

Disinfection of endoscopes from *Helicobacter pylori*-positive subjects: Evaluation of the effectiveness of the Chinese Calijing disinfection kit

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Background: The aim of this study was to evaluate the effectiveness of the Calijing disinfection kit (an endoscope disinfection method used in Chinese hospitals) in eradicating *Helicobacter pylori* and assess whether use of the kit in 1994 during endoscopies in the Shandong Intervention Trial (SIT), Shandong, China, could have resulted in iatrogenic transmission of *H pylori*.

Methods: Bacterial culture studies at the Veterans Affairs Medical Center, Houston, Texas, using endoscopes and forceps from 49 *H pylori*-positive patients were performed on contaminated endoscopes before and after disinfection with the Calijing kit.

Results: At least 1 endoscope culture site was *H pylori* positive in 39 of 49 (79.6%) specimens preinfection, whereas *H pylori* was not isolated from any endoscopic culture site postdisinfection. Non-*H pylori* bacteria and fungi were recovered from 22.6% of the postdisinfection cultures.

Conclusion: Although no viable *H pylori* were recovered following the disinfection procedures, levels of *H pylori* below the detection threshold of the bacteriologic assay may have contributed to an increase in *H pylori* seroprevalence noted in the SIT. In addition, the kit was unable to provide disinfection against non-*H pylori* organisms, suggesting the need to adhere to internationally accepted disinfection procedures for endoscope reprocessing. (Am J Infect Control 2005;33:197-201.)

Helicobacter pylori (*H pylori*) is one of the most common bacterial infections in humans worldwide and has been recognized as a major cause of gastritis.¹ It is also considered a risk factor for duodenal ulcer disease, gastric ulcer disease, and gastric lymphoma and has been linked to gastric cancer.²⁻⁴ Most epidemiologic data support a person-to-person mode of transmission, but nosocomial transmission of *H pylori* is the only proven mode of transmission.

We have been following the perplexing finding that an unusually high percentage of persons originally classified as *H pylori* seronegative in 1994 in the Shandong Intervention Trial (SIT), a blinded, randomized, 2³ factorial trial of 3411 subjects in 13 rural villages in Linqu County, Shandong Province, China, were found to have either a positive urease breath test (UBT) (39.7%) or a positive serologic test (41.3%) in 1996.⁵ This change in serostatus corresponds to an annual seroconversion rate of 23.4% between 1994 and 1996 compared with an annual seroconversion rate of 4.2% between 1989 and 1994. The annual rate of seroconversion in adult populations in developed countries appears to be small (on the order of 0.2%-1.0%); whereas higher rates (on the order of 6.4%-7.3%) have been documented among adults in less developed countries.⁶⁻⁸

One possibility for the high rate of seroconversion is that *H pylori* baseline serostatus could have been misclassified because *H pylori* was endemic in our study population (approximately 67% of the study population was seropositive at baseline) and that some of the "seroconvertors" may actually have harbored the *H pylori* organism in 1994 and, therefore, were not really "negative" as indicated by their baseline serology.

