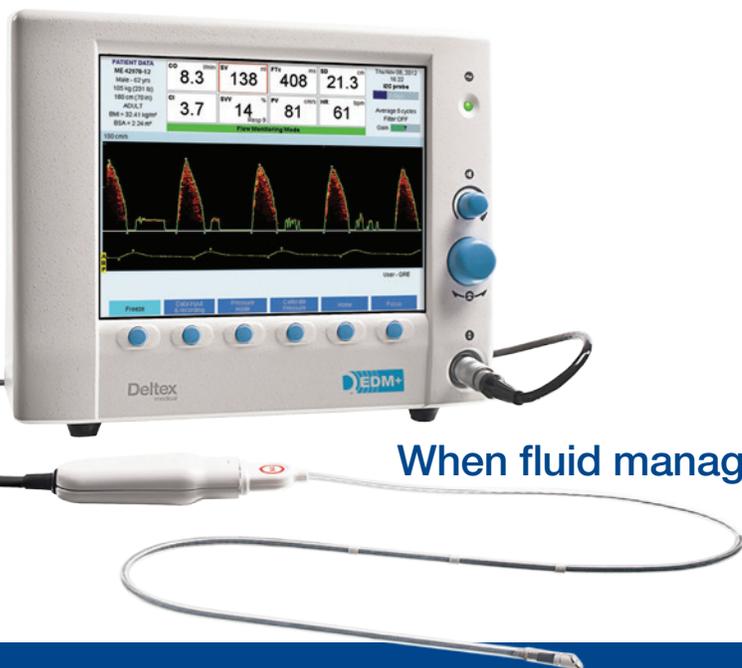
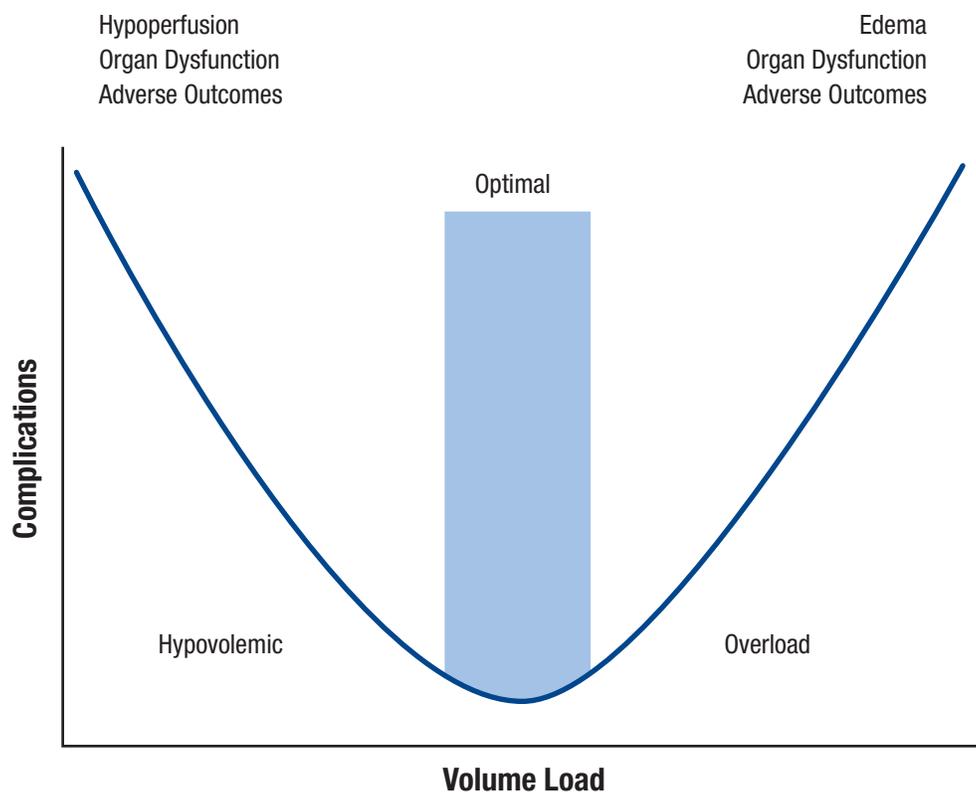


