

ANAESTHESIA

INTERNATIONAL

Haemodynamic management in major surgery



Haemodynamic optimisation of the surgical patient revisited

The use of a protocol to maximise haemodynamic flow parameters during surgery has been clearly shown to reduce the risk of complications and length of hospital stay. The limited adoption of a targeted intraoperative strategy, despite the evidence, points to poor acceptance of current monitoring technologies. The LiDCO*rapid* represents the first monitor specifically designed to guide the haemodynamic management and implementation of protocol-driven fluid management in patients undergoing major surgery. The monitor gives an early warning of haemodynamic change, together with an indication of both fluid responsiveness and actual response to a fluid or drug intervention. The graphical user interface has been specifically designed for theatre use and to be visually intuitive.

The report of the National Confidential Enquiry into Patient Outcome and Deaths in the UK (2000)¹ recognised that patients who die after surgery are more likely to be elderly, have coexisting medical disorders and require urgent or emergency surgery. The data showed clearly that there was a group of surgical patients whose postoperative mortality is 20–30% as compared to the surgical population as a whole whose mortality is 0.8–1%. This high-risk group of surgical patients is associated with 25,000+ deaths within 28 days of surgery each year in the UK (excluding Scotland). A significant improvement in surgical outcomes can only come from targeting this group.

The factor that makes this group so vulnerable appears to be the inability to mount an appropriate physiological response to major surgery. Poor cardio-respiratory performance results in a failure to increase oxygen delivery in response to surgical stress. The result is cellular hypoperfusion and anaerobic metabolism generating an oxygen debt whose magnitude and speed of resolution are causal to mortality. The proposition is that the speed at which this debt is repaid determines not only the likelihood of death but also the incidence of complications, such as infection and multiple organ failure, in survivors. This concept became the basis for the strategy of goal-directed therapy and it has been emphasised by a series of observational studies.

Shoemaker² initially defined the criteria that were associated with a poor prognosis and then showed that the ability to measure and increase oxygen delivery within this higher-risk group gave dramatic benefits, reducing mortality from 33% to 4%. The concept of 'goal-directed therapy' subsequently emerged and is evolving with a rapidly growing evidence base. The underlying premise is that the use of intravenous fluids - and possibly inotropes and vasoactive drugs - can restore or improve oxygen delivery to prevent, or more rapidly repay, outstanding oxygen debt. The scientific papers present a compelling history and they both give credence and allow insights into which patients to optimise, when to attempt it and what targets may be realistic.

Understanding the message from the interventional studies targeting physiological derangement is difficult because of the many methodological differences between the trials.

Using comparisons of studies with clear protocols and outcome data, a pattern emerges which helps distinguish successful from unsuccessful trials. Patient selection appears critical, with a focus on targeting those with the specific comorbidities considered to increase mortality significantly (>20%). Similarly, successful intervention requires timely involvement prior to there being evidence of end organ derangement. The accumulated evidence suggests that reductions in mortality were only found in studies where haemodynamic goals were targeted using fluid and inotropes, but that may be because none of the intraoperative fluid studies have been powered for mortality. What the intraoperative studies have shown is that targeted fluid administration results in a decreased length of hospital stay because of a reduction in postoperative complications, such as infection.

The recognition of hypovolaemia and oxygen flux derangement, and the prompt restoration of homeostasis, need to be monitored, as the potential to cause harm from inappropriate therapy has been clearly demonstrated in various studies.³ The more accurate and better focused the monitoring, the more able we are to target our interventions and assess their effects. The majority of clinical trials have used oesophageal Doppler intraoperatively to assess protocol-led interventions in an attempt to maximise flow-related haemodynamic variables.⁴ The evidence is clear: intraoperative management using additional haemodynamic parameters such as fluid responsiveness, cardiac output and stroke volume does produce additional clinical benefits.

