

# Comparison of Povidone Iodine and DuraPrep, an Iodophor-in-Isopropyl Alcohol Solution, for Skin Disinfection Prior to Epidural Catheter Insertion in Parturients

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**Background:** Although rare, infectious sequelae of epidural analgesia can occur. A recently marketed antiseptic solution (DuraPrep) which contains an iodophor in isopropyl alcohol, may provide enhanced and longer-lasting antimicrobial activity and thus be useful in the obstetric setting. The purpose of this study was to evaluate the antiseptics achieved with DuraPrep compared with povidone iodine (PI).

**Methods:** Sixty women in active labor who requested epidural analgesia were randomly assigned to receive skin preparation with either PI or DuraPrep solution. A total of three cultures were obtained from each subject. The first was obtained just prior to skin disinfection, the second was obtained immediately following antiseptics, and the third was obtained just before removal of the catheter. In addition, the distal tip of the catheter was also submitted for culture.

**Results:** The clinical characteristics and the risk factors for infection were similar in the two groups. The proportion of subjects with positive skin cultures immediately after skin disinfection differed significantly between the PI and DuraPrep groups (30 vs. 3%, respectively,  $P = 0.01$ ). The number of subjects with any positive skin cultures at the time of catheter removal was greater in the PI group as compared to the DuraPrep group (97 vs. 50%, respectively,  $P = 0.0001$ ), as was the number of organisms cultured from skin (log CFU  $1.93 \pm 0.40$  vs.  $0.90 \pm 0.23$ , respectively,  $P = 0.03$ ). Six catheters, all from the PI group, yielded positive cultures by the roll-plate technique.

**Conclusion:** As compared to PI, DuraPrep solution was found to provide a greater decrease in the number of positive skin cultures immediately after disinfection, as well as in bacterial regrowth and colonization of the epidural catheters.

NEURAXIAL techniques are increasingly popular for labor analgesia and anesthesia. Although infectious sequelae, such as bacterial meningitis and epidural ab-

cess, are rare following spinal, epidural, and combined spinal-epidural techniques, these complications do occur and can have devastating results,<sup>1-5</sup> including paralysis and death. Bacteria can be introduced to the puncture site from the blood stream,<sup>6</sup> in association with contaminants,<sup>7</sup> by spread to the epidural catheter from other sites, such as the vaginal tract,<sup>8</sup> or during breaches in sterile technique by the anesthesiologist.<sup>9,10</sup>

Hunt *et al.*<sup>11</sup> reported that a significant proportion (22%) of epidural catheters become contaminated by various organisms, including *Staphylococci*, *Neisseria*, diphtheroids, *Streptococci*, and gram-negative rods, and that the proportion of contaminated catheters is considerably higher (64%) in obstetric patients. These authors speculated that soiling of the back by amniotic fluid, urine, and feces during labor and delivery caused the increased risk of catheter contamination during childbirth. Skin colonization has been linked to increased risk of catheter colonization in a number of studies.<sup>12,13</sup> Although these studies have primarily evaluated colonization of intravascular devices rather than epidural catheters, these observations suggest that the adequacy of skin disinfection prior to catheter placement is of paramount importance for prevention of colonization and, potentially, of catheter-associated infection.

Povidone iodine solution (PI), an aqueous antiseptic commonly used to disinfect the skin prior to initiation of epidural analgesia, may not completely eliminate bacteria from the skin of the back, and the disinfection that occurs may be of limited duration.<sup>14,15</sup> In addition, previously opened, multiple-use bottles of PI can have decreased activity against skin flora and increased potential to support bacterial growth.<sup>16</sup> To minimize the risk of contamination, as well as to maximize convenience, many manufacturers of epidural and spinal anesthesia kits have begun to supply sterile single-use PI packages in the epidural tray. However, contamination can occur even when single-use PI packets are utilized.<sup>17</sup>

