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EFFECTIVENESS OF AGENT DISINFECTANT PRIOR TO INTRAVENOUS CATHETER PLACEMENT ON INFECTION AND POTENTIAL ADVERSE EFFECTS AMONG NEONATES: A SYSTEMATIC REVIEW

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ABSTRACT
Several disinfection agents have been proven to have controversial issues with neonates. These agents continue to be used to disinfect prior to the insertion of intravenous catheters, both peripheral and central venous catheters in neonatal care rooms. Objective to identify the effectiveness of disinfection agents used prior to intravenous catheter placement among neonates and the possible adverse events. A systematic review was conducted. Databases including Pubmed, Science Direct, Proquest, Ebscohost, Clinical Key Nursing, and Wiley were searched from inception to October 2024. The eligibility criteria were neonates who needed intravenous catheter placement (peripheral or central), with experimental research design, and articles written in English. The quality of studies was assessed depending on the study design. Our study is registered on PROSPERO number CRD42024618924. 1119 articles were found. After the screening processes, we finally included 7 articles. Disinfection agents frequently used in neonatal settings in the included studies were chlorhexidine (with varying concentrations), aqueous and alcohol-based, and povidone-iodine 10%. The disinfectant used prior to the insertion of the intravenous catheter was effective in reducing pathogen colonization on the skin and preventing bloodstream infection. Even so, there were some concerns regarding the adverse effects of the disinfectant agent used. The disinfection prior to invasive procedures in neonatal care is a debated topic. Despite this, inadequate disinfection poses more life-threatening due to the risk of bloodstream infection. Key factors to consider when choosing an appropriate topical agent disinfectant prior to intravenous catheter placement in neonates include gestational age, birth weight, and skin condition.

Keywords: adverse effect; disinfection agent; catheter-related infection; intravenous catheter placement; skin integrity

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INTRODUCTION

During hospitalization, neonates often undergo medical procedures such as punctures and intravenous (IV) catheter placement. Nearly 100% of neonates in the Neonatal Intensive Care Unit (NICU) received infusion therapy (Beauman & Swanson, 2006). Consequently, both peripheral and central intravenous catheters have become a frequent procedure in these neonates and also play an important role in the survival of neonates admitted in the NICU (Sathiyamurthy et al., 2016). However, despite its frequent use, intravenous catheters can potentially increase bloodstream infection (Sathiyamurthy et al., 2016).All hospitalized newborns are highly susceptible to infections, particularly premature infants. Nearly 25% of very low birth weight (VLBW, <1500 grams) neonates encounter multiple episodes of hospital-acquired infections (HAIs), posing a significant risk to their health (Cho & Cho, 2019). Based on a systematic review by Sadowska-Krawczenko et al. (2012), BSI was the most frequent hospital-acquired infection (HAI) in the NICU. BSI results in prolonged hospital stays and increased healthcare costs. A multicentre prospective study by (Johnson, et al., 2021) found that 226 of 4073 neonates (5.5%) experienced at least one episode of BSI, the mortality was higher in neonates with BSI compared to those without BSI. A study conducted

by Donovan, et al. (2013) that reviewed clinical and care cost data found that neonates who have BSI cost approximately $158,672 and significantly higher by $52,051 compared to infants without BSI.

One of strategy to reduce BSI is skin preparation. The density of skin flora at the insertion site is a major factor for bloodstream infection, both central line-associated bloodstream infection (CLABSI) and catheter-related bloodstream infection (CRBSI) (Ciccia, et al., 2018; Pengpis, Tangsathapornpong, Bunjoungmanee, & Prachukthum, 2020). The National Healthcare Safety Network (NHSN) included adequate using agent disinfectant in skin preparation as one of the bundle practices prior to intravenous placement.Effective skin disinfection with the topical disinfectant agent is important in reducing this risk (Ciccia, et al., 2018; Sathiyamurthy, Banerjee, & Godambe, 2016). The previous systematic reviews have indicated that the use of disinfectant agents such as chlorhexidine and povidone-iodine was effective as topical antiseptics for skin preparation prior to intravenous catheter placement in neonates with considerations (Sathiyamurthy, Banerjee, & Godambe, 2016; Helmi, Lai, Rostenberghe, Ayub, & Mading, 2023) related to the potential adverse effects on neonates.

