Anesthesiology 2001; 94:239–44

Chlorhexidine versus *Povidone Iodine in Preventing Colonization of Continuous Epidural Catheters in Children*

A Randomized, Controlled Trial

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Background: **Chlorhexidine is better than povidone iodine for skin preparation before intravascular device insertion or blood culture collection, but it is not known whether chlorhexidine is superior in reducing colonization of continuous epidural catheters.**

Methods: **Children requiring an epidural catheter for postoperative analgesia longer than 24 h were randomly assigned to receive skin preparation with an alcoholic solution of 0.5% chlorhexidine or an aqueous solution of 10% povidone iodine before catheter insertion. Using surgical aseptic techniques, catheters were inserted into either the lumbar or the thoracic epidural space based on the preferences of the anesthesia team, on clinical indication, or both. Immediately before epidural catheter removal, their insertion site and hub were qualitatively cultures. After their removal, the catheter tips were quantitatively cultured. Catheters were classified as colonized when their tips yielded 1,000 or more colony-forming units/ml in cultures.**

Results: **Of 100 randomly assigned patients, 96 were evaluable. The clinical characteristics of the patients and the risk factors for infection were similar in the two groups. Catheters were kept in place for a median (range) duration of 50 (range, 21–100) h. Catheters inserted after skin preparation with chlorhexidine were one sixth as likely and less quickly to be colonized as catheters inserted after skin preparation with povidone iodine (1 of 52 catheters [0.9 per 100 catheter days] *vs.* 5 of 44 catheters [5.6 per 100 catheter days]; relative risk, 0.2 [95% confidence interval, 0.1–1.0]; $P = 0.02$). Coagulase-negative staphylococci were the only colonizing microorganisms recovered, and the skin surrounding the catheter insertion site was the origin of all the colonizing microorganisms.**

Conclusions: **Compared with aqueous povidone iodine, the use of alcoholic chlorhexidine for cutaneous antisepsis before epidural catheter insertion reduces the risk of catheter colonization in children.**

THE use of epidural catheters to infuse analgesic agents continuously for pain management during the perioperative period has becoming an increasingly popular treatment method in the pediatric population. Epidural abscess is a recognized complication of the use of such catheters. Although rare, epidural abscess can progress rapidly to meningitis, paralysis, or death.[1–3]

Catheters kept in place for a short time are generally colonized by skin flora present on the insertion sites, mostly during catheter placement.[4] Colonization risk increases after a threshold level of skin colonization occurs.[5,6] Thus, effective cutaneous antisepsis before epidural insertion may reduce catheter colonization, epidural catheter sepsis, and, ultimately, deep space infection.

The French Society for Anesthesiology recommends the use of either povidone iodine or chlorhexidine for skin preparation before epidural catheter placement in children.[7] Iodine tincture is not used in this setting because of its possible toxic effects, particularly on the thyroid gland. Although chlorhexidine has been found to be superior to povidone iodine for skin preparation before intravascular catheter insertion[8–10] or blood culture collection,[11] its value in preventing epidural catheter colonization remains unknown.

The goal of this prospective trial therefore was to determine if an alcoholic solution of 0.5% chlorhexidine is more effective than an aqueous solution of 10% povidone iodine in reducing catheter colonization associated with short-term epidural catheter placement in children.

Methods

Patients

The study was conducted between December, 4, 1998 and December 20, 1999 in a 1,000-bed, university-affiliated hospital in France (Hôpital de Bicêtre, Le Kremlin Bicêtre). After ethics committee approval (Comité Consultatif de Protection des Personnes dans la Rechere Biomédicale de l'hôpital Ambroise Paré à Boulogne Billancourt) and informed parental written consent, patients younger than 15 yr of age who were to have an epidural catheter placed during surgery for abdominal, lower extremity, or urologic surgical procedures were eligible to be included in the study.

Exclusion criteria included patients with history of allergy to one of the antiseptic solutions used, the presence of a clotting defect, neutropenia, neurologic disease, local or generalized infection, and those receiving immunosuppressive therapy. No antimicrobial prophy-

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Received from the Department of Anesthesia and Intensive Care, Hôpital de Bicêtre, Assistance Publique-Hôpitaux de Paris, Le Kremlin Bicêtre, France. Submitted for publication June 20, 2000. Accepted for publication September 18, 2000. Supported by a grant from Laboratoires Zeneca Pharma, Cergy, France. The funding agency was not involved in the design, conduct, or reporting of this study or in the decision to submit the manuscript for publication.

