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Comparative evaluation of ERCP and endosonography in the diagnosis of extrahepatic biliary obstruction and a suggested algorithm

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Background/aims: *Endosonography is an effective diagnostic tool for evaluating pancreatobiliary diseases. However, it is scarcely used in our healthcare system because of limited resources and scarcity of trained personnel. The aim of this study was to evaluate the role of endosonography in patients presenting with extrahepatic biliary obstruction in the Indian subcontinent.* ***Methods:*** *Fifty consecutive patients presenting with suspected obstructive jaundice of unknown cause were enrolled in the study. All the patients underwent abdominal ultrasound followed by endosonography and finally endoscopic retrograde cholangiopancreatography. Final diagnosis was obtained on endoscopic retrograde cholangiopancreatography or surgery, where indicated.* ***Results:*** *Twenty-six patients had malignant cause for extrahepatic biliary obstruction and 24 patients had non-malignant cause for extrahepatic biliary obstruction. The etiological diagnosis was established by endosonography in 23/26 patients with malignant cause for extrahepatic biliary obstruction compared to in 21/26 patients with endoscopic retrograde cholangiopancreatography. For non-malignant cases of extrahepatic biliary obstruction, endosonography and endoscopic retrograde cholangiopancreatography were equally accurate (23/24 patients) in providing the correct etiological diagnosis.* ***Conclusions:*** *Endosonography and endoscopic retrograde cholangiopancreatography are equally efficient for diagnosing the cause of extrahepatic biliary obstruction. The evaluation of patients presenting with cholestasis should be based on careful clinical judgment supported by baseline investigations to suggest likely malignant or non-malignant etiology. Endosonography as first approach should be followed in patients with suspected malignant cause of extrahepatic biliary obstruction. Endoscopic retrograde cholangiopancreatography should be performed first in patients with suspected non-malignant cause of extrahepatic biliary obstruction.*

Key words: Obstructive jaundice, endosonography, endoscopic retrograde cholangiopancreatography

Ekstrahepatik biliyer obstrüksiyonun tanısında ERCP ve endosonografinin karşılaştırmalı değerlendirilmesi ve algoritma önerisi

Amaç: *Endosonografi, pankreatikobiliyer hastalıkların değerlendirilmesinde etkin bir tanı aracıdır. Ancak, maddi kaynak yetersizliği ve eğitimli personel eksikliği nedeni ile sağlık sisteminde nadiren kullanılabilmektedir. Bu çalışmanın amacı, Hindistan bölgesinde, ekstrahepatik safra yolu tıkanıklığı ile başvuran hastaların değerlendirilmesinde endosonografinin yerinin araştırılmasıdır.* ***Yöntem:*** *Tıkanma sarılığı süphesi ile başvuran 50 ardışık hasta çalışmaya alındı. Tüm hastalar, sırasıyla abdomen ultrason, endosonografi ve endoskopik retrograd kolanjiopankreatografi ile değerlendirildiler. Nihayi tanı, endikasyona göre endoskopik retrograd kolanjiopankreatografi veya cerrahi ile konuldu.* ***Sonuçlar:*** *Hastaların 26'sında malign ve 24'ünde malign olmayan ekstrahepatik safra yolu tıkanıklığı mevcuttu. Etiyolojik tanı, malign hastaların 23/26'sında endosonografi ile ve 21/26'sında endoskopik retrograd kolanjiopankreatografi ile ortaya konuldu. Malign olmayanlarda ise endoskopik retrograd kolanjiopankreatografi ve endosonografi tanıda eşit etkinlikte (23/24) bulundu.* ***Tartışma:*** *Endosonografi ve endoskopik retrograd kolanjiopankreatografi, ekstrahepatik safra yolu tıkanıklıklarının tanısında eşit etkinliğe sahiptir. Ekstrahepatik safra yolu tıkanıklığı olan hastaların değerlendirilmesi, bazal tetkiklerin desteğinde dikkatli bir klinik inceleme ile malign - maling olmayan ayrımına yönelik yapılmalıdır. Malign şüphesi olan hastalar öncelikle endosonografi ile, malign olmayan öntanısı olanlarda ise endoskopik retrograd kolanjiopankreatografi ile değerlendirilmelidir.*

