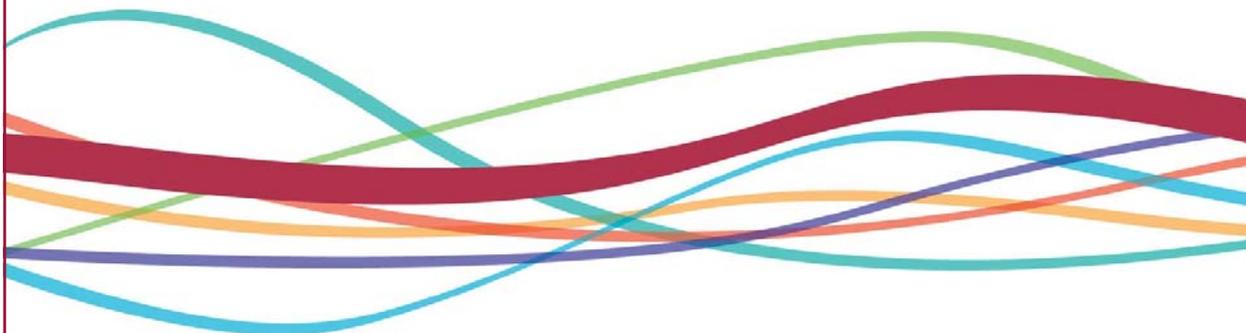


Evidence review

Oesophageal Doppler monitoring in patients undergoing high-risk surgery and in critically ill patients

CEP 08012

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Verdict

-  RECOMMENDED
-  SIGNIFICANT POTENTIAL
-  EVIDENCE INCONCLUSIVE
-  NOT RECOMMENDED

Informing procurement - Encouraging innovation

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This evidence review is a synopsis of a technology assessment report commissioned by the National Coordinating Centre for Health Technology Assessment (HTA). The full technology assessment report is due to be published in October 2008.

The product

Oesophageal Doppler monitoring (ODM) measures blood flow velocity in the descending thoracic aorta using a flexible ultrasonic probe inserted into the patient's oesophagus. This information, combined with an estimate of the cross sectional area of the patient's aorta (based on age, height, and weight) allows continuous monitoring of cardiac output and haemodynamic status. ODM is a relatively simple procedure, generally used only in patients undergoing surgery or critical care.

Field of use

In patients undergoing high-risk surgery and critically ill patients cardiac output monitoring may be used to guide fluid replacement and drug treatment, helping to maintain adequate blood supplies to the tissues. Thus monitoring may have the potential to reduce mortality, complication rates, length of stay in critical care facilities and overall hospital stay. Recent studies indicate that the pulmonary artery catheter, traditionally used to monitor cardiac output, may not be beneficial in these groups of patients. Patients undergoing surgery or critical care may receive only non-invasive assessment of markers such as heart rate, systolic blood pressure, and urinary output (conventional clinical assessment) with or without catheter-based measurement of central venous pressure (CVP); the anaesthetist generally decides which patients also need monitoring of their cardiac output. ODM is already widely used in the NHS: one type is used in around 25,000 patients each year; but considering the large number of potential patients its use seems to be relatively infrequent.

National guidance

There is no national guidance; practice varies within the NHS depending on individual clinician preferences, patient characteristics and local practices, guidelines or protocols. The National Institute for Health and Clinical Excellence (NICE) has decided not to consider ODM monitoring within its interventional procedures programme because it is considered to be standard clinical practice.

Evidence reviewed

This review is based on a recent high-quality systematic review by the US Agency for Healthcare Research and Quality of eight randomised controlled trials (RCTs) supplemented by two further RCTs that were found through literature searching. Of the eight studies in patients undergoing high-risk surgery, five considered the addition of ODM to conventional clinical assessment and CVP, and this was also the comparison made in the two studies in critically ill patients (following surgery). No studies were found comparing ODM with other methods of cardiac output monitoring and no relevant published economic evaluations were found.

CEP's verdict –**Significant potential**

Patients undergoing high-risk surgery

- Compared with CVP monitoring plus conventional clinical assessment, **addition** of ODM-guided fluid administration probably results in fewer deaths, fewer complications, and a shorter length of hospital stay. The costs of ODM are likely to be offset by reductions in both complications and length of hospital stay, although the costs of treatments initiated because of the different monitoring strategies are uncertain
- Compared with CVP plus conventional clinical assessment the evidence is inconclusive (both in terms of effectiveness and cost effectiveness) for **substitution of ODM-guided fluid administration instead of CVP**
- Compared with conventional clinical assessment (**without CVP**), addition of ODM-guided fluid administration probably results in a shorter length of hospital stay but the evidence is unclear for other outcomes. The costs of ODM seem likely to be compensated for by the reductions in length of hospital stay but overall differences in costs and effectiveness are unclear
- The decision about which patients need ODM is a clinical decision made in the light of available evidence for that patient group but the evidence base for all groups is limited.

Critically ill patients following surgery

- There is some evidence that addition of ODM-guided fluid administration to CVP monitoring plus conventional clinical assessment reduces complication rates and length of hospital stay in subgroups of patients. This evidence indicates that the costs of ODM are likely to be offset by reductions in lengths of hospital stay. However, there is not enough evidence on which to base a recommendation for widespread use of ODM for critically ill patients in the NHS
- The decision about which patients need ODM is a clinical decision made in the light of available evidence for that patient group but the evidence base for all groups is limited.

