

Operator Perception of a Single-Use Flexible Bronchoscope: Comparison With Current Standard Bronchoscopes

LiHua Liu, Momen Wahidi, Kamran Mahmood, Coral Giovacchini, Scott Shofer, and George Cheng

BACKGROUND: Single-use flexible bronchoscopes have gained popularity in recent years for various advantages over the traditional reusable bronchoscope. There are several commercially available disposable bronchoscopes; however, all have limitations compared to reusable bronchoscopes. The Vathin H-SteriScope is a single-use flexible bronchoscope that may have overcome some of these limitations. **METHODS:** We designed a survey to evaluate the performance of this new single-use bronchoscope on a bronchoscopy model with operators who are familiar with current single-use and reusable bronchoscopes. The operators were asked to rank overall assessment, scope quality, handling, maneuverability, tool interaction, and image quality of the H-SteriScope on a scale of 0–100. These operators were then asked to rank their current single-use and reusable bronchoscopes with the same scale. The results were evaluated to determine the operator perception of the H-SteriScope. **RESULTS:** The H-SteriScope and current reusable bronchoscopes were perceived to have significant differences compared with currently available single-use bronchoscopes in overall assessment of the scope, scope quality, handling, maneuverability, tool interaction, and image quality ($P < .001$). The H-SteriScope was perceived to have similar maneuverability as the reusable bronchoscope ($P = .86$). There were no differences among the H-SteriScope ($P = .88$), the current single-use bronchoscope ($P = .84$), and the current reusable bronchoscope ($P = .89$) between the training and nontraining interventional pulmonology subgroups. **CONCLUSIONS:** In terms of operator perception, the H-SteriScope appears to have similar maneuverability as the reusable bronchoscope. Both the H-SteriScope and the reusable bronchoscopes performed better in all measured sectors than the current single-use bronchoscope. Additional studies are required to evaluate the practicality, safety, and cost efficiency of the H-SteriScope in clinical practice. *Key words:* single-use; flexible bronchoscope; therapeutic bronchoscopy; interventional pulmonology. [Respir Care 2020;65(11):1655–1662. © 2020 Daedalus Enterprises]

Introduction

Since the introduction of the flexible bronchoscope in the 1960s, it has quickly become one of the most commonly

used modalities for diagnosing and treating diseases of the airways and lung parenchyma.¹ However, the flexible bronchoscope also has faced many challenges in clinical practice over the past 50 years. Notably, the conventional reusable flexible scopes have 3 major drawbacks: high cost of repairs, need for decontamination, and possible cross-contamination.

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During routine use, the flexible bronchoscope becomes heavily contaminated with blood, secretions, and microorganisms. Bronchoscope-related outbreaks and infections, most frequently involving *Pseudomonas aeruginosa* and mycobacteria, are significant and pose recurrent challenges.^{2,3} Transmission of infection via flexible bronchoscope may be related to inadequate cleaning, disinfection, final rinsing, and drying procedures as well as any luminal defects of the bronchoscope.⁴ In light of bronchoscope-related infections, the U.S. Food and Drug Administration published a safety communication in 2015 highlighting contamination of reusable bronchoscopes.⁵ In addition to cross-contamination, the maintenance cost of the reusable flexible bronchoscope is high. In this context, single-use bronchoscopes have recently been introduced in clinical settings to address these challenges.

A single-use flexible bronchoscope eliminates the risk of cross-contamination, highlighting a key advantage in improved patient safety. Meanwhile, single-use flexible bronchoscopes may be cost-effective for certain clinical settings, such as in the critical care unit.⁶ The world's first single-use flexible endoscope was the AMBU aScope (AMBU, Copenhagen, Denmark). It is also the main single-use flexible bronchoscope currently available on the market. In 2011, the National Institute for Health and Care Excellence guidelines recommended AMBU aScope 4 Broncho for use in unexpected difficult airways.⁷ Moreover, in a search of the U.S. Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database, we found no reports of adverse events relating to the AMBU aScope.

