Original Article

The Effectiveness of Personal Hygiene Practices on Non-Cuffed Central Vein Catheter-Related Infection in Patients Undergoing Hemodialysis: A Randomized Controlled Trial

Abstract

Infection of the internal jugular vein (IJV) catheter continues to be a common cause of death in patients with end-stage renal disease undergoing hemodialysis (HD). The present study aimed to evaluate the effectiveness of personal hygiene on the incidence of IJV catheter-related bloodstream infection (CRBSI). A randomized, controlled, parallel, and non-inferiority trial was conducted on patients initiated on maintenance HD via right IJV catheter. Patients were randomly allocated to control and intervention group via computer-generated random table. Intervention package for the intervention group included hand washing (2–4 hourly and whenever visibly dirty), feet washing (12 hourly), and axillary shave (at any point during the study, no hair growth in axilla). Patients were provided with a pamphlet and reinforced to continue package till IJV catheter was *in situ*. Patients were followed up twice a week for one month from the date of catheter insertion for the incidence of CRBSI. The primary outcome of the study was percentage of patients free from CRBSI. On intention-to-treat analysis, the percentage of patients without CRBSI was 53.7% and 29.3% in the intervention and control arm, respectively [$P = 0.04$; 25.12% (1.43–45.28%)]. Positive blood cultures were higher in control (73.3%) as compared to the intervention group (28.6%) ($P = 0.19$). Personal hygiene interventions are an effective method to reduce the incidence of CRBSIs among population undergoing maintenance HD via non-cuffed IJV catheter.

Keywords: *Catheter-related blood stream infection, end-stage renal disease, hemodialysis, internal jugular vein catheter, non-pharmacological intervention*

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Introduction

Infections are the second most prevalent cause of mortality in patients with end-stage renal disease (ESRD), next only to cardiovascular diseases as per the United States Renal Data System, 2012.[1] In the developing world, 80% of hemodialysis (HD) are initiated via a non-cuffed catheter.[2] Despite the increased risk of infections as compared to a tunneled vascular catheter, non-cuffed/non-tunneled vascular catheters continue to be the choice of vascular access. In the developing world, the reasons behind this flawed practice are multifactorial, namely, economy, followed by lack of expertise.

Central venous catheter (CVC) infection is the leading cause of hospitalization for infection followed by bloodstream infections or sepsis (24%).[3,4] Bloodstream infections are 11.2-folds higher in patients with CVC compared to arteriovenous fistula (AVF) as vascular access.[5] Various sites of colonization of organisms are anterior nares, skin, perineum, pharynx, and, to a lesser extent, gastrointestinal tract, vagina, and axilla. Hands are a principal vector for transmission of bacteria from these sites to the sensitive area. Hence, effective measures to prevent organism transmission from colonization sites to CVC are urgently needed.[6] Catheter-related bloodstream infection (CRBSI) prevention requires a multidisciplinary coordinated approach involving care at various levels. Education, training, and adoption of best practice guidelines, in combination with regular follow-up audits, lead to a reduction in infection rates and general improvement in the quality of vascular access care.[7] High prevalence of resistance toward pharmacological treatments among organisms call for an appropriate preventive strategy. Hence, the present study was aimed to evaluate the effectiveness of

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simple non-pharmacological personal hygiene-based intervention package on the incidence of an internal jugular vein (IJV) CRBSI among the patients initiated on HD.

Materials and Methods

Trial design and enrollment

A randomized, controlled, parallel, non-inferiority, open label study was conducted in the dialysis unit of Nehru Hospital, Chandigarh. The Institute Ethics Committee approved the study. All the patients provided a written informed consent. Adult patients with newly diagnosed ESRD initiated on maintenance HD via non-cuffed right IJV catheter were included. Patients with any other comorbidity such as liver disease, HIV-positive status, admission in intensive care units, any recent significant surgeries, history of infections treated with antibiotics in the past one month, recent history of antibiotics intake (before 3–4 weeks of IJV insertion), and renal allograft loss were excluded.

