A newly designed duodenoscope with detachable distal cap significantly reduces organic residue contamination after reprocessing

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GRAPHICAL ABSTRACT

ABSTRACT

Background A newly designed duodenoscope with detachable distal cap may reduce bacterial contamination by allowing better access to the elevator. We compared bacterial contamination and organic residue evaluated by rapid adenosine triphosphate (ATP) test and culture from duode-

noscopes with detachable vs. fixed distal caps after high-level disinfection (HLD).

Methods During December 2018–April 2019, 108 used newly designed duodenoscopes were enrolled. In group A (n = 54), the distal cap of the duodenoscope was detached before manual cleaning. In group B (n = 54), the distal cap was not detached. After HLD, samples were collected from the elevator, submitted for culture, and evaluated using the ATP test, using the cutoff value of 40 relative light units (RLUs).

Results After HLD, the proportion of potential bacterial contamination and organic residue in group A was significantly lower than in group B (37.0 % vs. 75.9 %; $P < 0.001$; relative risk 0.49, 95 % confidence interval 0.33–0.71), and also confirmed by median ATP values (45.2 vs. 141.0 RLU; $P < 0.001$). In group B, one sample culture was positive for nonpathogenic bacteria. Pathogenic bacteria were not found in any culture from either group.

Conclusions The detachable distal cap was more effective at eliminating bacterial contamination and reducing organic residue than a fixed cap. Nonpathogenic bacteria were detected in the fixed cap group after reprocessing. The ATP test with 40 RLU cutoff is a practical method to ensure the cleanliness of duodenoscope reprocessing without the need to wait for bacterial culture results.

Introduction

Despite high-level disinfection (HLD) protocols, several outbreaks of multidrug-resistant bacterial contamination of duodenoscopes with fixed distal caps have been documented over the past decade [1, 2]. Owing to the complex design with an elevator mechanism, duodenoscopes are more difficult to clean and disinfect than other endoscopes. This in turn can result in potential contamination of the duodenoscope even after standard HLD. Duodenoscopes with a fixed distal cap have a plastic or rubber cap permanently attached to the distal end; this design limits accessibility during manual cleaning and disinfection, with the brush being unable to access the distal end of the duodenoscope particularly behind the elevator. The US Food and Drug Administration (FDA) currently recommends that health care facilities and manufacturers begin to transition to duodenoscopes with disposable components in order to reduce the risk of infection in patients [3].

Recently, a newly designed duodenoscope with a detachable distal cap has been developed to make scope reprocessing easier and more effective. These devices may have an advantage over conventional duodenoscopes, which have a fixed distal cap, by allowing the brush to access the back of the elevator mechanism. However, no surveillance studies evaluating contamination rates of these newly designed duodenoscopes have been conducted. Furthermore, comparative data on the contamination rates after HLD between the two duodenoscope designs are lacking.

The Centers for Disease Control and Prevention (CDC) recommends surveillance culture for bacterial contamination from the elevator and the working channel [4], and the FDA suggests that endoscope surveillance sampling and culturing are specifically required or regulated by the state or local authority [5]. As the microbiologic testing of duodenoscopes is costly and requires 72 hours for culture, it remains to be evaluated whether this quarantine approach is practical and financially feasible in endoscopy centers with limited budgets. Recently, several studies have proposed the use of the adenosine triphosphate (ATP) test as an alternative method of point-of-care testing (POCT) to evaluate bacterial contamination and organic residue in duodenoscopes after HLD [6–16]. However, the recommended cutoff value of ATP to determine scope contamination has not been determined [6–16].

Our study aimed to compare the proportion of potential bacterial contamination and organic residue in the newly designed duodenoscopes with detached distal cap vs. those with a fixed distal cap after HLD by using ATP testing as POCT and bacterial culture to confirm bacterial contamination after ≥ 72 hours. Furthermore, we validated the optimal cutoff value of 40 relative light units (RLUs) based on our previous reports to ensure that the duodenoscopes were free of contamination [15, 16].

Methods

The study was conducted at the Excellence Center of Gastrointestinal Endoscopy, King Chulalongkorn Memorial Hospital, between December 2018 and April 2019. Following use, all newly designed duodenoscopes with detachable distal caps (ED 580XT; Fujifilm, Tokyo, Japan) were prospectively recruited to the study. Duodenoscopes were enrolled and divided into two groups in a 1:1 ratio: in group A the distal cap was detached prior to reprocessing and in group B the cap remained fixed in place.

