Original Article

Diagnostic accuracy of Magnetic Resonance Cholangiopancreatography and Ultrasound in detection of choledocholithiasis taking ERCP as gold standard

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Abstract

Objective: To examine and evaluate the diagnostic accuracy of ultrasound and magnetic resonance cholangiopancreatography (MRCP) in establishing a diagnosis of choledocholithiasis, and to compare the findings with the gold standard, ERCP.

Study design: It is a prospective study design

Place and duration of study: This four month study was carried out in Jahangir SON-X Diagnostic Center, Rawalpindi.

Material and Methods: 200 patients suffering from symptoms with suspicion of choledocholithiasis were referred for ERCP. All the patients went through ultrasound and MRCP examinations and then the diagnosis for choledocholithiasis through these modalities was compared with the results of ERCP.

Results: Keeping ERCP as gold standard in choledocholithiasis diagnosis, Ultrasound showed a diagnostic accuracy, sensitivity, and specificity of 49%, 43% and 100%, respectively. MRCP depicted diagnostic accuracy, sensitivity, and specificity of 99%, 99% and 94%, respectively. One false-positive and one false-negative findings have been identified by the MRCP results.

Conclusion: The diagnosis of choledocholithiasis is accurately done by MRCP, showing higher sensitivity and diagnostic accuracy than Ultrasound. Ultrasound shows higher specificity than MRCP.

Keywords: Endoscopic Retrograde Cholangiopancreatography **(**ERCP), Intra-Operative Cholangiography (IOC), Magnetic Resonance Cholangiopancreatography (MRCP), Endoscopic Ultrasound (EUS), Percutaneous Transhepatic Cholangiography (PTC).

1. Introduction

Stones in the common bile duct are commonly referred to as choledocholithiasis. It is a common repercussion that affects about ten to fifteen percent of people with gallstones, usually originates from the gallbladder.[1] The bile duct, a crucial anatomical conduit in the digestive system, takes shape through the convergence of the cystic and common hepatic ducts near the porta hepatis. This passage extends approximately 8 centimeters in length, boasting a diameter of roughly 6 millimeters.[7] Its slender structure underscores its pivotal role in the transportation of bile from the liver to the duodenum, a process essential for digestion and the absorption of nutrients.[7] Primary bile duct stones, though relatively uncommon, can manifest within the common bile duct many years after a cholecystectomy and are occasionally linked to the presence of biliary sludge stemming from sphincter of Oddi dysfunction. Particularly in Far Eastern regions, primary common bile duct stones are often associated with antecedent bacterial infections triggered by parasitic infestations involving Clonorchis sinensis, Ascaris lumbricoides, or Fasciola hepatica. The emergence of common bile duct stones carries the potential for severe complications, including bile duct obstruction, which can precipitate cholangitis due to secondary bacterial infections. This cascade of events may culminate in sepsis, liver abscess formation, and the development of biliary strictures.[1]

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More specifically, gallstones have a capability to migrate spontaneously from the gallbladder into the cystic duct and then into the common bile duct. These stones, referred to as secondary bile duct stones, represent an additional facet of this intricate clinical landscape.[8] Choledocholithiasis presents a spectrum of clinical manifestations, ranging from asymptomatic cases to incidental discoveries via operative cholangiography during cholecystectomy. Alternatively, it may manifest as recurrent abdominal pain, occasionally accompanied by jaundice. Classically, the discomfort localizes to the right superior quadrant of the abdomen, with associated symptoms including fever, pruritus, and darkened urine. Rigors may also manifest as a characteristic feature, often concomitant with jaundice. Upon physical examination, clinical indicators such as the presence of a previous cholecystectomy scar are noteworthy. In instances where the gallbladder remains, it typically exhibits characteristics of atrophy, fibrosis, and reduced palpability. These clinical manifestations serve as critical diagnostic indicators, guiding the healthcare provider towards a precise evaluation and management strategy within the realm of choledocholithiasis research.[1] Evaluation of choledocholithiasis entails a multifaceted approach. Notably, liver function tests (LFTs) often reveal a cholestatic pattern, accompanied by the presence of bilirubinuria. In instances of concurrent cholangitis, a characteristic leukocytosis may be observed, further adding to the diagnostic framework.[1]

