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MRCP VERSUS ERCP IN THE DETECTION OF CHOLEDOCHOLITHIASIS IN PATIENTS WITH OBSTRUCTIVE JAUNDICE

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Abstract:

*gallstones are a common clinical problem prevalent all around the world. choledocholithiasis is an important associated problem with known serious complications such as obstructive jaundice, pancreatitis and cholangitis. [1]recently there has been a rapid evolution in the modalities available to evaluate for choledocholithiasis. commonly used diagnostic modalities include ultrasonography [usg], computed tomography [ct], endoscopic retrograde cholangiopancreatography [ercp], percutaneous transhepatic cholangiography [ptc] and magnetic resonance rholangiopancreatography [mrcp]. [2] endoscopic retrograde cholangiopancreatography [ercp] is considered the 'gold standard' for the diagnosis of biliary obstruction and is among the several invasive techniques involving direct cholangiography with additional benefit of a higher spatial resolution. it is operator dependent and has an overall reported morbidity of up to 5 % and mortality of 0-1%.magnetic resonance cholangiopancreatography [mrcp] is a non-invasive alternative to diagnostic ercp for investigating biliary obstruction without any associated morbidity and mortality. [3]since the most common cause of biliary obstruction is choledocholithiasis the purpose of this study was to determine the sensitivity, specificity, accuracy, negative and positive predictive values of mrcp using 3 tesla mri systems in detecting choledocholithiasis compared to ercp.**objective of the study:** to determine the diagnostic accuracy of magnetic resonance cholangiopancreatography using 3 tesla mri systems for detection of choledocholithiasis in patients with obstructive jaundice using ercp as gold standard.**study design:** cross-sectional study.**study setting:** department of radiology.**duration of study:** a minimum of 6 months after the approval of study.**subjects:** all the adult patients of either gender aged 15 years to 65 years presenting with obstructive jaundice and subsequently referred by their primary treating physician to the radiology department for mrcp examination were included in this study. patients with contraindication to mrcp or those who did not undergo ercp or those who presented with obstructive jaundice due to causes other than biliary stones were excluded from the study.**methods:** mrcp will be performed using toshiba 3t mri system [toshiba medical systems, japan]. heavily t2 weighted axial sections with 3d reconstruction and maximum intensity images will be acquired. the mrcp and ercp examinations will be interpreted for the presence of choledocholethiasis by consultant radiologists, having at least 5 years of experience in mri imaging, in a blinded fashion. moreover, to further eliminate any possible bias, no clinical indication will be provided to the consultant radiologist.**results:** of the 153 subjects included in this study 87 were females and 66 were males. the mean age of subjects included in the study was 45 years with standard deviation 13.7 years. the age range was from 15 years to 65 years. mrcp correctly diagnosed choledocholithiasis in 146 of the 153 patients, there were 146 true positive cases and 1 false positive case. there were 1 false negative and 5 true negative cases. the sensitivity of mrcp was found to be 99.3% and specificity was 83.3%. positive predictive value of mrcp was 99.3% while the negative predictive value was found to be 83.3 %. the diagnostic accuracy of mrcp for choledocholithiasis was found to be 98.6%.**conclusion:** technical advances in the techniques of mrcp over the past two and a half decades both in terms of primary imaging and post processing are significant. this has made mrcp the radiological investigation of choice for diagnosis of biliary disorders including choledocholithiasis. this study further validates the imaging role of mrcp as a test fit for purpose and acknowledges that increased magnetic field strength of 3t mri system has a superior diagnostic yield.*

Keywords: *Choledocholithiasis, Magnetic Resonance Cholangiopancreatography, Endoscopic retrograde cholangiopancreatography, Jaundice, Ultrasonography.*

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INTRODUCTION:

Cholelithiasis is a common clinical problem with a worldwide prevalence. Among the general population the prevalence is as high as 5-20 % based on published literature, with male to female ratio of 1:3. Choledocholithiasis is an important associated problem often leading to serious complications such as obstructive jaundice, pancreatitis and cholangitis. [1-3]

Obstructive jaundice can be due to partial or complete occlusion of the biliary tree and this results in progressive jaundice which may be profound, with bilirubin > 100 µmol/L. In addition to jaundice the patient usually presents with pale-colored stools, dark urine, itching, abdominal pain in the right upper quadrant, fever, nausea and vomiting.