Reducing Variation in Perioperative
Fluid Utilization Results in Improved
Surgical Outcomes

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A Quality Improvement and Cost Savings Initiative for Hospitals, Surgeons and Anesthesiologists



When fluid management really matters



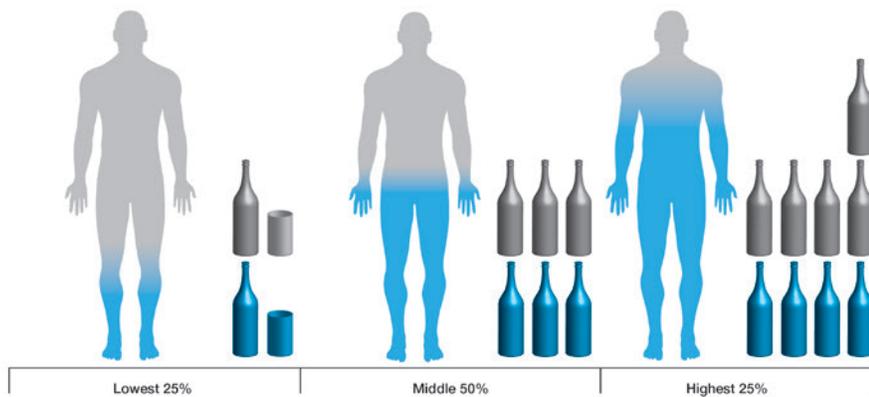
Wide Variation In Perioperative Fluid Administration

Research published in *Annals of Surgery*, 2015 titled “Perioperative Fluid Utilization Variability and Association with Outcomes: Consideration for Enhanced Recovery Efforts in Sample US Surgical Population” showed a wide variation in both intraoperative and postoperative fluid utilization. This was based on a retrospective, observational analysis of the Premier Research Services database of 655,000 patients in 524 hospitals from January 2008-June 2012 for colon, rectal, hip, and knee replacement.

Key finding 1

There is wide variation in fluid practice between individual practitioners

Fluid Utilization on Day of Surgery (mls)



The 25% of patients who received the most fluids on day of surgery were administered **THREE TIMES** or more fluid in both primary orthopedic and colonic surgery than those 25% receiving the least amounts of fluid.

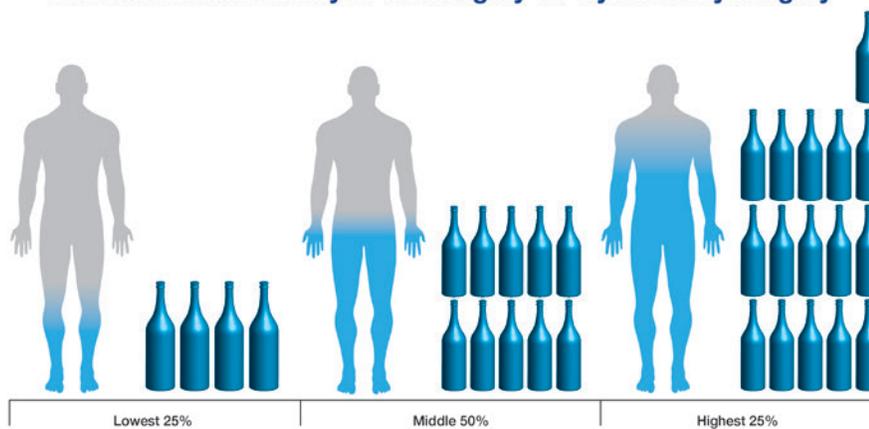
These data were consistent with a recent study looking at more granular level practice in two US academic medical centers, which found “a large patient-to-patient variability in fluid administration practices between and within anesthesia providers and surgical procedures” [Lilot, 2014].



