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ATP bioluminescence to validate the decontamination process of gastrointestinal endoscopes

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Abstract. ***Introduction*:** Gastrointestinal endoscopes play an effective diagnostic role in modern medicine. The endoscopes become heavily contaminated with microorganisms during procedures and need careful reprocessing.

***Methods*:** A prospective study was carried out at a gastroenterology hepatology unit to evaluate ATP bioluminescence, measured as relative light units (RLUs), to validate the decontamination processing of endoscopes. Flushes from endoscopes involved in 120 endoscopic procedures at four different stages: pre-patient (before the procedure), post-patient (after the procedure), post-cleaning (after manual cleaning) and post-disinfection were examined by ATP testing and microbiological culture. The hypothetical pass or fail limit of 100 RLUs was set according to previous studies in the literature. When the disinfection process failed, the above process was repeated.

***Results*:** Average RLU readings were: pre-patient: 48; post-patient: 124 052; post-cleaning: 1423; and post-disinfection: 144. The corresponding culture results were: pre-patient: all negative; post-patient: all positive except for four; post-cleaning: positive except for 26; and post-disinfection: all negative. Although 21 (17%) of post-disinfection specimens showed failed ATP levels of more than 100 RLUs, when the cleaning and disinfection process was repeated before they were used, all scopes then showed a pass level of less than 100 RLUs.

***Conclusions*:** ATP bioluminescence has the potential to play an important role in the validation process. This process would allow a quick turnaround time following a simple check procedure to be classified as safe in a busy endoscopic unit.

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Introduction

Gastrointestinal endoscopes play an integral part in delivering an effective diagnostic service in modern medicine. When endoscopes are inserted into the gastrointestinal tract, they become heavily contaminated with microorganisms, including potential pathogens. This emphasises the need for careful reprocessing between patients to prevent cross-infection. Inadequately decontaminated endoscopes have been implicated in several healthcare-associated infections (HCAIs) and outbreaks.[1,2] Endoscopes need to undergo cleaning and appropriate disinfection before re-use. Many guidelines for reprocessing of endoscopes have been produced.[3–6]

Currently in Australia quality reprocessing is checked by performing microbiological cultures according to the Gastroenterological Nurses College of Australia (GENCA) guidelines.[7] Accordingly, microbiological testing is performed on gastroscopes and colonoscopes 3-monthly with duodenoscopes tested monthly. The initial testing takes up to 1 week to receive a result and with further testing, results take up to 6 weeks (microbiological plus possible TB culture). A major disadvantage is that patients may be potentially exposed to pathogenic microorganisms before the laboratory can issue a result. This may cause increased costs financially, politically and emotionally for the healthcare facility and the patient if a problem is subsequently discovered. Continuity of care can be disrupted if procedures are cancelled because of a lack of equipment when a contaminated piece of equipment needs to be quarantined. Therefore, a more practicable and rapid testing method is desirable.

Adenosine triphosphate (ATP) bioluminescence utilises the light-producing reaction between ATP, luciferin and luciferase to estimate levels of ATP in a sample. The luminometer machine converts the number of photons released into relative light units (RLUs). Adenosine triphosphate is found in organic matter and microorganisms, making estimates of ATP levels a measure of organic soil and contamination. Over the last decade, ATP bioluminescence

Implications

- Gastrointestinal endoscopes become heavily contaminated with microorganisms during procedures and need careful reprocessing.
- A prospective study was carried out to evaluate ATP bioluminescence, measured as relative light units (RLUs), to validate the decontamination processing of endoscopes.
- ATP bioluminescence has the potential to play an important role in the validation process.

has become increasingly adopted for monitoring surface cleanliness mainly in the food industry and to a lesser extent in the pharmaceutical industry, and its use is predicted to increase substantially in the near future.[8,9]This method has been used for measuring levels of organic soil and cleanliness of environmental surfaces and equipment used in hospitals.[10–14] The ability to provide results within minutes, as opposed to days or weeks for microbiological testing, enables ATP testing to be used as a practical monitoring method. Residual organic matter is an indicator that the surface may be unclean and could provide a potential reservoir that may harbour bacteria, fungi and viruses, increasing the cross-infection risk between patients. Therefore ATP bioluminescence may have a potential role in validating the decontamination process for gastrointestinal endoscopes.