The importance of differentiating obstructive jaundice from non-obstructive jaundice lies in the fact that there is a great difference in the existing treatment between the two. It is believed that patients with common bile-duct stones should be identified and treated prior to laparoscopic cholecystectomy in order to avoid the possibility of an open exploration of the duct. [5]

Pathologies which can present in a similar fashion include biliary tumours, biliary strictures, pancreatic tumours and external biliary compression. They are associated with significant morbidity and mortality and hence require early diagnosis and initiation of therapy. It is a part of the clinical practices that choledocholithiasis to be ruled out as a cause of obstructive jaundice before other differentials are considered. [8]

Recently there has been a rapid evolution in the modalities available to access the possible aetiologies of obstructive jaundice. Commonly used diagnostic modalities include Ultrasonography [USG], Computed Tomography [CT], Endoscopic retrograde cholangiopancreatography [ERCP], percutaneous transhepatic cholangiography [PTC] and Magnetic resonance cholangiopancreatography [MRCP] [4].

Endoscopic retrograde cholangiopancreatography [ERCP] is considered the 'gold standard' for the diagnosis of biliary obstruction and is among the several invasive techniques involving direct cholangiography with additional benefit of a higher spatial resolution. However, it is operator dependent and has an overall reported complication rate of up to 5 % with possible complications including duodenal perforation, pancreatitis, bleeding and sepsis [5, 6]

While being invasive lends it the edge of potential for image-guided therapy the same renders it an imperfect diagnostic tool [7]. Additionally ERCP requires patient preparation and sedation during the procedure. There is a continued search for a more appropriate diagnostic tool which can replace it as the ‘gold standard’ in the future.

Magnetic resonance cholangiopancreatography [MRCP] is an alternative to diagnostic ERCP for investigating biliary obstruction. MRCP was developed in 1991 and techniques are continuing to improve. In comparison to ERCP it is a non-invasive technique without any associated morbidity and mortality. [8]

Several algorithms are employed to investigate a patient with obstructive jaundice. Indication for ERCP is based on clinical grounds, ultrasound findings and abnormal liver function tests [LFTs]. However, this has been shown to have a low specificity for common bile-duct stones with 40–75% of patients proving negative on subsequent ERCP.

While MRCP has similar indications it can be safely employed in patients considered to be at low risk of having pancreatic or biliary disease and can be more informative in patients with a suspected neoplastic cause for pancreatic or biliary obstruction. It is also an important option for patients with failed ERCP.

In the current practice ERCP and MRCP are used as complementary techniques. The sensitivity and specificity of MRCP for detecting choledocholithiasis has been shown to be 90% and 75%, respectively.

Over the years the MRI systems have seen gradual improvement. One of the features that have received boost is the magnetic field strength [SI units of Tesla]. The increased magnetic field strength is known to significantly improve image resolution. Most of the current literature regarding MRCP is based on 1.5 Tesla systems. This study was to determine the diagnostic accuracy of 3 TESLA MRI SYSTEMS IN DETECTING CHOLEDOCHOLITHIASIS taking ERCP as the gold standard.

MATERIALS AND METHODS:

Patients with either one or more than one of the following conditions were excluded from the study.
Patients with any contraindication to MRCP.

Patients who did not undergo either ERCP or surgery.
Patients with obstructive jaundice and CBD dilatation from causes other than stones, such as malignancy or stricture.

Data was recorded on a predefined pro-forma.
MRCP was performed using Toshiba 3T MRI system [Toshiba Medical Systems, Japan]. Heavily T2 weighted axial sections with 3D reconstruction and maximum intensity images were acquired.

The MRCP and ERCP examinations were interpreted for the presence of choledocholithiasis by consultant

In this Cross-sectional study, conducted in Department of Radiology., in which Data was collected over a one year period that is from April 2016 to December 2016.