What is surprising is the slow adoption of theatre-based goal-directed therapy. There may be a number of potential

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Table 1. Proposed characteristics of a theatre based haemodynamic monitor

| Displayed parameter | Graphical user interface |
|---|---|
| <i>Haemodynamic parameters</i> | |
| Arterial pressures MAP, systolic & diastolic Heart rate Stroke volume | <ul style="list-style-type: none"> • Shown in a way that indicates change/physiological stress • Heads-up view of pressures, HR & SV • Acute change & trend display shown • Short term, 2 minute, window display • Longer term, auto-scaling, trends |
| Factors influencing stroke volume | |
| Changes in parameters displayed should indicate the net balance of fluids, contractility and after load | |
| <i>Preload</i> Prediction of response to fluid PPV% and SVV% | <ul style="list-style-type: none"> • Fluid intervention event marker • Simple colour-coded display of responsive/nonresponsive zone • Signal quality indicator and warning of arrhythmias • Trend of parameter |
| <i>Contractility</i> | <ul style="list-style-type: none"> • Response window $\Delta\%$ change shown in SV • Trend indicates fluid responsiveness & potentially Starling curve changes • Trend display of SVR |
| <i>Afterload</i> | |



Table 2. Review of studies comparing PulseCO to other validated cardiac output measurements

| Study and control | No. of patients | No. observations | Differences to control technique | | | Limits of agreement | |
|--|-----------------|------------------|----------------------------------|-----------------|------------------------------|---------------------|--------------|
| | | | Bias L/min | Precision L/min | 95% c.i. L/min (%) | Lower L/min | Upper L/min |
| 1. Wilde <i>et al.</i> , 2007 ¹⁷ (a) COtd, intra op cardiac (b) Literature survey of PulseCO published data | 27 88 | 199 301 | -0.17 -0.02 | 0.69 0.65 | 1.38 (28.6%) 1.3 (25.7%) | -1.55 -1.28 | 1.20 1.32 |
| 2. Missant <i>et al.</i> , 2007 ²³ COtd intra op. off-pump | 20 | 149 | -0.03 | 0.65 | 1.3 (29%) | -1.33 | 1.26 |
| 3. Costa <i>et al.</i> , 2007 ²⁴ COtd – post op 48 hrs hyperdynamic liver transplant | 23 | 151 | 0.29 | 1.09 | 2.17 (16.8%) | -1.87 | 2.46 |
| 4. Kim <i>et al.</i> , 2006 ²⁵ COtd in children *Note results CI not CO | 20 | 73 | 0.19* | 0.14* | 0.28* (8.5%) | -0.09* | 0.47* |
| 5. Smith <i>et al.</i> , 2005 ²⁶ (a) Lithium dilution comp. MICU (24hr) (b) PiCCO vs. PulseCO 24 hourly comparisons | 12 12 | 69 276 | -0.01 0.06 | 0.67 0.79 | 1.33 (22.9%) 1.57 (26.9%) | -1.34 -1.63 | 1.32 1.51 |
| 6. Pittman <i>et al.</i> , 2005 ²⁰ Lithium dilution comp. ICU 24 hrs post surg | 21 | 83 | -0.01 | 0.82 | 1.64 (27%) | -1.65 | 1.63 |
| (7) Hamilton <i>et al.</i> , 2002 ²⁷ Post cardiac surg. (8hrs) | 20 | 80 | 0.1 | 0.6 | 1.2 (21.8%) | -1.1 | 1.3 |

Data are from studies that have used Bland & Altman²⁸ analysis. The agreement between PulseCO/pulse power and the control indicator dilution measurement of cardiac output is computed as the bias (difference between mean cardiac output), precision (SD of differences between PulseCO measurements and mean of the two measurements), with limits of agreement computed as bias + 2 SD.

reasons, but the ease of use and other perioperative limitations of the current haemodynamic monitoring technology must be contributory. A consensus approach to allow a more widespread adoption of this approach might include the design of a haemodynamic monitor specifically for the theatre management. A technology is required that has ease of use and intuition as principal ideals and that can both derive and present the necessary parameters in a simple, informative and easily interpretable way.

This rationale has led to the analysis of the limitations of existing haemodynamic monitors and the evolution of a new monitor and graphical user interface (the LiDCO*rapid*), which has been specifically designed to facilitate the haemodynamic optimisation of the surgical patient.

LIMITATION OF CURRENT TECHNOLOGY FOR INTRA-OPERATIVE USE

Pulmonary artery catheter

The pulmonary artery catheter (PAC) has been available to measure cardiac output for more than three decades and in some institutions is still considered the gold standard.⁵ The PAC, outside the cardiothoracic theatre, has failed to achieve general acceptance as a tool to measure flow intraoperatively. The notoriety associated with the PAC may not always have been deserved,⁶ but some related measurements such as the pulmonary artery occlusion pressure (PAOP) have now also been discredited as a means of evaluating cardiac preload.^{7,8} The perception, aside from issues related to invasiveness and complexity of insertion, is that the user interface is basic and lacks sophistication in relation to data display and interpretation.