The H-SteriScope is a new single-use video-bronchoscope (Vathin Medical Instrument Co. Ltd, Hunan, China). It requires no special handling or reprocessing and offers low acquisition and maintenance costs. According to the manufacturer, Vathin bronchoscopes are designed with outer diameters of 2.2–6.2 mm and working channel diameters of 1.2–3.2 mm with different types. Of note, the 2.2 mm bronchoscope does not have a working channel. In addition, the articulation allows flexion and retroflexion of 210°, and there is a rotary function that allows for rotation to left or right up to 90°. These designs aim to improve procedural efficiency as well as the handling and maneuverability of the bronchoscope.

The purpose of our study was to investigate operator perception of this new single-use flexible bronchoscope in comparison with operator perceptions of their current single-use flexible bronchoscope and their current reusable flexible bronchoscope.

Methods

The Duke University Institutional Review Board exempted this study because no patient, physician, or hospital identifiers were examined. Data were collected through

QUICK LOOK

Current knowledge

Single-use flexible bronchoscopes have gained popularity in recent years for the advantages over traditional reusable bronchoscopes. There are several commercially available disposable bronchoscopes, but all have limitations compared to reusable bronchoscopes.

What this paper contributes to our knowledge

We conducted a survey to evaluate the performance of this single-use bronchoscope in a bronchoscopy model with operators who are familiar with current single-use and reusable bronchoscopes. The disposable bronchoscopes were found to have similar maneuverability to reusable bronchoscopes and operator perceptions often favored the single use device.

the use of a survey that was conducted during the Second Conference of the American Association of Bronchology and Interventional Pulmonology (AABIP) held in August 2019 in Denver, Colorado. The operators used the H-SteriScope flexible bronchoscope (Vathin Medical Instrument Co., Hunan, China) on a bronchoscopy model on site. After hands-on evaluation, the operators were asked to complete a survey regarding the perception of the bronchoscope's quality, handling, maneuverability, tool interaction, and image quality. The operators were also asked to rate their current single-use flexible bronchoscope and their current reusable flexible bronchoscope at their home institution in the same survey. The survey contained 3 parts: operator-specific information, current flexible bronchoscope practice, and evaluation of the H-SteriScope. For the complete survey, please see the supplementary materials at <http://www.rcjournal.com>.

The data were entered into SPSS 20.0 (IBM, Armonk, New York) for statistical analysis. Continuous parameters are presented as means \pm SD when normally distributed or as medians and range. Categorical variables are reported as frequencies and percentages. Univariate analysis involved the use of analysis of variance for multiple continuous variables. Values were considered statistically significant for a level of $P < .05$ with 2-tailed tests.

Results

Demographics of Respondents

Demographic characteristics of the respondents are listed in Table 1. A total of 36 individuals responded to the survey. Of those, 26 (72.2%) completed the entire survey. Of these 26 respondents, 20 (76.9%) were attendings, and the rest were fellows. Further analysis revealed that 24 (92.3%)

OPERATOR PERCEPTION OF A SINGLE-USE FLEXIBLE BRONCHOSCOPE

Table 1. Respondent Demographics

Position	
Attending	20 (76.9)
Fellow	6 (23.1)
Department	
Medicine	22 (84.6)
Surgery	2 (7.7)
Pulmonary	2 (7.7)
Bronchoscopies in the past year	
< 50	1 (3.8)
0–150	3 (11.5)
150–250	7 (26.9)
250–500	10 (38.5)
> 500	5 (19.2)
Bronchoscopies in lifetime	
<50	1 (3.8)
50–150	2 (7.7)
150–500	0 (0)
500–1,000	2 (7.7)
> 1,000	21 (80.8)
Post-graduate year	
< 5	10 (38.5)
5–10	5 (19.2)
10–15	4 (11.5)
15–20	5 (15.4)
> 20	5 (15.4)
Interventional pulmonology training	
Yes	13 (50.0)
No	13 (50.0)

were from a medicine department and 2 (7.7%) were from a surgery department. Ten of the respondents mentioned that they had performed 250–500 bronchoscopy maneuvers in the last year; 5 (19.2%) performed > 500 bronchoscopies, and only 1 respondent (3.8%) performed < 50 bronchoscopies. Most respondents ($n = 21$, 80.8%) had performed > 1,000 bronchoscopies during their career, whereas 1 (3.8%) performed < 50 bronchoscopies, 2 (7.7%) performed 50–150 bronchoscopies, and 2 (7.7%) performed 500–1,000 bronchoscopies during their career. The respondents' years of practice spanned < 5 y post-graduate ($n = 10$, 38.5%) to > 20 y post-graduate ($n = 5$, 15.4%). Half of all respondents ($n = 13$) had formal interventional pulmonology training.