Choledocholithiasis has a significant association with Cholelithiasis, in the published literature the prevalence of Cholelithiasis has been reported as 20% [1-3]. Based on the 90% sensitivity and 75% specificity of MRCP with desired precision at 0.09, the required sample size for this study was calculated to be 150.SAMPLING TECHNIQUE: Non-probability consecutive sampling.All the adult patients of either gender aged 15 years to 65 years with obstructive jaundice and subsequently referred by their primary treating physician to the Radiology Department for MRCP examination were included in this study.

radiologists, having more than 5 years of experience in MRI imaging, in a blinded fashion. To further eliminate any possible bias, no clinical indication was provided to the consultant radiologist.

Data entry was done in SPSS statistical package version 20.0 software.Demographic data such as age and the duration of injury were expressed as mean ± standard deviation [SD].Frequencies and percentages were calculated for the presence of choledocholethiasis on both the MRCP and ERCP findings for either gender.A two-by-two [2 x 2] table was constructed for calculating sensitivity, specificity, positive predictive value, negative predictive value and overall accuracy of MRCP for the detection of choledocholethiasis using ERCP findings as the gold standard.

Table 1 – A 2 x 2 Table for calculating sensitivity, specificity and overall accuracy of MRCP in detecting choledocholithiasis using ERCP as the gold standard.

		ERCP	
		CHOLEDOCHOLITHIASIS PRESENT	CHOLEDOCHOLITHIASIS ABSENT
MRCP	CHOLEDOCHOLITHIASIS PRESENT	[True Positive]	[False Positive]
	CHOLEDOCHOLITHIASIS ABSENT	[False negative]	[True Negative]

ETHICAL CONSIDERATIONS:

No additional imaging or procedures are to be performed for the purpose of this study. Therefore, no additional cost or radiation hazards are to be expected from the study. Finally, all efforts to ensure confidentiality and anonymity of all the subjects were made and no patient identifiers were expressed.

RESULTS:

A total of 311 patients with obstructive jaundice underwent MRCP examination at our institution form April 2016 to December 2016. After excluding the patients with obstructive jaundice form causes other than choledocholithiasis a total of 153 those patients were included in the study who subsequently underwent ERCP examination. Time delay between MRCP and ERCP was less than 36 hours.

The details of subjects included and excluded from the study are given in figure below.

