

The Improvement of Endoscope Reprocessing with ATP-Bioluminescence Tool

Habip Gedik^{1*}, Leyla Günay¹, Ezgi Ceren Şahin², Mehriban Sharifzade²

¹Department of Infectious Diseases and Clinical Microbiology, Ministry of Health Bakırköy Sadi Konuk Training and Research Hospital, Turkey; ²Istanbul School of Medicine, Istanbul University, Turkey

Corresponding author:

Habip Gedik,
Department of Infectious Diseases
and Clinical Microbiology, Ministry of
Health Bakırköy Sadi Konuk Training
and Research Hospital, Istanbul,
Turkey,
Tel: 00905053362770;
E-mail: habipgedik@yahoo.com

Abstract

Background: The incidence rates of endoscopy use associated healthcare-associated infection were reported to be 1 in 1.8 million procedures, but contaminated endoscopes might cause outbreaks more often than other medical devices. **Aim:** The aim of this study was to describe the endoscope reprocessing procedure validated with microbiological cultures and ATP bioluminescence tool kits. **Material and methods:** We examined the endoscope reprocessing procedures at the Ministry of Health Bakırköy Sadi Konuk Research Hospital using microbiological cultures and ATP bioluminescence tool kit during 2014. **Results:** We examined 42 flexible endoscopes and 4 (9%) endoscopes were found to be contaminated. *Stenotrophomonas maltophilia* (>100,000 cfu/mL) was isolated from irrigation bottles and extended-spectrum beta-lactamases and plasmid-mediated carbapenamase producing *K. pneumonia* and AmpC beta-lactamase producing *P. aeruginosa* (>100,000 cfu/mL) were isolated from elevator behind, respectively. Each step of the reprocessing procedure has been examined and revised with microbiological cultures and ATP bioluminescence tool kit. All endoscopes were found to be clean after revising the procedure. **Conclusion:** ATP-bioluminescence method provides shorter time to examine the endoscopes as a cost-effective method in the endoscope reprocessing. Microbiological monitoring and cleaning procedures of endoscopes should be defined in the healthcare settings with the frequencies. In case of any outbreak related to endoscopes, each step of procedure should be examined and corrected taking into guidelines, reported outbreaks, as well as instructions of endoscope manufacturers.

Keywords: Endoscopes; Reprocessing; ATP- bioluminescence; Disinfection

Introduction

The cleansing and disinfection of flexible endoscopes have been a challenge due to endoscopes' intricate design, narrow and long lumens, and delicate materials.^[1] They contact with the mucosa and do not penetrate the tissue. They are defined as semi-critical items.^[2] The incidence rates of endoscopy use associated healthcare-associated infection were reported to be 1 in 1.8 million procedures, but contaminated endoscopes might cause outbreaks more often than other medical devices.^[3] Cleaning and disinfecting of flexible endoscopes contain all steps of pre- and post-procedural care, and disinfection of the reprocessing area. Endoscopes cause transmission of resistant microorganisms, including carbapenem-resistant Enterobacteriaceae, hepatitis B-/C-virus, HIV, Mycobacterium tuberculosis, and *Helicobacter pylori*.^[4,5] The validation of cleaning and disinfection of endoscopes is recommended by microbiological culture.^[5] However, they have many disadvantages, such as long microbiology culture completion time that blocks the use of endoscopes. Therefore, a rapid method is needed for the examination of endoscope reprocessing. There are reported guidelines for the endoscope surveillance and the FDA has recommended supplemental measures to enhance reprocessing with microbiological culture.^[6-8] The Centers for Disease Control and Prevention. [CDC] published in 2015 an interim guideline for the examination of duodenoscopes with the microbiological culture.^[8,9]

ATP (adenosine triphosphate) measurement is utilized as an indicator of cleaning control and for the examination of microbiological contamination.^[10] The tool measures the quantity of light which is emitted when the enzyme luciferase contacts with molecular ATP.^[11] ATP measurement is a suitable method for rapid examination and the quality of endoscope reprocessing.^[12-14]

The aim of this study was to present the endoscope-reprocessing procedures validated with microbiological cultures and ATP bioluminescence tool kit at our hospital.