These adverse effects of disinfectant agents continue to be studied, including their effectiveness to reduce bloodstream infection and related adverse. However, despite numerous studies conducted, no definitive conclusions have been reached on the recommended disinfectant agent prior to intravenous placement among neonates. There is considerable confusion among clinicians regarding the selection of the most appropriate disinfectant agent and the determination of which agent is most effective in preventing bloodstream infections should be used.We aimed to identify frequent disinfectant agents prior to intravenous placement including peripheral intravenous catheter (PIVC) and central venous catheter (CVC). We also identify the effectiveness of each disinfectant agent in reducing bloodstream infection, and also the possibility of adverse effects among neonates.

METHOD

We conducted a systematic review to find the related studies. This review was registered in the International Prospective Register of Systematic Review (PROSPERO) with the number CRD42024618924. The databases Pubmed, Science Direct, Proquest, EBSCHOhost; Clinical Key Nursing, and Wiley were searched by II and MHH with specific keywords (available in supplemental materials). The articles were also searched by hand to find any articles that met the eligibility criteria. The eligibility criteria were neonates (0-28 days or pre-menstrual age/ PMA <40 weeks) which need intravenous catheter placement (both peripheral or central) and do skin preparation before the catheter placement with disinfection agent, and experimental research design (quasi or randomized controlled study / RCT). We specify the outcomes for instance infection prevention, effectiveness of agent disinfection and any effect and potential effect on newborn infants. We exclude skin preparation for surgical procedures, umbilical cord care, or bathing. We also restrict our language to English only. We didn’t limit the year of articles published.

We performed the search strategy using PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The searches were carried out in several databases, including Pubmed, Science Direct, Proquest, Ebscohost, Clinical Key Nursing, and Wiley. We provide the search strategy and the keywords used for this systematic review are available in the supplementary material S1. We also search articles by hand for additional articles. [Supplemental Material S1)Two researchers (II and RBA) conducted an independent systematic search in databases and screened the reference lists of all the retrieved articles that met the inclusion criteria. If there difference of opinion between the two researchers, the third researcher (YR) will mediate and re-analyze the articles, and decide whether the article is

included or excluded. All studies included in the analysis will be extracted based on study characteristics, participant's characteristics, procedure (peripheral or central catheter insertion), neonatal skin reaction and measurement, and any outcome related to infection and possible effect on neonates including the absorption by II & RA. [Supplemental Material S2). To assess the quality of the study, we used Cochrane Risk of Bias (RoB) 2.0 for a *randomized controlled trial* (RCT). The interpretation of Rob was differentiated into the following categories: low risk (LR) and some concerns (SC). As for quasi-experimental design, methodological items for non-randomized studies (MINORS) were used. The MINORS are written in the form of the score (the maximum score for non-comparative studies is 16, and for comparative studies is 24). [Supplemental Material S2)

This study's outcomes were related to the effectiveness of the disinfection agents when used for infection prevention before intravenous catheter placement, including CRBSI, and the related factors of CRBSI, such as catheter colonization and clearance rate. The secondary outcome is potential adverse effects such as skin reaction and absorption of agent disinfectant. CRBSI is defined as the presence of bacteremia or fungemia in a patient with an intravascular catheter, without related to other infection sites (Xu et al., 2024). Catheter colonization is defined as a catheter that at the time of removal has either one or both segments cultured positive (Clarke, et al., 2023). Clearance rate is defined as the proportion of negative skin swabs after the application of a disinfectant agent (Sharma, et al., 2021). Adverse skin reactions in this study are defined as manifestations of contact dermatitis, evaluated using instruments i.e. the dermatitis contact severity index.

