Role of single-use flexible bronchoscopes

Shreya Podder[1], Octavio Perez[2], William Kivlin[2], Harpreet Singh[1], Bryan S. Benn[3], Jonathan S. Kurman[1]

[1]Division of Pulmonary & Critical Care, Medical College of Wisconsin, Milwaukee, WI, USA; [2]Division of Medicine, Medical College of Wisconsin, Milwaukee, WI, USA; [3]Pulmonary Department, Respiratory Institute, Cleveland Clinic, Cleveland, OH, USA

Correspondence to: Shreya Podder, MD. Pulmonary and Critical Care Fellow, Division of Pulmonary & Critical Care, Medical College of Wisconsin, 8701 W, Watertown Plank Rd, Milwaukee, WI 53226, USA. Email: spodder@mcw.edu.

Keywords: Single-use flexible bronchoscopes (SUFB); reusable flexible bronchoscope (RFB); advanced bronchoscopy

Received: 12 September 2023; Accepted: 02 February 2024; Published online: 19 April 2024.

doi: 10.21037/amj-23-178

View this article at: https://dx.doi.org/10.21037/amj-23-178

Introduction

The development of the first reusable flexible bronchoscope (RFB) in 1967 by Dr. Ikeda was a ground-breaking achievement (1). This invention facilitated a myriad diagnostic and therapeutic procedures to be performed to treat diseases of the airway and lung parenchyma. After decades of use, limitations of RFB have been identified, including the potential for cross-contamination, cost effectiveness and resource utilization (2-4). Unlike RFB, single-use flexible bronchoscopes (SUFB) come pre-sterilized and are intended for a single patient, eliminating the risk of cross-contamination and infection that can arise from inadequate reprocessing of RFB. Although SUFB may appear to incur higher cumulative costs over time, they are typically more cost effective when considering expenses associated with scope reprocessing, scope maintenance and treatment of iatrogenic infections. In addition, in times of staff shortage, the time spent on maintaining these scopes can be saved and used elsewhere. SUFB have been available for more than a decade, with the first product, the Ambu aScope (AMBU, Copenhagen, Denmark), introduced in 2009. More recently, SUFB garnered attention from professional pulmonary societies during the coronavirus disease 2019 (COVID-19) pandemic given the risk of viral transmission with RFB (5).

Despite its use in the intensive care unit or in the peri-operative setting by anesthesia, SUFB has not gained widespread acceptance within the bronchoscopy suite. Barriers to adoption in the bronchoscopy suite may be due in part to the lack of comparative studies demonstrating the equivalent performance of SUFB to RFB in advanced bronchoscopic procedures. In this review, we will summarize the current literature to discuss the advantages and disadvantages of using SUFBs and its implications in advanced procedures.

Infection control

Minimizing the risk of infection transmission and cross-contamination are important considerations when discussing SUFB and RFB. Since SUFB are delivered in a sterile manner, the risk of transmission and contamination due to its single-use nature is minimized. In contrast, RFB require appropriate cleaning, disinfection, leak testing, and drying that place it at risk for contamination, even when performed correctly. Organisms that are commonly identified in transmission of infections by bronchoscopy include *M. tuberculosis*, atypical mycobacteria, and *Pseudomonas* species (6). Despite well-controlled disinfection procedures, endogenous infections associated with bronchoscopy persist (7). Transmission can occur from previous patients or contaminated reprocessing equipment like RFB and their accessories. Strict endoscope disinfection procedures are crucial to prevent exogenous infections (8,9). Reprocessing RFB involves a multistep procedure, including manual cleaning, high-level disinfection (HLD) using automated endoscope reprocessors (AER), or sterilization with ethylene oxide (EO) or hydrogen peroxide (H_2O_2) plasma. Inadequate reprocessing, contaminated AER or malfunctioning RFB have been associated with infectious outbreaks following flexible bronchoscopy (10,11).

