



SHORT REPORT

A prospective clinical study to investigate the microbial contamination of a needleless connector

V. M. Seymour, T. S. Dhallu*, H. A. Moss, S. E. Tebbs and T. S. J. Elliott

Department of Clinical Microbiology and *Department of Anaesthetics and Intensive Care, University Hospital Birmingham NHS Trust, Queen Elizabeth Hospital, Edgbaston, Birmingham B15 2TH

Summary: Needleless connectors, which allow direct access to intravascular catheters, are widely used in clinical practice. The benefits of these devices to healthcare workers are well documented; however, the potential risk of microbial contamination and associated infection is unclear. This clinical study evaluated microbial contamination rates for a needleless connector, Connecta Clave[®] (CC[®]), as compared to a conventional three-way tap, which was connected to the hubs of central venous catheters (CVC) immediately following insertion. Patients in the study group had CC[®] attached to the three-way taps, whereas the control group had standard entry port caps. On removal (up to 72 h) the connectors were studied for microbial contamination. There was no significant difference between the number of three-way taps contaminated on the internal surface with micro-organisms in the control group with entry port caps (19/132, 14%) compared to the group with CC[®] (18/105, 17%). Sixteen percent (27/173) of the CC[®] were contaminated with micro-organisms on the internal surfaces. The external surface of 33% (27/82) of the CC[®] silicone seals were contaminated after clinical use. Micro-organisms were also isolated from 9% (8/91) of the silicone seals after disinfection. The use of this needleless connector, compared to standard caps therefore does not appear to increase the risk of infection via the internal lumen of three-way taps.

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Introduction

Needleless connectors have been introduced for use with intravascular catheters to reduce the risk of needlestick injury to healthcare workers.¹ These devices allow access to the patient's blood-stream for drug administration and monitoring via directly-attached syringes or by giving sets, thereby

eliminating the requirement of needles. The cost of needleless connectors have also been shown to be comparable to entry port caps, when the financial implications of needlestick injuries are taken into account.² It is, however, currently unclear whether or not these devices may act as a portal of entry for micro-organisms to central venous catheters (CVC).³ Micro-organisms may gain access to intravascular catheters through their internal lumen, via stopcocks and connectors.⁴ Colonization by this route is an important factor in the development of catheter-related sepsis (CRS).^{5–8} To date there have been only a limited number of studies on the potential of needleless connectors as a source of CRS. Seven cases of Gram-negative bacteraemia occurred when a needleless dispensing pin was used

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Author for correspondence: Professor T. S. J. Elliott, Department of Clinical Microbiology, Queen Elizabeth Hospital, Edgbaston, Birmingham B15 2TH.

Tel.: 0121 627 2366; Fax: 0121 414 1682;

E-mail: mary.mcdermott@university-b.wmids.nhs.uk

to withdraw saline.⁵ Similarly, an increase in bacteraemia associated with needleless devices in patients who were receiving home therapy has been reported.⁶ Conversely, other studies have shown no increased risk of CRS when needleless devices were used with appropriate aseptic technique.⁷

The Connecta Clave[®] (CC[®], ICU Medical Inc., San Clements, CA 92673, USA) is a needleless device which can be attached by a thread-lock to the entry ports of IV catheters or three-way taps.³ Unlike three-way tap entry port caps, the CC[®] does not require removal before, or replacement after, each manipulation. The risk of contaminating entry ports by re-using caps or leaving entry ports uncovered could therefore potentially be reduced. It has also been suggested that handling time is reduced when needleless connectors such as the CC[®] are used in place of a three-way tap with entry-port caps.³ A reduction in manipulation of such devices during infusion may also lead to a decrease in microbial contamination. The closed system design of the CC[®] allows fluids to be infused via an internal pathway without contacting the external silicone compression seal. This design feature may potentially further prevent micro-organisms from gaining access to the catheter. The present study evaluated the microbial contamination rate of the CC[®] compared to conventional three-way taps in clinical practice.

Methods

Patients

Ethical committee approval for the study was obtained before commencement. Patients admitted for a coronary artery bypass graft or heart-valve replacement and who required CVC for their clinical management were entered into the study, after giving informed consent. Immediately after catheter insertion, patients had three-way taps attached to the CVC hubs. Patients in the study group then had CC[®] placed on the entry ports of the three-way taps, whereas those in the control group had the standard entry port caps attached. Up to four three-way taps were attached to the catheter hubs of the CVC, resulting in a variable number of entry port caps or CC[®] per patient.

Connecta Clave[®] was used as recommended by the manufacturer. Prior to manipulation the silicone compression seal of the device was cleaned with a 70% isopropanol swab (Steret, Seton Healthcare,

Oldham, UK) which was allowed to dry for 2 min. All CC[®] were left in place for up to 72 h before removal. In comparison, the three-way taps with entry port caps were sprayed with 70% isopropanol which was allowed to dry for 2 min. After manipulation, new sterile entry port caps were placed on to the three-way taps. Following use (up to 72 h), three-way taps with CC[®] or entry port caps attached were removed aseptically and placed in a sterile container.

Determination of microbial colonization of three-way taps

The entry ports of three-way taps were sampled by inserting a sterile nasopharyngeal swab (Bibby Sterilin Ltd, Abergargaed, UK) moistened in brain-heart infusion broth (BHI) into the port and rotating through 360°, 10 times. The swab was then inoculated on to a Columbia agar plate containing 7% defibrinated horse blood and incubated at 37°C in air for 48 h.

