State of the Science Review

Methods for microbial needleless connector decontamination: A systematic review and meta-analysis

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Background: The objective of this review was to compare the effectiveness of connector decontamination with 70% alcohol wipes, alcoholic chlorhexidine gluconate wipes, or alcohol impregnated caps to prevent catheter-associated bloodstream infection (CABS). The exclusion criteria were: multimodal interventions, letters, and conference abstracts. Quality assessment with the Newcastle-Ottawa Scale, a narrative synthesis, and meta-analysis were conducted. Pooled data used a random effects model for pair-wise comparisons, due to clinical heterogeneity. Statistical heterogeneity was investigated by visual model inspection, χ², and I² statistics.

Methods: A systematic search was conducted in CINAHL, Cochrane Central Register of Controlled Trials, Medline, and PubMed. The primary outcome was CABS, with randomized and observational studies included. The inclusion criteria were: English language, any age group, no date limitations, and reporting connector decontamination interventions to prevent CABS. The results were analyzed with the Cochrane tool for assessing risk of bias.

Results: Ten studies compared 70% alcohol wipes with 70% alcohol-impregnated caps, and 2 studies (n = 1,216) tested an alcoholic chlorhexidine gluconate wipe. Alcoholic chlorhexidine gluconate wipes were associated with significantly less CABS than 70% alcohol wipes (risk ratio, 0.28; 95% confidence interval, 0.28-0.65). Studies were of low to moderate quality.

Conclusions: Alcohol impregnated caps and alcoholic chlorhexidine gluconate wipes were associated with significantly less CABS than 70% alcohol wipes. This requires confirmation in randomized controlled trials.

Since the 1990s, needleless connectors (NCs) have been used with vascular access devices to administer intravenous fluids, medications, blood products, and specialized treatments such as chemotherapy. Although NCs were introduced to reduce the risk of health care workers to needlestick injuries, some designs increase the risk of catheter-associated bloodstream infection (CABS). As they require a scrubbing mechanism during application, NCs can collect on the external surface of the NC.

The incidence of CABS can be up to 5.2%, with increased mortality in vulnerable populations. The most common and prevalent microorganisms associated with CABS are coagulase-negative Staphylococci, Staphylococcus aureus, and S. epidermidis. Currently, products for NC decontamination include wipes that contain either chlorhexidine gluconate (CHG) in 70% isopropyl alcohol (IPA) or 70% IPA alone. These are considered active decontamination, as they require a scrubbing mechanism during application. Alternatively, passive decontamination can be achieved with 70% IPA-impregnated caps, which are applied directly onto the NC, inverting the decontamination of the surface of the NC until the cap is removed and discarded prior to medication administration. To ensure decontamination, it is recommended that these products be applied for a minimum of 2-5 minutes, with a maximum use of 7 days.

There is little agreement in practice or clinical guidelines regarding the optimal decontamination type (active vs passive; IPA vs CHG). For example, United Kingdom guidelines (Epic3) recommend 2% CHG...
in IPA wipes, whereas some Australian guidelines recommend 70% IPA wipes. The Centers for Disease Control and Prevention guidelines suggest disinfection with a wipe, IPA, CHG in alcohol, or poviodone-iodine. In addition to these solutions, the Infusion Therapy Standards of Practice also recommends passive disinfection caps be considered.

With multiple decontaminant approaches recommended in guidelines, it is unclear which is the most effective. A recent systematic review highlighted the low quality of evidence for some products but did not directly compare all products available. An in vitro study highlighted the varying efficacy of a 70% IPA wipe, a 2% CHG in IPA wipe, and a 70% IPA-impregnated cap. In that study, 2% CHG and 70% IPA wipes (active decontamination) resulted in the greatest reduction of NC contamination. This laboratory study is not directly generalizable to the clinical setting. To our knowledge, to date, there has not been a direct comparison of all 3 products in the same clinical study or via meta-analysis. This has resulted in the uncertainty about the most clinical and cost-effective approach and underpins the considerable inconsistency in guidelines regarding the most effective approach to NC decontamination.

AIM AND RESEARCH QUESTION

The aim of this review was to evaluate the effectiveness of NC decontamination products to prevent CABSIs, addressing the following research question:

When comparing NC decontamination type (active: [eg, wipe] vs passive [eg, impregnated cap]) and solution (70% IPA vs CHG), which method is the most effective to prevent CABSIs?