Optimal management of cardiac output, fluid balance and haemodynamic status is considered to be a key factor in improving the outcomes of high-risk surgery and critically ill patients. Using cardiac output monitoring to guide fluid replacement and pharmacological treatment allows haemodynamic status to be optimised, and thus helps to maintain adequate blood supplies to the tissues. Monitoring, therefore, has the potential to reduce mortality, complication rates, length of stay in critical care facilities and overall hospital stay, all of which could reduce healthcare costs.

About three million surgical operations are done in the UK every year, with a hospital mortality rate of 0.8%-1.0% [1]. Following surgery, over 20,000 deaths occur annually in England, Wales and Northern Ireland alone [2]. Thus any improvement in morbidity and mortality after surgery could benefit large numbers of patients and markedly improve healthcare resource use.

Traditionally pulmonary artery catheters (PACs) have been used to monitor cardiac output and haemodynamic status and thus to guide treatment. Recent studies indicate, however, that PACs may not be beneficial for patients undergoing high-risk surgery or critically ill patients [3,4].

Aims

This report aims to assess the effectiveness and cost-effectiveness of an alternative method of monitoring cardiac function, oesophageal Doppler monitoring (ODM), in patients undergoing high-risk surgery or in critically ill patients, compared with

- standard care
- other methods of monitoring heart function (such as PACs or pulse contour monitoring devices).

Patients undergoing high-risk surgery

It is not yet clear how patients should be selected for cardiac output monitoring and practices vary, but cardiac output monitoring systems are widely used within operating theatres. They are mainly used in more major surgery, often for patients with significant co-morbidity or where significant blood loss or fluid shifts seem likely, either because of the patient's underlying condition, or the anticipated surgery. Generally, the anaesthetist decides whether cardiac output monitoring is needed based on their preoperative clinical assessment of the patient and possibly on the results of pre-operative non-invasive cardiac testing [5]. Occasionally, monitoring may be started during surgery (and continue after the operation).

Patients who are critically ill

Patients who need care in intensive care or high-dependency units, by definition, need high levels of care and monitoring. The decision to use these higher levels of care may be influenced by the patient's underlying surgical condition, their co-morbidities and the type of surgery. In addition to conventional clinical assessment and monitoring, cardiac output

monitoring may help to guide and monitor fluid therapy and help to distinguish between different causes of haemodynamic instability, which need different treatments.

Product description

ODM measures blood-flow velocity in the descending thoracic aorta using a flexible probe, in the tip of which is a Doppler transducer that transmits an ultrasound beam. The probe tip is inserted into the patient's oesophagus to mid-chest level and the ultrasound beam is directed towards the descending aorta. The rate of blood flow in the aorta is measured based on the Doppler principle. Combining the blood-flow information with an estimate of aortic cross-sectional area (based on the patient's age, height, and weight) allows continuous real-time monitoring of cardiac output and haemodynamic variables such as stroke volume and systolic flow time.

Knowledge of these variables allows the clinician to adjust fluids and inotrope therapy (agents that affect heart muscle contraction) to optimise blood and oxygen supplies to tissues. If other variables such as central venous pressure and blood pressure are known, other values, such as systemic vascular resistance, can be calculated.

ODM is a relatively simple procedure, generally used for patients undergoing critical care or surgery, particularly those with significant co-morbidity or those undergoing major surgery with a high incidence of blood loss and/or significant fluid shifts. Only brief training is needed to use the probe and monitor reliably [6]; both insertion and removal are straightforward. The duration of monitoring varies greatly but can extend to several weeks. The probe itself is uncomfortable and patients who are awake generally need to be sedated or anaesthetised, limiting ODM use mainly to operating theatres, high-dependency units or intensive care units. New softer probes designed to improve tolerability are not yet widely available.

ODM has been shown to have high validity (no bias and high clinical agreement with PAC thermodilution techniques) for monitoring changes in cardiac output during the management of critically ill patients both in operating theatres and intensive care units [7]. Cardiac output measurements from the ODM correlate well with those obtained with a PAC via thermodilution [6, 8-10]. A few minor complications (from the use of the probe), but no major ones, have been reported [11].

National guidance

Currently there are no universally accepted guidelines on how to select patients requiring cardiac output monitoring either during or after surgery, or in a critical care environment. Practice varies within the NHS depending on individual clinician preferences, patient characteristics and local practices, guidelines or protocols.

NICE has decided not to consider ODM monitoring within its interventional procedures programme because it is considered to be standard clinical practice, and because its risks and benefits are sufficiently well-known [12].

Current methods of assessing cardiac output and haemodynamic status

PACs, traditionally used to monitor cardiac output and haemodynamic status, have been much less used in recent years because of doubts about their benefits, concerns about procedural complications, and the increasing availability less invasive monitoring methods. These less invasive monitoring methods include ODM, trans-oesophageal echocardiography and systems based on pulse-contour analysis and dye-dilution methods (Table 1). These approaches may be used alongside conventional clinical assessments (e.g. heart rate, systolic blood pressure, and urinary output) with or without a measure of blood flow or central venous pressure.

