

A Clinical Audit of Endoscopic Retrograde Cholangiopancreatogram of Patients performed in a Secondary Care Hospital

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^{1,2} Conception of study

^{1,2} Experimentation/Study conduction

^{1,2,3,4} Analysis/Interpretation/Discussion

⁵ Manuscript Writing

^{3,4} Critical Review

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Abstract

Introduction: Recent advances in ERCP techniques are developed to improve its efficacy and safety but there are limited data regarding the efficacy and safety of ERCP carried out in secondary care hospital setting using modern techniques.

Objective: To perform a clinical audit of ERCP of patients performed in secondary care hospital.

Materials and Methods: Cross-sectional study conducted at the Department of Gastroenterology hospital, Lahore from Jan 2018 - Dec 2018. After approval from the ethical committee and informed consent from subjects, detailed demographic information was collected and entered into a structured questionnaire. A total of 66 ERCP were included in the study by non-probability consecutive sampling. Data was analyzed in SPSS ver: 21.0. Frequency and percentages were calculated for qualitative variables like gender and diagnosis and complications.

Results: A total of 66 ERCP were performed. The mean age of patients was 57.35 ± 12.30 . 36.4% were male and 63.6% were female in our study. 53.0% had malignant ERCP findings and 47.0% had benign pathology. Among malignant conditions were proximal CBD malignant strictures (25.8%), distal CBD stricture with ampullary growth (9.0%), distal malignant CBD stricture (6.0%), long distal malignant CBD stricture (9.0%), and complete malignant obstruction mid CBD (3.1%).

Conclusion: The ERCP services provided at secondary care hospital are standardized with a desirable outcome. The rate of its technical success is comparable to tertiary care setting and complication rates are low along with mortality related to the procedure.

Keywords: ERCP, Cholecystitis, CBD.

Introduction

ERCP is crucial in diagnostic and therapeutic intervention in the management of pancreaticobiliary disorders. ERCP is useful both as a diagnostic and therapeutic procedure for diagnosis and treatment of pancreaticobiliary conditions both benign and malignant and choledocholithiasis.¹

There is a significant risk of complications with the procedure that vary between 4% and 30%.¹⁻⁵ The nature of the procedure itself is very challenging and the rate of complications associated with the procedure is relatively high. Various national and international endoscopic societies have developed recommendations and guidelines to develop minimum standards for the training of specialists and their accreditations for ERCP. The American Society for Gastrointestinal Endoscopy recommends that there should be a minimum of 80% success rate is required in duct cannulation or basic treatment for the attainment of competency.⁶ Similar recommendations are required by the Joint Advisory Group on Gastrointestinal Endoscopy (JAGGE) states that every ERCP trainees should achieve a cannulation rate of 90% but the advisory group has not agreed upon the minimum number of procedures that a trainee should be performed before achieving a level of competence or he has achieved absolute compulsory cannulation and basic treatment rate.⁷ It is also expected that an accredited ERCP endoscopist must perform a minimum number of ERCP procedures per year to maintain a level of competency and proficiency.

The estimated workload of ERCP in tertiary care hospital, unlike other endoscopic procedures, is enormous time consuming, recently being performed at secondary care level hospital but with a relatively low volume and because of that a state of imbalance exists between providing of a readily available and prompt service for patients requiring ERCP and maintaining a minimum level of expertise.⁸ This clinical audit is carried in light of these facts to evaluate the outcome of ERCP performed at secondary care institutions.

Objective: The objective of the study was to perform a clinical audit of ERCP performed in secondary care hospitals for acute cholecystitis.

Materials and Methods

A cross-sectional study was performed at the Department of Gastroenterology hospital, Lahore.

After approval from the ethical committee and informed consent from subjects, detailed demographic information was collected and entered into a structured questionnaire. A total of 66 ERCP were included in the study by non-probability consecutive sampling. Data was analyzed in SPSS ver: 21.0. Frequency and percentages were calculated for qualitative variables like gender and diagnosis and complications.

Results

A total of 66 ERCP were performed. The mean age of patients was 57.35 ± 12.30 . The minimum age was 35 and the maximum age was 80 years in our study. 25.5% were less than 50 years of age and 74.5% were above 50 years. 36.4% were male and 63.6% were female in our study. 53.0% had malignant ERCP findings and 47.0% had benign pathology. Among malignant conditions were proximal CBD malignant strictures (25.8%), distal CBD stricture with ampullary growth (9.0%), distal malignant CBD stricture (6.0%), long distal malignant CBD stricture (9.0%), complete malignant obstruction mid CBD (3.1%). Among benign conditions were distal benign CBD stricture (19.7%), proximal CBD benign stricture (16.7%), mid-CBD benign stricture (7.6%), and distal benign CBD stricture pap orifice stenosis choledochal cyst (3.1%). 96.5% of ERCP were without complications (Table 1).

