



ERCP practice at a tertiary care hospital in Kashmir, North India: a large single-center cross-sectional study with focus on quality indicators, success rate, and indications

Shaheena Parveen, MD, DM^{a,*}, Altaf H. Shah, MD, DM^a, Ghulam M. Gulzar, MD, DM^a, Jaswinder S. Sodhi, MD, DM^a, Mushtaq A. Khan, MD, DM^a, Avinash Tiwari, MD^a, Tariq A. Mir, MD^a, Ankush Sharma, MD^a, Syed N. Ahmad, MD, DM^b, Nazir A. Dar, MSc^a

Introduction: Endoscopic retrograde cholangiopancreatography (ERCP) is the most technically demanding endoscopic procedure with significant adverse events that mandate appropriate training, competence and careful decision-making. The American Society for Gastrointestinal Endoscopy (ASGE) and the European Society of Gastrointestinal Endoscopy (ESGE) updated a list of quality indicators and performance measures for pancreatobiliary endoscopy. Nevertheless, real-life data are scarce, especially from developing countries. The study aimed to assess overall quality, procedural success, and indications of ERCP at our center.

Methods: An audit of our endoscopy center at the start of the study for quality and performance indicators and a retrospective analysis of the 4 years of the prospectively maintained data of patients who underwent ERCP regarding procedural success and indications was done.

Results: The study showed that ERCP is performed by meeting good quality standards, but structured training, sedation practice, and microbiological surveillance are subpar. A total of 3544 procedures were carried out with successful cannulation of the naive papilla in 93%, with 60% of procedures carried out on females, 80.5% of procedures done for benign diseases, and 19.5% on suspected or proven malignancy (47% men and 53% women) with perihilar obstruction being commonest in both sexes (32–33%) followed by carcinoma gallbladder in women (21%) and distal cholangiocarcinoma in men (27%). Among benign diseases (2711), 12% had benign pancreatic diseases, and 64.8% had common bile duct (CBD) stones, with 31% of CBD stones requiring more than one session for clearance.

Conclusion: ERCP at our center is performed by meeting quality standards and by competent endoscopists with good procedural success. Improving sedation strategies, microbiological surveillance, and training programs remains an unmet need.

Keywords: benign, biliary tract, endoscopic retrograde cholangiopancreatography, malignant, pancreatic duct

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) has evolved into a predominantly therapeutic endoscopic–radiologic procedure. An important consideration when implementing

^aDepartment of Gastroenterology and ^bDepartment of Medical Oncology, Sher-I-Kashmir Institute of Medical Sciences, Soura, Srinagar, Jammu and Kashmir, India
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*Corresponding author. Address: Department of Gastroenterology, Sher-I-Kashmir Institute of Medical Sciences (SKIMS), Soura, Srinagar, Jammu and Kashmir 190011, India. Tel.: +91-194-2401013. E-mail: shaheenaparveen2008@yahoo.com (S. Parveen).

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HIGHLIGHTS

- Endoscopic retrograde cholangiopancreatography is technically demanding with a high rate of adverse events.
- The American Society for Gastrointestinal Endoscopy and the European Society of Gastrointestinal Endoscopy have updated their list of quality indicators and performance measures.
- Data on the achievement of quality and performance indicators are scarce in developing countries.
- This study, the first of its kind in our country, sought to highlight these indicators.
- Future research should concentrate on the gaps in our endoscopic procedure quality.
- The goal should be to develop uniform, locally relevant, and acceptable protocols with regular auditing.

health technology is the patient's safety. Despite the advance in technology and devices, ERCP is still one of the most technically demanding endoscopic procedures, with relatively high adverse event rates ranging from 3 to 15%^[1]. This mandates a very

careful decision-making process that should consider the risk–benefit equation.

ERCP performance progressively is transforming into a platform for more complex advanced and therapeutic techniques like cholangioscopy and ERCP with altered anatomy. Training in ERCP has a long learning curve in both technical endoscopic skills and judgment. So appropriate training, experience, and competence are required when performing such a complex endoscopic procedure.

