Original Article

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Paediatrics Section

# Efficacy of Chlorhexidine Alcohol versus Povidone Iodine Alcohol in Reducing Peripheral Venous Catheter Colonisation in Paediatric Patients: A Randomised Controlled Trial

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## ABSTRACT

**Introduction:** Peripheral Venous Catheters (PVCs) are routinely used in paediatric patients but are associated with catheter-related infections. Adequate skin antisepsis prior to catheter insertion is critical in preventing these infections.

**Aim:** To compare the efficacy of 2% chlorhexidine in alcohol (CHA) with 10% povidone-iodine in alcohol (PI) in reducing catheter-tip colonisation in paediatric patients.

**Materials and Methods:** A double-blind randomised controlled trial was conducted at the Paediatric Ward of Acharya Vinoba Bhave Rural Hospital, Maharashtra, India, from May 2024 to December 2024. A total of 102 paediatric patients aged 1 month to 16 years, admitted to the paediatric ward with an indication for intravenous catheterisation, were randomly assigned to two groups: Group A received 2% CHA and Group B received 10% PI in alcohol before PVC insertion. Upon catheter removal, the distal tips were cultured for microbial colonisation. Parameters assessed included gender, age group, mean age, incidence of catheter-tip colonisation, and type of organism isolated. Statistical tests applied included Chi-square test, Independent t-test, and Fisher's exact test.

**Results:** Demographic data showed comparable gender distribution (M:F=31:20 in Group A, 30:21 in Group B) and mean age (6.6±3.05 years vs 7.14±3.42 years) between the two groups. Catheter-tip colonisation occurred in 1 (1.96%) patient in Group A and 6 (11.76%) in Group B (p-value=0.112). *Staphylococcus* was the predominant organism in both groups, while *Klebsiella* and Gram-positive Cocci (GPC) were additionally isolated in the PI group.

**Conclusion:** Catheter-tip colonisation was higher in the PI-alcohol group (6/51) compared with the CHA group (1/51); however, this difference did not reach statistical significance (p-value=0.112). A larger study is warranted to provide more definitive evidence.

**Keywords:** Antiseptic agents, Catheter-related infections, Infection prevention, Microbial colonisation

## INTRODUCTION

Intravenous devices are integral to modern medical care and are utilised in the majority of hospitalised patients. Among these, PVCs are the most frequently used medical devices in hospital settings [1]. However, their use is not without risk. Nosocomial infections associated with intravascular catheterisation contribute to prolonged hospitalisation, increased healthcare costs, and heightened psychological stress for patients and their families. Catheter insertion procedures expose patients to the possibility of both localised and systemic infections [2-4]. Bloodstream infections acquired in hospital settings have historically ranked among the leading causes of morbidity and mortality, particularly in developed countries such as the United States [5]. Complications associated with PVC use include local catheter-related infections such as cellulitis, soft-tissue infections, osteomyelitis, phlebitis, thrombophlebitis, and suppurative thrombophlebitis, as well as systemic infections such as septicaemia or bacteraemia [6].

Several antiseptic agents are available for skin disinfection prior to catheter insertion. Povidone-iodine (PI) has traditionally been the antiseptic of choice due to its affordability, proven efficacy, and widespread use across healthcare settings. More recently, chlorhexidine gluconate in alcohol (CHA)—typically comprising 2% chlorhexidine gluconate in 70% isopropyl alcohol—has emerged as a viable alternative. While it is relatively more expensive than PI, CHA is associated with a faster onset of action and provides prolonged antimicrobial activity, even in the presence of organic matter such as blood or bodily fluids [7]. Effective antiseptic skin preparation is vital for preventing healthcare-associated infections, as many of the pathogens responsible for sepsis have been isolated from the skin microbiota of hospitalised children [8].

While numerous studies [5,9,10] have compared antiseptic agents in the context of central venous catheterisation, there is a relative paucity of data regarding antiseptic use prior to PVC, particularly in paediatric populations—despite the procedure being far more commonly performed than central line insertion [9,10]. Since colonisation increases the risk of catheter-related bloodstream infections, the findings are expected to inform best practices in antiseptic selection, ultimately contributing to improved patient outcomes in paediatric care settings.

Therefore, the present study was conducted to compare the efficacy of 2% CHA and 10% PI alcohol in preventing catheter-tip colonisation in paediatric patients. The objective of the study was to assess and compare the rates of catheter-tip colonisation by culturing the catheter tips in both patient groups.