METHODS

Design

A systematic review and meta-analysis were undertaken, based primarily on Cochrane Collaboration systematic review methodology, incorporating quality assessment using the Newcastle Ottawa Scale (NOS). The review was prospectively registered on PROSPERO (CRD42018026597).

Inclusion criteria

The review included interventional clinical research, published in peer-reviewed journals, with data available in English, with no date limitations, that compared NC decontamination products using either active (eg, wipe) or passive (eg, impregnated cap) decontamination type, on any vascular access device type (peripheral and central) to prevent CABSIs. The populations were any age group in any clinical setting. Only articles published in English were included. The aim was to search for randomized controlled trials (RCTs); however, in the absence of RCTs, observational studies were included.

Exclusion criteria

Studies that included a multimodal approach to reducing CABSIs, such as the implementation of a bundle, were excluded because of the inability to determine the impact of the co-interventions. Letters to the editor and conference abstracts were also excluded, because of the lack of peer review.

Primary outcome

The outcome for this review was any type of CABSIs. This was pragmatically chosen a priori because of the variety in CABSIs definitions reported in the literature. Studies were included that had a primary outcome of CABSIs, including catheter-related bloodstream infection. Results were reported as CABSIs events per 1,000 catheter days where available. If results were reported per 100 catheter days, this was converted to 1,000 catheter days for consistency.

Search strategy

A systematic literature search was conducted on August 9, 2018, using CINAHL, Cumulative Index to Nursing and Allied Health Literature, Cochrane Central Register of Controlled Trials, Medline, and PubMed. The search was developed in consultation with a health librarian using medical subject headings wherever possible involving: ([disinfect* OR decontaminat*] AND [vascular access device OR hub OR connector]). The references of included studies were hand searched.

Data extraction

Screening of titles and abstracts, and data extraction were performed by 2 reviewers independently (J.F. and E.L.). A third reviewer (S.K.) was consulted to resolve any disparities. Data extracted were standardized via a Microsoft Word data extraction tool and included patient population, setting, control, and interventions used (70% IPA wipe, CHG wipe, and a 70% IPA-impregnated cap), and results for CABSIs (including rate per 1,000 catheter days). For studies with missing data, the corresponding authors were requested to supply additional data via e-mail. However, no authors responded.

Determining the quality of the studies

The quality of nonrandomized studies was assessed using the NOS by 2 study authors independently (J.F. and E.L.), with a third author (S.K.) consulted for consensus. The range is from a low to a high quality score. The NOS evaluates 3 domains of study methodology: the selection of study groups, the comparability of study groups, and the quality of determining the outcomes of interest. The 3 domains include 9 questions: 1 = Representativeness of the exposed cohort; 2 = Selection of the non-exposed cohort; 3 = Ascertainment of exposure; 4 = Demonstration that outcome of interest was not present at start of study; 5A and 5B = Comparability of cohorts on the basis of the design or analysis; 6 = Assessment of outcome; 7 = Was follow-up long enough for outcomes to occur; and 8 = Adequacy of follow-up of cohorts.

Data synthesis

We initially conducted a narrative review of the included studies according to NC decontamination product and entered quantitative data into RevMan (Review Manager 5.3; The Cochrane Collaboration, Copenhagen, Denmark). Eligible data were pooled for meta-analysis, and we used a random effects model for pair-wise comparisons, due to clinical heterogeneity. The degree of statistical heterogeneity was investigated by a combination of methods that involved visual inspection of the meta-analytic model and interpretation of the $\chi^2$ and $I^2$ statistics that examine the total variance across studies due to heterogeneity rather than chance. This test examines the percentage of total variations across studies caused by heterogeneity: categorized as low (0%-40%), moderate (30%-60%), high (50%-90%), or very high (75%-100%). A sensitivity analysis was then performed including studies of moderate to high quality and studies with at least 100 participants. Forest plots were used to display the data, and dichotomous outcomes were presented as risk ratio (RR) with a 95% confidence interval (CI). A rate per event analysis was planned; however, this could not be conducted because of issues with data availability.
Publication bias

We intended to use a funnel plot to identify small-study effects and to assess for publication bias, but there was an insufficient number of studies to allow this.