Table 1 Assessment methods that may be used currently

Cardiac output monitoring*options	Description/advantages	Disadvantages
None: conventional clinical assessment with or without CVP	Also used alongside cardiac output monitoring	No cardiac output monitoring
Oesophageal Doppler monitoring (ODM)	Relatively simple procedure Only brief training is needed	Probe is uncomfortable and patients need sedation or an anaesthetic
Pulmonary artery catheter (PAC)	Traditionally used, but global decline of usage in recent years because of its disadvantages	Evidence of no benefit in critically ill patients Doubts about benefits in surgery Possible complications of insertion and use
Pulse contour analysis monitoring <ul style="list-style-type: none"> • Lithium dilution cardiac monitor (LidCO®) • Thermodilution cardiac monitor (PICCO®) 	Use algorithms to give real-time continuous monitoring of cardiac output through arterial pulse contour analysis Have the advantage that they can be tolerated by patients who are awake	A good working arterial line is needed (often present anyway in the targeted populations) Needs calibration – which has potential hazards Takes slightly longer to set up than ODM
Trans-oesophageal echocardiography	Allows direct assessment of heart structure and function, and can be used to derive cardiac output by using Doppler to assess blood flow and direct measurement of the cross sectional area of the aorta	Probe is large and expensive Needs large amounts of sedation or an anaesthetic Highly skilled and trained operator is needed

CVP = catheter-based measurement of central venous pressure

*The decision about whether to use monitoring is based on patient assessment (and possibly pre-operative non-invasive cardiac tests)

Current usage of ODM in the NHS

In the NHS, practices for haemodynamic optimisation and patient monitoring vary but the most widely used ODM, the CardioQ (Deltex Medical, Chichester, UK) is present in about two-thirds of the 300 or so NHS hospitals that regularly do moderate or major surgery (Deltex Medical). Currently, in the NHS, the CardioQ is used in around 25,000 patients each year. Its use is divided roughly evenly between intensive care, intra-operative (theatre only) and peri-operative use. However, given the large number of potential patients, its use overall is relatively infrequent.

Many patients receive conventional clinical assessment, which usually refers to non-invasive assessment of markers such as heart rate, systolic blood pressure, and urinary output, with no measure of blood flow or of CVP, though practices are likely to vary.

Sources

This review is based on evidence contained in a high-quality 2007 systematic review of ODM in patients during surgery and post-operatively from the US Agency for Healthcare Research and Quality (AHRQ) [11], supplemented by evidence from additional studies identified by the searches detailed below. This review focuses on the evidence presented in the AHRQ report related to the following key questions.

- does therapeutic management based on ODM during surgery lead to improved patient outcomes (fewer complications and shorter hospital stay)?
- does therapeutic management based on ODM during hospitalisation (defined as the use of ODM amongst critically ill patients) lead to improved patient outcomes (fewer complications and shorter hospital stay)?

The comparators considered in the AHRQ report were:

- catheter-based measurement of central venous pressure (CVP)
- conventional clinical assessment (physical examination, fluid input and output measurements).

Search terms

The search strategy used to identify additional studies involved searching electronic databases and relevant websites, contact with experts in the field and scrutiny of bibliographies of retrieved papers. 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 a 25-question quality scale and the systematic review was assessed using a 10-item checklist. Where appropriate, meta-analysis was used to estimate a summary measure of effect on relevant outcomes. However, given the small amount of data available, these measures should be treated cautiously.

Inclusion and exclusion criteria

Study types

The types of studies considered were randomised controlled trials (RCTs) and systematic reviews of such evidence.

The following types of study were excluded:

- non-randomised studies
- studies in which ODM is used to measure a study outcome rather than as a clinical monitor
- non-English language studies
- animal models
- preclinical and biological studies
- narrative reviews, editorials, opinions
- reports published as meeting abstracts only.

Intervention and comparators

The intervention considered was ODM.

Comparator interventions considered were:

- no cardiac monitoring
- pulmonary artery catheters
- pulse contour analysis monitoring
- lithium dilution cardiac monitors i.e. LidCO® monitor; and
- thermodilution cardiac monitors i.e. PICCO® monitor.

Participants

The types of participants considered were:

- adults during major surgery
- adults being managed in critical care facilities who required cardiac monitoring.

Studies included in effectiveness review

The searches identified 663 reports, among which ten randomized controlled trials (RCTs) met the inclusion criteria, eight of which [13-20] were included in the AHRQ review [11]. The characteristics of the ten studies are summarised in Appendix 1. No studies were found that compared ODM with other methods of cardiac output monitoring. The evidence below is based on the AHRQ report, supplemented by the two additional studies and additional analyses [21,22].

The outcomes considered were mortality, major complications, total complications and length of hospital stay. None of the studies reported quality of life data. Note that the length of hospital stay may be shorter for an intervention because more people die in hospital with that intervention. This does not appear to be a problem with any of the comparisons reported below but it is noted where this might potentially be a problem.

Quality of included studies and AHRQ report

The quality rating was high for nine of the ten studies and moderate for the other study, based on a 25-question scale. A checklist used to assess the methodological quality of systematic reviews, gave the AHRQ report itself top scores for six of ten items, three items were 'partially met' and the other item, overall scientific quality, scored five (minor bias) on a scale from one (extensive flaws) to seven (minimal flaws).

Assessment of effectiveness

Comparison 1. ODM + CVP + conventional assessment versus CVP + conventional assessment in patients undergoing high-risk surgery

Five studies (453 patients) compared the above strategies during various types of surgery. In the ODM group there were fewer deaths, fewer major complications, fewer total complications and a shorter length of hospital stay (Tables 2 and 3). In the case of length of hospital stay, four of the five studies individually reported statistically significant reductions with the ODM strategy (Table 3). The fifth study amongst bowel surgery patients reported a longer length of stay although this difference was unlikely to be statistically significant. A meta-analysis of the two studies reporting data in a suitable format (one favouring ODM and one not) by the Aberdeen group (weighted mean difference approach) resulted in ODM having a 1.82 days shorter mean stay (95% CI -2.98 to -0.65 days). This result should be treated cautiously because (i) given the evidence from the other studies this result appears to be slightly biased against ODM (Table 3); and (ii) the results overall suggest that the effect on length of stay is influenced by the patient group.