Intervention and follow-up

Swabs from the throat, IJV insertion site, axilla, nose, and toe webs were taken and cultured from patients of both the groups before insertion of IJV catheter. Patients in the control group received routine catheter care. Patients in the intervention group received intervention including hand washing (4 hourly and when visibly dirty), feet washing (12 hourly), and axillary shave in addition to routine care. Intervention package was implemented before insertion of the right IJV catheter via direct demonstration with pamphlet in appropriate language and patients were reinforced to continue doing intervention themselves till IJV catheter is *in situ*. Patients in both the groups had curved, double lumen HD catheters inserted in right IJV as per Seldinger technique. Povidone iodine (10%) was used to prepare area before insertion of IJV catheter. Follow-up was done via telephonic approach twice a week and direct examination when patients came to the hospital for follow-up from the date of catheter insertion for the incidence of CRBSI. Patients in intervention arm maintained a record of continuing the intervention in a logbook. Blood cultures were taken for all patients who presented with signs of infection.

Outcome

The primary outcome of the study was the percentage of patients free of CRBSI at the end of 4 weeks. Diagnosis of CRBSI was based on Kidney Disease Outcome Quality Initiative as definite, probable, or possible CRBSI.[8]

Definite bloodstream infection: The same organism from a semiquantitative culture of the catheter tip (>15 colony-forming units per catheter segment) and from a peripheral or catheter blood sample in a symptomatic patient with no other apparent source of infection.

Probable bloodstream infection: Defervescence of symptoms after antibiotic therapy with or without removal of the catheter, in the setting in which blood cultures confirm infection, but catheter tip does not (or catheter tip does, but blood cultures do not) in a symptomatic patient with no other apparent source of infection.

Possible bloodstream infection: Defervescence of symptoms after antibiotic treatment or after removal of the catheter in the absence of laboratory confirmation of bloodstream infection in a symptomatic patient with no other apparent source of infection.

Statistical methods

An internal pilot study was conducted in June 2016 to assess feasibility and safety of the intervention and for sample size calculation. Based on the pilot study, where 60% of the patients in the intervention group were free from infections at four weeks compared to 42% in the control group, a total of 82 samples were required with 90% power and a non-inferiority margin of 10% with an assumed dropout rate of 10%. Consecutive sampling technique was used to enroll all the participants who met the inclusion criteria. Patients were randomly allocated to control and intervention group via computer-generated random table. Patients and microbiologists assessing the swab cultures and blood cultures were masked to group assignment. The primary analysis was intention-to-treat (ITT). Data were coded and entered in SPSS (Statistical Package for Social Sciences) version 20. Descriptive statistics (percentage, mean, standard deviation, and Chi-square) and inferential statistics (*t*-test) were used to analyze data. Chi-square test was used to calculate the primary outcome. Data access and submission responsibility were limited to study authors only. P value < 0.05 was considered significant.

Results

Participants were recruited between July 18, 2016 and October 20, 2016. Two-hundred cases were assessed for eligibility, and 82 participants were recruited (41 in each group) [Figure 1]. Mean age was 44.26 ± 14.43 years in control and 41.6 ± 12.8 years in the intervention group. Sixty-six percent of patients in both the study groups were males. There was no difference in baseline parameters in both the groups [Table 1]. All the patients received dialysis from their center of convenience. Similar organisms were found in pre-procedure swab cultures of both the groups. *Staphylococcus epidermidis* was the most common bacteria isolated from all sites (nasal, axilla, throat, and catheter insertion site) except toe webs where *Staphylococcus hemolyticus* was the most common.

In the ITT analysis, incidence of CRBSI was higher in the controls (32.2/1000 catheter days) compared with the intervention group (20.1/1000 catheter days) (P = 0.043) [the difference between proportions was 25.12% (1.43–45.28%)], and the intervention was found to be superior to the control in reducing the infections. Even the per-protocol analysis also revealed

higher CRBSI-free individuals in the intervention group compared to controls (P = 0.1) [the difference between proportions was 19.02% (−5.18–40.31%)]. The incidence of CRBSI is mentioned in Table 2. Blood culture was positive in a higher number of patients in the control group (73.3%) as compared to the intervention group (28.6%) (P = 0.19).