Healthcare authorities have shown increasing interest in improving and standardizing endoscopy quality in recent years. Accordingly, in 2015 the ASGE (American Society of Gastrointestinal Endoscopy) provided an updated list of quality indicators for ERCP^[2]. Similarly, the European Society for Gastrointestinal Endoscopy (ESGE) published a set of performance measures for pancreatobiliary endoscopy^[3]. Nevertheless, data on real-life fulfilment of these indicators are still scarce^[4,5].

Another concern related to ERCP in both developed and, more so, developing countries is duodenoscopy-related infections. A study from 37 hospitals in Canada found that 7% of duodenoscopy samples had microbial growth despite proper cleaning^[6]. There have been reports of outbreaks of ERCP-associated infections by carbapenem-resistant *Escherichia coli* and *Klebsiella*^[7,8]. All these reports are from developed countries and could be an indicator of impending major ERCP-associated nosocomial outbreaks in developing countries. So, our study aimed to assess the overall quality, procedural success, and indications of ERCP at our tertiary care center.

Methods

This study was undertaken in the endoscopic unit of the Department of Gastroenterology, after taking ethical clearance from the Institutional Ethical Committee (IEC) (Protocol number 141/2022, dated 30 August 2022) and as per the Declaration of Helsinki for good clinical practice. At the start of data entry, the audit of the endoscopy center was done for quality and performance indicators (Tables 1, 2) and entered in a set proforma regarding the following:

- (1) Facility details (number of beds, availability of radiological services and endoscopic ultrasound, etc.).
- (2) Organization (number of endoscopists, informed consent, ERCP setting, sedation practice, the policy of prophylaxis of post-ERCP pancreatitis, duodenoscopy surveillance, etc.).
- (3) Operator characteristics (education, number of procedures performed in their career/per year and years of experience in ERCP).

An anonymous hospital data was searched for ERCP performed between January 2018 and December 2021 in our endoscopy unit. Parameters like sex, the indication of ERCP (after complete evaluation in the department) and procedural success were included. Patients with duodenal deformity or infiltration and altered anatomy were excluded. All procedures were done by Olympus or Pentax duodenoscopes. The work was conducted in accordance with the STROCSS criteria^[10]. Our unique identifying number is researchregistry8737 and the registration link is as <https://www.researchregistry.com/browse-the-registry#home/>.

Table 1

Characteristics of center and profile of operators

Hospital size	
Large > 600 beds	
Hospital setting for ERCP	
(1) Independent gastro unit with beds	
(2) Independent endoscopy service with dedicated fluoroscopic ERCP equipment inside the endoscopy unit	
(3) Radiological services – available	
(4) Endoscopic ultrasound – not available	
ERCP performed	
6 days a week, usually during the day; only in the presence of experienced operators	
Medical staffing	
(1) Number of employed endoscopists	5
(2) Number of endoscopists performing ERCP	5
(3) Male	4
(4) Female	1
(5) The number of experienced operators	3
(6) Dedicated nurses	2
(7) Performs ERCP independently	5
(8) Trainee performing ERCP	0

ERCP, endoscopic retrograde cholangiopancreatography.

Definitions

The centers were considered as low (<100 ERCP), medium (100–300 ERCP) and high (>300 ERCP) volumes based on the reported number of ERCPs performed per year^[11,12].

ERCP endoscopists were defined according to their competence as

- (1) Experienced – those who performed ERCP independently; and
- (2) Trainees – those who were training in ERCP.

Hospital size as

- (1) Large ≥ 600 beds;
- (2) Medium 200–599 beds;
- (3) Small <200 beds.

Statistical analysis

Data analysis was done on an MS Windows-based computer. The data were first keyed into a Microsoft Excel spreadsheet and cleaned for any inaccuracies. Statistical analysis was done using IBM SPSS Statistics for Windows from IBM Corp. (released 2020, Version 27.0; Armonk, New York, USA). Categorical variables were shown in the form of frequencies and percentages.

Results

Sedation practice

Our center routinely uses conscious sedation (midazolam). Deep sedation or general anesthesia is used in cases of comorbidities, pediatric age group, or in case of emergency.

