4.0 Evidence Summary

Figure 1: Yield of Systematic Search of Articles Published January 2010–March 6, 2017

WHAT TO KNOW

Evidence summary of the Intravascular Catheter-related Infection (BSI) guideline.

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4.1 Patients Aged 18 Years and Older

Five RCTs addressed one or more types of intravascular catheter-related infections in this age group (Appendix Table 4).[8-12] CDC classified the following infection outcomes as critical for decision-making: CRBSI and catheter-related infections (CRI). Product-related adverse events and chlorhexidine resistance were considered important outcomes. The results of the five studies were not directly comparable because they differed regarding the following conditions that might influence rates of intravascular catheter-related infections and product-related adverse events: skin antiseptic agents used before catheter insertion and during catheter maintenance, catheter type and insertion site, use of silver sulfadiazine-chlorhexidine-impregnated catheters, clinical outcome definitions, other components of CLABSI prevention bundles, frequency of dressing changes, hospital unit, and severity and types of health conditions of study participants.

The authors of four[9-12] of the five RCTs reported receiving funds and/or materials from, and/or being employed by, the manufacturer of the C-I dressing under study.

4.1.1 Dressings and skin antisepsis

One of the five RCTs compared transparent C-I gel dressings[11] with highly adhesive transparent dressings o[illegible] hypoallergenic dressings. Four studies compared C-I sponges covered by transparent adhesive dressings wit[illegible] alone.[8-10,12] Each of these four studies specified that the transparent adhesive dressing and skin antisepsis m[illegible] intervention groups and control groups. However, descriptions of the transparent adhesive dressings varied by study, including: transparent, semipermeable, polyurethane, occlusive dressing;[8] semipermeable, transparent dressing;[12] standard, sterile, transparent wound dressing;[10] or occlusive dressing.[9] Whether these different dressings (hereafter called "standard dressings") affect the risk of intravascular catheter-related infection is unknown. The skin cleaning and skin antisepsis agents and methods used before catheter insertion and during catheter maintenance also varied by study. One RCT used alcohol spray,[10] one RCT used aqueous povidone-iodine,[8] one RCT used alcoholic povidone-iodine,[12] one RCT used alcoholic chlorhexidine,[9] and one multicenter RCT used alcoholic chlorhexidine or alcoholic povidone-iodine[11] depending on the facility's standard of care (Appendix Table 6).

4.1.2 Catheter-related bloodstream infection

High-quality evidence suggested a benefit of using C-I dressings to reduce the rate of CRBSI. This was based on four RCTs, all rated at low risk of bias. Reductions in rates of CRBSI were found in three RCTs evaluating C-I sponge dressings[8,10,12] and one RCT evaluating C-I gel dressings.[11] The three larger trials compared C-I gel dressings with highly adhesive or standard dressings,[11] and C-I sponge dressings with standard dressings[10,12] (Appendix Table 4). One of the studies[10] was stopped early due to observed benefit of the C-I sponge dressing. A fourth smaller RCT evaluating the efficacy of C-I sponge dressings found no difference in CRBSI rates by dressing type.[8] This study was stopped early due to low enrollment. Two of the large RCTs[11,12] enrolled patients receiving central venous and arterial catheters to achieve adequate study power. One of these RCTs[11] conducted subanalyses by catheter type and found a significant reduction in CRBSI rates among patients with CVCs, but found no difference in CRBSI rates among patients with arterial catheters (Appendix Table 6).

4.1.3 Catheter-related infection

Moderate-quality evidence suggested a benefit to using C-I dressings to reduce the rate of CRI. This was based on four RCTs, rated at moderate[9] and low[8,11,12] risk of bias, that compared C-I gel dressings with highly adhesive and standard dressings,[11] or C-I sponge dressings with standard dressings (Appendix Table 4). The two larger studies found a reduction in CRI when using C-I gel dressings compared with highly adhesive or standard dressings,[11] and when using C-I sponge dressings compared with standard dressings.[12] In order to achieve adequate study power, these two RCTs enrolled patients with CVC and/or arterial catheters. One of these studies[11] conducted subanalyses by catheter type and found a significant reduction in CRI rates among patients with CVCs, but not among patients with arterial catheters. Two smaller studies with lower study power found no difference in the incidence of CRI by dressing type[8,9] (Appendix Table 6).