Another skin disinfectant solution, DuraPrep (3M Health Care, St. Paul, MN), which contains an iodophor in isopropyl alcohol, is commercially available and has become popular for surgical disinfection.<sup>18</sup> Alcohol provides rapid antiseptics and may prolong the effects of other disinfectants<sup>19</sup>; thus, an iodophor-in-isopropyl mixture could potentially produce superior antimicrobial efficacy. In addition, DuraPrep may provide longer-last-

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ing antisepsis than other disinfectants because of its chemical properties when placed on skin, by producing a film of disinfectant. It has been suggested that this film may resist being washed away by fluids and blood and thus provide potential for longer-term protection.<sup>20</sup> The goal of this study was to compare these two currently available iodine-containing antiseptics (DuraPrep and PI) for their ability to reduce skin flora and the duration of their antimicrobial activity in laboring women receiving epidural analgesia. We also compared the ability of DuraPrep and PI disinfection at the time of catheter placement to prevent bacterial contamination of the epidural catheter.

## Materials and Methods

### Study Subjects

This study was approved by the Institutional Review Board (St. Luke's-Roosevelt Hospital Center, New York, New York), and written informed consent was obtained from all patients. Sixty women with American Society of Anesthesiologists physical status I or II in active labor and requesting labor analgesia were enrolled and randomly assigned *via* an envelope system to undergo skin decontamination prior to epidural anesthesia with either 10% PI or DuraPrep. Patients were excluded if they had fever, had received antibiotics in labor or within the previous 48 h, had diabetes, had HIV disease, were obese, or had preexisting skin infection.

### Skin Decontamination

Subjects in the PI group ( $n = 30$ ) had their backs prepared with three applications of PI solution according to standard protocol. A sterile Perifix<sup>®</sup> continuous epidural anesthesia tray (B Braun Medical Inc., Bethlehem, PA) that included three prep sponge sticks, a solution well, and a 1-oz packet of PI solution (Aplicare, Inc., Branford CT; Povidone Iodine USP, 10% aqueous povidone iodine, 1% titratable iodine), was used for each subject. After the PI solution was poured into the tray well, one of the three sponge sticks was dipped into the solution until saturated. The sponge was used to apply PI to an area of approximately 6 inches in diameter covering the L1-L5 interspace. The same procedure was followed for each of the two remaining sponges. The PI solution was allowed to air dry between each of the three applications. The backs of subjects in the DuraPrep group ( $n = 30$ ) were prepared according to the manufacturer's recommendation with a single-use, 0.6-ml-unit dose applicator that contained a sterile, crushable ampule and a solution of 0.7% available iodine and 74% w/w isopropyl alcohol. The ampule, which is located within the handle of the applicator, was crushed with a plunger affixed to the handle. The solution then flowed into the sponge tip and was applied to an area of approximately 6 inches in diameter covering the L1-L5 interspace. The solution was also allowed to air dry.

Following standard epidural catheter insertion at the L3-L4 interspace, each catheter was connected to a continuous infusion system equipped with a 0.2- $\mu$ m filter. An epidural infusion of 0.125% bupivacaine with 1  $\mu$ g/ml fentanyl was initiated and continued until delivery. A sterile Tegaderm<sup>®</sup> semipermeable polyurethane dressing (3M) was applied to the area surrounding the epidural insertion in all patients. No subject was receiving antimicrobials at the time of initiation of the block, and topical antibiotics or antiseptic ointments were not administered to any subject during the study.

### Cultures and Microbiology

A total of three cultures were obtained from the periepidural skin for each subject, using sterile Dacron-tipped (DuPont, Wilmington, DE) applicators (swabs) premoistened in sterile normal saline to sample a 5-cm<sup>2</sup> area. The first sample was obtained just prior to skin disinfection to determine baseline skin flora, and a second was obtained from the same area immediately following antisepsis of the skin to determine initial efficacy of the disinfectant. The third swab was obtained just prior to removal of the epidural catheter. Swabs were coded, placed in 1.0 ml thioglycolate broth (BBL; Becton-Dickinson, Cockeysville, MD) and hand-delivered to the Microbiology Laboratory at St. Luke's-Roosevelt Hospital Center, where cultures were immediately performed.