Prevention of post-ERCP pancreatitis

Our practice is the routine use of rectal diclofenac suppositories in all patients and preprocedural and intraprocedural hydration.

Duodenoscopy surveillance

Our center does not have a systematic duodenoscopy microbiological surveillance protocol.

Table 2**Quality indicators for ERCP in comparison to ASGE standards**

	Grade of recommendation	Measure type	Performance target%	Goal achieved, yes/no
Preprocedure				
(1) Frequency with which ERCP is performed for an indication that is included in a published standard list of appropriate indications and the indication is documented	1C +	Process	> 98	Yes
(2) Frequency with which informed consent is obtained, including specific discussions of risks associated with ERCP and fully documented	1C	Process	> 98	Yes
(3) Frequency with which appropriate antibiotics for ERCP are administered for settings in which they are indicated	2B	Process	> 98	Yes
(4) Frequency with which ERCP is performed by an endoscopist who is fully trained and credentialed to perform ERCP	3	Process	> 98	Yes
(5) Frequency with which the volume of ERCPs performed per year is recorded per endoscopist	1C	Process	> 98	Yes
Intraprocedural				
(6a) Frequency with which deep cannulation of the ducts of interest is documented	1C	Process	> 98	Yes
(6b) Frequency with which deep cannulation of the ducts of interest in patients with native papilla without surgically altered anatomy is achieved and documented (priority indicator)	1C	Process	> 90	Yes
(7) Frequency with which fluoroscopy time and radiation dose are measured and documented	2C	Process	> 98	No
(8) Frequency with which common bile duct stones <1 cm in patients with normal bile duct anatomy are extracted successfully and documented	1C	Outcome	> 90	Yes
(9) Frequency with which stent placement for biliary obstruction in patients with normal anatomy whose obstruction is below the bifurcation is successfully achieved and documented (priority indicator)	1C	Outcome	> 90	Yes
Postprocedure				
(10) Frequency with which a complete ERCP report that details the specific techniques performed, accessories used, and all intended outcomes is prepared	3	Process	> 98	Yes
(11) Frequency with which acute adverse events and hospital transfers are documented	3	Process	> 98	No
(12) Rate of post-ERCP pancreatitis (priority indicator)	1C	Outcome	N/A	Yes ^a
(13) Rate and type of perforation	2C	Outcome	≤ 0.2	No
(14) Rate of clinically significant hemorrhage after sphincterotomy or sphincteroplasty in patients undergoing ERCP	1C	Outcome	≤ 1	No
(15) Frequency with which patients are contacted at or greater than 14 days to detect and record the occurrence of delayed adverse events after ERCP	3	Process	> 90	No ^b

^aPublished data from our center^[9].^bPatients are asked to follow up on day 14 of discharge but are not contacted by the hospital.

ASGE, American Society for Gastrointestinal Endoscopy; ERCP, endoscopic retrograde cholangiopancreatography; N/A, not applicable.

Table 3
Distribution as per gender and procedures

Variable	n = 3555 (%)
Gender	
Male	1433 (40.31)
Female	2122 (59.69)
Procedures	
Actual procedures done	3371 (95.12)
Failure	184 (4.88)
Actual procedures	
Benign	2711 (80.42)
Malignant	660 (19.58)

Our center is having written a protocol for duodenoscope disinfection and storing duodenoscopes in a drying cabinet.

Informed consent

After a thorough discussion with the patient/family and written informed consent, we routinely perform ERCPs in our laboratory.

From January 2018 to December 2021, a total of 3555 procedures were carried out, with an average of 850–900 procedures per year, out of which 60% were done on females. Failed cannulation occurred in 184 patients, so the actual procedures were done on 3371 patients, among which 80% (2711) were done on benign diseases and 19.57% (660) on malignant diseases (Table 3). Among malignancies, the first-time procedures were done on 508 (76.96%) patients and among benign biliary disease first-time procedures were done on 1865 patients giving the total naïve papillary procedures of 2373. Keeping the total failed procedures of 184, the successful naïve papillary cannulation rate was 92.27%, and the failure rate of 7.75% (Fig. 1).