RESULTS

Search strategy

The database searches revealed 572 (PubMed, n = 233; Medline EBSCO, n = 185; CINAHL EBSCO, n = 112; and Cochrane, n = 42) articles that were retrieved for title and abstract review, as shown in the PRISMA flow in Figure 1. Two additional articles were located from other sources. After review and removal of duplicates, 33 studies were obtained for full-text review. Twenty-one articles did not meet the inclusion or exclusion criteria. No RCTs were identified. Twelve pre-test/post-test observational studies were included in this review.

Study characteristics

As described in Table 1, the majority of included studies compared active decontamination using 70% IPA wipes with passive decontamination using 70% IPA impregnated caps, although the control was unclear in 1 article. The remaining 2 studies compared CHG in 70% IPA wipes versus 70% IPA wipes, both using active decontamination. Most studies reported data from 2 time points only (single-measure pre-post intervention), with the exception of Wright et al, Martino et al (3 time points), and Kamboj et al (4 time points). Reporting of CABSI varied; however, most studies reported rates per 1,000 catheter days. Most of the studies were conducted in the United States (n = 9), with the remaining studies conducted in the United Kingdom (n = 3). Ages ranged from neonates to the elderly, with all studies focused on central venous access devices, except for 2 studies, which also included PIVCs. Industry support was declared by 6 authors, not stated by 5 authors, with 1 author stating that no industry funding was received.
Characteristics of included studies

<table>
<thead>
<tr>
<th>Author, year, and country</th>
<th>Setting</th>
<th>Sample size</th>
<th>Control</th>
<th>Intervention</th>
<th>CABSI type</th>
<th>CABSI rate (^*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cameron-Watson et al, 2016, UK</td>
<td>Various patient populations with a PIVC, CVAD, or arterial catheter</td>
<td>Control: ND</td>
<td>Intervention: n = 1,094</td>
<td>70% IPA wipe</td>
<td>70% IPA cap</td>
<td>CRBSI</td>
</tr>
<tr>
<td>DeVries et al, 2014, USA</td>
<td>Adult ICU patients with a CVAD or PIVC</td>
<td>Control: 185,950 patient days</td>
<td>Intervention: 187,444 patient days</td>
<td>70% IPA wipe</td>
<td>70% IPA cap</td>
<td>BSI in CVADs and PIVCs</td>
</tr>
<tr>
<td>Kamboj et al, 2015, USA</td>
<td>High-risk units; and general oncology with a CVAD</td>
<td>Control: 84,427 catheter days</td>
<td>Intervention: 83,659 catheter days</td>
<td>70% IPA wipe</td>
<td>70% IPA cap</td>
<td>CABSI</td>
</tr>
<tr>
<td>Martino et al, 2017, USA</td>
<td>Burn patients with a CVAD</td>
<td>Control: n = 107 Time 1: n = 153 Time 2: n = 136 Time 3: n = 287</td>
<td>70% IPA wipe</td>
<td>70% IPA cap</td>
<td>CABSI</td>
<td></td>
</tr>
<tr>
<td>Merrill et al, 2014, USA</td>
<td>Newborns and adults with a CVAD</td>
<td>Control: ND</td>
<td>Intervention: n = 20-25</td>
<td>70% IPA wipe</td>
<td>70% IPA cap</td>
<td>CABSI</td>
</tr>
<tr>
<td>Pichler et al, 2014, UK</td>
<td>Pediatric patients on TPN with a CVAD</td>
<td>Control: n = 42</td>
<td>Intervention: n = 50</td>
<td>70% IPA wipe</td>
<td>70% IPA cap</td>
<td>CRBSI</td>
</tr>
<tr>
<td>Ramirez et al, 2012, USA</td>
<td>Adult ICU patients with a CVAD</td>
<td>Control: ND</td>
<td>70% IPA wipe</td>
<td>70% IPA cap</td>
<td>CABSI</td>
<td></td>
</tr>
<tr>
<td>Soothill et al, 2009, UK</td>
<td>Pediatric HSCT patients and non-HSCT patients with a CVAD</td>
<td>Control: n = 553</td>
<td>Intervention: n = 571</td>
<td>70% IPA wipe</td>
<td>70% IPA cap</td>
<td>CRBSI</td>
</tr>
<tr>
<td>Stango et al, 2014, USA</td>
<td>Newborns and adults with a CVAD</td>
<td>Unknown</td>
<td>70% IPA wipe</td>
<td>70% IPA cap</td>
<td>CABSI</td>
<td></td>
</tr>
<tr>
<td>Sweet et al, 2012, USA</td>
<td>Adult oncology patients with a CVAD</td>
<td>Control: n = 472</td>
<td>Intervention: n = 282</td>
<td>70% IPA wipe</td>
<td>70% IPA cap</td>
<td>CABSI</td>
</tr>
<tr>
<td>Wright et al, 2013, USA</td>
<td>Adult ICU patients with a CVAD</td>
<td>Phase 1: n = 252</td>
<td>Phase 2: n = 364</td>
<td>70% IPA wipe</td>
<td>70% IPA cap</td>
<td>CABSI</td>
</tr>
</tbody>
</table>

