

The economic burden of post-endoscopic retrograde cholangiopancreatography (ERCP) procedure infections in Italy

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ABSTRACT

Introduction: The infections of multidrug-resistant organisms (MDROs) associated with duodenoscopes during endoscopic retrograde cholangiopancreatography (ERCP) procedure have become a significant cause for concern, especially in fragile patients. While the clinical impacts of these infections are well-documented, their economic implications remain underexplored. This study assesses the incidence and economic burden of post-ERCP infections in Italy using an administrative database.

Methods: We conducted a retrospective observational study using administrative databases from A.O.U. Città della Salute e della Scienza di Torino. The study included all patients who underwent their first inpatient ERCP between 2018 and 2021. Infections were identified using ICD-9-CM codes for *Pseudomonas aeruginosa*, *Clostridium difficile*, *Escherichia coli*, *Klebsiella* spp., and *Staphylococcus aureus*. A 1-year follow-up was defined in order to estimate healthcare resource utilization and related costs, including readmissions, drug prescriptions, and outpatient specialist and laboratory services.

Results: The study included 686 inpatient ERCP cases, an overall infection rate of 4.2% was observed. Higher infection rates were observed in women (4.6%), patients over 70 years old (4.6%), emergency admissions (5.1%), and transplant patients (19.1%). The average hospital stay doubled for infected patients (24.3 vs. 11.3 days; $p=0.001$). Post-ERCP infections led to a 28% increase in average costs (€12,256 vs. €9,561; $p=0.048$). With an annual volume of 25,000 ERCP procedures, post-ERCP infections in Italy contribute approximately €2.9 million in additional direct costs per year.

Conclusion: Post-ERCP infections impose substantial financial burdens on the healthcare system, underscoring the critical importance of implementing cost-effective prevention strategies to mitigate this public health threat in Italy.

Keywords: Economic burden, Endoscopic retrograde cholangiopancreatography, Healthcare resource utilization, Multidrug resistant, Post-ERCP infections, Real-world data

Introduction

The endoscopic retrograde cholangiopancreatography (ERCP) is a sophisticated endoscopic procedure and, as such, is burdened by potential complications. These complications are related to risk factors associated with the type of procedure or patient characteristics (age, gender, history of

previous pancreatitis, coagulation abnormalities, concurrent illnesses, etc.). Major adverse events reported in the literature include acute pancreatitis (3.5%, ranging from 1.6% to 15.7%), bleeding (1.3%, ranging from 1.2% to 1.5%), perforation (0.1% to 0.6%), and infections such as cholangitis (1%-2%) and cholecystitis (0.2%-0.5%) (1,2).

Endogenously transmitted infections related to endoscopic procedures are the most common infections involving the patient's intestinal flora. Simultaneously, exogenous transmission of microorganisms to patients undergoing ERCP is correlated with the prevalence of duodenoscope contamination (3). While exogenous infections can theoretically be prevented through effective reprocessing (4,5), a growing number of infection outbreaks associated with

Received: June 29, 2024

Accepted: November 12, 2024

Published online: December 31, 2024

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duodenoscopes have been reported in various healthcare systems (6-10).

Several studies have investigated the risk factors for the occurrence of infections following ERCP and the associated outcomes (11-15). Significant risk factors for the transmission of pathogens include non-compliance with disinfection guidelines, the promotion of biofilm deposition due to complex design and surface defects, and automated endoscope reprocessing. Indeed, a recent meta-analysis highlights that contaminations of reprocessed patient-ready duodenoscopes account for 15.25% (16). The precise risk of a patient contracting an infection from a contaminated endoscope remains uncertain; however, previous duodenoscope-associated outbreaks have shown attack rates ranging from 12% to 41% (17).

In the literature, *Pseudomonas aeruginosa*, along with carbapenem-resistant Enterobacteriaceae (CRE), has been increasingly recognized as the leading cause of infections associated with contaminated duodenoscopes (18-21).

