USE OF STERILE, SINGLE-USE BRONCHOSCOPES REDUCES PROCEDURE-ASSOCIATED READMISSIONS RATES AND ELIMINATES POTENTIAL DEVICE CROSS-CONTAMINATION

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PURPOSE AND BACKGROUND

Improper reprocessing of reusable bronchoscopes poses a serious patient safety and infection risk. The risk of patient infection resulting from use of contaminated bronchoscopes has been reported to be 2.8%. Recently, medical device manufacturers have introduced single-use flexible bronchoscopes (SFB) as an alternative to reusable flexible bronchoscopes (RFB). By virtue of being sterile, SFB may reduce the infection risk, subsequent readmission rates, and associated costs while enhancing operational efficiency. This study aimed to evaluate the differences between reusable bronchoscopes and sterile, single-use bronchoscopes in terms of 30-Day Readmissions. Readmissions following bronchoscopy may occur for many reasons, but most frequently are due to infection, bleeding, or pain. Each of these causes of readmissions increases cost and associated mortality and morbidity. Recent safety alerts from the United States Food and Drug Administration and analysis of MAUDE reports have demonstrated cross-contamination with reusable bronchoscopes to be a patient safety risk that could lead to the development of a Healthcare-Associated Infections. Reprocessing of reusable bronchoscopes is an error-ridden process due to the presence of humans in the process. These infections are preventable and can be eliminated with the use of a sterile, single-use bronchoscope when the device is used according to the manufacturer's instructions for use.

MATERIALS & METHODS

Bronchoscopies with SFB and RFB were identified along with their corresponding readmission information in the Premier Healthcare Database (PHD) from 2016- 2019. Summary statistics were calculated on readmissions segmented by scope type and clinical setting. A logistic regression analysis was conducted with 30-day readmission as the dependent variable. Independent variables included use of a RFB, gender, race, age, payer, and discharge status. For the inpatient setting, the 3M™ APR DRG Severity of Illness classification was included as an independent variable. This analysis provided a detailed snapshot comparison of the risk of readmissions associated with reusable bronchoscopes compared to that of sterile, single-use bronchoscopes. The sample included both impatient and outpatient clinical settings where bronchoscopy was performed.

30-Day Readmission Data Demographics

	Reusable Device	Sterile, Single-Use Device	Total
Sample Size	12, 433	1,795	14,228
%	87%	13%	

	Inpatient	Outpatient	Total
Clinical Setting	4,827	9,401	14,228
%	34%	66%	

RESULTS

A total of 14,228 procedures were identified, of which 1,795 used SFB and 12,433 used a RFB (9,401 outpatient and 4,827 inpatient). In the inpatient setting, the RFB group was ~2.5 times more likely to be readmitted within 30 days compared to the SFB group (OR=2.5, $p<0.01$), controlling for patient demographics and risk. In the outpatient setting, the RFB group was ~1.5 times more likely to be readmitted than the SFB group (OR=1.5, $p>0.05$). Across all settings, the RFB group was ~2.3 times more likely to be readmitted than the SFB group (OR=2.3, $p<0.01$). The inability to fully risk-adjust in the outpatient setting may have been a factor in the smaller OR and lack of statistical significance; this limitation will be addressed with further analysis that includes an outpatient severity of illness classification variable. The data analysis demonstrates significant clinical benefits of SFB in reducing readmissions and risks.

30-Day Readmission

	Reusable Device	Sterile, Single-Use Device
Inpatient	10%	4%
Outpatient	7%	4.90%
Total	**7.70%**	**3.60%**

30-Day Readmission Odds Ratio Reusable vs. Single-Use

	Inpatient	Outpatient	Total
Sample Size	2.5	1.5	2.3

CONCLUSIONS

The data analysis demonstrates significant clinical benefits of SFB in reducing readmissions and risks. Medical Device Adverse Event Reports continue to be filed with the United States Food and Drug Administration indicating that RFB can serve as a vector for cross contamination and potential device-related infections in patients. Patients undergoing bronchoscopy typically have significant comorbidities which increase their risk for the development of potential device-related infections. To reduce these risks, the use of a sterile SFB should be considered to eliminate reprocessing failures, improve overall operational efficiency, and reduce potential acquisition of healthcare-associated infections. Recent data from FDA 522 studies in the gastrointestinal clinical setting has demonstrated the widespread risks associated with reusable flexible endoscopes. These lessons learned must be adapted to the clinical procedure of bronchoscopy, especially in an era of an ongoing global pandemic.

REFERENCES

Premier Healthcare Database

DISCLOSURES AND AUTHOR CONTACT INFORMATION

Disclosure: Author is an independent consultant for Ambu, Inc. To contact Dr. Garrett: Hudson.garrett@Louisville.edu