Thieme

Assessment of endoscope reprocessing at World Gastroenterology Organisation training centers using adenosine triphosphate testing

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ABSTRACT

Background and study aims Adequacy of endoscope disinfection in resource-limited settings is unknown. Adenosine triphosphate (ATP) testing is useful for evaluation of endoscope reprocessing, and ATP <200 relative light units (RLUs) after manual endoscope cleaning has been associated with adequacy of endoscope disinfection.

Methods Consecutive endoscopes undergoing reprocessing at five World Gastroenterology Organisation (WGO) training centers underwent ATP testing before and after an on-site educational intervention designed to optimize reprocessing practices.

Results A total of 343 reprocessing cycles of 65 endoscopes were studied. Mean endoscope age was 5.3 years (range 1–13 years). Educational interventions, based on direct observation of endoscope reprocessing practices at each site, included refinements in pre-cleaning, manual cleaning, high-level disinfection, and endoscope drying and storage. The percentage of reprocessing cycles with post-manual cleaning ATP ≧200 decreased from 21.4% prior to educational intervention to 14.8% post-intervention (P= 0.11). In multivariable logistic modelling, gastroscopes were significantly less likely (odds ratio [OR] 0.04, 95% confidence interval [CI] 0.01–0.19; P<0.001) than colonoscopes to achieve post-manual cleaning ATP < 200. No

other factor (educational intervention, study site, endoscope age) was significantly associated with improved outcomes. Endoscope ID was not significantly associated with ATP values, and sites that performed manual versus automated HLD did not have significantly different likelihood of post-manual cleaning ATP <200 (OR 1.18, 95% CI 0.56–2.50; $P = 0.67$).

Conclusions In resource-limited settings, approximately 20% of endoscope reprocessing cycles may result in inadequate disinfection. This was not significantly improved by a comprehensive educational intervention. Alternative approaches to endoscope reprocessing are needed.

Introduction

Endoscope disinfection is a necessary component of safe endoscopy practice. However, endoscope reprocessing is a complex, tedious, multistep process that includes pre-cleaning, manual cleaning, high-level disinfection (HLD), rinsing and drying, and storage. Lapses in reprocessing protocols are identified in the vast majority of endoscope-related infection outbreaks [1].

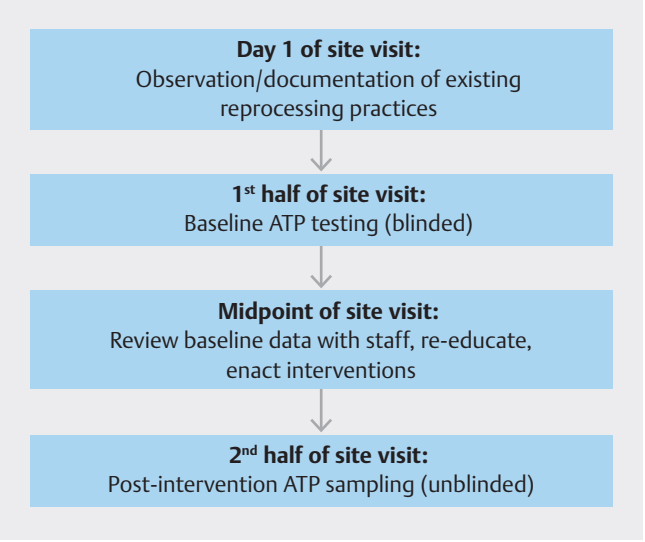
Methods to ensure adequate reprocessing are currently lacking. Surveillance bacterial cultures have been proposed for this purpose but are limited by inherently delayed results that are not immediately actionable for endoscopes inadequately reprocessed [2]. Point-of care testing for adenosine triphosphate (ATP), a marker of bioburden, may be a reasonable surrogate to assess the effectiveness of manual cleaning, which is critical for subsequent HLD but also the most prone to error. ATP testing has recently been shown to correlate with quality of endoscope cleaning [3], and ATP values <200 relative light units (RLUs) after manual cleaning of endoscopes and have been associated with subsequent adequate disinfection [4, 5].

The World Gastroenterology Organization (WGO) sponsors training centers that train digestive health professionals internationally. Many of these training centers are in limited resource regions, potentially impacting endoscope reprocessing capabilities. We sought to evaluate endoscope reprocessing across multiple WGO training centers using ATP testing, before and after optimization of reprocessing methods.