Oesophageal Doppler

The oesophageal Doppler measures red cell velocity in the descending thoracic aorta via a mid-oesophageal ‘acoustic window’. The calculation of cardiac output, however, requires the aortic cross-sectional area and an assumption of the ratio of blood flow distribution to the upper and lower body.⁹ These correction factors generate anomalies and inaccuracies when challenged with interventions that affect blood distribution (e.g. epidural anaesthesia or changing PaCO₂/ventilation),^{10,11} or when the patient demographics are out of the range of the algorithm. The poor tolerance of the Doppler probe by awake patients, variable and intermittent flow data requiring probe adjustments and the loss of trace with diathermy interference has decreased Doppler utility in theatre and perhaps limited the acceptance of this method.

Arterial waveform analysis monitors

The PiCCO*plus* monitor estimates cardiac output using a combination of thermodilution and arterial contour waveform analysis. Both the thermal indicator and the pressure waveform have to be measured from a central artery (femoral or axillary). Stroke volume is estimated from the portion of the arterial waveform which corresponds to systole. This pulsatile systolic area is then calibrated using the transpulmonary thermodilution method and is multiplied by the heart rate to give a continuous cardiac output estimate. Additional information about systemic vascular resistance is obtained using the diastolic decay pressure. The contour-based algorithm is dependent upon the shape of the arterial waveform and is therefore sensitive to damping and poor measurement



system dynamics. The algorithm has been extensively studied and appears under stable clinical conditions to be as accurate as thermodilution.¹² However, in clinical circumstances, where the systemic resistance changes by more than 50%, the algorithm's accuracy is significantly affected and needs recalibration. The use of PiCCOplus intraoperatively has been limited by both the need for a femoral or axillary artery catheter and central venous access to allow calibration.

The LiDCOplus uses a 'Pulse Power' algorithm which is morphology independent and with aortic impedance/compliance correction incorporated into the pressure to volume waveform conversion. Autocorrelation is used to derive the pulse power and estimate stroke volume.¹³ Typically the PulseCO algorithm is calibrated using lithium indicator dilution, although any validated cardiac output measurement technique can be used.

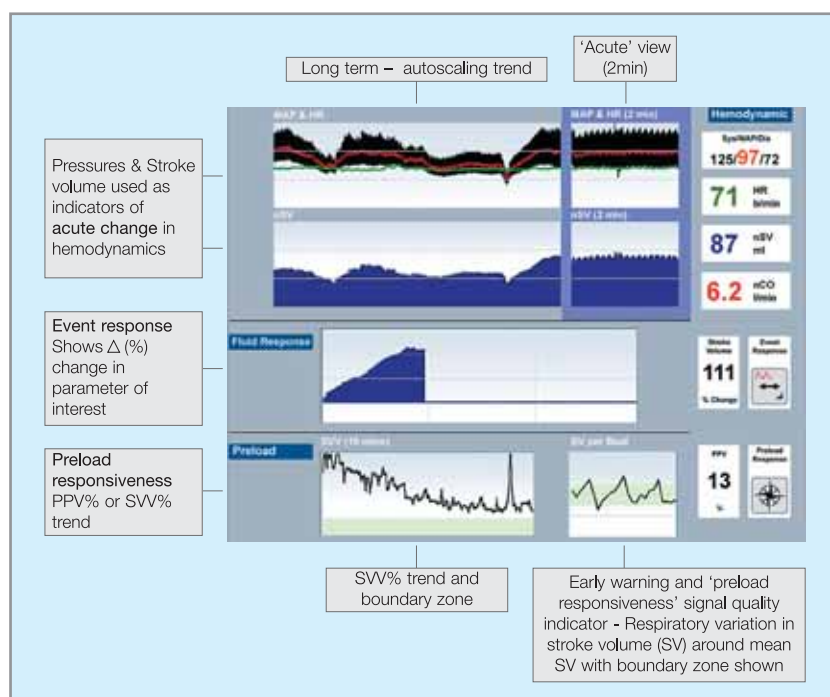
The LiDCOplus was conceived and designed as an intensive care monitor. Its physical size, ICU-focused graphical user interface and the training requirements for the indicator dilution calibration have failed to win it a large number of advocates in the theatre environment.