In a multi-centered prospective study, Ofstead and colleagues reported residual proteins and infectious

pathogens on fully reprocessed RFB that were ready for patient use despite complete adherence to HLD and reprocessing procedures (12). A recent systematic review by Travis *et al.* reported an estimated total cross-contamination rate of 8.69% for RFB that included a standardized threshold based on a well-established endoscopy surveillance-testing guideline (3). These data indicate that RFB cross-contamination rates remain high even though continuous improvements in reprocessing techniques and guidelines have occurred with more stringent reprocessing and sterilization requirements.

Reprocessing aims to stop the transmission of exogenous infection to the patient. However, flexible bronchoscopes, which are characterized by complex structures with narrow internal channels, are prone to heavy contamination during use. Cleaning and disinfecting these instruments can pose a significant challenge due to their intricate design (8,13). The narrow lumens of flexible bronchoscopes, cleaned without direct visualization, make it difficult to disinfect small scratches, facilitating bacterial adhesion and potential biofilm formation (14,15). Biofilms are characterized by microbial cells attached to surfaces and enclosed in a matrix of exopolymeric substances, are resistant to disinfectants and antibiotics, making them challenging to remove (16). The persistence of these biofilms can lead to reprocessing failures and outbreaks of bronchoscopic-related infections (14,15,17,18). Nevertheless, the major recommendations from the various guidelines (19-21) regarding the appropriate reprocessing of RFB are the same. Sterilization can be done, but the chemicals used, either EO or H_2O_2, are expensive and interfere with the mechanical properties of flexible bronchoscopes (20,21). In contrast, SUFB do not require any reprocessing after use, thus eliminating the need for further resources and personnel for reprocessing.

It is important to note that SUFB are not designed to tolerate the same decontamination process as RFB and standard hospital cleaning processes may not be adequate for infection control. A study by McGrath *et al.* showed that prolonged bedside storage of SUFB after initial use followed by flushing the working channel with saline and external decontamination still resulted in microbiological growth of organisms that can cause pneumonia (22). Thus, SUFB should be treated as single use devices not intended for multiple uses on a single patient.

Workflow and flexibility

Another benefit of SUFBs includes the ability to streamline workflow. Utilizing SUFB in institutions in which bronchoscopy carts and towers are limited allows for parallel as opposed to linear use. This approach can decrease delays between procedures and increase the number of bronchoscopies that can be performed (23), which may lead to improved access to care for patients.

Cost analysis of SUFB *vs.* RFB

Numerous studies have suggested that SUFB may offer better cost-effectiveness in the intensive care unit and bronchoscopy suite compared to RFB. These studies indicate that usage is linked to fewer instances of cross-contamination and bronchoscopy-related infections, resulting in potential cost savings from reduced infection-related expenses (24,25). One notable advantage of SUFB is their one-time use design, eliminating the need for reprocessing after each procedure, leading to lower cleaning and storage costs compared to RFB (23). It is important to note that the methodology used to calculate the cost differences varied greatly amongst studies.

In a systematic review, the cost of savings associated with use of SUFB compared to RFB was on average 157 United States Dollars (USD) per percutaneous dilatational tracheostomy (PDT) (26). However, RFB repair rates were also higher in PDT procedures compared to other bronchoscopic procedures, so the cost savings of SUFB utilization may vary based on the type of bronchoscopic procedure performed. A meta-analysis looking at the cost effectiveness of SUFB compared to RFB showed that when assuming equal clinical performance, SUFB demonstrated dominance over RFB as each procedure was associated with an incremental saving of 63 USD in American bronchoscopy suites, but the amount of savings was contingent upon individual hospitals' bronchoscopy suite setup, annual procedure volume, and SUFB cost (4). However, these cost-saving benefits may not be apparent in institutions with high volume bronchoscopic procedures. In a single French hospital performing more than 1,500 bronchoscopic procedures annually, found that using SUFB cost 154 Euro (EUR) more than RFB per procedure (27). The authors noted that the high procedure volume as well as having a centralized and automated washing unit helped reduced cost of RFB (27). Other hospitals may have individual units manually carry out the washing which may add to the cost of RFB. Recent studies have found that the break even point of SUFB and RFB to vary, with one study citing 306 annual procedures per site (28) and another study suggesting 756

procedures per year (4). These estimations allow individual hospitals to assess the cost advantages of RFB or SUFB based on factors such as size and procedure volume (4,28).