The distal tip of the epidural catheter from each subject was also submitted for culture. To reduce the risk of tip contamination by skin during removal, following collection of the third skin culture and just prior to removal of the catheter, the area surrounding the epidural site was disinfected with isopropyl alcohol. All catheters were removed aseptically by an anesthesiologist wearing sterile gloves and a mask and were transected with a sterile scissors and forceps, and the distal 3 to 4 cm was placed in a sterile tube and hand-delivered to the Microbiology Laboratory.

Tubes containing swabs in thioglycolate broth were vortexed for 1 min to suspend organisms. Each swab and 0.1-ml aliquots of suspension were inoculated to 5% sheep blood-trypticase soy agar (BAP), chocolate agar, and MacConkey agar plates (BBL). To allow estimation of the reduction in bacterial counts after disinfection, a 0.1-ml aliquot of each original suspension was diluted with broth to give a 1-in-100 dilution. For each dilution, 0.1 ml was inoculated to chocolate agar, and 0.9 ml was inoculated to 5 ml cooked meat glucose broth (CMG, BBL). Plates and broth were incubated at 37°C in 5% CO<sub>2</sub> for 72 h and examined daily for evidence of growth.

The distal catheter tips were cultured semiquantitatively by rolling the segment over a BAP. Each catheter tip was then placed in 5 ml CMG and vortexed vigorously to ensure that the lumen as well as the external surface of the catheter segment was sampled. Catheter cultures were incubated at 37°C for 96 h and examined

**Table 1. Positive Skin and Distal Catheter Tip Cultures Obtained from Parturients Who Requested Epidural Analgesia for Labor and Whose Backs Were Disinfected with DuraPrep or Povidone Iodine**

Positive Cultures	DuraPrep n (%)	Povidone Iodine n (%)	P*
<b>Skin</b>			
Before disinfection	27 (90)	27 (90)	NS
After disinfection	1 (3)	9 (30)	0.01
At catheter removal	15 (50)	29 (97)	0.0001
<b>Catheter tip</b>			
All positives	2 (7)	13 (43)	0.002
Roll plate technique	0	6 (20)	0.02

Data are expressed as the number of parturients (percent values are in parentheses).

\* Fisher exact test.

NS = not significant

daily for growth. Colonies on BAP were counted to determine the colony-forming units (CFUs) for each distal catheter tip. Microorganisms were identified using standard techniques. In each case, the anesthesiologist obtaining the culture specimens and the microbiologist handling the specimens in the laboratory were blinded to the disinfectant solution used.

#### Data Analysis

Sample size was estimated at 30 per group, based on a 30% absolute reduction in bacterial regrowth on previously disinfected skin, at an  $\alpha$  of 0.05. This sample size provided power for the statistical analyses in excess of 90%.

To evaluate the relative ability of PI and DuraPrep to reduce skin flora following initial application, raw bacterial counts were converted to log CFU, and results of skin cultures obtained before and after disinfection and at catheter removal were compared between the PI and DuraPrep groups by Student *t* test. The duration of the antimicrobial activity for each of the two skin disinfectants was evaluated by comparing the proportion of positive skin cultures at the time of catheter removal in subjects whose skin cultures were without growth after initial disinfection. The colonization rates of catheter tips from each group were also compared. These comparisons were evaluated by chi-square or Fisher exact test, as appropriate. *P* values of 0.05 or less were considered statistically significant. All analyses were performed with the Statistical Package for the Social Sciences (SPSS version 5.02 for Windows, Chicago, IL, 1993).

