Propofol: Can a Single Ampule Be Used for Multiple Patients?

To the Editor—The Center for Disease Control’s Center for Infectious Disease in May through June 1990 received reports of four postsurgical infections and/or hyperthermic reactions that developed in patients after a variety of surgical procedures. The reports were directed from four different states and have been associated with three different pathogens. All patients received propofol (Diprivan®), and there is some belief that the same syringe may have been used on different patients. The preliminary results of these investigations suggest that contamination of propofol was extrinsic (contaminated during the manipulation after receipt from the manufacturer).

We have performed the following study to determine if propofol would incur bacterial growth if aseptically aspirated and left at room temperature. Ten ampules of propofol were opened under standard aseptic technique. Ten milliliters of solution was withdrawn from each ampule. Then, in ten separate syringes, 5 ml was aspirated. These 5-ml aliquots were labeled and immediately sent to the laboratory. Each aliquot was cultured at 2, 4, 6, 8, and 12 h after the original collection. All specimens were independently cultured on 5% sheep agar for 72 h. There was no growth in any of the samples at the end of the 72 h. The specimens then were subcultured onto trypticase medium and showed no growth within an additional 72 h.

This study shows that if propofol is aspirated into sterile unit dose syringes using standard accepted techniques, it can be bacterial-free for 72 h. In theory, propofol can be used for up to 72 h after opening the ampule. However, in clinical practice, no medication such as this should be left open for this period of time. A single ampule of propofol could be used on multiple patients if aspirated aseptically into separate syringes immediately upon opening of the ampule.

Gregory J. Downs, M.D.
Chief, Anesthesia

Peter R. Haley, C.R.N.A.
Jaime B. Parent, M.S., M.T. (A.S.C.P.)

General Delivery
Box 2300
March Air Force Base, California 92518

REFERENCES


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In Reply—Downs et al.’s data support evidence in the literature that the use of standard aseptic technique minimizes the potential for any extrinsic contamination through inappropriate handling. In contrast to Downs et al.’s conclusion that propofol (Diprivan®) could be used on multiple patients from a single ampule, the Diprivan® label specifically indicates that Diprivan® should be prepared for single-patient use only and just prior to the initiation of each individual procedure.

ICI Pharmaceuticals Group’s Research and Development recently conducted a study to determine the potential for microbial contamination of Diprivan® using a specific handling technique.* Using this technique, Diprivan® was transferred from 140 vials into sterile syringes. Multiple samples were taken from each syringe over a 12-h test period using a randomized incomplete block design. Samples were tested microbiologically using bacterial filtration with both broth and agar media to maximize the detection of microorganisms.

As indicated in table 1, of the 2,040 test samples from syringes, only two (0.098%) tested positive for microorganisms. These two samples were from different syringes; one sample tested positive at 6 h and the other at 8 h. Testing of samples from these two syringes at all other test periods, including the 12-h time point, showed no contamination. The very low levels of contamination observed in these two samples are consistent with the background contamination inherent in the procedure used to test the samples.† It is not consistent with contamination of the Diprivan® during aspiration into syringes.

In response to reports of cases of postoperative infection where breaks in aseptic technique may have led to extrinsic contamination of Diprivan®, the company has, in conjunction with the Food and Drug

* Diprivan® handling technique specified in study:
1. Wear clean surgical scrubs.
2. Wash hands and fingernails using antimicrobial handwash.
3. Remove metal cap from vial.
4. Disinfect rubber stopper of vial using 70% isopropyl alcohol.
5. Insert vent spike through rubber stopper and remove Luer cap.
6. Connect sterile syringe(s) and withdraw entire content.
7. Immediately cap each syringe with sterile closure.
8. Discard vial and vent spike.
9. Label syringe with appropriate information.
10. Take labeled syringes to laboratory for testing.

<table>
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<th>Time (h)</th>
<th>Thio-glycollate Broth (Filter)</th>
<th>Chocolate Agar (Filter)</th>
<th>Spread Plate Technique</th>
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Data are positive test samples/total test samples.