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Prevent Bloodstream Infections by Using Appropriate Devices

Situation

Catheter-associated infections include exit, tunnel, pocket and bloodstream infections. In the United States, when these types of infections occur, they extend the length of hospital stays by an average of 12 days and result in an additional cost of some USD18,432 per patient.¹ As reported by the U.S. Centers for Disease Control (CDC), some 250,000 bloodstream infections (BSIs) resulting from central vascular catheters (CVCs) have been estimated to occur annually,² with an estimated death rate of some 12 - 25 percent (30,000 - 62,500) as a result of catheter-related bloodstream infections (CRBSIs). The prevention of CRBSIs is important for improving patient outcomes, and depends on having appropriate medical care, product guidelines, and infection control.

Potential Factors in Catheter Infection

Examples of the potential factors related to the catheter infection risk include:

1. The length of time the catheter remains inserted.
2. The frequency with which the catheter is inserted and removed.
3. The use of a multiple-lumen catheter.
4. Immunosuppression.

Local infection often arises in such areas as the catheter insertion site, or the tunnel for, or pocket of, an implanted port, and can occur concurrently with a BSI. The indications include local oppressive pain, the sensation of heat, sweating, hardened areas, and pus discharge.⁴ These can be identified by visual examination and by lightly tapping the dressing over an insertion site, tunnel, or port pocket. Should any abnormality be detected, the dressing should be removed and the site carefully inspected.³

Evaluating Catheter-related BSIs

- Regularly check catheter insertion sites.
- Observe a patient's general condition (including for fever, chills, sweating, malaise, lassitude, muscular pain, weakening,

tachycardia, changes in consciousness, and sharp pain).

- Pay attention to immunosuppressed patients, because symptoms of infection are not readily apparent.
- When infection is suspected, promptly start treatment (with blood culture, antibiotics) as instructed by the doctor. It has been estimated that fatalities exceed 50 percent for patients not treated within 24 hours of the onset of infection.

Reduce CRBSIs with Needleless Systems

Use of needleless systems is included in the 2011 CDC guidelines for preventing intravascular catheter-related infections: "a split septum valve may be preferred over a mechanical valve due to increased risk of infection with some mechanical valves."⁵ The recommendation was added because the CDC found evidence that the structure of needleless systems affects the incidence of CRBSIs.⁶ A study provides strong evidence that both positive- and negative-pressure mechanical valves are linked to increases in CRBSIs, in conditions where the CRBSIs, surveillance methods, and infection prevention measures are the same.⁷ When switching from a split septum to a positive- or negative-pressure mechanical valve, an increase in CRBSIs was observed in all ICUs and wards. In addition, switching the valves back to a split septum resulted in a significant decrease in CRBSIs in 14 ICU rooms. When planning the introduction of a closed type IV needleless system, hospital staff should keep an eye on CRBSIs to ascertain whether they result from use of mechanical valves.

Efficacy of PICCs in Reducing CLABSIs

The peripherally inserted central catheter (PICC) is a CVC that is inserted through elbow, forearm, or upper arm veins and places the catheter tip into the central vein. According to Morikane et al. (2009),¹⁰ it has been reported that PICC procedures reduce the rate of central line-associated bloodstream infection (CLABSI)

by approximately 45 percent compared with that of CVC procedures through the subclavian vein or jugular vein. In addition, the total cost of treatment per hospitalization decreases, given that the CLABSI-related cost of antibiotics (some JPY410,000 per infection) and additional hospitalization (about 22 days per infection) can be avoided.

Further, use of PICCs not only reduces the incidence of infection on insertion, but can ensure safety. The anti-reflux PICC reportedly decreases the risk of catheter occlusion caused by the anti-reflux valve, which is designed to resist backflow when the catheter is not being used.⁸⁻¹⁸

Current Policy

In Japan, medical fees are set without taking into account the possible use of medical devices to prevent CRBSI, and the pricing rules for Special Treatment Materials lack incentives for developing such devices.

Moreover, according to the Special Treatment Materials system, PICCs are classified as central venous catheters, which are further divided into subcategories, such as standard type and antithrombotic type. In April 2010, when the anti-reflux valve PICC was introduced, the reimbursement that was set for the standard type catheter (single lumen: JPY1,740; multilumen JPY2,870) was revised to JPY13,800. Following the 2012 revision, however, the reimbursement is now set at JPY12,900. As a result of the revisions that have taken place, the gap has closed between the price of a single lumen anti-reflux PICC (basic kit: JPY16,000; microintroducer kit: JPY24,000) and the reimbursement. This, in turn, has reduced the incentive for hospitals to purchase PICCs, since hospitals where the DPC/PPS system has been introduced avoid using expensive products, even if they help prevent infection.