Contaminated duodenoscopes have been reported also in Italy (22). In a recent Italian survey, 36 (69.2%) centers reported at least one episode of duodenoscope-related infection experienced with a variable number of patients per center contaminated during ERCP (23). However, to our knowledge, there are no studies aimed at estimating the economic burden of ERCP and the associated infections in Italy. Thus, this study aimed to fill the gap by assessing the incidence of post-ERCP infections and evaluating their economic burden.

Methods

Data sources

The study was based on data obtained from the administrative databases of the A.O.U. Città della Salute e della Scienza Di Torino. Specifically, the following datasets were made available for the period from January 1, 2018, to June 30, 2022:

1. Hospital Discharge Record (HDR), which records all hospitalizations and includes patient demographic and clinical information. Diagnoses and procedures performed during the hospital stay are classified using the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) system. HDR also includes Diagnosis-Related Group (DRG) information and related charges provided by the Italian National Health System (INHS).
2. Outpatient Specialist Services, which records all outpatient specialist healthcare services, including specialist visits and procedures performed on an outpatient setting, maternal and child health clinic activities, instrumental, diagnostic, and laboratory diagnostic services.
3. Pharmaceutical database, which records pharmaceutical services dispensed directly by the Institution's hospital pharmacy. It collects Anatomical-Therapeutic Chemical (ATC) code, marketing authorization code, number of packages, number of units per package, unit cost per package, and prescription date.

The use of a unique patient identifier code across all databases facilitated electronic linkage between these diverse datasets. To ensure patient privacy and comply with the European General Data Protection Regulation (GDPR) (2016/679), each subject included in the study was assigned an anonymous and unique numeric code. No personally identifiable information related to patients was accessible to the authors.

The study has been notified to and approved by Comitato Etico interaziendale, A.O.U. Città della Salute e della Scienza di Torino – A.O. Ordine Mauriziano di Torino – A.S.L. Città di Torino.

Study design and cohort

This retrospective observational study examines the healthcare costs of patients undergoing ERCP from the perspective of the healthcare system. The eligible population consisted of adult patients who underwent inpatient ERCP procedures with non-disposable duodenoscope. To identify the study population, all acute admissions in ordinary regimen with a discharge date between January 1, 2018, and June 30, 2021, and a primary or secondary procedure of ERCP (ICD-9-CM 51.10) were selected. In cases where a patient had multiple admissions with ERCP procedures during the enrolment period, the first admission in chronological order was selected as the index event.

The selected hospitalizations were stratified based on the presence of infections related to the ERCP procedure. Specifically, the presence of ICD-9-CM codes, listed in the appendix, related to infections caused by *Pseudomonas aeruginosa*, *Clostridium difficile*, *Escherichia coli*, *Klebsiella* spp., and *Staphylococcus aureus* was evaluated in either the primary or secondary diagnosis.

The enrolled patients were followed for a period of 1 year, with the end of the follow-up period set at June 30, 2022. During this time, healthcare resource utilization (HCRU) including readmissions, medication use, and outpatient specialist and laboratory services was estimated.

Specifically, during the follow-up period, all readmissions for reintervention and/or conditions related to the study pathology (see appendix), dispensation of antibiotic and/or anticoagulant medications, and all specialist services related to clinical chemistry laboratory, microbiology and virology, general surgery, gastroenterology, general medicine, and day hospital/day service were selected.

Hospitalizations were valued based on the regional tariffs for hospital services in the Piedmont region, the cost of medications was determined using the regional reimbursement price, and the value of outpatient specialist and laboratory services was calculated using the regional tariffs in effect in the year of service provision.

For each patient, the annual expenditure, including the index hospitalization, readmissions, medication use, and outpatient specialist and laboratory services, was calculated.

The proportions of post-ERCP infections and per-patient expenditure observed in the study population were used to estimate the economic burden of infections and the corresponding 95% confidence interval at the national level. National ERCP procedure volumes were derived from the

“Annual Report on Hospital Activity – year 2019” published by the Ministry of Health (24).