Current Bronchoscopy Practices

Table 2 displays information regarding current bronchoscopy practices of respondents, including the brands of currently reusable and single-use flexible bronchoscope and type of routinely used flexible bronchoscope. Unsurprisingly, Olympus was most commonly used for all respondents (100%) in their practices. Only 15.4% of respondents also used Pentax bronchoscopes in their

Table 2. Survey Responses Regarding to Current Bronchoscopy Practice

Current Practice	Responses*
Current flexible bronchoscope brand	
Olympus	26 (100)
Pentax	4 (15.4)
Fuji	1 (3.8)
Wolf	1 (3.8)
Current single-use brand	
AMBU	26 (100)
Verathon	2 (7.7)
Type of flexible bronchoscope routinely used	
Therapeutic	24 (92.3)
Diagnostic	21 (80.8)
Hybrid	6 (23.1)
Ultrathin	7 (26.9)

*Total exceeds 26 because some respondents provided > 1 answer.

Table 3. Survey Responses Regarding to Advantages of Reusable Bronchoscope Over Single-Use Bronchoscope

Advantage	Responses*
Reusable provide better maneuverability than single-use	14 (53.8)
Reusable provide better suction than single-use	15 (57.7)
Reusable allow for easier passage of tools than single-use	8 (30.8)
Reusable provide better image quality than single-use	17 (65.4)
Reusable provide better integration than single-use	13 (50)
Reusable is cheaper than single-use	8 (30.8)

Data are presented as n (%).

*Total exceeds 26 because some respondents provided > 1 answer.

practices, and a small number of respondents also used bronchoscopes from Fuji (3.8%) and Wolf (3.8%). In terms of single-use bronchoscopes, all respondents (100%) used the AMBU aScope, and 7.7% of respondents also used Verathon. Among the surveyed operators, 92.3% used therapeutic flexible bronchoscopes, and 80.8% used diagnostic flexible bronchoscopes. Hybrid and ultrathin flexible bronchoscope accounted for 23.1% and 26.9%, respectively.

Table 3 presents the respondents' answers to questions about the advantages of reusable flexible bronchoscopes compared to single-use flexible bronchoscopes. More than half of respondents felt that reusable flexible bronchoscopes provided better image quality than single-use flexible bronchoscopes. Additionally, compared to single-use flexible bronchoscopes, respondents indicated that the reusable flexible bronchoscope had better maneuverability (53.8%), suction (57.7%), and medical record integration (50%). In addition, 30.8% of respondents indicated that reusable flexible bronchoscopes allow for easier

OPERATOR PERCEPTION OF A SINGLE-USE FLEXIBLE BRONCHOSCOPE

Table 4. Survey Responses Comparing the Performance of 3 types of Flexible Bronchoscopy

	Overall Assessment	Scope Quality	Scope Handling	Scope Maneuverability	Scope Tools Interaction	Scope Image Quality
Vathin H-SteriScope	83.03 ± 11.95	82.19 ± 12.85	87.61 ± 10.32	90.15 ± 8.94	88.38 ± 8.47	87.61 ± 8.52
AMBU aScope	51.92 ± 19.23*	55.57 ± 18.40*	58.28 ± 18.75*	59.61 ± 20.78*	56.73 ± 22.53*	57.69 ± 16.68*
Olympus reusable	94.42 ± 6.97†‡	92.11 ± 10.78†‡	94.42 ± 6.68†‡	90.57 ± 8.98‡	94.42 ± 6.83†‡	95.96 ± 5.83†‡

Data are presented as mean ± SD.

* $P < .001$ comparing Vathin flexible bronchoscope with AMBU aScope bronchoscope.

† $P < .01$ comparing Vathin flexible bronchoscope with Olympus reusable bronchoscope.

‡ $P < .001$ comparing AMBU aScope bronchoscope with Olympus reusable bronchoscope.