Key finding 2

There is wide variation in fluid practice after surgery

Fluid Utilization on Days Post Surgery for Cystectomy Surgery



The 25% of patients who received the most fluids following surgery, were administered **FOUR TIMES** or more fluid in both rectal and cystectomy surgery than the 25% receiving the least amounts of fluid.

These data were consistent with the variation apparent in recent IRB approved perioperative fluid management trials: “Recommended control group baseline fluid regimens in recent prominent trials have ranged from dextrose water 5% (1ml kg⁻¹ h⁻¹) to isotonic crystalloid (10ml kg⁻¹ h⁻¹)” [Minto, 2015]. In the latter study the actual median amount of such fluid administered was nearly doubled at 17ml per kg per hour, over **FIFTEEN TIMES MORE** than many experts consider best practice.

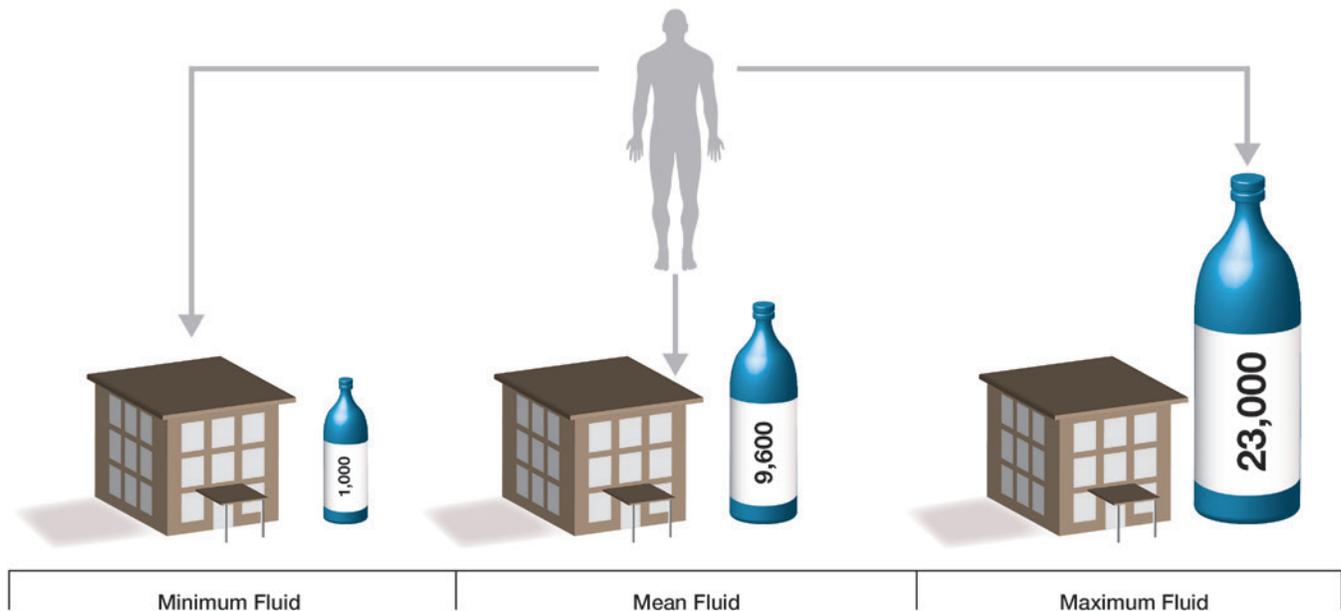
* Mythen, M, UKTI Presentation: Enhanced Recovery & Surgical Culture: Lessons Learned in the UK & BC, Vancouver, Canada, 7th May 2013

Similar trends were seen after rectal surgery, with the lowest quartile receiving 3100mls, the median 7070mls and the highest quartile receiving 12250mls.