4.1.4 Product-related adverse events

Moderate-quality evidence suggested that the use of C-I dressings was associated with an increase in the incidence of product-related adverse events. Two large RCTs found no incidence of systemic adverse events to C-I dressings in patients with ether C-I sponge dressings[12] or C-I gel dressings.[11] Four RCTs[8,10-12] evaluated contact dermatitis and local redness in patients with either C-I sponge dressings or C-I gel dressings versus patients with standard dressings alone (Appendix Table 4). All studies were rated at low risk of bias. Definitions of contact dermatitis varied by study, but all addressed reactions near the catheter insertion site (Appendix Table 6). Two large studies assessed adverse events using a standard rating system[11,12] and found that use of either C-I sponge dressings or C-I gel dressings was associated with significantly higher rates of severe contact dermatitis (requiring dressing removal) or local redness as compared with standard dressings. Two studies found no product-related adverse events.[8,10] Two studies[11,12] found no incidence of systemic adverse reactions.

4.1.5 Chlorhexidine resistance

Low-quality evidence from two RCTs that compared C-I sponge dressings with standard dressings suggested no difference by dressing type in measures of resistance to chlorhexidine in bacteria isolated from skin,[12] CVCs, or blood cultures (Appendix Table 4).[10] These RCTs assessed patients who underwent skin antisepsis with alcohol spray[10] or alcoholic povidone-iodine[12] (Appendix Table 6). Both studies were rated at low risk of bias. These studies were not directly comparable because standard methods to measure bacterial resistance to chlorhexidine are not available and each study used different methods to measure resistance.

4.1.6 Limitations of the evidence

The body of evidence for patients aged 18 years and older is limited by the factors noted above and by the fo

- The best available evidence published between 1998 and March 2017 that assessed the clinical outcomes RCTs evaluating only two types of C-I dressings. During this interval, the chlorhexidine concentration and t these C-I dressings may have changed.
- Three[8,10,12] of the five evaluated studies did not use insertion site skin antisepsis methods such as alcoholic chlorhexidine recommended for CVCs by the *2011 Guidelines*.[1] Only two[9,11] of the five RCTs evaluated patients who underwent chlorhexidine skin antisepsis before catheter insertion. One of these studies[11] found that use of C-I dressings significantly reduced intravascular catheter-related infections as compared with standard dressings, and the other, possibly underpowered study[9] found no difference. Whether the benefits of C-I dressings over standard dressings would be observed or achieve the same magnitude if skin antisepsis with alcoholic chlorhexidine were used for all patients is unclear.
- None of the studies evaluated the effect of chlorhexidine skin antisepsis in combination with C-I dressings on systemic reactions to chlorhexidine. There are increased reports of anaphylactic reactions to chlorhexidine skin preparations[23]. These reports raise questions about how C-I dressings may impact the effect of chlorhexidine skin preparation on anaphylactic reactions. Due to this uncertainty, surveillance should continue to monitor any possible association between use of C-I dressings and chlorhexidine skin antisepsis to determine if there is an increasing association with anaphylactic reactions. As stated in the FDA Safety Announcement on this topic: "Health care professionals should always ask patients if they have ever had an allergic reaction to any antiseptic before recommending or prescribing a chlorhexidine gluconate product. Advise patients to seek immediate medical attention if they experience any symptoms of an allergic reaction when using the products. Consider using alternative antiseptics such as povidone-iodine, alcohols, benzalkonium chloride, benzethonium chloride, or parachlorometaxylenol (PCMX) when any previous allergy to chlorhexidine gluconate is documented or suspected."
- None of the studies evaluated patients who were uniformly bathed with 2% chlorhexidine. One study[8] followed patients in five intensive care units (ICUs), (one of which contributed approximately 40% of study subjects) used both daily CHG bathing and C-I dressings. For this reason, the combined effect of CHG bathing and C-I dressings on CRBSI rates remains uncertain.
- None of the studies directly compared rates of intravascular catheter-related infections or product-related adverse events in patients with C-I sponge dressings versus patients with C-I gel dressings.
- All studies reported low incidence of infections and adverse events and minor differences in incidence between study groups. These minor differences may be difficult to detect in studies with limited study power or in clinical settings without highly sensitive surveillance for these infections. However, the infection rate at which use of C-I dressings would be cost-saving or cost-effective would vary by the cost of diagnosing and treating intravascular catheter-related infections, dressings, and other measures to prevent intravascular catheter-related infections in a given facility. Nevertheless, even a slight increase in infection rates may prompt health care facilities to introduce prevention strategies in order to improve patient health outcomes and satisfaction.
- The studies had limited power to detect chlorhexidine resistance associated with C-I dressings. Little is known about the influence of temporary C-I dressings on chlorhexidine resistance and the protective microbiome of human skin, or the impact of using multiple chlorhexidine-based interventions (e.g., C-I dressings, CHG skin preparation, and CHG bathing) on risk of chlorhexidine resistance. Studies describe associations between chlorhexidine products and clinical isolates with reduced susceptibility to chlorhexidine or other antimicrobials (i.e., colistin) or identified chlorhexidine resistance mechanisms (e.g., resistance genes and plasmid-mediated resistance).[24-29] These reports raise questions about how emerging resistance may affect the balance of benefits and harms of using C-I dressings to prevent intravascular catheter-related infections. Given this uncertainty, surveillance and research should continue to assess the association between use of C-I dressings and resistance to chlorhexidine or other antimicrobials and to determine if emerging resistance might reduce the benefits of using C-I dressings to prevent intravascular catheter-related infections.