Table 2 Mortality and complications in patients undergoing high-risk surgery (comparison 1)

	ODM + CVP + conventional assessment	CVP + conventional assessment
Mortality during or after surgery		
No. of deaths/no. of patients*	0/224 (5 studies)	4/224 (5 studies)
Odds ratio	0.13, 95%CI 0.02 to 0.96	
Major complications†		
No. of complications/no. of patients	0/110 (3 studies)	17/110 (3 studies)
Odds ratio	0.12, 95%CI 0.04 to 0.31	
Total complications		
No. of complications/no. of patients	42/144 (3 studies)	69/144 (3 studies)
Odds ratio (fixed)	0.43, 95%CI 0.26 to 0.71	

*This analysis should be treated with caution due to the low number of events and the overall small number of patients in the combined totals.

†Major complications = life-threatening or needing intensive or high-dependency care.

Reported odds ratios are from the meta-analysis (Peto method) of the Aberdeen group and are based only on those studies for which suitable data were available.

The analyses included a study in patients undergoing cardiac surgery, the results of which were consistent with those from the other four studies. All five studies reported that there were no ODM-related complications.

Table 3 Length of hospital stay in patients undergoing high-risk surgery (comparison 1)

Study reference	No. of patients	Measure	Length of hospital stay (days)		
			ODM group	Control group	p value
13	57	Mean (SD)	18.7 (20.2)	12.7 (6.0)	NR
		Median (range)	12 (7 to 103)	11 (7 to 30)	NR
14	100	Mean (SD)	5 (3)	7 (3)	NR
		Median	6	7	0.03
16	60	Mean (range)	6.4 (5 to 9)	10.1 (5 to 48)	0.01
17	103	Median (IQR)	7 (3 to 35)	9 (4 to 45)	0.005
20	128	Median (IQR)	10 (5.75)	11.5 (4.75)	0.03

NR, not reported; IQR, interquartile range.

The AHRQ report stated that in one study [13] a patient in the ODM group remained in hospital for 103 days, not because of complications but because a social/community placement could not be found.

Although no quality of life data were reported, one study [20] stated that quality of life questionnaires completed 4–6 weeks after surgery showed no differences between groups.

Comparison 2. ODM +conventional assessment versus CVP + conventional assessment in patients undergoing high-risk surgery

One study (61 patients) compared ODM plus conventional assessment versus CVP plus conventional assessment during surgery. In the ODM group there were fewer deaths, fewer total complications and fewer patients who experienced complications compared with the CVP group but none of the differences were statistically significant (Table 4). No data were

available on major complications. There was no statistically significant difference between the groups in the mean length of hospital stay.

Table 4 Mortality, complications and length of hospital stay in patients undergoing high-risk surgery (comparison 2)

	ODM + conventional assessment	CVP + conventional assessment
Mortality during or after surgery		
No. of deaths	3/30	6/31
p value	0.30	
Total complications		
No. of complications	14/30	16/31
Odds ratio	0.82, 95%CI 0.30 to 2.25	
No. of patients with complications	10/30	14/31
Odds ratio	0.61, 95%CI 0.21 to 1.72	
Length of hospital stay		
Days	13.5	13.3
p value	0.96	

Comparison 3. ODM +conventional assessment versus conventional assessment in patients undergoing high-risk surgery

Three studies (139 patients) compared ODM plus conventional assessment versus conventional assessment during surgery. There was no evidence of a difference in mortality either during or after surgery (Table 5). No data were available on major complications. The only study that reported total complications, found fewer complications in the ODM group than in the conventional assessment group but no difference between the groups in the number of patients with complications.

Table 5 Mortality and complications in patients undergoing high-risk surgery (comparison 3)

	ODM + conventional assessment	Conventional assessment
Mortality		
No. of deaths/no. of patients	5/70 (3 studies)	6/69 (3 studies)
Odds ratio (fixed effect)	0.81, 95% CI 0.23 to 2.77.	
Total complications		
No. of complications	14/30 (1 study)	23/29 (1 study)
Odds ratio	0.23, 95% CI 0.07 to 0.72	
No. of patients with complications	10	16
Odds ratio	0.41 95% CI 0.14 to 1.16	

Length of hospital stay was shorter in the ODM group compared with the conventional assessment group in all three studies, but only one study reported a statistically significant difference between the groups (favouring ODM; Table 6). In the AHRQ report a random-effects meta-analysis (refs 18 and 19 only) was statistically significant in favour of ODM (pooled mean difference -6.76 days, 95% CI -11.83 to -1.68 days; $p = 0.008$). The additional

study [22], despite a shorter median hospital stay for the ODM group, reported a longer median length of stay in the HDU for this group (3 days [n = 7]) compared with the control group (2 days [n = 5]).

Table 6 Length of hospital stay in patients undergoing high-risk surgery (comparison 3)

Study reference	No. of patients	Measure	Length of hospital stay (days)		p value
			ODM + conventional assessment	Conventional assessment	
18	40	Median (range)	11 (3 to 23)	20 (5 to 220)	<0.05
19	90	Mean (95% CI)	13.5 (10.9 to 17.5)	17.5 (13.9 to 24.4)	0.31
22	40	Median (range)	8 (5 to 34)	9 (5 to 27)	NR

Critically ill patients (after surgery)

Two studies (336 patients) compared ODM plus CVP plus conventional assessment versus CVP plus conventional assessment. The patient groups were quite different (cardiac surgery and multiple trauma plus surgery) but neither study, nor a meta-analysis, showed a statistically significant difference in mortality (Table 7). No data were available for major complications but fewer patients experienced complications in the ODM group.

