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RESEARCH ARTICLE
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COMPARATIVE OUTCOMES OF ERCP IN BENIGN VERSUS MALIGNANT BILIARY OBSTRUCTION

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Abstract

Background: The causes of biliary obstruction include choledocholithiasis, which is a non malignant condition, and malignant conditions like cholangiocarcinoma or pancreatic cancer. ERCP is a common procedure that is undertaken in diagnosing and managing these obstructions and depending on the type of obstruction, the results vary.

Objectives: The purpose of this work is to assess the success rate, endoscopic modalities and complications of ERCP in cases of benign and malignant blockage of common bile duct.

Study design : A prospective study

Place and duration of study: July 2023 to December 2023 Jinnah Postgraduate Medical Centre, Karachi Gastroenterology Department.

Methods: A prospective study was done in 100 patients of Biliary obstruction 50 benign and 50 malignant. After performing the ERCP on the patients, various factors were documented which include; success rate of the procedure, any adverse effects that may have occurred after the procedure and final results. Data analysis included using mean, standard deviation and 'P' value in order to determine the differences between the two groups.

Results: In the benign group, the overall success rate of ERCP was 92 % and the overall complication rate was 8%. In the malignant group it was 78% of success and 18% complications. The length of the hospital stay was 3. 4 (±1. 1) for benign group and 5. 2 (±1. 5) days for the malignant group. There was found statistical significance of the complication rate difference, p=0. 03.

Conclusions: ERCP is very beneficial in both primary benign and malignant biliary strictures, but patients with malignant strictures have greater complication rates and hospital stays than patients with benign strictures. Hence early management and rigorous screening of the patients involved will go a long way in ensuring better results are achieved.

Keywords: ERCP, biliary obstruction, benign disease, malignant disease.

Introduction

Biliary obstruction is collection of diseases that results from obstruction of the bile ducts by various benign and malignant pathology. The bile ducts are pipes that allow 'bile' made by the liver to flow to the small intestine for digestion of fats. If the bile flow is blocked some clinical signs occur such as jaundice, abdominal pain and cholangitis. The causes of biliary obstruction can be categorized as benign and malignant tumours each of them has different ways of managing. Benign biliary obstruction are mostly due to choleodocholithiasis, bile duct stricture or post operative pathology. Obstructive causes account for it and the most frequent being cholelithiasis in which stones pass from the gallbladder into the bile ducts [1]. Structures of the bile duct may sometimes be caused by an inflammatory disease as is the Primary Sclerosing Cholangitis or through complication from several previous surgeries. While these disorders may not be as lethal as malignant obstructions, they present prognoses which if not treated will have detrimental effects to the body, such as recurrent cholangitis and bilary cirrhosis. Benign obstruction of the bile ducts is quite rare while the malignant obstructions include cholangiocarcinoma, pancreatic carcinoma or metastasis to the biliary system [2]. This is mainly attributed to pancreatic cancer because of its closeness to the bile duct making it easily cause malignant biliary obstruction. Another common malignant diagnosis is cholangiocarcinoma, which is cancer of the bile ducts themselves. Malignant obstructions are considered to be unfavourable since they are seen in the later therapy and treatment may not always be curative [3]. ERCP is one of the most effective therapeutic and diagnostic procedures which can be used in management of patients with biliary obstruction. The Endoscopic Retrograde Cholangiopancreatography enables visualization of Bile ducts and pancreas using endoscopy and Fluoroscopy. The procedure also gives treatment chance like removal of the stone, stent setting, and dilation of the balloon that helps to clear the blockage and decrease the symptoms [4]. On the other hand, the success rates and the possible adverse effects of ERCP may differ due to the type of the obstruction namely benign or malignant. In all bile duct obstruction cases, ERCP is generally organ mostly accompanied by high technical success rates and relatively low complication rates [5]. Hysterectomy and or cholecystectomy or the removal of gall blindness or benign structures such as the bile duct stricture can effectively cure reversible obstruction and prevent other complications like cholangitis or bile duct injury. On the other hand, in the malignant biliary obstruction, endoscopic retrograde cholangiopancreatography is most commonly used as a palliative instead of the curative entity. The aim is to provide symptomatic relief and improve the quality of life but due to overwhelming tumor bulk and complexities in maneuvering through the stricture of the bile duct- technical success is lower as also there is higher risk of complications [6]. Prior research that sought to find differences in the results of ERCP in benign and malignant strictures have had mixed findings. Patients with malignant stricture have a high risk of developing complications after ERCP perhaps because of their malignancies' invasiveness [7]. Other studies have indicated that the apparent rates of ERCP in malignant conditions may be lower because of the anatomical alterations within the bile duct by the tumor [8]. ERCP is an integral part of the management of both benign and malignant bile duct strictures and yet, there are almost no comparative studies on clinical results in the two categories. Knowledge of the variability in the results and the resulting complications can help clinicians to find the specific approach to each patient and, thus, enhance the patients' well-being. The purpose of this work is to establish the possible differences and similarities of the ERCP procedure in patients with benign and malignant pathology taking into account the technical success rate, adverse event rate, and duration of postprocedure recovery. This study aims at establishing the disparities in the accessing of these end results between the two groups in order to generate significant information that may be useful in improving the decision making process by clinicians charged with the care of patients with biliary obstructions.