To account for the uncertainty in assuming that the proportion of post-ERCP infections observed in the study sample was representative at the national level, the random error of this proportion was estimated. Subsequently, a bootstrap procedure with 1,000 simulations was applied to calculate the 95% confidence interval for the number of post-ERCP infections at the national level. Additionally, to make the economic estimates more generalizable, the economic burden of post-ERCP infections was estimated using national reimbursement tariffs for hospital and outpatient specialist services, and ex-factory prices net of mandatory discounts for medications.

Statistical analysis

Descriptive analyses were undertaken, summarizing categorical data using numbers and percentages, and continuous data as mean and standard deviation (SD). The crude association between outcomes and study groups was assessed using χ^2 tests for categorical variables, Student’s t-tests for normally distributed data, and Mann-Whitney tests for non-normally distributed data.

All analyses were performed using SAS statistical package, version 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

A total of 853 patients who underwent an ERCP procedure between January 1, 2018, and June 30, 2021, were selected for the study. Among these, 686 (80.4%) were on an inpatient ordinary regimen (66.3% emergency and 33.7%

elective admissions), while 167 (19.6%) were treated in day hospital and, as per the protocol, were excluded from the analysis (Fig. 1).

Of the 686 patients included in the study, 55.4% were male, and the average age was 68.8 years, with a range from 20 to 98 years. Additionally, 9.5% of the patients had acute pancreatitis, 22.0% had or had previously been diagnosed with malignant tumors, 5.7% were undergoing chemotherapy or radiotherapy treatment, and 3.8% consisted of transplant patients (Tab. 1).

Infections related to the ERCP were reported in 4.2% of procedures. A higher proportion was reported for women (4.6% vs. 3.9%), for older patients, although a linear trend was not observed (4.6% for those over 70 years old and 3.6% for under 70), for emergency admissions (5.1% vs. 2.6%), for admissions where there was no diagnosis of acute pancreatitis (4.5% vs. 1.5%), and for transplant patients (19.1%) (Tab. 2).

The average length of hospital stay (LoS) for patients undergoing ERCP procedures was 11.9 days and doubles in the presence of infection (24.3 vs. 11.3; Mann-Whitney test p-value 0.001). Moreover, for patients with post-ERCP infection, there was a higher proportion of readmissions within one year (63.0% vs. 59.1%, chi-square test p-value 0.693) and a greater prescription of antibiotics and/or anticoagulants (44.4% vs. 29.8%, chi-square test p-value 0.106), although not statistically significant. The proportions of patients receiving at least one outpatient specialist service were similar (51.9% vs. 53.8%, chi-square test p-value 0.844) (Tab. 3).

The average expenditure per patient, including the index hospitalization and the HCRU during the follow-up year, was significantly higher for patients with post-ERCP

