

ED-580XT in Clinical Studies

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A New Designed Duodenoscope with Detachable Distal End Cap Can Significantly Reduce Organic Residue Contamination After Reprocessing Evaluated by Adenosine Triphosphate Test

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Background: Because of its complex structures with an elevator mechanism, cleaning and disinfection of the duodenoscope are more difficult than other endoscopes. Despite high level disinfection (HLD) protocol, several outbreaks of multidrug resistance bacterial contamination (BC) of the duodenoscope with fixed distal cap were reported. A new designed duodenoscope with detachable distal cap (ED 580XT, Fujifilm, Tokyo, Japan) may have advantage over the conventional duodenoscope with fixed distal cap by allowing the brush to access the backside of the elevator. However, comparative data on BC and organic residue of the conventional duodenoscope vs. the duodenoscope with detachable distal cap after HLD is lacking.

Methods: During December 2018-April 2019, 108 used duodenoscopes with detachable distal cap underwent HLD and were enrolled 1:1 into group A and group B. In group A (n=54), the distal cap of duodenoscope was detached before manual cleaning (figure 1A and 1B). Whereas in group B (n=54), the distal cap was not detached before manual cleaning (figure 1C and 1D) in order to imitate the conventional duodenoscope with fixed distal cap. After single round of HLD, sample was collected from the elevator site (ES) with swab rotation and submitted for culture and then rapid BC and organic residue evaluation were done by analyzing for Relative Light Units (RLU) that read by adenosine triphosphate (ATP) test (Clean-Trace Surface ATP, 3M, MN, USA). Based on our previous data that demonstrated 100% sensitivity and 100% negative predictive value for BC, the ATP threshold at 40 RLU was used in this study. We compared the proportion of potential BC and organic residue evaluated by rapid ATP test and confirmed BC evaluated by bacterial culture in group A vs. group B after HLD.

Results: After HLD, using the ATP threshold at 40 RLU as the cut-off value, the proportion of potential BC and organic residue in group A was significantly lower than that of in group B [20/54 (37%) vs. 41/54 (75.9%); $p < 0.001$] (Table 1). Mean ATP value in group A was also significantly lower than that of in group B [45.2 RLU (range 9-209) vs. 151.9 RLU (range 19-653); $p < 0.001$]. In group B, one culture sample was found to have non-pathogenic BC (coagulase negative *Staphylococcus*). Pathogenic BC confirmed by culture was not documented in the both groups.

Conclusions: Since a new design, detachable duodenoscope allows brushing the backside of elevator, it can reduce residual organic material confirmed by the ATP test. Although no pathological organism was found after HLD in both groups, BC from skin and membrane flora was still detected in duodenoscope with fixed distal cap.

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A. The backside of elevator



B. The frontside of elevator



C. The backside of elevator



D. The frontside of elevator



	Duodenoscope with detachable distal cap (n = 54)	Duodenoscope with fixed distal cap (n = 54)	P value
ATP [RLU]	45.2 (9-209)	141.0 (19-653)	< 0.001
Mean (range)			
ATP > 40 RLU	20/54 (37%)	41/54 (75.9%)	< 0.001
Culture positive for low-concern organism	0/54 (0%)	1/54 (1.9%)	0.32
Culture positive for pathogenic bacteria	0/54 (0%)	0/54 (0%)	N/A

Figure 1(at left). A new design duodenoscope with detachable distal cap (ED 580XT, Fujifilm, Tokyo, Japan). A. and B. The distal cap was detached before manual cleaning to allow brushing the backside of the elevator (white arrow). C. and D. The distal cap was not detached before manual cleaning in order to imitate the conventional duodenoscope with fixed distal cap.

FUJIFILM SUMMARY

The ED-580XT Duodenoscope has a removable and disposable distal end cap designed to improve access for cleaning. This study shows the impact of being able to remove the cap. By cleaning the ED-580XT with and without removing the end cap, they are able to hold all other design aspects of the scope constant, and only look at the impact of being able to remove the end cap. This study reported on the presence of bacterial contamination and residual organic material after high level disinfection.

Key Takeaways:

1. The ATP test is a measurement of cellular energy, and is used to identify if there are any active microorganisms present. This study set a threshold of 40 RLU, which is basically a pass/fail value for quantifying if any organic residue or bacterial contamination was present.
2. Using the threshold level, there was a significantly lower number of scopes that had potential bacterial contamination and organic residue in the group with removable distal caps compared to the group with fixed distal caps [20/54 (37%) vs. 41/54 (75.9%); $p < 0.001$].
3. In looking at the actual ATP values from each sample, the mean ATP value representing bacterial contamination and organic residue in the group with the removable distal cap was also significantly lower than the group with fixed distal cap [45.2 RLU (range 9-209) vs. 151.9 RLU (range 19-653); $p < 0.001$].
4. It continues to be critical to follow the manufacturers cleaning guidelines to provide thorough cleaning of the scope.

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