

Skin Preparation Prior to Epidural Anesthesia: Chlorhexidine or Povidone Iodine?

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ABSTRACT

Background: Infection in the epidural space is rare but if it occurs it is a serious complication of epidural catheter placement. This study aimed to compare 0.5% chlorhexidine and 10% povidone iodine in preventing bacterial colonization of epidural catheters in patients treated at the Dr. Sardjito Hospital.

Methods: A randomized, single-blind, controlled trial was performed to 52 subjects who underwent epidural anesthesia or a combination of general and epidural anesthesia at the Dr. Sardjito Hospital between January to April 2019. Subjects were divided into a control group (10% povidone iodine) and an intervention group (0.5% chlorhexidine in 70% alcohol). Examination of the epidural catheter (3-4 cm) tip culture on the 3rd day after installation.

Results: Chi-square test showed that the effectiveness in preventing bacterial colonization in epidural catheters of chlorhexidine 0.5% in 70% alcohol was did not differ significantly compared to povidone iodine 10%. This study found positive bacterial cultures on chlorhexidine 0.5% and povidone iodine 10% each in 13% of 23 epidural catheters ($p > 0.05$).

Conclusion: The effectiveness of 0.5% chlorhexidine in 70% alcohol compared to 10% povidone iodine did not differ significantly in preventing bacterial colonization in epidural catheters.

Keywords: Chlorhexidine; Povidone iodine; Bacterial colonization; Epidural catheter

Abbreviations: CHX: Chlorhexidine; PI: Povidone Iodine

INTRODUCTION

Infection in the epidural space is rare but if it occurs it is a serious complication of epidural catheter placement. Transmigration of skin bacteria through the needle pathway is the main way of entering microorganisms. Therefore, disinfection of skin according to aseptic and sterile guidelines for handling invasive devices used in regional anesthesia is very important. Aromaa et al. reported 8 cases of bacterial infection in the spinal or central nervous system (CNS) after 170,000 epidurals and 550.00 spinal anesthesia, with an overall frequency of 1.1 per 100,000 blocks [1]. This study aimed to compare chlorhexidine 0.5% and povidone iodine 10% in preventing bacterial colonization of epidural catheters in patients treated at the Dr. Sardjito Hospital.

METHODS

Design and study population

After getting approval from the ethics committee, the Faculty of Medicine Gadjah Mada University, Dr. Sardjito Hospital and consents from patients (No.KE/FK/0976/EC/2018), a randomised, single blinded, control trial was conducted in Dr. Sardjito Hospital, Yogyakarta from January to April 2019. Population was surgery patients who underwent epidural anesthesia or a combination of general and epidural anesthesia in Dr. Sardjito General Hospital.

The inclusion criteria were adult (18-65) years old, physical status American Society of Anesthesiology (ASA) 1-2, and have

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consented to participate in this study. The exclusion criteria were allergy allergic to chlorhexidine and povidone iodine, patients with sepsis and patients with local infections in the back. Furthermore, the dropout criteria were subjects refused to continue participation in the study, epidural anesthesia was carried out for more than 15 minutes and or puncture $\geq 3x$, allergic reactions occurred after antiseptic action with chlorhexidine 0.5% liquid or povidone iodine 10%, failed anesthetic block/epidural analgesia, epidural catheter or the epidural filter is released / released before the 3rd day after the epidural.

Data collection

Samples were obtained through non probability sampling with consecutive sampling. Randomization for subjects was done with block randomization using Microsoft excel. The sample size was calculated using analytic categorical sample size formula for unpaired two groups. Proportion was obtained from previous research. The subjects were divided into two groups of 0.5% chlorhexidine (CHX) and 10% povidone iodine (PI) group. The recorded data were name, age, sex, medical record, ASA status, history of diabetic, immunocompromised, type of surgery, prophylactic antibiotics. Examination of the epidural catheter (3-4 cm) tip culture on the 3rd day after installation.