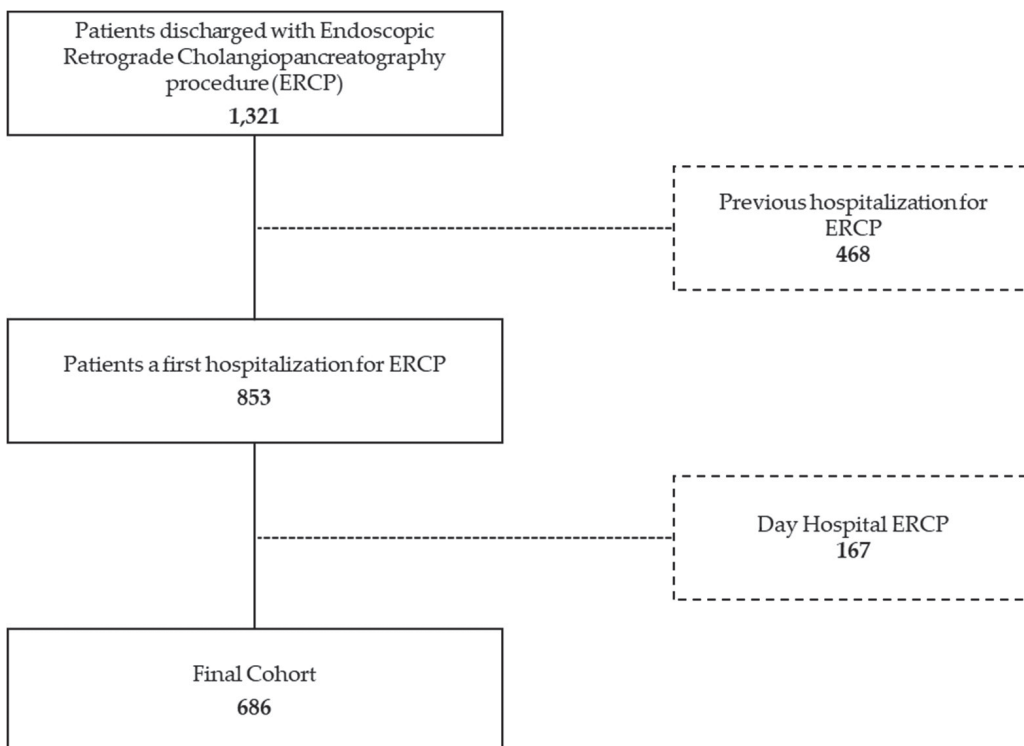


FIGURE 1 - Flowchart of study cohort selection. ERCP = endoscopic retrograde cholangiopancreatography.



TABLE 1 - Demographics and clinical characteristics of study population

Characteristics	N	%
Sex		
Male	380	55.4
Female	306	44.6
Age group		
18-59	165	24.1
60-69	133	19.4
70-79	217	31.6
80+	171	24.9
Type of admission		
Elective	231	33.7
Emergency	455	66.3
Acute pancreatitis		
No	621	90.5
Yes	65	9.5
Frailty		
None	470	68.5
Solid organ transplant	26	3.8
Chemo/radiotherapy	39	5.7
Cancer	151	22.0
TOTAL	686	100.0

TABLE 3 - Healthcare resource utilization by post-ERCP infection

HCRU	Post-ERCP infection		p Value
	No	Yes	
N	657	29	-
LoS index event	11.3	24.3	<0.0001
Discharged alive (N)	634	27	0.286
Readmitted within 1 year (%)	59.1	63.0	0.693
Patients with at least one antibiotics a/o anticoagulant dispensation (%)	29.8	44.4	0.106
Patients with at least one specialistic service (%)	53.8	51.9	0.844

ERCP = endoscopic retrograde cholangiopancreatography; HCRU = health-care resource utilization; LoS = length of hospital stay.

infection: €12,256 compared to €9,561 (Mann-Whitney test p-value 0.048). In detail, the most significant difference was related to the index hospitalization costs (€8,546 vs. €5,487; Mann-Whitney test p-value 0.000). Even the expenditure for specialized services during the follow-up, which primarily included blood chemistry and microbiological tests, liver and kidney function tests, specialized outpatient visits, and imaging services, was higher in the case of infection

TABLE 2 - Proportion of infection after ERCP by demographics and clinical characteristics

Characteristics	No infection N (%)	Infection after ERCP N (%)	p Value
Sex			
Male	365 (96.1)	15 (3.9)	0.685
Female	292 (95.4)	14 (4.6)	
Age group			
18-59	161 (97.6)	4 (2.4)	0.387
60-69	126 (94.7)	7 (5.3)	
70-79	209 (96.3)	8 (3.7)	
80+	161 (94.2)	10 (5.8)	
Type of admission			
Elective	225 (97.4)	6 (2.6)	0.130
Emergency	432 (94.9)	23 (5.1)	
Acute pancreatitis			
No	593 (95.5)	28 (4.5)	0.510
Yes	64 (98.5)	1 (1.5)	
Frailty			
None	448 (95.3)	22 (4.7)	0.000
Solid organ transplant	21 (80.8)	5 (19.2)	
Chemo/radiotherapy	37 (94.9)	2 (5.1)	
Cancer	151 (100.0)	0 (0.0)	
TOTAL	657 (95.8)	29 (4.2)	

ERCP = endoscopic retrograde cholangiopancreatography.

