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The effect of opioid-free anesthesia protocol on the early quality of recovery after major surgery (SOFA trial): A randomized clinical trial

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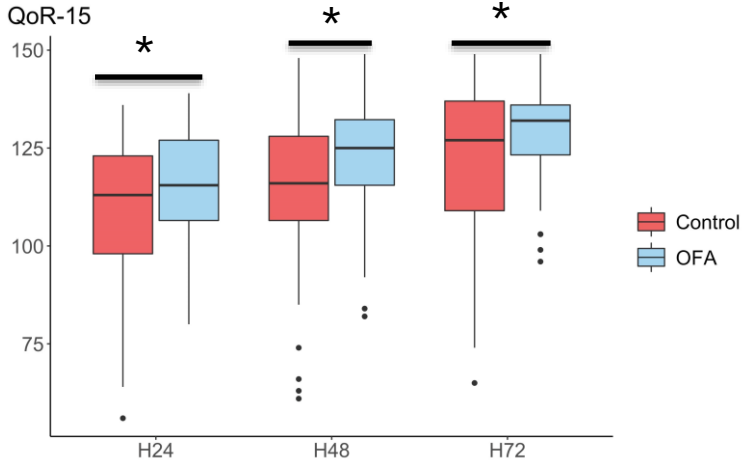
Background: Opioid-free anesthesia (OFA) is gaining popularity in reducing opioid consumption. Its impact on early postoperative recovery after major surgery has not been evaluated in comparative trials. The aim was to evaluate the early quality of recovery (QoR) of patients undergoing a major scheduled surgery under general anesthesia using an OFA protocol compared with standard anesthesia.

Methods: The SOFA study was a monocentric, randomized, controlled, double-blind clinical trial from July 10, 2021, to February 12, 2022. The eligible population was male and female patients operated for a scheduled major surgery without bone procedure, usually requiring opioids for postoperative pain management. Patients in the intervention group received a combination of at least two drugs among ketamine, lidocaine, clonidine, and magnesium sulfate, without opioids for anesthesia, while patients in the standard group received opioids. The primary outcome was early postoperative QoR, assessed by QoR-15 score at 24 hours (H24) after surgery. Secondary outcomes were QoR-15 at 48 hours (H48) and 72 hours (H72) after surgery, chronic pain incidence, and quality of life at three months.

Results: Among the 136 randomized patients, 135 were included in the primary analysis (mean age, 45.9±15.7 years; 116 females (87.2%); 85 underwent major plastic surgery (63.9%)), with 67 patients in the OFA group and 68 in the standard group. The mean QoR-15 at H24 was 114.9 in the OFA group versus 108.7 in the standard group (difference of 6.2, 95% CI, 0.4–12.0; ***p=0.026***). QoR-15 scores were also significantly different at H48 (difference of 8.7, CI 95% 2.9–14.5); ***p=0.004***) and at H72 (difference of 7.3, CI 95% 1.6–13.0, ***p=0.013***). There was no difference in other secondary outcomes. No major adverse event was noticed.



*Distribution of QoR-15 according the allocation group at 24 hours, 48 hours and 72 hours after surgery. The box plots display the median value of total QoR-15 score . *****: achieved statistical significance*

Conclusion:
OFA protocol improved the early quality of recovery after major elective surgery compared with the standard anesthesia protocol.