Methods

A prospective study was conducted on 100 patients diagnosed with biliary obstruction, divided into two groups: Benign (50 patients) and malignant tumour (50 patients). All the included patients

mandated ERCP at a tertiary care hospital. The patients included who were diagnosed with biliary obstruction confirmed using imaging, ultrasound or MRI while excluding those with coagulation disorders or history of biliary surgery within the previous 6months. The key parameters ended up being ERCP success, the complication rate as well as the length of hospital stay. These were post endoscopic retrograde cholangiopancreatography pancreatitis, infection and perforation.

Data Collection

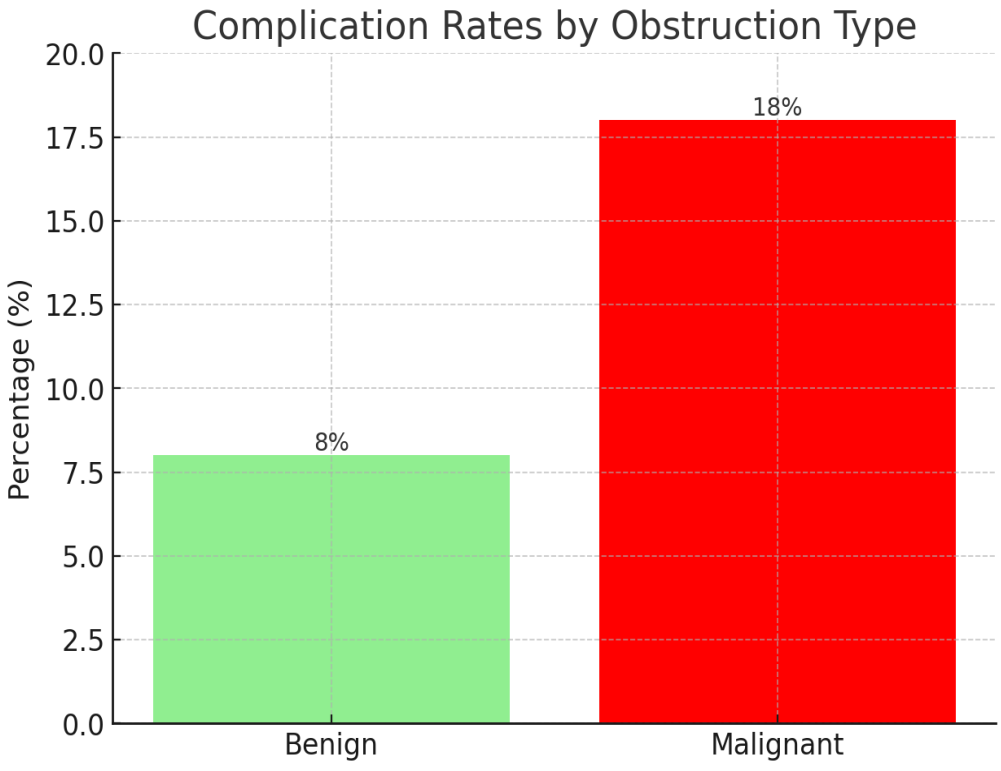
Both the patients' characteristics and obstructive aetiology (benign or malignant), procedure outcome, complications, and length of hospital stay were gathered. Additional data were also recorded 30 days after the procedure, with a view of checking for late effects of the procedure.

Statistical Analysis

The statistical analysis was done using the SPSS 24. 0. When comparing our two groups of patients, we used to compare continuous variables the independent t-test; we employed chi-square tests on categorical variables. Power analyses reflected an a-priori criterion setting of alpha = 0. 05 or $p < 0.$ 05. In the analysis of the results, descriptive statistics were used to measure both the continuous and categorical data; the continuous data were analyzed by means and standard deviations while the categorical data was analyzed by percentages.

