Original Article

Randomized Controlled Trial Comparing Efficacy and Safety of 2% Chlorhexidine Gluconate in 70% Alcohol versus 10% Povidone Iodine in Performing Neonatal Blood Culture

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Abstract

Background: Blood culture is the gold standard for diagnosis of septicemia, but it can be easily contaminated by microorganisms which colonize skin. Clear recommendations exist regarding suitable skin antiseptics in older children and adults but have not been established for neonates.

Objective: To evaluate the efficacy and safety of 2% chlorhexidine gluconate in 70% alcohol compared with 10% povidone iodine for performing of blood culture in neonates.

Methods: A prospective randomized controlled trial of neonates who were admitted to a Thammasat University Hospital, Thailand, from March to September 2016. 10% povidone iodine or 2% chlorhexidine gluconate in 70% alcohol was used as antiseptics at the time of blood culture sampling; blood cultures were taken by pediatric residents, general physicians, or nurses.

Results: General demographics for the 328 neonates enrolled were not significantly different: 2% chlorhexidine gluconate in 70% alcohol group (n = 164) and 10% povidone iodine group (n = 164). Seven (2.13%) were contaminated with coagulase negative staphylococci. The overall blood culture contamination rates were not significantly different: (1.83% with chlorhexidine-alcohol vs. 2.43% with povidone-iodine; P = 0.71; relative risk 0.75; (95%CI: 0.17-3.30). The risk difference of blood culture contamination was -0.61% (95% CI: -3.77-2.55), P = 0.70. No adverse skin reactions or systemic reactions were observed in antiseptic solution groups.

Conclusion: Both 2% chlorhexidine gluconate in 70% alcohol and 10% povidone iodine had similar efficacy in reducing blood culture contamination as they were well tolerated.

Keywords: Blood culture, Contamination, 2% chlorhexidine gluconate in 70% alcohol, 10% povidone iodine, Neonates

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Introduction

Infections are the single most important cause of neonatal deaths worldwide and are responsible for almost 30% of all neonatal mortality. The overall incidence of neonatal sepsis is 2 to 4 cases per 1,000 live births.[1-3] Globally, 350,000 neonates die yearly because of septicemia and meningitis.[4]

Blood cultures remain the standard laboratory test for diagnosis of septicemia. Blood culture contamination rates vary from 2% to more than 6%.[5] The American Society of Microbiologists targets the rate for contamination to be 2 to 3%.[6,7]

A false positive result from contamination leads to inappropriate antibiotic use, longer hospitalization and an increase of healthcare costs. The contaminants were correlated with 20% and 39% increases in total subsequent laboratory charges and intravenous antibiotic charges, respectively. Lower contamination rates improve diagnoses and help to avoid the inappropriate use of antibiotics, thus decreasing antibiotic-resistant organisms.[8,9]

The most common source of contamination is often from skin flora. Skin preparation plays an important role in reducing blood culture contamination. There are numerous antiseptic preparations that have been tested and shown to be effective in minimizing contamination. Among the most widely used are povidone iodine, isopropyl alcohol, tincture of iodine, and chlorhexidine. It was reported that blood culture contamination in pediatric patients at Thammasat University Hospital between 2002 - 2008 was 77% when 10% povidone iodine was generally used as antiseptic.[10]

Povidone iodine (PI) is used as skin antiseptic agent before taking blood culture in many neonatal centers, but recent studies found that the incidence of intravenous catheter colonization was lower among patients whose skin were disinfected with chlorhexidine gluconate (CHG) than among those for whom povidone iodine was used.[11-16]

CHG is a widely used broad-spectrum topical antiseptic agent.[17] The Centers for Disease Control and Prevention (CDC) recommends its use as a skin cleanser prior to insertion of central venous catheters in children and adults but does not recommend its use in infants less than 2 months of age due to lack of safety and efficacy data.[18] In adults, Suwanpimolkul G, et al have reported that the blood culture contamination rate was 4.3% in a group that used 2% chlorhexidine gluconate in 70% alcohol and 12.5% in a group that used 10% povidone iodine ($P < 0.001$).[19]

In pediatric patients, Tangsathapornpong A, et al have reported a lower rate of culture contamination in the CHG group 2.28% (95% CI: 1.25 - 3.79) compared with 3.21% (95% CI: 2.00 - 4.87) in the PI group, but not statistically significant. The risk difference of blood culture contamination was 0.93% (95% CI: 0.86 - 2.72), $P = 0.31$.[20]

A national survey of neonatology training program directors revealed that most NICUs use chlorhexidine solution for central venous catheter site preparation and maintenance, but often restrict its administration based on gestational age, chronological age, and/or birth weight.[21]

Clear recommendations exist regarding suitable skin antiseptics in older children and adults, but this is not the case for neonates. The standard solution is 10% povidone iodine but high contamination rate, so new better solution is needed. This study aims to evaluate the efficacy and safety of 2% chlorhexidine gluconate in 70% alcohol and 10% povidone iodine in preventing blood culture contamination in neonates at Thammasat University Hospital, Thailand.