Quality assessment

Overall, the studies were of medium quality, with the majority of studies receiving 4-5 stars (Table 2).

Selection

The participants from most studies included a specific population such as infants; however, 2 studies included a wider population, with 1 study examining oncology, acute care of the elderly, critical care, and a surgical ward. All studies examined a similar population in the nonexposed and exposed cohort. Most studies could demonstrate that the outcome of interest was not present at the commencement of the study.

Comparability

All studies were pre-posttest in design. However, it was difficult to compare studies because of the lack of reported data. Four studies reported participant demographics.

Outcome

Assessment of outcome was varied. All but 1 study described the assessment of outcome by record linkage or independent blind assessment. However, only 2 studies indicated the follow-up period of participants, with no studies describing whether all participants were accounted for from the commencement of the study to completion of the follow-up time period.

Decontamination product: 70% IPA wipe versus 2% CHG in 70% IPA wipe

Only 2 studies compared a 70% IPA wipe to 2% CHG in 70% IPA wipe using active decontamination (n = 1,216). All studied populations were pediatric and neonatal patients.

As displayed in Figure 2, 2% CHG in IPA wipes were associated in the meta-analysis with significantly less CABSI, in comparison to IPA wipes (RR, 0.28; 95% CI, 0.20-0.39). There was low heterogeneity evident (χ² = 0.03; I² = 0%), as reflective of the study population.

CABSI rate per 1,000 catheter days

The CABSI rate ranged from 3.1-12.0 per 1,000 catheter days in the IPA wipe group and 0.4-3.0 in the CHG in IPA wipe group. Whereas CABSI per 1,000 catheter days was reported for both studies in this group, only 1 study reported the total number of catheter days per group. Therefore, we were unable to carry out meta-analysis of CLABSI per 1,000 catheter days.
Decontamination type: active (wipe) versus passive (impregnated cap)

Of the 10 studies that compared an IPA wipe with an IPA-impregnated cap, only 3 had sufficient patient-level data to be included in the meta-analysis. All 3 studies reported data as CABSI. As displayed in Figure 3, the IPA cap was associated with significantly less CABSI, in comparison to IPA wipes (RR, 0.43; 95% CI, 0.28-0.65). There was moderate statistical heterogeneity (χ² = 3.44; I² = 42%).

CABSI rate per 1,000 catheter days

For the 3 studies reported in the meta-analysis, CABSI ranged from 1.31-7.43 per 1,000 catheter days in the IPA wipe group and 0.3-9.0 in the IPA-impregnated cap group. CABSI per 1,000 catheter days was reported for the 3 studies in this meta-analysis; however, most studies did not report the number of catheter days per group. Owing to the lack of available data on total number of catheter days per group, we were unable to carry out meta-analysis per 1,000 catheter days.

Sensitivity analysis

Owing to few remaining studies, a sensitivity analysis was only undertaken for the passive decontamination using the IPA-impregnated cap versus the IPA wipes. Of the 5 studies in the primary meta-analysis, 2 were excluded for the sensitivity analyses: 1 because <100 participants were studied (active decontamination) and 1 because of a low-quality NOS (passive decontamination). The results indicated that IPA caps, in comparison to IPA wipes, were associated with significantly less CABSI, which was consistent with the primary analysis.