## MATERIALS AND METHODS

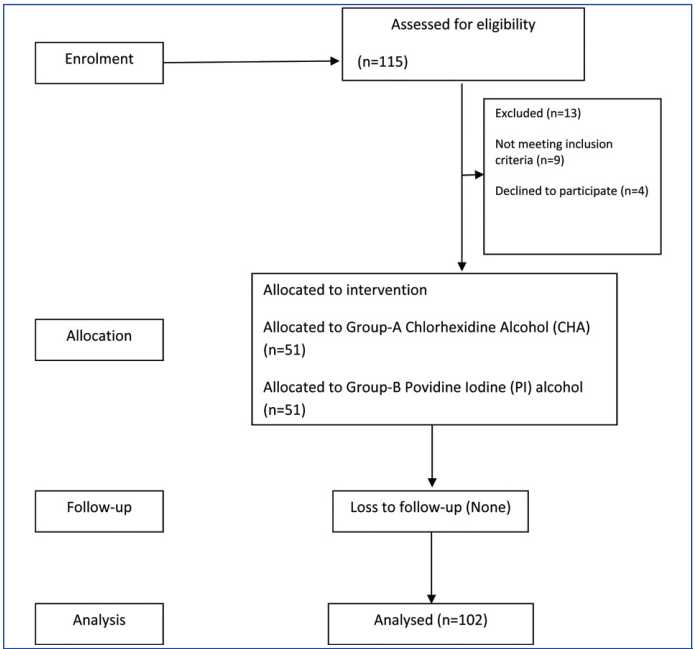
This was a double-blind randomised controlled trial conducted in the Paediatric Ward of Acharya Vinoba Bhave Rural Hospital, affiliated with Jawaharlal Nehru Medical College, Maharashtra, India. It was carried out between May 2024 and December 2024 and registered with the clinical trial number CTRI/2023/03/050292. Ethical clearance was obtained from the Institutional Ethics Committee (IEC) prior to initiation of the study (IEC number DMIMS(DU)/IEC/2022/306).

**Inclusion criteria:** Children aged 1 month to 16 years admitted to the paediatric ward with a clinical indication for PVC and whose

parents or guardians provided written informed consent were included in the study.

**Exclusion criteria:** Subjects with skin infections or injuries at the catheter insertion site. Catheter insertion in emergency settings. Known allergy to either antiseptic agent. Technically difficult catheter insertions (e.g., due to obesity or repeated attempts). Children with a poor prognosis (expected survival less than one week). Refusal of parental consent were excluded from the study.

**Sample size calculation:** A total of 102 paediatric patients requiring PVC insertion were enrolled. The sample size was calculated based on the findings of Guenezan J et al., assuming a two-sided significance level (α) of 0.05 and power (1-β) of 80% [11]. The anticipated proportion of catheter colonisation was 17% in the PI group and 1% in the CHA group, yielding an odds ratio of 20. With an equal allocation ratio of 1:1 between the two groups, the total sample size required was determined to be 102 participants (51 per group) as shown in [Table/Fig-1].




**[Table/Fig-1]:** Enrollment in the study given in CONSORT format.

The sample size calculation for comparing two proportions (i.e., incidence of catheter colonisation in two groups) is typically based on the following formula: $N= (Z1-\alpha/2+Z1-\beta)^2\times\{P1(1-P1)+P2(1-P2)\}/(P1-P2)^2$

Where:

- N=sample size per group
- P1=proportion in Group-1 (Chlorhexidine group=0.01)
- P2=proportion in Group-2 (PI group=0.17)
- Z1−α/2=Z-value for two-tailed significance level (1.96 for α=0.05)
- Z1−β=Z-value for power (0.84 for 80% power)
- A=Type-I error (0.05)
- B=Type-II error (0.20)
- N=46.25; to increased power of study 51 study participants in each group were taken, consisting of total 102.

**Data collection:** After obtaining informed written consent from the parents or legal guardians, demographic data including age and gender were recorded. Eligible participants were randomly assigned into two groups: Group A received 2% CHA applied to the skin at the catheter insertion site using sterile gloves, and Group B received 10% PI alcohol applied similarly. Participants were randomly assigned to either group A or group B using a computer-generated randomisation table. Allocation was concealed through sequentially numbered, sealed, opaque envelopes to ensure blinding.

