Cold Sterilization of Cardiac Catheterization Equipment with Ethylene Oxide Gas

By Alexander M. Schmidt, M.D., and Paul D. Hoeprich, M.D.

Occasional infections in sites of venous cutdowns and an episode of fever in a patient following cardiac catheterization caused us to review the procedures used in this laboratory for preparation of catheterization equipment. Materials not susceptible to damage by wet heat (surgical instruments, syringes and needles, drapes) are sterilized in a steam autoclave. Polyethylene catheters, cuvette oximeters,* Statham P23Db strain gages, and other fragile electronic or plastic apparatus, since they may be destroyed by autoclave sterilization, have been boiled in water or soaked with solutions containing variously alcohol, quaternary ammonium compounds, heavy metals, or acids. The standard Courand cardiac catheter may be boiled or sterilized in an autoclave, but its useful life is shortened by such treatment. Furthermore, since procedures such as boiling and soaking in “antisepic” solutions are ineffective against a variety of microorganisms, there is some basis for doubt that actual sterilization is thereby accomplished.

In order to evaluate the effectiveness of current methods of sterilizing fragile equipment, we obtained a series of cultures from cardiac catheterization equipment prepared according to the usual regimen. Bacterial growth was demonstrated. Cold sterilization with ethylene oxide gas was then introduced; subsequent cultures have indicated that all equipment was then sterile. These results and a brief description of the simple, inexpensive, and convenient apparatus used for cold sterilization with ethylene oxide gas are presented.

Methods

Cultures of equipment were obtained at the start of a cardiac catheterization on each of 3 days. All items not autoclaved were cultured. These included catheters and plastic connecting tubes (flushed through and then soaked for 2 hours prior to use in 1:1,000 aqueous benzalkonium chloride); strain gages and cuvette oximeters (flushed and then allowed to stand for 2 hours, filled with 1:1,000 aqueous benzalkonium chloride). The catheters, strain gages, and oximeters were cultured by flushing each with a 20-ml aliquot of sterile normal saline. Pickup forceps, stored with blades immersed in 70-per cent ethyl alcohol, were cultured by rinsing the blades in 20 ml of sterile saline. Five-milliliter aliquots of each saline specimen were inoculated into four tubes of broth—two of thioglycollate broth (anaerobic) and two of tryptic digest of casein-papaic digest of soybean broth (aerobic). One culture of each pair was incubated at 37 C., while the other was incubated at 20 C. If no growth had occurred after 1 week, the cultures were discarded as negative. Bacteria isolated were identified by standard methods.

Following the introduction of ethylene oxide gas as a sterilizing agent, cultures, taken as described above, again were obtained on three occasions. Test strips of paperimpregnated with spores of Bacillus subtilis (globigii)* were enclosed within the cloth-wrapped packets of apparatus exposed to ethylene oxide gas; these strips were also cultured. The results are given in table 1.

Results and Discussion

The initial cultures supported our impression that the strain gage-oximeter assembly was not actually sterilized by contact with a solution of benzalkonium chloride. Other heat-susceptible items, according to our limited observations, were not contaminated by viable bacteria. It may be significant that the strain

* Sporde-X strips, American Sterilizer Co., Erie, Pennsylvania.

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* Wood Oximeter; The Waters Corporation, 18-14th Street, S.W., Rochester, Minnesota.
Table 1