Environmental impact of using SUFB *vs.* RFB

It is a common misconception that SUFB produce more environmental waste than RFB. To determine the environmental impact of SUFB and RFB, life cycle analysis (LCA) needs to be performed (29). LCA involves evaluating how products impact the environment throughout their production, use and end-of-life phases (29). The production stage often has a more significant environmental footprint than other phases, with raw material for complex devices like bronchoscopes sourced globally, manufactured in different locations, and distributed to end-users (29). Transportation emissions vary based on production and destination locations, transportation methods and energy sources (29). A single-centered prospective observational study aimed to quantify the impact on waste mass production, energy consumption and recyclability of bronchoscopic procedures found that single-use instruments generated nearly twofold more recyclable waste than reusable instruments, but the latter constituted a higher portion of waste generated during the reprocessing phase (30).

A comparative study from the University of Southern Denmark assessed various factors including energy consumption, emission of CO_2-equivalent, and consumption of scarce resources for SUFB and RFB (31). The authors demonstrated that RFB had comparable or higher material and energy consumption, including higher emissions of CO_2-equivalents and values of resource consumptions (31). The factors with the greatest contribution to environmental detriment were the cleaning and drying demand of RFB (31). Repeated washing is required if a bronchoscope is unused for 72 hours (31). Though the environmental assessment is complex, further research optimizing the cleaning and drying portion of RFB could improve its significant environmental impact.

Comparison of clinical performance of SUFB *vs.* RFB

Since 2018, there has been a proliferation of SUFB from different manufacturers. This latest generation of SUFB may be suitable for advanced bronchoscopic or interventional pulmonology procedures. In 2020, Liu *et al.* compared the performance of H-SteriScope (Vathin Medical Instrument Co. Ltd., Hunan, China) against the current SUFB and RFB based on operators' perceptions (32). This comparative study was the first of its kind, evaluating multiple aspects of the SUFB, including scope quality, handling, maneuverability, tool interaction, and image quality. The H-SteriScope performed better in all categories compared to previous generation SUFB and appeared to have similar maneuverability as RFB, with operators favoring the single use device (32). More than half of the respondents did feel that RFB provided better image quality than SUFB (32). It is important to note that the majority of current SUFB on the market were not available at the time of this study.

In another single center study, nine physicians were surveyed on their perception of multiple SUFB, including the H-SteriScope Normal (Olympus America, CO, USA), Ambu aScope 4 (AMBU Inc., MD, USA), Verathon GlideScope BFlex (Verathon Inc., WA, USA), compared to the reusable Olympus EVIS EXERA III BF-H190 (Olympus America, CO, USA) (32). Although no SUFB was preferred over this RFB, the H-SteriScope was rated highest among other SUFB in terms of maneuverability into difficult airway segments both with and without a tool in the working channel (33). This finding is of particular interest to interventionalists as this could mean decreased deflection when the target lesion is more distal or apical.

In 2022, the first study highlighting the technical performance of the new SUFB was completed at two US sites with simulated bronchoscopy tasks (34). Fifteen physicians from various specialty backgrounds and levels of training were asked to complete three bronchoscopic tasks (water suction and visualization, "mucus" mass suctioned in 30 seconds and "mucus" plug suction) using each of the three sizes of SUFB from the EXALT Model B (Boston Scientific Coporation, Marlborough, Massachusetts, USA) Ambu aScope4 (AMBUR, Ballerup, Denmark) lines (34). In comparison of scopes with the same outer diameter, the EXALT Model B outperformed Ambu aScope 4 in aspirated mean mass by weight of water and "mucus" (34). Another study comparing the interaction of SUFB with biopsy tools such as forceps and aspiration needles and adjunct tools like dilation balloons, argon plasma coagulation catheters, cryoprobes, bronchial thermoplasty catheters, and endobronchial valve catheters to their RFB counterparts found that the newer generations of SUFB were comparable or even superior to RFB (35). Our institution has used the Ambu aScope 5 to perform some advanced bronchoscopic procedures such as evaluation of endobronchial valve