Prior to antiseptic application, all healthcare providers washed their hands thoroughly with soap and water and refrained from wearing wristwatches, rings, or other accessories. All procedures were performed using sterile gloves. The antiseptic solution was applied using a back-and-forth friction scrub technique and allowed to dry for 30 seconds prior to catheter insertion. The study used an intravenous catheter of 24 gauge (yellow) or 22 gauge, depending on venous access and the age of the child. A double-blind method was followed where the patient's parents and the microbiologist were blind to the antiseptic used before catheter insertion.

Catheter dressings were changed when visibly soiled. Catheters were removed either at the end of therapy, upon accidental dislodgement, due to signs of occlusion, phlebitis, or systemic infection, or after 72 hours—whichever occurred first. Upon removal, approximately 1-2 cm of the distal end of each catheter was aseptically cut and sent to the microbiology department in a sterile container for culture on sheep blood agar to assess catheter-tip colonisation. No dropouts were observed in the study. The primary outcome measured was the incidence of catheter-tip colonisation as determined by positive microbial culture.

## STATISTICAL ANALYSIS

All data were entered into Microsoft Excel, and statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) software, version 26.0. Comparative analyses between the two groups were conducted using Independent t-tests, Chi-square tests, and Fisher's exact tests, as appropriate. A p-value<0.05 was considered statistically significant.

## RESULTS

A total of 102 paediatric patients were enrolled, with 51 participants allocated to each group. Group A received 2% CHA, while Group B received 10% PI alcohol as the antiseptic prior to PVC insertion. The gender distribution was comparable, with group A comprising 31 (60.8%) males and 20 (39.2%) females, and group B comprising 30 (58.8%) males and 21 (41.2%) females. This difference was not statistically significant (p-value=1.000, Chi-square test). Age distribution was also similar across groups. The mean age in group A was 6.6±3.05 years, and in group B it was 7.14±3.42 years. This difference was not statistically significant (p-value=0.205, independent t-test). These results indicate that both groups were demographically comparable, minimising potential confounding effects [Table/Fig-2]. No adverse events or reactions were observed related to antiseptic use in either group.

| Demographic characteristics | Group A (Chlorhexidine) (n=51) | Group B Povidone Iodine (PI) (n=51) | p-value (Sig=<0.05) |
|---|---|---|---|
| **Gender of child** | | | 1.00 (Chi-square test of independence) |
| Male | 31 (60.8) | 30 (58.8) | |
| Female | 20 (39.2) | 21 (41.2) | |
| **Age group (years)** | | | 0.624 (Chi-square test of independence) |
| 1-5 | 17 (33.3) | 20 (39.2) | |
| 6-10 | 23 (45.1) | 23 (45.1) | |
| 11-16 | 11 (21.6) | 8 (15.7) | |
| Mean age of study population (Years±SD) | 6.6±3.05 95%CI 6.6±0.837 (±12.7%) | 7.14±3.42 95%CI 7.14±0.939 (±13.1%) | 0.205 (Independent t-test t value=0.824 |

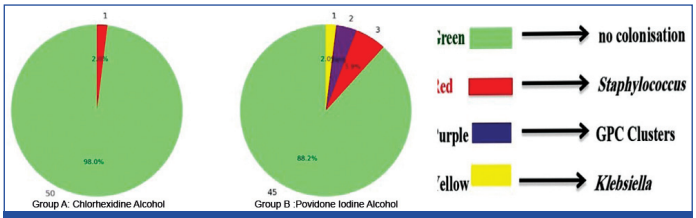
**[Table/Fig-2]:** Distribution of study population according to demographic profile.

In group A (Chlorhexidine), one out of 51 participants (1.96%) exhibited catheter-tip colonisation. In group B (PI), six out of 51 participants (11.76%) had positive catheter-tip cultures. Although the incidence was higher in the PI group, the difference did not reach statistical significance (p-value=0.112, Fisher's exact test) [Table/Fig-3].

| Outcome (catheter tip colonisation) | Group A (Chlorhexidine) | Group B (Povidone Iodine) | p-value (Fisher-exact test) |
|---|---|---|---|
| Present | 01 (01.96%) | 06 (11.76%) | 0.112 (Significant <0.05) |
| Absent | 50 (98.04%) | 45 (88.24%) | |

**[Table/Fig-3]:** Catheter-tip colonisation.

[Table/Fig-4] presents the distribution of microorganisms isolated from catheter-tip cultures in both groups. In group A, only one isolate (*Staphylococcus* spp.) was recovered. In group B, a total of six isolates were identified, including *Staphylococcus* spp. (n=3), *Klebsiella* spp. (n=1), and GPC in clusters (GPC cluster; n=2). This finding emphasises the greater microbial diversity and burden observed in the PI group, further supporting the comparative efficacy of Chlorhexidine in reducing catheter-tip colonisation.




