Results

From December 2011 till November 2012, 125 patients with CRBSI screened for possible inclusion, 100 patients met the inclusion criteria and randomized using closed envelope randomization into 2 groups, so we were left with 50 patients in GE group and 50 patients in CR group. Patients in GE and CR groups were similar to each other in terms of mean age (56.7 vs. 61.2 years), sex (61.2% vs. 60.6% male), frequency of diabetes (71.2% vs. 70.4%), and type of infective organism.Patient demographics among the two groups were similar to that in the prevalent dialysis population.Table II outlines the demographics of the study population. Patients in CR group had longer median lengths of hospital stay (12.2 vs. 1.4 days; $P < 0.001$). Recurrent CRBSI occurred in (1.8%) of GE group compared with (1.4%) of CR group ($P = 0.75$). There was no significant difference in mortality rate (1.3% vs. 1.7%; $P = 0.29$). The catheter infection-free survival time was similar for GE & CR groups ($P = 0.71$)(Fig 5), The catheter infection-free survival time was not affected by patient age, sex, diabetic status, serum albumin level or type of organism (Table III). There were five patients with exit site and three patients with tunnel infection in GE group in whom a new tunnel was created during catheter exchange away from the area of infection. There were Six patients in CR group in whom we failed to gain access to the central veins two managed by transhepatic one by translumber catheter and three patients shifted to peritoneal dialysis.

TableII. Demographic characteristics of the study population

Characteristic	GE[a] %	CR[b] %
Age, years		
Mean ± SD[c]	56.7 ± 9	61.2 ± 10
Female sex	61	70.4
Diabetes mellitus	69.9	69.6
Hypertension	85	82
Coronary artery disease	44	39
Congestive heart failure	8	10

[a]GE, guidewire exchange [b]CR, venipuncture insertion[c]SD, Standard deviation.

Table III. Univariate proportional hazard regression analysis of clinical factors as predictors of infection-free catheter survival

Variable	Hazard ratio	95% C.I.	*P* value
Treatment group	0.88	(0.43, 1.79)	0.71
Serum albumin (<3.5 vs. ≥3.5 g/dL)	1.3	(1.21, 6.53)	0.39
Age	1.00	(0.98, 1.02)	0.74
Sex	1.49	(0.73, 3.05)	0.27
Diabetic status	1.72	(0.83, 3.58)	0.15
Type of organism	1.60	(0.69, 3.73)	0.28