**Table 2. Comparison of Bacterial Yield from Skin Cultures Obtained from Parturients before and after Disinfection with DuraPrep or Povidone Iodine and at Catheter Removal**

	Log CFU*		<i>P</i>
	DuraPrep	Povidone Iodine	
Before disinfection	3.23 ± 0.36	2.85 ± 0.36	NS
After disinfection	0.35 ± 0.14	0.74 ± 0.22	NS
At catheter removal	0.90 ± 0.23	1.93 ± 0.40	0.03

\* Values shown are mean ± SEM.

CFU = colony forming unit; NS = not significant

## Results

### Subject Characteristics

The PI and DuraPrep groups were similar with respect to age, height, and weight. No diabetic or morbidly obese patients were enrolled. The groups did not differ with respect to the presence of skin organisms at the site of epidural insertion prior to disinfection (90% in each group, table 1) or the mean duration of catheter placement (PI = 9.9 h, DuraPrep = 10.5 h, not significant). The number of subjects from whom high numbers of bacteria were cultured (> 500,000/site) before skin disinfection was the same in both groups, and the overall level of skin colonization before disinfection did not differ significantly between the groups (table 2). The single most common bacterial isolate was *Staphylococcus epidermidis*, found in 48 of the 54 (87%) positive cultures. Other species isolated included other coagulase-negative *Staphylococci*, *Enterococcus* species, *Bacillus* species,  $\alpha$ - and  $\beta$ -hemolytic *Streptococci*, *E. coli*, diphtheroids, *S. aureus*, *Acinetobacter calcoaceticus*, and *Citrobacter* species.

### Efficacy of Disinfection

The results of the pre-disinfection, post-disinfection, and at-catheter-removal skin cultures and the catheter tip cultures from the PI and DuraPrep groups are summarized in table 1. The quantitative effect of PI and DuraPrep skin disinfection on skin colonization is summarized in table 2.

### *Reduction of Bacterial Burden and Inhibition of Regrowth*

Although the proportion of subjects with positive skin cultures immediately after skin disinfection (table 1) differed significantly ( $P = 0.01$ ) between the PI group (30%) and the DuraPrep group (3%), the difference in mean reduction in bacterial burden (expressed as log CFU  $\pm$  SEM, table 2) between the two groups did not reach statistical significance. Disinfection with either PI or DuraPrep resulted in a greater than 2-log decrease in bacterial burden (table 2).

In contrast, not only was the percentage of subjects with any positive skin cultures at the time of catheter removal (table 1) greater for the PI group (97%) than the DuraPrep group (50%) ( $P = 0.0001$ ), but so was mean bacterial burden. At catheter removal, skin cultures from the PI group (mean log CFU =  $1.93 \pm 0.40$ ) differed significantly ( $P = 0.03$ ) from those from the DuraPrep group (mean log CFU =  $0.90 \pm 0.23$ ).

The majority of cultures at catheter removal in both the PI and DuraPrep groups yielded growth of the same bacterial species that were present before disinfection. Of note, 8 of the participants in the PI group and 11 in the DuraPrep group who had positive skin cultures at the time of catheter removal had negative cultures after initial disinfection. The most common organism isolated remained *S. epidermidis*, and the overall distribution of species was similar to that obtained in the pre-disinfection cultures.

### *Colonization of Catheter Tips*

Six catheters yielded positive cultures by the roll-plate technique. All six were from the PI group, and none were from the DuraPrep group. Of these six cultures, five yielded 15 or more CFUs; intravascular catheters that yield growth of 15 or more CFUs by this technique are considered colonized according to the Centers for Disease Control and Prevention definition.<sup>21</sup> Three of these catheters were heavily contaminated and yielded several hundred CFU; all of these were from participants with higher bacterial burdens at catheter removal, consistent with heavy regrowth. Seven additional cultures from PI subjects yielded growth in CMG broth but not on roll plates, as did two catheter cultures from DuraPrep subjects. As shown in table 1, the difference in the rate of positive catheter tip cultures from the two groups was statistically significant, whether by the roll-plate method ( $P = 0.02$ ) or by inoculation in CMG broth ( $P = 0.002$ ).