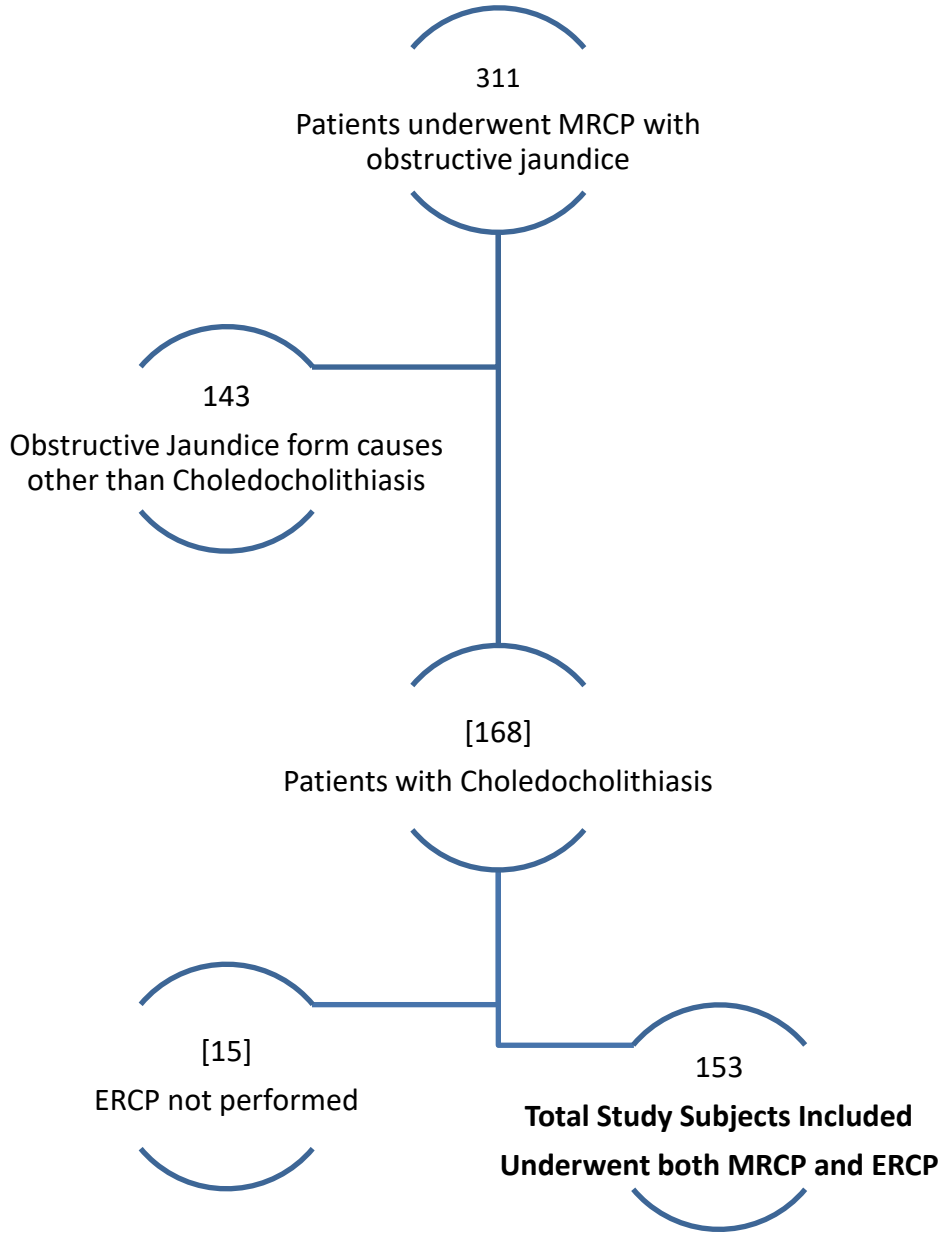

Figure 13: Flow diagram representing total number of study participants finally included along with the number and cause of excluded patients.

DEMOGRAPHICS – AGE AND GENDER:

Of the 153 subjects included in this study 87 were females and 66 were males.

The mean age of subjects included in the study was 45 years with standard deviation 13.7 years. The age range was from 15 years to 65 years. The histogram [shown in figure 11] shows the distribution of study subjects according to the age.