Table 7 Mortality and complications in critically ill patients (after surgery)

	ODM + conventional assessment	Conventional assessment
Mortality		
No. of deaths/no. of patients	17/169 (2 studies)	20/167 (2 studies)
Odds ratio (fixed)	0.84, 95%CI 0.41 to 1.70	
Total no. of patients with complications/no. of patients		
	32/169 patients (2 studies)	54/167 patients (2 studies)
Odds ratio	0.49, 95%CI 0.30 to 0.81	

In the ODM group, median length of hospital stay was statistically significantly shorter both in the study in patients with multiple trauma and in the additional study in patients in cardiac intensive care (Table 8). The latter study also reported a statistically significantly shorter length of stay in the ICU in the ODM group (7 days, interquartile range [IQR] 6 to 11 days) compared with the control group (8.5 days, IQR 6 to 16; p = 0.031).

Table 8 Length of hospital stay in critically ill patients

Study reference	No. of patients	Measure	Length of hospital stay (days)		p value
			ODM + conventional assessment	Conventional assessment	
21 (multiple trauma, after surgery)	162	Median (IQR)	14 (8.25 to 21)	17.5 (11 to 29)	0.045
15 (after cardiac surgery)	174	Mean	11.4	13.9	NR
		Median	7	9	0.02

IQR = interquartile range

The combined data should be treated with caution because of possible concerns about combining data from two such different patient groups.

Patient group and duration of ODM

The AHRQ report stated that its conclusions applied only to patients undergoing surgical procedures where a substantial blood loss or fluid shifts requiring fluid replacement were expected. The types of surgery done in the studies of ODM during surgery were moderate or high-risk procedures, such as hip-fracture repair surgery, elective cardiac surgery, elective general, bowel, urological or gynaecological surgery, and major general abdominal surgery.

The optimal duration of ODM-guided fluid administration in critical care after surgery is unclear. ODM-guided fluid administration was applied for 4 hours after patients were admitted to cardiac intensive care after cardiac surgery [15], while patients with multiple trauma and major blood loss were monitored for 12 hours after admission to the ICU.

Ongoing studies

A large French multicentre study currently underway is assessing the value of ODM-guided colloid titration in improving outcomes in elderly patients undergoing surgical repair of hip fracture.

Safety

The available evidence suggests that ODM probes are relatively low-risk devices. No serious, and only a few minor, patient-related complications associated with ODM appear to have been reported.

Assessment of cost effectiveness

Studies that reported both costs and outcomes of strategies involving ODM compared with no cardiac monitoring, PAC or pulse contour analysis monitoring for the monitoring of critically ill and surgical patients were sought from a systematic review of the literature. No language restrictions or limitations to searches were imposed. Studies were included even if they made no formal attempt to relate cost to outcome data.

No economic evaluations or cost analyses that met the inclusion criteria were identified from the systematic search of the literature so there is no available evidence on the comparative costs and/or effects of ODM compared with relevant comparators.

To give an idea of the impact of regular ODM use on the NHS, in terms of costs and effects, balance sheets were used to compare the likely trade-offs between resource use and effectiveness for different approaches to monitoring. The balance sheets show factors that favour the use of ODM, factors that favour the alternative, and factors for which it is not yet clear whether they favour ODM. PAC and/or thermodilution techniques could not be used as 'alternatives' in the balance sheets because there was no evidence available on their comparative effectiveness. For this reason the 'alternatives' used in the balance sheets are conventional clinical assessment (with or without CVP), based on the evidence in the effectiveness review.

These balance sheets use the data on clinical effectiveness reported earlier and thus the cautions about the interpretation of the effectiveness data also apply to the interpretation of the balance sheets.

Balance sheets for patients undergoing high-risk surgery

Comparison 1. ODM + CVP + conventional assessment versus CVP + conventional assessment

In this comparison (Table 9), to which five studies contributed data, using ODM consistently outperformed the no-ODM strategy. The balance sheet indicates that the ODM option is more effective and that the savings from reduced length of stay would more than offset the cost of ODM (rough costs indicated below). Potential longer term costs associated with improved survival rates also need to be considered.

The resources used are an ODM monitor and probe, and an anaesthetist to do the insertion, which takes only a few minutes. No additional staff will be involved in interpreting monitor outputs in addition to those normally present in an operating theatre (or HDU/ICU). Equipment costs include the cost of the monitor (approx. £8,000–11,000) or rental agreement and its maintenance, the main additional cost of ODM being the disposable probes (approx. £60–120). The total equipment costs of ODM per patient may be estimated as in the range £66–214 per patient (based on information from the manufacturer; see costs in next section). The use of monitoring may also lead to some forms of treatment being initiated (e.g. the use of intravenous fluids, etc). The magnitude of these costs and their influence on the net effect is uncertain. If ODM provides additional benefits then it might be expected that there is more intervention and/or more appropriate intervention in the ODM group.

The estimated reduction of 1.82 days in hospital stay with ODM use would lead to cost savings per patient of £3123, based on a Level 3 ICU ward (costed at £1716/day), £1431 based on a Level 2 HDU ward (£786/day) or £564 based on a general surgical ward (£310/day)[23,24].

Table 9 Balance sheet for patients undergoing high-risk surgery (comparison 1)

ODM + CVP + conventional assessment (Factors that favour ODM)	CVP + conventional assessment (Factors against ODM)
Reduction in mortality (OR 0.13, 95% CI 0.02 to 0.96) - Leading to increased patient benefits	Reduction in mortality following use of ODM - Potential increased management costs of survivors in the longer term
Reduction in major complications (OR 0.12, 95% CI 0.04 to 0.31) - Leading to increased patient benefits - Leading to lower treatment costs	Additional cost of ODM - Staff time, reusable and disposable equipment required for insertion, monitoring and removal of the probe
Reduction in total complications (OR 0.43, 95% CI 0.26 to 0.71) - Leading to increased patient benefits - Leading to lower treatment costs	
Reduction in length of hospital stay (WMD -1.82, 95% CI -2.98 to -0.65) - A proxy for earlier recovery - Implying lower treatment costs	
No evidence of a difference in:	
Cost of additional of interventions (e.g. use of intravenous fluid or drugs) prompted by the monitoring	

Comparison 2. ODM + conventional assessment versus CVP + conventional assessment

For this comparison the ODM strategy seems likely to incur additional costs (i.e. equipment and staffing), but there is no evidence of a difference in effectiveness (Table 10). Fewer studies contributed data to this comparison and the likely cost savings in terms of length of stay, for example, are not clear.

