Endoscopes used in positive and critically ill patients are SARS-CoV-2 negative at virological assessment

Ivo Boškoski, Anna Di Gemma, Maria Valeria Matteo, Fabio Grilli, Paola Cattani, Guido Costamagna

Digestive Endoscopy Unit, Policlinico Universitario Agostino Gemelli, Roma, Lazio, Italy

Correspondence to
Dr Ivo Boškoski, Digestive Endoscopy Unit, Policlinico Universitario Agostino Gemelli, Roma 00168, Italy; ivo.boskoski@policlinicogemelli.it

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MESSAGE

The risk of SARS-CoV-2 transmission in endoscopy is not only between patients and endoscopy staff but is also through inadequately reprocessed endoscopes. There are no studies that could confirm the efficacy of current ways of endoscope reprocessing on the elimination of SARS-CoV-2. The aim of this pilot study was to evaluate the efficacy of high disinfection of endoscopes with peracetic acid on eliminating SARS-CoV-2, but surprisingly we found that the virus cannot be detected on any part of endoscopes used in critically ill patients due to SARS-CoV-2 and this was the same for all types of endoscopies and procedures. If confirmed in larger studies, these findings will probably open a new scenario in the overall understanding of the real impact of the virus.

IN MORE DETAIL

Considering that the SARS-CoV-2 has high infectivity potential and can be transmitted through Flügge droplets and faeces,[1] all endoscopy staff is considered particularly vulnerable to infection.[2] Therefore, endoscopy units around the globe had massive workflow reorganisations to mitigate the risks of virus transmission. These recommendations have been given by the European Society of Gastrointestinal Endoscopy, the American Society of Gastrointestinal Endoscopy and the Asian Pacific Society for Digestive Endoscopy.[3–5] Recently, Repici *et al* found that that gastro intestinal (GI) endoscopy is relatively safe for both patients and medical personnel when using adequate protective measures.[6] In addition to this, correct endoscopes reprocessing is crucial to avoid cross-contamination and its importance has been raised with the pandemic. Currently, high disinfection with peracetic acid (PAA) is the most used and diffuse method[7 8] for endoscope reprocessing, but there is no scientific evidence on its efficacy on SARS-CoV-2. A single-centre pilot study was performed to evaluate the efficacy of high disinfection of endoscopes with PAA on eliminating SARS-CoV-2. The study was approved by the Ethical Committee and Institutional Review Board (IRB) of the Fondazione Policlinico Universitario Agostino Gemelli IRCCS (Number 0016760/20, approved on 17 April 2020). The aim of this pilot study was to evaluate the efficacy of endoscopes reprocessing through virological assessment of endoscopes used in critically ill patients due to SARS-CoV-2. Patients' characteristics, clinical status and current medical treatment were prospectively recorded. Eligible endoscopes for the analysis were those never used before in infected individuals and that were used in critically ill patients due to COVID-19. Samples were taken with swabs on the endoscopes immediately before the procedure (control) in a cleanroom before any contact with the patient (T0), immediately after the procedure (T1) and immediately after high disinfection (T2) with PAA (table 1). Samples were collected in sterile tubes and immediately analysed. The analysis was done with real-time RT-PCR for SARS-CoV-2 RNA. All samples were processed on CE-IVD marked NIMBUS Automated Liquid Handling Workstations, from nucleic acid extraction to PCR setup (Seegene, Arrow Diagnostics Srl, Genova, Italy), according to the manufacturer's directions. Nucleic acids from selected samples were also extracted and enriched using the automated EZ1 Advanced XL System (Qiagen, Italy) with the EZ1 DSP Virus Kit (Qiagen), following the manufacturer's instructions. SARS-CoV-2 RNA was detected by multiplex real-time reverse transcriptase-polymerase chain reaction (RT-PCR) assay using Allplex 2019-nCoV Assay (Seegene, Arrow Diagnostics, South Korea) on CFX96 Real-time Detection System (Bio-Rad, Italy) with automatic data system analysis software (Seegene viewer) for identifying positive samples (cycle threshold value less than 40 is interpreted as positive for SARS-CoV-2 RNA). Allplex 2019-nCoV Assay is a multiplex real-time PCR assay for simultaneous detection of three target genes of SARS-CoV-2 in a single tube. The assay is designed to detect RdRP and N genes specific for SARS-CoV-2 and E gene for all of Sarbecovirus including SARS-CoV-2 as in the WHO recommended protocols. Procedures to prevent specimen contamination and PCR carryover were rigorously observed at all stages.

REPROCESSING

Reprocessing of endoscopes at the Digestive Endoscopy Unit of the Fondazione Policlinico Universitario Agostino Gemelli starts with manual lavage with Umonium38 (spray). After this, the endoscope is placed in the washing

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Table 1 Sites and timings of swabs done on endoscopes

Site of swabs	Clean endoscope* (T0)	Immediately after the procedure (T1)	Immediately after reprocessing (T2)
Red valve housing	T0C1	T1C1	T2C1
Over the endoscope	T0C2	T1C2	T2C2
Operative channel	T0C3	T1C3	T2C3
Suction channel	T0C4	T1C4	T2C4

*Immediately before the procedure on endoscope never used before in a SARS-CoV-2-positive patient.

machine (ETD3, Olympus, Japan). EndoDis (Olympus, Japan, is a disinfectant based on PAA), EndoDet (Olympus, Japan, surfactant-based detergent) and EndoAct (Olympus, Japan, allows the Olympus PAA process to work in a neutral pH value range and thus efficiently protects sensitive endoscope materials) are the three products used for endoscopes reprocessing.

