Is there evidence for recommending needleless closed catheter access systems in guidelines: a systematic review of randomized controlled trials

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CRD summary
This review assessed different vascular access systems in hospitalised patients with intravascular catheters in terms of the prevention of catheter-related infections. The authors concluded that there is insufficient evidence at this stage to recommend the use of needleless closed catheter access systems. Overall, this was a well-conducted review and the authors’ tentative conclusions appear appropriate.

Authors’ objectives
To determine whether certain vascular access policies are better than others in terms of the prevention of catheter-related infections.

Searching
MEDLINE, the Cochrane Library and EMBASE were searched to May 2005 for published studies; the search terms were reported. The reference lists of included studies were checked for additional relevant publications. No language restrictions were applied.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs), quasi-randomised trials, and systematic reviews and meta-analyses of RCTs or quasi-randomised trials were eligible for inclusion.

Specific interventions included in the review
Studies that assessed vascular access gained by needleless closed systems, conventional closed systems or conventional open systems were eligible for inclusion. The included studies compared needleless closed systems with conventional open systems and needleless closed systems with conventional closed systems. The types of needleless connectors used were CLAVE (ICU Medical, Inc., San Clemente, USA), PosiFlow (Becton Dickinson, Utah, USA), Multiflo hub (Clave, Ohmeda, Trappes, France), Multilumen Smartsite DNFC (Alaris Medical Systems, San Diego, USA) and the InterLink System. Where specified, conventional open systems used standard luer caps or standard luer caps with a hub protection box which was impregnated with antiseptic twice daily. Conventional closed systems used the PRN Luer slip adaptor.

Participants included in the review
Studies of patients in the hospital setting, with intravascular catheters in situ, were eligible for inclusion. The patients in the included studies had diverse underlying diseases and diverse types and numbers of intravascular lines: major heart surgery patients with several intravascular lines simultaneously; cardiac surgery patients with a central venous catheter with several access points; medical, surgical and trauma patients with a multi-lumen central venous catheter; patients (unclear specification) with a central venous catheter; diabetic and immunosuppressed patients who required intravenous placement for blood drawing for up to 3 days.

Outcomes assessed in the review
Studies that reported sufficient data for calculating the risks of catheter-related infection in the treatment and control groups were eligible for inclusion. The studies reported data related to:

- catheter-associated bloodstream infection, defined according to the Centers for Disease Control and Prevention criteria;
- catheter tip colonisation, defined as the presence of 15 or more colony-forming units (cfu)/mL in the semiquantitative culture described by Maki et al. (reference given), or the isolation of at least 1,000 cfu/mL in an unclearly specified semiquantitative culture technique;
hub inlet colonisation, defined as the presence of bacteria in a standard semiquantitative culture or the isolation of at least 100 cfu/mL in the semiquantitative culture;

skin colonisation around the insertion site, defined as the presence of bacteria in a standard semiquantitative culture; and

adaptor fluid colonisation, defined as any growth on blood agar incubated for 4 days or in tryptic soy broth incubated for 7 days.

How were decisions on the relevance of primary studies made?
Two reviewers independently assessed studies for inclusion in the review. Any disagreements were resolved through discussion with a third reviewer.

Assessment of study quality
The studies were assessed for adequacy of randomisation, concealment of allocation, description of drop-outs, and whether the analysis was on an intention-to-treat basis. They were also assessed for subject-specific quality criteria, whether the trial groups were comparable for systemic antibiotic use, and the number of catheter-days within each study. Catheter-days was defined as the number of intravascular catheters that a patient received, multiplied by the number of days the catheters were in situ.

Two reviewers independently assessed the quality of the included studies. Any disagreements were resolved through discussion with a third reviewer.

Data extraction
Three reviewers independently extracted the data from the included studies and their data extraction was cross-checked. For categorical outcomes, relative risks (RRs) and 95% confidence intervals (CIs) were extracted. If the mean duration of catheterisation was not comparable between trial groups, the incidence-density relative rates were calculated as the total number of events divided by total catheter-days of follow-up. For continuous outcomes, means and standard deviations (SDs) were extracted.

Methods of synthesis
How were the studies combined?
Owing to clinical heterogeneity, the studies were combined in a narrative. In the absence of heterogeneity, the authors had planned to use a random-effects model to calculate the overall RR and 95% CI for categorical outcomes and the weighted mean difference for continuous outcomes.

How were differences between studies investigated?
The authors did not state how heterogeneity was assessed.

Results of the review
Five RCTs were included in the review. The authors did not report the number of included patients, but the number of access points was at least 3,179.

The quality of the included trials was poor: generation of the random allocation sequence and the concealment of allocation were unclear in all trials; four trials did not describe whether patients were lost after randomisation; and an intention-to-treat analysis was described in two trials. In one trial patients in the control group received more antibiotics than those in the intervention group, while two trials did not report data on antibiotic use. The trial groups were comparable for number of catheter-days in three trials; this was unclear in two trials.

Needleless closed systems versus conventional open systems (4 RCTs).

Three RCTs reported data related to catheter-associated bloodstream infection; there were no statistically significant
differences between the groups.

Three RCTs reported data related to catheter tip colonisation. Two found that the results were better in the needleless closed system group, but the difference only reached statistical significance in one trial (RR 0.63, 95% CI: 0.50, 0.80). The other trial found that the results were better in the conventional open system group, but the difference did not reach statistical significance.

Three RCTs (5 comparisons) reported data related to hub inlet colonisation. In four comparisons, colonisation of the hub inlet was more common in patients with the conventional open system; this was statistically significant in three comparisons (RR 0.30, 95% CI: 0.16, 0.56; RR 0.07, 95% CI: 0.01, 0.49; RR 0.46, 95% CI: 0.22, 0.94). The other trial reported that colonisation of the hub inlet was more common in the needleless closed system, but the difference did not reach statistical significance.

One RCT reported data related to skin colonisation around the insertion site. The results were statistically significantly better in the needleless closed group (RR 0.70, 95% CI: 0.54, 0.90).

Needleless closed systems versus conventional closed systems (1 RCT).

The RCT reported that the conventional closed system group had better results in terms of fewer patients with a colonised catheter tip, but there was more colonisation of the adaptor fluid; neither result reached statistical significance.

Authors' conclusions
The authors concluded that, from the point of view of infection prevention, there are no objections to using needleless closed catheter access systems. However, there is insufficient evidence at this stage to recommend their use.

CRD commentary
The review question was clear in terms of the study designs, participants, interventions and outcomes of interest. The authors searched three relevant electronic databases. However, only published studies were eligible for inclusion, thus increasing the potential for publication bias. The study selection and quality assessment processes were carried out in duplicate, while the data extraction was carried out in triplicate; this helps reduce the potential for reviewer bias or errors. Adequate details of the included studies were provided and full quality assessment results were presented. The narrative synthesis appeared appropriate in view of the clinical heterogeneity present.

Overall, this was a well-conducted and reported systematic review and the authors' tentative conclusions appear appropriate in view of the low quality of the included trials.

Implications of the review for practice and research
Practice: The authors stated that there was insufficient evidence to recommend the use of needleless closed catheter access systems.

Research: The authors stated that further research is required to confirm whether needleless closed catheter access systems reduce catheter-related infections and, if so, whether they are cost-effective.

Bibliographic details

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**Record Status**
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.