Materials and Methods

Study population and design

A prospective randomized controlled trial (RCT) was conducted at pediatric wards (general and private wards), high risk neonatal wards and neonatal intensive care unit (NICU) at Thammasat University Hospital, a tertiary care hospital. The study period was from March to September 2016.

The study was approved by the Ethics Review Committee of the Faculty of Medicine, Thammasat University, and informed consent was obtained from the parents prior to enrollment.

Participants

The study included 328 neonates with a birth weight of at least 1,500 g who needed percutaneous blood culture. We excluded newborns who had skin infections at the puncture site or had a history of allergy to both antiseptics. We defined preterm infants as babies born alive before 37 weeks of pregnancy are completed.

Interventions

Sample size of 328 cultures (164 specimens per group) was needed to have 80% power to detect a contamination risk difference between groups of 8.2% with the significant level of $P < 0.05$ [19]; therefore, 328 neonates were randomized into two groups according to antiseptic used: 2% chlorhexidine gluconate in 70% alcohol (CHG group) and 10% povidone iodine (PI group). Computer-generated randomization with blocks of 4 was employed. Blood cultures were taken by pediatric residents, general physicians and ward nurses using standard techniques.[22] Adverse skin reactions were observed for 2 days.

The blood cultures were subsequently incubated at 37°C for 5 days and analyzed using a BACTEC analyzer (Versatrek, PCL Company). Isolated organisms and their antimicrobial susceptibilities were determined using standard microbiological techniques.

Blood culture isolates were classified as a true pathogen or a contaminant by clinical observation combined with laboratory data. A blood culture was classified as a contaminant if common skin flora was isolated from one of the blood culture samples without isolation of the same organism from another potential infection site (for example, intravenous catheter), or a common skin flora was isolated in a patient with incompatible clinical observation and improved without specific treatment for that organism. The common skin flora includes coagulase-negative staphylococci, *Bacillus* species other than *Bacillus anthracis, Corynebacterium* species, *Propionibacterium acnes* and *Micrococcus* species.

Outcomes

The principle outcome was to compare the efficacy between 2% chlorhexidine gluconate in 70% alcohol and 10% povidone iodine in reducing blood culture contamination in neonates. Secondary outcome was to evaluate safety of both antiseptics between two groups.

Statistical analysis

The primary end point was the occurrence of blood culture contamination. All data were analyzed using the SPSS 22 software program. The categorical data of both groups were described and compared using the Chi-square test. The continuous data of both groups were described and compared by using an independent t-test. The risk of blood contamination of each group was presented with a 95% confidence interval (95% CI). Statistical significant level was set at $P < 0.05$.

Results

During March to September 2016, 328 neonates were enrolled and blood culture specimens were obtained from these patients. Each of antiseptic, 2% chlorhexidine gluconate in 70% alcohol and 10% povidone iodine, was used in 164 specimens. The baseline characteristics of the groups, including weight, gender, gestational age, mode of delivery, relevant antenatal details of the mothers were similar between two groups.

In our study, the lowest birth weights was 1,537 g in CHG group compared with 1,539 g in the PI group, and the number of neonates with birth weights less than 2,000 g between the two groups were similar (28 versus 30 in CHG group and PI group respectively, $P = 0.89$). There were no differences between the groups in the percentage of preterm infants (48.6% versus 51.4% in CHG group and PI group respectively, $P = 0.66$).

Regarding ward of admission, most neonates were admitted in the high risk neonatal ward, followed by the private pediatric ward; the staff performing the procedures was comparable between the two groups. In the CHG group, there were 6 physicians who took blood cultures and 8 physicians in the PI group. For demographic data, there were no statistical differences between the groups (Table 1).

