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Prevention of Central Line-Associated Bloodstream Infection by Poly (Hexamethylene Biguanide) Coatings: A Systematic Review

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Abstract

Background: The significance of central line-associated bloodstream infection (CLABSI) is that it increases morbidity, mortality, and treatment costs. The incidence of infections is reduced by the use of antibiotic-impregnated dressings at the central catheter insertion site. In this context, polyhexamethylene biguanide (PHMB)-containing dressings have been used instead of disinfectants like chlorhexidine gluconate and routine care in treating CLABSI. Therefore, the present comprehensive review of trials was conducted to examine the effect of PHMB on CLABSI.

Methods: The search was conducted using Google Scholar and databases like Medline, Cochrane Library, Science Direct, ISI Web of Science, Scopus, and ProQuest. The goal was to find English language randomized controlled trials (RCTs) according to PRISMA guidelines from October 2023 until April 2024.

Results: The available data obtained from three studies, which included 396 patients in the intervention group versus 400 patients in the control groups, suggest that PHMB is effective in reducing the CLABSI rate. Also, the dressing dwell time was not significantly different from the controls.

Conclusion: The results reviewed indicate that PHMB is effective in preventing CLABSI, and any reported complications can be managed or treated. Nevertheless, trials with larger sample sizes are recommended.

Keywords: Central line-associated bloodstream infection, Polyhexamethylene biguanide, Polihexanide, Bloodstream infections, Central venous catheters

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Introduction

Central line-associated bloodstream infection (CLABSI) can be found in various populations and has a prevalence range of 0.1 to 22.5% (1). Although we did not find data on the prevalence of CLBSI in Iran, a recent four-year retrospective study in Isfahan reported the prevalence of BSIs in the ICU and non-ICU wards as 1.67% and 0.47%, respectively. Similarly, in another study in southern Iran, the overall prevalence of BSI was reported to be 1.3 percent (4.1% for the ICU and 0.4–6.4% for other wards). The prevalence of BSIs in Iran from March 2007 to March 2008 was 14% in the ICU and 16.3% in total (2). CLABSI is a common, deadly, and costly consequence of central venous catheter insertion in the ICU, and can lead to increased morbidity and mortality among critically ill patients. To reduce mortality and complications, prevention is a necessary step alongside timely diagnosis and treatment. In the field of prevention, a number of preventive technologies have been introduced, including antiseptic-impregnated dressings and catheters (3). Several factors contribute to CLABSI, but in most cases, the microorganisms on the patient's skin infect the outside of the catheter and enter the blood. Some suggestions have been made for this purpose, among them using chlorhexidine gluconate (CHG) dressing; however, evidence reporting the formation of necrosis at the catheter insertion site raises questions about the safety of CHG for cancer and hemodialysis patients. Also, due to the limited

evidence available for chlorhexidine in other settings, it has mostly been studied for patients hospitalized in the ICU (4). Furthermore, the cost of chlorhexidine has led to the use of disc-like dressings containing polyhexamethylene biguanide (PHMB) in countries like Australia (5, 6). Biguanides, which have a positive electric charge, are absorbed by the outer membranes of both Gram-positive and Gram-negative organisms, which have a negative electrical charge, and replace calcium (the balancing force) inside the cell wall. It concentrates on the cell wall that has the highest electric charge density and alters the phospholipid environment. As a result, the cell wall is damaged, causing the contents of the cells to leak and the cell to be destroyed. Moreover, PHMB consists of a long polymer chain that occupies larger areas of the cell wall, causing more degradation than chlorhexidine, giving it possible superiority in antimicrobial properties (7). In vivo studies have shown that a 0.2% PHMB dressing reduces the incidence of skin infection compared to a saline dressing (8). Furthermore, studies have demonstrated that these types of broad-spectrum antibiotics decrease wound biofilms, discomfort, pain, and wound mass (9). Additionally, PHMB blocks the growth of *Staphylococcus aureus*, *Enterococcus* species, and *Enterobacter* species, making it a more effective option to prevent CLABSI (10). Also, adverse events have not been reported in most trials for the PHMB groups (11), and only a few instances of transient skin redness have been found (12). A systematic review and meta-analysis revealed that PHMB is an effective agent for reducing postoperative infections (13). Likewise, according to another review, there is evidence supporting the use of PHMB to prevent and treat wound infections (9). However, we have not found any reviews on the effect of PHMB on CLABSI rates, despite the importance of the topic. Thus, we decided to evaluate the clinical trials that have been done on the impact of PHMB on CLABSI.

