Summary

Influence of a defoaming agent — simethicone — on endoscope cleaning and disinfection: Prospective real-world study

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Background and rationale

Simethicone is widely used during gastrointestinal endoscopy because it reduces gas bubbles and mucus, thereby improving mucosal visibility. It can be administered orally or introduced directly through the endoscope during the procedure, most commonly via the biopsy channel or an auxiliary water channel. The use of simethicone during endoscopy is common in clinical practice, but its potential impact on subsequent endoscope reprocessing remains controversial.[1]

The concern relates primarily to the physical properties of simethicone. It is an inert, hydrophobic substance that may remain on the internal surfaces of endoscope channels after use. Previous investigations have demonstrated that residual fluid can remain within endoscope channels even after high-level disinfection and drying. The authors also refer to previous work suggesting that simethicone residues may interfere with reprocessing and potentially contribute to conditions conducive to microbial growth or biofilm formation.[2-3]

At the same time, there is no clear consensus that simethicone should be avoided during endoscopy. The Endoscopic Retreatment Guideline (ICEG), based on available evidence and clinical experience, has supported continued use because no publicly reported adverse events related to oral simethicone use during endoscopy had been identified.[4-6] Thus, there is a gap between the widespread clinical use of simethicone and the limited evidence regarding its behaviour during subsequent endoscope reprocessing.

The authors therefore considered it relevant to investigate the issue under real-world clinical conditions, rather than only in an experimental laboratory model.

Aim

The aim was to investigate whether the use of simethicone during gastrointestinal endoscopy affects subsequent endoscope cleaning and disinfection.

The study examined:

- How much simethicone remained in the biopsy and auxiliary water channels
- Whether simethicone accumulated over time with repeated clinical use
- Whether different simethicone concentrations affected ATP measurements
- Whether visible deposits or crystallisation developed in the channels
- Whether the findings differed between gastroscopes and colonoscopes

Study design

This was a prospective, single-centre, real-world observational study conducted over one year. The study was performed at the Affiliated Hospital of Nanjing University of Chinese Medicine in China. Thirty Olympus

endoscopes were included: 19 gastroscopes and 11 colonoscopes, all equipped with an auxiliary water channel. The endoscopes were used routinely for diagnostic gastrointestinal endoscopy and endoscopic treatment.

The investigation consisted of two stages.

First, a preliminary experiment evaluated simethicone concentrations of 0%, 0.5%, 1%, 2% and 3% to identify concentrations suitable for the subsequent real-world study.

Second, 30 endoscopes were divided into three groups of 10:

- 0% simethicone – control group
- 1% simethicone
- 2% simethicone

The assigned concentration was used during routine clinical procedures throughout the one-year observation period. Residual simethicone and ATP were assessed monthly. The internal surface of the biopsy channels was also examined using an EyeMAX endoscopic imaging system.

Methods

Simethicone use and study conditions

The simethicone preparation was supplied as a 40 mg/30 mL emulsion and diluted to the required concentrations. During endoscopy, simethicone was administered either through the biopsy channel using a 50-mL syringe or through the auxiliary water channel using an Olympus water pump. Each endoscope was assigned a fixed simethicone concentration, which was maintained throughout the study period.

Endoscope reprocessing and sampling

All endoscopes underwent the centre's routine manual cleaning and disinfection procedure, including:

1. Pre-treatment
2. Leak testing
3. Manual cleaning
4. Rinsing
5. Disinfection
6. Final rinsing
7. Drying

After reprocessing and complete drying, 200 mL of sterile saline was flushed through the biopsy and auxiliary water channels. The recovered fluid was then analysed for residual simethicone and ATP.

Assessment of residual simethicone

Residual simethicone was assessed indirectly by measuring silicon concentration using inductively coupled plasma mass spectrometry (ICP-MS). Silicon concentration was used as a marker of residual simethicone.

