Are Bacterial Filters Needed in Continuous Epidural Analgesia for Obstetrics?

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Zephiran chloride§ (benzalkonium chloride) has been recommended for preparation of the skin prior to blocks, and is still used in many hospitals.¹ Prepodyne¶, a new organic iodine compound, was found to have a wide-ranging and rapid germicidal effect when used for preparation of the skin prior to surgical procedures.²

The use of micropore bacterial filters in every continuous epidural block for obstetrics has been recommended.²⁻³ However, search failed to reveal a controlled study of the use of bacterial filters in connection with epidural analgesia.

Of the 7,000 deliveries per year at Magee-Womens Hospital, about 1,500 are conducted using epidural and/or caudal analgesia. No clinical manifestation of epidural infection has been noticed despite the omission of bacterial filters. Therefore, in order to compare Zephiran with Prepodyne, and to find out whether micropore filters are necessary, the following study was conducted.

**METHODS AND MATERIALS**

Ninety-five women of physical status I were in active labor necessitating continuous epidural analgesia. They were divided into two groups.

Group I consisted of 53 patients in whom tincture Zephiran (1:750 benzalkonium chloride in 50 per cent isopropyl alcohol) was used to prepare the skin of the back prior to epidural analgesia. This group was subdivided into: 1) 24 patients in whom a disposable 0.22-μm micropore filter, 25 mm in diameter with a surface area of 0.7 cm², ** was interposed in the epidural infusion line (fig. 1); 2) 29 patients for whom no filter was used.

Group II consisted of 42 patients in whom 1 per cent Prepodyne solution was used instead of Zephiran. This group was similarly divided into two subgroups according to the presence (n = 14) or absence (n = 28) of a filter. In all groups autoclaved sterile epidural trays with disposable 91.5-cm, 20-ga Teffon epidural catheters were used: † All blocks were performed by one anesthesiologist (EA). The back was scrubbed twice with the degemining solution under study, after which the excess fluid was removed with a sterile swab. Aseptic technique was adhered to throughout the procedure. The catheter was placed in the epidural space to about 4 cm. Using a disposable syringe for each injection, 0.5 per cent bupivacaine was administered during labor, and 2 per cent chloroprocaine for delivery. In all cases, the epidural catheter was sealed by the removable plug. During injection of the refill doses, the plug was temporarily removed and precautions were taken not to touch the portion fitting into the needle hub or into the bacterial filter.

In the Recovery Room, the skin at the site of entry of the epidural catheter was sterilized with 70 per cent alcohol. After the skin had dried, the catheter was removed under aseptic conditions and bacterial cultures, using 5 per cent blood agar, were obtained by the anesthesiologist

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from the following sites: 1) the fluid inside the epidural catheter; 2) the terminal 2 cm of the catheter, \textit{i.e.}, from the part in the epidural space; 3) 1 cm of the catheter extending to 0.5 cm from the skin entry, \textit{i.e.}, from the part in the tissues of the back; 4) the fluid inside the hub of the needle attached to the proximal part of the catheter; 5) the terminal plug; 6) the proximal surface of the filter, when a filter had been used. The total culture sites for each patient were five without a filter, and six with a filter. Therefore, the total number of cultures taken from the 95 patients was 513. Ten samples from each of the degeming agents and the local anesthetics were also cultured. All the cultures were examined at 24 and 48 hours by one person (AA).

A single-blind study protocol was observed; until the completion of the study the bacteriologist was not aware of the method used, and the anesthesiologist was not informed of the laboratory findings.

Depending on the agent and whether a filter was used or not, the study was composed of four treatment groups. Statistical comparison of these groups employed the logistic transform of the proportion of individuals having one or more positive cultures, the proportion of total cultures that were positive, and the proportion of positive cultures that had one or more colonies. These proportions were examined for each of the separate sites 1 through 4, and for sites 1 through 4 as one system. When a filter was used, sites 5 and/or 6 were compared with site 5 when no filter was present; these sites were used to compare the treatment groups as sites proximal to the filter, whereas sites 1 through 4 were used for comparison purposes as sites distal to the filter location.

\section*{RESULTS}

There was no significant difference among the various groups in regard to the ages of the patients, numbers of injections, or durations of catheter insertion (table 1). The organisms grown were saprophytes of the skin, mainly (88 per cent) \textit{Staphylococcus epidermidis} (coagulase-negative staphylococci). Other organisms were gram-negative rods and diphtheroids.

With respect to cultures distal to the filter location, when the individual sites 1 through 4 were examined, the proportions of positive cultures showed no statistically significant difference between the two agents, or between the presence and absence of a filter, and no interaction between agent and filter. However, the total number of positive cultures at sites 1 through 4 showed a difference ($P < 0.05$) for the two agents, but no difference for the presence or absence of a filter or for interaction (table 2). With respect to cultures proximal to the filter location, there was no statistical evidence of a difference. A comparison of the proportions of positive cultures having more than one colony provided no evidence of a difference. No organisms were cultured from the degemming or local anesthetic solutions used in this study.