4.2 Patients Younger Than 18 Years

Three RCTs addressed one or more types of intravascular catheter-related infections in this age group (Appendix Table 5).[13-15] CDC classified the following outcomes as critical for decision-making: CRBSI, catheter-associated bloodstream infection (CABSI), bloodstream infection (BSI) without a source, and local catheter infection. CDC classified chlorhexidine resistance and product-related adverse events as important outcomes. The results of the three studies were not directly comparable because they differed regarding the following conditions that might influence rates of intravascular catheter-related infections and product-related adverse events: skin antiseptic agents used before catheter insertion and during catheter maintenance, frequency of dressing changes, catheter type and insertion site, clinical outcome definitions, and severity and types of health conditions of study participants.

- The authors of one RCT[13] reported receiving funds from the manufacturer of the C-I dressing used in the study.

4.2.1 Dressings and skin antisepsis

Two studies compared outcomes among patients with C-I sponges covered by transparent polyurethane dressings with outcomes among patients with transparent polyurethane dressings alone (hereafter called "standard dressings").[13,14] The third study compared a C-I gel dressing with a sterile gauze pad.[15] Skin cleaning methods and antiseptic agents used before catheter insertion and catheter dressing change protocols varied by study (Appendix Table 7).

4.2.2 Catheter-related bloodstream infection

Very low-quality evidence from two RCTs suggested no difference in the incidence of CRBSI by dressing type (Appendix Table 5). The first RCT[13] of neonatal intensive care unit (NICU) patients with a mean gestational age of 30.9 weeks in the C-I group vs. 30.7 weeks in the control group compared C-I sponge dressings applied after skin antisepsis with 70% isopropyl alcohol with standard dressings applied after skin antisepsis with 10% povidone-iodine. This study, rated at moderate risk of bias, found that rates of CRBSI did not differ by dressing type. However, this RCT had low study power because enrollment was stopped early due to low rates of CRBSI and funding issues (Appendix Table 7). The second RCT[15] of pediatric intensive care unit (PICU) patients aged 1 month to 18 years compared C-I gel dressings with sterile gauze pads after skin antisepsis with 10% povidone-iodine (Appendix Table 5). This study, rated at moderate risk of bias, found that rates of CRBSI did not differ by dressing type (Appendix Table 7).