**[Table/Fig-4]:** Distribution of study population according to microbiological analysis of catheter tips.

## DISCUSSION

This randomised controlled trial evaluated the efficacy of two commonly used antiseptic agents—2% CHA and 10% PI alcohol—in preventing catheter-tip colonisation among paediatric patients undergoing PVC. Given the widespread use of PVCs in hospitalised children and the associated risk of catheter-related infections, identifying the most effective antiseptic solution is of paramount clinical importance. CHA is considered superior as it is thought to have longer antiseptic activity and is not susceptible to neutralisation by blood, serum, and other bodily fluids compared with PI. The study was conducted in a tertiary care setting, with a robust design, including blinding and microbiological confirmation of colonisation, thereby enhancing the reliability of the findings.

Present results revealed that catheter-tip colonisation occurred in 1.96% (1/51) of patients in the Chlorhexidine group (group A), compared to 11.76% (6/51) in the PI group (group B). No adverse events related to antiseptic use were observed in either group. No clinical infections due to the antiseptics were observed. Incidences of colonisation were higher with PI alcohol than CHA but did not reach statistical significance (p-value=0.112). Microbiological analysis further revealed that *Staphylococcus* species were the most commonly isolated organisms, with additional pathogens such as *Klebsiella* and GPC in clusters identified exclusively in the PI group. These findings suggest that CHA may offer broader or more sustained antimicrobial activity.

The results align with a growing body of literature supporting the superior efficacy of Chlorhexidine in preventing catheter-related infections. Lin MR et al., reported significantly higher flora detection and CRBSI rates in the PI group [12], while Guenezan J et al., [11] found a catheter-colonisation rate of 17% in the PVI group versus 1% in the CHG group, with a hazard ratio of 0.08. Similarly, Pages J et al., and Mimoz O et al., demonstrated a significant reduction in catheter colonisation and bloodstream infections with CHG use, supported by adjusted hazard ratios and relative risks favouring chlorhexidine [13,14]. Additional studies reinforce these findings. Maki DG et al., observed the lowest infection rates with CHG (2.3%) compared to alcohol (7.1%) and PVI (9.3%) (p-value=0.02) [15]. Myaneh ZT et al., found fewer positive catheter-tip cultures with CHG in neonates, and Mimoz O et al., reported the superior antiseptic effect of CHG-alcohol over PVI alcohol [16,17].

In a meta-analysis, Shi Y et al., concluded that catheter-related bloodstream infection rates were significantly higher in patients receiving PI antisepsis compared to those receiving Chlorhexidine [18]. However, some studies, including Ishizuka M et al., [19] and Humar A et al., which compared lower concentrations of CHG (0.05%) with 10% PVI, did not observe significant differences, highlighting the importance of using an adequate concentration—specifically 2% CHG—to achieve optimal efficacy [19,20]. McCann M et al., also found no significant difference when comparing 2% CHG with 70% isopropyl alcohol in a haemodialysis setting, suggesting that contextual factors such as patient population and catheter type may influence outcomes [21]. Taken together, present study findings and the broader literature provide strong support for including 2% CHA in standard catheter-care protocols, especially in paediatric wards.

While statistical significance was not achieved in this study, likely due to the small sample size, the clinical relevance of the observed reduction in colonisation cannot be overlooked. A comparison of the present findings with contrast studies is shown in [Table/Fig-5] [11-21].