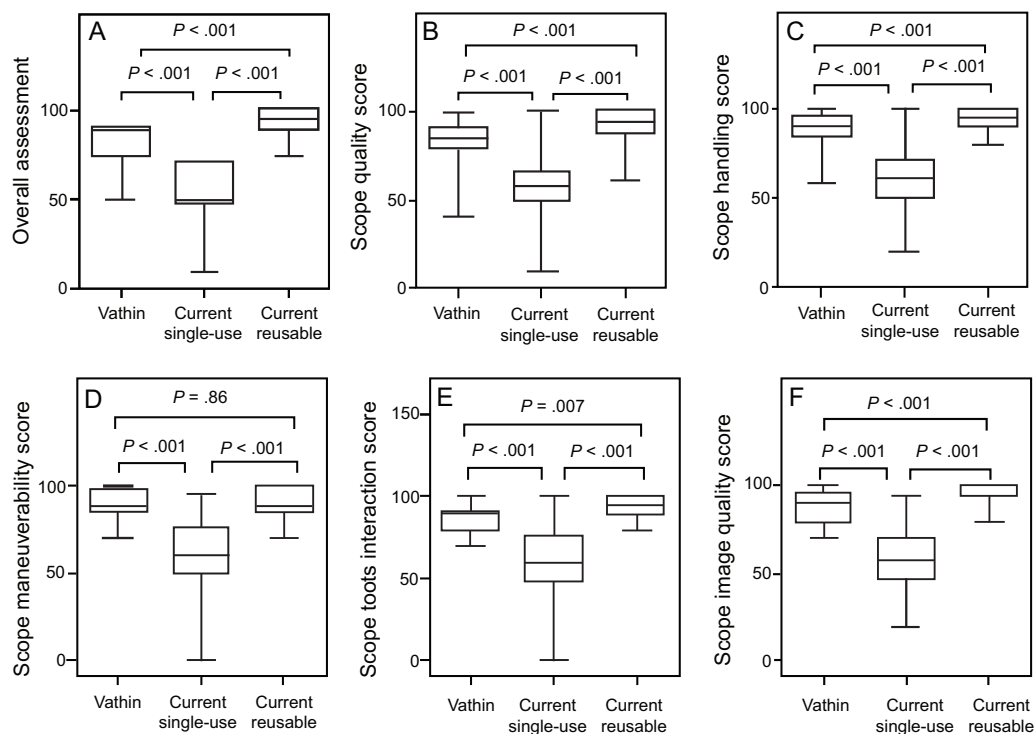


Fig. 1. Operator perception comparing the Vathin H-SteriScope flexible bronchoscope, the current single-use flexible bronchoscope, and the current reusable flexible bronchoscope. A: Overall assessment score. B: Scope quality score. C: Scope handling score. D: Scope maneuverability score. E: Scope tools interaction score. F: Scope image quality score.

passage of tools, and 30.8% of respondents thought reusable flexible bronchoscopes were cheaper than single-use flexible bronchoscopes.

Comparing Flexible Bronchoscopes

Six questions were used to evaluate the performance of 3 types of flexible bronchoscope (the H-SteriScope flexible bronchoscope, current single-use flexible bronchoscope, and current reusable flexible bronchoscope), including overall assessment, scope quality, handling, maneuverability, tool interaction, and image quality. With all evaluation indexes, current reusable flexible bronchoscopes received

the highest scores; the Vathin H-SteriScope ranked second above the single-use flexible bronchoscope (Table 4). The H-SteriScope and current reusable flexible bronchoscope both scored significantly higher than the current single-use flexible bronchoscope in all evaluated performance indicators ($P < .001$) (Fig. 1). The H-SteriScope did not score differently than the current reusable flexible bronchoscope in terms of maneuverability ($P = .86$). This suggests that the perception of maneuverability for the H-SteriScope is similar to that of current reusable flexible bronchoscopes.