RESULT

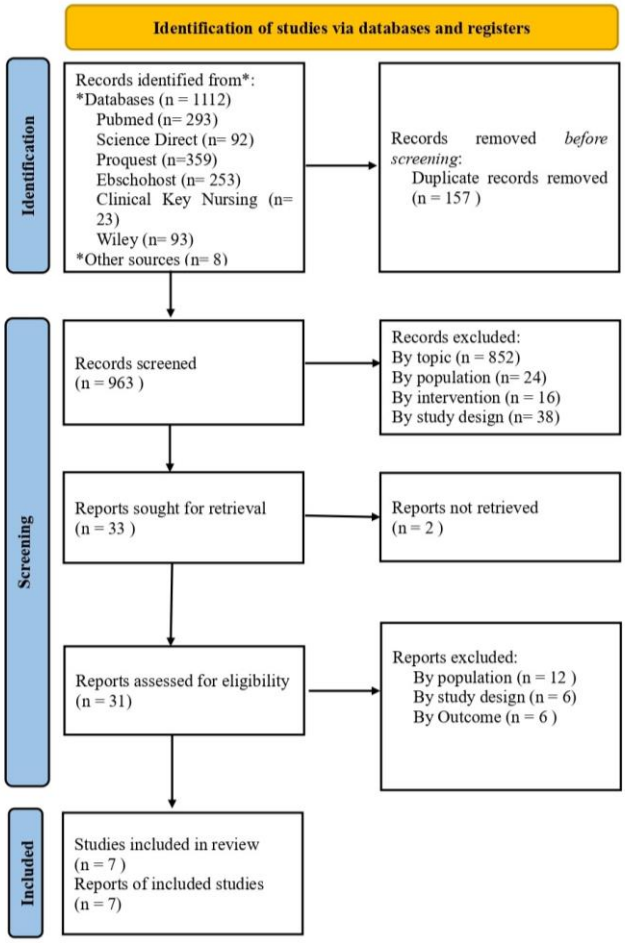

Figure 1 PRISMA Flow Diagram

Of the 1119 articles found, 157 were duplicate records and were removed. We screened all the articles left by the titles and abstracts and found 32 relevant studies. Of these 32 articles, 2 studies were excluded because we couldn't retrieve the full text of the articles. From 30 articles assessed for eligibility, we excluded 22 articles by population (n= 12), by study design (n= 4), and by outcome (n= 6). Finally, our review consisted of 6 studies that involved neonates and most of the population of studies were preterm (Figure 1).

The participants characteristic of the included studies based on gestational age (GA) were extremely preterm (2 studies) (Jain, et al., 2021; Kucuker, et al., 2023), preterm (4 studies) (Garland, et al., 2009; Clarke, et al., 2023; Sharma, et al., 2021; Kucuker, et al., 2023), late preterm (3 study) (Garland, et al., 1995; Sharma, et al., 2021; Kucuker, et al., 2023), and term (2 study) (Sharma, et al., 2021; Kucuker, et al., 2023). Based on birth weight, normal (2 studies) (Garland, et al., 1995; Sharma, et al., 2021); low birth weight (3 studies) (Clarke, et al., 2023; (Sharma, et al., 2021; Garland, et al., 2009); very low birth weight (2 study) (Clarke, et al., 2023; Kieran, et al., 2017); extremely birth weight (1 study) (Jain, et al., 2021). (Table 1)The intervention of the included studies was peripheral intravenous catheter / PIVC (3 studies) (Jain, et al., 2021; Sharma, et al., 2021; Garland, et al., 1995) and central catheter (4 studies) (Clarke, et al., 2023; Kieran, et al., 2017; Sharma, et al., 2021; Garland et al., 2009). We included the study by Sharma, et al., (2021) and Kucuker, et al., (2023) despite the study mentioned they used disinfectant agents for any clinical procedure including PIVC and CVC placement. (Table 1)

The most frequent CVC used in neonates in these included studies were peripherally inserted vein catheter/PICC, and umbilical venous catheter. And the disinfection agent prior to disinfecting the skin found in the included studies was AQC (aqueous chlorhexidine) 2% (3 studies (Jain, et al., 2021; Clarke, et al., 2023; Kieran, et al., 2017), AQC 1% (1 study) (Sharma, et al., 2021), 70% alcohol-based chlorhexidine (ALC) 2% (4 studies) (Jain, et al., 2021; Clarke, et al., 2023; Kieran, et al., 2017; Garland et al., 2009), and povidone iodine (PI) 10% (3 studies) (Kieran, et al., 2017; Garland et al., 2009; Garland, et al., 1995). (Table 1).

The main outcomes extracted from the included studies are as follows, the effectiveness of disinfection agents as infection prevention including the percentage of negative post-skin swabs consisted 2 studies (Jain, et al., 2021; Sharma, et al., 2021), and catheter colonization consisted of 3 study (Clarke, et al., 2023; Garland J. S., et al., 2009; Garland, et al., 1995); catheter-related infection rate (CRBSI) consisted of 5 studies. We also extracted the adverse effect of skin disinfection on neonates as follows, the possible of absorption (4 studies) (Kieran, et al., 2017; Sharma, et al., 2021; Garland J. S., et al., 2009; Kucuker, et al., 2023) and adverse skin integrity (5 studies) (Jain, et al., 2021; Clarke, et al., 2023; Kieran, et al., 2017; Sharma, et al., 2021; Garland J. S., et al., 2009; Kucuker, et al., 2023). (Table 2). Most of the included studies observed the skin using a contact dermatitis severity scale, 1 study used a contact dermatitis scale with minor revision, and 1 study used a Neonatal Skin Condition Score (see supplemental material S2).

