Meta-analysis on central line–associated bloodstream infections associated with a needleless intravenous connector with a new engineering design

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Meta-analysis
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Needleless connector
Positive-displacement valve

Background: Intravenous needleless connectors (NCs) with a desired patient safety design may facilitate effective intravenous line care and reduce the risk for central line–associated bloodstream infection (CLA-BSI). We conducted a meta-analysis to determine the risk for CLA-BSI associated with the use of a new NC with an improved engineering design.

Methods: We reviewed MEDLINE, Cochrane Database of Systematic Reviews, Embase, ClinicalTrials.gov, and studies presented in 2010-2012 at infection control and infectious diseases meetings. Studies reporting the CLA-BSIs in patients using the positive-displacement NC (study NC) compared with negative- or neutral-displacement NCs were analyzed. We estimated the relative risk of CLA-BSIs with the study NC for the pooled effect using the random effects method.

Results: Seven studies met the inclusion criteria: 4 were conducted in intensive care units, 1 in a home health setting, and 2 in long-term acute care settings. In the comparator period, total central venous line (CL) days were 111,255; the CLA-BSI rate was 1.5 events per 1,000 CL days. In the study NC period, total CL days were 95,383; the CLA-BSI rate was 0.5 events per 1,000 CL days. The pooled CLA-BSI relative risk associated with the study NC was 0.37 (95% confidence interval, 0.16-0.90).

Conclusion: The NC with an improved engineering design is associated with lower CLA-BSI risk.

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Health care workers (HCWs) risk accidental needlestick injuries and potential infection with bloodborne pathogens (BBPs) such as hepatitis B or C viruses or HIV when they use needles in conjunction with intravenous (IV) therapy. With the emergence of HIV infections and AIDS in the 1980s, HCWs, their unions, and U.S. federal and state agencies that regulate occupational safety and health became concerned about the potential risk of BBP infection among HCWs. As a result, in 1992, the U.S. Occupational Safety and Health Administration recommended that health care facilities use engineering controls to help protect HCWs from these pathogens. The use of such controls, including IV needleless connector (NC) systems, when applicable, became mandatory under the Needlestick Safety and Prevention Act in 2001. The NCs that we see today evolved from the industry’s initial efforts to make devices that comply with these Occupational Safety and Health Administration regulations. They were primarily designed for HCW safety, to prevent accidental needlestick injuries and BBP infections. With the initial introduction of split septum NCs, outbreaks of central line–associated bloodstream infections (CLA-BSIs) occurred. With the re-emphasis on the importance of infection control practices with these devices (eg, septum disinfection, cap changes, etc), infection...
risk was lowered. To further decrease the risk of needle use with such devices, negative displacement mechanical NCs were introduced. Then, to reduce the risk of CLA-BSIs and IV line occlusions, positive-displacement NCs were introduced. This led to a number of CLA-BSI outbreaks associated with some of these NCs. Ultimately, this led to the Food and Drug Administration (FDA) requesting that U.S. manufacturers of positive-displacement NCs provide data that their devices were associated with risk of CLA-BSI at or below the level associated with negative-displacement NCs.

Newer generations of NCs have been designed with the intention of improving patient safety, specifically, reducing CLA-BSI risks. These design features include the following: a visible fluid path so that clinicians can assess the efficacy of their flush technique; a solid, flat, smooth access surface that can be effectively disinfected; a 1-part activation of the fluid path for effective flush; an open fluid pathway to provide a high flow rate and avoid hemolysis; and other desired safety features (eg, tight septum seal, minimal internal complexity, ability to flush with saline alone). In spite of the improved design, there has been no systemic analysis on its associated CLA-BSI risk. We conducted an integrative review of the literature and meta-analysis to determine the risk of CLA-BSIs associated with the use of the new NC.