We analyzed the subgroup data (ie, the overall assessment index) to evaluate the difference between perceptions of attendings and fellows for the 3 types of flexible

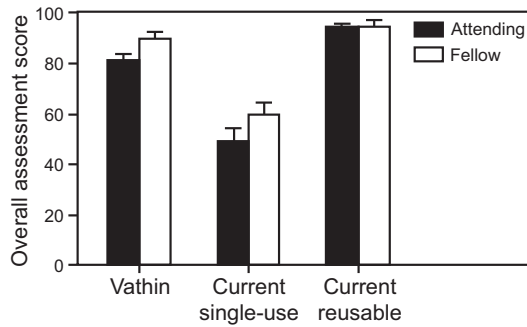


Fig. 2. Overall assessment score of the Vathin H-SteriScope, the current single-use flexible bronchoscope, and the reusable flexible bronchoscope from the attending group and the fellow group.

bronchoscopes. The mean score of the attending group ($n = 20$) was 80.95 for the H-SteriScope, 94.50 for current reusable flexible bronchoscopes, and 49.50 for current single-use flexible bronchoscopes. With fellows group ($n = 6$), the mean scores were 90.00 for the H-SteriScope, 94.16 for current reusable flexible bronchoscopes, and 60.00 for current single-use flexible bronchoscopes.

We did not analyze the data between these 2 groups given the small number of respondents in the fellow group; however, the scores for the H-SteriScope were similar to those for current reusable flexible bronchoscopes. Moreover, these 2 types of flexible bronchoscopes were both better perceived with the overall assessment score than the current single-use flexible bronchoscopes between in attending and fellow groups (Fig. 2).

Further analysis of the overall assessment scores of the 3 types of flexible bronchoscopes was no significant differences with respect to those who had received interventional pulmonology training ($n = 13, 50%$) and those who did not ($n = 13, 50%$) (Fig. 3).

Discussion

Our results indicate that operator perceptions of the Vathin H-SteriScope flexible bronchoscope were better in terms of the interaction between scope and tools and in terms of maneuverability than the current single-use flexible bronchoscope ($P < .001$), and that there was no significant difference in terms of maneuverability between the H-SteriScope and reusable flexible bronchoscopes ($P = .86$). With regard to the optical systems, the depths of field for the H-SteriScope, the AMBU aScope, and the Olympus reusable flexible bronchoscope are 3–50 mm, 8–19 mm, and 20–100 mm, respectively. Meanwhile, the fields of view for these flexible bronchoscopes are $110^\circ \pm 5\%$, 85° , and 120° , respectively.

In terms of image quality, we noted significant differences among them ($P < .01$). The H-SteriScope’s tip is

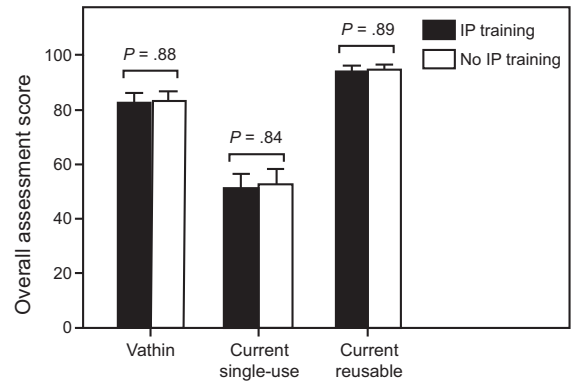


Fig. 3. Overall assessment score of the Vathin H-SteriScope, the current single-use flexible bronchoscope, and the reusable flexible bronchoscope from the IP training and no IP training group. IP = interventional pulmonology.

equipped with an advanced, high-quality camera system with an integrated LED light, which allows for high-definition image capture in the airway. Our respondents noted that their overall assessment of the H-SteriScope was much better than the current single-use flexible bronchoscope.

Based on its technical characteristics, the H-SteriScope represents a valid choice for clinicians who desire a single-use flexible bronchoscope with maneuverability similar to that of a reusable flexible bronchoscope. Table 5 compares different features of the single-use H-SteriScope, the single-use AMBU aScope, and the reusable Olympus flexible bronchoscope. Based on the technical parameters, the H-SteriScope has preferable characteristics that are not available in the current single-use bronchoscope market.

The H-SteriScope is available in a variety of outer diameter sizes (2.2–6.2 mm) and working channel sizes (1.2–3.2 mm) (Fig. 4). The H-SteriScope has the largest working channel (ie, 3.2 mm) among all currently available single-use flexible bronchoscopes. Comparing the H-SteriScope and the aScope single-use flexible bronchoscopes, our data suggest that there is a significant difference that could be explained by the devices’ technical parameters (Table 5). In terms of bronchoscopic deflection, the H-SteriScope has a $210^\circ/210^\circ$ up/down bending radius, and it can be also rotated left or right up to 90° . This design gives users a unique navigation and viewing range for diagnostic examination. Comparatively, to date, AMBU aScope flexible bronchoscope does not have a rotary function, while the Olympus reusable flexible bronchoscope has $180\text{--}210^\circ/210^\circ$ up/down range and left/right rotation up to 120° (Table 5).