As the study did not involve human subjects, it did not require approval from the institutional review board. The study protocol was registered at the national clinical registry (TCTR2019209002).

Duodenoscope reprocessing

After endoscopic retrograde cholangiopancreatography (ERCP) procedures, duodenoscope reprocessing was performed by well-trained staff according to the manufacturer's recommendations and standard guidelines [5], including precleaning, leak testing, manual cleaning, HLD, drying, and storage. After precleaning at the point of care, the duodenoscope was transferred to the reprocessing area using fully enclosed and labeled containers for subsequent steps. Leak testing was performed before formal reprocessing.

For manual cleaning, the duodenoscope was immersed in enzymatic detergent solution (3 M Low Foam Ultra Rapid Multi-Enzyme Cleaner; 3 M, Taipei, Taiwan). In group A, the distal

▶ **Fig. 1** A newly designed duodenoscope with detachable distal cap (ED 580XT; Fujifilm, Tokyo, Japan). **a,b** The distal cap was detached before manual cleaning to allow the brush to access the back of the elevator (white arrow). **c,d** The distal cap was not detached before manual cleaning in order to imitate the conventional duodenoscope with a fixed distal cap.

cap of the duodenoscope was detached before manual cleaning (▶ **Fig. 1a,b**), whereas in group B, the distal cap was not detached (▶ **Fig. 1c,d**) in order to imitate the conventional duodenoscopes with fixed distal cap. A single-use, manufacturer-recommended channel and elevator brush (WB1318DE; Fujifilm, Tokyo, Japan) was used to remove visible debris from the accessible area of the duodenoscope, including the elevator, suction port, air/water port, and instrument channel port. The elevator system, including the guidewire-locking groove and the forceps elevator recess, was cleaned using the brush. The elevator control lever was operated at least three times to raise and lower the forceps elevator while in the detergent solution. In addition, the forceps elevator recess, air/water channel, suction channel, and instrument channel were flushed through with the detergent solution.

Following manual cleaning, the duodenoscope was placed in an automated endoscope reprocessor (OER-AW; Olympus Medical Systems Corp., Tokyo, Japan) using a high-level disinfectant (Acecide; Olympus Medical Systems Corp.). The total cycle reprocessing time was approximately 20 minutes. After HLD, the duodenoscope was rinsed and flushed with filtered water to remove disinfectant solution and sampling procedures were then performed.

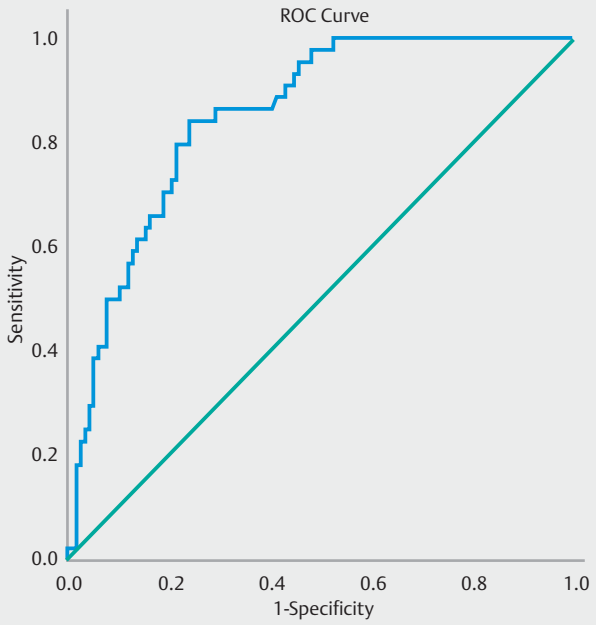
Sampling protocol

All sampling procedures were performed by staff who had received training and were certified from the ATP manufacturer according to the CDC protocol [5]. These were the same staff who performed manual cleaning and they were therefore not blinded to group allocation. After a single round of HLD, a sample was collected from the elevator site using swab rotation, with the cap removed in group A and the cap in place in group B, and submitted for culture. Then, the sample was rapidly evaluated for bacterial contamination and organic residue by analyzing the RLU with a luminometer (3M, Maplewood, Minnesota, USA). The ATP test (Clean-Trace Surface ATP; 3M) was used to evaluate the ATP-containing specimen obtained from the elevator.

