

# Accuracy of MRCP vs. ERCP in the Evaluation of Patients with Bile Duct Obstruction in the Setting of a Randomized Clinical Trial

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## PURPOSE

To compare the accuracy of MRCP vs. ERCP in diagnosing bile duct obstruction, choledocholithiasis, and to determine the etiology of bile duct obstruction when present, in the setting of a randomized clinical trial.

## BACKGROUND

ERCP is a well-established method of evaluating patients with suspected bile duct obstruction. However, it carries a morbidity of 1-7%, a mortality of 0.2-1%, and a failure rate of 3-10%. MRCP is a non-invasive modality that allows direct visualization of the biliary tree and pancreatic duct; it does not carry the associated risks of pancreatitis, bleeding, sepsis, perforation or bile leak as is the case with ERCP. The advantage of ERCP is that it allows for immediate therapeutic intervention. However, many ERCP studies are performed for diagnostic purposes. These patients could potentially avoid the risks of ERCP and alternatively be diagnosed by MRCP.

## METHODS

Two hundred and fifty-eight patients over the age of 18 years with intermediate clinical suspicion of bile duct obstruction were randomized to either MRCP or ERCP. Randomization was performed by the process of random numbers allocation with sealed envelopes in a 1:1 proportion, by blocks of 20. The sensitivity, specificity and diagnostic accuracy of MRCP and ERCP was determined for the diagnosis of choledocholithiasis, bile duct obstruction, and normal studies. The overall percent of correct and incorrect diagnoses was also calculated for both modalities. The gold standard used was ERCP, CT, MRI, US, pathology, or clinical follow-up. Patients with normal MRCP or ERCP studies were followed clinically for up to 12 months in order to evaluate the possibility of a false-negative interpretation. MRCP was performed using a GE Signa scanner with a phased array torso coil. Images were acquired using: 1) a 2D fast spin-echo sequence in the transverse plane, 8000/144 (TR/effective TE), echo-train length of 16, 512-256 matrix, 3 mm slice thickness; and 2) single shot fast spin echo (SSFSE) in the transverse, coronal and oblique planes, TE 400-800, 256 x 256 matrix, a slice thickness of 5 (multi-slice) – 40 mm (coronal oblique slab) no interslice gap was obtained.

## RESULTS

One of the 258 patients refused to be part of the study after randomization. There were 131 patients randomized to MRCP and 126 patients randomized to ERCP. The demographic data for both the MRCP and ERCP arm were similar; the mean age in the MRCP arm was 56 years, and in the ERCP arm was 52 years. There were two limiting MRCP studies due to claustrophobia, and 19 failed ERCP studies (2 patients refused the ERCP and 17 failed due to technical reasons). The results comparing the sensitivity, specificity and accuracy for MRCP and ERCP in determining bile duct obstruction, normal biliary tree, and choledocholithiasis are shown in the Table. The overall results for determining the correct diagnosis was 89% for both MRCP and ERCP, and both modalities provided incorrect diagnoses in 11% of patients in the study.

Variable Studied	MRCP	ERCP
Determining the presence of bile duct obstruction	Sensitivity = 96% (95% CI: 91-100) Specificity = 86% (95% CI: 78-93) Accuracy = 90% (95% CI: 84-95)	Sensitivity = 87% (95% CI: 77-98) Specificity = 100% Accuracy = 94% (95% CI: 88-99)
Determining normal vs. abnormal	Sensitivity = 98% (95% CI: 94-100) Specificity = 89% (95% CI: 81-97) Accuracy = 94% (95% CI: 89-98)	Sensitivity = 87% (95% CI: 76-98) Specificity = 100% Accuracy = 94% (95% CI: 88-99)
Determining the presence of choledocholithiasis	Sensitivity = 86% (95% CI: 71-100) Specificity = 90% (95% CI: 83-96) Accuracy = 89% (95% CI: 83-95)	Sensitivity = 85% (95% CI: 71-98) Specificity = 100% Accuracy = 95% (95% CI: 90-100)

## CONCLUSION

The results of our study suggest comparable effectiveness between MRCP and ERCP, when these modalities are used to identify a normal biliary system, bile duct obstruction, choledocholithiasis, and when used to determine the etiology for biliary disease in our patient population. Although ERCP has a potential therapeutic advantage over MRCP, it also carries increased risk of complications due to its invasiveness. For this reason, it would seem advantageous to perform MRCP studies on those patients with intermediate clinical suspicion of bile duct obstruction and avoid an unnecessary ERCP study. It remains outstanding to compare the cost effectiveness of performing initial MRCP studies on patients with intermediate clinical suspicion of bile duct obstruction, and comparing the complication rate between MRCP and ERCP.