Detailed procedures

Procedure was explained and written informed consent was taken from all the patients. An epidural catheter was placed under aseptic condition and at L4-L5/L3-L4/L2-L3 interspaces. The patient in PI group received 10% povidone iodine and patient in CHX group received 0.5% chlorhexidine for cutaneous antiseptis before epidural catheter insertion. Catheters were inserted using the maximal sterile-barrier precautions into the lumbar epidural space, based on the preferences of the anesthesia team, on clinical indication, or both. After surgical hand washing, resident anesthesiologists were gowned, gloved, and masked. The chlorhexidine or povidone iodine antiseptic liquid is applied to the skin and left for 2 minutes until it dries. Sterile drap are installed in the sterile area. An epidural anesthesia was performed with Tuohy's epidural needle no. 18G, with a median or para median approach. Epidural catheters were located using the loss-of-resistance technique with either saline solution or air within maximum of 15 minutes of epidural anesthesia. Puncture ≥ 3 times is considered eliminated from study. A 22-gauge polyamide epidural catheter (Perifix, B Braun, and Germany) was advanced 3 ± 4 cm into the epidural space to ensure secure placement without subcutaneous tunneling. All catheters were fixed in place with a sterile occlusive dressing. The proximal portion of the catheter was then directed cephalad and fixed on the back using tape.

The insertion site and the dressing were inspected daily by nursing staff and the acute pain service team, who were blind to the antiseptic solution used, to search for signs of infection (pus), inflammation (erythema, heat, tenderness), or cutaneous

allergic events to the disinfectant(edema, erythema). The decision to remove the catheter was made solely by the acute pain service team, who kept the catheter in place until it was no longer required or until an adverse event, such catheter-related infection or catheter migration out of the epidural space necessitated its removal. Catheter-related infection was suspected in a patient who became febrile without any other cause.

After 3 days postoperatively the epidural catheter was removed and the tip of the epidural catheter (3-4 cm) was cut using sterile cutting scissors and then inserted into a sterile screw capped transport tube with the assistance of an assistant. Then the tube is sent as soon as (maximum 1 hour) to the microbiology laboratory of Dr. Sadrjito Hospital in aseptic conditions.

Statistical analysis

Data was expressed as percentages for categorical variables. The significance of the differences between the two study groups was determined with the chi-square test for categorical variables. All P values were based on chi-square tests of significance with $p < 0.05$ used to determine significance. All computation was performed with SPSS 24.0 for Windows software.

RESULTS

The research flow chart was presented in Figure 1. A total of 52 patients requiring an epidural catheter were enrolled in the trial and randomly assigned (26 in the PI group and 26 in the CHX group). Completed data could be evaluated for 46 catheters (23 in the PI group and 23 in the PI group).

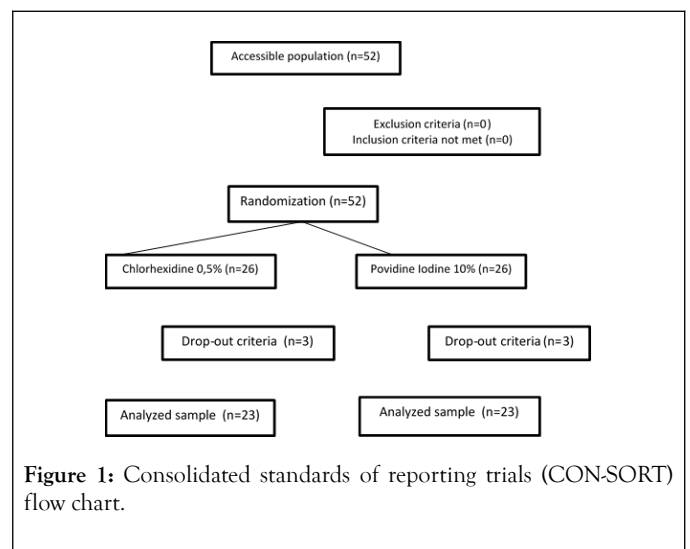


Figure 1: Consolidated standards of reporting trials (CONSORT) flow chart.

Three subjects in group CHX were not cultured because they went home on the second day after epidural placement (2 subjects) and failed to block (1 subject) while three subjects in group PI were not cultured because they went home on the second day after epidural (1 subject) and epidural filters were removed on the second day after epidural (2 subjects). The two groups of catheters were similar with respect to characteristics of patients and catheters (Table 1).