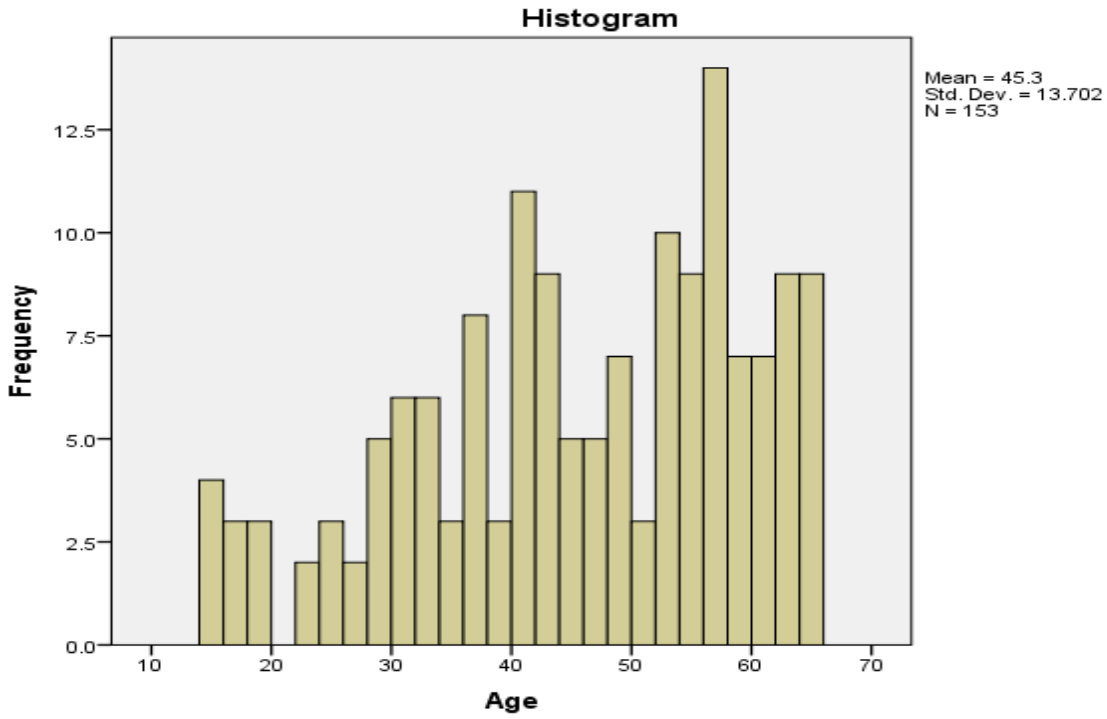

Figure 14: Histogram showing the frequency of subjects according to various age groups.

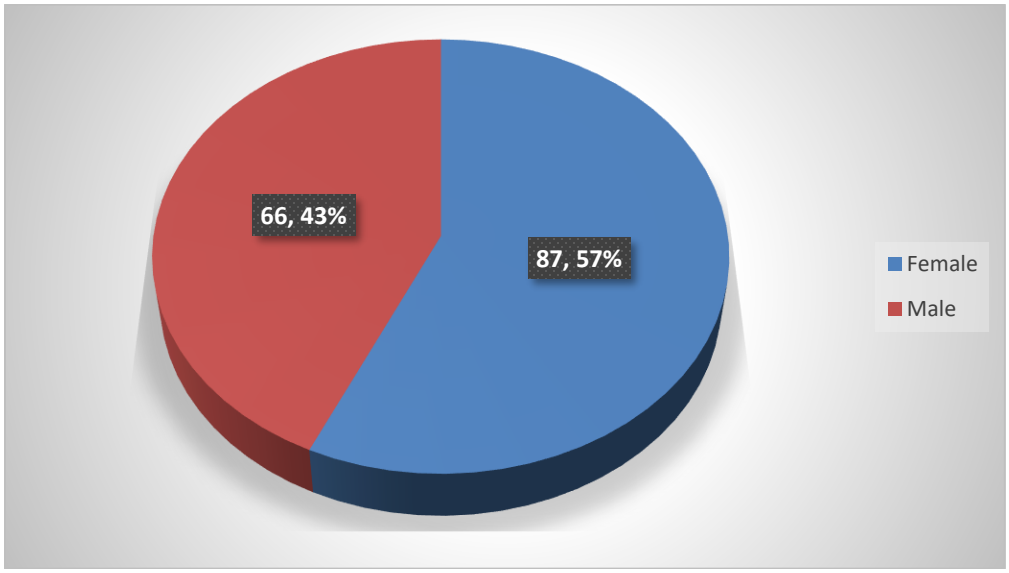

Figure 15: Pie-chart depicting the percentage of male versus female patients.