Key finding 3

There is wide variation in fluid practice between institutions

Fluid Utilization on Days Post Surgery for Rectal and Cystectomy Surgery (mls)*



* Thacker, J & Mythen, M, Webinar: Variability in Perioperative Fluid Delivery, 2015

OVER TWENTYFOLD variation exists in the median amount of perioperative fluid given to patients undergoing colonic surgery between the most restrictive and the most liberal hospitals.

Even excluding the outliers, hospitals in the upper quartile still routinely administer **TWICE** as much perioperative fluid as those in the lower quartile

Variation in Fluid Management Increases Risk of Complications, Length of Stay & Cost

The correlation of amount of fluid given to cost, length of stay and postoperative ileus (POI) is remarkable, in every instance both the low and high quartiles of fluid had worse outcomes. In colon surgery:

Low fluid volume (Q1) was associated with;

- **12%** greater odds (OR 1.12, 95% CI 1.06-1.18) of having postoperative ileus (POI)
- **9%** greater odds (OR 1.09, 95% CI 1.04-1.14) of prolonged LOS
- **17%** greater odds (OR 1.17, 95% CI 1.12-1.23) of higher hospitalization costs than moderate fluids (Q2-Q3), when controlling for patient and hospital covariates.

High fluid volume (Q4) was associated with;

- **10%** greater odds (OR 1.10, 95% CI 1.05-1.16) of having postoperative ileus (POI)
- **25%** greater odds (OR 1.25, 95% CI 1.20-1.31) of prolonged LOS
- **30%** greater odds (OR 1.30, 95% CI 1.24-1.36) of higher hospitalization costs than moderate fluids (Q2-Q3), when controlling for patient and hospital covariates.

Variation in Fluid Management Increases Risk in Laparoscopic Surgery

There were no statistically significant differences in LOS, costs or postoperative ileus, between open and laparoscopic surgery. In colon surgery:

Low fluid volume (Q1) in laparoscopic surgery, was associated with:

- **12%** greater odds (OR 1.12, 95% CI 1.02-1.23) of having postoperative ileus (POI)
- **9%** greater odds (OR 1.09, 95% CI 0.9999-1.20) of prolonged LOS
- **23%** greater odds (OR 1.23, 95% CI 1.13-1.33) of higher hospitalization costs than moderate fluids (Q2-3).

In each type of surgery reviewed, colon, rectal and hip/knee, the low and the high quartiles resulted in increased postoperative ileus, one type of postoperative complication associated with poor outcome. The impact on hip/knee, was marked and the opportunity for improvement is significant given the number of surgeries performed.

In each type of surgery reviewed, colon, rectal and hip/knee, the low and the high quartiles resulted in increased length of stay. Interestingly, the impact on hip/knee for fluid restriction is greater and though the high is not as severe, opportunity for improvement is significant given the number of surgeries performed.

High fluid volume (Q4) in laparoscopic surgery, was associated with:

- **8%** greater odds (OR 1.08, 95% CI 0.99-1.18) of having postoperative ileus (POI)
- **23%** greater odds (OR 1.23, 95% CI 1.12-1.35) of prolonged LOS
- **19%** greater odds (OR 1.19, 95% CI 1.10-1.30) of higher hospitalization costs than moderate fluids (Q2-3).

Finally in each type of surgery reviewed, colon, rectal and hip/knee, the low and the high quartiles resulted in increased cost. Although the relative impact on hip/knee is not as severe, opportunity for improvement is significant given the number of surgeries performed.