Table 1: Subjects' characteristics.

Characteristics	Chlorhexidine (n=26)	Povidone Iodine (n=26)	p-value
Age (years)			
>60	0 (0%)	7 (26.9%)	0.01
<60	26 (100%)	19(73.1%)	
Sex (n%)			
Male	9 (34.6%)	6(23.1%)	0.541
Female	17 (65.4%)	20 (76.9%)	
History of diabetic (n%)			
No	25 (96.2%)	26 (100%)	1
Yes	1 (3.8%)	0(0%)	
History of immunocompromised (n%)			
Autoimmune disease	0 (0%)	0 (0%)	
Sitostatic therapy	0 (0%)	0 (0%)	
HIV/AIDS	0 (0%)	0 (0%)	
Steroid therapy > 2 weeks	0 (0%)	0 (0%)	
Type of surgery			
Obstetric	14 (53.8%)	13 (50%)	0.961
General surgery	11 (42.3%)	12 (46.2%)	0.961
Orthopedic	0 (0%)	0(0%)	
Urology	1 (3.8%)	1(3.8%)	0.842
P value ≤ 0.05=different was statistically significant			

Table 2: Comparison of incidences of epidural catheter bacterial colonization.

Variable	Colony-forming Unit		p-value
	(+)	(-)	
Chlorhexidine n=23 (%)	3 (13%)	20 (87%)	1
Povidone Iodine n=23 (%)	3 (13%)	20 (87%)	1
P value ≤ 0.05=different was statistically significant			

Six cultures of catheter tips yielded microorganisms (Table 2). The bacterial species identified were *Staphylococcus aureus*, *Staphylococcus warneri*, *Staphylococcus haemolyticus*, *Cronobacter sakazakii* and *Bacillus*. Demographic data of research subjects on positive bacterial cultures in the age group showed that there was 1 positive cultured in the age subjects occurred in the >60 years group and 5 positive cultures in the age subjects occurred in the ≤ 60 years group. In the sex group, there were 3 positive cultures found in each group of men and women. The diabetes group showed 6 positive cultures in the negative diabetes group. Whereas in the autoimmune disease

group, sitostatica therapy, HIV/AIDS and steroid use were not found. Positive bacterial culture in the type of obsgin surgery, surgery and urology (Table 3). Table’s data showing the effect of prophylactic antibiotics on the cultured of epidural catheter bacteria shows that positive cultures occurred in the administration of cefazoline and ceftriaxone prophylactic antibiotics (Table 4). None of the catheters colonized was suspected of being infected before catheter removal. There were no presence of signs of infammation at the insertion site or sistemic complications (fever), backpain or neurologic deficits (Table 5).

Table 3: Demographic data of research subjects on positive bacterial cultures.

Characteristics	Chlorhexidine Culture (+) n=23	Povidone Iodine Culture (-) n=23	p-value
Age (years)			
>60	0 (0%)	1 (33.3%)	1
<60	3 (100%)	2(66.7%)	
Sex (n%)			
Male	2 (66.7%)	1(33.3%)	1
Female	1 (33.3%)	2 (66.7%)	
History of diabetic (n%)			
No	3 (100%)	3 (100%)	1
Yes	0 (0%)	0(0%)	
History of immunocompromised (n%)			
Autoimmune disease	0 (0%)	0 (0%)	
Sitostatic therapy	0 (0%)	0 (0%)	
HIV/AIDS	0 (0%)	0 (0%)	
Steroid therapy > 2 weeks	0 (0%)	0 (0%)	
Type of surgery			
Obstetric	1 (33.3%)	2 (66.7%)	0.531
General surgery	1 (33.3%)	1 (33.3%)	0.422
Orthopedic	0 (0%)	0(0%)	
Urology	1 (33.3%)	1(33.3%)	0.295
p-value ≤ 0.05=different was statistically significant			

Table 4: Effect of prophylactic antibiotics on the culture of epidural catheter bacteria.

Antibiotics	Results of Bacterial Culture in Epidural Catheters	
	Negative	Positive
Cefazoline	38	5
Ceftriaxone	1	1
Cefotaxime	1	0
Azitromicin	1	0
No prophylactic antibiotic	0	0

Table 5: Complications after 3 days of epidural anesthesia.