Thus far, single-use bronchoscopes have been evaluated in several clinical settings with management of difficult airways,^{7,8} tracheostomy,⁹ intubation,¹⁰ suction,^{11,12} and applications in ICU.¹³ Bronchoscope-related infections present a serious clinical outcome, including multi-drug-resistant *P.*

OPERATOR PERCEPTION OF A SINGLE-USE FLEXIBLE BRONCHOSCOPE

Table 5. Technical Features of Single-Use and Reusable Bronchoscopes

	Insertion Tube OD, mm	Distal End OD, mm	Working Channel ID (mm)	Bending (up/down)	Rotary Function (left/right)	Working Length, mm	Depth of Field, mm	Field of View
Vathin H-SteriScope	2.2–6.2	2.2–6.2	1.2–3.2	210°/210°	90°/90°	600	3–50	110° ± 5%
AMBU aScope	3.8–5.8	4.2–6.2	1.2–2.8	180°/160–180°	NA	600	8–19	85°
Olympus reusable	2.8–6.0	3.0–6.2	1.2–2.8	180–210°/130°	120°/120°	600	20–100	120°

OD = outer diameter; ID = inner diameter; NA = not applicable.

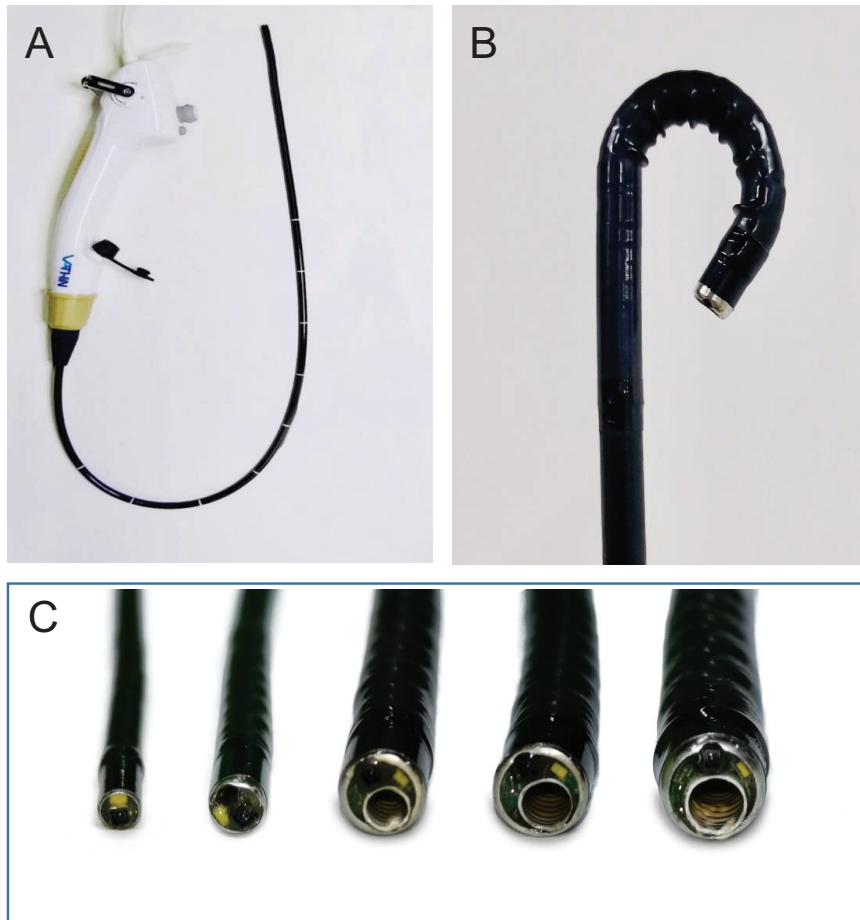


Fig. 4. A: Vathin H-SteriScope. B: Maximum flexion angle of the H-SteriScope. C: Different sizes of Vathin H-SteriScope.