| Study | Place/year of the study | Sample size | Objective | Study population | Main findings |
|---|---|---|---|---|---|
| Present study | AVBRH Sawangi /2024 | 102 | To assess and compare the number of catheter colonisation by culturing the catheter tips in both patient groups. (Chlorhexidine alcohol (CHA) vs Povidone Iodine (PI) Alcohol) | Paediatric patients, RCT | Colonisation: CHG 1.96%. vs PVI 11.76% (p-value=0.112) |
| Guenezan J et al., [11] | Poitiers University Hospital, France/2019 | 1000 | To assess superiority of 2%Chlorhexidine plus alcohol over 5% PI alcohol in preventing clinical complications | Adults, multi-centre RCT | Colonisation: CHG 1% vs PVI 17% (HR=0.08). |
| Lin MR et al., [12] | Chang Gung Memorial Hospital/2016-2017 | 446 | To compare the performance of 2% CHG and 10% PVI in CVC care bundles in two medical Intensive Care Units (ICUs). | ICU patients | Higher flora detection and CRBSI in PVI group. |
| Pages J et al., [13] | Multicentre study, France/2011-2014 | 3471 | To compare the risk of catheter infection according to the use of cutaneous antiseptics to clean CVC insertion sites and for catheter care thereafter among adult patients included in the 3SITES study | ICU patients | Significant reduction in colonisation and CRBSI with CHG. |
| Mimoz O et al., [14] | Poitiers University/2004-2006 | 482 | To compare a Chlorhexidine based solution with alcohol based PI for skin antisepsis in terms of rate of catheter colonisation and bloodstream infection in severely ill patients | Surgical patients | Lower colonisation and BSI with CHG (adjusted RR in favor of CHG). |
| Maki DG et al., [15] | University for Wisconsin Trauma and life support/1986-1987 | 668 | To assess the efficacy of cutaneous antisepsis to prevent catheter associated infection (10% PVI vs 70% alcohol vs 2% Chlorhexidine) | CVC patients | CHG significantly reduced infections (p-value=0.02). |
| Myaneh ZT et al., [16] | Qazvin University of Medical Sciences/2016-2017 | 106 | To evaluate and compare the effects of Chlorhexidine 2% and iodopovidone-alcohol solutions on bacterial colonisation associated with the PVC in premature infants | Neonatal ICU | Fewer catheter tip cultures positive with CHG. |
| Mimoz O et al., [17] | Multicentric (11 ICU) France | 5159 | To compare 2% CHG with 70%isopropyl alcohol with 5%PVI with 69% ethanol applied in one step or four step to reduce CRI and CR-BSI | CVC insertion | CHG showed superior antiseptic activity. |
| Shi Y et al., [18] | Meta-analysis/2018 | 10 RCT | Assess the efficacy of Chlorhexidine with Povidone solutions as a skin disinfectant for central venous catheter care | Meta-analysis (multiple RCTs) | Higher CRBSI rates in PVI group. |

| | | | | | |
|---|---|---|---|---|---|
| Ishizuka M et al., [19] | Dokkyo Medical University/2006-2008 | 584 | Comparison of 0.05% Chlorhexidine and conventional 10% PI during the period from catheter insertion to development of CVC-RBSI, in adult patient with colorectal cancer | Surgical patients | No significant difference. |
| Humar A et al., [20] | University Health network ,University of Toronto .(Affiliated Hospitals) | 242 | To compare 10% PI versus 0.5% tincture of Chlorhexidine solution for cutaneous antisepsis during CVC insertion and for subsequent line care | ICU patients | No significant difference. |
| McCann M et al., [21] | 3 outpatient haemodialysis units in Ireland/2010-2012 | 105 | To evaluate 2% Chlorhexidine in 70% isopropyl alcohol solution versus routine Chlorhexidine solution for reducing CVC-related infections in haemodialysis patients | Haemodialysis setting | No significant difference. |

**[Table/Fig-5]:** Comparison of present study with similar and contrasting studies on antiseptic efficacy in catheter colonisation [11-21].
CRBSI: Catheter related blood stream infection; CVC: Central venous catheter; CRI: Catheter related infection

## Limitation(s)

This was a single-centre study, and the findings may not be generalisable to other populations or healthcare settings. Future studies with larger sample sizes and multicentre participation are recommended to validate these results and strengthen the evidence base.

# CONCLUSION(S)

This study demonstrated that the use of 2% CHA results in a lower incidence of catheter-tip colonisation compared to 10% PI alcohol among paediatric patients undergoing PVC. Although the observed difference did not achieve statistical significance, the trend supports the greater efficacy of Chlorhexidine as a skin antiseptic in this clinical context. These findings reinforce the potential role of Chlorhexidine in reducing the microbial burden on catheter tips, thereby contributing to improved infection prevention strategies in paediatric care. Additional larger multicentre studies are recommended to conclusively determine the most effective agent for reducing catheter colonisation and preventing bloodstream infections, which can standardise antiseptic protocols across healthcare settings.

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