

Navigating Haemodynamics see your way to safety

Effect of goal-directed haemodynamic therapy on postoperative complications in low-moderate risk surgical patients: a multicentre randomised controlled trial” (FEDORA Trial)

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Clinical Application

The aim of this study was to determine the percentage of postoperative complications occurring in patients undergoing low to moderate risk elective surgery, when the oesophageal Doppler monitor (ODM+) was used to guide therapy compared to standard care. The primary endpoint was moderate or severe complications within 180 days of surgery and secondary endpoints included length of hospital stay, length of intensive care stay and 180-day mortality.

Protocol Outline

FEDORA included 420 low-moderate risk adult patients scheduled for major elective abdominal surgery at five university hospitals in Spain. Patients were randomised to the goal-directed haemodynamic therapy (GDHT) group or the control group. For patients in the GDHT group, anaesthetists used the ODM system to guide administration of fluids, inotropes and vasopressors by monitoring stroke volume, mean arterial pressure and cardiac index. During the 180 days post-surgery, researchers measured the percentage of patients who developed moderate or severe post-operative complications in both the GDHT and control groups.

Results

Patients in the GDHT group experienced 75% fewer complications. There were statistically significant reductions of between 75% and 100% in specific major complications including acute kidney injury (AKI), acute pulmonary oedema, respiratory distress syndrome, pneumonia, and superficial or deep surgical site infection. The number of patients suffering at least one post-operative complication was halved and hospital length of stay for patients in the GDHT group was an average of two days shorter than the control group.

Commentary

This RCT highlights a number of important points:

- Largest positive RCT published on haemodynamic management of patient's during surgery
- First RCT published on low-moderate surgical risk patients
- 420 patients having abdominal surgery, mainly colorectal but also includes gynaecological and urological patients
- 50% of patients laparoscopically
- Post-op complications reduced by 75%
- Significant reductions in specific major complications including AKI, acute pulmonary oedema, respiratory distress syndrome, pneumonia, and superficial or deep SSI's
- 2 days median shorter length of stay (5 vs 7)

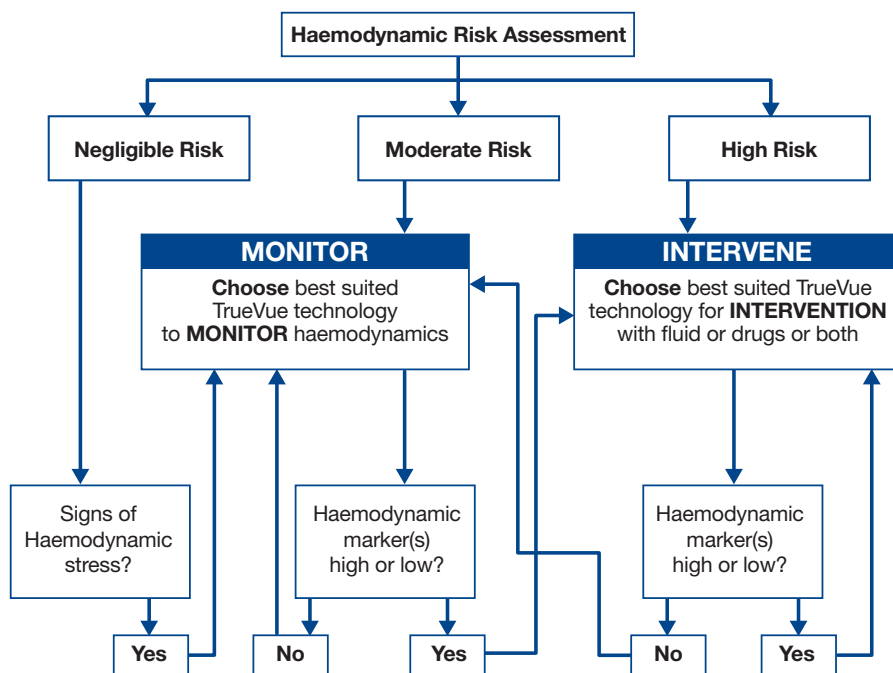
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Cleveland Clinic Researchers (Clinical Anesthesiology 2016)

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