<table>
<thead>
<tr>
<th>Item</th>
<th>Means of sterilization</th>
<th>Result of culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pickup forceps</td>
<td>Ethyl alcohol, 70% by volume</td>
<td>No growth</td>
</tr>
<tr>
<td>Plastic connecting tubes</td>
<td>Benzalkonium chloride, 1:1,000 in water</td>
<td>No growth</td>
</tr>
<tr>
<td>Cardiac catheters</td>
<td>Benzalkonium chloride, 1:1,000 in water</td>
<td>No growth</td>
</tr>
<tr>
<td>Strain gage-oximeter assemblies</td>
<td>Benzalkonium chloride, 1:1,000 in water</td>
<td>3/29 Staphylococcus albus; Achromobacter sp.; Flavobacterium sp.</td>
</tr>
<tr>
<td>Plastic connecting tubes</td>
<td>Ethylene oxide gas</td>
<td>No growth on three occasions</td>
</tr>
<tr>
<td>Cardiac catheters</td>
<td>Ethylene oxide gas</td>
<td>No growth on three occasions</td>
</tr>
<tr>
<td>Strain gage-oximeter assembly</td>
<td>Ethylene oxide gas</td>
<td>No growth on three occasions</td>
</tr>
<tr>
<td>Test strips of B. subtilis</td>
<td>Ethylene oxide gas</td>
<td>No growth on three occasions</td>
</tr>
</tbody>
</table>

The bacteria grown from the gage-oximeter system, Staphylococcus albus, Achromobacter and Flacobacterium species are not notably virulent. They have, however, caused death in human subjects from endocarditis. As is often the case with relatively avirulent bacteria that are widespread in natural occurrence, these bacteria are often little susceptible to antibacterial agents presently available for systemic therapy.

Following the introduction of ethylene oxide gas sterilization of the catheters, strain gages, and oximeters, all cultures were sterile.

Ethylene oxide (mixed with Freon)* is a safe, effective agent which in low concentrations will destroy all known microorganisms at room temperature. The chemical and sterilizing properties of the gas have been extensively reviewed by Phillips and Kaye.1-4 A simple technic for handling the gas is illustrated in figure 1. The apparatus consists of a tank of the gas, and a large, airtight jar † fitted with a screw-cap bearing a pressure gage and two needle valves. Objects to be sterilized are dried, wrapped (cloth, paper, or plastic may

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be used), and placed in the jar. The jar is then evacuated to approximately 20 inches of mercury below atmospheric pressure. Enough ethylene oxide-Freon gas mixture is then admitted to the jar to bring the pressure back to atmospheric, and the needle valves are closed. The jar and contents are left sealed at room temperature, overnight. The next morning the jar again is evacuated and flushed with air. Since the ethylene oxide is removed through the vacuum line, the jar may be opened without the use of a hood or other safety device. Small amounts of ethylene oxide may remain in porous materials, such as rubber and plastic. Articles containing these materials are therefore allowed to stand for 24 hours before use, thus assuring complete dissipation of the gas. Less than 5 minutes is required to set up the entire procedure of sterilization. The complete apparatus for cold sterilization with ethylene oxide gas can be obtained for less than $100.00 (including cost of ethylene oxide-Freon).

Catheters are sterilized while supported in plastic forms (fig. 1) so that the curve of the tip is preserved. Since the strain elements of Statham gages are vented through the cable, they are not harmed by the vacuum. Because neither gaseous ethylene oxide nor Freon is corrosive or wetting, electronic components are not injured.

Cuvette oximeters exposed repeatedly to the ethylene oxide-Freon mixture have eventually lost sensitivity. Measurements of the output of a selenium oxide test block left in the gas mixture for 150 hours demonstrated a decrease in output of 50 per cent over this time. It is therefore recommended that oximeters containing a selenium oxide sensing element not be sterilized by this method repeatedly. The plastic cuvette may be removed, sterilized, and replaced, thus avoiding exposure of the selenium to the gas. Vacuum-tube densitometers are not affected by ethylene oxide or Freon.

While use of ethylene oxide gas is not an innovation in sterilization, adaptation to the peculiar needs of the cardiac catheterization laboratory warrants comment. Generally, the methods in common use in cardiovascular laboratories are inadequate to assure sterilization of equipment that is placed in intimate contact with vital, often vulnerable, structures.

Summary and Conclusions
Commonly used methods of sterilization of cardiac catheterization equipment were shown by culture methods to be inadequate. A simple procedure of cold sterilization with ethylene oxide gas was devised, and has proved to be an inexpensive, time-saving, safe, and effective means of obtaining sterility of fragile, expensive equipment.

Acknowledgment
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References
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