The gold standard to detect any bacterial growth in samples was by culture for at least 72 hours. A sterile swab was used to collect the sample from the elevator by rotating it at the elevator mechanism in the raised/open position and in the lowered/closed position. Then, the collected sample was spread on to a blood agar plate and cultured for at least 72 hours. Culture samples from the elevator were kept on cold pack and promptly transferred to the laboratory. In the laboratory, culture samples from the elevator on the blood agar plate were incubated at 37 °C. Initial and final culture results were reported at 72 hours and at 7 days after receiving the specimen, respectively. If the culture result was positive for bacterial contamination, the bacterial species were identified and counted (colonies forming units [CFU]/mL), and antibiotic sensitivity testing was performed. Contamination of the duodenoscope was defined as any growth of pathogenic organisms such as Enterobacteriaceae species, *Staphylococcus aureus*, *Streptococcus viridans* group, and *Enterococcus* or the growth of more than 10 CFU of nonpathogenic organisms such as coagulase-negative *Staphylococcus*, *Bacillus*, and *Diphtheroid* [17, 18].

Management

Previous full publications were based on a higher cutoff value (200 RLU) and the specimens were obtained from the suction channel rather than from the elevator; the results from those studies showed that contamination was present [7, 8]. Subsequent studies using the cutoff value of 200 RLU still showed the inconsistent relationship between ATP and culture results [10,12–14]. Based on these previous data, the 2018 CDC guidelines postulated the ATP test as a useful marker for the scope cleaning process but its sensitivity was not sufficient to be used as a marker for the adequacy of the HLD process [5]. In real clinical practice, we require a rapid screening test to identify potentially contaminated duodenoscopes that need repeat HLD before they can return to clinical use; therefore, the test must achieve a perfect negative predictive value (NPV) of 100%. Our previous data [15, 16] on the ATP test demonstrated an area under the receiver operating characteristic curve of 0.85 (95% confidence interval [CI] 0.78–0.90) (▶ **Fig. 2**); the ATP threshold of 40 RLU had a sensitivity of 100% (95%CI 93.3–100) and NPV of 100% (95%CI 90.3–100), whereas the ATP threshold of 200 RLU had sensitivity, specificity, positive predictive value, and NPV of 86.8% (95%CI 74.7–94.5), 59.9% (95%CI 51.5–67.9), 43.8% (95%CI 34.1–53.8), and 92.6% (85.4–97.0), respectively (▶ **Table 1**). Furthermore, our additional tests [15, 16] in the validated group confirmed that at the ATP threshold of 40 RLU, all culture samples were negative for pathogenic bacterial contamination (100% sensitivity and 100% NPV).



▶ **Fig. 2** Receiver operating characteristic (ROC) curve of adenosine triphosphate test from the elevator compared with culture results (AUROC = 0.851) [16].

In the current study, in group A, if the ATP result passed the threshold after HLD, then the duodenoscope was returned to the clinic ready for use without waiting for the culture results. If the ATP levels were ≥ 40 RLU, then the duodenoscope was returned for another cycle of HLD until the ATP level was lower than the threshold before it could be used for the next patient. For all group B duodenoscopes, regardless of whether they met the ATP benchmark after initial HLD, repeat cap-off cleaning based on the manufacturer's reprocessing instructions was performed before they were returned to clinical use in patients. When there was disagreement between the POCT and the gold standard sample culture, for instance when a duodenoscope with an ATP test < 40 RLU was used in a patient but a positive culture result was subsequently recorded, then the patient was tracked for clinical evidence of duodenoscope-related infection until Day 90 after the procedure.

Statistical analysis

We assumed that the newly designed duodenoscope with the detachable distal cap would have a contamination rate of 1 % compared with conventional fixed-cap duodenoscopes, which have a contamination rate of 16 % [19]. The sample sizes for the two groups were calculated using a two independent proportions formula with a difference in contamination rate of 15 % between the two groups. A sample size of 54 in each group would give 80 % power to detect this difference at a 2-sided significance level of 5 %.

