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

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Position du problème et objectif(s) de l'étude:

The impact of Opioid-Free Anesthesia on early postoperative recovery after major surgery is uncertain. We aimed to compare Opioid-Free Anesthesia protocol versus standard anesthesia protocol on early Quality of Recovery (QoR)

Matériel et méthodes:

We performed a prospective randomized, controlled, single-blinded clinical trial (SOFA trial). The trial was conducted in the Angers University Hospital, in five surgery wards. Inclusion criteria were patients undergoing scheduled major elective surgery without bone procedure and requiring opioids during postoperative stay. The study group (n=67) received a combination of ketamine, lidocaine, clonidine, and magnesium sulfate, while the standard group (n=68) was based on opioids. The primary outcome was early postoperative QoR, assessed by QoR-15 score at 24 hours (H24) after surgery. The secondary outcomes were QoR-15 at 48 hours (H48) and 72 hours (H72) after the surgery, chronic pain incidence and quality of life at three months using the Brief Pain Inventory and EQ-5D-3L, respectively.

Résultats & Discussion:

Between July 10, 2021, and February 12, 2022, we randomized 136 patients with follow-up data through June 22, 2022. Among the 136 randomized patients, 135 were included in the primary analysis (mean age, 45.9 years; 116 women (87.2%); 85 undergoing major plastic surgery (63.9%)) and 133 completed the trial up to 3 months. Anesthesia protocols were respected for 84.6% of patients in the OFA group and 83.8% in the control group. The QoR-15 at H24 was 114.9 in the study group versus 108.7 in the standard group (difference of 6.2 [95% CI, 0.4–12.0]; p=.026). The comparisons of QoR-15 at H48 and H72 reached the significance: 123.0 in the study group versus 114.3 at H48 (difference of 8.7 [95% CI 2.9–14.5]; p=.004) and 129.2 in the study group versus 121.9 at H72 (difference of 7.3 [95% CI 1.6–13.0]; p=.013). There was no difference in chronic pain incidence or quality of life at three months. For both groups, no major event was noticed.

Conclusion:

For major elective surgeries, the OFA protocol improved the early quality of recovery, reaching clinical relevance with a safety profile.

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