The data is clear. Reduction of variance in fluid given will result in:

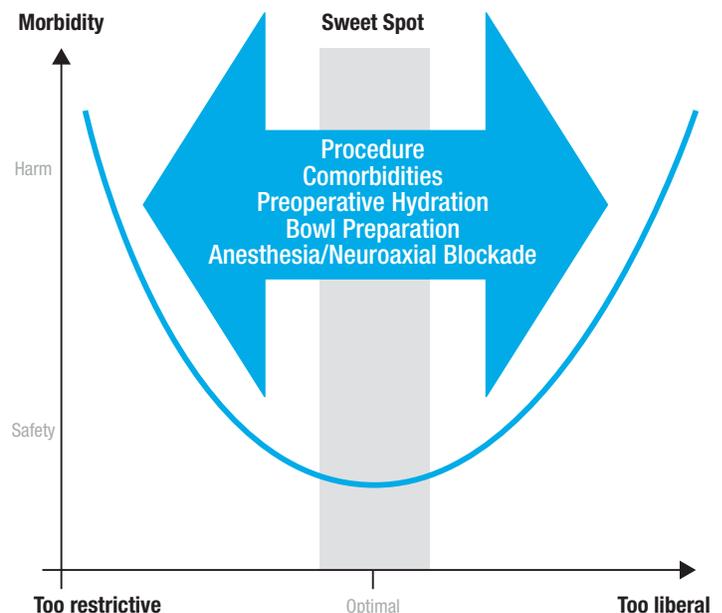
- Reduction of postoperative ileus
- Reduction of length of stay
- Reduction of total cost

TOO LITTLE FLUID increased risk of:

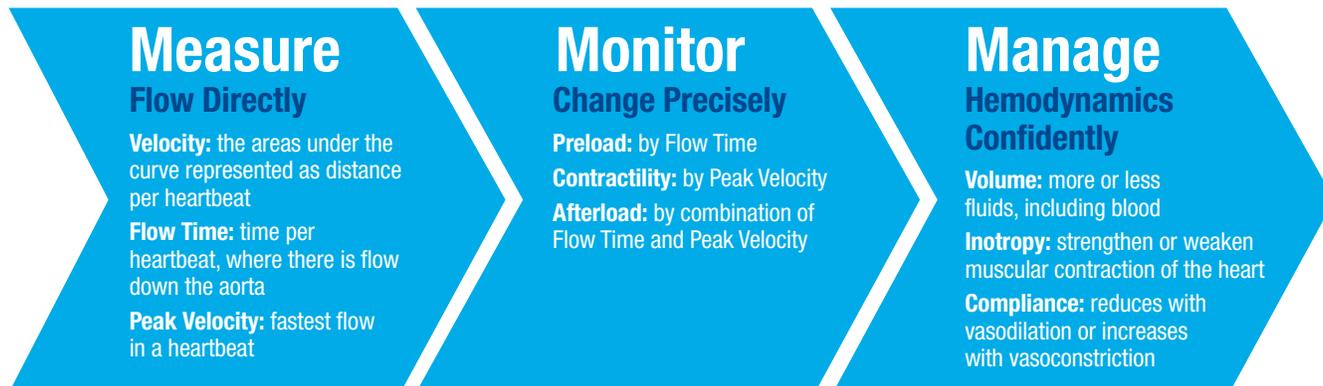
- Organ hypoperfusion
- SIRS
- Sepsis
- Multi organ failure
- Acute kidney injury

TOO MUCH FLUID increased risk of:

- Edema
- Ileus
- PONV
- Pulmonary complications
- Increased cardiac demands



EDM takes a highly precise measure of the velocity of red blood cells travelling down the aorta, 180 times per second. The Doppler Velocity Time Integral (VTI) gives clinicians absolute and relative displays to:

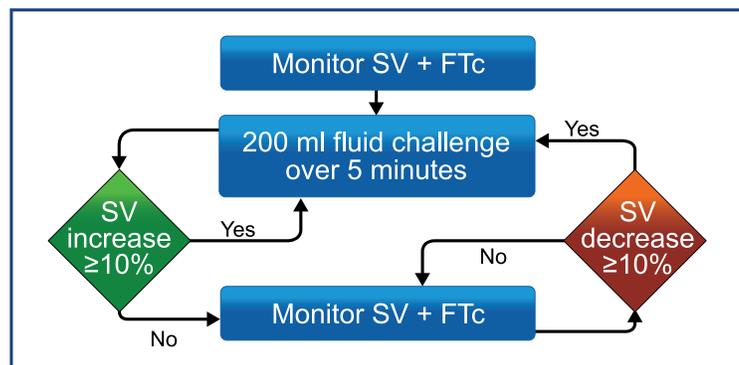


Making the case for precise fluid management

Precise and individualized fluid management are essential to improved outcomes and lower cost. Understanding that both too little and too much fluid exposes patients to harm, choosing a precise and reliable hemodynamic technology that is validated and evidence-based is critical.

The precision of a technology dictates its ability to guide fluid management. The 10% Stroke Volume (SV) change algorithm used to optimize SV is specific to the esophageal Doppler monitor (EDM) and is evidence-based. Other technologies that are less precise may not be as effective in guiding fluid management based on this algorithm.

Professor Singer, lead clinical developer of esophageal Doppler, established that the repeatability error of measuring Stroke Volume was 3.8% with the EDM. The user can be 99% confident that a measured change in Stroke Volume of >10% indicates fluid responsiveness.



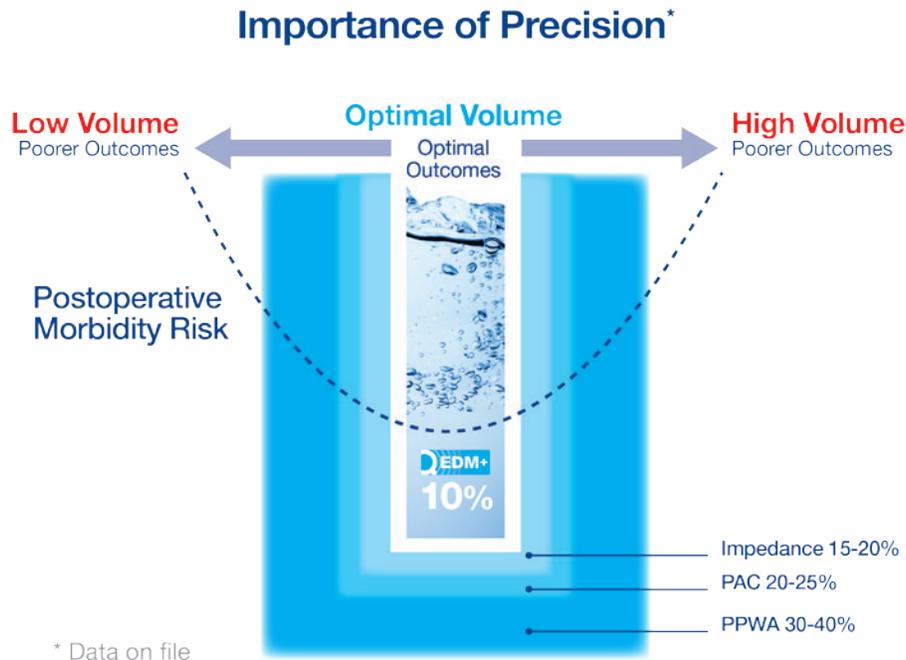
- This 10% change is specific to esophageal Doppler.
- It is based on the probe's precision when measuring central blood flow.
- Other devices may not be effective using this algorithm.

The EDM is a minimally invasive technology using highly precise Doppler ultrasound to measure blood flow directly in the central circulation at the descending aorta.

EDM is the most precise cardiac output monitoring technology available. EDM's high precision enables tighter fluid management through intervention with small doses of fluid against small measured changes in patients. Only EDM has the precision to drive the 10% Stroke Volume (SV) optimization algorithm widely acknowledged as the basis for fluid management protocols.