The aim of this study is to evaluate the overall efficacy of standard gastrointestinal (upper and lower) endoscope reprocessing in endoscopy units and to evaluate ATP as a means of assisting in the management of the decontamination process, compared with standard microbiological testing.

Methods

The study was carried out prospectively at The Canberra Hospital from July to December 2010. The gastroenterology hepatology unit (GEHU) of this hospital performed 4200 endoscopy procedures using five colonoscopes, four gastroscopes and four duodenoscopes from June 2009 to July 2010. The procedures involved banding, clipping of bleeding vessels, biopsies, removal of polyps, dilatation, sphinrectomies and visualisation of the upper or lower gastrointestinal tract. The reprocessing of the used endoscopes was undertaken in the central reprocessing unit (CRU) attached to the GEHU. The processing protocol consists of manual cleaning with an proteolytic enzyme detergent (Aseptic Release Plus, Ecolab Pty Ltd, Sydney) and then by an automated endoscopic reprocessor (Gallay Soluscope 3CC-PAA) using peracetic acid (Gallay Medical & Scientific, Melbourne, Vic., Australia).

Adenosine triphosphate testing was performed by using 3M 'Clean-Trace' Water-Total ATP swabs (3M, St Paul, MN, USA) with the bioluminometer machine according to the manufacturer's instructions.[15] Each ATP data point was measured using a single swab, except where some unexpected readings occurred, when additional confirmatory swabs were used. The machine indicates the ATP level in relative light units (RLUs) in less than 2 min. Firstly, external quality controls were checked by using the known ATP positive and negative control products which were commercially available. The internal quality controls were checked by using Brain Heart Broths (Merck KGaA, Darmstadt, Germany) at different dilutions with sterile distilled water. During the study period, quality-control testing was done using the commercially available known ATP positive and negative controls on a monthly basis. The internal positive controls (1 : 10 dilution of sterile Brain Heart Broth) and the negative controls (sterile distilled water) were done weekly.

The ATP levels were tested against different organisms such as *Staphylococcus aureus* ATCC 29213, *Enterococcus faecalis* ATCC 29212, *Escherichia coli* ATCC 25922, *Pseudomonas aeruginosa* ATCC 27853, *Candida albicans* ATCC 10231 and *Mycobacterium fortuitum* ATCC 6841. From each organism a 0.5 McFarland standard was made up with sterile Brain Heart Broth (Merck KGaA) and then diluted eight times with 1 : 10 dilution at each step with sterile distilled water. Each tube was tested for ATP level and at the same time cultured on to Horse Blood agar (bioMérieux, Marcy L'Etoile, France) and incubated at 30°C for 24 to 48 h.

During the study period we examined 120 endoscopes (59 colonoscopes, 50 gastroscopes and 11 duodenoscopes). The testing was performed at four different stages: before inserting the endoscope into the patient (pre-patient: step 1), just after the procedure (post-patient: step 2), after the manual cleaning with the detergent (post-cleaning: step 3) and finally after completion of the disinfection process (post-disinfection: step 4). At each step the endoscope biopsy and suction channels were flushed with 20 mL of sterile 0.9% saline. The flush fluid was collected aseptically in the CRU and sent to the microbiology laboratory without delay. If a delay was expected, the sample was stored at 4°C.

In the laboratory, the ATP testing was performed using the 'Clean-Trace' Water-Total ATP swabs (3M) and the RLU value recorded. Each flush fluid sample was inoculated onto blood agar (MacConkey) and incubated at 30°C and 35°C respectively for 7 days. The plates were examined daily for growth. Any growth was quantified and identified to species level using basic manual microbiological techniques.[16,17]

The hypothetical pass or fail limit of 100 RLUs (pass $\leq$ 100, fail >101) was set according to the results of Hansen *et al.*[18] When the post-disinfection fluid ATP level was >101 RLUs, the CRU was informed and requested to repeat the disinfection process and rechecked the flush fluid for ATP and microbiology culture. The failed specimens were tested for proteins[19] to exclude biological contamination.

Statistical analyses

Adjusted R-squared values from a linear regression were reported to indicate the fraction of the variance of the log ATP (RLU) explained by the log of bacterial concentrations for