

# **Patient's outcomes after endoscopic retrograde cholangiopancreatography (ERCP) using reprocessed duodenoscope accessories: a descriptive study using real-world data**

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## **Background**

The introduction of endoscopic retrograde cholangiopancreatography (ERCP) has had a significant impact on the management and prognosis of patients with biliary and pancreatic diseases.<sup>1-3</sup> The global number of ERCP procedures performed annually is increasing steadily due to the rising prevalence of main indications such as biliary stone disease and malignant biliary obstruction, as well as the ageing population and expanding therapeutic applications.<sup>1-3</sup> However, outbreaks of duodenoscope-related and duodenoscope accessories-related infection involving multidrug-resistant organisms have raised major concerns regarding the current standards of care and reprocessing methods.<sup>4,5</sup> In order to address this challenge, the adoption of single-use duodenoscopes accessories has emerged as a promising initiative aimed at eliminating the risk of this device-related infections.<sup>6-8</sup> In addition to the reduced risk of cross-patient infection, single-use duodenoscopes accessories showed equivalent technical performance when compared to reusable devices.<sup>6-8</sup> Moreover, disposable duodenoscopes accessories might also be cost-effective due to the removal of manual labor and reprocessing costs, elimination of reusable duodenoscope and accessories repairs, and reduction of costs related to complication rates.<sup>6-8</sup> On the other hand, concerns related to single-use duodenoscopes and their accessories such as safety, image quality, and environmental impact have been debated.<sup>8</sup> Importantly, findings derived from a limited number of patients in studies conducted by expert endoscopists may not apply to endoscopists with different levels of experience in a real-life context.<sup>8,9</sup> The use of real-world data provides insights into how medical devices are used in clinical practice, including off-label use, variations in treatment approaches, and the impact of device selection on patient outcomes.<sup>10</sup> Using Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) harmonized data from a Brazilian administrative dataset, we aimed: (i) to compare the percentage of readmissions post-ERCP in institutions that use single-use (referred as "Single-use group - SUG") and non-single-use (referred as "Non-single-use group - NSUG") ERCP materials.

## **Methods**

**Data source:** In Brazil, the national administrative database is referred to as DATASUS and is publicly available through the Brazilian Ministry of Health website.<sup>11</sup> The DATASUS databases used were the Hospital Information System ([Sistema de Informação Hospitalar] – SIH) and the Ambulatory Information System ([Sistema de Informação Ambulatorial] – SIA). A deterministic linkage algorithm was developed to connect hospitals with outpatient records using the key information of zip code, date of birth, and gender. Details about the methods to generate this dataset can be found in poster number 16 in this symposium. All datasets were mapped to the OMOP CDM v 5.4

**Study design:** an observational retrospective cohort.

**Inclusion and exclusion criteria and identification of ERCP procedure:** The study period included events from January 2020 to January 2023. We included patients with no history of cancer who underwent ERCP. Exclusion criteria included having a history of cancer or undergoing the ERCP procedure due to sepsis, acute pancreatitis, or cholangitis. Readmission post-ERCP is defined in this study as hospitalization that

occurred within 30 days after a patient's ERCP, with the conditions for readmission including sepsis, acute pancreatitis, or cholangitis. ERCP was identified by a specific SUS coding system, named Table of the Procedure, Medication, Orthotics, Prosthetics, and Special Materials Management System of the SUS ([*Tabela do Sistema de Gerenciamento de Procedimentos, Medicamentos, Órteses, Próteses e Materiais Especiais do SUS*] - SIGTAP), using the codes '0407030255', '0209010010'.<sup>12</sup> The identification of hospitals that utilized reprocessed duodenoscopes accessories for the ERCP procedure was conducted in collaboration with Boston Scientific Company. The purchase of medical equipment in the SUS is done through public tenders. We compared the number of ERCP procedures performed in hospitals using the DATASUS dataset with the number of duodenoscopes accessories supplied by Boston Scientific through the won tenders. In other words, the reprocessing of the device materials was determined if the number of procedures exceeded the number of devices supplied by Boston Scientific.

Statistical analysis: The analysis was conducted in ATLAS.

## Results

The number and locations of the institutions belonging to the SUG and NSUG groups are heterogeneous and unbalanced. The SUG group included a total of 3 hospitals, one institution from the Northeast and two from the Midwest of Brazil. The NSUG group included a total of 15 hospitals, twelve institutions from the Northeast, two from the North, and one from the Southeast of Brazil. Table 1 presents the number and characteristics of SUG and NSUG group. In the SUG group, there were 69 ERCP events, with a readmission rate of 2.9%. In the NSUG group, there were 887 ERCP events, resulting in a readmission rate of 4.8%, which is approximately 65% higher than that of the SUG group. In comparison to the readmitted patients from SUG, the readmitted patients from NSUG had a higher proportion of female individuals and patients with a lower mean age.

Table 1. Descriptive information of total and readmitted patients in SUG and NSUG groups

	SUG		NSUG	
	Total	Readmitted patients	Total	Readmitted patients
N	669	20	887	43
Male (%)	30.9	50.0	34.0	37.0
Mean age (SD)	55.0 (19.0)	55.0 (17.9)	55.0 (19.0)	51.0 (14.9)

Note. SUG – single-use group; NSUG – non-single-use group; SD – standard deviation;

Readmitted patients included patients who were hospitalized within 30 days after a patient's ERCP due to sepsis, acute pancreatitis, or cholangitis.

## Conclusion

This descriptive study utilized real-world data from Brazilian administrative datasets to evaluate patient outcomes after the reprocessing of duodenoscopes materials for ERCP procedures. We found a greater proportion of readmission of patients following ERCP procedures in the NSUG institutions compared to those observed in the SUG institutions. The findings shed light on the use of this dataset and its potential in assessing the effectiveness and risks of reprocessed duodenoscopes accessories in a clinical setting

The limitations of this study include the unbalance between the number and geographical distribution of SUG and NSUG institutions, which introduces bias and limits the generalization of the findings in a country-level. In addition, this is a descriptive study and no adjustment for variables related to readmission were conducted. Given these results, there is a clear need for a subsequent estimation study to assess and compare outcomes between institutions adjusting for potential confounders and unbalanced data. This

forthcoming research phase will play a vital role in acquiring deeper insights and enhancing our understanding of the implications of material reprocessing and the adoption of disposable accessories within medical facilities. Through this inferential study, we can obtain more comprehensive data to inform clinical decision-making and establish optimal practices for ERCP management, thereby ensuring safer and more effective outcomes for patients.

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