Anahtar kelimeler: Tıkanma sarılığı, endoskopik ultrasonografi, endoskopik retrograd kolanjiopankreatografi

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INTRODUCTION

Endosonography (EUS) has emerged as an efficient imaging modality of the pancreatobiliary system. The efficacy of EUS is comparable to that of endoscopic retrograde cholangiopancreatography (ERCP) in identifying the cause of extrahepatic biliary obstruction (EHBO) (1-4). ERCP is considered as a gold standard for imaging of the biliary tract because of its high diagnostic accuracy. The additional advantage of offering a therapeutic option makes it widely used in investigations in developing countries. On the other hand, ERCP is not a completely benign procedure and carries some risks, with potentially serious morbidity and mortality associated with the procedure (5-7). In contrast, EUS is a safe procedure with comparable performance to ERCP and minimal, minor side effects. EUS-guided therapeutic procedures for pancreatobiliary diseases are currently being evaluated in pilot trials, but presently, its role is not fully established (8-12). Therefore, for practical reasons for now, EUS is considered as a diagnostic imaging modality only. ERCP is generally considered for patients where therapy is anticipated.

Our hospital is one of the few centers in India where EUS is performed routinely. The role of EUS in patients with EHBO has not been studied in our population. This is important as the spectrum of diseases causing EHBO in our population is not the same as in western populations. We conducted a prospective study to evaluate the role of EUS in our patients presenting with EHBO.

MATERIALS AND METHODS

The study was conducted at a university medical center after approval from the local ethics committee. A total of 50 consecutive patients referred to our institution with suspected EHBO based on clinical evaluation, baseline laboratory investigations and/or abdominal ultrasonography (USG) findings were included in the study. Laboratory parameters for suspecting cholestasis was based on elevation of alkaline phosphatase and bilirubin. USG criterion for suspecting EHBO was dilatation of intrahepatic ducts with or without dilatation of the common bile duct (CBD dilation defined as ≥8 mm or ≥10 mm in patients who had prior cholecystectomy). The imaging procedures were performed independently by three different operators (MK, GJ and SZ) who were blinded to the results of the alternative imaging studies. All the patients underwent USG, which was followed by EUS. Finally ERCP was performed on all the patients. The cause of obstruction was predicted as choledocholithiasis, ampullary carcinoma, pancreatic cancer, chronic pancreatitis, parasitic infestation of the biliary tract, benign strictures, or others. The final diagnosis of non-malignant diseases was established during surgery or by recovery of stones or parasites on ERCP. The diagnosis of malignant disease processes as causes of EHBO was established by histopathological confirmation obtained from tissues taken at ERCP or during surgery.

Therapeutic intervention was performed during ERCP where indicated. Those patients, in whom surgery was indicated based on imaging results, were referred for surgery. Intra-operative findings were noted and biopsy material, if any, was sent for histopathological diagnosis.

Descriptive statistics were used to analyze the performance of each imaging modality.

RESULTS

Fifty patients (14 males, 36 females) falling in the age group of 15-70 years were evaluated in the study. Of the 50 patients, 26 had malignant cause for EHBO and 24 had non-malignant etiology for BO. Malignancy was a more common cause of EHBO in males (78.5%) compared to females (41.6%), in whom biliary stones and biliary ascariasis were the leading causes (Table 1). The clinical characte-

Table 1. Characteristics of lesions in 50 patients

Final diagnosis	No. of cases	Age (Mean [Range])	Sex (M:F)
Bile duct stone	15	44 (18-70)	3:12
Biliary ascariasis	8	30 (15-46)	0:8
Chronic pancreatitis	1	40	0:1
Ampullary tumor	7	55 (45-65)	1:6
Cholangiocarcinoma	12	44 (19- 70)	8:4
Pancreatic carcinoma	4	57 (50-65)	1:3
GB carcinoma	3	45 (40-45)	1:2