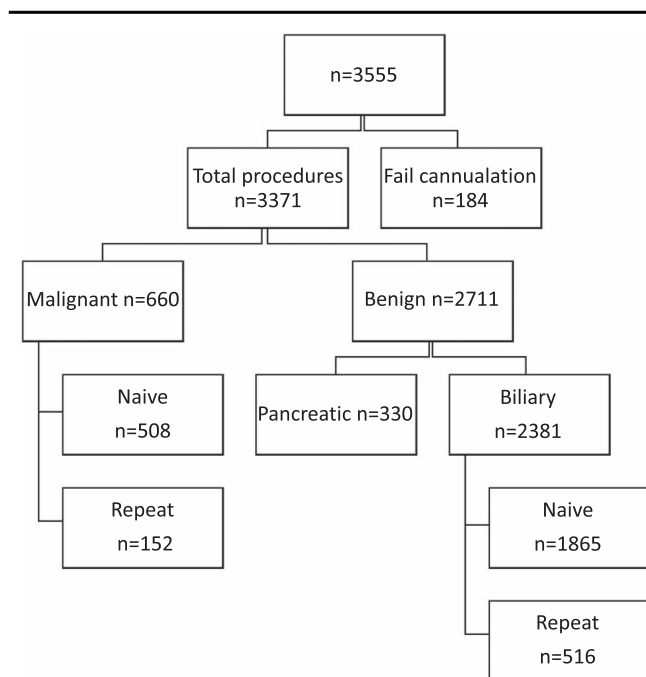


Figure 1. CONSORT (Consolidated Standards Of Reporting Trials) diagram.

Table 4
Type of malignancy

Distribution of malignancy types	Male	%M	Female	%F	Total
Perihilar lesion	83	32.55	84	33.20	167
Distal cholangiocarcinoma	70	27.45	47	18.58	117
Periampullary	44	17.25	36	14.23	80
Pancreatic	37	14.51	32	12.65	69
Gallbladder	21	8.24	54	21.34	75
Total	255	50.20	253	49.80	508

In men, perihilar lesions 83 (32.8%), distal cholangiocarcinoma 70 (27.4%), periampullary 44 (17.2%), pancreatic 37 (14.5%), and carcinoma gallbladder 21 (8.2%), respectively, were the causes of obstruction. In females' perihilar obstruction 84 (33.2%), carcinoma gallbladder 54 (21.34%), distal cholangiocarcinoma 47 (18.6%), periampullary 36 (14.28%), and pancreatic malignancy 32 (12.65%), respectively, were the commonest causes of obstruction. Repeat procedure was done on 152 (23.03%) patients for stent block or replacement (Table 4 and Fig. 3).

Among 2711 (80.42%) procedures on benign diseases, 330 (12.17%) were done on benign pancreatic diseases, 244 (73.9%) for chronic pancreatitis – 112 (46%) males and 139 (54%) females, 65 (19.6%) for biliopathy – 39 (60%) males and 26 (40%) females, 21 (6.36%) for PD disruption following severe pancreatitis – 13 (61%) males and 8 (38%) females (Table 5).

Among 1865 naïve biliary procedures, 1209 (64.82%) were done on CBD stones – 411 (33.99%) males and 798 (66%) females. Among 1209 biliary procedures for stones, 377 (31%) required more than one session for CBD clearance – 45 (38.4%) male and 232 (61.5%) females. Oriental cholangiohepatitis (OCH), based on history, imaging, and past ERCP, were labeled in 187 (7.8%) of total biliary procedures – 74 (39.5%) in males and 113 (60.4%) in females. Normal ERCP was found in 147 (7.8%) among naïve biliary procedures – 49 (33.33%) in males and 98 (66.66%) in females.