4.2.3 Catheter-associated bloodstream infection

Low-quality evidence from one RCT suggested no difference in the incidence of CABSI by dressing type (Appendix Table 5). This small RCT[14] compared C-I sponge dressings with standard dressings alone in pediatric cardiac ICU (PCICU) patients aged from birth to 18 years (mean age 21 to 31 months) who underwent skin antisepsis with chlorhexidine solution. This study was rated at moderate risk of bias. Rates of CABSI did not significantly differ by dressing type (Appendix Table 7).

4.2.4 Bloodstream infection without a source

Very low-quality evidence from one RCT suggested no difference in the incidence of BSI without a source by dressing type (Appendix Table 5). This RCT[13] in NICU patients compared C-I sponge dressings applied after skin antisepsis with 70% isopropyl alcohol with standard dressings alone applied after skin antisepsis with 10% povidone-iodine. This study, rated at moderate risk of bias, found that rates of BSI without a source did not differ by dressing type (Appendix Table 7).

4.2.5 Local catheter infection

Low-quality evidence from one RCT[15] suggested no difference in the incidence of local catheter infections by dressing type (Appendix Table 5). This RCT in PICU patients compared C-I gel dressings with sterile gauze pads. This study, rated at moderate risk of bias, suggested no statistically significant difference in the incidence of local catheter infection per patient by dressing type (Appendix Table 7).

4.2.6 Product-related adverse events

Moderate-quality evidence from two RCTs suggested that use of C-I dressings was associated with an increase in severe product-related adverse events (Appendix Table 5). One RCT[13] with NICU patients found severe and/or localized contact dermatitis developed in 5.7% of neonates with C-I sponge dressings and none of the control neonates with standard dressings. The incidence of severe and/or localized contact dermatitis among neonates using C-I sponge dressings was substantially higher (15%) among neonates who weighed ≤ 1,000 grams than among neonates who weighed 1,000 grams or more (1.5%). Two neonates developed pressure ulcers from the C-I sponge and two other neonates developed scars from severe contact dermatitis. Many of the dressings in affected neonates were placed on or before the eighth day of life. The second, smaller RCT[14] of PCICU patients younger than 18 years reported local redness in four neonates with C-I sponge dressings and one neonate with a standard dressing. Neonates with redness did not require dressing changes or CVC removal, and redness spontaneously resolved after catheter removal in all cases. The study did not report the weights and ages of the four neonates with C-I dressings. Both studies were rated at moderate risk of bias.

4.2.7 Chlorhexidine resistance

None of the studies addressed this outcome.

4.2.8 Limitations of the evidence

The three studies were limited by the factors noted above and these additional issues:

- None of the studies reported rates of clinical infection outcomes by patient age.
- All three studies reported few infections and so were statistically underpowered to detect differences in outcomes by dressing type. Additionally, the rates of CRBSI in the NICU study[13] and the PICU study[15] were not stratified by gestational age or infant weight; this precluded assessment of clinical outcomes by infant age and weight.
- One study[13] used different agents for skin antisepsis before dressing application in the two arms: alcohol spray in the intervention arm and aqueous povidone-iodine in the control arm. These differences precluded direct assessment of the outcomes by dressing type.
- The duration of catheter placement differed by study. The PCICU study[14] reported a mean of 4.7 days for catheters protected with C-I dressings, and a mean of 4.4 days for catheters protected with standard dressings. The PICU study[15] reported a mean of 13.78 days for children with C-I dressings and 14.24 days for children with standard dressings. In the largest study[13] of NICU patients, catheters were in place longer: a mean of 17.7 days for catheters protected with C-I dressings and a mean of 17.4 days for catheters protected with standard dressings. The potential effect of duration of catheter placement on infection outcomes and severe contact dermatitis limits the comparability of these studies.

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