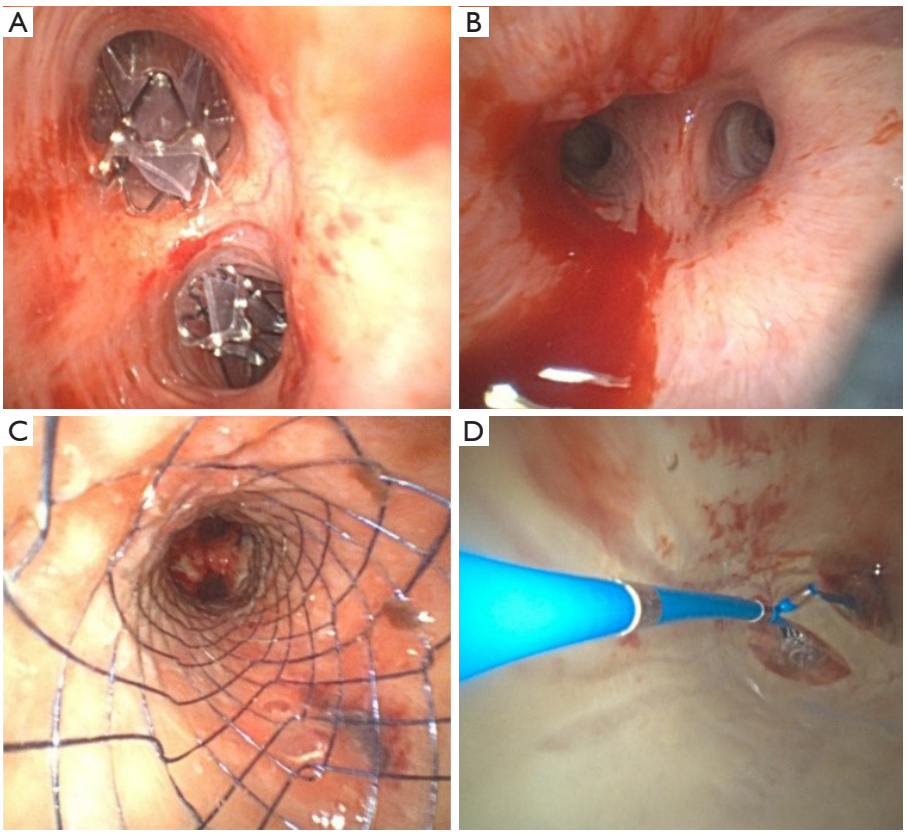

Figure 1 Endoscopic images using Ambu aScope 5 in patients. (A) Endoscopic view of endobronchial valves; (B) endoscopic view of airway bleeding; (C) endoscopic view of metallic airway stent; (D) endoscopic view of airway through inflated balloon.

placement, airway stents, bleeding, and airway balloon dilation (see *Figure 1*).

These studies have several inherent limitations. First, the evaluation of SUFB were completed on model airways or cadavers. *In vivo* experience could be divergent. Additionally, while these models simulate bronchoscopy completed under general anesthesia, it did not simulate bronchoscopy in patients who are under light or moderate sedation and may be coughing. Second, most of these studies were non-blinded, completed at single-centers, and involved surveying a small number of respondents, which could lead to sampling bias. Respondents tended to be self-selected individuals and may not be representative of all practicing bronchoscopists. Recently, a prospective, controlled study was published comparing the performance of SUFB in transbronchial biopsies and bronchoalveolar lavage (BAL) and found that SUFB are non-inferior to RFB in these procedures (36). Additional studies are needed to further substantiate these findings.

