

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

E Kaltenthaler,^{1*} Y Bravo Vergel,² J Chilcott,¹
S Thomas,³ T Blakeborough,⁴ SJ Walters¹
and H Bouchier¹



¹ SchARR Rapid Reviews Group, School of Health and Related Research, University of Sheffield, UK

² Nuffield Institute for Health, University of Leeds, UK

³ Northern General Hospital, Sheffield, UK

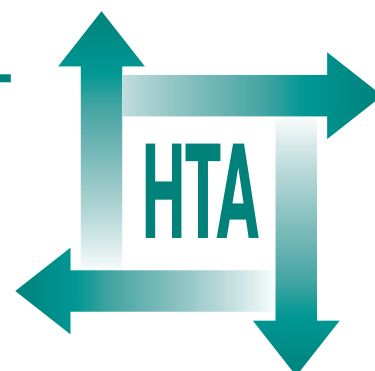
⁴ Royal Hallamshire Hospital, Sheffield, UK

* Corresponding author

Executive summary

Health Technology Assessment 2004; Vol. 8: No. 10

Health Technology Assessment
NHS R&D HTA Programme





Executive summary

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

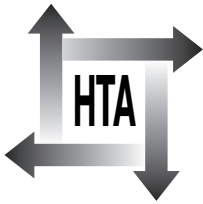
The following were identified as areas where further research is needed.

- 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

Kaltenthaler E, Bravo Vergel Y, Chilcott J, Thomas S, Blakeborough T, Walters SJ, *et al.* A systematic review and economic evaluation of magnetic resonance cholangiopancreatography compared with diagnostic endoscopic retrograde cholangiopancreatography. *Health Technol Assess* 2004;8(10).



INAHTA

How to obtain copies of this and other HTA Programme reports.

An electronic version of this publication, in Adobe Acrobat format, is available for downloading free of charge for personal use from the HTA website (<http://www.hta.ac.uk>). A fully searchable CD-ROM is also available (see below).

Printed copies of HTA monographs cost £20 each (post and packing free in the UK) to both public **and** private sector purchasers from our Despatch Agents.

Non-UK purchasers will have to pay a small fee for post and packing. For European countries the cost is £2 per monograph and for the rest of the world £3 per monograph.

You can order HTA monographs from our Despatch Agents:

- fax (with **credit card** or **official purchase order**)
- post (with **credit card** or **official purchase order** or **cheque**)
- phone during office hours (**credit card** only).

Additionally the HTA website allows you **either** to pay securely by credit card **or** to print out your order and then post or fax it.

Contact details are as follows:

HTA Despatch
c/o Direct Mail Works Ltd
4 Oakwood Business Centre
Downley, HAVANT PO9 2NP, UK

Email: orders@hta.ac.uk
Tel: 02392 492 000
Fax: 02392 478 555
Fax from outside the UK: +44 2392 478 555

NHS libraries can subscribe free of charge. Public libraries can subscribe at a very reduced cost of £100 for each volume (normally comprising 30–40 titles). The commercial subscription rate is £300 per volume. Please see our website for details. Subscriptions can only be purchased for the current or forthcoming volume.

Payment methods

Paying by cheque

If you pay by cheque, the cheque must be in **pounds sterling**, made payable to *Direct Mail Works Ltd* and drawn on a bank with a UK address.

Paying by credit card

The following cards are accepted by phone, fax, post or via the website ordering pages: Delta, Eurocard, Mastercard, Solo, Switch and Visa. We advise against sending credit card details in a plain email.

Paying by official purchase order

You can post or fax these, but they must be from public bodies (i.e. NHS or universities) within the UK. We cannot at present accept purchase orders from commercial companies or from outside the UK.

How do I get a copy of HTA on CD?

Please use the form on the HTA website (www.hta.ac.uk/htacd.htm). Or contact Direct Mail Works (see contact details above) by email, post, fax or phone. *HTA on CD* is currently free of charge worldwide.

The website also provides information about the HTA Programme and lists the membership of the various committees.

NHS R&D HTA Programme

The NHS R&D Health Technology Assessment (HTA) Programme was set up in 1993 to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS.

The research reported in this monograph was commissioned by the HTA Programme and was funded as project number 02/43/01. Technology assessment reports are completed in a limited time to inform decisions in key areas by bringing together evidence on the use of the technology concerned.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for any recommendations made by the authors.

Criteria for inclusion in the HTA monograph series

Reports are published in the HTA monograph series if (1) they have resulted from work commissioned for the HTA Programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA Programme Director: Professor Tom Walley
Series Editors: Dr Ken Stein, Professor John Gabbay, Dr Ruairidh Milne,
Dr Chris Hyde and Dr Rob Riemsma
Managing Editors: Sally Bailey and Caroline Ciupek

The editors and publisher have tried to ensure the accuracy of this report but do not accept liability for damages or losses arising from material published in this report.

ISSN 1366-5278

© Queen's Printer and Controller of HMSO 2004

This monograph may be freely reproduced for the purposes of private research and study and may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising.

Applications for commercial reproduction should be addressed to HMSO, The Copyright Unit, St Clements House, 2-16 Colegate, Norwich, NR3 1BQ.

Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.
Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.