ERCP for bile duct injury (BDI) was done in 83 (4.45%) patients – 22 (26.5%) in males and 61 (73.49%) in females. Repeat ERCP on BDI patients for either stent up-gradation or stent removal was done on 66 (79.51%) – 16 (24.24%) in males and 50 (75.5%) in females. ERCP was done for hydatid on 64 (3.4%) of naïve benign biliary diseases – 35 (54%) in males and 29 (45%) in females; for unexplained stricture in 84 (4.5%) patients – 37 (44%) male and 47 (56%) females. ERCP for primary sclerosing cholangitis (PSC) was done in 7 (0.3%) patients – 3 (42.85%) males and 4 (57%) females. Extrahepatic portal vein obstruction (EHPVO) with biliopathy was found in 27 (1.44%) of patients – 14 (51.8%) male and 13 (48.15%) females. However, EHPVO patients required 73 repeat procedures (almost

Table 5
Distribution as per pancreatic benign diseases

Pancreatic benign disease	Male	%M	Female	%F	Total
Chronic pancreatitis	112	45.90	132	54.10	244
Pancreatic biliopathy	39	60.00	26	40.00	65
Pancreatic disruption	13	61.90	8	38.10	21
Total	164	49.70	166	50.30	330

Table 6
Distribution as per benign biliary diseases

Disease type	Male	%M	Female	%F	Total
CBD stones	411	33.99	798	66	1209
Normal ERCP	49	33.33	98	66.6	147
Bile duct injury	22	26.5	61	73.49	83
Unexplained stricture	37	44	47	56	84
PSC	3	42.85	4	57	7
Portal biliopathy	14	51.8	13	48.15	27
Biliary ascariasis	6	19.35	25	80.65	31
Choledochal cyst	6	23	20	77	26
Hydatid disease	35	54	29	45	64
OCH	74	39.5	113	60.4	187
Total	657	35.23	1208	64.8	1865

CBD, common bile duct; ERCP, endoscopic retrograde cholangiopancreatography; OCH, oriental cholangiohepatitis; PSC, primary sclerosing cholangitis.

3 repeat procedures per patient). Biliary ascariasis was found in 31 (1.66%) patients – 6 (19.35%) males and 25 (80.65%) females and suspected choledochal cyst in 26 (1.39%) patients – 6 (23%) males and 20 (77%) females (Table 6 and Figs 2, 3).

Discussion

ERCP is a technically demanding, invasive procedure with a high risk of complications. It requires significantly focused training and experience to maximize success and minimize poor outcomes. ERCP practice should be critically evaluated in terms of quality, indications, success rate, and complications. Our objective was to describe ERCP practice in our center in terms of quality indicators and to report success rates and indications that could be compared with other studies.

Our study revealed that the overall quality of our center is almost in compliance with the ASGE procedural quality standards. A high-volume center with independent endoscopy services with the backup of radiologists and surgeons, ERCP is performed 6 days a week, especially during the day and by competent endoscopists with greater than 1000 ERCP in their carrier.

Successful cannulation of naive papillae was obtained in 92.24% of procedures with successful extraction of 10 mm or less stone and stent placement for distal obstruction as per ASGE targets. Malignant disorders accounted for 19.5% of total procedures, whereas benign diseases accounted for 80%. This is discordant with some studies from India, which showed malignant obstruction more than benign (75 vs. 24%)^[13], (63.3 vs. 36.6%)^[14], and (62.7 vs. 37.2%)^[15]. Another study from northeast India on 1038 patients showed benign versus malignant causes in 63 and 26.3%, respectively^[16].

A study from South India revealed stones in 76% and malignancies in 11.6%^[17]. A study from central Iraq showed CBD stones in 68%, followed by hydatid disease (7.26%)^[18].

A 10-year study from the United States on 1 606 850 patients showed the most common diagnosis of choledocholithiasis in 30–40%, followed by biliary pancreatitis (11%), ascending cholangitis (4.9%), and pancreatic head masses (2.3%)^[19].

Our study showed that 64% ERCPs were done for stones among benign etiologies (66% in females and 33% in males). Aside from having difficult stones, 31% of these patients needed more than one session to be cleared or referred, which could be attributed to a lack of general anesthesia, a lack of patient cooperation for the drawn-out procedure, a lack of advanced technologies like electrohydraulic lithotripsy or laser lithotripsy, or other factors.

