Original Article

The Impact of Open versus Closed Catheter Access System of Central Venous Catheter on Infection Prevention in Critically Ill Patients: A Comparative Evaluation

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Abstract

Background: Use of Central Venous Catheters (CVC) can be associated with increased incidence of Catheter-Related Bloodstream Infections (CRBSIs). The present study assessed the impact of open versus closed catheter access system of CVC on infection prevention in critically sick patients admitted in the Intensive Care Unit (ICU). **Materials and Methods:** After obtaining ethical clearance and consent of relatives of the patients admitted in ICU of our institute, the present study was carried out as a randomized, prospective, double-blind trial with parallel group design (of 200 patients in each group). In study group (Group I), closed catheter access system (Luer access split septum) was used, while open access (three-way) system was used in the control group. Among clinical parameters, if any patient developed fever, his/her blood, urine, and tracheal secretions were sent for culture and sensitivity. Collected data were analyzed using descriptive and inferential statistics. **Results:** Demographic profile was similar in both the groups. Significant clinical and statistical differences were observed in blood culture values (χ^2 = 58.30, df = 1, $p < 0.001$) as well as Total Leukocyte Counts (TLC) on day 1, 4, and 8 ($F_{2,260}$ = 80.61, $p < 0.001$). However, no statistically significant (t_{390} = 0.90, p = 0.367) difference was found in the duration of hospital stay among patients in both the groups despite significant differences in various clinical parameter. **Conclusion:** Luer access split septum connectors along with appropriate training of the nursing personals decrease CRBSI.

Keywords: *Bacteremia, catheter-related infections, central venous catheters, intensive care units*

Introduction

Use of Central Venous Catheters (CVC) has become essential in modern-day critical care practice as they fulfill numerous clinical goals such as measurement of central venous pressure, venous pressure-guided fluid administration, parenteral nutrition of higher osmolarity, portal for administer medicines, and collection of blood samples.[1] However, sometimes their use becomes a subject of clinical conundrum as is often seen in various critical care settings with a higher incidence of Catheter Related Bloodstream Infections (CRBSIs), leading to higher incidence of morbidity and mortality and an economic burden on patient and hospitals.[2] It has often been observed in various clinical studies that catheter hub contamination is a potential source of CRBSI.[3-6]

CRBSI can be appreciably minimized with closed access system and devices, as the catheter connection is not open to air during the change of infusion site.[4] It has also been emphasized that the use of needleless access ports on all lumens of intravenous lines is a better option so as to decrease morbidity and length of hospital stay.[7] The structural configuration of closed infusion system clearly inherits some proposed merits of needleless connectors, which include the standard split septum and the Luer-activated mechanical valve connectors. It has also been observed that increased CRBSIs are more associated with negative and positive displacement mechanical valves as compared to split septum connectors.[8] Split septum connectors do not have any internal mobility and provide only a straight fluid pathway directly through the lumen. The male Luer tip completely covers the opening and thus prevents any fluid extravasations into the

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interstitial space.[9,10] The current evidence supports the preferential use of split septum connectors over mechanical valves in critical care setting. However, to substantiate these facts, large prospective randomized clinical trials were necessary to effectively support the merits of needleless connectors. Considering the background of all these clinical conundrums, we designed the present study to assess the impact of open versus closed catheter access system of CVC on infection prevention in critically sick patients admitted in the Intensive care Unit (ICU) of our institute.

