Evaluation of the Stress Response in Bariatric Surgery With and Without the Use of Opioids

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Study protocol

Objective

Opioid Free Anaesthesia (OFA) has attracted the attention of clinicians since the outbreak of the opioid pandemic in the USA. It has been correlated with less intraoperative and postoperative opioid use. The Nociceptive Level Index algorithm allows for the intraoperative monitoring of the nociceptive pathways and targeted pain management. Furthermore, it is known that morbidly obese patients may be benefit from opioid sparing. Our objective is to investigate whether the implementation of an OFA intraoperative strategy affects postoperative pain scores in morbidly obese patients undergoing laparoscopic sleeve gastrectomy.

Design

This is a randomized, double blind, clinical trial. Participants are allocated using electronic software to be managed with either OFA or Opioid Based Anesthesia. Seventy adult patients (18-75 years old, ASA II-III) scheduled for elective laparoscopic sleeve gastrectomy will be recruited. Informed consent will be obtained by all patients. Exclusion criteria re preoperative bradycardia, bundle branch block, QTcF>470msec, Stop-BANG score >5, history of depression, chronic corticosteroid use or intraoperative administration of more than 8mg of prednisolone or equivalent. Patients will known bone marrow dysfunction will be also excluded.

Methods

All patients will be managed by the same surgical team and the same anesthesiologist. The anesthesiologist will be masked for the infusion given. Similar preparations will be prepared by an experience anesthetic nurse. The surgeon and the outcomes assessor will be blinded as to the intervention.

Group OFA

This arm will receive:

- 40mg magnesium sulfate in 100 ml N/S infusion
- 0.4 mcg/kg, max total dose 50mcg in 50 ml N/S infusion
- 0.3 mg/kg ketamine in 10 ml volume
- 0.2 ml/kg of the Multimix regimen in 100 ml N/S infusion The Multimix regimen consists of 50mcg dexmedetomidine, 500 mg lidocaine and 50mg ketamine.

Group OBA

This arm will receive:

- 2mcg/kg fentanyl in 10 ml volume
- 0.2 mL/kg/h remifentanil infusion
- 0.1 mg/kg morphine

Except for standard analgesic strategies, both groups will receive fentanyl as a rescue dose (1mcg/kg) based on a NOL value > 25 or elevation of Heart Rate and/or Blood Pressure >20%.

Statistical Analysis Plan

The SPSS v.26.0 software (SPSS, Inc., Chicago, Ill, USA) will be employed. The significance level is set at $p \leq 0.05$. Normality tests will be performed and data will be subsequently managed as appropriate. Independent samples T-test and/or independent samples Mann-Whitney test will be performed for group comparisons. The Fisher's Exact test and x^2 test will be used for comparisons of groups relative to qualitative variables. Data for biological markers will be explored within General Linear Models with the ANOVA method according to the model which involves one factor between patients (factor "Group" with two levels) and one factor within patients (factor "Time" with appropriate levels, with repeated measures).