Among malignancies, perihilar obstruction was commonest in both sexes (32–33%), followed by distal cholangiocarcinoma (27%), periampullary malignancy (17%), pancreatic malignancy

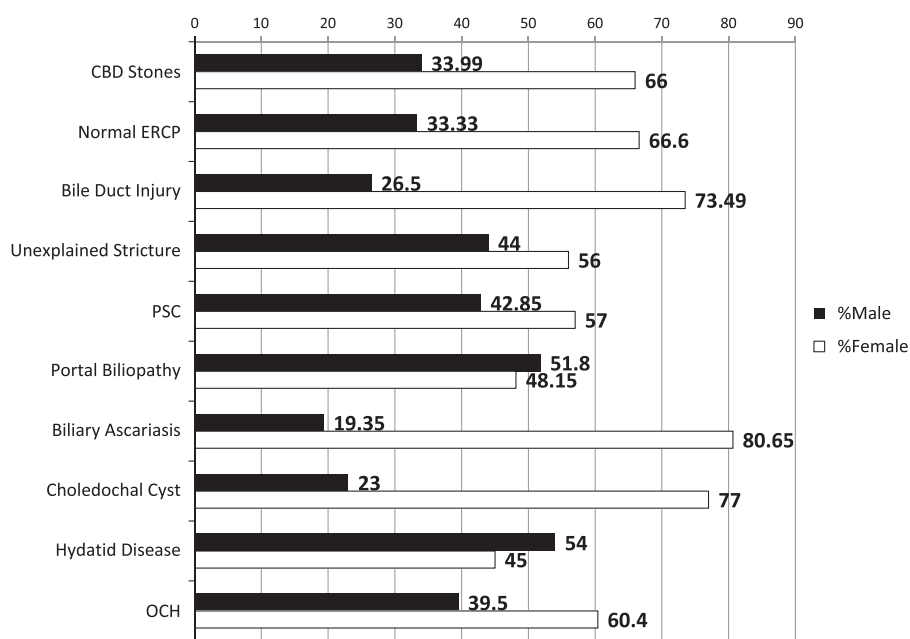


Figure 2. Benign biliary diseases. CBD, common bile duct; ERCP, endoscopic retrograde cholangiopancreatography; OCH, oriental cholangiohepatitis; PSC, primary sclerosing cholangitis.

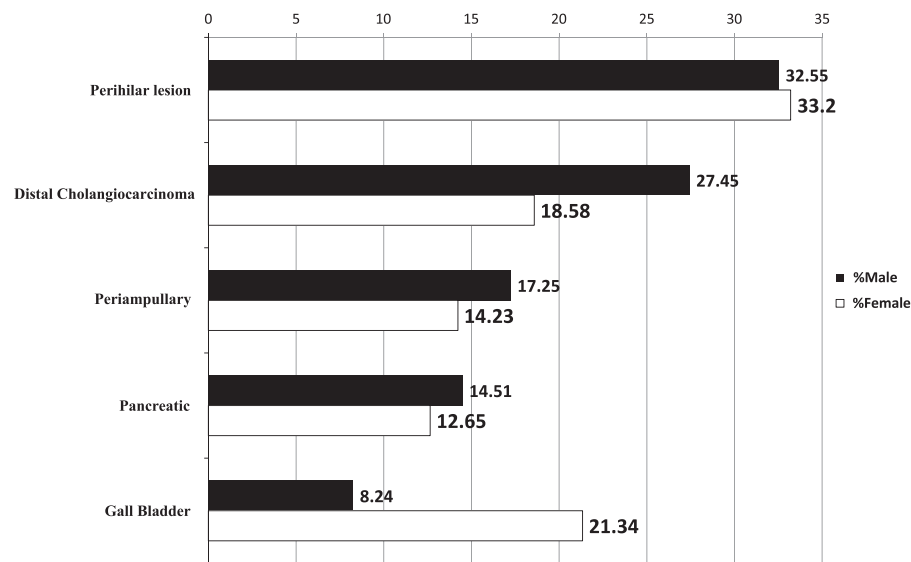


Figure 3. Distribution of malignancy types.

