ORIGINAL ARTICLE

DIAGNOSTIC ACCURACY OF MAGNETIC RESONANCE CHOLANGIOPANCREATOGRAPHY FOR DETECTION OF CHOLEDOCHOLITHIASIS IN OBSTRUCTIVE JAUNDICE PATIENTS TAKING SURGICAL FINDINGS AS GOLD STANDARD

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ABSTRACT

INTRODUCTION: Magnetic resonan cecholangio pancreatography (MRCP) is a non-invasive technique for diagnosing common bile duct stones. Rationale of this study was to gather data about MRCP in our settings to develop our local guidelines for early and non-invasive diagnosis of common bile duct stones. This will help in early initiation of definitive therapy in these patients. **OBJECTIVES:** To determine diagnostic accuracy of MRCP for detection of choledocholithiasis in obstructive jaundice patients taking surgical findings as gold standard. **MATERIALS AND METHODS:** It is a Cross-sectional (validation) study of six months duration. Study was performed in department of Diagnostic Radiology. MRCP of125 patients of either gender with age between 20-60 years who had clinical and laboratory evidence of obstructive jaundice, was performed. MRI machine of 1.5 Tesla was used. MRCP results were correlated with surgical findings. Sensitivity, specificity, PPV, NPV and overall accuracy was calculated. **RESULTS:** 36.0% (n=45) patients were males and 64.0% (n=80) were females. 72.0 % (n=90) of patients were positive on MRCP and 74.4% (n=93) of patients were positive on surgery. Sensitivity, specificity, PPV, NPV and accuracy were found to be 94.6%, 93.8%, 97.8%, 85.7% and 94.4% respectively. **CONCLUSIONS:** MRCP allows non-invasive detection of common bile duct stones with excellent accuracy.
Key words: Choledocholithiasis, obstructive jaundice, MRCP.

Introduction

Increased levels of bilirubin cause Jaundice i.e. yellowish discoloration of the skin, mucous membranes, sclera, and body fluids. Jaundice can be obstructive or non obstructive.[1] Obstructive jaundice results from obstruction to the passage of bilirubin from hepatocytes to duodenum. It is a common problem in surgical practice.[2] Different diseases results in obstructive jaundice, among which choledocholithiasis is the most common cause. The prevalence of choledocholithiasis in obstructive jaundice patients is 40.9%.[3,4] Common presentations of choledocholithiasis includes jaundice, pain in right upper abdomen, dark urine, pruritis, clay coloured stools, acute pancreatitis and acute cholangitis. Important laboratory findings includes increased levels of serum alkaline phosphatase and bilirubin.[5,6] Early detection of cause of the obstructive jaundice is essential because if obstruction is not relieved, it can lead to secondary billiary cirrhosis.[7]

Different invasive and non invasive imaging investigations are available for diagnosing the cause of obstructive jaundice. These includes ultrasound, Percu

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taneous Transhepatic Cholangiopancrea-tography (PTC), Endoscopic ultrasound, Computed Tomography (CT) scan, Endoscopic retrograde Cholangio pancreatography (ERCP) and Magnetic Resonance Cholangio pancreatography (MRCP).[8,9] Due to its technical versatility, superior soft tissue contrast resolution and multiplanar capability, MRCP is superior to other imaging techniques. Being highly sensitive, non-invasive, with high capability to evaluate lesions at all levels and lack of involvement of IV contrast, sedation and radiation exposure, MRCP has become a chief imaging modality to assess the etiology of obstructive jaundice.[10,11] MRCP is an excellent primary tool for detecting or excluding CBD stones before cholecystectomy. MRCP has a specificity of 90% and sensitivity of 95% in demons-trating common bile duct stones.[12] The present study was aimed to determine the importance of MRCP in diagnosing choledocholithiasis in obstructive jaundice patients. Results with higher diagnostic accuracy of MRCP will help to prevent patients from undergoing invasive and relatively unsafe imaging investigation and unnecessary surgeries.

Materials and Methods

STUDY DESIGN:
Cross sectional validation study

SETTING:
This study was carried out at the Radiology Department, PIMS Hospital Islamabad, in collaboration with Surgical Department of PIMS Hospital Islamabad.

DURATION:
Six months (01-01-2015 to 30-06-2015)

SAMPLE SIZE:
The calculated sample size 125. Keeping MRCP expected sensitivity as 95% and specificity as 90%,[12] prevalence of choledocholithiasis in obstructive jaundice patients 40.9%[3,4] and desired precision for sensitivity 5% and for specificity 10% with confidence level 95%.