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laxis was administered specifically for the epidural catheter insertion. However, most of the patients received antibiotics during the operative period that were stopped at the end of surgery (aminopenicillins or cephalosporins given mostly alone, but sometimes in combination with aminoglycosides), according to the French guidelines on antibiotic prophylaxis during surgery.[12]

Insertion and Maintenance of Catheters

Patients were randomized to receive either 0.5% chlorhexidine gluconate (Hibitane Champ; Zeneca Pharma, Cergy, France) or 10% povidone iodine (Bétadine; Asta Médica, Marignane, France) for cutaneous antisepsis before epidural catheter insertion using computerized randomization lists. Catheters were inserted using the maximal sterile-barrier precautions into either the lumbar or the thoracic epidural space, based on the preferences of the anesthesia team, on clinical indication, or both. After surgical hand washing, fellow or resident anesthesiologists were gowned, gloved, and masked. The skin was cleaned twice (before and after placement of sterile disposable drapes) by vigorously applying the designed antiseptic solution on an area more than 300 cm^2 for at least 10 s and allowing the area to dry between each antiseptic application. Epidural catheters were located using the loss-of-resistance technique with either saline solution or air (Tuohy 20-gauge needle). A 22-gauge polyamide epidural catheter (Portex, Berck, France) 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 (Opsite; Smith and Nephew Medical Ltd., Hull, UK). The proximal portion of the catheter was then directed cephalad and fixed on the back using tape (Albupore; Smith and Nephew Medical Ltd.). Continuous infusions of 0.1% bupivacaine with or without preservative-free morphine chlorhydrate (30–50 μg/kg) or clonidine (1 μg/kg) were administered through the catheters using an antimicrobial filter. The anesthetic solutions were changed at least every 24 h, and the connections were manipulated with gauze soaked with 70% isopropyl alcohol. Topical antibiotic or antiseptic ointments were not used on any catheter. The dressings were not changed until the catheters were removed to avoid catheter migration out of the epidural space. The following information was recorded when the epidural catheters were inserted: age, sex, weight, American Society of Anesthesiologists classification score, Altemeir class[13] and duration of surgery, status of doctor performing the epidural (resident or fellow), epidural solution used, perioperative antimicrobial prophylaxis administration, and duration of epidural infusion.

The insertion site and the dressing were inspected daily by nursing staff and the patient's physician, 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 patient's physician, 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.

Cultures

After removal of the occlusive dressing, dry swabs were taken at the site surrounding catheter insertion and at the catheter hub to help identify the sources of microorganisms that may colonize catheters. The skin was then cleaned with 70% isopropyl alcohol. After the alcohol was allowed to dry, the catheter was removed aseptically, and its tip (3–4 cm distal segment) was cut and cultured quantitatively by a method previously described for vascular catheters.[14] The laboratory technicians were unaware of the antiseptic solution used for skin preparation. Standard microbiologic methods and criteria identified recovered microorganisms. If a same bacterial species was isolated from different sites in a given patient, their *Sma*-I-restricted pulse-field gel electrophoresis patterns were visually analyzed for similarity.[15] Bacterial isolates were considered similar when pulse-field gel electrophoresis patterns differed by no more than one band, according to Tenover criteria.[15]

Definitions

We adapted the definition of catheter colonization proposed by the Centers for Disease Control and Prevention for intravascular devices.[16] Epidural catheter colonization was defined as the growth of 1,000 or more colony-forming units/ml in cultures from the catheter tip. Colonization of the catheter was related to the skin when the same bacterial isolate yielded from the catheter tip and the skin surrounding the insertion site, and was related to the catheter hub when the same bacterial isolate yielded from the catheter tip and the catheter hub.

Statistical Analysis

Before undertaking this study, we estimated the number of catheters that would be required for an adequate examination of the hypothesis that epidural catheters inserted after skin preparation with chlorhexidine are two thirds less likely to be colonized than catheters inserted after skin preparation with povidone iodine. This was based on our experience with intravascular devices.[9] Supposing that the use of povidone iodine will be associated with a 20% incidence of catheter colonization, randomly assigning approximately a total of 96 catheters would have allowed us to detect, with 80%

power, a significant difference in the rates of colonization between the two types of antiseptic solutions at a one-tailed significance level of 5%.