Table 2

<table>
<thead>
<tr>
<th>Author, year, and country</th>
<th>CHG wipes</th>
<th>IPA wipes</th>
<th>Risk Ratio (M-H, Fixed, 95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DeVries et al, 2014, USA</td>
<td>3</td>
<td>50</td>
<td>0.53 [0.31, 0.91]</td>
</tr>
<tr>
<td>Kamboj et al, 2015, USA</td>
<td>4</td>
<td>10</td>
<td>0.50 [0.27, 0.92]</td>
</tr>
<tr>
<td>Pavia and Mazza, 2016, USA</td>
<td>5</td>
<td>42</td>
<td>0.56 [0.30, 1.04]</td>
</tr>
<tr>
<td>Ramires et al, 2012, USA</td>
<td>6</td>
<td>50</td>
<td>0.54 [0.28, 1.06]</td>
</tr>
<tr>
<td>Soothill et al, 2009, UK</td>
<td>7</td>
<td>14</td>
<td>0.56 [0.27, 1.14]</td>
</tr>
<tr>
<td>Stango et al, 2011, USA</td>
<td>8</td>
<td>10</td>
<td>0.55 [0.28, 1.08]</td>
</tr>
<tr>
<td>Sweet et al, 2012, USA</td>
<td>9</td>
<td>20</td>
<td>0.55 [0.28, 1.09]</td>
</tr>
<tr>
<td>Wright et al, 2013, USA</td>
<td>10</td>
<td>10</td>
<td>0.55 [0.28, 1.09]</td>
</tr>
</tbody>
</table>

1, representativeness of the exposed cohort; 2, selection of the non-exposed cohort; 3, ascertainment of exposure; 4, demonstration that outcome of interest was not present at start of study; 5A, comparability of cohorts on the basis of the design or analysis; 5B, comparability of cohorts on the basis of the design or analysis; 6, assessment of outcome; 7, was follow-up long enough for outcomes to occur; 8, adequacy of follow-up of cohorts.
DISCUSSION
This systematic review and meta-analysis identified that CHG in IPA wipes (active decontamination) or IPA-impregnated caps (passive decontamination) for NC decontamination were associated with significantly lower CABSI risk than IPA wipes. These results suggest that despite widespread use, 70% IPA wipes are likely inadequate for NC decontamination.

Overall, 70% IPA wipes, in comparison to CHG wipes (active decontamination) or IPA-impregnated caps (passive decontamination), were associated with more CABSI, when used for NC decontamination. CHG in IPA wipes were associated with two-thirds less of a risk of CABSI than IPA wipes, with a highly precise estimate of effect (RR, 0.28; 95% CI, 0.20–0.39). In addition, 70% IPA caps were associated with less than one-half the risk of CABSI, than IPA wipes (RR, 0.43; 95% CI, 0.28–0.65). Therefore, the 70% alcohol wipe may be inadequate for NC decontamination.

Historically, CHG has been used more frequently as a skin antiseptic but is now recommended as an option for NC decontamination. Alcohol caps are also recommended, with additional disinfection if multiple vascular access device accesses are required. The practice of NC decontamination before and after every access is currently recommended by some guidelines, with no evidence to support this practice. Given the results of this meta-analysis, this recommendation seems prudent; however, RCTs of adequately large sample size are needed to confirm causality. An RCT comparing 70% IPA wipe, with a CHG wipe, and the 70% IPA-impregnated cap would assist in definitively determining which method of NC decontamination most effectively prevents CABSI.

There have been 2 previous systematic reviews comparing the 70% IPA wipe against the 70% IPA-impregnated cap. The first, highlighted the importance of NC decontamination; however, it did not include a meta-analysis and did not advocate for any 1 product over another. The second review included a meta-analysis of studies comparing an IPA wipe with an IPA-impregnated cap. This review identified that the IPA-impregnated cap was associated with significantly less CABSI, in comparison to IPA wipe (RR, 0.59, 95% CI 0.45–0.77). However, the authors also stated that an RCT is needed. Neither review included comparisons involving the CHG wipe, which is increasingly used for NC decontamination. Our findings regarding the superiority of IPA caps over IPA wipes, are consistent with these previous reviews.