Methods

Search strategy

The search for this systematic review (CRD42023463354) was conducted following PRISMA procedures and the PICO framework from October 2023 to April 2024.

Google scholar and databases such as Medline, Scopus, Web of Science, Cochrane Library, Science Direct, ProQuest were searched via the subsequent search lines in titles, abstracts, or keywords:

Google Scholar and Medline were searched using the subsequent search line: [("Polyhexamethylene-biguanide" OR "PHMB" OR "polyhexanide" OR "polymeric biguanide polihexanide" OR "polihexanide hydrochloride" OR " poly (iminocarbonimidoylimino carbonimidoylimino-1,6-hexanediyl) hydrochloride" OR "Baquacil" OR "cosmocil" OR "Vantocil IB of Vantocil" OR "Lavasept" OR "Vantocil") AND ("catheter colonization" OR "bloodstream infection" OR "cross infection" OR "Colonization Rate" OR "Central Line Infection Rates" OR "central-line-associated bloodstream infection" OR "catheter related blood stream infection" OR "CLABSI rates")].

The search lines below were utilized to investigate Science Direct, Web of Science, Cochrane Library, and Proquest:

[("Polyhexamethylene Biguanide" OR "PHMB" OR "polymeric biguanide polihexanide" OR "polihexanide hydrochloride" OR "Baquacil") AND ("catheter colonization" OR "bloodstream infection" OR "catheter related blood stream infection" OR "CLABSI rates")].

To search for studies in the Cochrane library, which did not yield any results, the keyword "PHMB" was utilized once again and the search was conducted in titles and abstracts, or keywords. The search was directed toward finding studies that looked into the effects of PHMB on CLABSI. Also, we ensured that the search was as complete as possible by checking the references of selected articles and relevant meta-analyses. Then, the selected articles were scrutinized to ensure they contained the desired information. The first author (M Z) carried out all procedures and the corresponding author (M G-Kh) gave their approval. End note version 20.2 (Bld 15749) was used for the search steps mentioned above.

Review question

The PICO criteria were incorporated into the question formulation process to explore the effect of PHMB on CLABSI. The population consisted of hospitalized patients at least 18 years old who had a central venous catheter (CVC) for more than 72 hours and a central line-associated bloodstream infection for the first time. The intervention was designed to investigate the effectiveness of PHMB in preventing CLABSI. The frequency of CLABSI in the intervention and control groups was compared. The desired primary outcome was the CLABSI rate. Also, secondary outcomes such as CLABSI incidence per 1000 catheters/days, BSI rate, BSI rate per 1000 catheters/days, and dressing indwelling time were taken into consideration.

Inclusion and exclusion criteria of included studies

Clinical trials that assessed the effect of PHMB on CLABSI were included, but in vitro studies were excluded.

The patients in the chosen study had the following characteristics: 1) being 18 years of age or older; 2) having a central catheter present for more than 72 hours; 3) being hospitalized (either in ICU or non-ICU); and 4) giving informed consent. Patients who had a laboratory-confirmed infection (BSI) within the past 48 hours, a concurrent CVC (for more than 24 hours), a history of PHMB allergy, and previous rash, dermatitis, or burns at the CVC insertion site were excluded.