(€307 vs. €256), although the differences were not statistically significant (Mann-Whitney test p-value 0.681). On the other hand, despite a higher readmission rate for infected patients, the average expenditure per readmission was lower (€3,395 vs. €3,804; Mann-Whitney test p-value 0.331), while pharmaceutical expenses were negligible for all patients (€14 vs. €9) (Figure 2).

Based on the estimates obtained from the study population, it was possible to estimate a proportion of post-ERCP



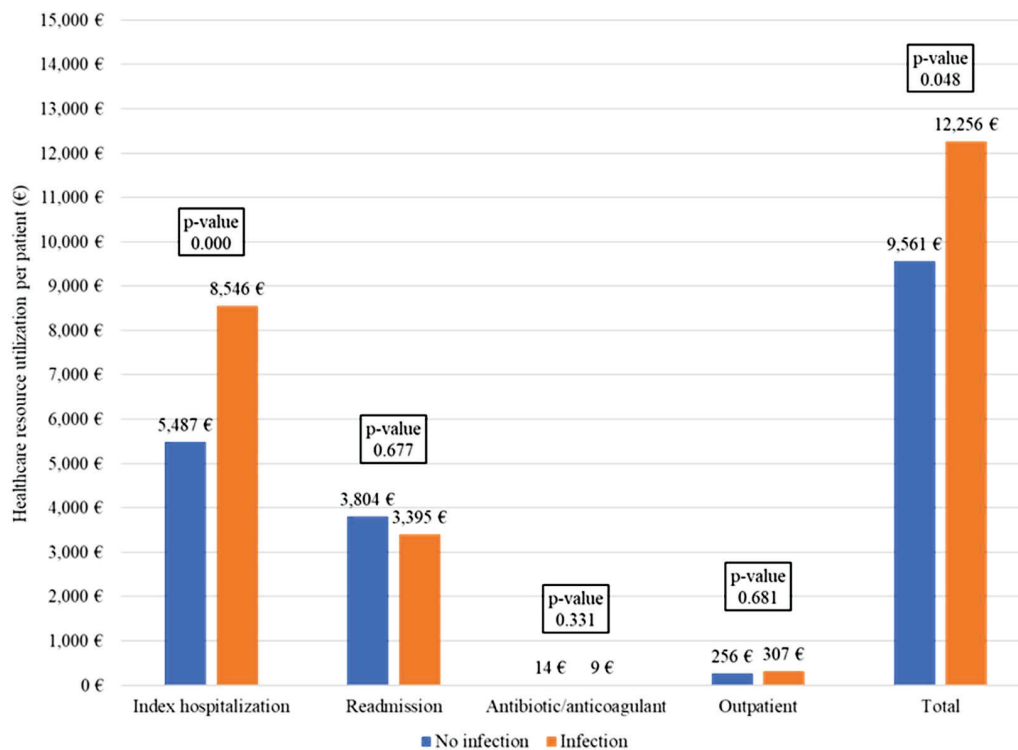


FIGURE 2 - One-year healthcare cost per patient by post-ERCP infection. ERCP = endoscopic retrograde cholangiopancreatography.

infections at the national level ranging from 2.7% to 5.7%. Assuming a constant differential in healthcare resource consumption attributed to post-ERCP infections and an annual volume of approximately 25,000 ERCP procedures performed in Italy in ordinary regimen, the economic burden of post-ERCP infections would amount to approximately € 3.0 million (95%CI € 1.9–€ 4.1 million) per year.