Antibiotics	Complications # days after Epidural Anesthesia	
	Negative	Positive
History of irritation		
Redness	0	0
Eritema	0	0
Papule	0	0
History of fever	0	0
History of Backpain	0	0
History of Neurologic deficits	0	0

DISCUSSION

This study assessed bacterial culture in epidural tip catheters. Characteristics of each group were not different (Table 1); means confounding factors of bacterial cultures were eliminated through inclusion and exclusion criteria. Data from Table 2 shows that chlorhexidine antiseptic microscopically is no better than povidone iodine antiseptic in preventing the growth of bacterial colonization in epidural catheters and not statistically significantly different. However, of the 6 subjects who grew bacterial colonization in their epidural cultures, none of the subjects showed clinical or systemic infections related to bacteria that grew and no neurological deficits were found. This is not surprising because it is estimated that the incidence of infections associated with epidural catheters is generally low [2].

Although colonization of the epidural catheter is often found, the development of infection in the epidural space is rare. Several factors including the location of the epidural installation, the epidural medication given, and the management of the installation and release of epidural catheters can affect the risk of infection. Catheter connectors, location of catheter placement and hematogenous spread are the three main routes of entry of microorganisms into the epidural space, with catheter hubs contributing almost half [3]. The incidence of bacterial colonization in this study (13%) was greater when compared to the average incidence of 5-year contamination of 5.8%/year reported by Steffen et al with the possible cause of

positive culture results was contamination when the catheter was removed [4].

The results of this study are in line with Kasuda who conducted a study of 62 research subjects at the end of the epidural catheter by administering 0.5% chlorhexidine in 70% alcohol and 10% povidone iodine to determine the incidence of bacterial colonization in epidural catheter cultures. Data were obtained where bacterial colonization was the same in the amount of chlorhexidine (3;9%) and povidone iodine (3;11%). So it was concluded that there was no difference between chlorhexidine versus povidone iodine in reducing bacterial colonization in epidural catheters. Possible causes of the results of bacterial culture in the study were the presence of areas of the skin that were not exposed to antiseptics due to the color of the antiseptic not adhering to the skin, widespread use of antibiotics in both groups could also influence the results of the study [5].

Similar results were reported by Adam *et al.* Studies on 294 epidural obstetrics showed no difference in the results of bacterial culture between povidone iodine and chlorhexidine. The drawback of the study was that it was not randomized and the skin was not cleaned before the epidural catheter was removed, so that contamination and bias could affect the results. The opposite results were reported by Kinirons et al. who compared chlorhexidine with povidone iodine to prevent the growth of epidural catheter bacterial colonization in 96

children where the administration of chlorhexidine colonization of bacteria in epidural catheters was as much as 2% lower than that of povidone iodine which was as much as 11%. The study has limitations, including the color of different antiseptic fluids so that doctors who put on epidurals are not disguised [6].

Epidural catheter contamination by skin flora at the insertion site is the main cause of the growth of colonization in the epidural catheter. Contamination can be caused by unfavorable aseptic and antiseptic actions during installation. Another mechanism is the entry of bacteria through drugs or infected fluids [7]. Adequate aseptic techniques before epidural anesthesia are needed to reduce the incidence of infectious complications. Infection in epidural anesthesia can increase morbidity and mortality so prevention strategies are needed by taking good aseptic and antiseptic measures [6].

CONCLUSIONS

In this study, the effectiveness of chlorhexidine 0.5% in 70% alcohol compared to povidone iodine 10% did not differ significantly in preventing bacterial colonization in epidural catheters.

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AVAILABILITY OF DATA AND MATERIALS

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

AUTHOR'S CONTRIBUTION

WYH was major contributor in writing drafting the manuscript. M and UW conceived this study and critically revised the

manuscript for important intellectual content. All authors read and approved the final manuscript.

ETHICS APPROVAL & CONSENT TO PARTICIPATE

The Medical and Health Research Ethics Committee of Faculty of Medicine, Universitas Gadjah Mada/Dr. Sardjito Hospital approved this study.

CONSENT FOR PUBLICATION

Written and informed consent were taken from the subject for publications of this study.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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