Study selection

Data extraction: The first author's name, publication year, country, study design, sample size, participants' characteristics (age, skin integrity, intensive care admission, absence of concomitant diseases, suspected bloodstream infection (BSI) at entry), IV antibiotics administered during enrolment, and CVC insertion location were collected and entered in Table 1 by the corresponding author (M.G.-Kh.), then were confirmed by the second author (M.J.).

Quality assessment

The selected RCTs were assessed using the Cochrane Collaboration's Risk of Bias tool (Table 2). In all RCTs, randomization was performed using either a central web-based program (5) or a computer-generated allocation sequence (6). Two studies (5, 6) addressed selection bias, but there was no information available from the third study due to a lack of data (14). Due to the nature of the trials, the results were masked in only outcome evaluation (5, 6), and the information from the third study (14) was not available. All studies had matched baseline data, complete outcome data, and no bias in reporting. An intention-to-treat analysis was used in two of the studies (5, 6); however, information regarding the analysis approach in the third study was not available (14). The quality was assessed by M.G.-Kh. and confirmed by M.J.

Results

Study identification process

Out of the 3078 studies included, 800 were discarded because of duplication. After examining the titles and abstracts of the articles, 2172 were rejected. In the subsequent phase, a thorough review of the complete texts of the selected articles was conducted, resulting in the exclusion of 103 articles. This included 87 instances where the studies were based on laboratory samples and 16 instances where the articles did not meet the entry criteria. Ultimately, three RCTs were chosen for systematic review (Figure 1).

Description of included studies

Three RCTs evaluated the impact of PHMB on CLABSI (5, 6, 14). One study assessed the effectiveness of PHMB discs (n = 37) compared to unmedicated dressings in preventing CVC infection in the ICU (5). The result was that the rates of CLABSI and local insertion site infection were zero in both groups. Hence, PHMB impregnated discs were found to be safe by researchers to prevent catheter insertion site (5). Also, the median dwell time of dressings per day was identical in both groups (Table 3).

Based on another study that compared the PHMB disk (n = 51) with chlorhexidine gluconate (n = 49), it was concluded that this type of dressing is safe and suitable for preventing infection at the catheter replacement site (6). Dwell time in the intervention group (PHMB) was 6.6 days, while in the control group (CHG), it was 6.1 days (Table 3). Two groups had identical CLABSI rates per 1000 catheter-days (1.8 in each group) (Table 3). There was only one case of reaction to dressing discs that was related to CHG (Table 3).

In the third study, polyhexanide-coated CVCs were compared with standard CVCs in the ICU or surgery room among 616 catheters. Two groups had similar insert sites, ward types, and dwell times (Table 3). There was no significant difference between the rate of CLABSI in two groups (1.33% vs. 1.94%, $P = 0.752$). The BSI rate and the BSI rate per 1000 catheter/days in the intervention group were significantly lower than those in the control group, with values of 2.00% compared to 6.47% ($P = 0.008$) and 3.21 versus 8.30 ($P = 0.036$), respectively. The rate of catheter colonization (CC) observed in the two groups was comparable, with rates of 17.36% and 18.67% respectively ($P = 0.747$) as presented in Table 3. Authors indicated that PHMB significantly reduced the incidence of bloodstream infections, while the rates of CLABSI and CC were comparable to those associated with standard CVCs.

To sum up, this systematic review suggests that PHMB has a significant effect on the prevention of CLABSI, as evidenced by three trials conducted in Australia (5, 6) and the Czech Republic (14). Also, the dressing dwell time was not significantly different from controls (5, 6, 14). Two studies have revealed that PHMB is also successful in treating local infections at the catheter insertion site (5,14). Moreover, PHMB had a positive impact on reducing BSI rates according to one study (14). Furthermore, the CLABSI incidence per 1000 catheter/days based on one study (6), and the BSI occurrence per 1000 catheter/days based on another study (14) were not significantly different from controls.