Methods

Setting

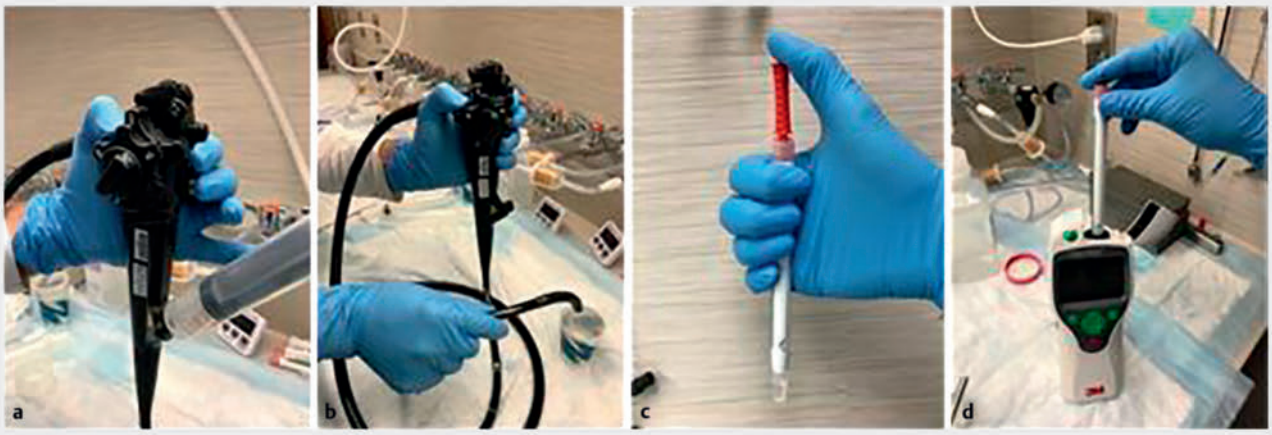
This was a multicenter study involving five WGO training centers that volunteered for study participation and met enrollment criteria: Bangkok, Thailand; Bogota, Colombia; San Jose, Costa Rica; Suva, Fiji; Nairobi, Kenya. A two-person study team consisting of one nurse (of 2 nurses total) with experience in performing and supervising endoscope reprocessing, and one physician (of 3 physicians total) with knowledge about reprocessing guidelines visited each site for 1 week. The study was conducted between May 2018 and February 2020. Two additional training centers planned to participate in the study, but COVID-19 pandemic-induced changes in endoscopy center practices and case volumes, as well as limitations on international travel, prevented these sites from participating.



▶ **Fig. 1** Study flow.

Prior to and upon arrival at the study site, the study protocol (▶ **Fig. 1**) was reviewed with local training center team members including physicians, nurses, and reprocessing personnel. Consecutive endoscopes used in patients who gave consent for endoscopic procedures were included for investigation. Baseline reprocessing practices were observed to understand workflow and study integration (0.5 days). Subsequently, baseline ATP testing was performed during the first half of the site visit (2 days). Following this period, a meeting was held among study staff and local team members to review baseline data and potential interventions to optimize reprocessing practices (0.5 days). Following the implementation of immediately feasible interventions, post-intervention ATP testing was repeated during the latter half of the visit (2 days). At one center, examination of endoscope suction/biopsy channels was performed with a borescope (Clarus Medical LLC, Minneapolis, Minnesota, United States).

Endoscopic procedures including upper endoscopy, flexible sigmoidoscopy, colonoscopy, endoscopic retrograde cholangiopancreatography, and upper endoscopic ultrasound were performed by each training center's endoscopy faculty and trainees using existing endoscopes. Endoscope data (manufacturer and model number, identification [ID] number, number of procedure/reprocessing cycles, and repair history), when available,



▶ **Fig. 2** ATP sampling protocol. The suction/biopsy channel is purged with air and then flushed with 40 mL of water. The channel is then purged again and the effluent is collected in a disposable cup. The distal portion of the ATP stick is submerged in the sample, and then returned to its holder and depressed to activate the bioluminescence reaction. This reaction is then quantified by the luminometer in the form of relative light units (RLUs).

were collected from each site. For each reprocessing cycle investigated, the endoscope ID number, the type of procedure (upper/lower), whether an endoscopic intervention (e. g., forceps biopsy) was performed, whether pre-cleaning was performed, reprocessing technician ID, as well as ATP results were recorded by study staff. No clinical information was collected.

Endoscope reprocessing was expected to adhere to existing manufacturer and WGO/World Endoscopy Organization (WEO) global guidelines [6]. This includes immediate bedside pre-cleaning with wiping of the exterior surface to remove visible debris and flushing of the suction/biopsy channel with 250 mL enzymatic cleaning solution suctioned through the endoscope. This is followed by endoscope transportation to a dedicated reprocessing room for manual cleaning including leak testing, brushing of internal channels and components, and irrigation of detergent and water through the channels. HLD is then performed, either manually or by automated endoscope reprocessors. The endoscopes are then dried and if not immediately reused, hung in a storage cabinet.