aeruginosa and carbapenem-resistant *Klebsiella pneumoniae* (*K. pneumoniae*).^{14,15} Mankikian et al¹¹ carried out a satisfaction questionnaire after using a single-use flexible bronchoscope for bronchoalveolar lavage (BAL) in the ICU with the following results: “acceptable” to “very good” for quality of aspiration, maneuverability, and quality of vision; and “very good” to “perfect” for setting up and insertion. The authors suggested that a single-use flexible bronchoscope may obviate the need for disinfection procedures and thereby eradicate potential cross-

contamination among ICU patients. In that study, there may have been several bronchoscopic procedures performed in a single ICU patient within 6 h using the same disposable flexible bronchoscope. Is it a reasonable strategy to re-use a disposable flexible bronchoscope with a single patient? McGrath et al¹⁶ reported that there was clinically important bacterial growth despite standard cleaning in disposable flexible bronchoscopes. As such, the authors suggested that the AMBU aScope flexible bronchoscope should not be re-used on the same ICU patient. In terms of

suction, Zaidi et al¹² performed a comparative study between single-use and conventional flexible bronchoscopes for BAL. With single-use bronchoscopes, the authors achieved a larger BAL volume yield than with conventional bronchoscopes, with comparable cell yield and viability.¹²

In terms of the cost of single-use flexible bronchoscopes, few studies had been performed. McCahon and Whynes⁶ reported potential savings of up to one third of total costs with single-use AMBU aScope bronchoscopes compared to reusable fiberscopes with a fiberoptic intubation (\$260 vs \$430 per use) in a large hospital in the United Kingdom. Aïssou et al¹⁷ analyzed acquisition and maintenance costs between 2006 and 2012 in France for reusable (Pentax) and single-use fiberscope (AMBU aScope), noting that total costs were \$20,379 and \$5,410, respectively (the cost of each single-use fiberscope was \$221).¹⁷ Edenharter et al¹⁸ described optimizing the cost efficiency of reusable and single-use bronchoscopy through mathematical modeling. The cost of parameters for economic analysis indicated that the purchases of reusable and single-use bronchoscope were \$10,752.50 and \$258.06, respectively. The annual cost of maintenance and repair for the reusable bronchoscope was \$3,225.75, whereas the cost of reprocessing per bronchoscopy was \$29.03. In 2017, Terjesen et al¹⁹ conducted an early cost-effectiveness analysis of single-use flexible bronchoscopes compared with the current reusable flexible bronchoscopes in a U.S. hospital intensive care setting. The authors noted a savings of \$118 per procedure as well as the elimination of 0.7% of the risk of infection with the single-use technology. Other studies, however, report variations between the costs of disposable and reusable bronchoscopes. Perbet et al²⁰ reported that the cost of BAL and percutaneous tracheostomy in the ICU with single-use flexible bronchoscopes was not superior to the cost with reusable flexible bronchoscopes in terms of the frequency of procedures and the number of bronchoscopes needed.

Our survey has several limitations. First, the evaluation is based on the bronchoscopy model on site, thus it does not accurately reflect the true experiences in patients compared to current disposable and conventional flexible bronchoscopes. Another major limitation of our survey was the small number of respondents and the potential sampling bias. Of the 26 respondents, only 6 respondents are fellows. Respondents were self-selected individuals who were attending the AABIP conference and thus may not be representative of practicing bronchoscopists as a whole. Lastly, there are inherent limitations to survey studies, and this study does not allow for clinical comparison of the single-use H-SteriScope with single-use flexible bronchoscopes and reusable flexible bronchoscopes currently in use.

Conclusions

To our knowledge, our survey study is the first to evaluate operator perceptions of the single-use H-SteriScope in comparison with another current single-use flexible bronchoscope and common reusable flexible bronchoscopes. Based on our data, the H-SteriScope may have advantages over the current single-use flexible bronchoscopes in terms of scope quality, imaging quality, maneuverability, handling, tool interaction, and overall assessment. More studies are needed to evaluate the H-SteriScope's functionality, safety, and cost efficiency in the future.

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OPERATOR PERCEPTION OF A SINGLE-USE FLEXIBLE BRONCHOSCOPE

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