Discussion

Based on this systematic review, it was found that PHMB has a significant impact on preventing CLABSI incidence when compared to controls. Moreover, the rate of local infection at the catheter insertion site did not differ significantly from that of controls.

A study evaluated 37 patients in the ICU with PHBG discs and 43 patients who had unmedicated dressings. In both groups, there were no confirmed cases of CLABSI (5). Negative cultures were found in the removed catheters, which were removed either due to suspicion of infection (2 catheters in each group) or to ensure infection was absent (3 in the intervention and 2 in the control) (5). In a different study (6), 51 patients had PHMB discs, whereas 49 patients had CHG discs. In both groups, there was a similarity in the frequency of confirmed CLABSIs and the CLABSI rate per 1000 catheter-days (6). The third study included a final analysis of 616 patients, who were initially

Table 1. Participants' characteristics

Author, Publication year	Study design	Sample size		Age (yrs)		Skin integrity						Intensive care admission						No. comorbidities										Suspected infection Bloodstream (BSI)		IV antibiotics administered during enrolment		CVC insertion location							
						I			C			I			C			I					C									I				C			
		I	C	I	C	Good	Fair	Poor	Good	Fair	Poor	Planned	Emergent	Interhospital transfer	Planned	Emergent	Interhospital transfer	0	1	2	3	<3	0	1	2	3	<3	I	C	I	C	R) internal jugular	L) internal jugular	R) femoral	L) femoral	R) internal jugular	L) internal jugular	R) femoral	L) femoral
India Pearse RN, 2022 (4)	A pilot RCT	37	43	68 (58-73)	71 (63-75)	18 (49)	17 (46)	2(5)	15 (35)	25 (58)	3 (7)	31 (84)	4(11)	2(5)	39 (91)	2 (5)	2 (5)	1 (3)	2 (5)	2 (5)	8 (22)	24 (65)	0 (0)	2 (5)	6 (14)	10 (23)	25 (58)	0 (0)	1 (2)	25 (68)	32 (74)	34 (92)	1(3)	1 (3)	1 (3)	42 (98)	1 (2)	0 (0)	0 (0)
Webster J,2017 (5)	A feasibility RCT	51	49	56.5 (14.98)	60.65 (15.78)	29 (57%)	14 (28%)	8 (16%)	26 (53%)	16 (33%)	7 (14%)	13 (26%)	25 (49%)	13 (25%)	17 (35%)	22 (45%)	10 (20%)					24 (47%)					25 (51%)			37 (73%)	30 (78%)	43 (84%)				44 (90%)			
Krikava I, 2010 (13)	A prospective RCT	308	308	Same	Same																											Same				Same			

IV: Intravenous CVC: Central Venous Catheters I: Intervention C: Control Same: The results in the intervention and control groups are statistically the same.

Table 2. Evaluation of bias risk of included randomized-controlled trials by usage of Cochrane criteria checklist for involved RCT

First author, year published	Randomization	Allocation concealment (selection bias)			Blinding of participants (performance)	Blinding of care providers (performance)	Blinding of outcome assessment (detection bias)	Similarity of baselines	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Intention to treat analysis
		Sequence generation	Allocation concealment	Allocation implementation							
India Pearse RN, 2022 (4)	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Not	Not	Yes
Webster J,2017 (5)	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Not	Not	Yes
Krikava I, 2010 (13)	Yes	Not- available	Not- available	Not- available	Not- available	Not- available	Not- available	Not- available	Not	Not	Not- available

