National Guidance for Oesophageal Doppler Monitoring (ODM)

Background

The oesophageal Doppler monitor (ODM) was first released onto the market place in 1992 with the first Randomised Controlled Trial (RCT) being published in 1995.

Since its release the ODM has been used on over 1,000,000 patients in over 40 countries around the world.

ODM-guided fluid management has repeatedly shown reductions in post-op complications and length of hospital stay across 24 published RCT's in multiple different types of surgery.

These trials have been subject to a number of meta-analyses and systematic reviews:

- A health technology assessment (HTA) published by ECRI for the Agency for Healthcare Research & Quality (AHRQ);
- NICE recommendation (MTG3) for over 800,000 medium and high-risk surgery patients;
- Included within NICE pathway for 'Major haemorrhaging in hospital';
- Multiple meta-analyses re ODM in abdominal surgery published;
- Multiple meta-analysis re ODM across all surgical applications published;
- Multiple meta-analysis re ODM and GDTF in all hospital settings;
- A report by the Centers for Medicare and Medicaid Services based upon the ECRI HTA;
- A report by the UK Centre for Evidence-based Purchasing (CEP);
- An HTA by the Aberdeen University Health Economic Research Unit commissioned by the NHS National Institute for Healthcare Research (NIHR);
- Assessment of ODM evidence as Level 1A for abdominal surgery and Level 1B for orthopaedic surgery for UK consensus fluid guidelines;
- 24 Randomised Clinical Trials across different surgical applications (colorectal, urology, gynecology, orthopaedic, hepatic) in adult and paediatric patients
- Over 1,000 peer reviewed publications of utilising the ODM in the operating room, intensive care and emergency room.

All the above have concluded positively on the benefits of ODM. The AHRQ/ECRI report concluded that, 'for a large group of surgical patients, no further clinical trials on ODM were necessary'.

Main Recommendations

UK

National Institute For Health and Care Excellence (NICE)

https://www.nice.org.uk/guidance/MTG3/chapter/1-recommendations

> The case for adopting the CardioQ-ODM in the NHS, when used as described in 1.2, is supported by the evidence. There is a reduction in post-operative complications, use of central venous catheters and in-hospital stay (with no increase in the rate of re-admission or repeat surgery) compared with conventional clinical assessment with or without invasive cardiovascular monitoring. The cost saving per patient, when the CardioQ-ODM is used instead of a central venous

catheter in the peri-operative period, is about £1100 based on a 7.5-day hospital stay.

1.2The CardioQ-ODM should be considered for use in patients undergoing major or high-risk surgery or other surgical patients in whom a clinician would consider using invasive cardiovascular monitoring.

NICE Pathway Major haemorrhaging in hospital'

https://pathways.nice.org.uk/pathways/trauma

USA

Medicare National Coverage Decision (NCD)
https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/MM8330.pdf

The Centres for Medicare and Medicaid Services (CMS) provides coverage for use of Esophageal Doppler Monitor (EDM). CMS determined that EDM is "reasonable and necessary" for all Medicare beneficiaries who meet the criteria for the following patient populations:

- Monitoring of cardiac output for ventilated patients in the ICU; and
- Operative patients with a need for intra-operative fluid optimization

The 2015 national average Medicare payment level for G9157 is $97.97 (based on 2.74 RVUs). Professional services associated with EDM are separately payable under the Medicare Physician Fee Schedule (MPFS). Medicare adjusts professional payment based on regional differences in practice costs, thus payment may vary based on physician location. Other payers, including private payers, may base their payments on Medicare payment rates.

AHRQ Technology Assessment

https://www.ecri.org/Resources/EPC_Sample_Reports/Esophageal_Doppler_Ultrasound_Based_Cardiac_Output_Monitoring.pdf

Esophageal Doppler Ultrasound-Based Cardiac Output Monitoring for Real-Time Therapeutic Management of Hospitalized Patients

Spain

Spanish Ministry of Health, Social Services and Equality

http://portal.guiasalud.es/contenidos/iframes/documentos/opbe/2015-07/ViaClinica-RICA_English.pdf (English Version)

National guidance for Spain to conduct all surgery within enhanced recovery protocols. Oesophageal Doppler is the recommended technology to use within the protocol.

