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Major Article

Simethicone residue remains inside gastrointestinal endoscopes despite reprocessing

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Background: During a study designed to assess endoscope reprocessing effectiveness, a borescope was used to examine lumens and ports. Cloudy, white, viscous fluid was observed inside fully reprocessed gastroscopes and colonoscopes. This fluid resembled simethicone, which is commonly administered to reduce foam and bubbles that impede visualization during gastrointestinal endoscopy. This article describes methods used to determine whether the observed fluid contained simethicone.

Methods: Photographs of residual fluid were taken using a borescope. Sterile cotton-tipped swabs were used to collect samples of fluid observed in 3 endoscope ports. Samples were evaluated using Fourier transform infrared spectroscopy (FTIR)–attenuated total reflection analysis.

Results: Residual fluid was observed inside 19 of 20 endoscopes. Fluid photographed in 8 endoscopes resembled simethicone solutions. FTIR analysis confirmed the presence of simethicone in 2 endoscopes.

Conclusions: Fluid containing simethicone remained inside endoscopes despite reprocessing. Simethicone is an inert, hydrophobic substance that may reduce reprocessing effectiveness. Simethicone solutions commonly contain sugars and thickeners, which may contribute to microbial growth and biofilm development. Studies are needed to assess the prevalence of residual moisture and simethicone in endoscopes and determine the impact on reprocessing effectiveness. We recommend minimizing the use of simethicone pending further research into its safety.

During gastrointestinal (GI) endoscopy, optimal visualization may be impeded by the presence of foam and bubbles.[1] Solutions containing simethicone are commonly administered to patients undergoing gastroscopy and colonoscopy to prevent or reduce bubbles.[1-4] Benefits associated with simethicone use include improved visibility during procedures,[4-7] reduced procedure time,[6] improved endoscopist and patient satisfaction,[7] and reductions in bloating and abdominal discomfort experienced by patients.[4]

Simethicone can be administered as chewable tablets or oral solutions during bowel preparation or shortly before procedures (eg, over-the-counter medications, including Gas-X, Mylicon, or Mylanta Gas).[1,8] Liquid simethicone solutions are also infused through endoscope channels for lavage performed during GI procedures (eg, Infants Mylicon, PediaCare Gas Relief, Equate Infants' Gas Relief, Major Infants' Gas Relief Drops).[1,3,7,9-11]

During a longitudinal study conducted to assess endoscope reprocessing effectiveness, we observed residual fluid inside channels and ports of patient-ready endoscopes that had been reprocessed in accordance with guidelines. The fluid was similar in appearance to simethicone products used at the study site. This article describes the methods used to evaluate the characteristics of the fluid and determine whether it was simethicone.

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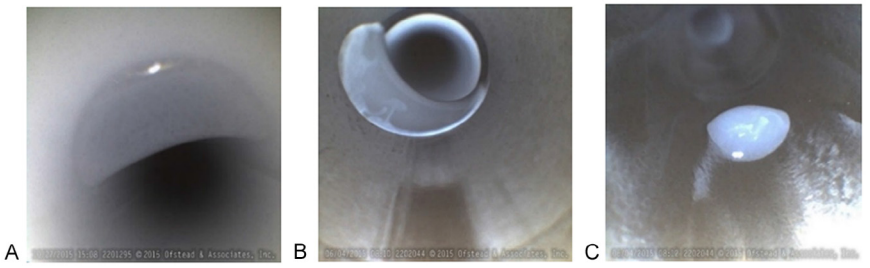

Fig 1. Fluid observed in endoscope channels and ports. (A) Cloudy fluid partially occluding suction-biopsy channel. (B) Shimmery, opaque fluid inside biopsy port. (C) Viscous, white, shimmery fluid inside biopsy port.

MATERIALS AND METHODS

This prospective study was conducted in the GI endoscopy unit of a large ambulatory surgery center that had 17-20 endoscopes during the study period (GIF-HQ190, CF-HQ190L, and PCF-H190L; Olympus America, Center Valley, PA). The institutional review board for this site granted a waiver because no human subjects were involved. Reprocessing consisted of immediate bedside precleaning, leak testing, manual cleaning, high-level disinfection (HLD) in an automated endoscope reprocessor (AER; Medivators Inc, Minneapolis, MN), flushing with alcohol, air purge in the AER, and wiping with a lint-free towel prior to vertical storage in a ventilated cabinet. Single-use precleaning kits, manual cleaning materials, valves, and caps were used. Technicians followed the instructions-for-use (IFU) provided by manufacturers of reprocessing equipment and materials. The AER manufacturer performed routine maintenance and provided additional training for reprocessing technicians after the baseline assessment. Researchers periodically performed unannounced audits to assess technician adherence with endoscope reprocessing protocols. Additional details about reprocessing protocols and materials have been previously described, along with information about study methods and findings.[12]