ATP testing

ATP testing was performed on rinsates from the endoscope suction/biopsy channel at four junctures of reprocessing: 1) before manual cleaning; 2) after manual cleaning; 3) after HLD; and 4) after overnight storage (for endoscopes immediately reused after HLD, after overnight storage testing was not possible for that specific reprocessing cycle). ATP levels were assessed using Clean-Trace Water ATP tests and a compatible luminometer (3 M, St. Paul, Minnesota, United States) quantifying ATP bioluminescence in relative light units (▶ **Fig. 2**). Prior validation studies for this specific ATP assessment kit support the post-manual cleaning benchmark of <200 RLUs used in this study [4, 5]. ATP testing was performed by first purging the channel with an air-filled syringe to clear any gross residual channel contents. Forty milliliters of local tap water was then flushed through the channel followed by air, and the effluent was collected in a disposable cup. Background ATP measurements of the cup containing 40 mL of locally available tap water (prior to any contact with an endoscope) were performed to assess for significant confounding, and showed negligible values of 3 to 11 RLUs. The training center team, including reprocessing personnel, was blinded to baseline ATP testing results in an effort avoid impacting baseline reprocessing practices.

Intervention

Following baseline ATP testing, a meeting was held among the study staff and local training center stakeholders including physicians, nurses, and reprocessing personnel. Baseline ATP testing data were reviewed in the context of existing reprocessing practices and reprocessing guidelines. Opportunities for improvement in each phase of the reprocessing protocol (pre-cleaning, cleaning, HLD, rinsing and drying, and storage) were identified collaboratively by training center members and study staff. Modifications of local reprocessing practices were determined according to WGO/WEO global guidelines for endoscope disinfection [6]. Specifically, these were based on Cascade options, which outlines a hierarchy of standard procedures that allow for alternatives in resource-sensitive steps in endoscope reprocessing, particularly in areas of the world in which external factors limit available options. For example, in a training center in which renewing the cleaning detergent solution for each new procedure ("medium-extensive" resources level) was not possible, renewal at an interval that the center's resources allowed was permitted ("limited" resources level). After implementing the maximum feasible interventions in consensus with local stakeholders, follow-up ATP testing was performed in similar fashion to baseline ATP testing except training center staff (including reprocessing personnel) were no longer blinded to ATP results. Of note, endoscopes with a post-manual cleaning ATP ≥200 RLUs (pre- or post-intervention) were not triaged individ-

ually to any specific intervention (e. g., repeat manual cleaning or cycle of reprocessing), and were permitted to proceed with the existing reprocessing protocol.

Interventions in reprocessing practices that were implemented at each study site are detailed in ▶ **Table 1**. These most commonly included the performance or optimization of bedside pre-cleaning, more frequent exchange or increased volumes of manual cleaning solution, longer rinsing times, and longer drying times with vertical storage after HLD in accordance with manufacturer recommendations and/or WGO/WEO global guidelines. At Site D, staff had recently been trained in endoscope reprocessing, and no suggestions for improvement were identified.

Endpoints and sample size

The primary endpoint of this study was comparison of mean ATP levels after manual cleaning between baseline and post-intervention results among all participating sites. To detect a difference of ≥30% in mean ATP levels after intervention with 90% power, a total of 200 pre- and 200 post-intervention endoscopes were needed across all centers. To detect a difference of ≥30% with 70% power at each individual site, 26 pre- and 26 post-intervention endoscopes were needed per site; this number of reprocessing cycles was not achieved pre-intervention at one of the five study sites. Secondary endpoints included changes in mean ATP measurements at all other time points after intervention, and analysis of the association between the study variables and ATP measurements.

Statistical analysis

ATP levels were compared pre- and post-intervention using the Pearson chi-squared and Kruskal-Wallis tests. Differences in RLU measurements before and after the intervention were formally analyzed using a hierarchical model. ATP levels were log-transformed to mitigate the effect of right-skewed data on the model estimates. We expected substantial variability in the pre-intervention results and intervention effect from site to site, and thus modeled separate site-effects (for intercept and treatment) as random effects in the hierarchical model. The estimate of the overall fixed treatment effect (with 95% confidence interval [CI] and *P* value) served as the primary estimate for each model. The treatment effect for post-manual cleaning time point served as the primary endpoint. Other time points were analyzed as secondary endpoints. Additionally, we calculated the 95% confidence interval for the proportion of post-intervention, post-manual cleaning ATPs which are below the recommended benchmark of 200 RLUs.

