Evaluation of the Outcome of Three Cleaning Methods on Flexible Endoscope Residual Soil Levels

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INTRODUCTION

- Infection after routine endoscopy has been reported around 1 in 1,000 procedures
- Roughly 22.2 million endoscopic procedures occur annually in the United States
- Residual soil can interfere with high-level disinfection or sterilization
- **Goal: identify cleaning methods that achieve the lowest residual soil, and are feasible to implement**

OBJECTIVES

- Determine residual soil levels after 3 cleaning processes (MC, PAM, EM)
- Compare effectiveness using protein and hemoglobin extraction assays
- Interview technician for feasibility, ease, and fatigue
- **Recommend best practice based on outcomes plus implementation realities**

METHODS

Design:
Prospective laboratory comparison of three manual cleaning methods

Methods Compared:
- MC: Traditional manual cleaning per IFU
- PAM: Pump-assisted manual cleaning (automated flushing and rinsing)
- EM (Method C): Enhanced manual cleaning with added inspection and verification steps beyond IFU

Endoscopes: One colonoscope and one bronchoscope

Sample Size: 264 total extracted samples including positive and negative controls

Test Soil: ATS2015 artificial test soil (dried)

Analysis:
- Protein: BCA assay (LOD 5 to 20 µg/mL)
- Hemoglobin: TMB assay (LOD 5 to 2000 µg/mL)

Statistics: Compare mean residual soil across methods (ANOVA)

Qualitative Arm: Technician interview, fatigue rating, workflow observation

ISO 15883-5 ACCEPTABLE LEVELS (µg/cm²)

Protein: alert ≥3.0 | action ≥6.4
Hemoglobin: alert ≥1.0 | action ≥2.2

RESULTS

Primary Findings (Quantitative):

- All three methods produced nondetectable protein and hemoglobin for both scopes
- No statistically significant differences between methods on residual soil endpoints in this lab model
- Quantitative endpoints were below assay LOD across all methods, limiting differentiation

All test results were below ISO alert and action levels

QUALITATIVE RESULTS

Technician Feedback:

Traditional Manual Cleaning (MC):
- Most physically taxing and exhausting
- Risk of repetitive injuries from manual syringe flushing
- Could lead to abbreviated/skipped steps due to fatigue

Pump-Assisted (PAM) & Enhanced (EM) Methods:
- Less physically exhausting
- Required more counter space and equipment
- Took longer to complete
- Higher cost implications

All methods caused significant splashing:
Reinforcing need for proper PPE for biohazard protection

LIMITATIONS

- Single technician and only one unit of each scope model tested
- New endoscopes and artificial test soil, not clinical samples
- Assay LOD limited ability to distinguish among methods

DISCUSSION

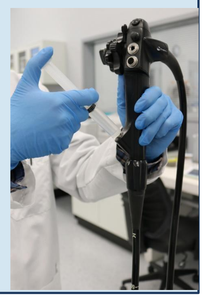
Key Implications:

1. Quantitative data alone insufficient for method selection
All three methods achieved soil levels below the limit of detection

2. Implementation considerations mattered most:
Fatigue, injury risk, counter space, time, cost

3. Automated flushing reduced fatigue
May reduce step skipping and repetitive injuries

4. Safety considerations paramount
Splashing occurred across all methods
Proper PPE essential for staff protection



CONCLUSIONS

1. All three methods achieved nondetectable protein and hemoglobin in this lab model

2. Based on qualitative data:

RECOMMENDED: PAM and EM methods
- Less physically taxing
- Reduce repetitive injury risk
- Minimize potential for skipped steps

NOT RECOMMENDED: Traditional MC method
- High physical demand and fatigue
- May increase risk of abbreviated steps

3. PPE should be mandated due to observed splashing

FUTURE RESEARCH

- Larger sample sizes, multiple technicians, more scope models & aged devices
- Clinical studies using patient samples
- More sensitive assays and additional markers such as ATP or TOC
- Evaluation of other automated cleaning technologies
- Staff safety and exposure risk assessment

CONTACT INFORMATION

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