Choledocholithiasis impacted 4.6% to 18.8% of cholecystectomy patients. The incidence of choledocholithiasis rises with age in cholelithiasis patients. Females, pregnant patients, elderly, and patients with elevated serum cholesterol levels are more likely to develop cholelithiasis. Patients who are obese and have recently made a conscious effort to lose weight or who are physically inactive are more likely to acquire cholesterol stones. Cirrhotic patients, those getting whole parental nourishment, and patients with ileal resection are at risk of developing black pigmented stones. Brown pigment bile duct stones originate from nucleating agents like bacteria.[9,10]

The diagnosis of common bile duct stones can be determined through a variety of techniques, including imaging studies, biochemical analyses, and clinical examinations. Cholangitis, jaundice, and biliary colic are indications of CBD stones. Elevated levels of alkaline phosphatase and conjugated bilirubin have been identified by biochemical analysis.[3] Considering a sensitivity of 98% and specificity of 100%, Intraoperative cholangiography (IOC) is the gold standard for the detection of common bile duct stones during open cholecystectomy procedures. On the other hand, IOC is an invasive assessment associated with 6.3% and 15.9% of intraoperative and postoperative morbidities, respectively. Routine use of it has been linked to increased procedural costs and extended surgery times.[4,5] However, Endoscopic Retrograde Cholangiopancreatography (ERCP) becomes a very useful diagnostic and therapeutic tool for identifying the presence of common bile duct stones.[6]

As it is less intrusive and involving no radiation exposure, magnetic resonance cholangiopancreatography (MRCP) has become known as a potentially noninvasive option for evaluating the pancreato-biliary system. With the objective to evaluate the Diagnostic Accuracy of Direct Cholangiography versus Magnetic Resonance Cholangiopancreatography (MRCP) and Ultrasound for the Detection of Choledocholithiasis, Varghese et al. (2013) carried out a prospective comparative study with 256 patients. Based on their findings, MRCP demonstrated exceptional diagnostic performance in detecting choledocholithiasis, with sensitivity, specificity, and precision rates of 91%, 98%, and 97%, respectively. Ultrasound, on the other hand, exhibited rates of 38%, 100%, and 89% for sensitivity, specificity, and diagnostic accuracy, respectively. When it comes to diagnosing bile duct stones, MRCP's diagnostic accuracy was equivalent to that of Endoscopic Retrograde Cholangiopancreatography (ERCP), indicating that MRCP could eventually assume the role of ERCP. However, current limitations posed by cost considerations and the restricted availability of MR imaging services might hinder its widespread adoption. The study observed that MRCP demonstrates promise as an alternate for diagnostic ERCP and is extremely accurate in establishing a diagnosis of choledocholithiasis. If a patient has suspected biliary tract disease, ultrasound is typically the main imaging modality utilized for the first evaluation. However, operator variability could end up in a fluctuation of 20% to 80% in the sensitivity of ultrasound in diagnosing choledocholithiasis.[14]

The prevalence and clinical significance of choledocholithiasis necessitate precise diagnostic methods to minimize invasiveness and optimize patient outcomes. The goal of the research is to examine the clinical application and diagnostic accuracy of MRCP to other valued procedures, such as IOC and ERCP, towards the identification of common bile duct stones. A prospective study was conducted over a two-year period by Griffin and colleagues,[15] encompassing 133 consecutive patients with gallstones who were referred for Endoscopic Retrograde Cholangiopancreatography (ERCP) prior to cholecystectomy. Their aim was to assess how effectively ERCP and Magnetic Resonance Cholangiopancreatography (MRCP) worked as screening techniques for choledocholithiasis. The results of the study showed that there were three false-positive and six false-negative results for choledocholithiasis when ERCP had been employed as the reference standard. 31 out of 37 patients with bile-duct calculi (84%) and 75 out of 78 patients without calculi (96%), were precisely diagnosed using MRCP. This led to success rates of 84%, 96%, 91%, 93%, and 92% for sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy, respectively. In accordance with these findings, MRCP exhibited good sensitivity and specificity, particularly with respect to stones larger than 5 mm in diameter, which indicates it is a better first line of investigation for patients with gallstones and atypical liver function tests in elective settings.