**METHODS**

**Data sources**

We developed research protocol and data collection tools consistent with the recommendations per the Preferred Reporting Items for Systematic Reviews and Meta-Analyses. We searched the MEDLINE database for relevant studies published from January 2006-December 2012. We also searched ClinicalTrials.gov, Embase, and the Cochrane Database of Systematic Reviews. Because the study NC was relatively new and published studies were scant, we extended the scope of the search to include published abstracts from a comprehensive list of major relevant infection control, infusion therapy, and infectious diseases scientific meetings where early data could be presented and identified. We performed Internet searches to locate relevant studies presented at the following research meetings (2010-2012): Association for Professionals in Infection Control and Epidemiology, Association for Vascular Access, Interscience Conference on Antimicrobial Agents and Chemotherapy, Infectious Disease Society of America, Infusion Nurses Society, National Home Infusion Association, The Fifth Decennial International Conference on Healthcare-Associated Infections, and Society for Healthcare Epidemiology of America.

**Study selections and data extraction**

Study inclusion criteria were randomized controlled trials or observational studies that reported the CLA-BSI rate in patients with the new MaxPlus positive-displacement connector (CareFusion, San Diego, CA) (study NC) compared with negative- or neutral-displacement NCs. We used the following Medical Subject Headings and key words: "bloodstream (infection OR infections) AND (needleless connector) OR (mechanical valve) OR (needleless valve) OR (venous access)" for the search. An Internet search was conducted independently by 2 investigators. All abstracts identified were read independently by 2 investigators (1 with a PhD, 1 with an MD). Disagreement was resolved by discussions with a third investigator. Data were extracted on standardized forms on study design, setting, patient population, facility location, number of CLA-BSIs (numerator), and number of central venous line (CL) days (denominator) during the study NC device versus comparator device periods for the studies included. We recorded CLA-BSI incidence density (infections per 1,000 CL days) at each site. We contacted authors to obtain the numerators and denominators when the study only reported the summary CLA-BSI rates.

**Additional data regarding IV line care practices and the case mix index**

To further evaluate potential risk factors associated with CLA-BSI, we contacted authors to obtain IV management and disinfection practices related to CLs during the study NC and comparator periods. These variables included use of a dedicated IV team, blood draws through the connector attached to the CL, type of disinfectants used in the cleaning of the NC, type of skin antiseptic used for CL placement and maintenance, maximum sterile barrier precaution usage, catheter securement method, and use of stopcocks in the line. Finally, we obtained the case mix index (CMI) from the Centers for Medicare and Medicaid Services as an aggregated measure of patient disease severity for each study site.

**Statistical analysis**

Using the aggregated CLA-BSI rates during the comparators versus the study NC periods, we estimated the relative risk (RR) for CLA-BSIs associated with the study NC for each study. Then, we estimated the pooled effect using the random effects method. For sensitivity analysis, we fit a random effect Poisson model with WinBUGS software (Cambridge Institute of Public Health, Cambridge, UK) for the pooled effect. We further tested the impact of the time trend covariate on the RR estimate of the study NC. The Poisson model does not require normal distribution approximation for the effect of each study. It also applies when the number of events for a study is zero. We used the Centers for Disease Control and Prevention’s (CDC) Healthcare Infection Control Practices Advisory Committee review by Lee and Umscheid and the U.S. FDA recommended methods to compute a noninferiority margin allowing comparison against both a relative risk of 1.0 and a noninferiority margin.

We examined the distribution of the use of dedicated IV teams, blood draws in the line, choice of NC disinfectants, skin antiseptics used during CL insertion, use of maximum barrier precautions, methods of catheter securement, and use of stopcocks in the lines at each site. We examined whether any of these factors would influence the risk of CLA-BSI associated with the study NC, using the Poisson regression method.

**Evaluation of heterogeneity across studies**

To address the issue of potential heterogeneity and its impact on the estimate, we conducted systematic analyses. We assessed heterogeneity between studies for the outcome using the Cochrane Q statistic, with P < 0.1 indicating significant heterogeneity, and I², with suggested thresholds for low (25%-49%), moderate (50%-74%), and high (>75%) values. We generated a funnel plot to determine study bias. A funnel plot is a graph of the study effect (log scale of RR) plotted on the horizontal axis and a measure of within-study variance (standard error of log RR) on an inverted vertical axis.