Page 51 – Summary and Recommendations

60. The use of SV (Stroke Volume) or of SVV (Stroke Volume Variation) by monitoring is recommended to guide the intraoperative administration of fluids.

    Strong recommendation +. High Level of Evidence.

62. Restrictive continuous fluid perfusion must be maintained in order to avoid fluid overload.

    Strong recommendation +. High Level of Evidence.

63. Intraoperative hypotension must be treated with vasopressors.

    Strong recommendation +. High Level of Evidence

64. A mean blood pressure range of 70 mmHg must be established

    Strong recommendation +. Moderate Level of Evidence

65. A CI of > 2.5 l/min/m2 must be maintained, using inotropes in cases where there is no response to volume.

    Strong recommendation +. Moderate Level of Evidence.

66. **Monitoring with oesophageal Doppler is preferred**, or else methods based on validated pulse contour analyses.

    Strong recommendation +. Moderate Level of Evidence.

France

Société Française d'Anesthésie et de Réanimation ('SFAR')

http://sfar.org/strategie-du-remplissage-vasculaire-perioperatoire-2/

(National guidelines for peri-operative optimisation during surgery)

The guidelines are divided into 15 recommendations regarding fluid management, with 3 directly relevant to the use of the ODM

Each recommendation made within the document is graded in a binary system:

- High: You must do or not do (**GRADE1+** or **GRADE1-)**
- Low: It is possible to do or not do (**GRADE2+** or **GRADE2-)**

All 3 recommendations relating directly to ODM fluid management received a GRADE1+ rating.

This means that they must all be carried out in the case of high-risk patients, as the evidence level is high. It has been assessed by the SFAR that future evidence is unlikely to change any conclusions drawn from current evidence.

The three relevant recommendations provided are as follows:

Q1: Filling guided by the measurement of the systolic ejection volume of (SV) reduces post-operative morbidity and duration of stay.

A1: Fluid titration for high-risk surgical patients should be guided by stroke volume to reduce post-operative morbidity, get earlier return to oral feeding and reduce length of stay. **GRADE1+**.

Q2: Should we interrupt the filling in the absence of the SV increase?
A2: It is recommended to discontinue filling if SV does not increase. **GRADE1+**

Q3: Should we regularly reassess the SV?
A3: Reassess SV regularly and the SV response to a fluid challenge, especially during periods of haemodynamic instability. **GRADE1+**.

Poland

Polskie wytyczne okołooperacyjnego leczenia płynami

https://ojs.kardiologiapolska.pl/kp/article/download/KP.2014.0193/7958.

Page 8 - National recommendations for the use of SV Optimisation using the ODM

Enhanced Recovery After Surgery (ERAS)

Development and Feasibility Study of an Algorithm for Intraoperative Goal Directed Haemodynamic Management in Noncardiac Surgery

A Feldheiser, P Conroy, T Bonomo, B Cox, T Ruiz Garces and C Spies on Behalf of the Anaesthesia Working Group of the Enhanced Recovery After Surgery (ERAS®) Society

'Preload optimization guided by stroke volume, as measured by oesophageal Doppler ultrasonography, was almost always associated with a significant reduction in length of hospital stay and postoperative morbidity (Table 2). In contrast to these studies, investigations based on the measurement of stroke volume by the Vigileo™ monitor/FloTrac™ sensor (Edwards Lifesciences, Irvine, CA, USA) or by the lithium indicator dilution cardiac output (LiDCO™; Lidco, Cambridge, UK) system did not uniformly improve outcome (Table 2).

'There is no evidence that the use of a pulse contour method to guide intraoperative fluid therapy by measuring stroke volume is equivalent to guiding fluid administration by oesophageal Doppler ultrasonography'.

ERAS Recommendation

'Oesophageal Doppler ultrasonography was chosen as the preferred method of monitoring intraoperative stroke volume due to the broader evidence base in this context.'

Enhanced Recovery Partnership Guidance UK
http://perioperativemedicinejournal.biomedcentral.com/articles/10.1186/2047-0525-1-2

'The Enhanced Recovery Partnership fully supports the use of intra-operative fluid management technologies to deliver individualised goal directed fluid therapy. This is recommended in the 2012-13 NHS Operating Framework, in the Innovation, Health and Wealth Review and in NICE Guideline MTG3.'

Oesophageal Doppler Monitoring (ODM)
Published Randomised Controlled Trials (RCT's):-

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