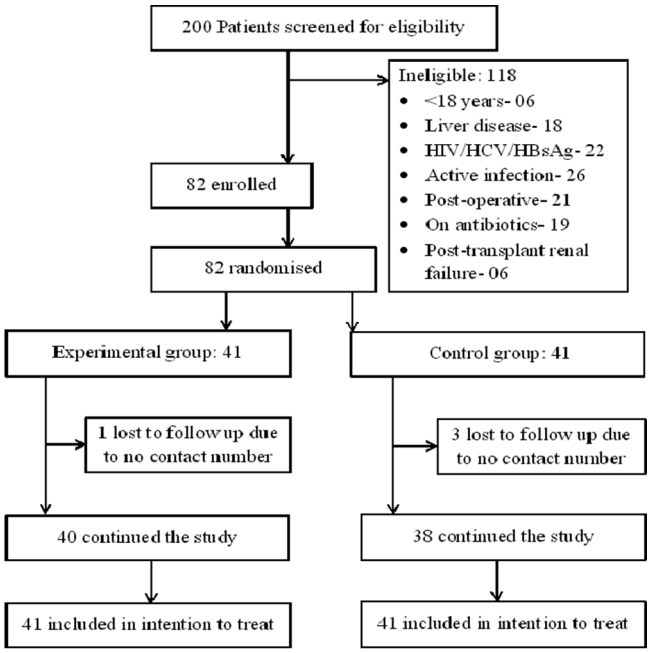

Figure 1: Trial design

Table 1: Sociodemographic and clinical variables of control and intervention group

Sociodemographic and clinical variables of patients	Control group n_1=41 *f* (%) or mean±SD	Intervention group n_2=41 *f* (%) or mean±SD
Age (years)	44.26±14.43	41.6±12.8
Gender		
Male	27 (65.9)	27 (65.9)
Female	14 (34.1)	14 (34.1)
BMI (kg/m^2)	20.5±4.62	21.8±3.75
Known native kidney disease	18 (43.9)	21 (51.2)
Diabetes mellitus	14 (34.1)	11 (26.8)
Hypertension	33 (80.5)	31 (75.6)
Coronary artery disease	5 (12.2)	2 (4.9)
Hospitalization last 6 months to 1 year	15 (36.6)	15 (36.6)
Previous *Staphylococcus aureus* infection	7 (17.1)	04 (9.8)

SD=Standard deviation, BMI=Body mass index

Organisms isolated from blood cultures in the intervention group included *S. epidermidis* (14.28%), *Raistonia pickettii* NF (14.28%), and *Pseudomonas aeroginosa* (14.28%), whereas those isolated from control group included *Staphylococcus aureus* (14.28%), *S. epidermidis* (14.28%), *Stenotrophomonas* (14.28%), *yeast* species (7.14%), and *Enterobacter aeroginosa* (7.14%).

Discussion

In the present randomized controlled trial, we evaluated the effectiveness of simple non-pharmacological personal hygiene-based intervention versus routine care on incidence of CRBSI in patients with ESRD initiated on HD via right IJV catheter. In the current study, we witnessed a reduced rate of CRBSI including blood culture positivity in patients who received the intervention.

Various non-pharmacological interventions such as maximum sterile barrier,[9-11] avoidance of femoral vein catheterization,[9,12] use of appropriate disinfectant solution for preparing catheter insertion site,[9,11,13] use of sterile gauze dressing on CVC, use of CVC insertion checklist[14] and avoiding prophylactic antimicrobials in CVC,[14-16] catheter care education of dialysis staff,[11,17] hand washing,[9,18] repetitive education and training of dialysis staff,[19] and removing unnecessary catheters[9,11] are found to be successful in reducing incidence of CRBSI in HD patients. Although inconclusive, transparent dressings may increase the risk of CVC tip infection due to the accumulation of moisture at the insertion site in tropical population.[20] Patient-specific factors also influence the occurrence of CRBSI.[21] Patients should be educated about the risks associated with vascular access-related infections.[22] The above mentioned approach enhances the patient's active participation in the treatment process and promises better outcomes. Poor personal hygiene is identified as a risk factor for CRBSI by 3.48-fold.[22,23] Common sites of the colonization of organisms in patients are skin crevices including the nasal cavity, throat, axilla, and toe webs. Organisms are transmitted to the vascular access site via various direct or indirect portals. Two-third of bacteremia cases are known to be caused by *S. aureus* and *S. epidermidis*.[24] *S. aureus* infection is the leading cause of infectious morbidity and mortality (>8%) in HD patients. Approximately 10% of patients die within 30 days