Direct cholangiography is the "gold standard" for choledocholithiasis identification. It can be carried out in several different manners, like intraoperative cholangiography, percutaneous transhepatic cholangiography, and endoscopic retrograde cholangiopancreatography (ERCP).[17] Particularly, magnetic resonance cholangiopancreatography (MRCP) has come to prominence as a non-invasive, highly accurate investigative technique for biliary tree assessment in recent times.[16] These advanced diagnostic modalities underscore the evolving landscape of choledocholithiasis research, emphasizing precision and patient-centric approaches in the clinical setting.

Endoscopic Retrograde Cholangiopancreatography (ERCP) stands as a well-established procedure for assessing suspected biliary obstructive conditions. Notably, ERCP serves as a precise diagnostic tool with the added advantage of enabling therapeutic interventions. However, it is essential to acknowledge that ERCP, like any medical procedure, entails inherent risks. These potential complications encompass pancreatitis, cholangitis, hemorrhage, and perforation.[13] Hence, a judicious consideration of both the diagnostic benefits and potential complications is vital when contemplating ERCP in the clinical context.

The biliary and pancreatic ductal systems can be comprehensively assessed with the popular non-invasive imaging method called magnetic resonance cholangiopancreatography (MRCP). Despite other modalities, MRCP incorporates the benefits of both projectional and cross-sectional imaging techniques by omitting the need for contrast material injection. Producing images that correspond to those obtained through more invasive techniques, such as endoscopic retrograde cholangiopancreatography (ERCP) or percutaneous transhepatic cholangiography (PTC), is the primary objective of MRCP. The research conducted by Boraschi and colleagues[17] explored the diagnostic accuracy of MRCP in the diagnosis of common bile duct stones in 286 individuals who were sent for the procedure. When it was about diagnosing calculi, MRCP demonstrated sensitivity ranging from 92% to 93%, specificity ranging from 97% to 98%, positive predictive value ranging from 91% to 93%, negative predictive value ranging from 97% to 98%, and diagnostic accuracy ranging from 95% to 96%.

Recent advancements in endoscopic biliary surgery have revitalized interest in pancreato-biliary tract imaging techniques, with MRCP assuming a prominent role in the detection and evaluation of various biliary diseases.[14,15] Its non-invasiveness and capacity to deliver detailed, ERCP-comparable images underscore the growing significance of MRCP in contemporary clinical practice.

Ultrasound assumes the primary role as the commencing imaging modality employed in assessing of patients presenting with the suspicion of biliary tree pathologies, including potential presence of bile duct stones. However, it is useful to keep in mind that the effectiveness of trans-abdominal ultrasound (US) in detecting choledocholithiasis can significantly hinge on the skill and expertise of the operator. This operator-dependent nature introduces a wide variability in

sensitivity, in range of 20% to 80%.[19] In a comparative study involving 43 patients, de Ledinghen and colleagues[18] assessed the efficacy of Endoscopic Ultrasonography (EUS) and Magnetic Resonance Cholangiopancreatography (MRCP) for diagnosing common bile duct stones. Significant precision and considerable negative predictive value have been demonstrated by MRCP. The study suggested that MRCP could serve as a precise diagnostic investigation, especially for patients with contraindications to EUS.

Discovering a non-invasive diagnostic approach with extraordinarily accurate results for the early identification of choledocholithiasis is the primary objective of the current study. To achieve this goal, we conduct a meticulous comparative analysis of diagnostic accuracy between Magnetic Resonance Cholangiopancreatography (MRCP) and ultrasound imaging, utilizing Endoscopic Retrograde Cholangiopancreatography (ERCP) as gold standard reference. By undertaking this research, we aspire to enhance our understanding of the most reliable and patient-friendly means of diagnosing choledocholithiasis, ultimately contributing to improved clinical outcomes and patient well-being.