Table 1 Demographic features of neonates enrolled in the study

Demographic features	CHG group (n= 164)	PI group (n= 164)	P-value*
Mean Age, days (± SD)	2 ± 1.9	2 ± 1.7	0.95
Mean birth weight, g (± SD)	2,753 ± 647	2,659 ± 671	0.19
BW 1,500-1,999 g	28 (17.1%)	30 (18.3%)	0.89
BW >2,000 g	136 (82.9%)	134 (81.7%)	
Male sex, N (%)	97 (59.1%)	102 (62.2%)	0.57
Mean gestational age, weeks (± SD)	36.5 ± 2.3	36.4 ± 2.3	0.74
Preterm, N (%)	72 (48.6%)	76 (51.4%)	0.66
AGA, N (%)	157 (95.7%)	160 (97.5%)	0.36
Mode of delivery, N (%)			0.98
Vaginal delivery	89 (54.2%)	87 (53.0%)	
Forceps or vacuum extraction	5 (3.0%)	5 (3.0%)	
Cesarean delivery	70 (42.6%)	72 (43.9%)	
Ward of admission, N (%)			0.07
General pediatric ward	18 (10.9%)	10 (6.1%)	
Private pediatric ward	38 (23.2%)	41 (25.0%)	
High risk neonatal ward	92 (56.1%)	83 (50.6%)	
Neonatal intensive care unit	16 (9.8%)	30 (18.2%)	
Pre-delivery steroids, N (%)	30 (18.2%)	29 (17.7%)	0.89
Pre-delivery antibiotics, N (%)	29 (17.7%)	27 (16.5%)	0.77
PROM	8 (4.9%)	7 (4.3%)	0.79
Mean maternal age, years (± SD)	30.0 ± 5.5	29.8 ± 6.2	0.67
Staff performing procedure, N (%)			0.25
First-year pediatric residents	1 (0.6%)	3 (1.8%)	
Second- year pediatric residents	3 (1.8%)	1 (0.6%)	
Third- year pediatric residents	0	3 (1.8%)	
General physicians	2 (1.2%)	1 (0.6%)	
Nurses	158 (96.3%)	156 (95.1%)	
Puncture attempts (>1 time), N (%)	2 (1.2%)	0	0.16
Puncture site (arm), N (%)	100%	100%	0.99
Babies given antibiotics before procedure, N (%)	7 (4.3%)	5 (3.0%)	0.56
Babies given antibiotics after procedure, N (%)	155 (94.5%)	155 (94.5%)	0.99

Abbreviations: SD, Standard deviation; BW, birth weight; AGA, appropriate for gestational age; PROM, premature rupture of membrane
*P<0.05 is considered significant difference.

Of these 328 cultures, 7 cultures (2.13%) grew organisms interpreted as being contaminants of skin flora, while 6 cultures (1.83%) were truly positive blood cultures. Characteristics of the 7 patients who had blood culture contamination are shown in Table 2.

Table 2 Characteristics of patients with culture contaminationa

GA (weeks)	BW (g)	Age (days)	Staff	Diagnosis	Antiseptics	Time to positive	Antibiotics (ATBs)	Duration of ATBs
37	2,788	5	Nurse	Neonatal sepsis	CHG	42	Cefotaxime + amikacin	7
39	3,482	2	Nurse	Neonatal sepsis, jaundice	CHG	19	Ampicillin + gentamicin	7
38	2,094	2	Nurse	Neonatal sepsis, polycythemia	CHG	36	Cloxacillin + gentamicin	7
36	2,152	26	Nurse	Neonatal sepsis,	PI	26	Cefotaxime + amikacin	7
34	2,198	1	Nurse	Neonatal sepsis, mild RDS	PI	33	Ampicillin + gentamicin	7
38	3,456	12	Nurse	Neonatal sepsis, TTNB	PI	28	Cloxacillin + amikacin	7
36	2,478	2	Nurse	Omphalitis	PI	34	Cloxacillin + gentamicin	7

[a] All culture contaminants were coagulase-negative staphylococci (CoNS).

Abbreviations: GA, gestational age; BW, body weight; CHG, chlorhexidine gluconate; PI, povidone-iodine; RDS, respiratory distress syndrome; TTNB, transient tachypnea of the newborn

The risks of contamination from using CHG and PI were 1.83% (95% CI: 0.38 - 5.35) and 2.43% (95% CI: 0.67 - 6.25), respectively. The relative risk of blood culture contamination among patients whose skin was cleaned with chlorhexidine-alcohol versus povidone-iodine was 0.75 (95% CI: 0.17 - 3.30) with P = 0.71.