DATA ANALYSIS

During the study period, 13 endoscopes were used in 12 critically ill COVID-19-positive patients and were analysed. Procedures were upper (six endoscopes) and lower endoscopies (three endoscopes), endoscopic ultrasound (one endoscope), endoscopic retrograde cholangiopancreatography (one endoscope) and bronchoscopy (two endoscopes). The mean age of the patients was 73 years (53–93—five females). All patients were critically ill due to a SARS-CoV-2 infection. All procedures and patients' characteristics are reassumed in table 2. Swabs of the endoscopes were collected according to the protocol (table 1) and were analysed immediately in the hospital virology laboratory with real-time RT-PCR for SARS-CoV-2 RNA. As expected, the samples taken with swabs on the endoscopes immediately before the procedure (T0) gave all negative results. Interestingly, the swabs taken immediately after the endoscopic procedure on all the described sites of the endoscopes (T1) were all negative for SARS-CoV-2 RNA. The results obtained after high disinfection with PAA (T2) were also all negative.

COMMENT

There is reasonable concern that COVID-19 may be spread through droplets and faecal shedding from COVID-19-positive patients during endoscopic procedures,[2] but this risk is low when personal protective equipement (PPE) is used correctly.[6] Endoscopes reprocessing is very important and was a hot topic also in non-COVID times. In our institution, endoscope reprocessing is done according to the indication of the scientific societies and basically, this study aimed to validate the process of high disinfection of endoscopes with PAA and to prove its efficacy on the elimination of SARS-CoV-2. It is expected that any kind of high disinfection process could eliminate the SARS-CoV-2, but to the best of our knowledge this has never been scientifically proven and current ways of endoscopes reprocessing have never been shown to be effective on this virus. To compare the results, samples taken with swabs on the endoscopes immediately before the procedure were considered a control group. The same endoscopes were used on SARS-CoV-2-positive and critically ill patients and swabs were taken immediately after the procedure and then immediately after reprocessing. As expected, the results before the use and after reprocessing were all negative. It is incredibly surprising that the swabs done on endoscopes immediately after the procedure were all negative. Currently, we do not have a scientific explanation for these unexpected results. If Quintus Horatius Flaccus could see us doing all the efforts for this study, he would say: 'Parturient montes, nascetur ridiculus mus', that literary translated from Latin means 'so much work and the result is ridiculous' (Ars poetica, 139). Rather

Table 2 Procedures and patients' characteristics

Patient	Age	Sex	Type of procedure	Clinical manifestations	O_2 support	High-flow oxygen	NIV	OTI	Antiviral drugs	Antibiotics
1	85	M	Colonoscopy	Respiratory failure	Yes	Yes	No	No	No	Yes
2	93	F	Colonoscopy	Respiratory failure and fever	Yes	No	No	No	Yes	Yes
3	68	F	EUS	Respiratory failure and fever	Yes	No	No	No	Yes	No
4	77	M	Colonoscopy	ARDS	Yes	Yes	Yes	Yes	Yes	Yes
5	77	M	Colonoscopy	ARDS	Yes	Yes	Yes	Yes	Yes	Yes
6	73	F	Bronchoscopy	Fever, dyspnoea and cough	Yes	No	No	No	Yes	Yes
7	73	F	Bronchoscopy	Fever, dyspnoea and cough	Yes	No	No	No	Yes	Yes
8	71	M	OGDS	ARDS	Yes	Yes	Yes	Yes	Yes	Yes
9	71	M	ERCP	Fever, dyspnoea and cough	Yes	No	Yes	No	Yes	No
10	53	M	Bronchoscopy	Cough and dyspnoea	Yes	No	No	No	No	No
11	61	M	OGDS+colonoscopy	Fever and respiratory failure	Yes	Yes	Yes	No	Yes	Yes
12	73	F	OGDS	Fever and respiratory failure	Yes	Yes	No	Yes	Yes	Yes

ARDS, acute respiratory distress syndrome; ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound; NIV, non-invasive ventilation; O_2, oxygen; OGDS, oesophagogastroduodenoscopy; OTI, orotracheal intubation.

than ridiculous, we consider these results as a discovery that could open a new scenario in the overall understanding of the nature of this virus. However, even if the SARS-CoV-2 could not be detected on the endoscopes this does not mean that endoscopy in positive patients is safe since personnel infections are mainly related with airborne spreading of the virus. Finally, we could not draw any conclusions regarding the efficacy of endoscope reprocessing with PAA.

Twitter Ivo Boškoski @ivoboskoski

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ORCID iD

Ivo Boškoski http://orcid.org/0000-0001-8194-2670

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