GB: Gallbladder.

ristics of the patients are given in Table 2. Presence of dull or no pain, itching, anorexia, weight loss, and passage of acholic stools were more common in patients with malignant cause of EHBO, while colicky abdominal pain and fever were more common in non-malignant cases of EHBO. High leukocyte count in blood was seen in 4 patients with stones in the bile duct, 2 patients with biliary ascariasis, and 1 patient with pancreatic carcinoma. A high serum alkaline phosphatase level was seen in all except one patient in the study group. Cannulation at ERCP failed in 1 patient. Accuracy of providing a correct etiological diagnosis by the three techniques is given in Table 3. For malignant lesions, EUS could provide correct etiological diagnosis in 23/26 cases (88.46%), while ERCP could establish a correct diagnosis in 21/26 cases (80.76%). For non-malignant lesions causing EHBO, EUS and ERCP were equally accurate (95.83%) in providing a correct etiological diagnosis.

Table 2. Characteristics of patients with malignant and non-malignant etiology of EHBO

Clinical features	Malignant group	Non-malignant group
Colicky	4	18
Dull	14	5
No pain	12	2
Pruritus	12	3
Weight loss	9	None
Anicteric stools	8	None
GI bleed	1	None
Fever	4	12
Hepatomegaly	13	5
Tender upper abdomen	3	9
Palpable GB	8	none

GI: Gastrointestinal. GB: Gallbladder.

DISCUSSION

Endosonography (EUS) has been shown consistently as a highly efficacious imaging modality for the pancreatobiliary system (1-4,13); however, its routine use in the evaluation of patients with EHBO is still limited. This is partly the result of very limited availability of the professionals trained to perform EUS. In addition, the ease of availability of ERCP for diagnosis and therapy has led to restricted use of EUS in the management of pancreatobiliary diseases in our health system. EUS is comparable to magnetic resonance cholangiopancreatography (MRCP) for diagnosis of bile stones (14,15), but for diagnosing malignant EHBO, it has been reported to be superior to MRCP (16). In addition, MRCP is a costly investigation and is not readily available in developing countries. Over the last two decades, several studies have attempted to establish the role of EUS in the management of patients with EHBO. Most of the studies performed in the recent years suggest performing EUS in select patients with suspected EHBO for therapeutic ERCP (17-20). This would translate into performing EUS in all patients with suspected EHBO and then performing ERCP only in a select number of patients guided by results from the EUS. This idea seems plausible as it will minimize the number of unnecessary ERCPs and the resultant complications. However, it is not practically feasible in developing countries where, in view of limited resources, the number of tertiary care centers is far too inadequate in relation to the patient population. In addition, there are fewer trained personnel to perform EUS in our country. As a result, the waiting time for patients to undergo sophisticated investigations including EUS is long.

Table 3. Accuracy of diagnosis of different etiologies of EHBO by USG, EUS and ERCP

Diagnosis	No. of Patients	USG (%)	EUS (%)	ERCP (%)
Malignant causes				
Ampullary tumor	7	2 (28%)	7 (100%)	6 (85%)
Cholangiocarcinoma	12	5 (41%)	9 (75%)	12 (100%)
Pancreatic tumor	4	1 (25%)	4 (100%)	3 (75%)
GB carcinoma	3	3 (100%)	3 (100%)	0 (0%)
Non-malignant causes				
Bile duct stone	15	10 (66%)	14 (93%)	14 (93%)
Biliary ascariasis	8	6 (75%)	8 (100%)	8 (100%)
Chronic pancreatitis	1	0 (0%)	1 (100%)	1 (100%)
Total	50	27 (54%)	46 (92%)	44 (88%)

GB: Gallbladder. USG: Ultrasonography. EUS: Endosonography. ERCP: Endoscopic retrograde cholangiopancreatography.