Table 1.
Participant of Included Studies Characteristic

Studies	Design	Number of Participants	Gestational Age (Weeks)	Birth Weight (Gram)	Agent Disinfectant			Clinical Procedure
					AQC	ALC	PI	
(Jain, et al., 2021) Canada	RCT	N= 199 G1 = 99 G2 =100	G1= 27.3 (2.3) G2= 27.5 (2.8)	G1= 954 (265) G2= 956 (287)	2%	2%	-	PIVC
(Clarke, et al., 2023) UK	RCT	N= 116 G1: 28 G2: 88	G1: 28 (26–30) G2: 28 (26–30)	G1: 1075 (366,3) G2: 1089 (340,5)	2%	2%	-	CVC

Studies	Design	Number of Participants	Gestational Age (Weeks)	Birth Weight (Gram)	Agent Disinfectant			Clinical Procedure
					AQC	ALC	PI	
(Kieran, et al., 2017) Ireland	RCT	N= 304 G1= 148 G2= 156	G1= 27 (2) G2= 27 (2)	G1= 1017 (289) G2= 1014 (326)	-	2%	v	CVC
(Sharma, et al., 2021) India	RCT	N= 308 G1= 158 G2= 150	G1= 34 (31-37) G2= 35 (32-37)	G1= 2018 (759) G2= 2029 (769)	1% and 2%	-	-	PIVC, CVC
(Garland J. S., et al., 2009) USA	RCT	N= 48 G1= 24 G2= 24	G1= 32.4 (2.9) G2= 33 (4.1)	G1= 2085 (846) G2= 1929 (789)	-	2%	v	CVC
(Garland, et al., 1995) USA	Quasi	N= 254 G1= 143 G2= 111	G1= 35.7 (1.02) G2= 35 (5.1)	G1= 2650 (1020) G2= 2450 (1070	-	0.5.%	v	PIVC
(Kucuker, et al., 2023) Turki	RCT	N= 208 G1= 104 G2= 104	G1= 33.3 (23.6-40.7) G2= 34.4 (26.6-40.1)	G1= 1940 (655-4845) G2= 2320 (495-3950)	-	2%	v	PIVC, CVC

Data presented as mean (SD) or median (IQR)
(70 ALC % Alcohol-based Chlorhexidine); AQC (Aqueous Chlorhexidine); G1 (Group 1) G2 (Group 2); PIVC (peripheral intravenous catheter); CVC (Central Venous Catheter, including UVC, PCVC, PICC)

Table 2.
Outcomes of Included Studies

Studies	Clearance Rate	Catheter Colonization	CRBSI	Skin Reaction	Absorption	
					CHX	PI
(Jain, et al., 2021)	v			v		
(Clarke, et al., 2023)		v	v	v		
(Kieran, et al., 2017)			v	v		v
(Sharma, et al., 2021)	v			v	v	
(Garland J. S., et al., 2009)		v	v	v	v	
(Garland, et al., 1995)		v	v			
(Kucuker, et al., 2023)				v		v

CHX (Chlorhexidine); CRBSI (Catheter Related Bloodstream Infection); NPSS (Negative Post Skin Swabs); PI (Povidone Iodine)

DISCUSSION

100% of the hospitalized neonates in the NICU need infusion therapy, due to the need for fluid therapy, parenteral nutrition, intravenous medications, electrolyte correction, and blood transfusion (Beauman & Swanson, 2006). The types of intravenous devices were short peripheral (PIVC) and central (CVC). Consequently, due to intravenous placement categorized as skin breaking procedure and involves blood, coupled with an immature immune system, poor skin integrity, prematurity, and prolonged hospital stay, this frequent procedure has a huge risk of infection, including the CLABSI and CRBSI (Johnson, et al., 2021; Kalu et al., 2023).CRBSI can be prevented by applying clinical practice, including skin disinfection prior to intravenous catheter placement using agent disinfection (Hewlett & Rupp, 2012; Pengpis et al., 2020), but among neonates, the use of disinfection agents in neonates, however, remains controversial issues. Despite the controversies, disinfection agents are needed, especially in procedures such as IV line or central line insertion as skin preparation to prevent bloodstream infection. In the included study, the disinfection agents used were chlorhexidine (with varying concentrations, 2%, 1%, and 0.5%) in aqueous-based (AQC) or alcohol-based (ALC), and povidone-iodine (PI) 10%.