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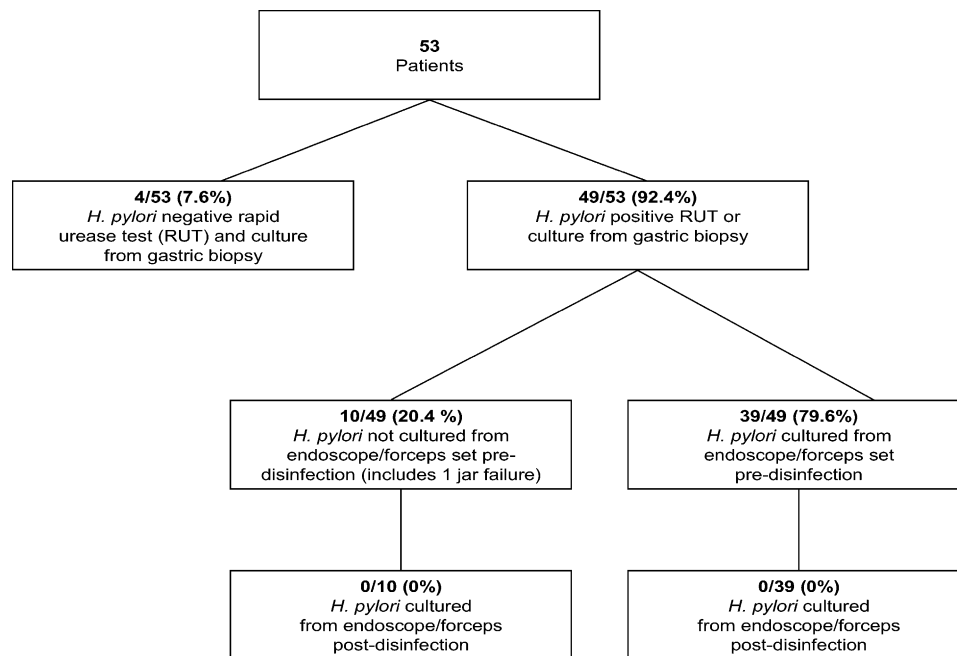


Fig 1. *Helicobacter pylori* contamination pre- and postdisinfection with the Calijing disinfection kit.

Another possibility is that some people who underwent endoscopy in 1994 as part of a previous cross-sectional study of gastric lesion progression (GLP) conducted from 1989 to 1994 might have been infected as a result of that endoscopy. Up to 75 endoscopies were performed each day, using 3 endoscopists and 6 endoscopes. The endoscope disinfection procedures used in Shandong in 1989 for the GLP study met the standards of the Working Party Report to the World Congresses of Gastroenterology, Sidney, 1990.^{9,10} However, the endoscope disinfection procedures used in 1994 were modified by Chinese collaborators at the Beijing Institute for Cancer Research (BICR). A 1:2000 chlorhexidine solution, a skin antiseptic not approved for medical device reprocessing in the United States, was utilized for rinsing the endoscope. Instead of soaking the endoscopes in Cidex (Johnson & Johnson, Advanced Sterilization Products, Irvine, CA) (2.4% alkaline glutaraldehyde in water) for 10 minutes, the endoscopes were cleaned using Calijing disinfection kits (synthetic sponges saturated with 2.4% glutaraldehyde and used to wipe the outside of the endoscope) manufactured in a factory in Tianjin, China. Forceps were cleaned and disinfected by soaking for 10 minutes in Cidex (Johnson & Johnson) squeezed from the Calijing sponge. Although the Calijing kit is currently used in approximately 1500 hospitals in China for endoscope disinfection, there have not yet been any reports on its efficacy against transmission of *H. pylori* from contaminated endoscopes. The purpose of this study is to assess whether use of the Calijing

disinfection kit could have resulted in iatrogenic transmission of *H. pylori* during the 1994 endoscopies and to present data on the effectiveness of the Calijing disinfection kit.

MATERIALS AND METHODS

Fifty-three patients at the Veterans Affairs Medical Center, Houston, Texas, underwent medically indicated gastric endoscopy and had rapid urease testing (RUT) (*Hpfast*) and culture in gastric biopsies. The endoscopes and forceps that had been used in these patients were evaluated for *H. pylori* and other bacteria and fungi before and after disinfection. The endoscopy suite was adjacent to the microbiologic laboratory, allowing immediate microbiologic evaluation of the endoscopes. Human subjects and institutional review were not required for this laboratory study because data were not linked to the patient's name or hospital record.

Following endoscopy, but before disinfection, the following procedure was performed on each endoscope. One entire side of the endoscope was swabbed with a sterile cotton swab (moistened in transport medium) and plated onto a nonselective plate of Mueller-Hinton agar medium containing 7% horse blood and a selective plate of Mueller-Hinton agar culture medium containing 7% horse blood and *H. pylori* selective antibiotics to prevent overgrowth of other bacteria. The biopsy channel was flushed with a small amount of saline, and the washings were plated onto a nonselective and a selective agar plate. Next, the inner and

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