Continuous variables were presented as the median (range) for non-normal distributions. Categorical variables were reported as numbers and percentages. Using the threshold of ATP < 40 RLU, we calculated the number and percent of duodenoscopes with organic residue requiring an additional cycle of HLD to ensure 100 % NPV, and the relative risk between groups. A two-sided *P* value of < 0.05 was considered to be significant. Statistical analyses were performed using SPSS version 23 for Windows software (IBM Corp., Armonk, New York, USA).

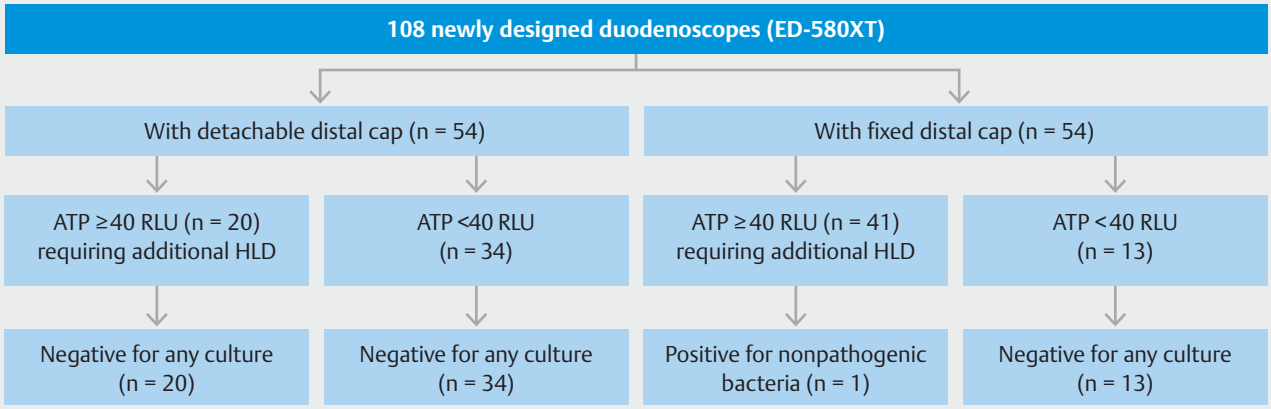
Results

During the 5-month study period, 108 used newly designed duodenoscopes (54 in each group) were enrolled into the study (▶ **Fig. 3**). The indications for ERCP were not different between the groups: bile duct stones (36 [66.7 %] vs. 30 [55.6 %]; *P* = 0.23), malignant biliary stricture (15 [27.8 %] vs. 20 [37.0 %]; *P* = 0.30), benign biliary stricture (2 [3.7 %] vs. 3 [5.6 %]; *P* = 0.65), and pancreatic duct stones (1 [1.9 %] vs. 1 [1.9 %]; *P* > 0.99) in group A vs. group B, respectively. No patient with a history of carbapenem-resistant Enterobacteriacae infection was found during the study period.

▶ **Table 1** Performance characteristics of adenosine triphosphate test from the elevator sites compared with cultures.

ATP cutoff, RLU	Sensitivity, % (95 %CI)	Specificity, % (95 %CI)	PPV, % (95 %CI)	NPV, % (95 %CI)
40	100 (93.3–100)	24.5 (178–32.3)	32.3 (25.2–40.1)	100 (90.3–100)
50	98.1 (89.9–100)	35.4 (27.7–43.7)	35.4 (27.7–43.7)	98.1 (89.9–100)
60	98.1 (89.9–100)	41.5 (33.4–49.9)	37.7 (29.6–46.3)	98.4 (91.3–100)
70	96.2 (87–99.5)	46.3 (38–54.7)	39.2 (30.8–48.2)	97.1 (90.1–99.7)
80	96.2 (87–99.5)	46.9 (38.7–55.3)	39.5 (31–48.5)	97.2 (90.2–99.7)
90	94.3 (84.3–98.8)	46.9 (38.7–55.3)	39.1 (30.6–48.1)	95.8 (88.3–99.1)
100	94.3 (84.3–98.8)	46.9 (38.7–55.3)	39.1 (30.6–48.1)	95.8 (88.3–99.1)
150	88.7 (77–95.7)	53.7 (45.3–62)	40.9 (31.8–50.4)	92.9 (85.3–97.4)
200	86.8 (74.7–94.5)	59.9 (51.5–67.9)	43.8 (34.1–53.8)	92.6 (85.4–97)

ATP, adenosine triphosphate; RLU, relative light units; CI, confidence interval.