During the hospital stay and within 40 days after delivery, none of the patients developed manifestations of a space-occupying lesion suggestive of an epidural abscess or mass, \textit{e.g.}, severe backache and tenderness, motor weakness, sensory abnormalities, rigors and/or associated high fever.
DISCUSSION

Zintel (1956) found iodine, used as a skin antiseptic, to be superior to hexachlorophene, Zephiran, and alcohol. However, inorganic iodine is very irritating in its most effective form, the tincture. The high incidence of cutaneous damage and other sensitivity reactions has precluded its use in many centers during the past two decades.10

Recently, organic forms of iodine have been developed and used for preparation of the skin. These are the iodophor compounds, and are watersoluble; therefore, there is no need for alcohol as a vehicle. They release iodine steadily, thus producing a prolonged germicidal effect. They are less toxic than inorganic iodine. They do not produce appreciable pain even when applied to denuded surfaces, or damage skin or tissues.11 They cause virtually no cutaneous irritation, and produce less cutaneous reaction than Zephiran.10 They are effective against gram-negative and gram-positive organisms, aerobes and anaerobes, as well as fungi, viruses, protozoa, yeasts, and tubercle bacilli. Most of the organisms are killed within 15 to 30 seconds of contact with the solution.12 In both in vivo and in vitro studies, there was no difference in the germicidal effectiveness between Betadine® (polyvinylpyrrolidone–iodine complex) and the newer preparation, Prepodyne.2 Our results have shown the superiority of Prepodyne over Zephiran.

11 The Purdue Frederick Co., Norwalk, Connecticut 06856.

Table 1. Material

<table>
<thead>
<tr>
<th></th>
<th>Age of Patients Mean (±SD)</th>
<th>Number of Injections Mean (±SD)</th>
<th>Duration of Catheter Insertion (Hours) Mean (±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zephiran Filter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n = 24) No filters</td>
<td>27.09 (± 6.94)</td>
<td>2.62 (± 0.68)</td>
<td>5.06 (± 1.5)</td>
</tr>
<tr>
<td></td>
<td>25.83 (± 4.61)</td>
<td>2.52 (± 0.59)</td>
<td>4.80 (± 1.9)</td>
</tr>
<tr>
<td>Filter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(n = 14) No filters</td>
<td>25.64 (± 3.58)</td>
<td>2.36 (± 0.86)</td>
<td>4.66 (± 1.63)</td>
</tr>
<tr>
<td></td>
<td>27.32 (± 5.45)</td>
<td>2.54 (± 0.69)</td>
<td>5.29 (± 1.78)</td>
</tr>
</tbody>
</table>

It is interesting that most of the positive cultures and the greater number of colonies were present with segments 2 and 3 of the catheter system when Zephiran was used. This is an evidence of the need for a stronger degeming agent, especially at the skin–catheter interface. The application of an iodophor ointment at this site for purposes such as hyperalimentation was found to be superior to use of antibiotic ointments such as bacitracin, neomycin and polymyxin,13 and can be a further improvement in the epidural technique.

In general, micropore filters are recommended with epidural analgesia for two reasons: 1) to filter bacteria; 2) to prevent foreign material from gaining access to the epidural space.34

Table 2. Results

<table>
<thead>
<tr>
<th>Study Groups</th>
<th>Number of Patients</th>
<th>Total Cultures Done</th>
<th>Number of Positive Cultures</th>
<th>Cultures Positive to the Filter (Sites 1 through 4)</th>
<th>Cultures Positive to the Filter (Sites 5 and/or 6 with Filter, Compared with 6 without Filter)</th>
<th>Colonization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zephiran</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>With filter</td>
<td>24</td>
<td>96</td>
<td>14</td>
<td>48</td>
<td>9</td>
<td>19</td>
</tr>
<tr>
<td>Without filter</td>
<td>29</td>
<td>116</td>
<td>7</td>
<td>29</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>Prepodyne</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>With filter</td>
<td>14</td>
<td>56</td>
<td>2</td>
<td>28</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Without filter</td>
<td>28</td>
<td>112</td>
<td>4</td>
<td>28</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Logistic transform</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agent</td>
<td>2.06 (P &lt; 0.05)</td>
<td>0.653 (NS)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Filter</td>
<td>1.18 (NS)</td>
<td>0.714 (NS)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Interaction</td>
<td>0.950 (NS)</td>
<td>0.177 (NS)</td>
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</tbody>
</table>

NS = not significant.
In regard to the first, epidural abscesses have occurred despite the utilization of micropore filters.\textsuperscript{2,3} Adhering strictly to aseptic techniques, utilizing a disposable blunt needle instead of a reusable adapter at the end of the epidural catheter, and using a disposable syringe for each injection\textsuperscript{9} are important factors in lowering the incidence of contamination. The use of a filter is not a substitute for these rules.

The epidural space and/or the epidural catheter may be contaminated by: 1) dissemination from the skin via the needle track, 2) hematogenous spread, and 3) injections through the catheter. Concerning the first route, this study has shown a significant difference in the occurrences of contamination for the different skin preparations. Regarding the second route, all the patients studied were of physical status I, and sepsis was considered a contraindication to epidural analgesia.

The first and second routes are obviously beyond control by the bacterial filter in the epidural system. Concerning the third route, there was no significant difference regarding the use of filters due to the precautions taken with each refill dose, the antimicrobial activity of the local anesthetics,\textsuperscript{7,13} the small number of injections, and the limited duration of catheter insertion. Further studies are necessary to find out the efficacy and the need for bacterial filters with the epidural technique when analgesia is required for several days, the patient is diabetic or debilitated, or the dura has been inadvertently punctured.

In regard to the second reason for the use of a micropore filter, it is not a guarantee against the access of foreign materials that can be introduced into the epidural space prior to the interposition of the filter, e.g., friable or shreddable material can be caught within the epidural needle and projected into the epidural space as the catheter is inserted.\textsuperscript{3} Moreover, the threads of the filter itself can be dislodged into the epidural space and constitute a nucleus for formation of a space-occupying lesion.\textsuperscript{3}

In conclusion, Prepodyne, as a degenering agent for preparation of the skin prior to epidural analgesia, is superior to Zephiran, and its use is recommended. For the healthy obstetric patient, a micropore filter is not needed.

REFERENCES