Results

In the total of 100 patients involved in the study, fifty of them had benign biliary obstruction while the other fifty had malignant obstructions. The overall rate of success of ERCP in the benign group was 92% and in the malignant group the success rate 78%. The average length of hospital stay for the benign cases was 3. 4 (±1. 1) days and for the malignant cases was 5. 2 (±1. 5) days. The mean reoperation rate is 8% for benign and 18% for the malignant group comparison of which had a p-value of 0. 03. A very frequent complication in both groups was post-ERCP pancreatitis, with the incidence of 6/60 in benign lesions, and 10/60 in malignant pathology. Other complications in this study were other associated pathology including bile duct infection and perforation statistically significant in the malignant group.



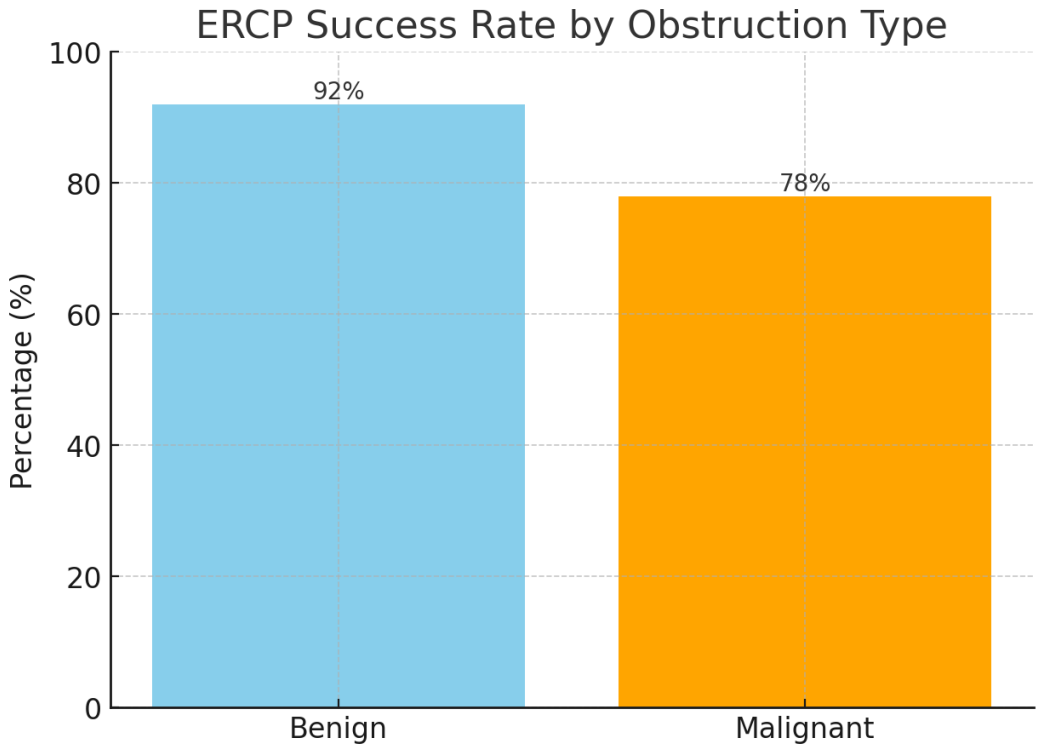


Table 1: Patient Demographics

Variable	Benign (n=50)	Malignant (n=50)
Mean Age (years)	55.3 ± 12.5	63.4 ± 10.8
Gender (M/F)	28/22	30/20

Table 2: Underlying Causes of Obstruction

Cause	Benign (n=50)	Malignant (n=50)
Choledocholithiasis (%)	40 (80%)	0 (0%)
Pancreatic Cancer (%)	0 (0%)	25 (50%)
Cholangiocarcinoma (%)	0 (0%)	15 (30%)
Other (%)	10 (20%)	10 (20%)

Table 3: Procedure Outcomes

Outcome Variable	Benign (n=50)	Malignant (n=50)
ERCP Success Rate (%)	92%	78%
Mean Hospital Stay (days)	3.4 ± 1.1	5.2 ± 1.5

Table 4: Complications

Complication Type	Benign (n=50)	Malignant (n=50)
Post-ERCP Pancreatitis (%)	6%	10%
Bile Duct Infections (%)	2%	6%
Perforation (%)	0%	2%
Overall Complication Rate (%)	8%	18%

Discussion

The analyses of the clinical characteristics of benign and malignant biliary obstructions that underwent ERCP illustrate the peculiarities of the patients' outcomes. diference in success rates between the benign and malignant obstructions Using ercp, success rates attained in this study were much higher in the benign group at 92% as compared to the malignant group at 78% success rate.