Materials and Methods

Cleaning and disinfection procedure of hospital

The endoscopes and endoscope reprocessing procedures of the Ministry of Health Bakırköy Sadi Konuk Training and Research Hospital were examined using microbiological cultures and ATP bioluminescence tool kits during 2014. Each endoscope was

This is an open access article distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as the author is credited and the new creations are licensed under the identical terms.

How to Cite this Article: Gedik H, Günay L, Şahin EC, Sharifzade M. The Improvement of Endoscope Reprocessing with ATP-Bioluminescence Tool. Ann Med Health Sci Res. 2018; 8: 6-9

disinfected with an enzymatic solution (Cidezyme, Johnson and Johnson Company, İstanbul, Turkey) for one minute and then with high-level disinfectant (0.55% ortho-phthalaldehyde, Cidex OPA, Johnson and Johnson Company, İstanbul, Turkey) for five minutes after the intervention. At the end of day, all flexible endoscopes were undergone to manual leak testing and cleaning followed by mechanical leak testing, cleaning and high-level disinfection in the automated flexible endoscope reprocessors (Endoclear, ALX 1011; EndOclear Wiper Device for the Cleaning and Visualization of Endotracheal Tubes, EndOClear LLC, San Ramon, CA) using 0.55% ortho-phthalaldehyde (OPA). High-level disinfectants, such as OPA, inactivate all microorganisms (bacteria, viruses, fungi, mycobacteria), but not bacterial spores. When the disinfection cycle began, each endoscope was pressurized and tested for leakage. That checks the internal integrity of each endoscope. The pressure was sustained throughout the disinfection cycle. In case any defect, such as a hole in the instrument or poor connection of seals, was detected, and the cycle was automatically stopped. The standard cycle ran for five minutes and consisted of pre-cleaning with an enzymatic cleaner, rinsing, disinfection, rinsing, and air-drying, respectively. All cycles were documented on a printed validation ticket that detailed the machine serial number, cycle selected, date, time and endoscope processed. Those records were attached to patient list of that day. Detailed records all endoscopes were also kept. No research or ethics approval was needed, as this was an *in vitro* study.^[15]

Microbiological sampling and ATP bioluminescence measurement

Sterile swabs were moisturized with sterile 0.9% NaCl and then rubbed on biopsy button, elevator behind, distal end, rinsing valve, endoscope storage cabinets, endoscopy tower. Rinsed the operating channel, biopsy channel, and air-water channel were sampled with 20 ml sterile 0.9% NaCl. Water samples were taken from water tanks as well. We did not use neutralizers. Swabs and 0.5 ml of rinsing fluid were inoculated on 5% sheep-blood agar (Salubris Inc., İstanbul, Turkey), or chocolate agar (Salubris Inc., İstanbul, Turkey) and MacConkey agar (Salubris Inc., İstanbul, Turkey), respectively. Bacterial species were identified by the Phoenix automated microbiology system (BD Diagnostic Systems, Sparks, MD), followed routine microbial laboratory proceedings. Bacterial growth was defined as the number of colony forming unit (CFU). ATP bioluminescence was determined using 3M™ Clean-Trace™ Hygiene Monitoring System (MN, USA). The tool was used according to the instructions. Bioluminescence measurement was defined as a relative light unit (RLU). Swab was defined to be clean, if it measured 200 RLU according to the instructions of the manufacturer.^[12,16]