There was a reduction in the incidence of blood culture contamination in the 2% chlorhexidine gluconate in 70% alcohol group. The risk difference of blood culture contamination was -0.61% (95% CI: -3.77 - 2.55%) with P = 0.70 (Table 3).

Table 3 Blood culture contamination rate

Blood culture results	CHG group (n = 164)		PI group (n = 164)		P-value*
	Number (95%CI)	Incidence risk	Number	Incidence risk (95%CI)	
Contaminated	3	1.83% (0.38% - 5.35%)	4	2.43 % (0.67% - 6.25%)	0.71[a]

[a] Relative risk, 0.75 (95% confidence interval, 0.17 - 3.30)

* P<0.05 is considerd significant diferrence.

Abbreviations: CHG, chlorhexidine gluconate; PI, povidone-iodine

The septicemia rate was similar among two study groups (3 of 164 in both group, P = 0.99). In the case of true pathogens isolated from the blood culture, gram negative organisms were more commonly identified (6/6, 100%). *Klebsiella* spp. (4/6, 66.7%) were the most common isolates (Table 4).

Table 4 Pathogens causing true bacteremia

Microorganisms	Number (%)		P-value*
	CHG group (N=6)	PI group (N=7)	
Citrobacter spp.	1 (16.7%)	0	0.32
Klebsiella spp.	0	3 (42.8%)	0.15
Enterobacter spp.	1 (16.7%)	0	0.32
E.coli and *K.pneumoniae*	1 (16.7%)	0	0.32

* P<0.05 is considered significant difference

Abbreviations: CHG, chlorhexidine gluconate; PI, povidone-iodine

The rate of skin contamination was different between wards of admission. The contamination rate was higher in general and private wards compared with NICU and high risk neonatal wards (3.7% vs. 1.4%; P = 0.18) but this did not reach statistically significant differences (Table 5).

Table 5 Distribution of positive blood cultures and ward

Blood culture results	Number (%)		P-value*
	High risk neonatal wards and NICU (n=221)	General and private pediatric wards (n=107)	
True pathogens	6 (2.7)	0 (0)	0.21
Contaminated	3 (1.4)	4 (3.7)	0.18
No growth	212 (95.9)	103 (96.3)	0.89

* P<0.05 is considered significant difference.

Abbreviations: NICU, neonatal intensive care unit

No adverse skin reactions or systemic adverse effects were observed in both antiseptic solution groups. None of the group had any neonatal mortality.

Discussion

Our primary objective was to compare the efficacy of two skin disinfection solutions in reducing blood culture contamination in neonates. The overall contamination rates when using 2% chlorhexidine gluconate in 70% alcohol compared to using 10% povidone iodine were not significantly different.

Chlorhexidine utilizes superior clinical protection as compared to povidone - iodine by its rapid bactericidal effect, persistent activity despite exposure to body fluids and its residual effects as the alcohol itself is an effective antiseptic agent and speeds the drying time when combined with CHG.[23-25] But CHG in an alcohol solution has been reported to increase the risk of skin irritation, which may be related to alcohol irritating skin or to CHG induced hypersensitivity.[17, 26]

Previous studies reported the effectiveness of CHG as being better than PI but in different concentrations (0.25 - 4% CHG) and different preparations of the CHG base (water versus alcohol base). Data on the efficacy of CHG as a topical antiseptic for prevention of culture contamination in neonates were very limited.[17, 22, 26-29]

Nuntnarumit and colleagues reported that 1% aqueous chlorhexidine gluconate was more effective than 10% povidone iodine as a skin antiseptic in neonates associated with significantly less culture contamination (P = 0.026). No skin erythema, burn, or contact dermatitis was observed in either group.[30]

The general and private wards had higher contamination rates than NICU and high risk neonatal wards (3.7% vs. 1.4%; P = 0.18) but without statistically significant differences. This was probably due to higher skill in performing blood cultures from neonates of staffs in NICU and high risk wards.

In this study, using cutaneous disinfection with 2% CHG in 70% alcohol was not associated with an increased risk of contact dermatitis or systemic adverse effects when compared to using cutaneous disinfection with 10% PI. Chemical burns and severe contact dermatitis have been reported in association with topical application of chlorhexidine in extremely premature infants, especially in preterm with birth weights less than 1,000 g.[31-35] Furthermore, 10% povidone iodine as a skin antiseptic in neonates, especially in premature infants was no longer acceptable, due to thyroid dysfunction effect.[36-38]

However, our study used 2% chlorhexidine gluconate in 70% alcohol in term and preterm newborns with birth weights of at least 1,500 g; therefore, further study is needed to determine the most appropriate and safe antiseptic to use in extremely premature infants with birth weight less than 1,500 g.

