A prospective clinical trial on prevention of catheter contamination using the hub protection cap for needleless injection device

Jun Oto, MD,[a] Hideaki Imanaka, MD,[a] Masatoshi Konno, MD,[b] Emiko Nakataki, MD,[a] and Masaji Nishimura, MD[a]
Tokushima and Tokyo, Japan

Background: Catheter hub contamination has been recognized as a source of catheter-related bloodstream infections. We have investigated the efficacy of a protection cap for a needleless injection device in preventing intraluminal catheter contamination, compared with a conventional 3-way stopcock.

Methods: Adult patients requiring an intravascular catheter placement for at least 48 hours in an intensive care unit were randomly assigned to receive either the needleless injection device with protection cap (test group, n = 31, number of devices = 151) or with a conventional 3-way stopcock (comparator group, n = 33, number of devices = 179). To evaluate intraluminal contamination, we examined the bacteria isolated in the inline bacterial filters, which were attached downstream of the injection ports.

Results: The incidence of bacterial contamination was significantly different between the groups (test group 2/151 (1.3%) vs comparator group 11/179 (6.2%), $P = .04$). There was no correlation between the microbial contamination rate and the in situ time of catheter or numbers of injections.

Conclusion: The protection cap for needleless injection devices decreased microbial transfer from the injection port to the intraluminal fluid pathway and lowered the risk of catheter-related bloodstream infections.

Key Words: Needleless injection device; hub protection cap; catheter-related bloodstream infection; CR-BSI; intraluminal catheter contamination.

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Intravascular catheters are widely used in clinical practice, and their use can predispose a large number of patients at risk of catheter-related bloodstream infection (CR-BSI).[1,2] CR-BSI is particularly evident in critically ill patients and is associated with increases in morbidity and mortality, length of hospital stay, and medical costs.[2,3]

There are 2 main routes that microorganisms access intravascular catheters and reach the bloodstream: the spread of skin flora around the catheter insertion site and the catheter hub colonization with subsequent intraluminal spread to the intravascular portion of the catheter.[4] With long-term intravascular devices, the catheter hub is the most common site for CR-BSI.[4,5] To prevent CR-BSI, it is essential to reduce intraluminal microbial spread from the hubs toward the catheter tip.

The needleless injection devices have been primary introduced into clinical practice to reduce needlestick injuries.[6] In addition to reducing the rate of needlestick injury, they were claimed to lower the risk of contamination of the catheter by reducing manipulation time and avoidance of ports being left open.[7] However, studies investigating this hypothesis have produced conflicting results.[8-16] The increasing risks of CR-BSI by needleless injection devices were reported in the surgical and home health care setting when manufacturer guidelines were not strictly followed without thorough training.[8,9] Conversely, when an appropriate disinfection regime was employed, needleless injection devices decreased[10-13] the risk of infection acquired via catheter but at least did not increase it.[14-16]

The surface of needleless injection device is externally contaminated by microorganisms on the skin or the environment because the injection surface of the port is not protected.[10,13,14] Injection ports are recognized sites for microbial contamination and are usually disinfected by alcohol; however, previous studies showed that the technique did not reliably eliminate surface contamination.[10,14,17] In the in vitro setting, antiseptic barrier cap

From Emergency and Critical Care Medicine, Tokushima University Hospital, Tokushima, Japan[a]; and Teikyo University, Tokyo, Japan.[b]

Address correspondence to Jun Oto, MD, Department of Emergency and Critical Care Medicine, Tokushima University Hospital, 3-18-15 Kuramoto, Tokushima 770-8503, Japan. E-mail: joto@clin.med.tokushima-u.ac.jp.

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that allows a chlorhexidine-impregnated sponge to come into continuous contact with the needleless injection device seal provided high levels of protection even in the presence of heavy contamination.[17] However, no clinical trial has prospectively examined the efficacy of a protection cap to prevent the needleless injection device-related line contamination.