The results from our study showed better accuracy of EUS in diagnosing tumors in the lower half of the CBD. EUS failed to locate two cases of cholangiocarcinoma in the upper part of the biliary tract, which were further identified by ERCP. This is consistent with the observations from other studies (21), which demonstrated the inferiority of EUS for evaluating lesions in the upper part of the biliary tract. However, ERCP failed to provide etiological diagnosis in gallbladder (GB) cancer, which was interpreted as cholangiocarcinoma.

For ampullary and pancreatic tumors, EUS was highly accurate in providing a correct diagnosis (100% for both) compared to ERCP (85.7% and 75%, respectively), which is consistent with the results from other studies (22-24). EUS and ERCP were equally accurate in providing etiological diagnosis of EHBO in patients with non-malignant causes for EHBO. For biliary ascariasis, EUS and ERCP had 100% accuracy (Figures 1, 2). Therefore, ERCP would be the preferable imaging modality in EHBO of non-malignant etiology because therapeutic intervention, if needed, can be performed during the same procedure. Biliary ascariasis is a common cause of bile duct stones in our population, and these stones are soft; therefore, they may not cast a shadow on EUS. As a result, these stones could potentially be missed on EUS (25).

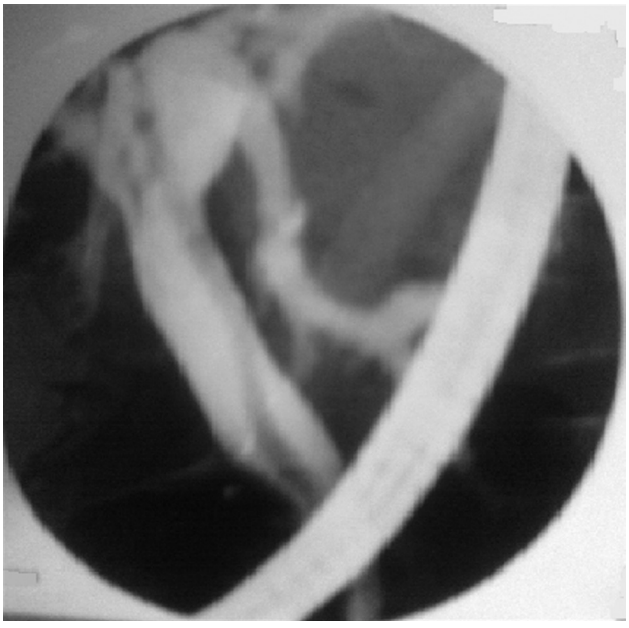

Figure 2. ERCP showing adult worm of *Ascaris lumbricoides* in the common bile duct.