Data are expressed as medians with range for continuous variables or percentages for categorical variables. The significance of the differences between the two study groups was determined with the Mann–Whitney U test for continuous variables and the Fisher exact test or the chi-square test for categorical variables. The proportions of catheters that were free of colonization as a function of time they had been in place were compared between the groups with use of a log-rank test on Kaplan-Meier estimates. All *P* values were based on two-tailed tests of significance with $P < 0.05$ used to determine significance. All computations were performed with SPSS 10.0 for Windows software (SPSS Inc. Headquarters, Chicago, IL).[17]

Results

A total of 100 patients requiring an epidural catheter were enrolled in the trial and randomly assigned (48 in the povidone iodine group and 52 in the chlorhexidine group). Completed data could be evaluated for 96 catheters (44 in the povidone iodine group and 52 in the chlorhexidine group). The remaining four catheters sited after povidone iodine skin preparation were not cultured (three were not inserted as a result of failure to catheterize the epidural space and one migrated outside the skin and was grossly contaminated before catheter culture). The two groups of catheters were similar with respect to characteristics of patients and catheters, although the duration of surgery was not significantly higher in the chlorhexidine group (table 1). Neither local nor systemic hypersensitivity reactions were observed with the use of either antiseptic solution.

Twenty cultures of catheter tips yielded microorganisms (table 2). The bacterial species isolated were coagulase-negative staphylococci (mainly methicillin resistant) in 19 cases and *Enterococcus faecalis* in one case. Cultures of catheter tips in the chlorhexidine group were significantly less likely to yield microorganisms on removal (five events [4.3 per 100 catheter days]) than were catheter tips in the povidone iodine group (15 events [16.7 per 100 catheter days]; relative risk, 0.2 [95% confidence interval, 0.1–0.7]; $P < 0.001$, log-rank test).

Six of the 20 catheters tips yielding microorganisms in culture yielded more than 1,000 colony-forming units/ml, and the corresponding catheters were considered as colonized (table 2). As shown in figure 1, catheter colonization occurred less frequently and less quickly when chlorhexidine was used for skin preparation (one event [0.9 per 100 catheter days]) than when povidone iodine was used (five events [5.6 per 100 catheter days]; relative risk, 0.2 [95% confidence interval, 0.1–1.0]; $P = 0.02$, log-rank test). None of the catheters colonized wassuspected of being infected before catheter removal. The presence of signs of inflammation (mainly erythema) at the insertion site was not more frequent when the catheter was colonized (one catheter colonized among the 11 patients [9%] with signs of inflammation *vs.* five catheters colonized among the 85 patients [6%] without signs of inflammation; relative risk, 1.5 [95% confidence interval, 0.2–11.8]; $P = 0.54$, Fisher exact test). Methicillin-resistant coagulase-negative staphylococci were the only colonizing microorganisms recovered. In no patient did an epidural abscess, meningitis, or any serious local or systemic infection develop.

Cultures of the sites surrounding catheter insertion in the chlorhexidine group were less likely to yield microorganisms at catheter removal than were insertion sites in the povidone iodine group (table 2), whereas the number of catheter hubs contaminated were similar between the two study groups. The skin surrounding the catheter insertion site was the origin of all the colonizing microorganisms.

Table 1. Characteristics of the Patients and Epidural Catheters*

	Povidone iodine (n = 44)	Chlorhexidine (n = 52)	*P* Value
No. of patients	44	52	
Male sex, n (%)	17 (39)	29 (56)	0.11
Age (months)	22 (1–180)	24 (1–180)	0.87
Weight (kg)	12 (3–56)	12 (2–42)	0.81
ASA score, n (%)			0.79
I	15 (34)	20 (38)	
II	27 (61)	29 (56)	
III	2 (5)	3 (6)	
Altemeier class, n (%)			0.32
Clean	33 (75)	33 (63)	
Clean–contaminated	9 (20)	18 (35)	
Contaminated	2 (5)	1 (2)	
Antibioprophylaxis, n (%)			
Yes	39 (89)	50 (96)	0.26
Amino-penicillin	23 (52)	30 (58)	0.28
Cephalosporin	9 (36)	20 (38)	0.56
Aminoglycoside	2 (5)	1 (2)	0.59
Type of clinician, n (%)			0.96
Resident	25 (57)	29 (56)	
Fellow	19 (43)	23 (44)	
Insertion site levels, n (%)			0.22
Thoracic	2 (5)	1 (2)	
L2–L3	11 (25)	11 (22)	
L3–L4	21 (47)	19 (36)	
L4–L5	8 (18)	19 (36)	
L5–S1	2 (5)	2 (4)	
Duration of surgery (min)	180 (80–550)	240 (90–840)	0.12
Duration of placement (h)	50 (21–74)	50 (24–100)	0.59
Reason for removal, n (%)			0.53
Catheter no longer needed	41 (93)	49 (94)	
Suspected catheter infection	2 (5)	1 (2)	
Catheter displacement	1 (2)	2 (4)	

* Continuous variables are expressed as medians with ranges and compared with the Mann–Whitney U test. Categorical variables are expressed as numbers with percentages and compared with the Fisher exact test or the chi-square test.