**RESULTS**

**Data synthesis**

**Published studies**

A flow diagram outlining the search strategy and study selection for MEDLINE is shown in Figure 1A. Our search strategies produced...
7 observational studies that compared CLA-BSI rates associated with NCs, all of which used a pretest versus posttest design. Among them, 5 did not involve the study NC; 1 involved an earlier version versus a later version of the study NC device; and only 1 involved a negative-displacement NC versus the study NC, which was included in our meta-analysis. We did not find any randomized controlled trials or other observational studies that involved the study NC in other published study databases or registries.

Studies presented at infection control, infusion therapy, and infectious diseases scientific meetings

A flow diagram showing the search strategies for studies presented at professional meetings is shown in Figure 1B. Our search strategies produced an additional 6 citations from 10 observational study sites that met the search criteria. We excluded 3 studies involving the study NC: 2 used another positive-displacement NC as the comparator and 1 used mixed NC devices as comparators. All 3 excluded studies reported outcomes favoring the study NC.

Descriptive statistics

All 7 observational studies that met the inclusion criteria used a pretest versus posttest design (Table 1). All studies used the CDC’s National Healthcare Safety Network CLA-BSI definition for outcome measure. Six studies used a negative- or neutral-displacement NC as the comparator device during the pretest period and the study NC as the test device during the posttest period. One study used the study NC as the pretest device and a neutral NC as the posttest device. Four studies were conducted in intensive care units, 1 in a home health setting, and 2 in long-term acute care settings.

In the comparator period, the total number of CL days was 111,255 (range, 2,605–61,816), and the overall weighted CLA-BSI rate was 1.5 events per 1,000 CL days (range, 0.18–5.73 events per day).
I the heterogeneity analysis produced consistent and slightly more favorable results associated with the study NC compared with treating 5 sites in the Lange study as a single aggregated site (Table 3 and Fig 3B).

### Analysis of seasonality, CMI, and IV line care practice

Across all the studies there was a total of 194 months covered. Only 7 months failed to overlap. Hence, the seasons were well balanced in the study NC and comparator periods. Our analysis on the CMI showed very similar patient severity during the study NC and comparator periods. The site-specific IV line care and cleaning practices were virtually identical across the study NC and comparator periods. Detailed appendices with supplemental information are available on request.

### DISCUSSION

#### Desired engineering design of the NCs

Our meta-analysis demonstrated that the study NC with improved engineering design features that facilitate effective disinfections was associated with a lower risk of CLA-BSI. In the continuing evolution of the NCs, many have become complex in design. The complexities might have made some NCs harder to disinfect, flush completely, or use correctly, all of which could contribute to CLA-BSI risk. In contrast, the design of the study NC has 8 of the 9 desired features outlined by infection prevention experts, including a solid, smooth external septum surface; a tight housing seal; a clear fluid pathway; minimal internal complexity; reduction or elimination of interstitial or dead space; elimination of a specific disinfection-clamping sequence; a straight fluid pathway; no blood reflux; and the ability to flush with saline alone. These desired features might explain, in part, the lower CLA-BSI rates seen in our meta-analysis. The favorable results also are supported by previous in vitro studies. For example, the study NC was found to be the second best NC in low colony forming units (CFU) among all devices tested. Another in vitro study also demonstrated a smaller number of Staphylococcus aureus (CFU/mL) detected in saline collected after passing through various NCs. These favorable results may have been related to the NC design, which may have influenced the efficacy of the decontamination and disinfection process.