All heavily contaminated catheters were colonized with coagulase-negative *Staphylococci*, as were the majority of catheter cultures. *Enterococcus faecalis*, *S. viridans*, and *Bacillus* species were isolated from one catheter each.

## Discussion

Effective skin disinfection is an important measure for prevention of infection as a consequence of procedures that disrupt the skin barrier. The degree of skin colonization has been linked to the risk of intravascular catheter contamination and catheter-related bacteremia in many studies,<sup>12,13,22</sup> but the extent to which these results apply to epidural catheters is unknown. For example, the physical interaction between an epidural catheter that passes through surrounding tissue may not be the same as that between an intravascular catheter and the vessel wall. Because epidural catheter infections are relatively infrequent, studies directly linking skin colonization levels at the epidural site to a clinical infectious outcome have not been reported.

Our baseline (pre-disinfection) cultures suggest that mean bacterial counts are higher for skin at the site of epidural catheter insertion than described for vascular insertion sites at the arm or wrist by 10- to 100-fold and are also somewhat higher than those described for subclavian sites.<sup>22</sup> *S. epidermidis* and other coagulase-negative *Staphylococci* were the organisms we isolated most frequently from skin and from epidural catheters, although a variety of potentially pathogenic gram-positive and gram-negative organisms were isolated. Coagulase-negative *Staphylococci* are well recognized as increasingly common causes of nosocomial infection, particularly those related to intravascular catheters,<sup>21</sup> and *S. epidermidis* was the most frequently isolated organism isolated in local infections in a recent study of epidural analgesia in the intensive care unit.<sup>23</sup> *S. epidermidis* was also the most frequent cause of epidural abscess in a series of over 90 patients receiving chronic epidural analgesia.<sup>24</sup>

In our study, disinfection with either PI or DuraPrep solution substantially decreased the number of bacteria present on the skin. Neither disinfectant decreased bacterial flora below the level of detection in all cases. However, participants in the DuraPrep group were more likely to have negative cultures immediately after skin disinfection than those in the PI group. This result is consistent with the report by Sato *et al.*<sup>15</sup> that microorganisms can persist in lumbar skin after disinfection. Since contamination of the catheter by skin flora at the time of placement is a proposed mechanism for catheter infection, the presence of bacteria at the insertion site would be expected to correlate with an increased risk of catheter contamination.

DuraPrep was also more effective at limiting regrowth of skin flora than PI. Participants in the PI group were more likely than those in the DuraPrep group to have regrowth of bacteria at the insertion site detected at the time of catheter removal. Individuals with positive catheter tip cultures and particularly those with heavily contaminated catheters were mostly those with heavy

growth on skin culture taken at the time of catheter removal. The association between regrowth of skin flora and catheter colonization is intriguing in light of recent discoveries that some pathogenic behavior requires the presence of a critical bacterial mass or "quorum."<sup>25</sup> Biofilm formation, a bacterial characteristic important for colonization of catheters<sup>26</sup> and prosthetic devices,<sup>27</sup> has been linked to quorum-sensing requirements in both gram-positive and gram-negative bacteria. The ability of a skin disinfectant such as DuraPrep to provide a sustained effect to limit bacterial growth could be even more important for longer durations of catheterization.

It should be noted that catheter colonization did not result in infection in any of the patients we studied. This is not surprising since estimates of the incidence of infections related to epidural catheters are generally low.<sup>28</sup> Our patients were all healthy parturients and not otherwise immunocompromised. The presence of other conditions, such as diabetes, sepsis, chronic renal failure, corticosteroid therapy, intravenous substance use, or HIV infection, could potentially increase susceptibility to infection after catheter colonization.