Results

We examined 42 flexible endoscopes (made by Pentax, Olympus, Fujinon and Storz) in the gastroenterology and general surgery endoscopy units after reprocessing. There were 10 Automated Endoscope Reprocessors for cleansing, five water tanks, two endoscopy towers, and eight endoscope storage cabinets. The

number of endoscopes that were found contaminated was 4 (9%). *Stenotrophomonas maltophilia* (>100,000 cfu/mL) was isolated from irrigation bottles. Extended-spectrum beta-lactamases and plasmid-mediated carbapenemase producing *K. pneumonia* and AmpC beta-lactamase producing *P. aeruginosa* (>100,000 cfu/mL) were isolated from elevator back. AmpC beta-lactamase producing *P. aeruginosa* (>100,000 cfu/mL) was isolated from outer surface of the gastroscope. Diphtheroid bacilli and methicillin-sensitive *Staphylococcus aureus* were isolated from endoscope hanger. After extension of disinfection time to 10 minutes and re-disinfection of all equipments before intervention in the morning, control cultures did not yield any microorganism. However, 40 endoscopes and approximately 400 cultures caused a remarkable workload and cost. Hospital infection control committee decided to use ATP-bioluminescence tool for the microbiological examination of endoscopes. Examination resulted in 30 seconds, and prevented not to be used of endoscopes until cultures yielded. Hospital infection control committee took those decisions taking into consideration guidelines and reported studies:

- ATP-bioluminescence tool will be used in the microbiological examination of endoscopes every three months.
- Endoscopes were re-disinfected, in case they remained in the unit longer than 12 hours of standby time after washing
- Bottles and connecting hoses used for endoscope irrigation were cleaned and sterilized. In addition, sterile water was used.
- Elevator wire channel of endoscopes should be washed using a syringe, because the flushing pressure might be insufficient.
- pH neutral and non-foaming detergents or enzymatic cleaners use were recommended. Enzymatic cleaners were recommended instead of pH-unknown detergents.
- The manufacturer should define the effective time of enzymatic cleaners in the instructions.
- Contact time of 0.55% ortho-phthalaldehyde (OPA) was increased to 10 minutes
- Endoscopes were extended on a flat surface and their air ducts were aired with an injector after disinfection. High pressure was used only at the end portions, as that might damage the gun channel. In addition, elevator inside and back areas was recommended to dry with a sponge carefully.
- Elevator in duodenoscopy channel could cause difficulty, as brushing is not possible. The washing, enzymatic cleaning, drying were performed by a syringe. Once placing the disinfected connection hose into elevator channel with a suitable adapter and then disinfection, rinsing, and drying were performed. Diameter of channel was too small, so maximum 5 cc syringe was used.^[4-6,11]

After implementation of those steps, we achieved appropriate endoscope reprocessing validated by ATP-bioluminescence

tool, and an infection-related complication was not reported at hospital.

Discussion

Endoscopes are temperature sensitive items, so low-temperature chemical methods, such as liquid chemical germicide, must be used rather than steam sterilization. In the guidelines, The manual washing, high level disinfection (HLD) with automated endoscope reprocessing and drying were reported issues for the infection prevention and control during gastrointestinal (GI) endoscopy.^[17] Inadequate cleaning or disinfection is linked to GI endoscope – associated outbreaks compare to other medical devices. The number of contaminated endoscopes in our study was 4 (9%) less than those reported in the study of Moses and Lee, who found positive between 12% and 24% of the cultures during a 10-year study period.^[15] Moses and Lee examined only endoscopes used in a clinical institution and reprocessed in an automated washer. They used culture method for surveillance, whereas culture and ATP-bioluminescence methods were used in our study. ATP-bioluminescence tool provides a fast and cost-effective microbiological monitoring of endoscopes in healthcare settings, where the number of daily endoscopy applications is high. The monitoring of endoscope reprocessing is an essential component of the safe endoscopy services, because endoscope reprocessing is a multistep procedure involving numerous factors that can interfere with its efficacy. However, there is no consensus on the frequency of routine microbiological testing of endoscopes.^[17,18] Routine microbiological testing of endoscopes was recommended every 3 to 6 months in different guidelines.^[17] Microbial growth was reported to be in 5.0% of specimens (8.4% of encounters), with environmental microbes. Enteric bacterial flora was isolated in 6% of specimens (9% of encounters) in spite of compliance with 2014 U.S. guidelines and manufacturers’ recommendations about cleaning and high-level disinfection process.^[18] Therefore, each healthcare setting should define its microbiological monitoring procedure investigating each step of cleaning and disinfection.