Materials and Methods

From July 2015 to February 2017, a randomized, prospective, parallel group, double-blind trial [Cinical Trial Registry of India (CTRI) /2017/09/009955)] in a 24-bedded open-type ICU at Gian Sagar Medical College and Hospital, Ram Nagar, Rajpura, Patiala, Punjab, India was carried out. Inclusion criteria included all the patients of either gender who were admitted in the ICU and needed central line catheter. Based on results of pilot study and the available data of similar studies, the sample size was calculated by Epi info version 3.2 by keeping $\alpha < 0.05$ (confidence limit:−95%), power 0.80, and assuming exposure of 20% with a ratio of 1:1, which was calculated to be approximately 192 in each group. However, we included 200 patients so as to avoid any dropout from the study. Patients having CVC inserted in internal jugular or subclavian of either side were included in the trial. Exclusion criteria included patients with any positive culture of urine, surgical drain fluid, respiratory secretions, wound swab, and pleural fluid, as well as patients with HIV infection or immunodeficiency states. Randomization was achieved by using sequentially numbered, sealed, opaque envelopes. For data collection, socio-demographic profile and clinical profile sheets were prepared. Socio-demographic sheet included age, gender, diagnosis, date of admission in ICU, type of CVC, site of insertion, and list of prescribed antibiotics. Clinical sheet included signs of local infection or inflammation, vital parameters (blood pressure, pulse rate, respiratory rate, and temperature), laboratory investigations (Total Leukocyte Count [TLC], differential leukocyte count, blood culture, tracheal secretion culture, and urine culture), and date of discharge/death/leave Against Medical Advice (LAMA). After extensive review of literature, training protocols based on the Centre for Disease Control and Prevention (CDC) guidelines for prevention of CRBSI were prepared for staff nurses. All staff nurses working in ICU were trained regarding precise care of central line and they were unaware of the type of study being carried out, thereby making the allocation and randomization easier. Randomization was based on computer-generated random code numbers which were handed over to the staff members who were also blinded to the type of study being carried out. In study group (Group I), closed catheter access system (Luer-access split septum) was used, while in control group open access (three-way) system was used. Daily assessment and monitoring were done to see development of any local signs of infection such as redness, inflammation, and localized increase in temperature as well as for systemic signs of infection such as fever, chills, hypotension, and various other relevant parameters. If any patient developed fever, blood culture was obtained by withdrawing sample from two different sites, peripheral venous catheter and CVC, at an interval of 2 hours. Urine culture and tracheal secretions were also sent for culture and sensitivity. At the end of the study, data were collected and analyzed by Statistical Package for the Social Sciences software (version 20; Armonk, NY: IBM Corp.) for Windows for descriptive statistics (i.e., percentage, mean, range, and SD) and inferential statistics (i.e., independent *t*-test, χ^2 test, ANOVA, RMANOVA, and post hoc analysis [Bonferroni]). Value of $p < 0.05$ was considered as significant and $p < 0.001$ was considered as highly significant.

Ethical considerations

Ethical clearance was obtained from Hospital Ethics Committee (ECR/572/Inst/PB/2014, dated May 9, 2014). Permission was taken from Medical Superintendent of hospital and Head of Department of Intensive Care Medicine. All participants were explained about the purpose and method of study, voluntary nature of study, and confidentially of their information. Written consent was taken from patients/relatives of unconscious patients admitted in our ICU. All those patients whose relatives did not give consent for the study were not included in the study.

Results

A total of 400 patients were recruited. Two patients from study group and six patients from control group were excluded from the analysis as they LAMA [Figure 1]. The demographic profile of the two groups was almost similar, which eased the comparative statistical analysis [Table 1]. Both groups had male predominance. Maximum patients had cardiac diseases and were distributed evenly in both the groups, followed by postoperative cases of gastrointestinal surgeries. Among all these patients, 70% were cannulated at internal jugular vein with triple-lumen catheter, and in both the groups antibiotic prescription was uniform without any statistical significance. In the interventional group, only 2.50% patients had fever, while only one patient had redness and inflammation. There was no significant difference ($p > 0.05$) in baseline vital parameters of patients among study group and control group. Typical scenario of significant difference in TLC in clinical and statistical values was observed. From the baseline established clinical parameters, significant values were observed in both the groups (Group I: $F_{2, 60} = 80.61$, $p < 0.001$; and Group II: $F_{2, 260} = 14.86$, $p < 0.001$), which did not reveal

Table 1: Demographic and clinical profile of the patients enrolled in both the groups

Demographic profile	Control group			Study group		
	Mean (SD)	Range	Ratio	Mean (SD)	Range	Ratio
Age (in years)	55.90 (18)	13-100	-	54.30 (18)	18-92	-
Gender						
Male:Female	-	-	115:85	-	-	132:68
Number of observation (days)	5.90 (7.30)	1-49	-	4.50 (3.60)	1-22	-
Type of intervention						
Double:Triple lumen	-	-	18:182	-	-	13:187
Duration of hospital stay (days)	8 (7.30)	1-46	-	7 (6.20)	1-40	-
Mortality rate						
Survived:not survived	-	-	193:7	-	-	195:5