Some authors have suggested that epidural catheter cultures can represent colonization of the skin at the catheter insertion site and subsequent contamination of the catheter tip during catheter removal, rather than colonization of the catheter itself.<sup>29</sup> Several steps were taken in our study to decrease the likelihood of false-positive cultures due to artifactual contamination of the catheter tip, specifically preparation of the back with isopropyl alcohol just prior to removal of the catheter, use of sterile technique for catheter removal, and sterile transport of the catheter tip to the Microbiology Laboratory. In addition, only the distal catheter was cultured. Thus, in our study, positive cultures most likely represent true catheter colonization.

The difference we found between the number of positive epidural catheter cultures in the PI and DuraPrep groups was significant whether or not the 15 CFU cutoff criterion recommended for determination of contamination for intravascular catheters was applied. It should be emphasized that the applicability of this criterion for epidural catheters and the risk of epidural space infection have not been established. Positive cultures that do not meet this cutoff may be significant for this body site. Thus, in some studies, the presence of any organisms in epidural catheter cultures has been considered to indicate colonization or infection.<sup>23</sup> In contradistinction, some authors have proposed that positive epidural catheter cultures in the absence of clinically identifiable epidural space infection are irrelevant<sup>29</sup> or that quantitative cultures with a 100 or 1,000 CFU cutoff should be used.

Catheter contamination may also be a result of inoculation of the inside of the catheter secondary to contam-

ination of the infusant. In this study, however, all patients had a closed epidural infusion system with a 0.2- $\mu$ m filter. In addition, bupivacaine, the local anesthetic administered in this study, has been shown to be bacteriocidal or bacteriostatic<sup>30</sup> and is an unlikely source of catheter contamination. Thus, in our study, the skin remains the most likely potential source for catheter colonization and related infections.

Alcohol has long been known to have disinfectant effects and is routinely used for skin disinfection of injection sites because of its immediate effect and quick drying. The use of disinfectant solutions that combine alcohol with PI for presurgical disinfection has been reported to produce significantly higher reduction in bacteria as compared to the use of PI alone.<sup>31,32</sup> Routine use of alcohol in combination with other disinfectants, however, has not become standard practice among anesthesiologists. The use of DuraPrep solution is not the only method for combining alcohol with povidone iodine. Although convenient because of applicator design, this product is more costly than standard PI solution. While the actual dollar cost of DuraPrep may be greater than PI, prices vary considerably among institutions, and the charges incurred for treating one infectious complication far exceeds the modest increased cost associated with the use of a more expensive disinfectant.

It is possible that use of a simple alcohol swab following antisepsis with PI would provide initial disinfection equivalent to DuraPrep solution, but we did not evaluate that in this study. In addition, our results suggest that DuraPrep disinfection also inhibits bacterial regrowth, possibly because of formation of a protective film on the skin. Any direct comparison of DuraPrep with sequential PI/alcohol should evaluate the ability to inhibit regrowth in addition to initial disinfection. A recent study comparing chlorhexidine and PI antisepsis prior to epidural catheter placement in children has reported that the risk of catheter colonization was markedly reduced in the chlorhexidine group but provided only limited information regarding skin colonization.<sup>33</sup> DuraPrep compared favorably with chlorhexidine for presurgical disinfection in a veterinary study,<sup>34</sup> but similar studies are not yet available for humans.

In conclusion, our results suggest that the addition of alcohol to iodinated disinfectant offers advantages over PI alone in initial skin disinfection and in limiting colonization of the epidural catheter. DuraPrep provided improved skin antisepsis, despite a reduced iodophor concentration and a decreased number of antiseptic applications to the skin, and prevented bacterial regrowth in many cases. Antisepsis that eliminates bacteria at the time of insertion and that minimizes bacterial regrowth may be particularly important for indwelling labor epidural catheters that remain *in situ* for extended periods of time or in immunocompromised patients.

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