Our study revealed that the study NC, a new generation of NCs with improved patient safety design, was associated with reduced CLA-BSI risk. Previously, the study NC was not implicated in any previously published studies that showed increased CLA-BSI risk associated with positive-displacement NCs. The only published study involving the study NC is from Boston's Children's Hospital, which demonstrated a reduced CLA-BSI rate associated with using the study NC. Unfortunately, that study was not cited in the review by Lee and Umscheid that was presented to the CDC's Healthcare

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**Table 2**

<table>
<thead>
<tr>
<th>Study lead author, principal investigator, or presenter</th>
<th>Number of CL days</th>
<th>Number of CLA-BSI events</th>
<th>CLA-BSI rate (per 1,000 CL days)</th>
<th>Number of CL days</th>
<th>Number of CLA-BSI events</th>
<th>CLA-BSI rate (per 1,000 CL days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costello30</td>
<td>5,234</td>
<td>30</td>
<td>5.73</td>
<td>3,675</td>
<td>11</td>
<td>2.99</td>
</tr>
<tr>
<td>Taft31</td>
<td>4,123</td>
<td>17</td>
<td>4.12</td>
<td>2,838</td>
<td>4</td>
<td>1.41</td>
</tr>
<tr>
<td>Cain12</td>
<td>61,816</td>
<td>11</td>
<td>0.18</td>
<td>50,148</td>
<td>2</td>
<td>0.04</td>
</tr>
<tr>
<td>Gould33</td>
<td>5,391</td>
<td>22</td>
<td>4.08</td>
<td>6,011</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Steininger14</td>
<td>8,947</td>
<td>20</td>
<td>2.24</td>
<td>6,930</td>
<td>8</td>
<td>1.15</td>
</tr>
<tr>
<td>Chernecky16</td>
<td>2,605</td>
<td>4</td>
<td>1.54</td>
<td>2,766</td>
<td>12</td>
<td>4.34</td>
</tr>
<tr>
<td>Lange22</td>
<td>23,139</td>
<td>66</td>
<td>2.85</td>
<td>23,015</td>
<td>11</td>
<td>0.48</td>
</tr>
<tr>
<td>Sum</td>
<td>111,255</td>
<td>170</td>
<td>1.5</td>
<td>95,383</td>
<td>48</td>
<td>0.5</td>
</tr>
</tbody>
</table>

CL, central venous line; CLABSI, central line–associated bloodstream infection; NC, needleless connector.

1,000 CL days). In the study NC period, the total number of CL days was 95,383 (range, 2,766-50,148), and the overall weighted CLA-BSI rate was 0.5 events per 1,000 CL days (range, 0-4.34 events per 1,000 CL days) (Table 2).

**RR estimate**

The estimated RR of CLA-BSIs associated with the study NC ranged from 0.02-2.83 across the 7 studies. The pooled random effect method showed a 63% CLA-BSI risk reduction associated with the study NC (RR, 0.37; 95% confidence interval [CI], 0.16-0.90) (Fig 2). The sensitivity analysis using a random effect Poisson model showed a 69% CLA-BSI risk reduction associated with the study NC (RR, 0.31; 95% CI, 0.19-0.47). The model including time trend as a covariate yielded a slightly larger estimate (RR, 0.43; 95% CI, 0.29-0.69).

**Heterogeneity analysis**

Analysis revealed significant heterogeneity between studies ($I^2 = 75.5\%$, $P = 0.0004$) (Table 3). This heterogeneity was largely explained by the outlying study of Chernecky et al. The funnel plot illustrated the potential bias of this study (Fig 3A). When the study by Chernecky et al was removed from the analysis, the heterogeneity index reduced from high ($I^2 = 75.5\%$, $P = 0.0004$) to moderate ($I^2 = 54.9\%$, $P = 0.026$), with a RR of 0.28 (95% CI, 0.13-0.60). When the studies by Gould et al and Chernecky et al were both removed, the $I^2$ was reduced to 46.0% ($P = 0.004$), indicating low heterogeneity with a slight change of the RR of 0.33 (95% CI, 0.16-0.66).