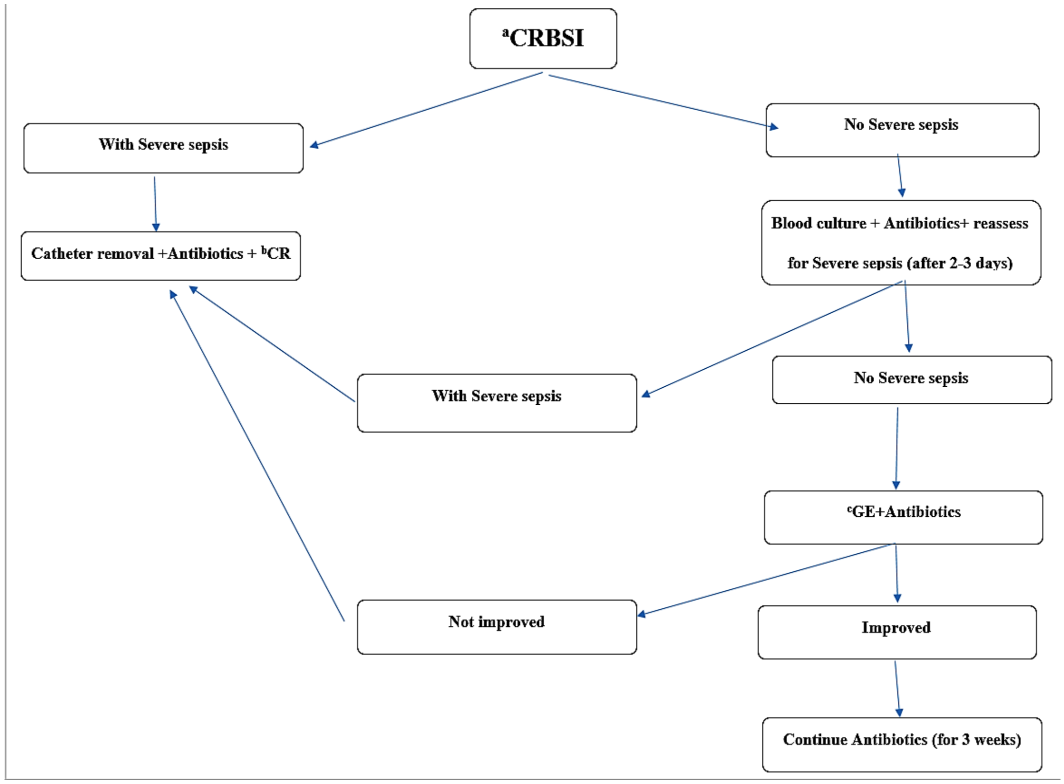

Figure 6: Protocol used for management of catheter related blood stream infection ([a]CRBSI) at our institution utilizing catheter removal with delayed insertion ([b]CR) in patients with severe infection and guidewire exchange ([c]GE) in all other patients.

4. Discussion

Treatment of CRBSI with systemic antibiotics without catheter removal is not usually effective. Only 22 to 32% of tunneled catheters can be salvaged without catheter removal.[4,5,9,10] In addition, treatment of CRBSI with antibiotics alone carries the risk of serious systemic complications, including epidural abscess and endocarditis.[11] Several studies have reported that exchanging infected dialysis catheters over a guidewire, in combination with systemic antibiotics, results in successful resolution of the infection, however, none of these studies reported a concurrent control group for comparison of the outcomes.[6,11-19]

In our prospective randomized study, the patients in GE & CR groups were closely matched in terms of their clinical characteristics. The infection-free survival time was similar whether the initial dialysis catheter was exchanged with a new one over a guidewire (GE group) or whether it was removed with delayed placement of a new catheter 3 to 10 days later (CR group). Vascular hemodialysis access sites preservation is in the best long-term interest of the vascular surgeon, nephrologist and dialysis patient. GE strategy is a single, relatively simple procedure, with no interruption of the outpatient hemodialysis schedule. Moreover, the catheter exchange strategy reduces the number of procedures, reduces potential complications of new stick specially in patients with bleeding tendency, save veins for future access, and decrease the cost. In contrast, the VI strategy involves two separate procedures, at least one femoral dialysis catheter placement, and longer hospital stay. Moreover, catheter removal carries the risk of losing a potential vascular access site and we reported such critical situation in six patients managed by either shifting to peritoneal dialysis or alternate vascular access. So, from the view of cost-benefit, patient convenience & saving future access sites the strategy of GE is clearly preferable in those patients. GE strategy is successful even in patients with exit site or tunnel infection provided that a new tunnel was created during catheter exchange. But we do not recommend GE in patients with severe infection (septic shock or metastatic infection) in whom delay in catheter removal carries a great risk of mortality, so GE strategy is not for routine use but for selective use. The protocol used for management of CRBSI at our institutions is highly successful utilizing VI in patients with severe infection and GE in all other patients is illustrated in figure 6.

Bekir T. etal[14] reported that patients with hypoalbuminemia (serum albumin < 3.5 g/dL) had a higher hazard of a second episode of catheter-associated bacteremia than patients with a normal serum albumin however in our study the rate of infection was not affected by serum albumin

Conclusions

Exchange of the infected tunneled cuffed hemodialysis catheter over a guidewire with a new catheter is equally effective to catheter removal and delayed venipuncture insertion in treatment of catheter related bloodstream infection, but the former strategy is more superior in saving veins for future access, cost reduction, reduce the number of procedures, reduces potential complications of new venipuncture and avoid the disruption of the outpatient hemodialysis schedule.

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