Table 10 Balance sheet for patients undergoing high-risk surgery (comparison 2)

ODM + conventional assessment (Factors that favour ODM)	CVP + conventional assessment (Factors against ODM)
Additional cost of CVP - Staff time, reusable and disposable equipment required for insertion, monitoring and removing of catheter	Additional cost of ODM - Staff time, reusable and disposable equipment required for insertion, monitoring and removal of the probe
No evidence of a difference in:	
Mortality, major complications, total complications or length of hospital stay, Cost of additional of interventions(e.g. use of intravenous fluid or drugs) prompted by the monitoring	

Comparison 3. ODM + conventional assessment versus conventional assessment

The available evidence indicates that the reduction in length of hospital stay might be considerable (pooled mean difference -6.76 days 95% CI -11.83 to -1.68), and, if so, the resulting savings would more than compensate for the cost of using ODM (Table 11). However, it is uncertain whether total costs will actually be less because there is not enough evidence to identify possible differences in mortality, complications, or the costs of treatments initiated because of monitoring. It is also uncertain whether the use of ODM increases total benefits.

Table 11 Balance sheet for patients undergoing high-risk surgery (comparison 3)

ODM + conventional assessment (Factors that favour ODM)	Conventional assessment (Factors against ODM)
Reduced length of hospital stay (point estimate -6.76 95% CI -11.83 to -1.68) - A proxy for earlier recovery (provided mortality in the ODM is no greater than conventional assessment) - Implying lower treatment costs	Additional cost of ODM - Staff time, reusable and disposable equipment for probe insertion, monitoring and removal
No evidence of a difference in:	
Mortality (OR 0.81, 95% CI 0.23 to 2.77) - Unclear if there is any additional benefits to patients following use of ODM - Unclear if there is any additional long-term cost for ODM, for care in the longer term	
Major complications Total complications per patient (OR 0.41, 95% CI 0.14 to 1.16) - Unclear if there is any additional benefit to patients following use of ODM - Unclear if there are any savings for ODM following any reduction in total complications	
Cost of additional of interventions (e.g. use of intravenous fluid or drugs) prompted by the monitoring	

Balance sheets for critically ill hospitalised patients

For this group data were available only for the comparison of ODM plus CVP plus conventional assessment versus CVP plus conventional assessment. The balance sheet shows probable reductions in total complications and length of hospital stay though the evidence base for this subgroup of patients is sparse and comes from two very different patient groups (Table 12). The likely cost savings from the reduction in length of stay (reported as 1 to 2 days for this comparison), depend partly on the type of ward involved (costs noted above), but it is likely that the reductions in length of stay would compensate for the cost of ODM (although, as noted above, the costs of treatments initiated by the different types of monitoring compared are unclear). Because the effects of ODM on mortality and major complications in critically ill patients is uncertain, a decision to adopt ODM for these patients would be partly based on the assumption that the reduced mortality and complications seen in some surgery patients would be likely to apply to this group.

Table 12 Balance sheet for critically ill hospitalised patients

ODM + CVP + conventional assessment (Factors that favour ODM)	CVP + conventional assessment (Factors against ODM)
<p>Reduced total complications (OR 0.49, 95% CI 0.30 to 0.81)</p> <ul style="list-style-type: none"> - Leading to increased patient benefits - Leading to lower treatment costs <p>Reduced length of hospital stay (1 to 2 days less)</p> <ul style="list-style-type: none"> - A proxy for earlier recovery (provided mortality in the ODM is no greater than CVP + conventional assessment) - Implying lower treatment costs 	<p>Additional cost of ODM</p> <ul style="list-style-type: none"> - Staff time, reusable and disposable equipment required for insertion, monitoring and removal of the probe
<p>No evidence of a difference in:</p> <p>Mortality (OR 0.84, 95% CI 0.41 to 1.70)</p> <ul style="list-style-type: none"> - Unclear if there is any additional benefits to patients following use of ODM - Unclear if there is any additional cost in the long-term for ODM for care in the longer term 	
<p>Major complications</p> <ul style="list-style-type: none"> - Unclear if there is any additional benefit to patients following use of ODM - Unclear if there is any savings for ODM following any reduction in major complications 	
<p>Cost of additional of interventions e.g. use of intravenous fluid or drugs prompted by the monitoring</p>	

Additional information relevant to the NHS

Although no evidence was available for the comparison of ODM with alternatives, a previous HTA report including findings from a systematic review and randomised controlled trial of PAC for patients in intensive care suggested that PAC was unlikely to be cost effective for these patients [3], and indicated that the primary cost drivers were differences in length of stay.

Information reported on www.reducinglengthofstay.org.uk [25] (website of the manufacturer of CardioQ) suggests that the use of ODM in one NHS hospital has, since 2004, saved approximately £1 million a year mainly as result of the need for less post-operative care. The formal analyses underpinning such information are not, however, readily available.

