CLINICAL FUNCTION TEST REPORT

A study on the In-vitro test to evaluate the degree of washing in endoscopic application of cleaning balls

Clinical function test institution	:	Gachon University Gil Medical Center
Principal Investigator	:	Department of Gastroenterology Associate Professor Cho,JaeHee
Sponsor	:	Silverex Pte.

- **Overview of the Clinical function test**

Title of Clinical function test	A study on the In-vitro test to evaluate the degree of washing in endoscopic application of cleaning balls
Sponsor	Silverex Pte. 115, Neungheodae-ro 577beon-gil, Namdong-gu, Incheon
Clinical function test Institution	Gachon University Gil Medical Center 21, Namdong-daero 774beon-gil, Namdong-gu, Incheon
Principal Investigator and Sub-investigator	1. Principal Investigator Gachon University Gil Medical Center Department of Gastroenterology Associate Professor Cho,JaeHee M.D. 2. Co-investigator Gachon University Gil Medical Center Department of Gastroenterology Kim, Eui Joo M.D. 3. Research Coordinator Gachon University Gil Medical Center Researcher Shin Jee Hoon
Indications	Upper gastrointestinal endoscope 50EA, lower gastrointestinal endoscope 50EA
Duration of Clinical function test	August 27th, 2018 ~ September 14th, 2018

- **Summary of Clinical function test report**

Title of Clinical function test	A study on the In-vitro test to evaluate the degree of washing in endoscopic application of cleaning balls
Phase	In-vitro Test
Clinical Trial Institution	Gachon University Gil Medical Center
Investigational Device	Investigational Device: EZ-JET Clean ball
Purpose	Evaluation of cleaning performance for cleaning ball and conventional endoscopic cleaning methods
Targeted sample size	Targeted sample size : 100 case (Upper gastrointestinal endoscope 50 case, lower gastrointestinal endoscope 50 case)
Inclusion Criteria and Exclusion Criteria	**1. Inclusion Criteria** 1) Upper and lower gastrointestinal endoscope in center 2) Upper and lower gastrointestinal endoscope used for endoscopy **2. Exclusion Criteria** 1) Upper and lower gastrointestinal endoscope that can not be properly cleaned due to leakage, leakage tests are conducted during the cleaning process, and endoscopes whose breakage has been confirmed are excluded.
Methods	Three evaluation items (ATP test, protein test, environmental culture test) for endoscopic flushing performance were evaluated. 1) pre-washing - Remove surface debris with gauze with enzyme cleaning solution on the outer surface and end of the endoscope - Experimental group: Aspirate (100 ml of upper gastrointestinal endoscope: 150 ml of lower gastrointestinal endoscope: 100 ml) containing the enzyme cleaning solution and two washing balls and suck it in the air for 10 seconds. - Control group: Aspirate the washing solution containing the enzyme washing liquid (upper gastrointestinal endoscope: 100 ml, lower gastrointestinal endoscope: 150 ml) and suck in air for 10

	seconds. 2) washing - Remove all detachable accessories, perform leakage test, confirm that there is no damage, install a waterproof cap, immerse in a small cleaning diluent, and wipe the surface of the endoscope with a soft cloth - Experimental group: ① Wipe off parts such as cylinders that are difficult to clean by using a valve cleaning brush. ② After installing the channel plug and the injection tube on the endoscope, repeatedly syringe to the air supply / discharge port and the suction port to clean the inside of the channel by passing it through the cleaning solution of about 100 mL - Control group: ① Wipe off parts such as cylinder liner which are difficult to clean by using valve cleaning brush. ② Inside the endoscope channel, use a channel cleaning brush to thoroughly brush the inside of the channel from the end of the endoscope (45 °), the universal cord direction (90 °), and the biopsy channel to the endoscope end (3 directions in total) do. ③ After attaching the channel plug and the injection tube to the endoscope, the inside of the channel is cleaned by repeatedly syringe to the air supply / discharge port and the suction port through the cleaning solution of about 100 mL 3) rinsing - Rinse the inside of the endoscope channel thoroughly with clean water using a channel plug and an injection tube. **1. ATP Test** 1) Pre-wash, 2) Wash 3) After rinsing, inject 10cc of physiological saline in the tip direction and discard the first 5cc of saline. Then add 5 cc of saline into the first sample tube. Repeat this procedure to add 5 cc of saline solution to the second test tube. The saline solution in the first sample tube is embedded in Lucipac W, inserted into an ATP measuring instrument, and the ATP level is measured. After the measurement, the experimental group and the control group are compared / analyzed. **2. Environmental Culture / Protein Test** 1) Pre-wash, 2) Wash 3) After rinsing, inject 10cc of physiological

