Standard Operating Procedure
Management of Control Group Patients

Authors: FLO-ELA Trial Management Group
Authorisation: Mark Edwards (Chief Investigator)

Scope

- To provide guidance on management of patients who have been allocated to the control group in the FLO-ELA Trial.

Procedure

- Following induction of anaesthesia, patients allocated to the control group will be managed by the clinical staff according to usual practice at their sites.

Monitoring

- Patients should not be randomised if the clinician intends to use cardiac output monitoring regardless of study group allocation; this is considered 'clinician refusal' and is a specific exclusion criteria. The use of **any** form of cardiac output monitoring technology in a control group patient – whether based on oesophageal Doppler, arterial waveform analysis (including anaesthetic monitor modules displaying stroke volume variation / pulse pressure variation / systolic pressure variation), bioimpedance or other discrete technology – is a protocol deviation. However, clinical staff are able to request cardiac output monitoring if this is required to inform the treatment of a patient who becomes critically ill (e.g. because of severe haemorrhage); in this situation a protocol deviation form will be completed.
- If a specific haemodynamic end-point for fluid challenges is to be used, the most appropriate would usually be a sustained rise in central venous pressure of at least 2 mmHg for 20 minutes or more.

General haemodynamic measures

Care for all patients has been loosely defined to avoid extremes of clinical practice but also practice misalignment, as follows:

- Patients will receive one of the following fluids at 1 ml/kg/hr as maintenance fluid:
    - 5% dextrose
    - 4% dextrose with 0.18% NaCl (+/- KCl)
    - 5% dextrose with 0.45% NaCl (+/- KCl)

It is recommended that this maintenance fluid is delivered at a fixed rate using an infusion device. Routine maintenance requirements should be satisfied in line with NICE guidance (20-30ml/kg/day of water, approximately 1mmol/kg/day of potassium, sodium and chloride and 50-100g/day of

glucose). In certain clinical scenarios such as electrolyte imbalance, an alternative fluid may be selected at the clinician's discretion. In obesity, the maintenance fluid rate should be adjusted to the ideal body weight, available within the NELA webtool (1).

- Additional fluid will be administered at the discretion of the clinician, guided by the pulse rate, arterial pressure, urine output, core-peripheral temperature gradient, serum lactate and base deficit/excess.

- For fluid challenges, 250ml of one of the following solutions should be used:
    - "Balanced" crystalloid: Hartmann's solution (compound sodium lactate, Ringer's lactate), Plasmalyte 147.
    - 0.9% sodium chloride
    - Gelatin-based colloid
    - Albumin

- Blood will be transfused at clinicians' discretion but should maintain haemoglobin at greater than 8 g/dl.

- Oxygen will be administered to achieve a target $Sp0_2$ of ≥94%.

- Core temperature will be maintained between 36.5°C and 37.5°C.

- Mean arterial pressure will be maintained between 60 and 100 mmHg using an alpha adrenoceptor agonist or vasodilator as required, although other measures such as adjustments to anaesthesia and analgesia should be considered first.

Post-operative analgesia

- Post-operative analgesia will be provided at the discretion of the clinician in accordance with local protocols.

Other aspects of care

- All other aspects of care should be in line with local protocols and recommendations on the care of emergency laparotomy patients by the National Emergency Laparotomy Audit (2).

References

1. NICE. Intravenous fluid therapy in adults in hospital (Clinical Guidance 174). 2014. Available from: http://www.nice.org.uk/

2. NELA project team. The Second Patient Report of the National Emergency Laparotomy Audit. 2016. Available from: http://nela.org.uk/reports