Vigileo/Flotrac is a recently introduced continuous cardiac output monitor that uses an arterial pressure waveform from a modified pressure transducer to derive cardiac output. This is a pulse pressure algorithm incorporating a correction factor generated by the patient's size, sex and age, subsequently adjusted following a mathematical interpretation of the waveform shape/characteristics over varying time intervals depending on which software is used. Since its introduction, the Vigileo algorithm has undergone several revisions; these complicate review of the clinical trials as the results cannot be compared. Unlike the LiDCOplus or PiCCO systems, no external calibration is possible and more validation is awaited with the most current version of the software.¹⁴ A recent study, however, investigating this software,¹⁵ suggests a tendency to overestimate cardiac output with vasoactive drugs and have a mean bias which increases with increasing pressure.

OPPORTUNITY FOR A NEW MONITOR: LIDCORapid

The apparent reluctance of anaesthetists to adopt existing technologies implies a poor acceptance of the currently available haemodynamic monitoring. It also provides the opportunity to design and develop a theatre-focused fluid and haemodynamic monitor with reference to the limitations discussed. The design team used the LiDCOplus software engine PulseCO as a blueprint for this monitor, as this algorithm has been available and extensively validated over the last seven years. Additionally, unlike the pulse pressure and pulse contour algorithms, it has never been modified and so all published data are valid and attributable. The original design focus included:

- Use of published, validated arterial waveform algorithm from the LiDCOplus
- Ability to track, trend and discriminate flow and resistance changes
- Speedy set-up (in less than a minute) with use of standard arterial cannula (any artery) and transducer kits
- Compliance correction and scaling of stroke volume (SV) and cardiac output (CO) by a nomogram using patient-specific data
- Intuitive, anaesthetically targeted, user interface with trended haemodynamic (BP, HR, and SV), preload



responsiveness parameters (SVV or PPV) and response to intervention (maximisation of flow parameters SV or CO) clearly shown in Figure 1

- Small footprint designed for the theatre environment.

Table 1 summarises the evidence-based characteristics of a monitor designed for use in the perioperative environment.

PulseCO algorithm validation and reliability

The ability of the PulseCO algorithm to trend changes in stroke volume accurately has been validated in a wide number of clinical situations, including general surgical, liver transplantation, cardiac surgery and general intensive care. Table 2 summarises some of the published data currently available. As can be seen, the 95% limits of agreement range between 16.8% and 29% in adults and are 8.5% in children. All these studies support the assertion that this algorithm can accurately estimate changes in stroke volume and cardiac output.¹⁶ The tracking and trending power of the PulseCO algorithm has been studied by comparing changes in cardiac output generated by the algorithm for each CO measurement, compared to changes in CO from an indicator dilution control. This form of analysis, performed by Wilde *et al.*,¹⁷ demonstrated that 88% of all changes in cardiac output of greater than 0.5 l/min were detected by the PulseCO algorithm.

The pulse pressure and pulse contour algorithms are recognised to be adversely affected by vasoactive drugs, especially by those with effects on arterial tone resulting in deteriorating accuracy. In contrast there have been several studies investigating the ability of the pulse power algorithm to follow changes in CO in the face of changing arterial tone. Theoretically, being power-, rather than waveform morphology-based, the algorithm should not be as affected by vascular resistance changes within the physiological range. The accuracy of PulseCO in an equine model was shown not to have been materially affected by changes across a range of CO and SVR of up to 200%.¹⁸ The correlation coefficient (r^2) was 0.93 with limits of agreement equivalent to

Figure 1. Primary User Interface, LiDCORapid Hemodynamic Monitor (LiDCO Ltd).

Table 3. Predictive value of PulseCO derived fluid responsiveness parameters before fluid challenge in responders and in nonresponders (adapted from Belloni *et al.*, 2007)

| Parameter | Responders | Non Responders | P value |
|-----------|---------------|----------------|---------|
| PPV% | 19.93 ± 9.65 | 8.49 ± 4.04 | 0.006 |
| SVV% | 18.61 ± 5.25 | 8.96 ± 4.1 | 0.001 |
| LVEDA | 14.38 ± 4.6 | 17.45 ± 5.23 | NS |
| LVEDV | 56.25 ± 20.95 | 64.97 ± 20.89 | NS |
| CVP | 8.91 ± 2.88 | 10.5 ± 2.78 | NS |
| PCWP | 7.63 ± 3 | 9.26 ± 3.0 | NS |

The differences in mean PPV and SVV between the two groups are statistically significant (probability using the Student *t* test shown). Abbreviations: NS = not significant; LVEDA/P = left ventricular end diastolic area/pressure; CVP = central venous pressure; PCWP = pulmonary capillary wedge pressure.