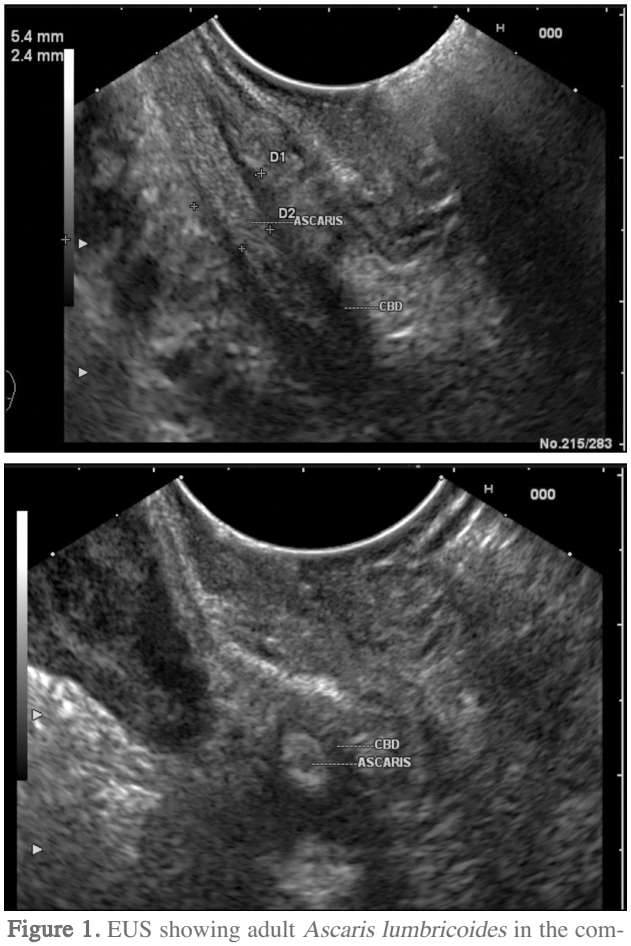

Figure 1. EUS showing adult *Ascaris lumbricoides* in the common bile duct in longitudinal view (1a) and in transverse view (1b).

The results of this prospective study support previous data demonstrating the high accuracy of EUS for diagnosing EHBO of malignant etiology (1,2,26,27). For non-malignant causes for EHBO, ERCP and EUS were equally accurate. Therefore, we suggest the evaluation of patients presenting with cholestasis should be based on careful clinical judgment supported by baseline investigations to suggest whether the cholestasis has malignant or non-malignant etiology. If there is a suggestion of malignant etiology for extrahepatic cholestasis, then EUS should be performed first in these patients. EUS, having comparable accuracy for diagnosing EHBO of malignant etiology, additionally could provide information on loco-regional spread of the tumor. In most cases, this could help in planning further management in these patients, i.e. whether surgery or palliation with endoscopic/percutaneous placement of a stent for drainage of the biliary tree is required. For non-malignant causes of EHBO, since EUS and ERCP have similar accuracy, we suggest an ERCP first approach in these patients, as a therapeutic procedure can

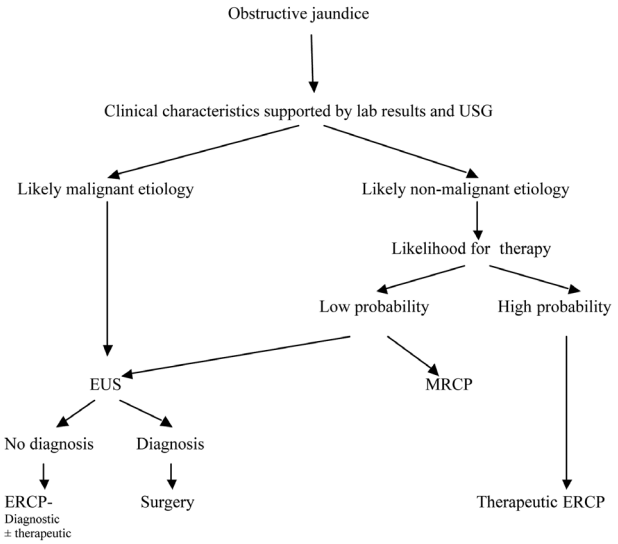

Figure 3. Diagnostic algorithm for patients with suspected EHBO.

be performed at the same time. However, in order to minimize the risk of unnecessary intervention, there is a strong need to construct a mathematical model for predicting the probability of performing therapeutic ERCP in these patients. Several models have previously been described to predict the likelihood of therapeutic ERCP, most of which are based on the studies that have been conducted in western populations (28,29) and may not be applicable to our population. Developing one such mathematical model based on our patient population could potentially serve as a useful guide to minimize unnecessary ERCPs in our healthcare system. Based on the results of our study, we suggest the algorithm given in Figure 3 to help the clinician in the work-up of patients with suspected obstructive jaundice. However, additional larger prospective trials are needed to validate our results.

In conclusion, our study depicts the usefulness of EUS in the evaluation of obstructive jaundice in our patients. There is a need to exploit this highly efficient imaging modality for pancreatobiliary diseases, since it has been largely neglected in this part of the world. Even though there are limited healthcare resources in developing countries, selective use of these technologies can be efficient and cost effective.

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