A systematic review and economic evaluation of magnetic resonance cholangiopancreatography compared with diagnostic endoscopic retrograde cholangiopancreatography

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Executive summary

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Background

Magnetic resonance cholangiopancreatography (MRCP) is an alternative to diagnostic endoscopic retrograde cholangiopancreatography (ERCP) for imaging the biliary tree and investigating biliary obstruction. MRCP is a purely diagnostic test with no therapeutic value. It does not have the small but definite morbidity and mortality associated with ERCP.

Biliary obstruction may be due to choledocholithiasis, tumours or trauma including injury after gallbladder surgery, among other causes. Choledocholithiasis is the most common cause. Between 5 and 22% of the Western population has gallstones. The overall prevalence rate for symptomatic gallstones for England and Wales in 1991-2 was 182 per 10,000 person-years at risk. The incidence rate was 8 for cholelithiasis, 9 for other disorders of the gallbladder and 2 for other disorders of the biliary tract per 10,000 person-years at risk. At the time of cholecystectomy for symptomatic cholelithiasis, 8-25% of patients under 60 years and 15-60% of patients over 60 years also have choledocholithiasis.

MRCP refers to selective or partially selective magnetic resonance imaging (MRI) of the pancreatic and biliary ducts. It was developed in 1991 and techniques have progressively improved since then. Patients should be fasting and the procedure takes a few minutes, usually without sedation. Claustrophobia is a problem with some patients. A major feature of MRCP is that it is not a therapeutic procedure, whereas ERCP is used for diagnosis and treatment. The impact of this is that if ERCP is necessary after MRCP as a therapeutic intervention, MRCP could have been avoided and patients would be able to proceed immediately to treatment. However, if no therapeutic intervention is found to be necessary, MRCP avoids the potential morbidity and mortality associated with ERCP. MRCP is particularly useful where ERCP is difficult, hazardous or impossible. It is also an important option for patients with failed ERCPs. ERCP and MRCP have different contraindications, allowing them to be used as complementary techniques.

There are opportunity costs associated with MRCP, in that if an MRI scanner is used for MRCP it cannot be used for other types of imaging.

Objective

The aim of this review is to compare the clinical and cost-effectiveness of MRCP with diagnostic ERCP for the investigation of biliary obstruction.

Number and quality of studies and direction of evidence

Initially 67 potentially relevant papers were considered for inclusion, of which 38 were excluded owing to poor quality or comparators other than ERCP. In total, 28 prospective diagnostic studies were identified comparing MRCP with diagnostic ERCP. One study of patient satisfaction was also identified. The 28 studies reported several suspected conditions. Choledocholithiasis was included in 18 studies, malignancy in four, obstruction in three, stricture in two, dilatation in five and primary sclerosing cholangitis (PSC) in two studies.

The quality of the studies was moderate. In all but one study, patients selected to have both MRCP and diagnostic ERCP did not have both and often the reasons why were unclear. Only 13 of the 28 studies reported blinding to both clinical information for patients and ERCP results, and only six of the 28 studies reported information on agreement of MRCP results for more than one investigator. Nine studies gave no information on other diagnostic tests and most studies did not adequately report inclusion and exclusion criteria and relevant patient characteristics. Of the 28 studies, seven reported results comparing MRCP with final diagnosis, which included ERCP and other test results. The remaining 21 studies reported results comparing MRCP with ERCP.

Effectiveness was assessed by condition. For choledocholithiasis 15 of the 18 studies reported adequate data for analysis; two of these were removed as they differed in some aspects from the other studies. Owing to statistically significant heterogeneity between the studies, the median values were considered the most appropriate to report. The median sensitivity for the 13 studies of choledocholithiasis was 0.93 (range 0.81–1.00) and the median specificity 0.94 (0.83–0.99). A likelihood ratio describes how many times a person with disease is more likely to receive a particular test result than a person without disease. The median positive likelihood ratio was 15.75 (range 5.44–64.78) and the median negative likelihood ratio 0.08 (0.00–0.19).