The aim of the present study was to investigate whether the needleless injection device with the protection cap reduced intraluminal contamination when compared with a standard 3-way stopcock. We performed a prospective, randomized, and comparative study to assess the efficacy of these devices in the prevention of needleless injection device-related line contamination.

MATERIALS AND METHODS

Setting and population

The study was conducted at Tokushima University Hospital, which is a tertiary care teaching hospital and has an infection control program with physicians trained in internal medicine, infectious disease, and hospital epidemiology, as well as infection control nurses. It has 10 medical-surgical intensive care unit beds. The study protocol was approved by the Ethical Committee of the hospital. Patients who required central venous catheter or peripheral venous catheter placement were enrolled into the study when they were admitted to the intensive care unit.

Intravenous infusion device and randomization

Informed consent was obtained from all participating patients. During the study period, patients were randomly allocated to receive intravenous infusion therapy with either the needleless injection device (Planecta SC, Japan Medical Supply Co, Ltd, Hiroshima, Japan) with protection cap (PN cover, Japan Medical Supply Co, Ltd) (test group) or conventional 3-way stopcock (Japan Medical Supply Co, Ltd) (comparator group). Randomization was controlled by the clinical research center of the hospital. Both the 3-way stopcock and the needleless injection device were set in the middle of the intravenous infusion line. A bacteria filter (F-2 filter, pore size: 0.2 μm, membrane size: 10 cm^2; Japan Medical Supply, Co, Ltd) was inserted downstream of the needleless injection device or 3-way stopcock (Fig 1). All intravenous injection fluids, additives, and medications were administered from the needleless injection device or 3-way stopcock upstream of the filter. All antibiotics and the drugs that do not pass through the bacteria filter were injected through the injection ports placed downstream of the filter. To prevent back flow from antibiotic injection port, the infusion line was locked by a clip upstream of the port during antibiotic infusion (Fig 1). Intravenous drug therapy was determined by the attending physician. Data were excluded when any of the following cases were noted: accidental removal of the catheter, accidental administration of antibiotics through the bacterial filter, use of <48 hours or no infusion through the 3-way stopcocks or needleless injection devices, loss of microbiologic cultures because of technical reasons.

The needleless injection device and protection cap

The needleless injection device (Planecta SC) was a split-septum needleless injection device, which consisted of a main body and a synthetic rubber septum with preslit. When a syringe is inserted, a membrane slit is opened allowing infusion. The rubber slit then reseals upon removal of the syringe. The protection cap (PN cover) was a simple clip-on polypropylene device, and it can cover all areas of the membrane surface of the injection port completely (Fig 1).

Hub and infusion line manipulation

The injection ports were used for single shot of drug or continuous infusion. When the injection port was used, the protection cap was detached. The needleless injection device was disinfected with 84% ethanol containing 4% isopropyl alcohol swab twice, with a drying time of at least 30 seconds, and the surface of the device was confirmed to be dry before each use. Next, the surface was wiped, and the protection cap was recapped. The 3-way stopcocks and standard luer caps were also disinfected in the same way. All infusion lines contain infusion devices were in use at least 48 hours in clinical setting. All nursing staffs were reeducated every 3 months in the method for device disinfection. All staffs included in the present study were fully trained in the disinfection of the devices. After 72 hours of use in situ, both groups of infusion lines were considered to be changed aseptically.

Microbiologic analysis

The bacteria filter traps all microorganisms mechanically in infusate. In the present study, we defined the contamination rate of the filter as the contamination rate of the line. After clinical use, the whole infusion line was removed from the patient, and infusate was replaced with Soybean-Casein-Digest (SCD) bottles (Trypcase Soja (TSB-ST); bioMerieux s.a., Marcy l'Etoile, France) with meticulous care not to contaminate the line. One hundred milliliters of SCD broth was gravitationally passed through the infusion device and inline filter until no medium was left. The upstream side of

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