Results

Among the five study sites, a total of 343 endoscope reprocessing cycles were studied (160 pre-intervention and 183 post-intervention) and a total of 1182 ATP tests were performed (▶ **Table 2**). Sixty-five endoscopes were studied. Many had been acquired used, and data on the date of manufacture, number of uses, and date of most recent servicing by the manufacturer were not available for a substantial number of endoscopes. For endoscopes with available data, mean scope age was 5.3 years (range 1–13, N = 38), and mean time since last servicing was 2.0 years (range 0.1–8, N = 46).

The majority of procedures with gastroscopes were for upper endoscopy (63.8%) and involved an endoscopic procedural intervention requiring passage of a device via the suction port (61.0%), most commonly biopsies. Only 4.0% of procedures were endoscopic retrograde cholangiopancreatographies or endoscopic ultrasound, requiring the use of an endoscope with an elevator. Total ATP values and values for individual sites are shown in ▶ **Table 2**. Pre-intervention, 34 (21.4%) reprocessing cycles had an ATP measurement greater than the threshold of 200 RLUs following manual cleaning.

Interventions

Pre- and post-intervention procedures were similar in the proportions of diagnostic-only procedures as well as the type of scope used (▶ **Table 2**). Each site performed a similar number of procedures before and after the intervention. Pre- and post-intervention ATP data from individual sites are shown in **Supplemental Fig. 1**. Intervention resulted in a dramatic decrease in pre-manual cleaning ATP values at one site that had not been consistently performing bedside pre-cleaning prior to the study intervention (Site C, median ATP 158,807 RLUs pre-intervention, and 1,730 RLUs post-intervention, *P* <0.001). However, there were no meaningful changes in ATP values by site after manual cleaning, or at any later stage in the reprocessing cycle.

Considering all sites together, there were significant improvements in the performance of bedside pre-cleaning from 82.4% to 100% (*P* <0.001) as well as in median ATP values before manual cleaning. This difference in pre-manual cleaning ATP values remained significant after removing Site C (median ATP 1951 RLUs vs. 603 RLUs, *P* <0.001). However, there was no significant reduction in ATP values after manual cleaning or at later stages of the reprocessing cycle or after overnight storage (▶ **Table 1**). The relative post-intervention reduction in mean ATP values after manual cleaning was 19% (*P* = 0.17; 95% CI: 40% reduction, 10% increase). There was a post-intervention downward trend in the proportion of endoscopes with ATP ≥200 RLUs after manual cleaning, which was not statistically significant (21.4% vs. 14.8%, *P* = 0.11, odds ratio [OR] 0.64; 95% CI 0.36–1.11). Mixed-effect modeling, recognizing that measures within each site may be correlated, yielded similar results (analysis not shown).

Associations with post-manual cleaning ATP levels below 200 were inspected separately before and after the educational intervention with study site, type of endoscope (upper vs. lower), and endoscopic procedure intervention (▶ **Table 3**). Colonoscopes consistently demonstrated lower ATP values than gastroscopes. Across pre- and post-intervention observations, post-manual cleaning ATP values were ≥200 RLUs in 1.6% of colonoscope reprocessing cycles vs. 27.1% of gastroscope reprocessing cycles (*P* <0.001). Post-manual cleaning ATP levels were <200 RLU in 80.8% endoscopes undergoing manual HLD versus 84.1% endoscopes undergoing automated HLD (*P* = 0.67).

In multivariable logistic modeling, gastroscopes were significantly less likely (OR 0.04, 95% CI 0.01, 0.19; *P* <0.001) than

▶ **Table 1** Reprocessing interventions performed at each site.

