

Systematic review of the clinical effectiveness and cost-effectiveness of oesophageal Doppler monitoring in critically ill and high-risk surgical patients

G Mowatt,¹ G Houston,³ R Hernández,²
R de Verteuil,^{1,2} C Fraser,¹
B Cuthbertson^{1,3} and L Vale^{1,2*}

¹Health Services Research Unit, Institute of Applied Health Sciences, University of Aberdeen, UK

²Health Economics Research Unit, Institute of Applied Health Sciences, University of Aberdeen, UK

³NHS Grampian, UK

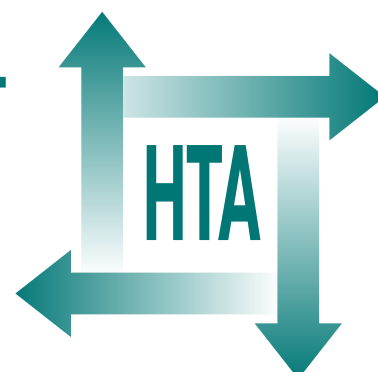
*Corresponding author



Executive summary

Health Technology Assessment 2009; Vol. 13: No. 7
DOI: 10.3310/hta13070

Health Technology Assessment
NIHR HTA Programme
www.hta.ac.uk





Executive summary

Description of proposed service

Oesophageal Doppler monitoring (ODM) measures blood velocity in the descending thoracic aorta using a flexible probe inserted into the patient's oesophagus. This information is combined with an estimate of aortic cross-sectional area (derived from a nomogram based on the patient's age, height and weight) allowing continuous monitoring of cardiac output and haemodynamic status. ODM is a relatively simple procedure, generally limited in use to a critical care or theatre setting, that requires no calibration and minimal training.

Epidemiology and background

Optimal management of cardiac output, fluid balance and haemodynamic status is considered key to improving outcome in high-risk surgical and critically ill patients. Traditionally, pulmonary artery catheters (PACs) have been used to monitor cardiac output and haemodynamic status to guide treatment, but they have been shown to provide no benefit to this patient group.

Less invasive methods of monitoring cardiac output and other haemodynamic variables include ODM, transoesophageal echocardiography, transthoracic impedance, carbon dioxide elimination and systems based upon pulse contour analysis and dye dilution methods. These may be used alongside conventional clinical assessment which involves assessment of various clinical markers, e.g. heart rate, systolic blood pressure and urinary output, with or without a measure of blood flow or central venous pressure.

Objective

To assess the effectiveness and cost-effectiveness of ODM, in comparison with conventional clinical assessment and other methods of monitoring cardiovascular function.

Methods

A systematic review of studies of effectiveness and cost-effectiveness was conducted.

Data sources

Searches of electronic databases [including MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and the Cochrane Library] and relevant websites until May 2007 were undertaken to identify published and unpublished reports, including previous systematic reviews.

Study selection

For the review of effectiveness, randomised controlled trials (RCTs), or systematic reviews of RCTs, assessing the effects of ODM in the target populations were identified. Comparator interventions considered were standard care, PACs, pulse contour analysis monitoring and lithium or thermodilution cardiac monitoring. Non-English language studies and studies reported only as abstracts were excluded.

For the review of economic evaluations studies had to compare, in terms of both costs and outcomes, strategies involving ODM compared with standard care, PACs, pulse contour analysis monitoring and lithium or thermodilution cardiac monitoring. No language restrictions or other limitations to searches were imposed.

Data extraction

For the review of effectiveness a recent high-quality systematic review, conducted by the US Agency for Healthcare Research and Quality (AHRQ), was identified. A judgement was made to base this review on this study, supplemented by evidence from any additional studies identified. Data were extracted on mortality, length of stay overall and in critical care, complications and quality of life.

The quality of primary studies was assessed using the Emergency Care Research Institute (ECRI) 25-question quality scale. The systematic review was assessed using a 10-item checklist developed

by Oxman and Guyatt. Where appropriate, meta-analysis was employed to estimate a summary measure of effect on relevant outcomes. Where a quantitative synthesis was considered to be inappropriate or not feasible, a narrative synthesis of results was provided.

Economic modelling

Partial economic modelling exercises were explored for pairwise comparisons between strategies that used ODM and those that did not. Differences in mortality and length of stay were considered within these exercises. Where data allowed, probability distributions were attached to model parameters [e.g. lognormal probability distributions for odds ratios and normal distributions for length of hospital stay differences using information on the confidence intervals (CIs) surrounding point estimates], and probabilistic analyses were conducted. Costs were stated in £ sterling for 2006–7. Cost-effectiveness results were expressed in additional cost per additional quality-adjusted life-year (QALY), as well as the average extra cost per additional survivor that would need to be incurred before ODM would no longer be considered cost-effective. For the former the results were presented in the form of incremental cost-effectiveness planes and for the latter the data were presented as histograms.

