Sterilization of Talc for Pleurodesis*  
Available Techniques, Efficacy, and Cost Analysis

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Although talc has been used as a pleurodesis agent since 1935, a sterilization protocol has not been established. We obtained USP asbestos-free talc from six different suppliers and sterilized each using dry heat, gamma irradiation, and ethylene oxide gas. Aerobic, anaerobic, and fungal cultures were obtained prior to sterilization, and 1, 30, and 90 days after sterilization. Bacillus species were cultured from all six unsterilized specimens and coagulase-negative Staphylococcus grew from two unsterilized specimens. No growth of organisms was found following any method of sterilization. The cost of sterilization per 5-g packet of talc was $4.74, $7.85, and $16.25 for heat, ethylene oxide, and gamma irradiation, respectively. In conclusion, untreated talc is not sterile. Sterilization by prolonged dry heat exposure, ethylene oxide gas, and gamma irradiation are all effective, with dry heat being the least expensive.

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Key words: pleurodesis; sterilization; talc

The interest in talc pleurodesis in the United States has escalated over the past few years. A recent review of over 1,200 talc pleurodesis procedures1 reiterates the excellent success rates when talc is administered via slurry (87%) or poudrage (93%) and in the treatment of both pneumothorax (91%) and pleural effusion (91%).

Talc is an inert, trilayered, magnesium sheet silicate that has significant lubricative properties that make it useful in cosmetics and industry. Talc that is used for pleurodesis is asbestos free but sterility is not required by US Pharmacopeia (USP) standards.2 Although talc has been used as a pleurodesis agent since 1935, a sterilization protocol has not been established. The purpose of this study was to determine the microbiology of unsterile talc from different suppliers, to evaluate the effectiveness of the various available sterilization techniques, and to determine the costs of these procedures.

MATERIALS AND METHODS

Six suppliers of USP talc were identified from standard chemical supply catalogues: (1) Humco, Texarkana, Tex; (2) Spectrum Chemical Manufacturing Corporation, Gardenia, Calif; (3) J.T. Baker, Phillipsburg, NJ; (4) City Chemical Corporation, New York; (5) Integra Chemical Company, Renton, Wash; and (6) Mallinckrodt Specialty Chemical Company, Chesterfield, Mo.

One pound of talc was purchased from each supplier. The talc from each supplier was weighed into 5-g portions and placed into self-seal sterilization pouches (Baxter Healthcare Corporation, Valencia, Calif). Since the talc, talc container, and self-seal packages were not sterile prior to packaging, no attempt at sterile handling was made during the process.

Six samples from each supplier were not sterilized, six were submitted for heat sterilization (132°C for 6 h), six for ethylene oxide gas sterilization (12% ethylene oxide for 1.75 h at 130°C), and six for gamma irradiation (30 kilograys, 565 min total exposure time (Isomedix, Morton Grove, Ill)).

Unsterile specimens from each supplier were submitted for culture immediately, and 30 and 90 days following packaging. Heat, gas and irradiated specimens from each supplier were submitted for culture at 1, 30, and 90 days following sterilization.

All specimens were submitted for aerobic, anaerobic, and fungal culture. Each talc aliquot was suspended in 10 mL of 0.9% saline solution. The suspension was divided equally between an aerobic (Bactec Plus 12; Becton Dickinson, Cockeysville, Md) and anaerobic (Bactec Plus 27) blood culture (BC) bottles using aseptic technique. All BC bottles were incubated at 35°C; the aerobic BC bottle was shaken during the incubation period. Each bottle was read periodically for up to 5 days on an instrument (Bactec 660). Aerobic bottles indicated by this instrument as being positive were Gram stained and subcultured to blood agar, chocolate agar, MacConkey agar, and CDC anaerobic blood agar. The blood, chocolate, and MacConkey agar plates were incubated at 37°C in CO2 or O2; the anaerobic blood agar plates were incubated at 35°C under anaerobic conditions for up to 48 h. Isolates were identified to genus, and species where appropriate, according to standard microbiology practice.

The conditions described for incubation and reading aerobic bottles will detect yeast, but not molds. Any aerobic BC bottle negative for bacteria and yeast was subcultured to brain heart infusion agar with gentamicin and cycloheximide (BBL). The plates were incubated at 25°C for up to 12 days.

RESULTS

Unsterile specimens from each supplier cultured Bacillus species immediately and at 30 and 90 days after packaging (Table 1). Specimens from suppliers

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positive rods that are ubiquitous in nature and are commonly found in rock, soil, dust, and water. With the exception of *Bacillus anthracis*, Bacillus species are generally thought to be nonpathogenic. However, clinically significant disease has been reported primarily in immunocompromised hosts and intravenous drug abusers but also in normal hosts. Bacillus species have been cultured from both heroin and intravenous drug user paraphernalia and *Bacillus* species panophthalmitis is a well-recognized complication of intravenous drug abuse. The production of spores by *Bacillus* species would account for its persistent presence in unsterilized specimens. It is likely that the coagulase-negative *Staphylococcus* that was obtained on the initial cultures resulted from skin, instrument, or package contamination. No fungal elements were cultured as has been reported in an earlier study. As previously stated, there were no attempts at sterile handling during the time that the specimens were placed into individual packets.