Table 3. Obtained results of RCTs included in systematic review

Author, Publication year	Study design	Sample size		Catheter colonization (CC)		*P* value	skin reactions		Time to first dressing change (hours), median (IQR)d		Device dwell time (days), median (IQR)		*P* value	Catheter-related BSI (CLABSI)		*P* value	BSI rate		*P* value	CLABSI or BSI rate per 1000 catheter-days		*P* value
		I	C	I	C		I	C	I	C)	I	C		I	C		I	C		I	C	
									16	23												
India Pearse RN, 2022 (4)	A pilot RCT	37	43	No data	No data	No data	33	30	25.5 (16.9 -43.8)	29.8 (18.0 -72.8)	5(4-6)	5 (4-6)	NR	0(0)	0(0)	NR	No data	No data	NR	No data	No data	No data
Webster J,2017 (5)	A feasibility RCT	51	49	No data	No data	No data	8	3	No data	No data	6.6	6.1	NR	1	1	NR	No data	No data	No data	CLABSI rate 1.8	1.8	NR
Krikava I, 2010 (13)	A prospective RCT	308	308	17.36%	18.67%	*P*=0.747	No data	No data	No data	No data	same	same	*P*>0.05	1.33 %	1.94 %	0.752	2.00%	6.47%	0.008	BSI rate 3.21	8.30	0.036

