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Drug Contamination from Opening Glass Ampules

To the Editor:—Recently Zacher *et al.*[1] demonstrated that drug solutions could be contaminated by artificially inoculating the exterior of the glass ampule with bacteria prior to opening. Do these data support the authors' conclusion that glass ampules should routinely be swabbed with alcohol prior to opening? The only conclusion that we could draw from this study is that ampules should *not* be swabbed with a bacterial culture. In our opinion, the important question that needs to be addressed relates to the infection risk (if any) with *routine* handling of glass ampules in the operating room.

Despite the widespread use of propofol (Diprivan®) (which has been available in Europe since 1987), there have only been 24 reported cases (from four centers) of postoperative sepsis associated with propofol.[2] At each center, infection was associated with a single anesthesia care provider, and in two centers (18 cases) this person was carrying the same bacterial strain responsible for patient infection, in one case on their hands and in the other in their throat. Unfortunately, the means by which infection spread from anesthesia personnel to patients was not identified in either case.[2] Contamination of a propofol infusion has been reported at only one site (2 cases); however, contamination of the anesthesia provider was not found in this instance.[2]

While it is clear that propofol is a highly suitable growth medium for bacteria,[1,3,4] growth does not appear to be significant in less than 12 h.[4] In at least two of the reported cases, it has been alleged that the propofol solution was left in the syringe pump overnight (unreported data). It has also been shown that external contamination of a glass ampule may result in contamination of its contents.[1,5] However, there have been no proven cases of clinical infection as a result of contamination from a glass ampule following routine handling.

Care should also be exercised in handling all intravenous drugs, and the risk associated with routine clinical practice needs to be carefully assessed. In addition to evaluating the effect of "disinfecting the neck surface of the ampule using 70% isopropyl alcohol (wipe in one direction and let dry)",* the value of commonly used measures such as using a gauze swab or mechanical ampule opener (which also protect anesthesia personnel from lacerations) should also be evaluated. More extreme measures (*e.g.*, the use of antimicrobial handwash and the wearing of sterile gloves, clean garments, a facemask, and/or a hair cover*) should not be implemented *without* first proving their value in well-conducted and appropriate clinical trials. Otherwise we may be expending inappropriate time and money correcting a problem that does not exist!

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* Stuart Pharmaceuticals: Diprivan® package insert, 1991.

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In Reply:—We appreciate the comments of Smith and White concerning our recent article on the contamination of propofol ampules.[1] In this article, we provided evidence that glass ampules containing sterile solutions could be contaminated by merely breaking open the vial and that this risk may be reduced by wiping the neck of the vial with an alcohol swab. Whether this mechanism of contamination was involved in any or all of the numerous reported cases of postoperative fever and/or infection due to contaminated propofol (84 cases from 28 hospitals over 13 months ending January 11, 1991) will probably never be known.* Assessment of the actual clinical risk associated with opening glass vials will await the large scale prospective study suggested by Smith and White. In the meantime, it must be noted that the recommendation to wipe the neck of the propofol vials with alcohol is not ours, but rather that of Stuart Pharmaceuticals. In a letter detailing the new handling instructions for propofol, they state, "Disinfect neck surface of ampule using 70% isopropyl alcohol. Swab neck of ampule by wiping in one direction and let dry."* Our study simply demonstrated that this maneuver effectively decontaminates the outside of the glass ampule even when it has been heavily soiled with *Staphylococcus* bacteria.

* New Safety and Handling Information for Diprivan. Stuart Pharmaceuticals, Wilmington, Delaware, February 5, 1991

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Effects of Resuscitation Using Hypertonic Saline

To the Editor:—The report by Prough *et al.* on the use of hypertonic saline (HS) for resuscitation from hemorrhagic shock in the presence of increased intracranial pressure[1] seems a worthwhile contribution to a growing literature regarding the use of HS, and points once more to the potential clinical usefulness of this particular therapy. However, in reviewing their data, I noted that resuscitation with HS did not significantly increase cardiac output and in fact appeared inferior to resuscitation with normal saline in restoring cardiac output to baseline levels. This finding is not in keeping with multiple previous studies,[2–4] which have consistently shown HS to be quite effective in restoring cardiac output to normal or supernormal levels after hemorrhage and in many cases to be more effective than normal saline in this regard. Given that cardiac output indirectly affects cerebral perfusion pressure and cerebral blood flow, how might this anomalous finding affect the validity of Prough *et al.*'s conclusions?

In addition, I was surprised by the authors' assertion that HS can increase mycocardial contractility. The studies that are widely quoted to show such an effect actually looked at the effects of serum hyperosmolality induced by sucrose or urea on the heart[5] and the effects of hyperosmotic sucrose on mycocardial contractility.[6] Later reports have shown that HS is, as opposed to other hyperosmotic agents, a direct mycordial depressant.[7,8] Other authors have proposed a pulmonary/vagally mediated reflex resulting in systemic circulatory changes and increased cardiac contractility in response to HS[9,10]; recent studies have cast doubt on that assertion.[11,12] From the available data, I think it is safe to conclude that the improvement in cardiac output seen after resuscitation with HS is secondary to changes in preload alone and is not related to improved cardiac contractility.

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