SAMPLE TECHNIQUE:
Non-probability Consecutive sampling technique

SAMPLE SELECTION:
INCLUSION CRITERIA:
1. Patients of 20-60 years of age.
2. Both genders.
3. Patients with clinical (It includes yellowish discoloration of body with any of the followings, pruritis, anorexia, weight loss, abdominal pain, fever and vomiting), laboratory (It includes all of the followings, Alkaline Phosphatase > 670U/L, Gamma Glutamyl Transpeptidase > 90U/L, Serum Bilirubin > 1mg/dl) or sonological (Common bile duct diameter > 6.5 mm) evidence of obstructive jaundice.

EXCLUSION CRITERIA:
1. Post-operative patients of choledocholithiasis (to exclude residual or recurrent disease process).
2. Patients not fit for MRCP including those with, brain aneurysm clips, cochlear implants, cardiac pacemakers and prosthetic heart valves.

DATA COLLECTION PROCEDURE:
Demographic data of all the patients fulfilling the inclusion criteria was taken after taking informed written consent. MRCP on Philips MRI machine of 1.5-T was then carried out. Patients were nil orally for 6-8 hrs prior to the examination. A three dimensional (including axial, coronal and oblique images), fat suppressed, heavily T2 weighted FSE sequence with multislab acquisition was made during MRCP. All pulse sequences were acquired in breath-hold (10 seconds) except T2 HASTE transverse gated sequences. In addition, Maximum intensity projection (MIP) reconstruction were generated from each multislice data set. Images were analyzed by consultant radiologist of the PIMS diagnostic radiology department, being positive or negative for intraluminal filling defects representing choledocholithiasis (as per operational definition). Findings obtained were confirmed on surgery by consultant surgeon, of PIMS general surgery department and final results were concluded.

DATA ANALYSIS PROCEDURE:
Data was entered and analyzed by using SPSS version 10. For quantitative variables (like age and mean) standard deviation was calculated. For qualitative variables (like gender) frequency and percentage were calculated. Data was stratified for

age (20-40, 41-60 years) and gender (male/female) to control effect modifier and post stratification chi-square was applied. The sensitivity, specificity, positive predictive value, negative predictive value and diagnostic efficacy was reported in percentage using formulae based on 2×2 table as follows.

Results

A total of one hundred and twenty five (n=125) patients fulfilling the inclusion and exclusion criterias were studied. Demographic profile in study population is shown in (Tab.1) and (Tab. 2). The results were analyzed by creating 2 x 2 contingency tables. For the validation purpose, we calculated five parameters; sensitivity, specificity, positive predictive value, negative predictive value and overall accuracy for our study population as shown in (Tab. 2). Our study results showed that sensitivity, specificity, positive predictive value, negative predictive value and accuracy of 94.6%, 93.8%, 97.8%, 85.7% and 94.4% respectively.

	Number (percentage)	Mean Age ± SD (years)
Male	45 (36.0%)	45.3 ± 8.9
Females	80 (64.0%)	46.5 ± 7.9
Total	125 (100%)	46.1 ± 8.3

Table 1: Demographic Profile of the study population

	Sugical Findings		
MRCP	**Positive**	**Negative**	**Total**
Positive	88 (True Positives)	2 (False Positives)	90
Negative	5 (False Negatives)	30 (True Negatives)	35
Total	93	32	125

Sensitivity: 94.6%,
Specificity; 93.8%
Positive Predictive Value ; 97.8%
Negative Predictive Value; 85.7%
Over all Accuracy; 94.4%

Table 2: Cross-tabulation of MRCP and surgery results

Discussion

Occurrence of gallstones within the common bile duct is known as Choledocholithiasis. The exact incidence of choledocholithiasis is not known among the patients with gallbladder disease, However it has been estimated that 5 to 20 percent of patients have choledocholithiasis at the time of cholecystectomy, with the incidence increasing with age.[13,14] Most cases of choledocholithiasis results from the passage of gallstones from the gallbladder to the common bile duct. Primary choledocholithiasis (i.e, formation of calculi within the common bile duct) is less frequent. It usually occurs in the background of biliary stasis (i.e in patients with cystic fibrosis), having increased tendency for intraductal calculi formation. Elderly people with large bile ducts and periampullary diverticulae are at high risk for the formation of bile duct stones. Patients with recurrent or persistent infection involving the biliary system are also at high risk. Patients with choledocholithiasis typically present with colicky pain and raised bilirubin and alkaline phosphatase levels. Patients without any complications are usually afebrile and have a normal complete blood count and pancreatic enzyme levels. Very rarely, patients are asymptomatic. Complications of choledocholithiasis include acute pancreatitis and acute cholangitis. Seldom, patients with long-standing biliary obstruction may develop secondary biliary cirrhosis. The first imaging investigation done is usually a transabdominal ultrasound. Additional investigations may include magnetic resonance cholangiopancreatography (MRCP), endoscopic ultrasound (EUS), and/or endoscopic retrograde cholangiopancreatography (ERCP). The aim of the diagnostic evaluation is to confirm or exclude the presence of common bile duct stones using the least invasive, most accurate, and most cost-effective imaging modality.[15] The specific approach is determined by the level of clinical suspicion, availability of imaging modalities, and patient factors. EUS and MRCP have largely replaced ERCP for the diagnosis of choledocholithiasis in patients at intermediate risk for choledocholithiasis. EUS is less invasive than ERCP, and MRCP is noninvasive. Both tests are highly sensitive and specific for choledocholithiasis.[16] MRCP is preferred for many patients because it is noninvasive. However, the sensitivity of MRCP may be lower for small stones (<6 mm)[17] and biliary sludge can be detected by EUS, but generally not by MRCP. As a result, EUS should be considered in patients in whom the suspicion for choledocholithiasis remains moderate to high despite a negative