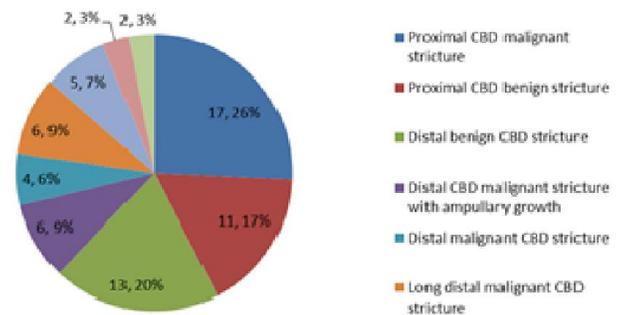


Figure 1: Final diagnosis

Table 1: Demographic and clinical profile of patients

Variables n=66	Frequency	Percent
Age Mean= 57.56 SD= 12.30 Min= 35 Max= 80		
< 50 years	17	25.5
> 50 years	49	74.5
Gender		
Male	24	36.4
Female	42	63.6
Endoscopic findings		
Malignant	35	53.0
Benign	31	47.0
Diagnosis		
Proximal CBD malignant stricture	17	25.8
Proximal CBD benign stricture	11	16.7
Distal benign CBD stricture	13	19.7
Distal CBD malignant stricture with ampullary growth	6	9.0
Distal malignant CBD stricture	4	6.0
Long distal malignant CBD stricture	6	9.0
Mid-CBD benign stricture	5	7.6
Complete malignant obstruction mid CBD	2	3.1
Distal benign CBD stricture pap orifice stenosis choledochal cyst	2	3.1
Complication		
Yes	3	4.5
No	60	96.5

Discussion

The audit of ERCP done in a secondary care hospital offers broader aspects of all the procedures that are being performed in a secondary care hospital at the district level during one year period. To the best of our knowledge and extensive data search, this ERCP performed in secondary care level hospital is of the first kind at a non-tertiary referral center providing comprehensive research and evaluating the ERCP procedures at a district-level hospital with an audit of ERCP performed in one year.

The significant strengths of our audit are that the findings of ERCP procedures were evaluated by expertise who is not a part of procedures and secondly, the history notes that were reviewed are likely to have systematically noted down all the complications. It also judicious to compare our patient's strata with patients that are being reported in tertiary care hospitals as the demographic details of both these populations are the same and these patients usually shift and refereed between these hospitals.

In this study and appropriate consent was taken from all patients before undergoing ERCP procedure and these patients had confirmation of structural defects on radiological imaging before performing their first ERCP procedure. All the procedures were done with a diagnostic aim but interventions were also done where necessary and the safety of the patients was ensured. Less than 5% of patients had complications as this rate is slightly higher than studies done in developed countries.^{10,16}

The technical success rate was better and comparable to other settings done in tertiary care hospitals. The complications related to ERCP were similar to other audit performed and were much below documented figures in other studies.¹⁻⁵

In a study by Nallankilli et al their audit findings were in accordance with national data. In this study, a total of 478 procedures were performed including therapeutic ERCP and all patients had pre-procedure imaging. In all procedures, wire-guided biliary cannulation was done and a success rate of 97% was achieved. The adverse-event rate among these procedures was 0.8% overall and the major indication for procedure was choledocholithiasis (72%).¹⁷ In our study success rate was similar to a bit higher rate of

4.5% complication probably due to the advance stage of disease and patients presenting in at advanced disease state.^{11 12,17}

However, those patients who were unable to give consent due to the severity of their illness excluded their ERCP findings from the audit. Therefore, the complication rates of our audit might probably do not precisely reflect the whole scenario. One of the important findings of our audit was that no death was reported due to the procedure. Our audit also showed no procedural complications and difficulty grade on cannulation of the bile duct. Both our success rates and the incidence of complications were comparable to an audit of similar nature.¹³⁻¹⁵

One of the important findings of this audit was compliance with the protocols and procedures and every precaution was taken not to compromise the safety of patients as the procedures were day-case procedures, we anticipated all complications of procedure within the 6 hours during the observation period and there were at least two endoscopists present in all the time in our setting. The specialist performed a significantly high number of ERCP procedures than the suggested minimum number of ERCP that may have contributed to successful cannulation with a high success rate with relatively fewer complication rates. This possibly favors the requirement for performing a minimum number of procedures to be performed by ERCP endoscopists per year. This audit was done retrospectively and we included all those patients who underwent ERCP in the current year for data analysis.

Conclusion

The ERCP services provided at secondary care hospital are standardized with a desirable outcome. The rate of its technical success is comparable to tertiary care setting and complication rates are low alone with mortality related to the procedure.

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