Study site	Potential for optimization	Intervention
A	Pre-cleaning: ▪ Suctioned fluid by time, not volume of enzymatic solution ▪ Duodenoscope/echoendoscope elevator was stationary while suctioning water (open or closed) ▪ The air/water cleaning button was not used during pre-cleaning ▪ Delays after pre-cleaning and before leak testing and manual cleaning Final Rinsing: ▪ Suboptimal volumes of rinsing to clear ortho-phthalaldehyde (OPA)	Pre-cleaning: ▪ Standardized suctioning of 250 mL enzymatic solution ▪ Toggle duodenoscope/echoendoscope elevator up and down while suctioning water ▪ Use the air/water cleaning button during pre-cleaning ▪ Minimize delays after pre-cleaning and before leak testing and manual cleaning Final Rinsing: ▪ Use higher rinsing volumes to clear all OPA
B	Pre-cleaning: ▪ Frequent delays in pre-cleaning ▪ Inadequate volume of enzymatic solution (approximately 50 ml) ▪ The air/water cleaning button was not used during pre-cleaning ▪ Water jet channels not pre-cleaned ▪ Dirty scopes hung temporarily on the endoscope tower alongside clean scopes Manual cleaning: ▪ Leak testing not performed prior to scope immersion in liquid ▪ Gloves used to plug the sink left in place overnight ▪ Water in the cleaning sink is cold, preventing activation of enzymes in the enzymatic detergent solution ▪ All endoscope channels not brushed during cleaning ▪ Biopsy ports not adequately brushed HLD ▪ No suggestions (automated reprocessing machine) Final rinsing ▪ No suggestions (automated reprocessing machine) Drying and Storage ▪ Air is applied briefly, and borescope exam shows retained water in the suction/biopsy channel ▪ Scopes sometimes stored with valves and caps on ▪ Scope umbilicus stored in a “U” configuration, facing up Accessories ▪ Water bottles and caps not cleaned daily ▪ Biopsy port caps not opened prior to disinfection	Pre-cleaning: ▪ Pre-cleaning performed immediately after endoscope withdrawal from the patient, by the endoscopist if other staff are busy ▪ Increase bedside pre-cleaning volume to 250 mL enzymatic solution ▪ Use the air/water cleaning button during pre-cleaning ▪ For scopes with water jet channels, flush by activating the foot pedal or using a syringe ▪ Do not bring clean scopes into the endoscopy room until dirty scopes have been taken to the cleaning room Manual cleaning: ▪ Perform leak testing before immersing scope in liquid ▪ All devices in the cleaning sink discarded, changed or disinfected at the end of each day ▪ Use water >20°C in the cleaning sink ▪ Brush the entire suction/biopsy channel via the suction valve port (2 directions) and also through the biopsy port ▪ A short, large caliber brush (“stubby brush”) should be used HLD ▪ No suggestions (automated reprocessing machine) Final Rinsing ▪ No suggestions (automated reprocessing machine) Drying and Storage ▪ Longer duration drying (10 minutes) using compressed air, per manufacturer’s recommendations ▪ Do not leave valves and caps on scopes while in storage ▪ Both the insertion shaft and the umbilicus should be stored hanging downward Accessories ▪ Water bottles should be disinfected by steam sterilization daily ▪ Open and clean biopsy port caps prior to disinfection
C	Pre-cleaning: ▪ Not performed ▪ Endoscope transported by hand to reprocessing area Manual cleaning: ▪ Occasionally delays to initiation of manual cleaning ▪ Insufficient volume of enzymatic in sink to allow complete endoscope immersion ▪ Enzymatic recycled and replaced daily HLD: ▪ Use of water/dishwashing soap to rinse OPA disinfectant Drying and Storage: ▪ Short drying times using low pressure forced air (<1 min) prior to coiling and laying horizontally on bench, in carrying cases, or vertically with distal top foam protectors	Pre-cleaning: ▪ Initiate bedside pre-cleaning with 250 mL enzymatic solution ▪ Transport endoscope in bins to reprocessing area Manual cleaning: ▪ Minimize delays to initiation of manual cleaning ▪ Increase volume of enzymatic in sink to allow complete endoscope immersion ▪ Replace enzymatic solution every 3 endoscopes (ideally replace with each endoscope) HLD: ▪ Immersion in fresh water without additives Drying and Storage: ▪ Increase drying times to minimum 10 minutes before hanging (without distal tip foam protectors), with eventual acquisition of high pressure forced air drying system and ventilated cabinet storage

▶ **Table 1** (Continuation)

Study site	Potential for optimization	Intervention
D	No suggestions for improvement	No suggestions for improvement
E	Pre-cleaning: ▪ Pre-cleaning with 30 mL enzymatic solution using intermittent suction Manual cleaning: ▪ Delays between pre-cleaning and manual cleaning ▪ Rinse with recycled water ▪ Residue on scope exterior prior to HLD ▪ Gloves not being changed when moving from dirty to clean areas HLD: ▪ Pockets of air when flushing through channels ▪ Imprecise HLD dwell times ▪ Rinse with recycled water Drying and Storage: ▪ Scope hung for overnight storage without drying	Pre-cleaning: ▪ Increase pre-cleaning enzymatic solution volume to 250 mL using continuous suction Manual cleaning: ▪ Minimize/eliminate delays between pre-cleaning and manual cleaning ▪ Rinse with fresh water ▪ Remove detergent residue from scope exterior ▪ Change gloves every time moving from dirty to clean areas HLD: ▪ Avoid pockets of air when flushing solution through channels ▪ Use of a timer to ensure appropriate dwell times ▪ Continuous supply of fresh water for rinsing Drying and Storage: ▪ Dry the scopes prior to hanging for overnight storage

colonoscopes to achieve post-manual cleaning ATP <200 RLU. No other factor (educational intervention, study site, endoscope age) was significantly associated with improved cleaning outcomes. Sites which performed manual versus automated HLD did not have significantly different likelihood of post-manual cleaning ATP <200 RLU (OR 1.18, 95% CI 0.56–2.50; P= 0.67).