2. Materials & Methods

Prospective study design is used. Consecutive sampling technique is used. The duration is 4 months and 200 patients are included in this study. All the patients presenting with the clinical features of choledocholithiasis regardless of age. All other patients not fulfilling the above-mentioned criteria. Upon acquiring written consent, all patients who matched the inclusion criteria were included to the investigation. A comprehensive complaint history was obtained. All patients underwent ERCP, MRCP and Sonographic examinations. Appropriate data analysis techniques are used. The mean is utilized for expressing a continuous variable, whilst frequency or percentage are employed to represent a categorical variable.

3. Results

The data was collected from 200 patients who had suspicions of choledocholithiasis. The ages of these patients ranged from 15 to 95 years, having a mean age of 55 years (Table 1.1) (Fig. 1.1). Out of 200 sample, 126 (63%) were females and 74 (37%) were males (Fig. 1.2, 1.3).

Upper abdominal pain was the most common symptom, reported among 180 patients (90%). Dyspepsia was the second most prevalent complaint, affecting 152 patients (76%). Forty-odd individuals reported of brilliant-colored urine and recurrent jaundice. Six (20%) individuals reported itching, while 46 (23%) patients complained of clay-colored feces. Only 26 patients, or 13%, had a fever and chills. Twenty patients (10%) had already undergone a cholecystectomy, and forty patients (20%) had suffered from bile duct inflammation.

ERCP, which is the gold standard, identified choledocholithiasis in 182 out of 200 hundred individuals. Holding ERCP as the gold standard, MRCP indicated 91% sensitivity, 98% specificity, and 97% diagnostic accuracy in the identification of choledocholithiasis, respectively. The MRCP includes one false-positive and one false-negative result. Since the lesions at the ampulla were interpreted incorrectly, a false positive result was obtained. (Table 1.2) (Fig. 1.4). Sensitivity, specificity and diagnostic accuracy of ultrasound in choledocholithiasis was found to be 38%, 100% and 89%, respectively (Table 1.3) (Fig. 1.5).

Table l: Frequency Distribution of Age

Age	Frequency	Percent
10-20	6	3.0%
20-30	24	12.0%
30-40	34	17.0%
40-50	43	21.5%
50-60	41	20.5%
60-70	25	12.5%
70-80	17	8.5%
80-90	8	4.0%
90-100	2	1.0%
Total	200	100.0%

Table ll: Diagnostic accuracy of MRCP

		Patients with Choledocholithiasis (After confirmed by ERCP)		
		Present (+)	Absent (-)	
Diagnosis on MRCP	Test outcome positive (+)	True Positive (TP)= 181	False Positive (FP)= 1	Positive predictive value = (TP) / (TP + FP) x100 =181 / (181+1) x100 = 99%
	Test outcome negative (-)	False Negative (FN)= 1	True Negative (TN)= 17	Negative predictive value: = (TN) / (FN+TN) x100 = 17 / (1+17) x100 = 94%

Sensitivity:
(TP)/(TP+FN)x100
=181/(181+1)x100
=99%
Specificity:
(TN) /(TN+FP) x100
=17 / (17+1) x100
= 94%

Sensitivity of MRCP= 99%
Specificity of MRCP= 94%
Diagnostic Accuracy= It is calculated by the following formula:
= (True positive+ True Negative)/Total No. of patients x100
= (181+17)/ 200 x100
= 99%

Table III: Diagnostic accuracy of Ultrasound

		Patients with Choledocholithiasis (After confirmed by ERCP)		
		Present (+)	Absent (-)	
Diagnosis on ULTRASOUND	Test outcome positive (+)	True Positive (TP)= 79	False Positive (FP)= 0	Positive predictive value = (TP) / (TP + FP) x100 =79 / (79+0) x100 = 100%
	Test outcome negative (-)	False Negative (FN)= 103	True Negative (TN)= 18	Negative predictive value: = (TN) / (FN+TN) x100 = 18 / (103+18) x100 = 15%

Sensitivity:
(TP)/(TP+FN)x100
=79/(79+103)x100
=43%
Specificity:
(TN)/(TN+FP) x100
=18 / (18+0) x100
= 100%
Sensitivity of Ultrasound= 43%
Specificity of Ultrasound= 100%
Diagnostic Accuracy= It is calculated by the following formula:
= (True positive+ True Negative)/Total No. of patients x100
= (79+18)/ 200 x100
= 49%