Discussion

This study aimed to assess the burden of post-ERCP infections in Italy by estimating the prevalence of hospital-acquired infections and evaluating their associated HCRU and economic impact. The observed proportion of post-ERCP infections in our study was 4.2%, with notable prevalence in older patients and emergency admissions, consistent with the literature. A recent study (12) identified 823,575 patients undergoing ERCP between January 2015 and December 2021 in the US, of which 3.5% were hospitalized for infection within 7 days from ERCP. Urgent ERCP, chronic conditions, older age, and non-white race were identified as the strongest risk factors for infection. Ayres et al. (14) aimed to evaluate variables that affect the risk of contamination for ERCP, and endoscopic ultrasound endoscopes found an overall pathogenic contamination rate of 4.72%. Finally, a single-center retrospective study of the first 200 ERCPs performed in the hospital reported an acute cholangitis rate from 4% to 1%, with a tendency to reduce with increased experience of the practitioner (25).

Our study highlighted a significant impact of post-ERCP infections on HCRU, resulting in prolonged hospital stays, higher readmission rates, and increased prescription of

antibiotics and/or anticoagulants. In cases of infection following ERCP, the length of hospitalization more than doubled (24.3 days compared to 11.3 days). This result aligns with findings highlighted by Kuduva Rajan et al. (26), in a retrospective cross-sectional study utilizing data from 4,411 U.S. hospitals. In this case, the occurrence of post-ERCP infections resulted in an 89.7% increase in the LoS. The same impact was observed in a retrospective cohort study conducted in the United States using the National Readmission Database for the year 2016. The authors analyzed a total of 135,704 ERCPs; out of these, 8% were associated with post-ERCP bacteremia that led to significantly longer stays (10.71 vs. 5.64 days, +89.9%) (27).

Few studies have investigated the economic impact of post-ERCP infections, and all were conducted in the United States. Specifically, Kuduva Rajan et al (26) highlighted how patients with post-ERCP infection incurred significantly higher costs compared to those without infection (\$107,520 vs. \$53,554; p value <0.0001). Similarly, Bhurwal et al (27) estimated the impact of infections on costs, showing an increase from \$58,351 to \$119,517 (p=0.016). Our findings reveal a statistically significant increase in the average expenditure per patient, particularly evident in the context of hospitalization costs, which saw a notable rise of 55.75%. The economic burden, when extrapolated nationally, amounted to approximately €3.0 million per year, emphasizing the financial strain posed by these infections on the healthcare system.

Despite the comprehensive nature of our study, several limitations should be acknowledged. The reliance on administrative databases, which, by their very nature, were not designed for epidemiological research, introduces potential sources of bias such as underreporting and misclassification

of key variables. Another notable limitation pertains to challenges in identifying patient-related clinical variables, leading to potential inaccuracy regarding disease severity and overall clinical history. The study also encounters constraints in tracking the specific utilization of medical devices.

Additionally, due to the retrospective nature of the study, the lack of information on pre- and post-treatment laboratory tests to confirm the presence of infection for all patients inherently introduces some limitations. This absence may result in the underdetection of post-ERCP infections that were managed exclusively in the community without hospital referral. Moreover, it poses a risk of overlooking patients already infected before undergoing the ERCP procedure.

However, the study is based on data from one of the largest hospital facilities in Italy, providing a sample that is representative of the national case scenario and offering insights into the economic implications of post-ERCP infections. The national extrapolation of economic burden provides a valuable perspective for healthcare policymakers. The identification of consistent risk factors aligns with existing literature, enhancing the reliability and generalizability of our findings.

Conclusions

The study provides valuable insight about the economic impact of post-ERCP infections within the Italian healthcare context, addressing a previously existing informational gap. The identified burden of infections is substantial in Italy, emphasizing the need for proactive preventive measures. By comparing our findings with existing literature, we further strengthen the robustness of the identified risk factors and their implications for healthcare outcomes and costs. Effectively addressing the challenge of post-ERCP infections is essential not only for enhancing patient care, but also for alleviating economic burden for the healthcare system and advancing the field of endoscopy.

Disclosures

Conflict of interest: The authors have no relevant financial or non-financial interests to disclose.

Financial support: This study was funded by Boston Scientific. The funder had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

Author's contribution: PS and FC: Conceptualization; AF and SMAG: Data Curation; PS: Formal Analysis and Software, Writing – original draft; All authors: Writing – review & editing.

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