Precision of EDM explained:

- Error of repeatability of measuring Stroke Volume (SV) with EDM was 3.8%, the most precise in the market
- Only Doppler ultrasound can measure flow velocity directly, this is the basis of the SV precision
- Our confidence is in the measurement of a real hemodynamic change
- The user can be 99% confident that a measured change in SV of >10% indicates fluid responsiveness.



Validation and Evidence

The performance of EDM has been validated both through independently conducted, randomized controlled trials and through audited implementations into routine practice. Based on this evidence, EDM has been recommended by government entities, health payers and technology assessment bodies.

The Agency for Healthcare Research and Quality (AHRQ) published a health technology assessment of EDM in 2007. AHRQ concluded that EDM guided fluid management leads to: 1) Reduction in the rate of major complications, 2) Reduction in the rate of total complications, and 3) a reduction in hospital length of stay (LOS).

The Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Determination for EDM in 2007 covering the procedure “for ventilated patients in the ICU and operative patients with a need for intraoperative fluid optimization”. Based on the AHRQ report and other published evidence, as a result of the coverage policy, CMS also established reimbursement for physicians using EDM.

The UK National Institute for Health and Care Excellence (NICE) published specific guidance on EDM in 2011 that considered both clinical and economic evidence. NICE recommended that “EDM should be considered for use in patients undergoing major or high-risk surgery or other surgical patients for whom a clinician would consider using invasive cardiovascular monitoring” and concluded that “the case for adopting EDM in the NHS,... is supported by the evidence”. As a result of reducing complications and length of stay, NICE estimated savings of £1,100 (\$1,800) per patient.

The evidence and recommendations are unique to Doppler.

No other fluid monitors have this level of evidence for clinical and economic outcomes.

- ✓ Review your patients' outcomes
- ✓ Convene multi-specialty surgical quality improvement team
- ✓ Develop evidence-based fluid protocols
- ✓ Evaluate evidence for fluid technologies
- ✓ Implement program
- ✓ Assess outcomes and compliance to protocols

Deltex Medical is uniquely experienced to help you achieve the outcomes that only EDM Doppler-guided fluid management has been proven to deliver. Please contact us to create a customized education and support program, for your hospital.

The full webinar is available to view from:

http://www.premierpedia.com/multimedia/premierconnect/21696_Recording-6/Recording/lib/playback.html

References:

- Bellamy, MC, Wet, Dry or Something Else? BJA, 2006, 97:755-757
- Thacker, J, Mountford, W, Ernst, F, Krukas, M, Mythen, M, Perioperative Fluid Utilization Variability and Association With Outcomes; Considerations for Enhanced Recovery Efforts in Sample US Surgical Populations, 2015, Annals of Surgery
- Minto, G, Mythen, MG, Perioperative Fluid Management: Science, Art or Random Chaos? British Journal of Anaesthesia, 2015; 114(5): 717-721
- Thacker, J and Mythen, M, Advisor Live: Variability in Perioperative Fluid Delivery - Protocols to Improve outcomes, Premier 2015, http://www.premierpedia.com/multimedia/premierconnect/21696_Recording-6/Recording/lib/playback.html
- Singer, M., Clarke, J., Bennett, E. D., Continuous hemodynamic monitoring by esophageal Doppler. Crit Care Med, 1989. 17(5): p. 447-52.
- Lilot, M, Ehrenfeld, J, Lee, C, Harrington, B, Cannesson, M and Rinehart, J, British Journal of Anaesthesia, 2015 May;114(5):767-76
- Centers for Medicare and Medicaid Services (CMS), 2007, Update to the CY 2013 Medicare Physician Fee Schedule Database, <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8169.pdf>
- Agency for Healthcare Research and Quality (AHRQ), 2007, Esophageal Doppler Ultrasound-Based Cardiac Output Monitoring for Real-Time Therapeutic Management of Hospitalized Patients <https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id45TA.pdf>
- National Institute for Health and Care Excellence (NICE), 2011, Medical Technology Guidance [MTG3] <https://www.nice.org.uk/guidance/mtg3>

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