Results

Number and quality of studies and direction of evidence

The AHRQ report contained eight RCTs involving 757 adult patients. Two additional RCTs, involving 202 patients, were identified. Eight of these primary studies were judged to be of high quality and two were judged to be of moderate quality. The AHRQ report was judged to be of high quality overall. The 10 primary studies reported four comparisons (one study reported two):

- ODM plus central venous pressure (CVP) monitoring plus conventional assessment versus CVP monitoring plus conventional assessment during surgery
- ODM plus conventional assessment versus CVP monitoring plus conventional assessment during surgery
- ODM plus conventional assessment versus conventional assessment during surgery
- ODM plus CVP monitoring plus conventional assessment versus CVP monitoring plus

conventional assessment in critically ill patients postoperatively.

For the review of cost-effectiveness no studies were identified and as a consequence the data from the review of effectiveness were organised into a series of balance sheets.

Summary of benefits

During surgery

Five studies (453 patients) compared ODM plus CVP monitoring plus conventional assessment with CVP monitoring plus conventional assessment during surgery. There were fewer deaths [Peto odds ratio (OR) 0.13, 95% CI 0.02–0.96], fewer major complications (Peto OR 0.12, 95% CI 0.04–0.31), fewer total complications (fixed-effects OR 0.43, 95% CI 0.26–0.71) and shorter length of stay (pooled estimate not presented, 95% CI –2.21 to –0.57) in the ODM group. These analyses included a study of patients undergoing cardiac surgery, the results of which were consistent with those from the other four studies. The results of the meta-analysis of mortality should be treated with caution owing to the low number of events and low overall number of patients in the combined totals.

One study (61 patients) compared ODM plus conventional assessment with CVP monitoring plus conventional assessment during surgery. Confidence intervals for differences in mortality, total complications and length of hospital stay were wide enough to include clinically important differences favouring either intervention.

Three studies (139 patients) compared ODM plus conventional assessment with conventional assessment during surgery. There was no evidence of a difference in mortality (fixed-effects OR 0.81, 95% CI 0.23–2.77). No data were available on major complications. One study reported total complications, with fewer in the ODM group (OR 0.23, 95% CI 0.07–0.72) but no fewer patients experiencing complications (OR 0.41, 95% CI 0.14–1.16). Length of hospital stay was shorter in all three studies in the ODM group.

Critically ill patients

Two studies (366 patients) compared ODM plus CVP monitoring plus conventional assessment versus CVP monitoring plus conventional assessment. The patient groups were quite different (cardiac surgery and major trauma) and neither study, nor a meta-analysis, showed a statistically significant difference in mortality (fixed-effects OR

0.84, 95% CI 0.41–1.70). No data were available for major complications but fewer patients in the ODM group experienced complications (OR 0.49, 95% CI 0.30–0.81) and both studies reported a statistically significant shorter median length of hospital stay in the ODM group.

No evidence was available on quality of life and five studies reported the outcome of ODM-related complications, with all stating that none occurred.

Costs

No studies reporting costs were identified. The addition of ODM would incur the cost of a monitor (approximately £10,000) which will last several years and typically a single disposable probe per patient (approximately £60–£120). In addition, maintenance contracts might be necessary (approximately £550). Apart from the few minutes required to insert the probe there are few other additional costs. Any changes in length of stay, complications and mortality would also affect total costs.

Cost-effectiveness

No economic evaluations that met inclusion criteria were identified from the existing literature and a series of balance sheets were constructed to highlight the choices and trade-offs that may exist. For ODM plus CVP monitoring plus conventional assessment versus CVP monitoring plus conventional assessment during surgery, the ODM strategy is likely to be more effective and the costs of ODM are likely to be offset by reductions in length of stay and complications. However, the cost of interventions prompted by monitoring (intravenous fluids and vasoactive drugs, etc.) is not known. For ODM plus conventional assessment versus conventional assessment during surgery, it is likely that the costs of ODM will be offset by the reductions in length of stay, but the overall differences in costs and effectiveness are unclear as there is insufficient evidence on mortality and complications. For ODM plus conventional assessment versus CVP monitoring plus conventional assessment during surgery, there is insufficient evidence available and where data are available the confidence intervals are sufficiently wide to cover clinically and economically important differences favouring either intervention. In critically ill patients the cost of ODM appeared to be compensated for by differences in length of

stay and its use may reduce complications, but the effect on mortality and on the cost of interventions prompted by monitoring is unclear.