ATP measurement

ATP was measured using a 3M Clean-Trace LM1 handheld ATP system as an indicator of residual organic material and cleanliness. ATP may reflect organic material such as cell debris and biofilm-associated material, but it is not a direct measure of viable microorganisms or disinfection efficacy.

Visual inspection

The biopsy channels were examined using an EyeMAX endoscope to identify any visible deposits or suspected crystallisation that developed during the one-year study period.

Results

Preliminary concentration experiment

The initial experiment showed that residual simethicone could be detected after use and subsequent routine cleaning. In the biopsy channel, increasing the concentration of simethicone resulted in increasing residual simethicone. The difference became statistically significant when the concentration exceeded 1%. A similar concentration-dependent pattern was observed in the auxiliary water channel, with statistically significant differences when the concentration exceeded 2%.

Importantly, however, the preliminary experiment did not demonstrate a corresponding increase in ATP values with increasing simethicone concentration. Thus, increasing residual simethicone was not directly accompanied by evidence of increased organic residue as measured by ATP.

On the basis of these preliminary findings, the investigators selected 1% and 2% simethicone for the one-year real-world study.

Residual simethicone the one-year period

At the beginning of the one-year study, there were no significant differences in residual simethicone between the three groups. Over time, however, residual simethicone became more evident.

In the biopsy channels, the 1% group showed significantly higher residual simethicone than the control group by approximately month 11. The 2% group showed increased residual simethicone by month 12.

In the auxiliary water channels, the 2% group showed a significant increase in residual simethicone compared with the control group. When the results were analysed across the full year, increased residual simethicone was observed in both the 1% and 2% groups in the auxiliary water channel.

Overall, the results therefore indicate that simethicone can remain within endoscope channels despite routine cleaning and disinfection, and that higher concentrations are associated with greater residual levels.

ATP results

Despite the accumulation of residual simethicone, the study did not demonstrate a consistent effect on ATP values. No significant differences were found in ATP measurements between the 0%, 1% and 2% groups over the one-year period in either the biopsy or auxiliary water channels. Overall ATP measurements also did not show a significant difference between the two channel types.

This is an important finding because it suggests that the presence of residual simethicone did not necessarily translate into higher ATP measurements, despite the measurable accumulation of simethicone. The authors therefore concluded that simethicone use did not appear to compromise the cleaning performance assessed by ATP under the conditions of this study.

Visual inspection

Visual examination of the biopsy channels revealed no crystals at the beginning of the study.

After one year, suspected adherent simethicone crystals were observed in the 2% group, whereas no crystals were identified in either the 1% group or the control group. No visible damage to the biopsy-channel wall was observed.

The finding is potentially relevant because it suggests that prolonged exposure to higher concentrations may result not only in measurable residues but also in visible deposits.

Gastroscopy versus colonoscopy

A sensitivity analysis was performed to determine whether the findings differed between gastroscopy and colonoscopy. The analysis did not demonstrate significant differences between the two procedure types with regard to residual simethicone or ATP measurements. The authors therefore considered the overall findings to be relatively robust across the two endoscopy subgroups.

Interpretation of findings

The main finding of this study is that simethicone can remain within endoscope channels after routine cleaning and disinfection, and that residual levels tend to increase with higher concentrations and repeated use over time. This finding is consistent with earlier studies demonstrating that simethicone may remain inside endoscope working channels despite reprocessing.[1-2] The authors suggest that the hydrophobic nature of simethicone may contribute to its retention on internal channel surfaces.

Importantly, the presence of residual simethicone should not automatically be interpreted as evidence of inadequate cleaning or disinfection. Although residual simethicone increased over time, the study did not demonstrate a corresponding increase in ATP levels in the 1% and 2% groups during the one-year study period. ATP was used as an indicator of residual organic material and cleanliness, but it does not provide information about the presence of viable microorganisms or directly assess the effectiveness of high-level disinfection.