For malignancy, sensitivity ranged from 81 to 94.4% and specificity from 92 to 100%. Positive likelihood ratios ranged from 10.12 to 43 and negative likelihood ratios from 0.15 to 0.21. The sensitivity for dilatation ranged from 87 to 100% and the specificity from 91 to 100%. For obstruction, both sensitivity and specificity ranged from 91 to 100%. Sensitivity for stricture was 100% and specificity ranged from 98 to 99%.

Claustrophobia associated with MRCP in at least some patients was reported in ten of the 28 studies, with no information on claustrophobia reported in the remaining 18 studies. There were no adverse effects associated with MRCP in any of the studies, although six studies reported adverse effects associated with ERCP, including pancreatitis, bleeding and pain. Twenty studies reported no information regarding adverse effects.

One study was identified that dealt with patient satisfaction: most patients preferred MRCP, but there were still some who preferred ERCP. Nearly half of the patients in this small study complained of claustrophobia associated with MRCP, although only 5.9% refused MRCP for this reason.

Summary of benefits

The median sensitivity for choledocholithiasis (13 studies) was 93% (range 81–100%) and the median specificity 94% (83–99%). The median likelihood ratio for a positive value was 15.75 (range 5.44–64.78) and for a negative value 0.08 (0.00–0.19). Reported sensitivities for malignancy were somewhat lower, ranging from 81 to 86%, and specificities ranged from 92 to 100%.

In the 28 studies, which included 38 subgroups, one positive likelihood ratio was less than 5 and four negative likelihood ratios were greater than 0.2. There is therefore some evidence that MRCP is an accurate diagnostic test in comparison to ERCP, although the quality of studies was moderate. Claustrophobia prevented at least some patients from having MRCP in ten of the 28 studies. The other 18 studies did not mention claustrophobia.

Cost-effectiveness

The probability of avoiding unnecessary diagnostic ERCP, that is, the probability of a true-negative MRCP, is estimated at 30% [95% confidence interval (CI) 20 to 40%]. These patients could avoid the unnecessary risk of complications and death associated with diagnostic ERCP, and substantial cost saving would be gained. The overall expected cost saving associated with MRCP is £149 (£325 to -£15); the overall expected gain in quality-adjusted life-year is estimated at 0.011 (0.000, 0.030).

Conclusions

There is some evidence that MRCP is an accurate investigation compared with diagnostic ERCP, although the values for malignancy compared with choledocholithiasis were somewhat lower. The quality of studies was moderate. The limited evidence on patient satisfaction showed that patients preferred MRCP to diagnostic ERCP.

The estimated clinical and economic impacts of diagnostic MRCP versus diagnostic ERCP are very favourable. The baseline estimate is that MRCP may both reduce cost and result in improved quality of life outcomes compared with diagnostic ERCP. The uncertainty analysis, investigating the impact of parametric uncertainty within the model, indicates that this result is robust. However, there are marked uncertainties in the structure and assumptions within the decision analytical model that are not captured within this parametric uncertainty analysis. The results presented in this assessment will thus overstate the robustness of the economic outcomes for MRCP.

Recommendations for research

The following were identified as areas where further research is needed.

 Good quality studies are needed comparing MRCP and diagnostic ERCP with final diagnosis, stating inclusion/exclusion criteria and relevant patient characteristics. This would help to overcome some of the shortcomings of comparisons with diagnostic ERCP.

- Studies are needed comparing MRCP with diagnostic ERCP for the full range of target conditions, in particular differentiation of benign and malignant strictures and the impact on management and outcome.
- More research is needed in the area of patient satisfaction and ways to reduce problems with claustrophobia and make MRCP more acceptable to patients.
- Protocols, assessing prior risk, are needed to help to identify which patients with which suspected conditions would most benefit from MRCP and which would benefit from ERCP.
- To understand the real opportunity costs associated with MRCP, studies are needed to assess the relative need and urgency of patient access to MRI services.

• As the development of MRCP (a non-invasive test) may result in an increase in requests over what would be expected for ERCP (an invasive test), research is needed to determine how this will affect availability and potential cost savings.

Publication

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