<table>
<tr><td></td><td>saline in the tip direction and discard the first 5cc of saline. Then add 5 cc of saline into the first sample tube. Repeat this procedure and place 5 cc of saline into the second syringe barrel. Two specimen tubes are transferred to the inspection laboratory to confirm presence or absence of cultured bacteria, quantification, and presence of protein.</td></tr>
<tr><td>Evaluation item and its method</td><td>1. ATP items
(1) ATP mean value and range statistical analysis for experimental group and control group
(2) Overestimation of ATP 100 RLU standard for sanitary inspection of endoscopic suction channel
2. Protein Test items
Identification and analysis of residual protein
3. Environmental Culture Test
Statistical analysis of culture cultures and culture frequency</td></tr>
<tr><td>Statistical analysis</td><td>Continuous variables that do not follow the standard normal distribution using the SPSS for windows (ver. 23.0; IBM, Armonk, NY, USA) are expressed in median and range. Mann-Whitney U test was used to compare the two groups. The nominal variables are tested for statistical significance using a chi-square test. The difference of each item is analyzed at a significance level of 0.05.
1. ATP items
<table>
<tr><th></th><th colspan="3">Upper gastrointestinal endoscope (n=50)</th><th colspan="3">Lower gastrointestinal endoscope (N=50)</th></tr>
<tr><th></th><th>Experimental group (n=25)</th><th>Control group (n=25)</th><th>P</th><th>Experimental group (n=25)</th><th>Control group (n=25)</th><th>P</th></tr>
<tr><td>ATP, median (range), RLU</td><td>5.0 (0 – 56)</td><td>2.0 (0 – 13)</td><td>0.01</td><td>2.0 (0 – 45)</td><td>2.0 (0 – 174)</td><td>0.192</td></tr>
<tr><td>ATP>100RLU, n (%)</td><td>0 (0)</td><td>0 (0)</td><td>NA*</td><td>0 (0)</td><td>1 (4.0)</td><td>> 0.999</td></tr>
</table></td></tr>
</table>

2. Protein items

	Upper gastrointestinal endoscope (n=50)		Lower gastrointestinal endoscope (N=50)	
	Experimental group (n=25)	**Control group (n=25)**	**Experimental group (n=25)**	**Control group (n=25)**
Protein negative, n (%)	50 (100)	50 (100)	50 (100)	50 (100)

3. Environmental Culture items

	Upper gastrointestinal endoscope (n=50)			Lower gastrointestinal endoscope (N=50)		
	Experimental group (n=25)	**Control group (n=25)**	**P**	**Experimental group (n=25)**	**Control group (n=25)**	**P**
Colony count, n (%)	-	-	0.408	-	-	0.911
No growth	11 (44)	11 (44)		9 (36.0)	11 (44.0)	
0 – 10 CFU/mL	1 (4.0)	3 (12.0)		3 (12.0)	4 (16.0)	
10 – 50 CFU/mL	2 (8.0)	5 (20.0)		4 (16.0)	2 (8.0)	
50 – 100 CFU/mL	4 (16.0)	1 (4.0)		1 (4.0)	1 (4.0)	
>100 CFU/mL	7 (28.0)	5 (20.0)		8 (32.0)	7 (28.0)	

Evaluation results

1. ATP items

ATP levels were higher in upper gastrointestinal endoscopy specimens using wash ball than in the control group, but both groups satisfied less than 100 RLU of ATP standard for endoscopic suction channel. In the lower gastrointestinal tract, there was no statistically significant difference in ATP levels between the two groups.

2. Protein items

	In all cases of upper and lower gastrointestinal endoscope, residual protein in the channel was not identified. **3. Environmental Culture items** There was a statistically similar culture frequency between the two groups and there was no significant difference in culture frequency between the two groups in the subgroup analysis according to the species.
Conclusion	The cleaning ball does not show superior cleaning effect as compared with the conventional brush cleaning method, but it is analyzed that at least a similar cleaning effect is exhibited. However, since the cleaning ball is not brushed, it may be used as an easier cleaning method for the cleaner.