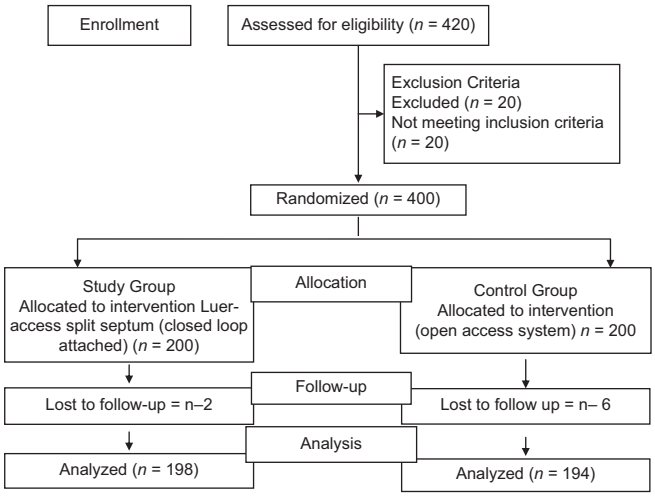

Figure 1: CONSORT flow diagram

any significant difference between the mean values on the first, fourth, and eighth day upon statistical analysis with independent sample *t*-test. Table 2 reveals the results of blood culture samples from both the groups with a marked clinical and statistical difference in the values of results. As compared to positive results of blood culture samples among 64 (100%) patients indicating pathognomonic organisms in the control group, only 37.10% blood culture samples tested positive for pathognomonic organisms in the study group patients, as revealed in Table 2. There was no statistically significant difference ($\chi^2 = 0.002$, df = 1, $p > 0.05$) in urine culture reports among patients of both the groups. The laboratory analysis of urine culture reports established the presence of gram-positive and gram-negative bacteria, *Candida albicans*, and a picture of mixed flora in few cases, which did not reveal any statistically significant difference on comparison among the two groups ($\chi^2 = 0.92$, df = 3, $p > 0.05$). The tracheal secretions culture report from patients of both the groups also did not reveal any statistically significant difference on comparison ($\chi^2 = 0.01$, df = 1, $p > 0.05$). In spite of various clinical and statistical differences between the parameters of the two groups, there was no statistically significant ($t_{390} = 0.90$, $p > 0.05$) difference in the duration of hospital stay among patients in both the groups, as revealed in Table 3.

Discussion

Prevention of CRBSI is a major challenge in critical care settings across the world. In spite of various advances in critical care arena, controlling CRBSI has always been an uphill task for the critical care staff as it invariably leads to higher morbidity and mortality. The present study was designed and carried out to compare the efficacy of open versus closed catheter access system for the prevention of CRBSI so as to possibly minimize all the hazards associated with CRBSI. In one of the previous studies, the researchers have stressed on the fact that nurses are on front line of health care delivery process for improving patient safety and standard of patient care.[11] Observations of another study revealed that infection rates had come down remarkably as nurses gained experience and also overcame the challenges of using the closed access system, i.e., needleless system.[9] We adopted a similar approach for proper implementation of the study design and components as well as to rule out any bias. Therefore, before the beginning of the study, all staff nurses working in the ICU were trained regarding the precise care of central line and prevention of Central line–Associated Bloodstream Infections (CLABIs).

In the present study, 64 patients in the control group had positive blood culture which included various pathogenic organisms such as gram-negative bacilli, *Escherichia coli*, and *Klebsiellapneumoniae*. The findings of our study closely correlate with another study from an Asian country that reported a similar picture of microbes on positive culture reports of blood samples attributed to CRBSI.[12] Previous Indian studies reported an incidence rate of CRBSI to be 8.75/1,000 and 3.38/1,000catheter days,[13,14] and a CLABSI rate of 7.90 per 1,000 catheter days.[15] In few other studies conducted in various Indian hospitals, the reported rate of CLABSI was 2.80 per 1,000 catheter.[16,17] Incidence density of CVC tip infections was at 7.67 per 1,000 catheter days and that of CRBSI was 2.79 per 1,000 catheter days.[16,18] Considering the results of the present study, the incidence rate of CRBSI is 11% among the patients of study group, while it is 32% among patients of control group, which highlights the possible merits of split septum connectors. Thus, doing