The finding of suspected crystallisation in the 2% group is nevertheless noteworthy. No visible damage to the channel walls was observed during the one-year observation period, but the longer-term consequences of such deposits remain uncertain. The absence of visible crystallisation in the 1% group led the authors to suggest that simethicone concentrations of 1% or less may be preferable. However, this should be interpreted cautiously. The study was not designed to establish a universally applicable concentration threshold, and the comparison was conducted within a single centre using one specific reprocessing protocol.

The findings also need to be considered in relation to the real-world conditions under which the study was conducted. The results may depend on factors such as the endoscope models, simethicone preparation, method of administration, manual cleaning procedure, disinfectant, drying process and local workflow. Consequently, the findings may not be directly transferable to other settings.

Most importantly, the study does not establish whether residual simethicone has any clinically relevant effect on microbial transmission or patient safety. No culture-based microbiological outcome or clinical infection outcome was used to investigate this. Thus, while the study adds to the evidence that simethicone can persist within endoscope channels and may accumulate with repeated use, it does not demonstrate that this residual material results in impaired disinfection or an increased risk of infection.

The main limitations include the use of ATP as an indirect indicator of cleanliness, the single-centre design and the relatively short one-year observation period. The authors therefore call for larger multicentre

studies, ideally including microbiological outcomes, to further investigate the clinical significance of residual simethicone.

Implication for practice

The study provides a useful reminder that substances introduced into an endoscope channel during an examination may remain in the channel despite subsequent reprocessing.

The findings support a cautious approach to simethicone use, particularly with regard to concentration. The authors recommend using concentrations of 1% or lower when simethicone is administered through the biopsy or auxiliary water channel. However, the findings should not be interpreted as evidence that simethicone use makes endoscope reprocessing ineffective. In this study, residual simethicone was measurable, but ATP measurements did not indicate a corresponding deterioration in cleaning performance.

From a reprocessing perspective, the findings reinforce the importance of:

- Following the endoscope manufacturer's instructions for use
- Using the lowest effective simethicone concentration
- Ensuring thorough manual cleaning of all channels
- Paying particular attention to channels through which simethicone has been administered
- Maintaining effective rinsing and drying procedures
- Avoiding conclusions about microbial contamination or infection risk based solely on the presence of residual simethicone

The study also highlights the importance of considering repeated exposure over time. Although a single exposure may not result in substantial residue, repeated use over many months may lead to measurable accumulation and, at higher concentrations, visible deposits.

Importantly, the findings do not establish 1% as a universally safe or optimal concentration for all endoscope systems. Rather, they suggest that lower concentrations may be preferable under the specific clinical and reprocessing conditions investigated.

Key message

The evidence on simethicone and endoscope reprocessing has evolved from demonstrating the presence of residual simethicone after reprocessing, to investigating the influence of concentration, and more recently to examining its accumulation during prolonged real-world use. Ofstead et al. (2016)[1] demonstrated that simethicone could remain inside endoscope channels despite reprocessing. Barakat et al. (2019)[2] subsequently showed that simethicone concentration influenced fluid retention and ATP measurements, providing further evidence that the amount of simethicone used may be relevant to reprocessing.

Huang et al. (2025) extends this evidence by examining repeated clinical use over one year. Under the conditions investigated, residual simethicone increased with higher concentrations and prolonged use. Use of 1% simethicone or less was associated with less residual material and no visible crystallisation, whereas 2% simethicone was associated with greater residual levels and suspected deposits after one year. However, the study did not demonstrate impaired disinfection or an increased risk of microbial transmission.

Taken together, these studies show a progression from identifying residual simethicone, to investigating the influence of concentration, to examining potential accumulation during repeated clinical use**.** The findings support the use of the lowest effective concentration and careful adherence to validated cleaning and reprocessing procedures. However, the clinical significance of residual simethicone remains uncertain, and further studies incorporating microbiological outcomes are needed.

Referencer

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