Suction/biopsy channels of 12 endoscopes were examined with a borescope at Site B, and findings were rated using a previously described scale [7]. Total scores ranged from 5 to 16, with channel scratches observed in all endoscopes, adherent peel in four, buckling in one, and channel perforation in one. Scores did not correlate with mean post-manual cleaning ATP levels (correlation coefficient 0.32).

Discussion

Endoscope reprocessing is a critical component in the safe performance of endoscopic procedures, but is inherently challenging and prone to error. Recent endoscope-related infection outbreaks have obligated endoscopy units to reevaluate their overall reprocessing practices. We observed baseline reprocessing practices at five international WGO training centers in resource-limited settings and assessed the impact of interventions on reprocessing quality, as measured by ATP levels. Several interventions were made, aligning reprocessing procedures with best practices and resulting in a downward trend in the proportion of endoscopes with post-manual cleaning ATP above the benchmark of 200 RLUs from 21% to 14%, a difference that was not statistically significant. Our findings suggest that a significant proportion of endoscope reprocessing cycles may not result in adequate endoscope disinfection, even after expert review and optimization of local practices.

In an effort to reduce the risk of endoscope-related infection transmission, several modalities for assessing reprocessing quality assurance have either been recommended or proposed. However, most are associated with significant barriers, especially in limited resource settings. For example, some guidelines recommend routine microbiological surveillance of endoscopes and reprocessing equipment with bacterial cultures which carry high sensitivity for microbial contamination but are inherently limited by results that require over 1 to 2 days to become available and are not immediately actionable for endoscopes that may be inadequately reprocessed [2]. For duodenoscopes specifically, recent recommendations to acquire partially or fully disposable endoscopes is often not economically feasible in resource-constrained contexts. This underscores the importance of optimizing existing reprocessing practices.

Bioluminescent testing for ATP in biologic residue has been used for quality reassurance in the food service industry and recently applied to the healthcare setting. ATP testing is relatively easy to perform and provides real-time results. Alfa and colleagues established a post-manual cleaning benchmark of <200 RLUs of the suction/biopsy and air/water channels (specific to the commercially available kit used in this study, but using sterile water) in simulated use settings [4, 5]. This benchmark has been proposed as an indicator of adequate cleaning prior to submitting the endoscope for HLD. Manual cleaning remains perhaps the most critical step in the reprocessing cycle, because biofilm can form when contaminated endoscopes undergo repeated cycles of reprocessing, creating a protective matrix allowing viable organisms to survive HLD. Subsequent disinfection or sterilizing processes can fail if the instrument has not been sufficiently cleaned.

Despite identifying and addressing gaps throughout the reprocessing cycles, we did not find a satisfactory reduction in the post-manual cleaning ATP level. We suspect this is multifactorial in etiology. For example, upper but not lower endoscopes were associated with greater post-manual cleaning ATP levels, an observation made previously and possibly related to a narrower or more damaged suction/biopsy channel that renders manual cleaning more challenging [8]. Although reprocessing

▶ **Table 2** Total, pre-intervention and post-intervention ATP measurements.

	Total	Pre-intervention	Post-intervention	P value
No. reprocessing cycles studied per site N = 343				0.84
A	102 (29.7%)	52 (32.5%)	50 (27.3%)	
B	75 (21.9%)	34 (21.2%)	41 (22.4%)	
C	58 (16.9%)	27 (16.9%)	31 (16.9%)	
D	46 (13.4%)	19 (11.9%)	27 (14.8%)	
E	62 (18.1%)	28 (17.5%)	34 (18.6%)	
Pre-clean performed N = 342				**<0.001**
No	28 (8.2%)	28 (17.6%)	0 (0.0%)	
Yes	314 (91.8%)	131 (82.4%)	183 (100.0%)	
Type of procedure N = 333				0.22
▪ Diagnostic only	130 (39.0%)	55 (35.5%)	75 (42.1%)	
▪ Endoscope intervention	203 (61.0%)	100 (64.5%)	103 (57.9%)	
Type of scope N=343				0.68
▪ Lower	124 (36.2%)	56 (35.0%)	68 (37.2%)	
▪ Upper	219 (63.8%)	104 (65.0%)	115 (62.8%)	
Before manual cleaning ATP (RLUs) N = 337				**<0.001**
Median (Q1, Q3)	1343 (352, 5403)	2709 (540, 12491)	760 (257, 2346)	
Range	15–739650	51–739650	15–44145	
After manual cleaning ATP (RLUs) N = 342				0.23
Median (Q1, Q3)	52 (20, 134)	56 (24, 158)	51 (18, 122)	
Range	2–6760	2–2840	3–6760	
After manual cleaning ATP (RLUs) N = 342				0.11
≥200	61 (17.8%)	34 (21.4%)	27 (14.8%)	
<200	281 (82.2%)	125 (78.6%)	156 (85.2%)	
After HLD ATP (RLUs) N = 333				0.54
Median (Q1, Q3)	26 (10, 69)	26 (11, 69)	27 (9, 70)	
Range	2–1473	2–513	2–1473	
Before clinical use ATP (RLUs) N = 171				0.72
Median (Q1, Q3)	44 (12, 162)	41 (8, 165)	44 (16, 161)	
Range	1–7389	1–7389	1–4313	