In the case of double lumen anti-reflux PICCs

(basic kit: JPY32,000; microintroducer kit: JPY40,000), the gap between the hospital purchasing price and the reimbursement is significant. Therefore, for financial reasons, hospitals may avoid using these catheters, setting aside necessity and high clinical efficacy. Since April 2014, the anti-reflux valve PICC has been separated into single lumen and multiple lumens. Reimbursement for a single lumen is now set at JPY13,200 and JPY20,500 for multiple lumens. Although the material costs may rise with the use of PICCs, overall, use of these catheters will reduce cost, through reductions in medical treatment and the management of complications, while enhancing patient safety.

Recommendations

- Encourage medical institutions to use innovative medical products as an integral part of their infection control policies.
- Ensure medical fees reflect the cost and use of medical devices and materials, in both inpatient and outpatient settings.
- Revise reimbursements for PICCs upward, considering the clinical efficacy and economic efficiency of PICCs from a healthcare perspective.

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15. Low infection rate from PICCs (evidence Level I). In the Guidelines for the prevention of intravascular catheter-related infections (2002), use of PICCs was reported to have caused fewer instances of CRBSI than conventional CVCs. In the meta-analysis by Crnich et al. (2002), it was reported that, when catheter insertion exceeds 1,000 days, PICCs had a statistically lower rate of CRBSI occurrence (0.4) than non-tunnel CVCs without coating (2.3).
16. Lower infection rate for anti-reflux valve PICCs (domestic, evidence Level II). According to Morikane et al. (2009), the number of CRBSIs occurring when catheter placement exceeds 1,000 days is 5.6 for anti-reflux valve PICCs and 7.0 for non-tunnel CVCs. When a logistic regression analysis was conducted on CRBSI factors, it was reported that anti-reflux valve PICCs were a factor (odds ratio 0.55, $p = 0.019$) that significantly reduced the risks of CRBSI occurrence. (The infection rate with 100 units can be translated into 17.8 percent for CVCs and 9.8 percent for PICCs.)
17. Safety of PICC insertion (evidence Level I – III). According to McGee et al. (2003), it is said there is roughly a 10 percent possibility of mechanical complications (including arterial puncture, hematoma, pneumothorax, and hemothorax) occurring for each CVC placement inserted through subclavian, internal jugular, and femoral veins (evidence Level I). Furthermore, the British National Health Service (2002) reported one fatality from among 3,000 CVC procedures as a result of a procedure-induced pneumothorax. Based on these findings, in 2008 the Japanese joint commission on medical safety and collective action plans published the second version of a how-to guide, in order to “prevent fatalities attributable to mechanical complications.” The book recommends that insertion through

the subclavian or internal jugular vein should be avoided, and that the procedure should, instead, be from the upper arm, where safety can be assured, with mechanical complications reduced 10 percent, safety ensured, medical costs resulting from complications reduced, adverse physician–patient relations avoided, and the overall quality of healthcare improved. PICCs are considered extremely safe, both theoretically and clinically, and can be inserted without serious complications. In fact, Morikane’s multicentre trials reported no serious complications following insertion of anti-reflux valve PICCs.

18. Low occlusion rate and simple care and maintenance with anti-reflux valve PICCs (evidence Level III). According to a cost savings clinical report (evidence Level III) by Hinson et al., (1996), anti-reflux valve PICCs have a lower catheter occlusion rate compared with standard PICCs. In addition, with the lower frequency of medication use to prevent occlusions and fewer catheter replacements, cost relative to care and maintenance reportedly can be reduced. Furthermore, since a heparin lock is not necessary, anti-reflux valve PICCs are suitable for intermittent chemotherapy and infusion therapy by homecare workers.

37. Guidelines on Prevention of Catheter Related Blood Stream Infections

2008

SHEA, IDSA “Strategies to prevent central line-associated bloodstream infections (CLABSI) in acute care”

Do not routinely use positive-pressure needleless connectors with mechanical valves before a thorough assessment of risks, benefits, and education regarding proper use (B-II) (Maragakis et al., 2006; Field et al., 2007; Salgado et al., 2007; Rupp et al., 2007).

Routine use of the currently marketed devices that are associated with an increased risk of CLABSI is not recommended.

2011

CDC - Guidelines for the prevention of intravascular catheter-related infections

When needleless systems are used, a split septum valve may be preferred over some mechanical valves due to increased risk of infection with the mechanical valves [197–200]. Category II

From the above, increases of BSI is thought to be caused by inappropriate infection prevention, device design, or both, and it is necessary to understand the features of each device when selecting and using the device. It is necessary to reconfirm the management of infusion both in terms of software and hardware, e.g. whether or not CRBSI can be achieved, what is the appropriate use of the device, whether other measure for infection prevention is fully considered.