I: Intervention C: Control NR: Not-written

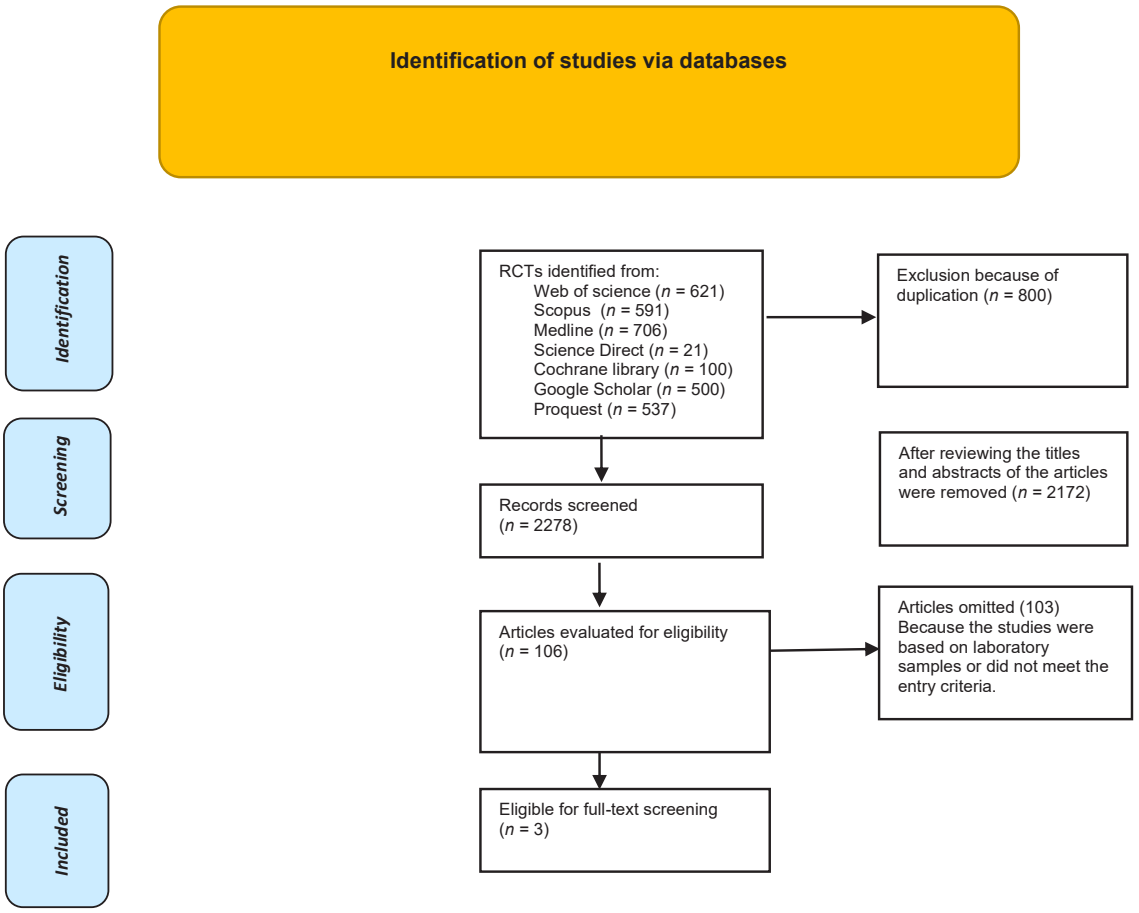

Figure 1. PRISMA flow diagram of included studies

divided into groups of polyhexanide-impregnated CVC and standard CVC (14). The rates of CLABSI and catheter colonization were statistically the same in the two groups. Furthermore, the interventional group had a lower BSI rate and BSI per 1000 catheters/days (14). Although there are only a few related published studies, PHMB seems to have a broader spectrum than CHG. Also, it is capable of stopping the expansion of microscopic organisms, including *Candida* species, Enterococci, *Staphylococcus aureus*, and coagulase-negative staphylococci, which are the primary causes of CLABSI (10, 15-16). The advantages listed above, as well as the affordable cost of polyhexanide-coated disks, and the challenges of chlorhexidine gluconate, have enabled polyhexanide to be an effective method for preventing CLABSI and local infection both in the short and long term (17-19).

Although not the primary objective of our study, the dressing indwelling time during intervention was not significantly different from controls, as demonstrated by the results from three studies (5, 6, 14).

The researchers reported that during the central venous catheter dwell period, 34 patients in the intervention group versus 50 in the control group needed a dressing change. Also, the time to first change in the interventional group was 25.5 hours, compared to 29.89 hours in the control group. Furthermore, the primary reason for changing the dressing was adhesive failure, occurring in 35% and 42% of the patients in the intervention group and control group, respectively (5). Therefore, the overall integrity of the dressing is not affected by the usage of a PHMB.

Two studies (5, 6) revealed skin problems. In one of them, itching was reported in 4% of participants ($n=3$ in intervention and $n=0$ in control), but all were mild and resolved without treatment (for this purpose). Pain was present in 32% of patients ($n=13$ in intervention and $n=11$ in control). Tenderness was observed in 46% of the sites where central venous catheters (CVC) were replaced ($n=16$ in intervention and $n=19$ in control). There was no evidence of anaphylaxis or hypersensitivity in either group (5). In another study, only one rash, which was related to CHG, was noticed, but it resolved within two days (6).

As a result, dressings that contain PHMB have a lower rate of complications and problems compared to standard or unmedicated dressings. In addition, the expense in the intervention group was lower than that in the control group (8.92 Australian dollars versus 11.37 Australian dollars) (5).

A systematic review and meta-analysis showed that PHMB could be a favorable solution to reduce

postoperative infections (13). Considering that similar microorganisms can cause CLABSI and postoperative infections, the findings of the above study confirm the present study results. Likewise, researchers have pointed out that PHMB accelerates the healing process by affecting the bioburden of both chronic and acute wounds (20-23). The improvement of wound conditions and healing response is another positive effect of PHMB (17,24). Similarly, PHMB treatment has been shown to decrease the presence of biofilm in chronic wounds (25). Numerous studies have also shown that PHMB treatment reduces the levels of antimicrobial-resistant microorganisms in wounds (9-26).

This review study presented a solution to prevent CLABSI, which is valuable. Although the sample was small, it is hoped that this review will open the door to conducting large-sample trials, as they are expensive to conduct.

Conclusion

The results reviewed indicate that PHMB is effective in preventing CLABSI, and any reported complications can be managed or treated. Nevertheless, trials with larger sample sizes are recommended.

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Authors' Contribution

Conceptualization: Masoomeh Goodarzi-Khoigani.
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Supervision: Masoomeh Goodarzi-Khoigani.
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Competing Interests

The authors declare that they do not have any conflict of interest.

Data Availability Statement

All data generated or analysed during this study are included in this published article.

Ethical Approval

Not applicable.

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