ASA = American Society of Anesthesiologists.

Table 2. Positive Bacteriologic Cultures

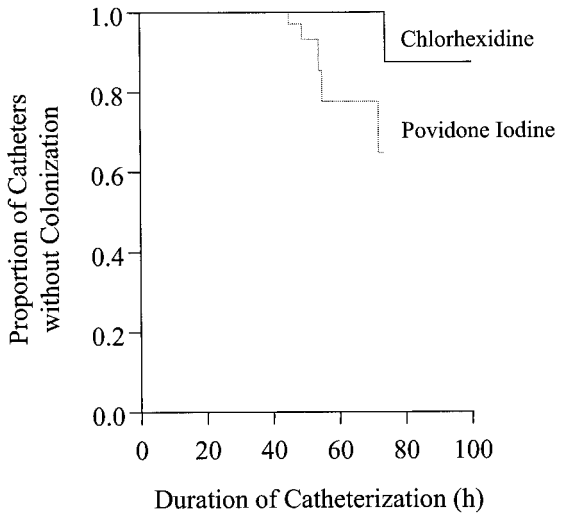
	Povidone Iodine (n = 44)	Chlorhexidine (n = 52)	*P* Value
Catheter tip, n (%)			
<1,000 cfu/ml	10 (23)	4 (8)	0.04
≥1,000 cfu/ml	5 (11)	1 (2)	0.07
Catheter hub, n (%)	1 (2)	4 (8)	0.4
Insertion site, n (%)	20 (45)	12 (23)	0.03

cfu = colony-forming units.

Discussion

Our study demonstrates that in the pediatric population studied, an alcohol solution of 0.5% chlorhexidine used for skin disinfection before short-term epidural catheter insertion was more effective than an aqueous solution of 10% povidone iodine in preventing catheter colonization. No patient had an epidural space infection.

Although there are several studies assessing colonization of epidural catheters in the pediatric population, interstudy comparisons are difficult to make because of differences in definition of catheter colonization, route of epidural used (caudal *versus* lumbar) and differences in the choice of antiseptic solution used before epidural catheter insertion. The presence or absence of prophylactic antibiotics and the varying duration of epidural catheterization also make interstudy comparisons difficult. Colonization of epidural catheters is common in the pediatric population, with incidences varying from 12 to 35%.[1–3] Our results suggest that despite high colonization, the risk of epidural space infection in this population is low. This finding is consistent with previous reports. Strafford *et al.*,[18] in a study of 1,620 children who received epidural analgesia, reported only one thoracic epidural infection occurring with very prolonged use in palliative care of a patient with immunosuppression. Likewise, Kost-Byerly *et al.*,[2] in a study of 210 children who received caudal or lumbar epidural analgesia, demonstrated that despite a 35% colonization rate, no serious systemic infection occurred. McNeely *et al.*[1] reported an overall colonization rate of 20% in caudal epidurals and similarly reported no deep tissue infections. Although rare, catheter infection can rapidly progress to epidural abscess, meningitis, paralysis, or death.[1–3] Such complications are unacceptable in this setting.



No. of Catheters at Risk						
Chlorhexidine	52	52	45	12	5	1
Povidone Iodine	44	44	39	9	0	0

Fig. 1. Kaplan-Meier curves for freedom from catheter colonization after skin preparation with either chlorhexidine or povidone iodine. The number of catheters in each group that were at risk to be colonized at various times are shown below the figure. The risk of catheter colonization was significantly lower when skin preparation was performed with chlorhexidine solution than with povidone iodine ($P = 0.02$, log-rank test).

Although the precise mechanism of epidural infection associated with epidural block has yet to be defined, several possible mechanisms have been proposed. Contamination of drug or material may be a factor. Raedler *et al.*[19] assessed bacterial contamination of 114 spinal and 20 epidural needles after subarachnoid or epidural block performed under strict aseptic guidelines. Bacterial contamination occurred in 18% of the needles, suggesting than even when following strict aseptic guidelines, needle contamination by skin pathogens is common. Similarly, skin flora introduced either at the time of puncture or as a result of bacterial migration along a catheter or needle tract has been implicated as a potential source of epidural abscess. Sato *et al.*[4] assessed 69 paired skin specimens that had been excised from the incisional site (laminectomies) after disinfection with 10% povidone iodine or an alcoholic solution of 0.5% chlorhexidine. They found viable microorganisms in 13 biopsies, mainly in the povidone iodine group (32% *versus* 6%; $P < 0.01$). They explained the superior performance of chlorhexidine by its more potent bactericidal activity and its high permeability into the hair follicles. Hematogenous spread from another site of infection has been postulated as another potential source of epidural infection. Darchy *et al.*[20] reviewed infectious complications in 75 intensive care patients who received epidural analgesia. Twenty-four other site infections occurred in 21 patients. The microorganisms isolated were different from those isolated from swab or catheter cultures. They stated that the presence of other infection sites did not increase the incidence of epidural infection. Finally, catheter colonization can arises from clinicians' and nurses' handling of syringes and solutions, via the catheter hub. To determine if catheter colonization was the result of unsatisfactory skin antisepsis or septic manipulation of the catheter line, we cultured the insertion site and the catheter hub at catheter removal.