Conclusions

SUFB offers distinct advantages over RFB. These benefits include portability, immediate availability, reduction in iatrogenic infections, and improved flexion/extension. Despite these advantages, familiarity with RFB has helped maintain its position as the default option for more complex bronchoscopic procedures such as 185 management of hemoptysis, tracheal stenosis, endobronchial obstruction, and staging and diagnosis of lung malignancy. Based on growing evidence and experience, the latest generation of SUFB can be safely and effectively used for advanced bronchoscopic procedures, beyond traditional therapeutic mucous aspiration, bronchoalveolar lavage, and transbronchial biopsy. Further research is required to substantiate this experience.

Acknowledgments

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the editorial office, *AME Medical Journal* for the series "Diagnostic & Therapeutic Bronchoscopy". The article has undergone external peer review.

Peer Review File: Available at https://amj.amegroups.com/article/view/10.21037/amj-23-178/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://amj.amegroups.com/article/view/10.21037/amj-23-178/coif). The series "Diagnostic & Therapeutic Bronchoscopy" was commissioned by the editorial office without any funding or sponsorship. B.S.B. and J.S.K. served as the unpaid Guest Editors of the series. The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

References

1. Miyazawa T. History of the flexible bronchoscope. In: Bolliger CT, Mathur PN. editors. Progress in respiration research, Vol. 30: Interventional bronchoscopy. Basel, Switzerland: Karger; 2000:16-21.
2. Ho E, Wagh A, Hogarth K, et al. Single-Use and Reusable Flexible Bronchoscopes in Pulmonary and Critical Care Medicine. Diagnostics (Basel) 2022;12:174.
3. Travis HS, Russell RV, Kovaleva J. Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. J Infect Prev 2023;24:95-102.
4. Kristensen AE, Kurman JS, Hogarth DK, et al. Systematic Review and Cost-Consequence Analysis of Ambu aScope 5 Broncho Compared with Reusable Flexible Bronchoscopes: Insights from Two US University Hospitals and an Academic Institution. Pharmacoecon Open 2023;7:665-78.
5. Barron S, Kennedy MP. Single-use Bronchoscopes: Applications in COVID-19 Pandemic. J Bronchology Interv Pulmonol 2021;28:e3-4.
6. Spach DH, Silverstein FE, Stamm WE. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. Ann Intern Med 1993;118:117-28.
7. Srinivasan A. Epidemiology and Prevention of Infections Related to Endoscopy. Curr Infect Dis Rep 2003;5:467-72.
8. Botana-Rial M, Leiro-Fernández V, Núñez-Delgado M, et al. A Pseudo-Outbreak of Pseudomonas putida and Stenotrophomonas maltophilia in a Bronchoscopy Unit. Respiration 2016;92:274-8.
9. Rutala WA, Weber DJ. Disinfection and Sterilization in Health Care Facilities: An Overview and Current Issues. Infect Dis Clin North Am 2016;30:609-37.
10. Cosgrove SE, Ristaino P, Caston-Gaa A, et al. Caveat emptor: the role of suboptimal bronchoscope repair practices by a third-party vendor in a pseudo-outbreak of pseudomonas in bronchoalveolar lavage specimens. Infect Control Hosp Epidemiol 2012;33:224-9.
11. Peaper DR, Havill NL, Aniskiewicz M, et al. Pseudo-outbreak of Actinomyces graevenitzii associated with bronchoscopy. J Clin Microbiol 2015;53:113-7.
12. Ofstead CL, Quick MR, Wetzler HP, et al. Effectiveness of Reprocessing for Flexible Bronchoscopes and Endobronchial Ultrasound Bronchoscopes. Chest 2018;154:1024-34.
13. Beilenhoff U, Neumann CS, Rey JF, et al. ESGE-ESGENA guideline for quality assurance in reprocessing: microbiological surveillance testing in endoscopy. Endoscopy 2007;39:175-81.
14. Kovaleva J, Meessen NE, Peters FT, et al. Is bacteriologic surveillance in endoscope reprocessing stringent enough? Endoscopy 2009;41:913-6.
15. Pajkos A, Vickery K, Cossart Y. Is biofilm accumulation on endoscope tubing a contributor to the failure of cleaning and decontamination? J Hosp Infect 2004;58:224-9.
16. Donlan RM, Costerton JW. Biofilms: survival mechanisms of clinically relevant microorganisms. Clin Microbiol Rev 2002;15:167-93.