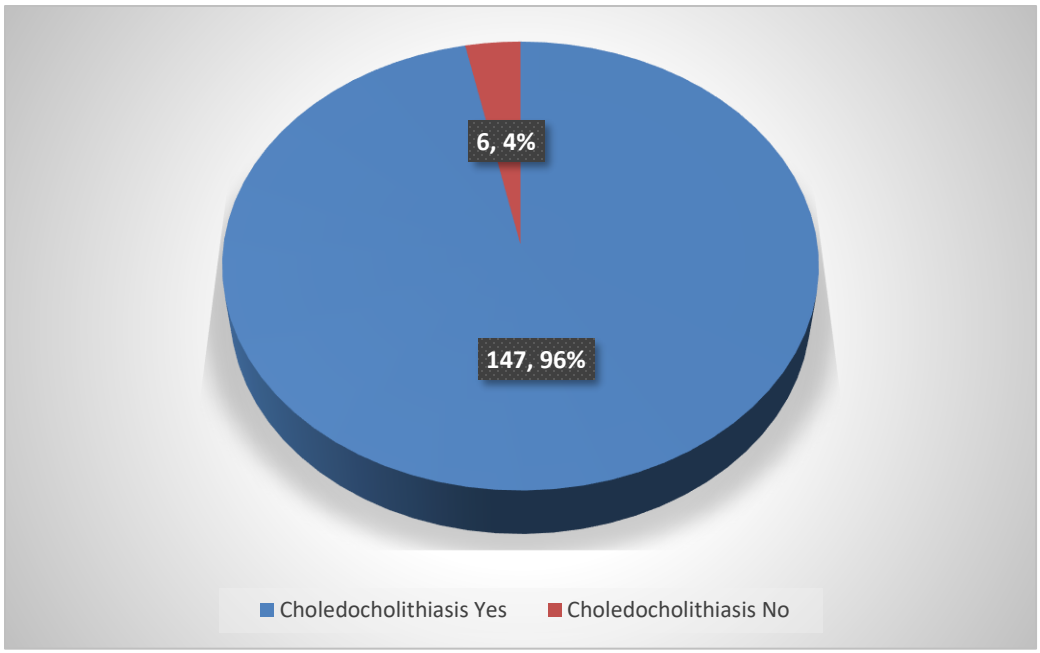

Figure 16: Pie-chart depicting the incidence of choledocholithiasis in our study population.

FREQUENCY OF CHOLEDOCHOLITHIASIS: GENDER-BASED:

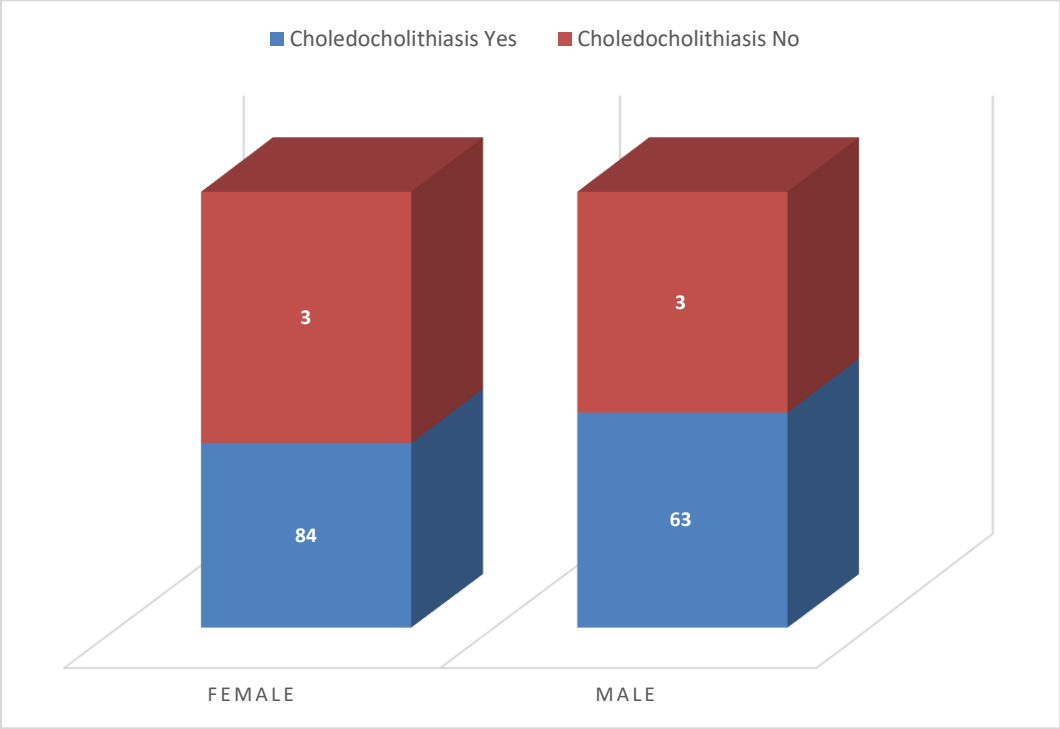

Figure – 17: Study population choledocholithiasis according to gender.