ATP, adenosine triphosphate; Q, quarter; RLU, relative light unit; HLD, high-level disinfction

practices were optimized, this was still limited by training center-specific availability of resources, so manufacturer reprocessing recommendations may not have been fully met. For example, in an effort to conserve pre-cleaning enzymatic solution, one training center was exchanging solution daily as opposed to with every scope. In discussion with training center stakeholders it was decided to exchange solution every third endoscope. It also is unknown if the persistent proportion of endoscopes with elevated ATP level can be further reduced by a second consecutive round of manual cleaning (or HLD), which has been variably successful in other studies [3, 9].

We attempted to determine the number of previous procedures as well as repair and servicing history for each endoscope but this information was not available for many endoscopes. Defects in an endoscope combined with inadequate reprocessing (including drying and storage) increase the potential for biofilm formation. Although not part of the study design a priori, we explored the use of a thin fiberoptic borescope at one study site to pass through and inspect the suction/biopsy

▶ **Table 3** Unadjusted comparison of associations with post-manual cleaning ATP < 200 RLUs.

	Pre-intervention		Post-intervention	
	% ATP <200 RLUs	**P value**	**% ATP <200 RLUs**	**P value**
Site				
A	82% (42/51)	0.62	90% (45/50)	0.25
B	71% (24/34)		90% (37/41)	
C	74% (20/27)		87% (27/31)	
D	84% (16/19)		74% (20/27)	
E	82% (23/28)		79% (27/34)	
Pre-clean performed*				
No	75% (21/28)	0.62	NA (0/0)	NA
Yes	79% (103/130)		85% (156/183)	
Any endoscopic intervention*				
Diagnostic only	87% (48/55)	**0.037**	88% (66/75)	0.32
Any intervention done	73% (72/99)		83% (85/103)	
Type of scope				
Lower	98% (55/56)	**<0.001**	99% (67/68)	**<0.001**
Upper	68% (70/103)		77% (89/115)	
	Median (Q1, Q3)	**P value**	**Median (Q1, Q3)**	**P value**
Before manual cleaning ATP (RLUs)*				
Post-manual ATP <200 RLUs	1866 (437, 8773)	**<0.001**	518 (206, 1584)	**<0.001**
Post-manual ATP ≥200 RLUs	11916 (3620, 27964)		5433 (1862, 8422)	
After HLD ATP (RLUs)*				
Post-manual ATP <200 RLUs	20 (8, 45)	**<0.001**	20 (8, 48)	**<0.001**
Post-manual ATP ≥ 200 RLUs	78 (42, 183)		91 (54, 182)	
Before clinical use ATP (RLUs)*				
Post-manual ATP <200 RLUs	22 (6, 114)	**<0.001**	42 (12, 129)	**0.011**
Post-manual ATP ≥200 RLUs	170 (72, 867)		148 (38, 408)	

*Missing data: There was 1 pre-intervention observation with pre-cleaned performed unknown (with post manual cleaning [PMC] ATP < 200 RLU). There were 5 pre-intervention observations and 5 post-intervention observations with endoscopic intervention unknown (all with PMC-ATP < 200 RLUs). There were 6 post-intervention observations with pre-manual cleaning ATP unknown (5 with PMC-ATP < 200 RLUs). There were 8 post-intervention observations with after HLD ATP unknown (6 with PMC-ATP < 200 RLUs). There were 74 pre-intervention observations (58 with PMC-ATP < 200 RLUs) and 98 post-intervention observations (83 with PMC-ATP < 200 RLUs) with before clinical use ATP unknown.
ATP, adenosine triphosphate; RLU, relative light unit; PMC, ; Q, quarter; HLD, high-level disinfection.

channel for damage that may predispose to biofilm formation and/or interfere with reprocessing [7]. All examinations were performed by a single study team member and assessed using a previously described scoring system. A median damage score 6.5 (range 2–14) and median total score of 9.5 (range 5–16) were calculated with notable findings including debrided area of channel and one potential channel perforation, although the significance of these findings and their correlation with ATP levels is unclear at this time and remain an area of future investigation.