(14%), and carcinoma gallbladder (8.2%) in males, and carcinoma gallbladder (21.5%), distal cholangiocarcinoma (18.6%), periampullary (14%), and pancreatic malignancy (12.69%) in females; gallbladder malignancy being significantly more common in females than in males. In a study from Korea^[20], neoplasms of the liver and intrahepatic ducts (32.1%), extrahepatic biliary duct or ampulla of Vater (26.1%), pancreatic cancer (22.1%), and carcinoma of the gallbladder (8.1%) were the commonest malignant causes of biliary stricture. In a study from India^[21], carcinoma of the gallbladder (50%) was the commonest cause of malignant extrahepatic obstruction, followed by carcinoma of the head of the pancreas (18%), cholangiocarcinoma (11%), and biliary obstruction due to metastasis (3%).

While analyzing the basic characteristics of the center, certain important issues became evident.

- (1) Despite the evolution of endoscopy with advanced procedures, sedation practice in our center has not evolved. The routine use of conscious sedation and lack of anesthesiologist attendance, unless the patient is in critical condition or of pediatric age, is an element of concern.
- (2) Our center does not have a systematic duodenoscope microbiological surveillance protocol.
- (3) Teaching programs for operators are lacking, and ERCP continues to be performed by purely self-taught operators.

Strength of our study

- (1) Our study is one of the largest volumes ever published from a single center in our country despite being the period of the COVID-19 (coronavirus disease 2019) pandemic.
- (2) Our center, the main referral government sector institutions in the region, may give actual disease status in our community.

Limitations of our study

This is a retrospective study and certain questions need to be clarified by future prospective studies.

- (1) Perihilar obstruction, the main cause in both sexes, needs to be reassessed as obstruction secondary to metastasis from other malignancies was not clarified.
- (2) Thirty-one percent of CBD stones needed more than one session; need subgroup analysis for the actual number and reason and percentage failed ultimately.
- (3) Postprocedure follow-up needs to be maintained for delayed complications.

Conclusion

The study showed that ERCP is performed by almost meeting quality standards and by competent endoscopists in the high-volume center with good procedural success. The study also revealed that improving quality standards of ERCP-related practices, that is sedation strategies, microbiological surveillance, and training programs remains an unmet need. Training and maintaining competence are key to success. Stone disease is the commonest indication for ERCP, and difficult stones need the incorporation of more advanced technology and training for better success.

Ethical approval

This study was undertaken in the Endoscopic Unit of the Department of Gastroenterology, Sher-I-Kashmir Institute of Medical Sciences (SKIMS) after taking ethical clearance from the Institutional Ethical Committee (IEC) (Protocol number 141/2022, dated 30 August 2022) and as per the Declaration of Helsinki for good clinical practice.

Patient consent

As this was a retrospective, cross-sectional hospital-based study of anonymous patient data, so patient consent was not required.

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Author contribution

S.P. and A.H.S.: study concept/design; S.P.: data collection; S.P., N. A.D., A.H.S., G.M.G., J.S.S., M.A.K., A.T., T.A.M., A.S., S.N.A.: data analysis/data interpretation; S.P., N.A.D., A.H.S., G.M.G., J.S.S., M.A.K., A.T., T.A.M., A.S., and S.N.A.: writing the paper. All authors were involved in the final approval.

Conflicts of interest disclosure

There were no conflicts of interest.

Research registration unique identifying number (UIN)

1. Name of the registry: Research Registry.
2. Unique identifying number or registration ID: research-registry8737.
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): <https://www.researchregistry.com/browse-the-registry#home/>.

Guarantor

Dr Shaheena Parveen, Assistant Professor, Department of Gastroenterology, Sher-I-Kashmir Institute of Medical Sciences (SKIMS), Soura, Srinagar, Jammu and Kashmir, India. E-mail: shaheenaparveen2008@yahoo.com.

Provenance and peer review

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