95% confidence limits of ±20.1%. Yamashita *et al.*¹⁹ recently looked at the effects that resistance changes (vasodilation) have on the ability of the PulseCO algorithm to track flow changes, while administering increasing doses of prostaglandin PGE₁ in 20 patients preceding ‘off-pump’ cardiac surgery. SVR fell by up to 23.5%. The agreement seen between thermodilution and PulseCO was between 8.4% and 26.7% at four different administration levels, all within the 30% limit calculated by Critchley.¹⁶ The accumulated data from these studies suggest that the PulseCO algorithm continues to trend accurately with changes of SVR within the physiological range.

Arterial signal damping and reliability

Pittman *et al.*²⁰ looked at the frequency response of their catheter/transducer systems and demonstrated that, despite the fact that less than 40% were underdamped, the dynamic response characteristics of the arterial pressure measurement system had little effect on the agreement between PulseCO and control dilution measurements. This shows that, although these systems are less than optimal in terms of frequency response, within the boundary conditions of a clinically acceptable pressure waveform, the characteristics of the arterial pressure transducer, and its set-up, do not have a significant effect on the accuracy of PulseCO. This means that, unlike the Vigileo and PiCCO systems, the PulseCO does not need a specialised or ‘hi fidelity’ pressure transducer and manometer system.

PulseCO and the prediction of fluid responsiveness

The use of both CVP and PAOP values as conventional predictors of the effect of intravenous filling and the likely response to volume have been largely discredited.⁷ Newer, dynamic markers of volume responsiveness such as pulse pressure variation (PPV%), and stroke volume variation (SVV%) are proving more useful for determining the appropriate endpoints in fluid resuscitation.⁸ These parameters are derived from the pressure waveform itself and should be useful for predicting preload responsiveness in ventilated surgical patients; the relationship between the two has in addition been suggested to provide an indication of arterial tone. The PPV% and SVV% derived from use of the PulseCO algorithm have been shown (Table 3) to predict fluid responsiveness in mechanically ventilated patients during general anaesthesia, compared to conventional parameters and those derived from transoesophageal echocardiography.²¹

Accuracy, calibration versus nomogram trending

The stroke volume is estimated by the PulseCO algorithm using a signal processing technique (autocorrelation), which generates a power function of a standardised volume waveform itself derived from the arterial pressure waveform. This transformation of the arterial pressure to the ‘standardised’ waveform is made, by application of a generalised equation:

$$\text{Volume} = \text{CF} * 250 * (1 - \exp(-k * P))$$

where CF is the calibration factor, 250 is the nominal volume (nVmax in mls) of the aorta/arterial system, P is pressure (mmHg) and k is an exponential function that relates pressure to volume (compliance).

This equation and the associated factors were derived from an analysis of previously published data that explored the relationship between aortic volume and pressure in explanted human aorta.²²

The inherent accuracy of the LiDCO*plus* is a function of the lithium dilution calibration process, which determines the actual value of the maximum arterial volume or Vmax for that particular patient. The Vmax has been found to vary by up to 400% between adult patients and appears to be determined by a number of factors such as age, sex, size and underlying clinical pathology.

Once the actual volume has been established, the nominal volume for Vmax (250 ml in the standard equation) can then be scaled up or down specific to that individual. The Vmax volume is unlikely to change over the short term and this absence of variation in Vmax means that trends in stroke volume can be estimated correctly by the PulseCO software, regardless of whether a nominal or estimated value for Vmax is used. This also applies to the calculation of SVV and PPV.

The new monitor (LiDCO*rapid*) uses a nomogram which creates an estimate for Vmax that is used to scale the PulseCO algorithm to give an improved estimate of stroke volume. Validation of this algorithm has been undertaken in both medical and surgical ICU patients, where comparisons were made between Vmax generated with no calibration (nominal Vmax = 250 ml), with calibration and finally using the nomogram. The nominal and the nomogram values of Vmax were then compared to the calibrated Vmax. The nomogram Vmax reduced the variation from 34% (median, 11–93% IQR) to 16% (9–39%) when compared to the nominal value.

