

tion, which is defined to achieve at least a 6 log₁₀ reduction of mycobacteria, would have been expected to destroy the entire titer of *T. whipplei* used in this study (ie, 10⁹ inclusion-forming units/mL), instead of reportedly achieving only a 3 log₁₀ reduction. Contrary to the results of this study by La Scola et al., other studies have consistently demonstrated that high-level disinfection, achieved using several different products including 2% (alkaline) glutaraldehyde, destroys all pathogenic microorganisms including vegetative bacteria, mycobacteria, and some types of spore-forming bacteria, such as *Clostridium difficile*.²

Several factors may have contributed to the unique results of the study by La Scola et al. For example, the temperature of the 2% glutaraldehyde solution (and the two peracetic acid products) to which *T. whipplei* was exposed was not recorded or discussed. According to the label of virtually every 2% glutaraldehyde solution sold in the United States, it is necessary to elevate (and monitor) the immersion temperature to 25°C or higher to achieve high-level disinfection.² Indeed, small increases in the temperature of a high-level disinfectant can significantly increase its biocidal properties. It is unclear whether the temperature of the 2% glutaraldehyde solution, which the study reported was produced by thawing and diluting a frozen concentrate just prior to testing, was several degrees below 25°C during testing, reducing its effectiveness and preventing it from achieving high-level disinfection. Studies that do not report the temperature of a high-level disinfectant used to destroy bacteria or reprocess instruments can provide data and conclusions of limited, if any, significance.

Moreover, the 2% glutaraldehyde solution used for this study was produced on site and was not a prepackaged product manufactured in accordance with appropriate regulatory guidelines, such as those typically required by the U.S. Food and Drug Administration of manufacturers of high-level disinfectants and liquid chemical sterilants. As a result, the effectiveness, consistency, and chemical composition of this 2% glutaraldehyde solution, each of which is a factor crucial to the reproducibility, reliability, and integrity of the study's data,

may be questioned. Also, although it was demonstrated to destroy *P. aeruginosa*, this 2% glutaraldehyde solution, like the study's two peracetic acid products, was not shown to destroy mycobacteria, which generally are the appropriate and necessary microorganisms to use as positive controls whenever testing the biocidal effectiveness of high-level disinfectants. Failure to have used mycobacteria as a positive control limits the validity and significance of the study's data and conclusions.

Although perhaps due to a protective effect provided by an amorphous glycoprotein material that La Scola et al. reportedly observed surrounding its cells,¹ it is unlikely that *T. whipplei* is more resistant to high-level disinfection than other vegetative bacteria and mycobacteria (to which *T. whipplei* is phylogenetically related) and may require sterilization for its destruction. Some other factor, such as the temperature and/or chemical composition of the three high-level disinfectants used during testing, is a more likely explanation for this study's reported unusual resistance of *T. whipplei* to high-level disinfection.

Noteworthy, this study reported that both of the patients diagnosed as having Whipple's disease 3 years earlier had undergone intestinal biopsy during gastroscopy. This study, however, solely focused on the potential for inadequate high-level disinfection of the GI endoscope and did not consider or discuss whether instead inadequate reprocessing of the biopsy forceps used during gastroscopy could have played a significant role in the study's two reported cases of transmission of Whipple's disease. Recent studies have identified failure to adhere to reprocessing guidelines for reusable biopsy forceps, which require cleaning and sterilization, as the cause of transmission of infectious agents, including hepatitis C, during GI endoscopy.³

The finding by La Scola et al. that *T. whipplei* may survive high-level disinfection and be transmitted via GI endoscopes should not cause alarm or raise undue concern. Failure to record the temperature of each high-level disinfectant during testing, as well as selection of a vegetative bacterium for a positive control instead of mycobacteria, limit this study's scope and significance. Most

important, application of this study to the clinical setting is somewhat tenuous. Specifically, the results of this study do not reflect the significant reduction in the risk of disease transmission and nosocomial infection achieved by cleaning, a mechanical process that is the standard of care, required before disinfection (and sterilization) of endoscopes and their accessories and, as acknowledged by La Scola et al., reported to achieve a 5 log₁₀ reduction of microorganisms. If this study had either mechanically cleaned surfaces or devices contaminated with *T. whipplei* prior to exposure to each of the three high-level disinfectants, or acknowledged, corrected for, and incorporated into its methodology and results the expected log reduction reportedly achieved during cleaning, then for each of these three high-level disinfectants the entire titer of *T. whipplei* would have been destroyed and high-level disinfection achieved. In short, cleaning followed by high-level disinfection of a GI endoscope contaminated with *T. whipplei* (or any other infectious agent) would be expected to prevent disease transmission.

Therefore, although it is plausible that GI endoscopy and intestinal biopsy may be risk factors for Whipple's disease, more research is necessary to evaluate this study's conclusion and place its results in better perspective. Publication of additional corroborating data is essential before specific conclusions can be drawn and guidelines provided that recommend that patients who have previously undergone intestinal biopsy during esophagogastroduodenoscopy be examined and assessed for Whipple's disease.

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The authors reply.

Dr. Muscarella raises doubts about the conditions of our experiments testing the susceptibility of *Tropheryma whipplei* to biocides¹ and emphasizes that our results were unique. We agree with Dr. Muscarella that the conclusions of our preliminary study need to be confirmed by others, especially with appropriate monitoring of the temperature. However, the fact that our results will have to be confirmed by other studies is a common feature of all preliminary studies.

In the test conditions used, biocides reduced the control suspension of *Pseudomonas aeruginosa* by at least 5 log₁₀. The limited reduction of *T. whipplei* evidenced in our study demonstrated that this bacterium has, at least, reduced susceptibility to biocides. This reduced susceptibility to biocides, previously described for *Mycobacteria*, has been demonstrated to be responsible for hospital-acquired cases of mycobacterial infections.² In such cases, an error usually occurs during endoscope reprocessing,^{2,3} but lowered susceptibility to biocides may lead to trans-

mission. In a recent study, Srinivasan et al. noticed that even experienced bronchoscopists were unfamiliar with reprocessing guidelines.⁴ Thus, preventing transmission of microorganisms during endoscopy is not solely related to the effectiveness of biocides. We agree that temperature was not well monitored in our study and future studies of disinfection of *T. whipplei* should record this variable.

Our intent was not to recommend that patients who have previously undergone intestinal biopsy during esophagogastroduodenoscopy be assessed for Whipple's disease, but rather that any history of intestinal biopsy during esophagogastroduodenoscopy be sought during examination of patients with newly diagnosed Whipple's disease. We also suggest that disinfection protocols for endoscopy equipment must include scrupulous cleaning of the endoscope prior to disinfection because this has been shown to be essential for effectiveness of the disinfection.⁵ Further controlled studies are needed to assess the possible importance of

biopsy procedures in transmitting *T. whipplei*.

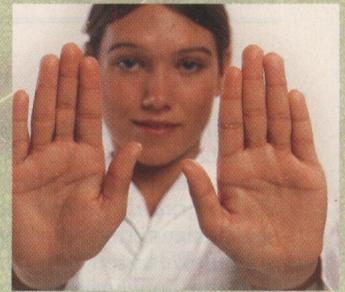
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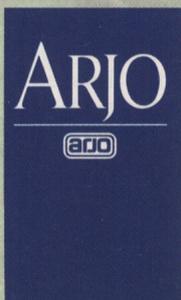
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