Several sorts of disinfectants are present in the markets with advantages and disadvantages. Short contact time with disinfectant is a major issue because of too many uses of endoscopes. Glutaraldehyde solution (2%) is the most frequently used disinfectant in GI endoscope reprocessing with a contact time of at least 20 minutes, whereas OPA, which is more time-efficient and expensive than use of glutaraldehyde solution and has a contact time of only 5-12 minutes varying in the countries, is recommended. OPA (0.55%) is used for 5-12 minutes in Europe, Latin America and Asia; 5 minutes in Canada, 10 minutes in Australia and 12 minutes in the USA as a high-level disinfection solution.^[19,20] When the contact time with OPA was increased to 10 minutes, better disinfection was achieved in our study.

Bottles for irrigation and connecting hoses might be contaminated and colonized during the implementations and then they might harbor resistant microorganisms, such as *P. aeruginosa*, *Acinetobacter* spp. that survive for a long time in a humid environment. Biofilm formation constitutes a nidus for

resistant microorganisms in the connection hoses. Mechanic cleaning is important to remove the nidus.^[1-4,20] Studies were reported that neither the detergent nor high-level disinfectant provided the removal or killing of bacteria at the desired level due to biofilm formation in the channels.^[21,22] Detergents and enzymatic cleaners are not enough to remove biofilm in the endoscopes, mechanical cleaning must be performed. Syringe should be used, as flushing pressure might be insufficient and debris might not be removed exactly. The preparation of enzymatic cleaner for the cleaning of endoscopes by staff should be audited as well. The effective time and of enzymatic cleaner use should be defined and instructed to relevant staff according to instructions of the manufacturer. Neutral pH and non-foaming detergents or enzymatic cleaners are important to prevent corrosion in the endoscopes that might be nidus for microorganisms and their biofilm formations. Air ducts should be aired with an appropriate pressure to dry and prevent biofilm formation under humid. Elevator mechanism could fail the reprocessing. Olympus has recent designed a smaller brush for improvement of elevator cleaning to address this problem. Flocked swabs were recommended to use, capture and release the organisms more efficiently than cleaning brush.^[23]

Limitations

This study had several limitations. First, we used a qualitative method to evaluate the dirtiness of endoscopes. Two methods were not compared in terms of their effectiveness, but they were used for the examination. We have investigated each step in the disinfection and cleaning of endoscopes to find the troubles without emphasizing any method and guideline. However, any standard method has been established for the assessment of endoscope reprocessing yet.^[24]

Conclusion

As a result, ATP-bioluminescence method is a cost-effective method to monitor and examine the endoscope reprocessing. Biofilm formation is very important for harboring of the resistant microorganisms in the endoscopes. Microbiological monitoring and cleaning procedures of endoscopes should be defined at the settings with its frequency. In case of any outbreak related to endoscopes, each step during cleaning should be checked and corrected taking into guidelines, reported outbreaks, as well as instructions of endoscope manufacturers.

Conflict of Interest

All authors disclose that there was no conflict of interest.

References

1. Martiny H, Floss H, Zuhlsdorf B. The importance of cleaning for the overall results of processing endoscopes. *J. Hosp. Infect.* 2004; 56: S16-S22.
2. Leung J, Vallero R, Wilson R. Surveillance cultures to monitor quality of gastrointestinal endoscope reprocessing. *Am. J. Gastroenterol.* 2003; 98: 3-5.
3. Leung JW. Reprocessing of flexible endoscopes. *J. Gastroenterol. Hepatol.* 2000; 15: G73-G77.
4. Epstein L, Hunter JC, Arwady MA, Tsai V, Stein L, Gribogiannis M, et al. New Delhi metallo-beta-lactamase-producing carbapenem-re-

