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EFFECT OF OPEN AND CLOSED INFUSION SYSTEM ON CENTRAL VENOUS CATHETER ASSOCIATED BACTEREMIA - A COMPARATIVE STUDY

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ABSTRACT

Background: Central line-associated bloodstream infections (CLABSI) are common in ICU settings. This study determines whether switching over from an open infusion system to a closed infusion with VAMP (Venous Arterial Blood Management and Protection system) system would reduce the incidence of CLABSI.
Method: 200 adult patients were divided equally into open system group and closed system group for invasive pressure monitoring and blood sample collection. Incidence of CLABSI in each group was recorded.
Results: In Open group, the incidence of CLABSI was 11% with an incidence density of 18.86 CLABSI per 1000 central catheter days. In Closed system group the incidence was 4% with incidence density of 6.60 per 1000 central catheter days.
Conclusion: Use of closed infusion containers with VAMP System prevents CLABSI.

KEYWORDS : Central line-associated bloodstream infections, closed infusion, Venous Arterial Blood Management and Protection system

Introduction

The Center for Disease Control and Prevention (CDC) defines Central line-associated bloodstream infections (CLABSI) as an infection in a patient who had a central line in place within the 48-hour period before the onset of infection.[1] An estimated 250,000 to 500,000 CLABSI occur in US hospitals each year[2] and few published studies of incidence of CLABSI in India are available.[3] CLABSI is an important cause of morbidity and excess cost of care for hospitalized patients with an attributable mortality rate of 4% to 20%.[4,5] Prevention of CLABSI is a multidisciplinary approach and evidence-based interventions for patients with central lines when implemented have shown to reduce rates of CLABSI by two thirds or more.[6] Open infusion containers may increase the risk of contamination and administration-related CLABSI because they allow the entry of air into the system, thereby also providing an opportunity for microbial entry. The closed infusion container that was investigated (a fully collapsible, plastic container not requiring or using any external vent (air or needle) to empty and having self-sealing ports with VAMP (Venous Arterial Management Protection system) was designed to overcome this flaw.

Simple, cost-effective, evidence-based interventions, coupled with necessary supplies that are readily available, use of checklists, and nursing supervision to ensure healthcare worker adherence to guidelines and bundle procedures, have been extraordinarily effective at reducing CLABSI rates in ICUs. Use of closed infusion systems and increased emphasis on tracking and preventing CLABSI throughout entire healthcare facilities, not just in ICUs is the need of the day.

Materials & Methods

After approval by the institution's ethics committee, 200 adult patients were divided into two groups of 100 patients each. All of them were hospitalized in the ICU with a Central Venous Catheter in place for 24 hours or more. They were included in this prospective, controlled study for a period of 96 hours (4 days). Group I was the open system group where a commercially standard externally vented semi rigid, non-collapsible, one–port plastic container was used. Group II is the closed system group, a non-vented, Baxter Viaflex®, a fully collapsible plastic closed infusion container that does not require an external vent along with VAMP (venous arterial blood management and protection system) for invasive pressure monitoring and blood sample collection was used. The demographic profile of the patients in both the groups was the same. Patients with drug coated Central Line, on immuno-suppressants or steroids and those with evidence of sepsis at the time of start of study were excluded. Central Venous Catheter was inserted via the internal jugular or subclavian vein using the Seldinger technique under aseptic protocols. Hand washing compliance and placement of sterile gauze dressing over site of CVC insertion was ensured and supervised in both groups. The fluid bags had double packing outer cover and were opened and cleaned with available disinfectant just prior to usage. Blood for culture was collected at the time of ICU admission and thereafter if there was any of the clinical features of blood stream infection as described below. On completion of 96 hrs of CVC placement in situ, the catheter was changed and the tip sent for culture.

Laboratory confirmed CLABSI was defined as recognized pathogen cultured from percutaneous blood sample and catheter tip culture and at least one of the following signs and symptoms: fever > 100.4^{0}C, chills, hypotension or elevated total lymphocyte count > 11,000 cells/cu mm with the catheter as the only obvious source of infection. In the absence of laboratory confirmation, resolution of fever following the removal of a CVC suspected of infection was considered as indirect evidence of CLABSI. Outcome that was assessed in group I (Open system) and Group II (Closed system) was incidence of Central Line Associated Blood Stream Infection (CLABSI).

Statistical analyses were carried out using SPSS Statistical software version 12.0. p value for all primary and secondary outcomes was measured and p values < 0.05 was considered significant.

Results

Patients in both the groups were statistically similar regarding patient demographics, underlying illness, number of catheter days, associated conditions and the diagnosis. More than 60% patients in both the groups had the right internal jugular vein cannulated and the next commonest vein to be cannulated was right subclavian vein. The left sided internal jugular and left subclavian was not the vein of choice for cannulation. More than three quarter of patients in both the groups were cannulated using Triple Lumen Central line. Strict aseptic precautions were followed in maintaining the lumens and asepsis of the hub was also ensured. The total number of the Central Catheter days was 583 in Group I. The average days of central catheter per patient were 5.83 days. This was comparable with Group II in which the total number of central catheter days was 606 with average days per patient being 6.06. This difference was not statistically significant.

In Group I where the Open Infusion system was used, the incidence of CLABSI (Central Line Associated Blood Stream Infection) was 11 out of 100 patients or 11%. This was an incidence density of 18.86 CLABSI per 1000 central catheter days.