The LiDCO*rapid* monitor was designed to be simple, with set-up time in minutes and have the ability to target continuously the variables shown by the literature to reduce length of stay. The use of a nomogram is not intended to replace calibration for critically ill patients, for the reasons discussed above. In these patients, especially if using oxygen delivery as a target, accuracy is important and an exact CO with a known, reliable measurement of cardiac output, is required to scale Vmax.

The LiDCO*rapid* concept represents an approach both to evaluate and to track/drive haemodynamic changes in perioperative surgical patients. The nominal values are considered to be of an accuracy suitable for intraoperative goal-directed therapy, but for critical applications where absolute values of SV and SVR are required, Vmax has to be calculated through a calibration process. The development group recognised the importance of having this ability to scale actual values from nominal values and so the LiDCO*rapid*



has a facility to enter an actual accurate value of CO via the user interface using any technique.

CONCLUSION

The PulseCO algorithm has been designed and validated to provide a consistent trend of stroke volume and preload responsiveness variables. Absolute scaling of the PulseCO-derived stroke volume is not necessary in order to provide reliable trends that can be used to optimise stroke volume or cardiac output or to predict fluid responsiveness. The use of a nomogram-based scaling factor will reduce the bias between the nominal and true stroke volume or cardiac output.

Perioperative monitoring of BP, SV, PPV/SVV and CO allows individualised interventions to maximise flow-related haemodynamic variables. Surgical patients treated in this way have reduced hospital stay and complication rates.⁴

Existing haemodynamic monitors are underutilised perioperatively to implement such care. The LiDCO*rapid* uses an established, clinically validated algorithm to derive PPV and SVV, and to trend changes in SV. Trending of these haemodynamic variables remains accurate during significant changes in CO and SVR and in the presence of moderate arterial line damping. The LiDCO*rapid* combines ease of use and simple 'head-up' data display to integrate into the perioperative environment. The novel display and user interface were carefully considered by the design group with a key objective of intuition using a data display with more graphics and fewer numerics.

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M Jonas is a clinical adviser to LiDCO Ltd, and has received consulting fees from the company. He was part of the LiDCO multidisciplinary design team that developed the LiDCO*rapid* Monitor, which also included Dr T O'Brien, J Barry, A Thomas, E Mills and J Douglas. LiDCO holds and has applied for patents relating to the LiDCO*rapid* Monitor. The authors acknowledge that some help was given by the company in the preparation of this manuscript. A full description (White Paper) of the design brief, software clinical validation review, indications for use/warnings/contraindications and product regulatory status is available from the company.

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Introducing the **NEW**

LIDCO *Rapid*

Fluid and patient management made easier with the *LIDCOrapid* Monitor

- The *LIDCOrapid* monitor is designed to be quick to set-up, simple to interpret and a cost effective way of managing the hemodynamics of surgical or any hemodynamically unstable patient requiring fluid and drug support.
- The product's continuously available, beat-to-beat hemodynamic data can facilitate the implementation of enhanced fluid and drug based surgical optimization programs in patients undergoing moderate and high-risk surgical procedures.
- This form of advanced care has been previously demonstrated to reduce complications and hospital length of stay.¹

The *LIDCOrapid* displays the following parameters:

- Pressures – MAP, Systolic and Diastolic
- Heart Rate
- Stroke Volume and Cardiac Output (Nominal or Actual)
- Dynamic Preload parameters – Pulse Pressure Variation (PPV) and Stroke Volume Variation (SVV)²
- User selected event response window

¹ Rupert Pearse, Deborah Dawson, Jayne Fawcett, Andrew Rhodes, R Michael Grounds and E David Bennett (2005) Early goal-directed therapy after major surgery reduces complications and duration of hospital stay. A randomised, controlled trial. [ISRCTN38797445]. *Critical Care* 2005, 9:R687-R693 (DOI 10.1186/cc3887).

² Belloni et al (2007) Assessment of fluid responsiveness parameters for off pump coronary artery bypass surgery: A comparison among LIDCO, Transesophageal Echocardiography and Pulmonary Artery Catheter. *Journal of Cardiothoracic and Vascular Anesthesia* 2007 [Epub ahead of print] (DOI 10.1053/j.jvca.2007.07.007).

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