MRCP correctly diagnosed choledocholithiasis in 146 of the 153 patients, there were 146 true positive cases and 1 false positive case. There were 1 false negative and 5 true negative cases. The sensitivity of MRCP was found to be 99.3% and specificity was 83.3%. Positive predictive value of MRCP was 99.3% while the negative predictive value was found to be 83.3 %. The diagnostic accuracy of MRCP for choledocholithiasis was found to be 98.6%.

Table 2: Table showing the number and frequency of true positive, true negative, false positive and false negative cases.

Parameters	Frequency
True Positive	146
True Negative	5
False Positive	1
False Negative	1
Total	207

DIAGNOSTIC ACCURACY:

Table 3: 2 x 2 table for calculating the sensitivity, specificity, positive predictive value, negative predictive value and overall accuracy of MRCP for choledocholithaisis using ERCP as gold standard.

		ERCP		
		CHOLEDOCHOLITHIA-SIS PRESENT	CHOLEDOCHOLITHI-ASIS ABSENT	
MRCP	CHOLEDOCHOLIT-HIASIS PRESENT	146	1	147
	CHOLEDOCHOLIT-HIASIS ABSENT	1	5	6
		147	6	153

Table 4: Table summarizing the sensitivity, specificity, positive predictive value, negative predictive value and overall accuracy of MRCP for detecting choledocholithiasis.

Parameters	Formula	Data	Value
Sensitivity	TP/[TP+FN]	146/[146+1]	99.3%
Specificity	TN/[TN+FP]	5/[5+1]	83.3%
Positive Predictive Value	TP/[TP+FP]	146/[146+1]	99.3%
Negative Predictive value	TN/[TN+FN]	5/[5+1]	83.3%
Accuracy	[TP+TN]/ [TP+TN+FP+FN]	[146+5]/ [146+5+1+1]	98.6%

DISCUSSIONS:

Choledocholithiasis is a frequent and potentially treatable cause of obstructive jaundice. Initial workup for choledocholithiasis is dictated by initial lab workup, local expertise and available imaging modalities. [4,5,7] In the setting of a tertiary care hospital early diagnostic workup and intervention makes possible for appropriate algorithms choledocholithiasis management to be followed in time. In our institute after initial laboratory workup suggests obstructive jaundice imaging is done to rule out biliary pathology.

Among the clinical predictors of choledocholithiasis none is fully reliable in identifying bile duct stones. In a recent study conducted by Ankur Mandelia et al. various clinical predictors of CBD stones were

evaluated. Among these age more 50 years was found to have a sensitivity, specificity and positive and negative predictive values of 55%, 80%, 84.62% and 47.06%.[11] Female gender on the other had showed sensitivity, specificity and positive and negative predictive values of 60%, 50%, 70.59% and 38.46% respectively. Among the laboratory markers studied serum alkaline phosphatase was described to have highest sensitivity of 65% with a specificity and positive and negative predictive values of 40%, 59.9% and 42.5% respectively. Total bilirubin had showed highest specificity of 70% with sensitivity and positive and negative predictive values of total bilirubin being 35%, 70% and 35% respectively. [11] In another study conducted by Saltzstein et al., alkaline phosphatase was described to better predict common duct stones than bilirubin. [12]

Depending on the clinical decision radiological workup includes ultrasound examination and or Magnetic Resonance Cholangiopancreatography examinations.

Ultrasonography is usually the initial imaging test used. Sonography examination has significant limitations with relatively low described sensitivity, specificity, positive and negative predictive values of 65%, 60% 76.47% and 46.15%. [11] Advantages for ultrasound examination include a short imaging time, its portability/bed side evaluation and cost effectiveness. Disadvantages of ultrasound examination include operator dependence and limited visualization of anatomic structure. There is especially poor/non-visualization of the distal most part of CBD which is a common potential site of choledocholithiasis.