In Group II however, the incidence of CLABSI was 4 out of 100 patients (4%). The incidence density of CLABSI was 6.60 per 1000 central catheter days. The p value of number of patients who got CLABSI was 0.014, which means that a significant number of patients developed CLABSI in Open System group as compared to the Closed system group. Similarly there was a statistically significant difference in the incidence density of CLABSI per 1000 central catheter days with p value of 0.011. (Table1)

Table 1: Incidence of CLABSI

INCIDENCE OF CLABSI				
	Group I	Group II	95% CI	p value
Central Catheter days (n)	583	606		
CLABSI (n)	11	04		
CLABSI / 1000 central catheter days	18.86	6.60	0.21-0.82	0.011
% patients with CLABSI	11	4	0.22-0.86	0.014

In Group I, of the 11 CLABSI cases only 7 (63%) patients had Laboratory confirmed culture positive CLABSI. Of this 42% had Blood culture positive for blood drawn from peripheral line and 58% had Central catheter tip culture positive. 45% of these patients also had associated Fever of > 100^{0}F. 80% (4) of the patients with fever had associated chills. Inotropic support was required in 27% of patients who developed hypotension. Only 03 patients showed leucocytosis with TLC > 11,000/cu mm. In Group II, all patients had CLABSI with evidence of Laboratory confirmed blood culture positivity in blood drawn from a peripheral site. All patients had fever and associated chills and one patient had leucocytosis. (Table 2)

Table 2: Microbial Profile of CLABSI

MICROBIAL PROFILE OF CLABSI		
Micro-organism	Group I	Group II
Culture documented CLABSI n (%)	07 (63%)	02 (50%)
Blood Culture positive n (%)	03 (42%)	02 (100%)
Catheter tip culture positive n (%)	04 (58%)	-
Gram positive bacteria n (%)	06 (85%)	02 (100%)
Gram negative bacteria n (%)	1 (15%)	-
Fungus n (%)	-	-

The microbial picture showed Gram positive organism in majority of Laboratory confirmed CLABSI and none had fungal growth. Of the remaining 37% patients, the fever resolved on removal of the central line, and hence a diagnosis of CLABSI with indirect evidence was made in these patients.

Discussion

Contamination of infusate or catheter hubs of the central catheter access have resulted in epidemics of infusion-related CLABSI. The risk of extrinsic contamination of infusate during administration in the hospital has been reduced with widespread use of closed infusion systems. However, open infusion systems are still widely used throughout the world. A high rate of CLABSI was associated with use of open infusion containers in this study, whereas there was a significant reduction in CLABSI rate with use of a closed infusion container. [7]

Rosenthal et al examined the timing of when the first CLABSI was acquired comparing open versus closed infusion containers. Prior investigation published in 2004 did not include this additional analysis. From this additional analysis, it was demonstrated that when using an open infusion container, the risk of acquiring CLABSI increases over time. However, if the patient receives infusate via a closed infusion container, the probability of acquiring a CLABSI remains relatively constant. The patient also acquires a CLABSI significantly later, suggesting that closed infusion containers reduce risk of CLABSI acquisition over time. Subsequently, the use of a closed infusion containers could especially benefit those patients with more severe illness who may require Central catheters for longer periods of time. The delayed onset of CLABSI may also benefit patients with Central catheters early during the course of treatment when their underlying illness might be most severe. Our study design did not permit us to study the timing of first appearance of CLABSI.

Along with the use of Baxter viaflex containers for closed group, we also used VAMP system. This provided an additional advantage of needleless blood sampling. It also aborted the chances of needle stick injuries in the healthcare personnel, and conserved blood while sampling. The self-sealing sampling port minimized the risk of system being exposed to the ambient air and thus the risk of contamination, making the system totally closed. [8]

In our study, blinding the treatment assignment was not practical. In order to minimize the effects of confounding factors no new infection control interventions, training programs, products or technologies were introduced during the study periods and all of the investigators, key study personnel and diagnostic techniques remained constant throughout the study.

Another study limitation was that the study design did not allow for determination of the epidemiologic mechanisms responsible for the striking differences in outcome (e.g., reduced contamination of infusate).

In a separate study by Munoz et al (1997), infusions were cultured at a second-level general teaching hospital in Mexico wherein a 29.6% contamination rate was found during the baseline period. A 2% contamination rate was reported by Macias et al (1999) in a multi-center cross-sectional study in Mexico; lapses in aseptic technique, and breaks in the infusion system while injecting IV medications were risk factors for in-use contamination. [9,10]

Time to CLABSI in open and closed container are apparently related to increased attributable mortality as reported by Pittet and colleagues [11,12] who cited an attributable mortality of 25%. The CDC guideline for prevention of CLABSI recommends limiting manipulations of and entry into running infusions, and that persons handling or entering an infusion should first wash their hands or wear clean gloves. Our findings pose questions about the safety of all open i.v. infusion containers (rigid glass, burette or semi-rigid plastic containers). We have demonstrated that the adoption of a closed i.v. infusion container alongwith VAMP system will prevent cases of CLABSI. Many hospitals still use open rigid or semi-rigid i.v. fluid containers which must be vented to allow ambient air entry and fluid egress. Switching to closed, non-vented, fully collapsible bags, with VAMP System, could substantially reduce rates of CLABSI.

Conclusion

This study has demonstrated that the use of closed infusion containers with VAMP (Venous Arterial Management Protection) System prevents CLABSI (central line associated blood stream infection) and reduces mortality. Hospitals that continue to use burettes and/or open rigid or semi-rigid fluid containers (which must be vented to allow ambient air entry and fluid egress) should evaluate switching to closed, non-vented, fully collapsible bags along with VAMP System to reduce rate of CLABSI, the probability of acquiring CLAB, and mortality.

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