A recent meta-analysis found CRBSI incidence was 8.66 per 1000 catheter days globally (Bolormaa, Kang, Choe, Heo, & Cho, 2023). Overall, we found 4 studies with the rate of CRBSI per 1000 catheter days as one of the outcomes. Disinfect by AQC 2% 4.5/1000 catheter days (Clarke, et al., 2023), ALC 2% 1.5-6.8/1000 catheter days (Clarke, et al., 2023;

Kieran, et al., 2017), PI 6,2/1000 catheter days (Kieran, et al., 2017). In a study by (Garland J. S., et al., 2009) who used PI and AQC 2%, CRBSI didn't occur in both treatment groups. This mixed finding might be attributed to variations in disinfection methods across the studies (see table supplemental table S2). We couldn't retrieve the CRBSI rate in lower concentrations of 2% chlorhexidine in the neonate population. However, the CDC (Centres for Disease Control and Prevention) recommends disinfection with chlorhexidine-based disinfectant agents at concentrations greater than 0.5% (O'Grady, et al., 2011) and use of alcohol-based chlorhexidine in neonates, but this topic was classified as a conditional recommendation (CDC, 2024).

Several factors impact CRBSI, including the presence of bacterial colonization on the skin after disinfection by a disinfectant agent (clearance rate). Practically, all neonates undergoing clinical procedures are assumed to have skin colonization over the skin and need to be disinfected. Two studies (Jain, et al., 2021; Sharma, et al., 2021) addressed the clearance rate of disinfectant agents of AQC 1%, AQC 2%, and ALC 2%. The clearance rate for AQC 2% was 90.9-95.6% (Jain, et al., 2021; Sharma, et al., 2021), AQC 1% was 93% (Sharma, et al., 2021), and ALC 2% was 88% (Jain, et al., 2021). We did not find the clearance rates of ALC 0.5% and PI in the included studies. The overall efficacy of ALC 2% was slightly lower than AQC 2% and AQC 1%. This finding may be attributed to the application of diverse disinfection techniques (see supplementary table S2). To date, no consensus has been reached regarding the ideal method of disinfection (Sharma, et al., 2021).

The colonization of tip catheters was also associated with CRBSI without a source (Garland J. S., et al., 2009). The factors related to the catheter colonization could be because of the agents' disinfection characteristics. PI has bactericidal activity against gram-positive, gram-negative, some spore-forming bacteria, and could kill fungi (WHO, 2009). Chlorhexidine is a broad-spectrum antimicrobial and can kill yeast by disrupting bacterial cytoplasmic membranes and denaturation of protein, but its microbial activity is slower than alcohol (WHO, 2009; Sathiyamurthy et al., 2016; Prasanna & Lakshmanan, 2016). The alcohol-based solution has also a broad spectrum of antimicrobials that cause damage to bacteria cell membranes and denaturation of proteins and have a faster onset of action (Sathiyamurthy et al., 2016; WHO, 2009). When chlorhexidine and alcohol are combined, it results in a greater significance of residual activity (Sathiyamurthy et al., 2016). In the included studies with this outcome, catheter colonization occurred in 3 of 24 (13%) and 2 of 18 (11.1%) (Garland J. S., et al., 2009; Clarke, et al., 2023) or 5 of 42 catheters (11.9%) in the AQC 2% group; 1 of 24 (4%) and 6 of 143 (4.2%) in the PI group (Garland et al., 2009; Garland, et al., 1995) or 7 of 167 (4.2%); 5 of 111 (4.5%) in ALC 0.5% group (Garland, et al., 1995); and 3 of 79 (3,8%) in the ALC 2% group (Clarke, et al., 2023). These data indicated that disinfection with the disinfectant agent ALC2% results in the lowest incidence of bacterial colonization on tip catheters, followed by PI and ALC 0.5%. However, this does not imply that these disinfectant agents are superior to ALC 2%, as the number of catheters examined in this group was smaller than in other studies, making the results questionable.