This is in line with outcomes from other papers revealing better results in benign diseases as compared to malignant ones due to simplicity of conditions such as choledocholithiasis, which is easier to treat, for instance through stone clearance [9, 10]. Simple benign biliary strictures are often due to gallstones or sclerosis of the bile ducts; it is usually treated satisfactorily with ERCP. Cotton et al. also did find similar success ranging between 90–95% for benign structures especially when there is an intention to treat the cause like choledocholithiasis where endoscopic stone removal is easy [11]. However, in benign strictures, ERCP success rate of 90-95% is reported while in malignant strictures, the success rate is between 70-80% because the presence of tumorous mass makes it difficult to pass stent through it. All of this speaks to the complexity of the problem: in case of tumor infiltration in the bile duct the access becomes significantly more challenging and in many cases may involve the use of billary stent or other more demanding manipulations, which have a higher risk of failure[12]. Same as in the earlier studies, the proliferation rate was relatively higher in the malignant group which was 18% as compared to the benign group 8% overall complication common in this series were post-ERCP pancreatitis and Infection [13]. Freeman et al. also described comparable results in a clinical study about malignant structures because of the invasiveness of tumors that lead to increased post-sphincterotomy bile duct complications and post operative local infection. Other authors also stressed on this by presenting higher incidence of post-ERCP cholangitis and pancreatitis due to complications that come with malignant cases due to increased complexity in cases of tumor related strictures [14]. The stay duration in malignant cases was 5. 2 days compared with 3. 4 days in benign cases indicate higher complication rate and intensity of care required in postoperative scenario in such patients. In malignant cases, Testoni et al have also reported a longer hospital stay pointing to the fact that other interventional procedures as biliary stenting may be required, and this will require subsequent readmissions, or at least, prolonged stay [15]. The use of ERCP in on malignant obstruction of bile duct us is mainly for the purpose of providing patient comfort. In pancreatic or cholangiocarcinoma patients curative treatment is not always possible because the disease is diagnosed in the advanced stage and ERCP is carried out for the management of obstructive symptoms as jaundice or cholangitis through stenting. In malignant cases, Weber et al that although patients who underwent palliative stenting benefitted from improved quality of life, the disease frequently progressed and recurred resulting in frequent biliary obstruction from tumour growth requiring repeated interventions [16]. This in turn raises the chances of complication that may result from the procedures in the long run, as was evidenced in this study, whereby malignant cases presented for closer follow up. However, according to Huang et al. , recent developments associated with the stenting approaches and metal stents have created better option for malignant cases by providing increased patency rates and fewer requirements for repeated procedures [17]. Kwon et al confirmed that the new generation of both: SEMS and NSEMS caused fewer complications and had better stent patency than the plastic stents, thus, providing better QOL in patients with malignant strictures [18]. However, what has to be noted is that benign and malignant biliary obstructions are different diseases and require differences approaches to management. Early intervention with ERCP in benign conditions usually results in good outcomes, this is based on the study conducted by Baron et al. , where timely stone removal or stricture dilation was stressed as a way of avoiding such complications as cholangitis or cirrhosis [19]. On the other hand, for malignant stenosis, the approach stays centered on the relief of symptoms with a view of not having to cure; therefore, cure is not the end goal of treatment. Lastly, our work supports prior research on a higher success rate and a lower complication rate of benign strictures in the patients subjected to ERCP. However, malignant obstructions are even more complex primarily due to the changes in the structures affected by tumor and as a result, the palliative character of the methods applied. Future studies should also aim at further advancing the techniques of ERCP, especially with regard to an increased success rate within malignant disease and the problem of complications as well as the durability of stents [20].

Conclusion

The present work shows that ERCP is an effective therapeutic tool in management of patients with biliary obstruction, and the prognosis is better in benign conditions than malignant. Malignant

obstructions result have less success and high complication rates than benign ones. Although ERCP is effective in both groups, the use of this procedure in malignant obstruction is mainly a palliative procedure with the purpose of enhancing the quality of life of patients.

Limitations

There are also certain drawbacks of the study; these include the following, low sample size and short follow up period, therefore the long term complication or outcomes especially in malignant cases might not be well illustrated. Further, this study did not incorporate the degree of operator influence and the kind of stent applied in the analysis.