In brief, researchers assessed gastroscopes and colonoscopes 3 times during a 7-month period. Endoscope age, number of reprocessing cycles, and repair history were recorded. Researchers used an aseptic technique to sample each endoscope after manual cleaning and again after HLD by swabbing the biopsy port and gathering effluent from the suction-biopsy channel. Samples were transported to an external laboratory for microbial cultures, and the research team conducted onsite rapid indicator tests for adenosine triphosphate (CleanTrace ATP; 3M, Saint Paul, MN) and protein (ProCheck-II; HealthMark Industries, Fraser, MI) to measure residual contamination. After endoscopes were sampled, they were reprocessed and dried before researchers inspected external surfaces and performed examinations of lumens using a 3-mm borescope (Flexible Inspection Scope Camera; HealthMark Industries). Photographs of irregularities and residual fluid were captured using the borescope software. Clinical educators employed by the manufacturers of the rapid indicator tests and the borescope provided training for the research team on the use of these systems prior to data collection.

During the baseline and interim assessments, residual fluid was observed inside most patient-ready endoscopes that had been flushed with alcohol and purged with forced air prior to removal from the AER. Fluid characteristics varied considerably (eg, clear, cloudy, shimmery, white, opaque, viscous). After the interim assessment, researchers decided to sample any nonclear fluid if it was observed during the final assessment. Swabs used to collect fluid samples were immediately placed in sterile conical tubes.

An external laboratory conducted Fourier transform infrared spectroscopy (FTIR)–attenuated total reflection analysis of blinded samples using a germanium crystal. Analysis included reference samples of the clinically used simethicone solutions, 5 positive controls (swabs dipped in reference solutions), 5 negative controls (swabs dipped in sterile water), and 5 clinically obtained samples from endoscopes A, B, and C. Results for the clinical samples were compared with the reference samples and known FTIR spectra for silicone (simethicone) and cellulose.

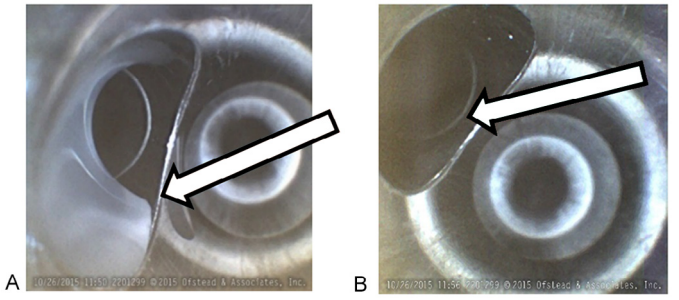

Fig 2. Fluid captured from suction port of pediatric colonoscope. (A) Before attempting to capture a sample. (B) After capturing the sample.

RESULTS

Technician adherence with endoscope reprocessing policies was confirmed during 9 unannounced audits by the research team. During baseline and interim assessments, researchers photographed fluid that appeared cloudy, white, opaque, shimmery, or viscous (Fig 1). In some cases, fluid occluded or nearly occluded channels and ports. This fluid appeared similar to simethicone products used at the study site to reduce foam and bubbles during endoscopy (Qualitest Pharmaceuticals Infants' Simethicone Drops and Major Infants' Gas Relief Drops).

During the final borescope examinations, researchers observed multiple fluid droplets inside ports and channels of 19 of 20 endoscopes. In 8 endoscopes, fluid appeared cloudy, white, opaque, shimmery, or viscous. In 3 of these endoscopes, the fluid was located in ports that could accommodate sampling with a sterile cotton-tipped swab. Samples were obtained from suction ports of endoscopes A and B and the biopsy port of endoscope C. Repeat borescope examinations confirmed removal of fluid from endoscopes A and B using 1 swab each (Fig 2). Three swabs were used to capture samples from the biopsy port of endoscope C because we could not visually confirm fluid removal.

Analysis of material on the swabs from endoscopes A and B showed spectra consistent with the presence of silicone identified in reference samples. The samples from endoscopes A and B had FTIR profiles that were similar to the results for all 5 positive controls. Results were negative for the 3 swab samples from endoscope