MRCP. Multiple studies have compared test characteristics of MRCP with other imaging modalities in detection of choledocholithiasis. Studies comparing MRCP and ERCP for detecting choledocholithiasis had similar to accuracy (specificity 85 to 100% and sensitivity 80 to 100 %).[18,19] Rationale of this study was to gather data about MRCP in our settings to develop our local guidelines for early and non-invasive diagnosis of common bile duct stones. This will help in early initiation of definitive therapy in these patients. Our main objective was to determine diagnostic accuracy of MRCP for detection of choledocholithiasis in obstructive jaundice patients taking surgical findings as gold standard. 125 patients of either gender with age between 20-60 years who had clinical and laboratory evidence of obstructive jaundice were enrolled. MRCP was performed of every patient and correlated with surgical findings. Sensitivity, specificity, PPV, NPV and overall accuracy was calculated. Our results showed that 36.0% (n=45) patients were males and 64.0% (n=80) were females. 72.0 % (n=90) of patients were positive on MRCP and 74.4% (n=93) of patients were positive on surgery. Sensitivity, specificity, PPV, NPV and accuracy were found to be 94.6%, 93.8%, 97.8%, 85.7% and 94.4% respectively. There were five (n=5) false negative results which occurred because small or impacted calculi at the distal common bile duct or ampulla were difficult to detect or distinguish from stenosis.There were two (n=2) false negative results which occurred due to mistaking a prominent ampullary sphincter for a lower bile duct stone. Our results are similar with the already published data on the same subject.

Fulcher AS, et al[20] prospectively determined the clinical applications and diagnostic accuracy of MRCP. MRCP yielded an accuracy of 100% in determining the presence of pancreaticobiliary disease, the presence and level of biliary obstruction, and obstruction due to bile duct calculi.

Varghese JC,et al[21] conducted a comparative study on magnetic resonance cholangiopancreatography (MRCP) and direct cholangiography for the detection of biliary tract disease. Their results showed that MRCP diagnosed choledocholithiasis with a sensitivity of 93%, specificity of 99% and accuracy of 97 %. The overall sensitivity, specificity and accuracy of MRCP in the detection of bile duct lesions were 97%, 98% and 97%, respectively. Authors concluded that MRCP has a high diagnostic accuracy when compared with direct cholangiography in the detection of bile duct disease. Lomanto D, et al[22] aimed to assess the feasibility of MRCP versus ERCP in the diagnosis of biliarytract and pancreatic diseases. One hundred and thirty-six patients were undergone MRCP. Their results demonstrated that in choledocholithiasis, MRCP showed 91.6% sensitivity, 100%specificity, and overall diagnostic accuracy 96.8%.

Becker CD, et al[23] evaluated the accuracy of MRCP for detecting bile duct calculi and stenosis. Their results demonstrated that choledocholithiasis was diagnosed with a sensitivity of 88%-92% and a specificity of 91%-98%. Authors concluded that with MR cholangiopancreatography, bile duct calculi and stenoses can be diagnosed with high accuracy and good inter-observer agreement. Studies conducted in Pakistan also showed similar results. A study conducted in Karachi shows sensitivity of 97% and specificity of 75% with overall diagnostic accuracy of 80%.[24]

In summary, Magnetic resonance cholangio pancreatography (MRCP) is a new, noninvasive imaging technique for the visualization of the biliary ducts with high detection efficiency. No contrast medium injection is used. Multiple studies showed its excellent accuracy in detecting common bile duct stones. Our study results also showed excellent accuracy (97%). We recommend further large scale studies to be done in our setup to validate this technique in routine clinical practice.

Figure 1: Cholidocholithiasis showing meniscus sign

Conclusion

MRCP allows non-invasive detection of common bile duct stones with excellent accuracy. Our study results showed sensitivity, specificity, positive predictive value, negative predictive value and accuracy of 94.6%, 93.8%, 97.8%, 85.7% and 94.4% respectively. Further large scale studies are needed in our setup to validate this technique in routine clinical practice.

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