The complicated, multistep, tedious nature of endoscope reprocessing lends itself to human error and so-called human

factors and observations during our study are supportive of this. In a recent large survey of US and international health care workers on endoscope reprocessing, 70% reported feeling pressured to work more quickly and 17% admitted to skipping steps or performing them more quickly [10]. In our study we identified multiple sites that deferred bedside pre-cleaning or performed it with suboptimal volume. While this and other omissions may be related to pressures of endoscope/procedure turnaround time, this is likely to be compounded in limited resource settings where the limited number of available endoscopes, shortages and cost of reprocessing supplies, and training and competency testing may be less favorable. With education of training center medical team and reprocessing staff, pre-cleaning in this study improved to 100%, and study staff observed adherence to study team recommendations post-intervention, but results still fell short of expectations. This suggests that the site-specific optimized process of endoscope reprocessing is not adequate to achieve desired levels of disinfection in some cases.

We found ATP testing to be feasible, informative for guiding reprocessing interventions, and well received by reprocessing personnel for quality assurance. Enrolling consecutively used endoscopes and testing them after each phase of reprocessing did not appear to significantly impede procedure workflow. Because collection and testing of samples for ATP is rapid (1–2 minutes), is most valuable after the manual cleaning phase, and may only be necessary for periodic surveillance, a surveillance program is unlikely to interfere with typical workflow. Reprocessing staff generally were engaged throughout the study and at the time of intervention were collaborative in identifying potential sources of residual bioburden and solutions to address them. The study visit and intervention also were used as an opportunity for reprocessing staff to inquire about preexisting reprocessing questions, because many reprocessing staff had not received formal training or were uncomfortable interpreting manufacturer reprocessing instructions. In the post-intervention period, reprocessing staff were eager to understand the impact of the various interventions on reprocessing quality as assessed by ATP. Quantitative ATP RLUs provided instant feedback, and values meeting the benchmark resulted in positive reinforcement. Moreover, reprocessing staff were taught to perform ATP testing in the post-intervention period and demonstrated competency in doing so, further supporting its ease of adoption.

Our study has some notable limitations. Although this was a multicenter, prospective study, baseline reprocessing techniques were not standardized across all institutions. For example, there were variations in reprocessing techniques, supplies, equipment (e. g., manual vs automated HLD), and drying/storage techniques. Moreover, study teams varied at most of the sites. Therefore, reprocessing interventions varied at each site but we attempted to standardize the approach to these interventions using published, hierarchical Cascades and also statistically controlled for this variation using multivariable analysis. It is also important to note that we used an established ATP threshold as a benchmark to assess quality of manual cleaning, but cannot draw conclusions regarding risk of infection transmission because we did not perform microbiological cultures and ATP levels do not correlate well with culture data [9]. Moreover, the absence of a statistically significant difference in pre- and post-intervention post-manual cleaning ATP in this study limits our conclusions about the impact of interventions on subsequent phases of reprocessing. As noted previously, we also did not assess whether additional interventions such as repeat manual cleaning or HLD would further reduce post-manual cleaning ATP particularly in those endoscopes measuring above the benchmark. Of note, we performed an air-purge of the instrument channel to clear variable gross residual contents prior to sampling for ATP testing, which despite being standardized, may have resulted in underestimation of bioburden. It is also important to note that only a subset of all interventions made were directly related to the manual cleaning phase and it is unclear how interventions made after the post-cleaning phase impact post-cleaning ATP. We had planned to include two additional training centers, but due to the COVID-19 pandemic, that was no longer possible and thus, enrollment ended early. To our knowledge, ATP testing has not been well studied in resource-limited settings, and we assumed that a cutoff of 200 RLUs should similarly be applied as a benchmark of acceptable residual bioburden. Although we used locally sourced tap water instead of sterile water at each site, ATP testing of tap water revealed negligible results and there were no statistically significant differences in post-manual cleaning ATP pre- and post-intervention. Finally, the baseline condition of endoscopes between and within sites likely varied and may have introduced confounding that we attempted to control for by retrieving endoscope service/repair history and performing borescope assessment, but this was not be possible for every endoscope.

Conclusions

In conclusion, we found observation of reprocessing practices and ATP testing by an experienced study team to be valuable in identifying opportunities to optimize reprocessing at multiple training centers. Although this did not result in a statistically significant reduction in post-manual cleaning ATP, the intervention was well received by training center staff and adoptable. Further investigation is warranted to understand the significant proportion of endoscope reprocessing cycles that fail to meet ATP benchmarks following manual cleaning and how this can be addressed, especially in limited resource settings. This might include study before and after endoscope channel and valve replacements, aiming to remove potential sanctuaries harboring organisms despite standard endoscope reprocessing.

Conflict of Interest

The authors declare that they have no conflict of interest.

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