When we split one aggregated study into 5 individual study sites, the pooled risk reduction was slightly more favorable to the study NC (random effect model: RR, 0.30; 95% CI, 0.15-0.59). The heterogeneity analysis produced consistent and slightly more
Table 3
Relative risk and heterogeneity analysis

<table>
<thead>
<tr>
<th>Study inclusion and exclusion</th>
<th>Pooled relative risk (95% confidence interval)</th>
<th>Q statistic-$\chi^2$</th>
<th>$I^2$ value (%)</th>
<th>Heterogeneity category</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Poisson model</td>
<td>Fixed-effect model</td>
<td>Random-effect model</td>
<td>$\chi^2$</td>
</tr>
<tr>
<td>Lange’s study treated as a single aggregated site</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All studies (n = 7)</td>
<td>0.31 (0.19-0.47)</td>
<td>0.38 (0.27-0.54)</td>
<td>0.37 (0.16-0.90)</td>
<td>0.82</td>
</tr>
<tr>
<td>Removing Chernecky (n = 6)</td>
<td>0.25 (0.17-0.36)</td>
<td>0.31 (0.21-0.44)</td>
<td>0.28 (0.13-0.60)</td>
<td>0.56</td>
</tr>
<tr>
<td>Removing Chernecky and Gould (n = 5)</td>
<td>0.30 (0.20-0.42)</td>
<td>0.32 (0.22-0.47)</td>
<td>0.33 (0.16-0.66)</td>
<td>0.40</td>
</tr>
<tr>
<td>Lange’s study treated as 5 independent sites</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All sites (n = 11)</td>
<td>0.32 (0.23-0.43)</td>
<td>0.40 (0.28-0.56)</td>
<td>0.30 (0.15-0.59)</td>
<td>0.84</td>
</tr>
<tr>
<td>Removing Chernecky (n = 10)</td>
<td>0.25 (0.17-0.35)</td>
<td>0.32 (0.22-0.47)</td>
<td>0.23 (0.11-0.47)</td>
<td>0.43</td>
</tr>
<tr>
<td>Removing Chernecky and Gould (n = 9)</td>
<td>0.29 (0.20-0.42)</td>
<td>0.34 (0.23-0.49)</td>
<td>0.26 (0.12-0.54)</td>
<td>0.26</td>
</tr>
</tbody>
</table>

Fig 3. (A) Funnel chart: Lange’s study treated as a single aggregated site. (B) Funnel chart: Lange’s study treated as 5 independent sites. RR, relative risk.

Infection Control Practices Advisory Committee, which formed the basis of the 2011 CDC’s IV guideline recommendations related to NCs. In July 2010, the FDA requested postmarketing surveillance data from manufacturers of positive-displacement NCs under Section 522 of the Federal Food and Drug Act. Because it was considered possible that this was a class effect for positive-displacement NCs, all positive-displacement NCs on the U.S. market were included in the request, despite the fact that the study NC showed favorable results in the published study.30 Our analysis of the study NC suggests that CLA-BSI rates associated with positive-displacement NCs may not be a class effect. It might be that the specific design features of individual devices may facilitate or hinder effective disinfection and IV line care, which may in turn be associated with higher or lower CLA-BSI risk.6

Our study found that 5 out of 6 recent studies presented at infection control, infusion therapy, and infectious diseases research meetings demonstrated that the study NC was associated with lower CLA-BSI risk.27,31-34 These studies encompass pediatric, neonatal, and adult intensive care units; home health care settings; and long-term acute care settings with >200,000 CL days.

Of the 3 studies excluded from our meta-analysis because another positive-displacement or mixed device was used as a comparator,26-30 all showed results favoring the study NC. The fourth study reported sustained zero CLA-BSI cases for 17 consecutive months in the study NC period.29

The only study that found an unfavorable association of the study NC and CLA-BSI rate was the one by Chernecky et al.35 This study was a multicenter comparison of bloodstream infection rates associated with use of the split septum, positive or negative pressure mechanical valves to a zero fluid displacement connector. Only a single facility out of 6 facilities in the Chernecky study involved using the current study NC as the comparator. As can be seen in data Table 2, the total number of CLA-BSI events in the Chernecky study throughout the entire study period (14 months) was relatively small (n = 16). Because of its small sample size, its influence on the pooled RR estimate was minor despite its significant influence on heterogeneity. In addition, the result from this single facility in Chernecky’s observational study was not consistent with the results from her previous in vitro study39 that compared 5 different NCs, in which the current study NC ranked second best in terms of CFUs. Furthermore, there was no significant difference in mean CFUs between the study NC and the leading device.