The number of micro-organisms present within the three-way tap following swabbing was also determined by flushing 100 µL of BHI through the port. Eighty mL of the BHI flush were then inoculated on to the surface of a blood agar plate and incubated as described above.

Assessment of microbial contamination of the CC[®]

Sampling the external CC[®] surface

Ninety-one CC[®] received from the first 19 patients were cleaned by passing a 70% isopropanol swab 10 times over the surface of the silicone compression seal which was then allowed to dry for 2 min. Eighty-two CC[®], received from the remaining 16 study group patients, were not cleaned prior to sampling the external surface, in order to determine the number of CC[®] that were contaminated after clinical use. The compression seals of the CC[®] were sampled by imprinting the silicone surface of the device on to the surface of a blood agar plate 10 times, which was then incubated as above.

Sampling the internal surface of the CC[®]

After sampling of the external surface of the CC[®], the internal surface was sampled for microbial contamination. The silicone compression seals of all CC[®] (173) were disinfected with 70% isopropanol, as above, prior to 100 µL BHI being flushed through the device. Eighty millilitres of the flush

fluid was collected and inoculated on to the surface of a blood agar plate which was incubated as above.

Statistical analysis

Data obtained from the two independent patient groups were analysed by the chi-square (χ^2) test.

Results

Patients

A total of 77 patients, with a mean age of 62 years (range 46–77), was studied. The control group consisted of 42 patients from whom a total of 132 three-way taps was examined. The study group consisted of 35 patients from whom 105 three-way taps and 173 CC[®] were examined.

Microbial contamination of CC[®]

The external silicone compression seals of the CC[®] were sampled either following cleaning ($N=91$) or immediately after clinical use ($N=82$). Micro-organisms were isolated from eight (8.8%) compression seals that were cleaned prior to sampling, compared to 27 (32.9%) that were not. The use of isopropanol significantly reduced the number of externally contaminated CC[®] ($P<0.001$). After flushing with sterile BHI, 27 of the 173 CC[®] (15.6%) were found to be contaminated on the internal surface.

Microbial contamination of three-way taps

The numbers of three-way taps contaminated following clinical use are shown in Table I. There was no significant difference in numbers of contaminated entry ports of three-way taps with caps attached compared with those with CC[®] ($P>0.1$). Similarly, the microbial with contamination rate of the internal pathway of the three-way taps with

entry port caps and CC[®] were comparable ($P>0.1$), with similar numbers of micro-organisms being present in both groups.

Micro-organisms isolated from three-way taps and CC[®]

Similar numbers of micro-organisms were recovered from each patient group. Most positive cultures yielded growth of various species of coagulase-negative staphylococci (78%). Other Gram-positive skin commensals such as diphtheroid bacilli, *Micrococcus* spp. and viridans streptococci were isolated with an overall frequency of 14%. The remaining 8% of positive cultures yielded either coliforms or non-fermentative Gram-negative micro-organisms such as *Pseudomonas* spp. and *Stenotrophomonas* spp.

Discussion

Needleless connectors have been introduced into clinical practice to reduce the risk of needlestick injuries, to prevent entry ports being inadvertently left open and to facilitate aseptic technique.³ The associated risk of sepsis with these connectors has, however, not been fully evaluated. Some reports suggest that they may act as a potential source for microbial contamination, particularly when strict aseptic techniques are not applied⁶, whereas other findings suggest that they are relatively safe to use.⁷

In this current evaluation, many of the CC[®] were contaminated on both the internal and external surfaces following clinical use. Micro-organisms were present on the external surfaces of 9% of the silicone seals, despite thorough disinfection with isopropanol. These results did not concur with other studies in which similar disinfection procedures removed micro-organisms from all the devices, even when contaminated with a heavy inoculum.³ This difference may be explained by the deposition of blood in the clinical situation which

Table I Total number of three-way taps contaminated on the internal surfaces with micro-organisms

Patient group	Three-way taps		
	Total	No. from which micro-organisms were isolated	No. from which micro-organisms were not isolated
Three-way taps with entry port caps	132	19 (14.4%)	113 (85.6%)
Three-way taps with CC [®]	105	18 (17.1%)	87 (82.9%)

could offer the micro-organisms protection from the disinfectant. Further studies are needed to establish improved disinfection methods. Other regimes, for example those which involve two cycles of disinfection, have been shown to be more effective,³ but may not be practical in the clinical setting.

A high proportion of CC[®] in clinical use showed evidence of internal microbial contamination. This suggests that the internal mechanism of the connector, which is designed not to come into contact with the silicone seal or external surfaces, may have become contaminated during the injection process. Micro-organisms may also have been introduced via contaminated infusates, although this seems a less likely explanation due to stringent manufacturing processes of fluids intended for clinical use.

It was interesting that the three-way tap entry ports were contaminated at a similar rate when either an entry port cap or CC[®] was attached. This concurs with our previous studies which have shown three-way tap entry port contamination rates of 23% after three days use in the intensive therapy unit situation⁹ and suggests that the CC[®] offers no more risk of microbial contamination than the conventional three-way taps currently used. The CC[®] does, however, offer protection from needlestick injury, and it is conceivable that with improved cleaning schedules it may also reduce the risk of sepsis.

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