Table 2: Blood culture distribution among patients in both groups

Blood culture	*F* (*n*=126)	Study group (*n*=62) *n* (%)	Control group (*n*=64) *n* (%)	χ^2	df	*p*
Sterile	39	39 (62.90)	0 (0.00)	58.30	1	0.001
Positive	87	23 (37.10)	64 (100)			
E. coli	74	19 (82.60)	55 (85.90)	0.002*	1	0.05
K. pneumoniae	13	4 (17.40)	9 (14.10)			

*Yate's corrected test

Table 3: Duration of hospital stay among patients in both groups

Duration of stay (days)	Study group (*n*=198)	Control group (*n*=194)	*t*	df	*p*
Mean days	7.40	8	-0.90	390	0.367
No of days	6.20	7.30			

an overall comparison with above-mentioned studies, the results of our study definitely favor the use of split septum connectors. In India, CRBSI rate is 7.70 per 1,000 catheter days. These values are in stark contrast when compared with the similar values from intensive care set-ups published in western literature that have a mean CLABSI rate of 1.50 cases per 1,000 catheter days.[18] From the conclusions of one meta-analysis, reduction in the rate of CRBSI is possible with intravenous needleless connectors, which may also facilitate effective intravenous line care.[19] In another study conducted on female patients, no significant difference was observed on the incidence rate of CRBSI with the use of positive pressure valve or standard caps.[20] The ease of use of Luer access split septum system was the basis of another study, which compared it with conventional Luer lock caps.[21] The user friendliness of the split septum system helped in simplified handling by the staff that was adequately trained for hand hygiene care, which finally resulted in reduced risk of CRBSI infection. Present study obtained better results as the staff was precisely trained for use of split septum connector and was continuously under the vigilance of intensivists. However, another study found no difference in CRBSI rates on comparison between needleless connector and a three-way stopcock connection.[22] Even the comparison of a closed needleless valve with a conventional open system yielded no difference in incidence of CRBSI rates.[23] In contrast to these studies, another published study revealed a lower incidence of bacteremia with the use of closed system as compared to the use of open system on CVCs (2.36 vs. 6.52/1,000 catheter days, relative risk = 0.36, 95% confidence interval = 0.14–0.94, p = 0.02).[7] Apart from that, the incidence of bacteremia caused by gram-negative bacilli also declined by 64% in the study. The contrary results from previously published literature encouraged few researchers who concluded from their study that strict adherence to CL bundle has no positive correlation with CLABSI rates in adult patients but it was definitely associated with reduction in CLABSI rates in critically ill children who were admitted in ICU at varied interval over a period of 18 months of study.[24] Another study concluded that not a single entity but a combination of aseptic dressing, minocycline/rifampin catheters, and other behavioral changes can reduce the rate of CLABSI for longer periods.[25] Yet another study provided direct evidence that practicing of all CL bundles entirely and precisely can definitely bring down the rate of CLABSI among critically ill patients.[26]

Our study is an attempt in encompassing and imbibing almost all these factors so as to fill the voids and overcome the limitations in the earlier studies by not only focusing on the merits of mechanical devices but also ensuring the practices of maintaining complete asepsis as well as bringing behavioral modifications and raising work culture standards during the entire duration of our study so as to possibly bring down the rates of CLABSI. A study based on similar principles concluded that active educational interventions for clinicians appeared effective at reducing CLABSI rates.[27] Similarly, other researchers have also stressed on the fact that proper implementation of central-line bundles has the potential to reduce the incidence of CLABSIs.[28-30] In one of the Indian studies, it was concluded that following the basic standards of care strictly, such as maintaining hand hygiene and use of closed infusion system along with regular surveillance, can bring down the infection rates in developing nations to almost the levels reported in the literature from western countries.[16] The main limitation of present study was that it was a single-center study and the results can be more precise and uniform if a multicenter study is undertaken in future.

Conclusion

The results of our study convey that the merits of split septum connectors, in addition to the functional superiority of the device, can best be obtained by emphasizing on other aspects such as appropriate training of the caregivers, maintaining aseptic techniques, behavioral modifications of the nursing staff and also by maintaining a good work culture which decreases the incidence of CRBSI. The specific weaknesses of the bundle performance can be overcome by providing customized education to the nursing staff. The superiority of split septum connectors over conventional ones seems convincing theoretically but can be obtained practically by adhering to the above-discussed method.

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Conflicts of interest

Nothing to declare.

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