All studies included in our meta-analysis were quasi-experimental pre-post designs. This design presumes no time trend across the preperiod and postperiod. When we adjusted for the time trend, this covariate showed a RR of 0.71 (95% CI, 0.50-0.97), indicating a significant decline of CLA-BSI over time, consistent with the nationwide trend.41 Nevertheless, even after adjusting for the effect of the time trend, the RR for CLA-BSIs associated with the study NC was still significantly lower than the comparators (RR, 0.43; 95% CI, 0.29-0.69).

IV line care, NC disinfection practice, and influence of the CMI

The use of various preventive measures that were implemented as part of the CLA-BSI prevention insertion bundle, including maximum barrier precautions (ie, full drapes, gowns, masks, gloves), hand hygiene, and chlorhexidine with alcohol for skin antisepsis, together with strict adherence to aseptic precautions and vigilant management of the catheter and exit site, might also have contributed to the decrease in CLA-BSI density. Nevertheless,
from the data collected through our follow-up with the authors, nearly identical IV line and NC care and cleaning practice were used during both the study NC and comparator periods. The single discordant pair occurred in the Taft study,\(^{31}\) where blood draws in the line, which could increase CLA-BSI risk, were allowed during the study NC period. However, the CLA-BSI rate fell during the study NC period. Hence, the reduced CLA-BSI risk associated with study NC use appears independent of IV line care and NC disinfection practices.

The CMI takes into account the relative numbers of various types of patients being treated as categorized by diagnosis-related groups.\(^{10}\) It is an aggregated measure of patient composition and severity of illness being cared for at the health care site level. It is a system for classifying patient severity of illness based on principal and secondary diagnoses, demographic variables, hospital procedures performed, and the interaction of these factors. Our analysis showed very similar CMI values during the study NC and comparator periods. Hence, the reduced CLA-BSI risk associated with the study NC use appears independent of severity of illness of the patient population.

**Study limitations**

Given that the study NC is a relatively new device, we were only able to find 7 studies; most of them were abstracts presented in infection control, infusion therapy, and infectious diseases scientific research meetings. Because of limited publications, we expanded our search to abstracts presented at research meetings for more current studies. Including grey literature, such as abstracts presented in research meetings for meta-analysis, may influence the meta-analysis results, but their inclusion is gaining acceptance.\(^{42}\) Some experts even recommend in favor of its use\(^ {43}\) because not including such literature could represent a potential form of underreporting bias, especially for studies that fail to find significant differences.\(^ {44}\) Although reasonable concerns over the quality of unpublished studies are warranted, some studies suggest similar quality in published and unpublished studies.\(^ {45}\) Furthermore, there is a good correlation between effect estimates when the grey literature is included.\(^ {46}\) In part, this may be because the most common are abstracts, which most often do receive some form of peer review prior to acceptance. None of the studies in the meta-analysis were funded by the manufacturer of the study NC, and none of the authors of the studies included in the meta-analysis were employees of the study NC manufacturer.

We contacted study authors to gather additional information on antiseptic practices and central line protocols to assess potential confounding factors during the study NC versus comparator periods. Because these data were collected poststudy, there might be recall bias. To minimize the potential recall bias, we sent authors a concise data collection form and received completed responses from all but 1 author regarding the clinical practice during their study periods.

**CONCLUSION**

A NC with improved engineering design that facilitates effective IV line care is associated with lower CLA-BSI risk. Because of the limited number of publications, the current meta-analysis was expanded to studies presented in scientific research meetings. Additional publications in the future should continue to shed light in this area.

**Acknowledgments**

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