MRCP is a non-invasive highly sensitive method for diagnosing diseases of the biliary tract. MRCP [Magnetic Resonance Cholangiopancreatography] has evolved as an important non-invasive tool since Wallner et al. described for the first time a T2-weighted gradient recall [GRE] technique for imaging dilated biliary tracts in 1991. Over the decades MRCP has seen significant improvement and refinement in the imaging techniques. [9,10] Current MRCP examination can produce diagnostic quality images in even normal/non-dilated bile ducts. This makes MRCP as the imaging modality of choice among available non-invasive diagnostic options for choledocholithiasis.

Current available literature concerning role MRCP in the evaluation of choledocholithiasis is based on 1.5 Tesla MRI systems. In one such study conducted in Karachi by Mubarak Aki et al. reports sensitivity, specificity, accuracy, positive predictive value [PPV] and negative predictive value [NPV] of MRCP as 97%, 75%, 80%, 99%, and 60% for MRCP using 1.5T MRI systems. In another more recent study conducted by Ankur Mandelia et al. the reported sensitivity, specificity, positive predictive value [PPV] and negative predictive value [NPV] of MRCP as 95%, 90%, 95%, and 90% for MRCP using 1.5T MRI systems.

There is limited data available in which diagnostic accuracy of 3T MRI systems has been evaluated. However, studies have been conducted to evaluate safety and imaging benefits of a 3T MRI system. On such study was conducted by Hiroyoshi Isoda et al to evaluate MRCP Imaging at 3.0 T vs. 1.5 T in healthy volunteers. It was concluded that MRCP can be performed safely without complications using 3T MRI systems. A significant improvement in the image noise was observed while no significant difference in the imaging artefacts appreciated. Images acquired by 3T MRI system demonstrated improved intrahepatic biliary ducts. In addition, superior visualisation of cystic duct, CBD and pancreatic duct was achieved. Signal to noise ratio [SNR] being an important factor depicting imaging detail and resolution was observed to be far superior for the 3T MRI images. Similar observations were also observed for the contrast to noise ratio [CNR].

The spatial and contrast resolutions of MRCP imaging are important for detecting smaller pathologies like small stones. The value of MRCP using 1.5T MRI systems to evaluate small changes and anatomy is limited because of its lower spatial resolution compared to ERCP images. MRI scanners with higher magnetic field strength like the 3T MRI systems have demonstrated to have a higher spatial resolution.

In this cross-sectional study, we evaluated the diagnostic accuracy of MRCP using 3T MRI system for evaluation of CBD stones. Using defined inclusion and exclusion criteria 153 patients with obstructive jaundice referred for MRCP examination at the department of radiology of a tertiary care teaching hospital were evaluated. Of 147 patients with CBD stones MRI correctly diagnosed choledocholithiasis in 146 patients and missed choledocholithiasis in 1 patient. In 5 patients no CBD stone was found on either MRI or ERCP examination.

Gender demographics reveal that among patients with choledocholithiasis 84 were female and 63 were male. Mean age was 45 years. This can be attributed

to the fact that there is an increase incidence of gallstones in the middle aged female population. The female predominance is well described in literature can be linked to multparity with additional factors like obesity and oral contraceptive pills palying there role. Hormonal factors during pregnancy are known to effect the normal gall bladder motility and sphincter of oddi contraction resulting in increased biliary stasis and gallstone formation.

With respect of diagnostic performance of 3T MRI system application in MRCP examinations the current study shows sensitivity of 99.3% and specificity of 83.3%. Diagnostic accuracy of 98.6%. A positive predictive value PPV of 99.3% and negative predictive value NNV of 83.3%. These results in view of discussed previous studies imply that 3T MRI system has a superior diagnostic yield which can be attributed to its higher magnetic field strength. This higher magnetic field strength not only improves SNR, CNR and spatial resolution but also opens up venues for improved gradients and development of newer imaging techniques further overcoming various artefacts and identifying smaller pathologies which were previously missed.

CONCLUSIONS:

Technical advances in the techniques of MRCP over the past two and a half decades both in terms of primary imaging and post processing are significant. This has made MRCP the radiological investigation of choice for diagnosis of biliary disorders including choledocholithiasis. This study further validates the imaging role of MRCP as a test fit for purpose and acknowledges that increased magnetic field strength of 3T MRI system has a superior diagnostic yield.

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