17. Einav S, Wiener-Well Y. Anesthesia in patients with infectious disease caused by multi-drug resistant bacteria. Curr Opin Anaesthesiol 2017;30:426-34.
18. Kenters N, Huijskens EG, Meier C, et al. Infectious diseases linked to cross-contamination of flexible endoscopes. Endosc Int Open 2015;3:E259-65.
19. Culver DA, Gordon SM, Mehta AC. Infection control in the bronchoscopy suite: a review of outbreaks and guidelines for prevention. Am J Respir Crit Care Med 2003;167:1050-6.
20. Ethylene Oxide Sterilization | Disinfection & Sterilization Guidelines | Guidelines Library | Infection Control | CDC. Available online: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/ethylene-oxide.html
21. Sterilization for Medical Devices. FDA. Available online: https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices
22. McGrath BA, Ruane S, McKenna J, et al. Contamination of single-use bronchoscopes in critically ill patients. Anaesthesia 2017;72:36-41.
23. Barron SP, Kennedy MP. Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy? Adv Ther 2020;37:4538-48.
24. Mouritsen JM, Ehlers L, Kovaleva J, et al. A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. Anaesthesia 2020;75:529-40.
25. Terjesen CL, Kovaleva J, Ehlers L. Early Assessment of the Likely Cost Effectiveness of Single-Use Flexible Video Bronchoscopes. Pharmacoecon Open 2017;1:133-41.
26. Sohrt A, Ehlers L, Udsen FW, et al. Cost Comparison of Single-Use Versus Reusable Bronchoscopes Used for Percutaneous Dilatational Tracheostomy. Pharmacoecon Open 2019;3:189-95.
27. Châteauvieux C, Farah L, Guérot E, et al. Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. J Eval Clin Pract 2018;24:528-35.
28. Andersen CØ, Travis H, Dehlholm-Lambertsen E, et al. The Cost of Flexible Bronchoscopes: A Systematic Review and Meta-analysis. Pharmacoecon Open 2022;6:787-97.
29. Kumar V, Gaurav G, Khan V, Choudhary S, Dangayach GS. Life cycle assessment and its application in medical waste disposal. Materials Today: Proceedings. 2023. doi: 10.1016/j.matpr.2022.12.255.
30. Patrucco F, Gavelli F, Balbo PE. Environmental Impact of Bronchoscopy: Analysis of Waste Mass and Recyclability of Bronchoscopic Equipment and Consumables. Respiration 2023;102:905-11.
31. Lilholt Sørensen B. Comparative Study on Environmental Impacts of Reusable and Single-Use Bronchoscopes. American Journal of Environmental Protection 2018;7:55.
32. Liu L, Wahidi M, Mahmood K, et al. Operator Perception of a Single-Use Flexible Bronchoscope: Comparison With Current Standard Bronchoscopes. Respir Care 2020;65:1655-62.
33. Darrell N, Grant S, Abdurrahman H, et al. Operator Perception of The Performance of Multiple Single-Use Bronchoscopes Compared to Standard Re-Usable Bronchoscope. Am J Biomed Sci Res 2022;17:191-7.
34. Lamb CR, Yavarovich E, Kang V, et al. Performance of a new single-use bronchoscope versus a marketed single-use comparator: a bench study. BMC Pulm Med 2022;22:189.
35. Kurman J, Wagh A, Benn B, et al. Large Capacity 2.8mm Forceps A Comparison of Single-Use Bronchoscopes and Reusable Bronchoscopes for Interventional Pulmonology Applications.
36. He S, Xie L, Liu J, et al. Single-use flexible bronchoscopes vs traditional reusable flexible bronchoscopes: a prospective controlled study. BMC Pulm Med 2023;23:202.

doi: 10.21037/amj-23-178
Cite this article as: Podder S, Perez O, Kivlin W, Singh H, Benn BS, Kurman JS. Role of single-use flexible bronchoscopes. AME Med J 2024.