To our knowledge, there are no reports of patients given unsterilized talc for pleurodesis. Although the need for sterilization has not been clearly established in human studies, the development of clinically important infection with both *Bacillus* species and *Staphylococcus* is well known. Furthermore, even with sterilized talc, empyema has been reported with both talc slurry (0 to 11% incidence) and with poudrage (0 to 3%). The data currently support the need for

- Talc used for pleurodesis is USP asbestos free and must meet minimal criteria with regard to loss on ignition, acid-soluble substances, water-soluble substances, arsenic, lead, and heavy metals. Additional product specifications vary among manufacturers. Although talc is not packaged sterilely by the manufacturer, limitation on the number of microorganisms is a part of USP specifications and total bacteria count cannot exceed 500/g. Several protocols for sterilization have been described briefly. Ethylene oxide gas and heat sterilization have been reported most frequently; irradiation has also been used. Protocols often involve either culture of the talc for bacterial pathogens or the inclusion of biologic indicators during the sterilization process.

<table>
<thead>
<tr>
<th>Method of Sterilization</th>
<th>Supplier</th>
<th>Immediately or Day 1</th>
<th>Day 30</th>
<th>Day 60</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Humco</td>
<td>Bacillus species; coagulase-negative staph</td>
<td>Bacillus species</td>
<td>Bacillus species</td>
</tr>
<tr>
<td>None</td>
<td>Spectrum</td>
<td>Bacillus species</td>
<td>Bacillus species</td>
<td>Bacillus species</td>
</tr>
<tr>
<td>None</td>
<td>J.T. Baker</td>
<td>Bacillus species</td>
<td>Bacillus species</td>
<td>Bacillus species</td>
</tr>
<tr>
<td>None</td>
<td>City Chemical</td>
<td>Bacillus species; coagulase-negative staph</td>
<td>Bacillus species</td>
<td>Bacillus species</td>
</tr>
<tr>
<td>None</td>
<td>Integra</td>
<td>Bacillus species</td>
<td>Bacillus species</td>
<td>Bacillus species</td>
</tr>
<tr>
<td>None</td>
<td>Malinckrodt</td>
<td>Bacillus species</td>
<td>Bacillus species</td>
<td>Bacillus species</td>
</tr>
<tr>
<td>Heat</td>
<td>All</td>
<td>No growth</td>
<td>No growth</td>
<td>No growth</td>
</tr>
<tr>
<td>Ethylene oxide</td>
<td>All</td>
<td>No growth</td>
<td>No growth</td>
<td>No growth</td>
</tr>
<tr>
<td>Gamma irradiation</td>
<td>All</td>
<td>No growth</td>
<td>No growth</td>
<td>No growth</td>
</tr>
</tbody>
</table>

*Staph* = *Staphylococcus*

Table 1—Culture Results Before and After Sterilization

Table 2—Cost of Preparation of Talc for Pleurodesis

<table>
<thead>
<tr>
<th>Sterilization Techniques</th>
<th>Components of Talc Preparation</th>
<th>Dry Heat (132⁰C for 6 h)</th>
<th>Ethylene Oxide (12%, 1.75 h at 132⁰C)</th>
<th>Gamma Irradiation (30 kilorays for 565 min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talc (125 g at $0.019/g)</td>
<td>$2.40</td>
<td>$2.40</td>
<td>$2.40</td>
<td></td>
</tr>
<tr>
<td>Self-seal pouches (25 at $0.67 per pouch)</td>
<td>$16.75</td>
<td>$16.75</td>
<td>$16.75</td>
<td></td>
</tr>
<tr>
<td>Cultures (aerobic, anaerobic, fungal)</td>
<td>$87.00</td>
<td>$87.00</td>
<td>$87.00</td>
<td></td>
</tr>
<tr>
<td>Sterilization procedure</td>
<td>$12.50</td>
<td>$90.00</td>
<td>$300.00</td>
<td></td>
</tr>
<tr>
<td>Total cost</td>
<td>$118.55</td>
<td>$196.15</td>
<td>$406.15</td>
<td></td>
</tr>
<tr>
<td>Cost per 5-g packet</td>
<td>$4.74</td>
<td>$7.85</td>
<td>$16.25</td>
<td></td>
</tr>
</tbody>
</table>
sterilization prior to pleurodesis, particularly in these immunocompromised patients.

The sterile shelf life of the specimens is unknown. It is current practice in the sterile processing area of our institution to guarantee sterility of gas- and heat-treated instruments until the package is opened or damaged. Further cultures of the sterilized talc are planned for 6 months and 1 year after sterilization.

Safety concerns following ethylene oxide gas sterilization have been raised. A 24-h aeration period was required to ensure adequate dispersal of the ethylene oxide gas. Specimens tested following the standard 12-h aeration period still contained 2 ppm of gas, but those tested at 24 h were free of gas.

The cost of talc for pleurodesis reflects primarily the sterilization method and cultures required to verify sterility. The actual cost of sterilization pouches and talc itself is nominal, from $0.68 to $0.80 for each 5-g packet. The greatest cost, $300, involved in packaging and preparing talc for pleurodesis is incurred if talc is sterilized by gamma irradiation. This charge is irrespective of the quantity of talc sterilized and is based on the size of the container in which the talc is shipped; the price charged is for a 1-cubic-foot carton. Because of the longer time required for aeration, the fee from the sterile processing division for ethylene oxide gas sterilization was higher than the customary charge. The final cost incurred in preparation of talc for pleurodesis is that of cultures to prove sterility. Since fungal cultures have been negative in the unsterile specimens, this additional cost could be eliminated. Pharmacy charge for preparation of talc in a slurry will no doubt vary from institution to institution; the charge at our institution is $86. Therefore, because of the fixed costs, the greater the number of packets prepared for sterilization, the lower cost will be per patient.

In conclusion, untreated talc is not sterile and contains a Bacillus species. Sterilization by prolonged dry heat exposure, ethylene oxide gas, and gamma irradiation are all effective. Dry heat sterilization is the least expensive method of sterilization.

ACKNOWLEDGMENT: We would like to thank Gloria Infinger for her assistance with sterile processing.

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