Cost-effectiveness analysis

Cost of ODM

Data from a manufacturer, Deltex Medical, and from public sources has been used to estimate the extra (incremental) costs associated with ODM. Table 13 shows the annual total cost of ODM assuming a 5-year lifetime for the monitor. The costs of ODM are based on data provided by Deltex Medical (personal communication August 2007).

Table 13 Cost per year for ODM equipment (2007/2008) assuming a 5-year lifetime for the monitor

Concept	CardioQ	CardioQP*
<i>Total cost of monitor</i>	£8,000	£11,000
Yearly instalments for monitor (for 5 years)	£1,600	£2,200
Other yearly costs (maintenance and software)	£1,200	£1,200
Total yearly cost	£2,800	£3,400

* CardioQ can only be used for adults while CardioQP can be used for both children and adults.

The cost of the probes varies from £60 for a 6-hour oral/nasal Doppler probe for use intra-operatively or peri-operatively, to £121 for a 10-day sterilised oral Doppler probe for use in critical care. According to the manufacturer the use of more than one probe per patient is rare, suggesting that the number of probes used per monitor per year is similar to the number of patients receiving ODM per year. Whether this is true in practice is unclear and whether more than one probe is used will depend upon the choice of probe and the clinical judgement made before monitoring is started about how well the patient will respond.

It is not clear how many patients might use a monitor per year or what would be the optimal use rate. In the absence of data on ODM usage rates, three usage rates have been considered in Table 14 to explore the importance of different levels of use.

Table 14 ODM equipment cost (monitor only) per patient (£, 2007/2008)

Assumption	CardioQ	CardioQP*
(a) 36 patients per monitor per year	£76.71	£93.15
(b) 125 patients per monitor per year	£22.40	£27.20
(c) 500 patients per monitor per year	£5.60	£6.80

* CardioQ supports only adult probes while CardioQP support both adults and paediatric probes.

Table 15 shows estimations of the total cost for ODM equipment and probe per patient. Based on the assumptions stated above and depending on the probe used the total equipment cost can range from around £66 to £214 per patient.

Table 15 Total equipment cost (monitor and probe) for ODM per patient (£, 2007/2008)

Assumptions*	CardioQ	CardioQP
Using assumption (a) and £121 probe price	£197.71	£214.15
Using assumption (b) and £96 probe price	£118.40	£123.20
Using assumption (b) and £60 probe price	£82.40	£87.20
Using assumption (c) and £96 probe price	£101.60	£123.20
Using assumption (c) and £60 probe price	£65.60	£66.80

* £121 for a 10-day sterilised oral Doppler probe (critical care); £96 for a 72-hour awake nasal Doppler Probe (intra and peri-operative); £60 for a 6-hour oral/nasal Doppler probe (intra and peri-operative).

In addition to the equipment costs, the marginal staff cost of using ODM may be minimal because the staff needed to interpret monitor outputs will be there anyway. Further, the time taken to insert the probe and obtain the initial readings is also minimal (e.g. about 5 minutes. Personal communication July 2007). Other direct costs associated with the procedure like ultrasound gel, or other disposal materials are negligible. Other costs may be incurred due to treatments initiated because of the monitoring and, as noted above, it is unclear whether these are likely to be greater following the use of ODM compared with its non-use.

Table 16 Assumptions made in cost-effectiveness modelling*

Assumption *	Best-case scenario	Worst-case scenario
Cost of ODM equipment per patient (from Table 15)	£66	£214
'Cost' of 1-day reduction in length of hospital stay	£1680 (ICU)	£310 (general medical ward)
Mean length of survival per additional survivor	5 years	1 year
Quality of life weight at 12 months for ICU survivors	0.66	

*Assumptions are somewhat arbitrary but help to illustrate trade offs.

Economic models

The economic models assess the relative cost-effectiveness of using ODM by looking at possible pathways that care may follow when ODM is or is not used for the comparisons presented in the previous section. Only partial models could be developed, taking into account only differences in mortality and length of stay, and only for the strategies compared in the balance sheets. These models have not included the cost of treatment initiated because of the monitoring. As noted above the net effect of including these unknown costs is uncertain. Worst-case and best-case scenarios for the use of ODM were explored, which differed in the costs used for ODM equipment, the cost attached to any reduction in the length of stay due to ODM and the mean length of survival per additional survivor (Table 16). The numbers used are to some extent arbitrary but help to illustrate the possible trade-offs.

Results are based on quality adjusted life years (QALYs), and a quality of life weight at 12 months of 0.66 was used, based on quality of life of survivors of ICU at 12 months.

Table 17 Summary of cost-effectiveness results

			Extra cost per additional survivor that would need to be incurred before ODM was no longer considered cost effective	
Group	Comparison	Results (best-case scenario and worst-case scenario)	Best-case scenario	Worst-case scenario
Patients undergoing high-risk surgery	1. ODM + CVP+ conventional assessment vs CVP + conventional assessment	The option including ODM is more effective and less costly than the alternative in almost every case	£4441 (95%CI £2151 to £6732)	£642 (95%CI £225 to £1060)
Patients undergoing high-risk surgery	2. ODM + conventional assessment vs CVP + conventional assessment	Not possible to estimate incremental costs and benefits of ODM for this scenario since no data were available on which calculations could be based		
Patients undergoing high-risk surgery	3. ODM + conventional assessment vs Conventional assessment	The option including ODM is more effective and less costly than the alternative in the majority of cases; in the majority of the remainder it is both less costly and less effective	£11588 (95%CI -£2529 to £25,705)	£1879 (95%CI -£920 to £4678)
Critically ill patients	ODM + CVP+ conventional assessment vs CVP + conventional assessment	In about 70% of cases, the option including ODM is more effective and less costly than the alternative. In the other 30% it is less effective and less costly. The probability that the ODM option is cost effective (at a threshold of £30 000 per ICER) is 90% (best case) or 80% (worst case)	£4978 (95%CI -£2655 to £12611)	£364 (95%CI -£1211 to £1978)

Table 17 summarizes both the best-case and worst-case scenario results for the cost-effectiveness model explorations, for each of the four comparisons considered and shows the estimate of the extra cost per additional survivor that would need to be incurred before ODM was no longer considered cost effective for each scenario.