▶ **Fig. 3** Flow chart of the study. ATP, adenosine triphosphate; RLU, relative light units; HLD, high-level disinfection.

▶ **Table 2** Comparison of rapid adenosine triphosphate testing and culture results between the duodenoscope with detached (group A) vs. fixed (group B) distal cap after high-level disinfection.

	Group A (n = 54)	Group B (n = 54)	*P* value
ATP, median (range), RLU	45.2 (9–209)	141.0 (19–653)	<0.001
ATP ≥ 40 RLU, n/N (%)	20/54 (37.0)	41/54 (75.9)	<0.001
Positive cultures, n/N (%)			
▪ Nonpathogenic bacteria	0/54 (0)	1/54 (1.9)	0.32
▪ Pathogenic bacteria	0/54 (0)	0/54 (0)	N/A

ATP, adenosine triphosphate; RLU, relative light units; N/A, not applicable.

ATP testing

Overall, after a single round of HLD, median ATP value in group A was significantly lower than that of group B (45.2 RLU [range 9–209] vs. 141.0 RLU [range 19–653]; P <0.001) (▶ **Table 2**). Using 40 RLU as the ATP cutoff value, the proportion of potential bacterial contamination and organic residue in group A was significantly lower than that of group B (20/54 [37.0%] vs. 41/54 [75.9%]; P<0.001; relative risk ratio 0.49, 95%CI 0.33–0.71). Of the 108 used duodenoscopes, 34 in group A and 13 in group B with ATP levels of <40 RLU after one cycle of HLD were returned to the clinic ready for use. The remaining duodenoscopes with ATP values of ≥40 RLU after the initial HLD (group A = 20, group B = 41) underwent a second cycle of HLD until the duodenoscopes passed the ATP benchmark. All 61 duodenoscopes passed the ATP threshold after the second cycle of HLD and were returned to clinical use.

Culture results

In group A, all 54 culture samples were negative for pathogenic and nonpathogenic bacterial contamination after HLD (▶ **Table 2**). In group B, one sample taken after the first HLD was found to have nonpathogenic bacterial contamination (coagulase-negative *Staphylococcus*) with an ATP value of 137 RLU from the same duodenoscope. Pathogenic bacterial contamination confirmed by culture was not documented in any of the group B cultures. There was no disagreement between POCT and the culture result (i.e. no patient developed clinical evidence of duodenoscope-related infection).

Discussion

Several studies on microbiological surveillance after duodenoscope reprocessing have shown pathogenic bacterial contamination in duodenoscopes with a fixed distal cap [1, 20–23]. Recently, the position statement of the European Society of Gastrointestinal Endoscopy and European Society of Gastroenterology Nurses and Associates recommended the use of duodenoscopes with a detachable distal cap in order to make it easier to clean difficult-to-reach areas such as the elevator [24]. In 2015, the FDA letter stated that infectious outbreaks of multidrug-resistant bacterial contamination of duodenoscopes were reported in duodenoscopes with a fixed distal cap [25]. Another nationwide study by Rauwers et al. evaluated the prevalence of bacterial contamination of 10 different duodenoscope types and designs, including the elevator channel and the distal cap, and found that the contamination was not associated with one particular duodenoscope type (P≥0.20) [26]. This led manufacturers to design duodenoscopes with detachable caps in order to reduce the risk of contamination at the elevator site. Our study demonstrated that the duodenoscope with the detachable distal cap had a significantly reduced amount of organic material, as tested by ATP, from 76% to 37% (P<0.001) when compared with duodenoscopes with the fixed distal caps. More importantly, bacterial culture confirmed that none of the duodenoscopes with the detachable distal cap were contami-

nated, whereas bacterial contamination from skin and membrane flora was still detected in one sample from a duodenoscope with a fixed distal cap.