Table 2: Comparison of levels of CRBSI between control and intervention group

Diagnostic criteria	Intention to treat analysis[a]		Per-protocol analysis[b]	
	Control group (n_1=41) *f* (%)	Intervention group (n_1=41) *f* (%)	Control group (n_1=38) *f* (%)	Intervention group (n_1=40) *f* (%)
CRBSI	29 (70.7)	19 (46.3)	26 (68.4)	20 (50)
No CRBSI	12 (29.3)	22 (53.7)	12 (31.6%)	20 (50)

[a]P-value=0.043; [b]P-value=0.11. CRBSI=Catheter-related blood stream infection

of being diagnosed with *S. aureus*-induced bloodstream infection.[25] Axilla (40%) has been found to be the most common carrier of *S. aureus* followed by other body sites such as web spaces (32.9%), nasal (27.1%), throat (11.4%), and vascular access site (4.3%).[26]

In the present study, pre-procedure swab culture showed that in all cultures, *S. epidermidis*, *S. hemolyticus*, and *S. hominis* were more common as compared with *S. aureus*. There was no significant difference in the prevalence of staphylococcal colonization at various locations. Present study primarily had an intervention, which worked on improving the personal hygiene of those areas that are most commonly colonized by organisms such as axilla, hands, and toe webs, and to prevent transmission of microorganisms from these sites to the catheter. Hand washing, feet washing, and axillary shave in total were found to be effective in reducing the incidence of CRBSI. The frequency of probable CRBSI was significantly higher in the control group as compared to the intervention group. Blood culture positivity was considerably higher in patients in the control group as compared to the intervention group. Organisms isolated included *S. aureus*, *S. epidermidis*, *Stenotrophomonas* spp., *Enterobacter aerugenes*, *Pseudomonas*, and *yeast*. Previous studies have shown that coagulase-negative *Staphylococci* accounted for nearly one-third of all nosocomial bloodstream infections, followed by *S. aureus*, *Enterococci*, and *Candida* species.[27] Similar interventions tested by a quality improvement project showed that access-related bloodstream infections decreased from 0.73 events per 100 patient months in the pre-intervention period to 0.42 events per 100 patient months in the post-intervention period.[28] There was a significant reduction in the incidence of CRBSI and blood culture positivity in the intervention group as compared with control group. This can be attributed to the improved personal hygiene of the participants and probable reduction in transmission of the organisms from the site of colonization to the catheter by the nature of the intervention.

Patients with ESRD are known to have nutritional stress and inflammation, even more than the systemic stress noted in other conditions,[1] predisposing them to infection. An area of concern is the high incidence of CRBSI (32.2/1000 catheter days in control and 20.1/1000 catheter days in experimental group) witnessed by this study as compared with the global incidence rate which ranges between 0.5 and 6.6 episodes per 1000 catheter days.[29,30] Reason for such drastic difference can be attributed to the fact that study was done in a setting where out-patient HD is not done. All the participants got dialyzed from different centers. Every center has their own protocol for catheter care and different patient management guidelines. As any invasive procedure in this setting leads to the introduction of skin bacteria into the system, it is not surprising that basic cleansing has decreased the infection, as seen with other conditions.[8]

In addition, such high incidence of CRBSI calls for improvement in catheter care practices such as regular training of the health-care personnel dealing with the catheters, gentle reminders about the protocol by having checklist on every HD machine, frequent supervisions, and audits. As patients are the main focus of care, repeatedly telling patients about catheter care, taking remonstrations, catheter care nurse with on call number and written standing orders about catheter care in patient HD follow-up book are means to have all corners covered. Patients and health-care personnel should be made aware about the importance of vascular access for a patient with kidney failure and what can happen if it fails.

Merits of the study are that it was a randomized controlled trial performed in a real-life scenario in the developing world using simple interventions, which promoted the comfort of the patient as well as caregivers. Non-pharmacological interventions encourage autonomy on the part of nurses; telephonic follow-up aids in prompt treatment are reducing chances of complications associated with infections, especially in a developing country such as India, where significant ESRD population travel over 100–200 miles for consultation at public sector hospitals compounded by inadequate transport facilities. Limitations of the study include short duration of follow-up, telephonic interviews and dialysis being delivered at different centers.

Conclusion

Non-pharmacological interventions such as axillary shave and repeated hand and foot washing reduce the incidence of CRBSI in adult patients on maintenance of HD via non-cuffed IJV catheter.

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Conflicts of interest

There are no conflicts of interest.

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