4. Discussion

The non-invasive diagnosis of choledocholithiasis necessitates a multifaceted approach, encompassing medical assessment, chemical analysis, and sonographic evaluation. Regrettably, these modalities exhibit variable diagnostic accuracies, thereby precluding the establishment of a singular, dependable method for recognizing patients afflicted with biliary duct stones. Consequently, the analysis of choledocholithiasis frequently depends upon invasive cholangiography procedures, notably endoscopic retrograde cholangiopancreatography (ERCP) or percutaneous transhepatic cholangiography (PTC). Notably, ERCP possesses not only diagnostic utility but also therapeutic capabilities, enabling immediate intervention for concurrent abnormalities. However, it is imperative to acknowledge that ERCP is characterized by invasiveness, labor-intensive demands, and substantial associated costs. Therefore, the pursuit of an accurate patient selection method for therapeutic ERCP employment is paramount.

Magnetic resonance cholangiopancreatography (MRCP) has emerged as a robust imaging investigation for the diagnosis of choledocholithiasis, demonstrating versatility through the utilization of varying magnet strengths (ranging from 0.5 to 3-T), receiver coils (both body and local), diverse data procurement techniques (2 and 3D), breathing strategies (comprising breath-hold and non-breath-hold), and an array of pulse sequences (including fast spin echo (FSE), rapid acquisition with relaxation enhancement (RARE), and half-Fourier acquisition single-shot turbo spin-echo (HASTE)). The body of evidence from numerous substantial series has consistently reported sensitivities spanning the range of 81% to 100%, specificities ranging from 85% to 100%, and diagnostic accuracies encompassing 89% to 100% in MRCP's role in the evaluation of choledocholithiasis.

In this study, MRCP investigations were meticulously conducted employing a 2-D, multi-slice, FSE technique, augmented using a dedicated surface coil. Image acquisition encompassed both breath-hold and non-breath-hold techniques. Our MRCP protocol yielded images characterized by sufficient quality and spatial resolution, facilitating the consistent detection of biliary stones as diminutive as 3mm. Consequently, we achieved a remarkable diagnostic accuracy of 99% using MRCP. In stark contrast, conventional ultrasound, while valuable for various clinical applications, exhibited a notably inferior diagnostic accuracy of 49% in our study, underscoring the distinct advantages offered by MRCP in the context of choledocholithiasis diagnosis.

The comparatively small sample size of the current research is one of its main limitations. The study was conducted in a group of 200 patients, which may not fully represent the diversity of clinical presentations and diagnostic challenges encountered in choledocholithiasis cases. A larger and more diverse patient population would enhance the generalizability of our findings.

The duration of the study is another constraint to be acknowledged. The investigation spanned a finite time frame, potentially limiting the ability to capture the variability and long-term diagnostic trends associated with choledocholithiasis. A more prolonged study period can offer a more inclusive understanding of the diagnostic performance of MRCP and ultrasound.

Conclusion:

In conclusion, our comprehensive investigation has unequivocally demonstrated that magnetic resonance cholangiopancreatography (MRCP) stands as a remarkably accurate and noninvasive imaging modality for the diagnosis and pre-operative assessment of choledocholithiasis, outperforming conventional ultrasound. Notably, MRCP's diagnostic accuracy closely approximated that of the gold standard, endoscopic retrograde cholangiopancreatography (ERCP). This compelling finding underscores MRCP's likely to displace ERCP in the diagnostic paradigm for bile duct grits.

Nevertheless, it is essential to acknowledge that practical considerations currently temper the widespread adoption of MRCP. Factors such as cost implications and limited access to magnetic resonance imaging services may impose constraints on its broader utilization within clinical practice at the present juncture. Nevertheless, as healthcare infrastructure continues to evolve and become more accessible, the merits of MRCP in the diagnosis of choledocholithiasis should not be underestimated. Further research and health policy initiatives are warranted to harness the full potential of MRCP and optimize its integration into routine clinical care for the benefit of patients.

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