For all the comparisons explored, the strategies that involved the use of ODM seem to have a fairly high chance of being considered cost effective under the assumptions made.

Although some of these assumptions are based on limited data and it has not been possible to estimate some costs. However, these cost-effectiveness results seem to be heavily dependent on the mean cost for the NHS of treating extra survivors. The thresholds for these costs, before ODM might not be considered cost-effective, ranged from £364 to £11,600 (depending on the comparison and the underlying assumptions) but the actual costs in current practice are not clear from the current work.

Limitations

The main limitation of the cost-effectiveness data is the lack of existing studies. Even so, organising the available data has highlighted the choices and trade-offs. Judgements based on these data should consider the pros and cons of using ODM, the considerable uncertainty surrounding the estimates of relative effectiveness and the implications of not including the costs of treatments initiated because of monitoring or of treating complications. The modelling exercise incorporated some of the uncertainty around effectiveness estimates and gave an indication of the extent to which the use of ODM might be considered cost-effective. However, this exercise has limitations, in particular the partial modelling approach, which did not take into account all of the factors in the balance sheets. A full economic model might help decision making by fully incorporating other factors (e.g. numbers of complications) for all of the relevant alternatives.

Note that the limited evidence base is suggestive rather than firmly conclusive.

In patients undergoing high-risk surgery, addition of ODM-guided fluid administration to CVP monitoring plus conventional clinical assessment (comparison 1) is likely to result in fewer deaths, fewer complications, and a shorter length of hospital stay. The costs of ODM are likely to be offset by reductions in both complications and length of hospital stay (although the costs of treatments prompted by monitoring are uncertain).

In patients undergoing high-risk surgery, the evidence on ODM-guided fluid administration plus conventional clinical assessment compared with CVP plus conventional clinical assessment (comparison 2) was inconclusive (both in terms of effectiveness and cost effectiveness).

In patients undergoing high-risk surgery, addition of ODM-guided fluid administration to conventional clinical assessment (comparison 3) is likely to result in a shorter length of hospital stay but no conclusions were possible for other outcomes. The costs of ODM seem likely to be compensated for by the reductions in length of hospital stay but overall differences in costs and effectiveness are unclear.

In critically ill patients following surgery, there is some evidence that addition of ODM-guided fluid administration to CVP monitoring plus conventional clinical assessment reduces complication rates and length of hospital stay in subgroups of patients. This evidence indicates that the costs of ODM are likely to be offset by reductions in lengths of hospital stay. However, there is not enough evidence on which to base a recommendation for widespread use of ODM for critically ill patients in the NHS.

The available evidence suggests that ODM probes are relatively low-risk devices and the use of ODM might be considered safe.

The costs of addition of ODM would be the cost of a monitor (approximately £8,000–11,000) and a single disposable probe per patient (approx £60 to £120) plus maintenance costs and costs of probe insertion. Changes in lengths of stay, complications and mortality would also affect costs.

Further research is needed and should include economic evaluations or provide data suitable for use in an economic model.

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Appendix 1 Characteristics of the included studies

Characteristics of the included studies

	AHRQ report	Additional studies	Total
Number of studies	8	2	10
Number of patients	757	202	959
Age, Years (range of means/medians)	ODM group: 56 to 82 Control group: 59 to 85	ODM group: 33 to 76 Control group: 40 to 76	33 to 82 40 to 85
Sex	M: 258 (52%) F: 234 (48%) NR: 265	M: 163 (81%) F: 39 (19%) NR: 0	M: 421 (61%) F: 273 (39%) NR: 265
System used	CardioQ (7 studies) TECO (1 study)	CardioQ (1 study) HemoSonic 100 (1 study)	8 studies 1 study 1 study 5 studies; 453 patients
During surgery	ODM+CVP+conventional assessment versus CVP+conventional assessment (5 studies; 453 patients)		
	ODM+conventional assessment versus CVP+conventional assessment (1 study; 61 patients)		1 study; 61 patients
	ODM+conventional assessment versus conventional assessment (2 studies; 99 patients)	ODM+conventional assessment versus conventional assessment (1 study; 40 patients)	3 studies; 139 patients
Critically ill patient	ODM+CVP+conventional assessment versus CVP + conventional assessment (1 study; 174 patients)	ODM+CVP+conventional assessment versus CVP+conventional assessment (1 study; 162 patients)	2 studies; 336 patients
Type of surgery:	Elective bowel surgery (3 studies; 293 patients)		3 studies; 293 patients
	Hip fracture repair surgery (2 studies; 130 patients)		2 studies; 130 patients
	Elective cardiac surgery (1 study; 60 patients)		1 study; 60 patients
	Elective general, urological or gynaecological surgery (1 study; 100 patients)		1 study; 100 patients
		Colorectal surgery (1 study; 40 patients)	1 study; 40 patients

NR, not reported.

The study by Venn and colleagues (Venn 2002) reported two comparisons: ODM plus conventional assessment (n = 30) versus CVP plus conventional assessment (n = 31) versus conventional assessment (n = 29). Hence the ODM group appears twice.

Evidence review: Oesophageal Doppler monitoring in patients undergoing high-risk surgery and in critically ill patients

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