The factors related to the catheter colonization could be because of the agents' disinfection characteristics. PI has bactericidal activity against gram-positive, gram-negative, some spore-forming bacteria, and could kill fungi (WHO, 2009). Chlorhexidine is a broad-spectrum antimicrobial and can kill yeast by disrupting bacterial cytoplasmic membranes and denaturation of protein, but its microbial activity is slower than alcohol (WHO, 2009; Sathiyamurthy et al., 2016; Prasanna & Lakshmanan, 2016). The alcohol-based solution has also a broad spectrum of antimicrobials that cause damage to bacteria cell membranes and denaturation of proteins and have a faster onset of action (Sathiyamurthy et al., 2016; WHO, 2009). When chlorhexidine and alcohol are combined, it results in a greater significance of

residual activity (Sathiyamurthy et al., 2016). Ideally, all venous catheters removed by reason should be cultured, especially in neonates suspected of having a CRBSI. A multicentre prospective study by Johnson, et al. (2021) found that 226 of 4073 neonates (5.5%) experienced at least one episode of BSI, 1.6% of neonates experienced early-onset BSI, and 5.5% experienced late-onset BSI caused predominantly by gram-negative bacteria (Johnson, et al., 2021). The tip catheter should be cultured to diagnose CRBSI and needs to be confirmed by a second blood culture. Implementing this practice remains challenging (Johnson, et al., 2021) especially in low-resource settings, because to diagnose whether the neonates have CRBSI, specific laboratory testing is required to identify if the catheter was the source of the infection (APSIC, 2015). Further studies are required to determine the actual CRBSI rate, particularly in low-resource settings.

Despite the recommendation for disinfectant agents in neonates remains controversial due to its potential adverse on neonates's skin. Three studies found no skin reaction in the group with AQC 2%, ALC 2%, and PI (Jain, et al., 2021; Garland et al., 2009; Kucuker, et al., 2023); 2 studies reported skin reaction occurred below 3% reported in groups ALC 2%, AQC 2%, and AQC 1% (Kieran, et al., 2017; Sharma, et al., 2021); and one study reported grade 2 of skin dryness occurred in 3.7% and 8%, erythema 18.5% and 17.2%, and skin breakdown 7.4% and 5.7% in group AQC 2% and ALC2% (Clarke, et al., 2023). Most neonates did not experience severe skin reactions following disinfection, but several studies show that those disinfectant agents can cause dryness, erythema, and skin breakdown. Medicines and Healthcare Products Regulatory Agency (MHRA) reported 44 severe chemical burn cases after using AQC and ALC prior to CVC placement. Most cases occurred in infants weighing less than 1000 grams with GA 26 weeks or less, with most of the CVC placement were umbilical vein catheter (UVC) (MHRA, 2014).

Preterm face a higher risk of adverse effects on the skin due to their thin stratum corneum, sparse dermal elastic fibres, and weak dermal-epidermal junction (Sharma, et al., 2021).This thin skin layer also increases the risk of other side effects: absorption of disinfectant agents into the bloodstream. Both PI and chlorhexidine can be absorbed. Sharma, et al. (2021) and Garland J. S., et al. (2009) reported the detectable of chlorhexidine in neonates plasma in their study. Two studies also reported PI. Kieran, et al. (2017) and Kucuker, et al. (2023) found elevated thyroid-stimulating hormone (TSH) levels in neonates exposed to PI, with Kucuker et al. reporting a higher median TSH value in the PI group compared to another group. We did not delve further into this matter as further analysis and studies are required more, regarding these issues.This review has some limitations. First, we couldn't retrieve the full text of 2 articles ought to full text screening. Second, we only searched 6 databases and did not search in the clinical register, but we also searched some related articles by hand for additional articles. Thirdly, our analysis of the articles may be insufficient due to the extensive range of topics, even though meticulous effort was applied. But despite those limitations, this review may provide one of the references for the considerations of selecting appropriate disinfectant agents prior to intravenous catheter placement among neonates

CONCLUSION

The disinfection prior to invasive procedures using disinfection agents in neonatal care settings remains debated. Chlorhexidine can cause skin reactions, and chemical burns, and also has the potential to be absorbed into the blood. PI too, has the risk of skin reaction issues and if absorbed has a high potential to elevate TSH levels. The exposure of agent disinfectant to neonate's skin depends on the procedure applied, CVC or PIVC. CVC placement would require more agent disinfectant than PIVC as the risk of infection is higher and life-threatening due to the CRBSI if the disinfection is inadequate. Although CDC recommends chlorhexidine-based disinfectant at concentrations greater than 0.5% (O'Grady, et al., 2011)

and alcohol-based chlorhexidine for neonates, but this topic was classified as a conditional recommendation (CDC, 2024; APSIC, 2015). Gestational age, birth weight, and skin condition are important considerations in selecting the appropriate disinfectant agent for topical disinfection prior to intravenous catheter placement among neonates. Consensus is needed regarding the disinfectant agents among neonates including application and methods for disinfection.

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