

PERFORMANCE METRICS OF A NOVEL SINGLE-USE THERAPEUTIC GASTROSCOPE

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INTRODUCTION

The first single-use therapeutic gastroscope (SUTG) (4.2mm working channel) was cleared by the FDA in April 2024. Given its increased working channel size versus most other therapeutic gastroscopes (3.7mm), this SUTG has the potential to not only provide increased suctioning abilities to help facilitate the evacuation of fluids and blood from the upper gastrointestinal tract, but to do so in a safer manner given that it is sterile and always available for use. The purpose of this study was to evaluate the performance of the novel SUTG.

METHODS

- 30 procedures requiring a therapeutic gastroscope (4.2mm working channel) were completed by 17 physicians at 6 large university hospital systems across the United States.
- The Ambu aScope Gastro Large was utilized for all cases in the study.
- After each procedure, each physician completed a survey to assess their experience and clinical performance of the novel SUTG with 1 = Very Poor, 3 = Acceptable, and 5 = Very Good.
- Data was collected from April to June 2024.

RESULTS

- 93% (27/29) of the procedures were performed successfully with the SUTG.
- Two failed cases:
 - Failed Case #1: Issues with insufflation connections did not allow for case completion with the SUTG but did with a reusable therapeutic gastroscope (RTG).
 - Failed Case #2: Patient complications did not allow for case completion with either a SUTG or a RTG
- One excluded case:
 - Scope length limitations prevented the SUTG from reaching a bleed in the distal duodenum. Therapeutic gastroscopes are not regularly used for controlling bleeding in this location and thus was excluded.
- The SUTG was rated at least a 4 out of 5 in all 22 variables captured by the survey.
- Ease of distal attachment removal (4.93) and mounting (4.87) were rated highest amongst all the variables.
- When stratifying by procedure type, physicians who performed hemostasis, food impaction, or foreign body removal rated the ability of the scope to suction a 4.72 and the ability to suction with an inserted tool a 4.25.
- The full results can be found in Table 1.

Table 1. aScope Gastro Large Performance Metrics

Metric	Average Rating	N
	1=Very Poor, 2=Poor, 3=Acceptable, 4=Good, 5=Very Good	
Overall Satisfaction with Gastro Large	4.64	28
Overall Satisfaction with Maneuverability	4.59	29
Maximum Retroflexion	4.72	29
Ability to Orient to Target Area	4.62	29
Insertion/Intubation	4.55	29
Insertion Tube Stiffness	4.55	29
Ease of Distal Attachment Removal	4.93	14
Ease of Distal Attachment Mounting	4.87	15
Ease of Instrument Passage Through Working Channel	4.77	22
Ability to Angulate with a Tool Inserted in the Channel	4.77	22
Ability to Maintain a Clear Field of View	4.32	28
Lens Rinsing	4.18	28
Ability to Suction	4.72	29
Ability to Suction with Inserted Tool	4.61	23
Overall Satisfaction with Tools	4.77	22
Overall Satisfaction with Scope Ergonomics	4.45	29
Weight of Endoscope	4.76	29
Wheel Reach	4.52	29
General Handle Fit	4.48	29
Wheel Force	4.41	29
Haptic Feedback of Buttons	4.29	28
Placement of Button #3 and #4	4.19	27

DISCUSSION

- The excellent therapeutic performance measured by the study demonstrates that the novel SUTG from Ambu may be a suitable alternative to RTGs.
- Given that the SUTG rated well for ergonomics, its use may help reduce workplace injuries such as carpal tunnel syndrome, lateral epicondylitis, and De Quervain tenosynovitis.
- In addition to performing well, SUTGs are not subject to the same availability limitations as RTGs since they cannot be sent out for repairs, damaged, and/or reprocessed which is of utmost importance during emergent procedures and after-hours cases.

CONCLUSION

The novel SUTG showed a high procedural success rate and received high ratings in all 22 of the categories measured in the survey. Every metric was rated at least a 4 out 5 with the overall satisfaction of the SUTG rated a 4.64 out of 5. Given the high performance ratings, SUTGs should be considered suitable alternatives to RTGs.