Proper skin preparation plays an important role in reducing blood culture contamination leading to decrease of inappropiate antibiotic use, antibiotic-resistant organisms, and overall healthcare costs.

Other limitations need to be addressed. First, a true, blinded comparison of these two antiseptics would not be possible due to distinctive antiseptics in colors. Second, contaminated blood culture is a particularly difficult challenge in neonatology as only limited blood volume is taken from sick neonates. Taking 2 or 3 samples of blood cultures are extremely impossible when compared with older children or adults.

Conclusion

Both 2% chlorhexidine gluconate in 70% alcohol and 10% povidone iodine had similar efficacy in reducing blood culture contamination. In addition, neither of the antiseptics solutions resulted in adverse skin reactions, nor had any systemic adverse effects. Chlorhexidine is safe in both term and near-term neonates.

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บทคัดย่อ

ประสิทธิภาพและความปลอดภัยของ 2% คลอเฮกซิดีน กลูโคเนทใน 70% แอลกอฮอล์เปรียบเทียบกับ 10 % โพวิโดนไอโอดีน ในการเพาะเชื้อในกระแสเลือดในผู้ป่วยทารกแรกเกิด

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บทนำ: การเพาะเชื้อเป็นวิธีมาตรฐานในการวินิจฉัยภาวะติดเชื้อในกระแสเลือด ซึ่งอัตราปนเปื้อนค่อนข้างสูง การทำความสะอาดผิวหนังจึงเป็นขั้นตอนสำคัญในการลดการปนเปื้อน ปัจจุบันยังไม่มีคำแนะนำเกี่ยวกับน้ำยาที่ใช้ทำความสะอาดผิวหนังในกลุ่มผู้ป่วยทารกแรกเกิด

วิธีวิจัย: การศึกษาแบบ randomized controlled trial prospective cohort study ในผู้ป่วยเด็กอายุไม่เกิน 1 เดือน ที่โรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ ตั้งแต่เดือนมีนาคม ถึงกันยายน 2559 เพื่อเปรียบเทียบประสิทธิภาพของ 2% Chlorhexidine gluconate in 70% alcohol กับ 10 % povidone iodine ในการลดการปนเปื้อนจากการเพาะเชื้อในเลือด และเปรียบเทียบผลข้างเคียงของน้ำยาทั้งสองชนิด โดยมีแพทย์ประจำบ้าน แพทย์ใช้ทุนและพยาบาลเป็นผู้เจาะเลือด

ผลการวิจัย: ไม่พบความแตกต่างของข้อมูลพื้นฐานในประชากรทั้งสองกลุ่ม โดยแบ่งผู้ป่วยเป็น 2 กลุ่ม กลุ่มละ 164 ราย กลุ่มที่ 1 เช็ดผิวหนังด้วย chlorhexidine in alcohol และกลุ่มที่ 2 ใช้ Povidone iodine พบเชื้อปนเปื้อนทั้งหมดร้อยละ 2.13 คือ coagulase-negative staphylococci และไม่พบความแตกต่างของอัตราการปนเปื้อนจากการเพาะเชื้อทั้งสองกลุ่ม (ร้อยละ 1.83 และ ร้อยละ 2.43 ตามลำดับ) ค่า risk difference เท่ากับร้อยละ -0.61 (95% CI: -3.77-2.55) และไม่พบผลข้างเคียงจากการใช้น้ำยาสองชนิด

สรุปผลงานวิจัย: น้ำยาทั้งสองชนิดมีประสิทธิภาพเท่าเทียมกันในการลดการปนเปื้อนจากการเพาะเชื้อในกระแสเลือด และมีความปลอดภัยในการใช้เป็นน้ำยาทำความสะอาดผิวหนังก่อนเจาะเลือดเพื่อเพาะเชื้อในผู้ป่วยทารกแรกเกิด

คำสำคัญ: การเพาะเชื้อในเลือด, การปนเปื้อน, 2% คลอเฮกซิดีน กลูโคเนทใน 70% แอลกอฮอล์, 10 %โพวิโดนไอโอดีน, ทารกแรกเกิด