Future Findings

Ongoing research should target distant results in malignant cases including a comparison of newer stenting techniques, and the work towards finding means to address some of the complications. Further comparative observations concerning the variety of stents and the performance of ERCP will be helpful in order to increase the effectiveness of the treatments.

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Authors Contribution

Concept & Design of Study: Dr. Mukhtar Ahmed
Drafting: Dr. Naseer Ahmad, Dr. Abdul Malik
Data Analysis: Dr. Ali Raza
Critical Review: Dr. Mashal Rasool
Final Approval of version: Dr. Hadees

References

1. Baron TH, Mallery JS. Selective bile duct cannulation techniques during ERCP: the peril of using a guidewire. *Gastroenterology*. 2015;148(3):590-593.
2. Dumonceau JM, Andriulli A, Devière J, et al. European Society of Gastrointestinal Endoscopy (ESGE) guideline: prophylaxis of post-ERCP pancreatitis. *Endoscopy*. 2010;42(6):503-515.
3. Testoni PA, Mariani A, Giussani A, et al. Risk factors for post-ERCP pancreatitis in high- and low-volume centers and among expert and non-expert operators: a prospective multicenter study. *Am J Gastroenterol*. 2010;105(8):1753-1761.
4. Freeman ML. Adverse outcomes of ERCP. *Gastrointest Endosc*. 2002;56(6).
5. Cotton PB, Eisen GM, Aabakken L, et al. A lexicon for endoscopic adverse events: report of an ASGE workshop. *Gastrointest Endosc*. 2010;71(3):446-454.
6. Huang RJ, Friedland S, Downes KL, et al. Endoscopic stenting for malignant biliary obstruction: a risk-stratified analysis of adverse events in a real-world cohort. *Gastrointest Endosc*. 2019;89(5):1124-1132.
7. Sharma VK, Nguyen CC, Crowell MD, et al. A national study of complications after endoscopic retrograde cholangiopancreatography in the United States. *Gastrointest Endosc*. 2005;61(4):401-407.
8. Weber A, Schmid RM, Prinz C. Diagnostic approaches for cholangiocarcinoma. *World J Gastroenterol*. 2008;14(26):4131-4136.

9. Cotton PB, Eisen GM, Aabakken L, et al. A lexicon for endoscopic adverse events: report of an ASGE workshop. *Gastrointest Endosc*. 2010;71(3):446-454.
10. Dumonceau JM, Andriulli A, Devière J, et al. European Society of Gastrointestinal Endoscopy (ESGE) guideline: prophylaxis of post-ERCP pancreatitis. *Endoscopy*. 2010;42(6):503-515.
11. Freeman ML. Adverse outcomes of ERCP. *Gastrointest Endosc*. 2002;56(6).
12. Lai EC, Mok FP, Tan ES, et al. Endoscopic biliary drainage for severe acute cholangitis. *N Engl J Med*. 1992;326(24):1582-6.
13. Sharma VK, Nguyen CC, Crowell MD, et al. A national study of complications after endoscopic retrograde cholangiopancreatography in the United States. *Gastrointest Endosc*. 2005;61(4):401-407.
14. Testoni PA, Mariani A, Giussani A, et al. Risk factors for post-ERCP pancreatitis in high- and low-volume centers and among expert and non-expert operators: a prospective multicenter study. *Am J Gastroenterol*. 2010;105(8):1753-1761.
15. Weber A, Schmid RM, Prinz C. Diagnostic approaches for cholangiocarcinoma. *World J Gastroenterol*. 2008;14(26):4131-4136.
16. Huang RJ, Friedland S, Downes KL, et al. Endoscopic stenting for malignant biliary obstruction: a risk-stratified analysis of adverse events in a real-world cohort. *Gastrointest Endosc*. 2019;89(5):1124-1132.
17. Kim HS, Kim SW, Ju CI, et al. Analysis of clinical results of short segment pedicle screw fixation for thoracolumbar burst fractures. *J Korean Neurosurg Soc*. 2007;42(4):317-21.
18. Zhou ZH, Wang B, Huang YM, et al. Selective extension of short segment fixation for thoracolumbar fractures: a new technique for improved clinical outcomes. *Orthop Surg*. 2019;11(5):811-7.
19. Baron TH, Mallery JS. Selective bile duct cannulation techniques during ERCP: the peril of using a guidewire. *Gastroenterology*. 2015;148(3):590-593.
20. Weber A, Schmid RM, Prinz C. Diagnostic approaches for cholangiocarcinoma. *World J Gastroenterol*. 2008;14(26):4131-4136.