There are few studies comparing the efficacy of chlorhexidine *versus* povidone iodine used as skin disinfectant in reducing epidural catheter colonization. Adam *et al.*,[21] in a study of 294 obstetric epidurals, were unable to demonstrate any benefit of chlorhexidine over povidone iodine. Methodologic deficiencies of this study include lack of randomization and the fact that the skin was not cleaned before catheter removal. Thus, bias and unavoidable contamination may have altered the results. In contrast, Shapiro *et al.*[22] demonstrated that use of a chlorhexidine dressing reduced microbial colonization of epidural catheters. The chlorhexidine group was one seventh as likely to be colonized as those in the control group.

Our study supports these findings. Catheters inserted after skin preparation with chlorhexidine were one sixth as likely and less quickly colonized as catheters inserted after skin preparation with povidone iodine. Our results are in accordance with those from the previously quoted study of Sato *et al.*,[4] indicating that fewer viable microorganisms were cultured from skin biopsies after cutaneous disinfection with chlorhexidine. Chlorhexidine gluconate is a potent broad-spectrum germicide, which is effective against nearly all nosocomial bacteria and yeasts.[8,9,11] In addition, chlorhexidine has a low skin irritancy and sensitization potential. It has a strong affinity for the skin and demonstrates prolonged duration of antimicrobial effect. Unlike povidone iodine, the antibacterial activity of chlorhexidine persists for hours after topical application. In contrast to iodine-containing compounds, chlorhexidine is not neutralized by contact with proteinous solutions. Iodine-containing compounds lack persistence and may induce allergic reactions in sensitive individuals. Finally, bacterial resistance to chlorhexidine is rare.

Coagulase-negative staphylococci were the only colonizing microorganisms recovered in our study. This concurs with previous studies indicating that coagulase-negative staphylococci, the predominant species on the human skin, are the most common agents of cannula-related infections.[1,9,19] The superiority of chlorhexidine over povidone iodine in preventing catheter colonization and catheter-related sepsis as a result of Gram-positive bacteria has already been noted in various studies,[9,23] and was reported to be the result of a more prolonged activity of chlorhexidine against staphylococci.[23] This superiority may explain, at least in part, the lower epidural catheter colonization rate that we observed after chlorhexidine disinfection.

Our trial had several limitations. Because color differences between the two solutions used, the physician was not blinded, and this may have introduced bias into the study. However, both solutions are in common use, and we do not believe that physicians knew that one solution was better than the other. Furthermore, the microbiologists who performed the cultures as well as the patient's physician who decided to remove the catheters were not aware of the antiseptic solutions used. The duration of epidural use was short, with a median of 50 h in both groups. Although a short duration may mitigate against colonization, this duration represents current practice in our unit. We did not evaluate whether the use of chlorhexidine reduces colonization of caudal catheters, despite the fact that caudal catheters are frequently placed in the pediatric population and that the incidence of catheter colonization is higher after caudal than lumbar catheter placement, because of the few number of caudal catheters inserted in our unit. The widespread use of antibiotics in this study may have influenced culture results. However, prophylactic antibiotic use was guided by national guidelines, and their use was similar in both groups. Moreover, no patient received antibiotic potent against methicillin-resistant coagulase-negative staphylococci, the causative agent for catheter colonization. Finally, we could not evaluate if the use of chlorhexidine reduces the risk of lumbar catheter infection because of the very low incidence of subcutaneous or epidural space infection with short-term catheterization. However, the use of catheter colonization as a surrogate marker of true risk of infection is reasonable, because colonization generally precedes infection.

In conclusion, the use of chlorhexidine solution rather than povidone iodine may be a better choice for cutaneous antisepsis before short-term epidural catheter placement in children. Whether this antiseptic agent reduces colonization for longer lumbar catheterization or of caudal catheters requires further investigation.

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