We found only 2 studies that tested active decontamination with a CHG wipe, and the total number of participants included was relatively small (n = 1,216). Both studies reported catheter-related bloodstream infection. This method of NC decontamination is currently being suggested in some clinical guidelines with little evidence to support this. It could be concluded that use of a CHG in alcohol wipe is superior to alcohol alone for infection prevention; however, this has not been well established. It is also noted that CHG has prolonged decontamination activity; however, again, there is insufficient evidence whether this results in less CABSI.

Ten studies tested active decontamination with an alcohol wipe compared to passive decontamination using an alcohol-impregnated cap. All studies reported a reduction in bloodstream infection with passive decontamination. This method theoretically minimizes the risk for noncompliance when using active decontamination; however, this product is not yet widely used, and cost could be a limitation. For example, Reynard 70% alcohol wipes cost approximately $0.01 each; and Reynard 2% CHG in 70% alcohol prep pads cost approximately $0.02 each (https://www.pharmacydirect.com.au/), whereas the alcohol-impregnated cap can cost as much as $0.17 each. An acutely ill patient may require > 20 NC decontamination products each day leading to a total cost of a minimum of approximately $0.29, $0.43, and $3.33, respectively. Given the significant number of NC decontamination products used, even small differences in product cost can generate significant implications for hospital budgets. However, the costs associated with CABSI management can range from $17,896–$94,879, suggesting that the initial outlay of purchasing the NC decontamination products could be cost effective.

Although not addressed in this review, active decontamination, scrub time, drying time, and scrub technique are important. However, these remain as an unresolved issue in practice and research. The IPA and CHG wipes often contain from 0.6–1.5 mL of solution, making adequate drying time essential to ensure adequate exposure time for microorganism decontamination and that the solution does not inadvertently get infused into the bloodstream. Moreover, a chemical residue can form on the NC with the use of the CHG wipe. It remains unclear if this forms a protective barrier or may attract microorganisms to adhere to the NC. Moving forward, designing and conducting a clinical trial that accommodates and tests NC decontamination solution, method, and timing would be challenging, as this would lead to a potential 3 × 3 factorial trial, which, although clinically appropriate, may be challenging in practice.

STRENGTHS
This review supports previous reviews into similar NC decontamination products, concluding that the IPA wipe alone is potentially inadequate for NC decontamination. However, these results need to be taken with caution because of the lack of RCT evidence to confirm efficacy. To our knowledge, this review is also the first to include NC decontamination with a CHG in 70% IPA wipe, giving readers a wider understanding of the products available and their effectiveness. This review highlights the need for a suitably large RCT to provide evidence for the best approach for NC decontamination.

LIMITATIONS
The first limitation of the meta-analysis and review was the moderate study heterogeneity for the active versus passive IPA comparison, meaning the conclusions are more susceptible to change as new studies are conducted. Comparatively, the alcoholic CHG versus IPA wipe studies had low heterogeneity. Second, because of the absence of RCTs, only observational studies were included. RCTs are needed to identify cause and effect relationships and given the design of the included studies the true effect of the interventions may be underestimated or overestimated. Third, a rate-per-time period analysis could not be completed, owing to unavailability of data. This would have been a more sensitive examination of the effectiveness of these interventions. Future trials examining these interventions should report catheter days, to enable such analysis. Fourth, it is unclear if patients may have had >1 vascular access device as this was not reported. We assumed each patient only had 1 device, as no secondary devices were mentioned. Finally, not all studies reported what type of funding, if any, was received. If industry funding was received, this could potentially be a source of bias.

CONCLUSIONS
NC decontamination is an essential component of infection control practices in the health care system, and 70% IPA wipes are likely to be the least-effective approach currently available. Quality postinsertion and maintenance care of the vascular access device is essential to prevent CABSI. Both alcoholic CHG wipes and IPA passive decontamination caps are associated with significantly lower CABSI than IPA wipes in nonrandomized studies. However, there have been no high-quality RCTs undertaken on the impact of NC decontamination for the prevention of introducing microorganisms into this.
device. There is a lack of high-quality evidence to confirm the superi-
or decontamination method when accessing and maintaining a vas-
cular access device. With newer methods now available, RCTs are
urgently needed to establish the optimal decontamination method
to prevent CABSI.

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