- sistant *Escherichia coli* associated with exposure to duodenoscopes. *JAMA*. 2014; 312: 1447-1455.
5. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2002; 45: 395-411.
 6. Beilenhoff U, Neumann CS, Rey JF, Biering H, Blum R, Schmidt V, et al. ESGE-ESGENA guideline for quality assurance in reprocessing: microbiological surveillance testing in endoscopy. *Endoscopy* 2007; 39: 175-181
 7. Whitby M, Fielding D, Todman M, Rapley L. Infection control in endoscopy, 3rd ed. Gastroenterological Society of Australia, Victoria, Australia 2007.
 8. United States Food and Drug Administration. 2015. FDA safety communication: supplemental measures to enhance duodenoscope reprocessing.
 9. Centers for Disease Control and Prevention. 2015. Interim sampling method for the duodenoscope: distal end and instrument channel. Centers for Disease Control and Prevention, Atlanta, GA.
 10. Seeger K, Griffiths MW. Adenosine triphosphate bioluminescence for hygiene monitoring in health care institutions. *J Food Prot*. 1994; 57: 509-512.
 11. Baumgart J. Möglichkeiten und Grenzen moderner Schnellverfahren zur Prozesskontrolle von Reinigungs- und Desinfektionsverfahren. *Zentralbl Hyg Umweltmed*. 1996; 199: 366-375.
 12. Alfa MJ, Fatima I, Olson N. Validation of adenosine triphosphate to audit manual cleaning of flexible endoscope channels. *Am J Infect Control*. 2013; 41: 245-248.
 13. Fushimi R, Takashina M, Yoshikawa H, Kobayashi H, Okubo T, Nakata S, et al. Comparison of adenosine triphosphate, microbiological load, and residual protein as indicators for assessing the cleanliness of flexible gastrointestinal endoscopes. *Am J Infect Control*. 2012; 41: 161-164.
 14. Shin SP, Kim WH. Recent Update on microbiological monitoring of gastrointestinal endoscopes after high-level disinfection. *Clin Endosc*. 2015; 48: 369-373
 15. Moses FM, Lee J. Surveillance cultures to monitor quality of gastrointestinal endoscope reprocessing. *Am J Gastroenterol*. 2003; 98: 77-81.
 16. Alfa MJ, Fatima I, Olson N. The adenosine triphosphate test is a rapid and reliable audit tool to assess manual cleaning adequacy of flexible endoscope channels. *Am J Infect Control*. 2013; 41: 249-253.
 17. Gillespie EE, Kotsanas D, Stuart RL. Microbiological monitoring of endoscopes: 5-year review. *J Gastroenterol Hepatol* 2008; 23: 1069-1074
 18. Brandabur JJ, Leggett JE, Wang L, Bartles RL, Baxter L, Diaz GA, et al. Surveillance of guideline practices for duodenoscope and linear echo-endoscope reprocessing in a large health care system. *Gastrointest Endosc*. 2016.
 19. Petersen BT, Chennat J, Cohen J, Cotton PB, Greenwald DA, Kowalski TE, et al. Multisociety guideline on reprocessing flexible GI endoscopes: 2011. *Infect Control Hosp Epidemiol* 2011; 32: 527-537.
 20. Augustin M, Ali-Vehmas T, Atroshi F. Assessment of enzymatic cleaning agents and disinfectants against bacterial biofilms. *J Pharm Pharm Sci* 2004; 7: 55-64
 21. da Costa Luciano C, Olson N, Tipple AF, Alfa M. Evaluation of the ability of different detergents and disinfectants to remove and kill organisms in traditional biofilm. *Am J Infect Control*. 2016.
 22. da Costa Luciano C, Olson N, DeGagne P, Franca R, Tipple AF, Alfa M. A new buildup biofilm model that mimics accumulation of material in flexible endoscope channels. *J Microbiol Methods*. 2016; 127: 224-229
 23. Gazdik MA, Coombs J, Burke JP, Lopansri BK. Comparison of two culture methods for use in assessing microbial contamination of duodenoscopes. *J Clin Microbiol*. 2016; 54: 312-316
 24. Rutala WA, Weber DJ. Healthcare Infection Control Practices Advisory Committee (HICPAC). Guideline for Disinfection and Sterilization in Healthcare Facilities. 2008.