A partial economic modelling exercise was conducted for ODM plus CVP monitoring plus conventional clinical assessment versus CVP monitoring plus conventional clinical assessment and ODM plus conventional clinical assessment versus conventional clinical assessment for high-risk surgical patients, as well as for ODM plus CVP monitoring plus conventional clinical assessment versus CVP monitoring plus conventional clinical assessment comparison for critically ill hospitalised patients. Results show that ODM strategies are likely to be considered cost-effective. More specifically, the threshold value for the extra cost per additional survivor that would need to be incurred before ODM would no longer be considered cost-effective was estimated. The required magnitude of these costs ranged from £581 to £11,600. However, these results are heavily dependent on the underlying assumptions of the analyses (e.g. pairwise comparisons rather than comparisons of all relevant methods of monitoring, limited number of studies, limited or non-existent data on relevant outcomes, small sample sizes and different underlying conditions).

Recommendations for research

Although some modest data are available and consideration can be given to the balance of costs and benefits using the data from the balance sheets, more formal economic evaluation would be desirable to make better use of the data available and to make valuations implicit in any decision more explicit. Furthermore, well-designed, multicentre RCTs are required among high-risk surgical patients to address the following question: Does ODM-guided fluid therapy plus conventional clinical assessment improve outcome with and without CVP monitoring compared with conventional clinical assessment with and without CVP monitoring?

All the identified studies were conducted in unconscious patients. Newer ODM probes that may be tolerated by awake patients are now manufactured and further research is needed to evaluate these.

Further research is required to assess the benefits of ODM-guided fluid administration during

surgery and continuing into the early postoperative period versus the benefits of ODM-guided fluid administration during surgery alone. Further research is also required to determine the optimal number of hours for ODM-guided fluid administration to continue after surgery once the patient has been admitted to a critical care facility.

Given the paucity of the existing economic evidence base any further primary research should

include an economic evaluation or should provide data suitable for use in an economic model.

Publication

Mowatt G, Houston G, Hernández R, de Verteuil R, Fraser C, Cuthbertson B, *et al.* Systematic review of the clinical effectiveness and cost-effectiveness of oesophageal Doppler monitoring in critically ill and high-risk surgical patients. *Health Technol Assess* 2009;**13**(7).

NIHR Health Technology Assessment Programme

The Health Technology Assessment (HTA) Programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The research findings from the HTA Programme directly influence decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC). HTA findings also help to improve the quality of clinical practice in the NHS indirectly in that they form a key component of the 'National Knowledge Service'.

The HTA Programme is needs led in that it fills gaps in the evidence needed by the NHS. There are three routes to the start of projects.

First is the commissioned route. Suggestions for research are actively sought from people working in the NHS, from the public and consumer groups and from professional bodies such as royal colleges and NHS trusts. These suggestions are carefully prioritised by panels of independent experts (including NHS service users). The HTA Programme then commissions the research by competitive tender.

Second, the HTA Programme provides grants for clinical trials for researchers who identify research questions. These are assessed for importance to patients and the NHS, and scientific rigour.

Third, through its Technology Assessment Report (TAR) call-off contract, the HTA Programme commissions bespoke reports, principally for NICE, but also for other policy-makers. TARs bring together evidence on the value of specific technologies.

Some HTA research projects, including TARs, may take only months, others need several years. They can cost from as little as £40,000 to over £1 million, and may involve synthesising existing evidence, undertaking a trial, or other research collecting new data to answer a research problem.

The final reports from HTA projects are peer reviewed by a number of independent expert referees before publication in the widely read journal series *Health Technology Assessment*.

Criteria for inclusion in the HTA journal series

Reports are published in the HTA journal series if (1) they have resulted from work 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.

The research reported in this issue of the journal was commissioned by the HTA Programme as project number 07/20/01. The contractual start date was in April 2007. The draft report began editorial review in August 2007 and was accepted for publication in June 2008. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health.

Editor-in-Chief: Professor Tom Walley

Series Editors: Dr Aileen Clarke, Dr Peter Davidson, Dr Chris Hyde, Dr John Powell, Dr Rob Riemsma and Professor Ken Stein

ISSN 1366-5278

© 2009 Queen's Printer and Controller of HMSO

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: NCCHTA, Alpha House, Enterprise Road, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk), on behalf of NCCHTA.

Printed on acid-free paper in the UK by the Charlesworth Group.