Contamination of the duodenoscope usually develops during ERCP, as many of the indications for ERCP are related to infection such as acute cholangitis and acute cholecystitis. Technically, the elevator system of the duodenoscope has a high risk of trapping contaminated debris and stone fragments. In our study, all specimens were obtained from the elevator site after standard reprocessing of duodenoscopes that had been used for standard ERCP performed in real patients. Although we showed a statistically significantly higher proportion of ATP ≥ 40 RLU in the duodenoscopes with the fixed distal cap compared with those with detachable caps, none of them were found to be contaminated with pathogenic bacteria. The only concern is that nonpathogenic bacteria were found in one duodenoscope with a fixed distal cap ($P = 0.32$), whereas all the detachable duodenoscopes had negative bacterial cultures (▶ **Table 2**). The coagulase-negative *Staphylococcus* detected in group B is part of the normal flora of human skin (nonpathogenic bacterium). This in turn may represent contamination from skin or scope contamination during transportation.

Duodenoscopes are complex reusable devices that are composed of hard-to-clean components, particularly the elevator mechanism. Previous studies have demonstrated higher ATP levels in samples from the elevator compared with samples from the working channel of conventional duodenoscopes with a fixed distal cap [6, 7, 12, 14, 27]. In the study by the Indiana group focusing on the impact of double HLD, the water irrigated from both working channels and the elevator of conventional duodenoscopes with fixed distal caps was randomly selected for bacterial culture. All 120 initial cultures from the working channels were found to be negative, whereas all positive cultures were from the elevator [28]. Furthermore, the study by Verfaillie et al. reported on a large outbreak of VIM-2-producing *Pseudomonas aeruginosa*, which was linked to the use of duodenoscopes with a fixed distal cap and sealed elevator wire channel port (TJF-Q180V; Olympus) [23]. The TJF-Q180V duodenoscopes were evaluated by an expert from Delft University of Technology and a delegation from Eramus MC at Olympus (Zoeterwoude, The Netherlands); it was found that the fixed distal cap precluded cleaning and disinfection [23]. Eventually, the high monthly number of newly infected patients with VIM-2-producing *P. aeruginosa* during the outbreak period (7.5 cases during January to April 2012) decreased to 1.8 cases after the TJF-Q180V device was withdrawn from clinical use [23]. These data suggest that bacterial contamination mainly originated in the elevator mechanism of used duodenoscopes.

The elevator is a complex area of the duodenoscope in terms of cleaning; despite brushing and adequate HLD, these areas had persistent bacterial contamination [23, 27, 29, 30]. Results from our study suggest that the detachable distal cap allows the area behind the elevator to be cleaned with the brush during manual cleaning, potentially reducing the contamination rate of the duodenoscopes. Our study also suggests that this new duodenoscope with a detachable cap should undergo careful manual cleaning using specific cleaning devices, such as brushes, with special attention paid to the elevator mechanism. In addition, brushing while raising and lowering the forceps elevator, particularly at the back of the elevator, should be an important part of this process.

Although the FDA recommends a gradual transition to duodenoscopes with disposable components in order to reduce the risk of infecting patients, it is important to perform post-market surveillance using a larger volume of tests than our study in order to evaluate and confirm the lower contamination rate with these newly designed duodenoscopes before conventional duodenoscopes with fixed distal caps are withdrawn from the market.

The limitations of our study include the lack of blinding in personnel who performed the manual cleaning and sampling of the duodenoscopes; however, this would have been impossible given the need to detach the cap from group A duodenoscopes. Second, the duodenoscopes with detachable caps used in the study had been developed by a single company. Additional studies are warranted to test other duodenoscopes with detachable caps made by other companies. In addition, our group B duodenoscopes were not conventional fixed-cap duodenoscopes but the same duodenoscopes as those used in group A but with the cap left in place during cleaning; thus, genuine randomized head-to-head comparisons of duodenoscopes with detachable vs. fixed distal caps are needed to confirm these results.

In conclusion, use of a newly designed detachable duodenoscope significantly reduced contamination with residual organic material, as confirmed by ATP testing and bacterial culture. The detachable cap provided easier access to the back of the elevator during manual cleaning with brushes. The ATP test with a cutoff of 40 RLU was the practical POCT to ensure cleanliness of duodenoscope reprocessing without waiting for the bacterial culture result.

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An earlier version of these data were accepted as an oral presentation at the Asian Pacific Digestive Week, 2019, Kolkata, India, and has been selected for an oral presentation in the ASGE Presidential Plenary session at the annual meeting of Digestive Diseases Week, 2020, Chicago, Illinois, USA.

Competing interests

The authors declare that they have no conflicts of interest.

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