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ORIGINAL RESEARCH

The effect of oxycodone *vs.* sufentanil on postoperative delirium in elderly patients undergoing major abdominal surgery: a randomized trial

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Abstract

Background: Postoperative delirium (POD) is a neurological disorder that frequently affects elderly patients undergoing major abdominal surgery. Existing research indicates that perioperative administration of oxycodone may enhance postoperative cognitive function. This study was conducted to examine the impact of preemptive analgesia with oxycodone on the occurrence of POD in elderly patients undergoing major abdominal surgery. Methods: We randomly assigned 120 patients to receive oxycodone versus sufentanil. Both oxycodone and sufentanil were administered ten minutes before the induction of anesthesia. The primary outcome was the incidence of POD within 7 days post-surgery (or before discharge). Delirium was assessed twice daily using either a Diagnostic Interview for the Confusion Assessment Method or the Confusion Assessment Method for the Intensive Care Unit. Secondary outcomes included postoperative opioid consumption, pain score, patient satisfaction score, and adverse events. **Results**: The final analysis included 112 patients and the incidence of POD was similar between oxycodone and sufentanil(risk ratio, 0.64; 95% confidence interval, 0.28 to 1.45; $p = 0.282$). However, patients treated with oxycodone had lower postoperative opioid consumption, reduced pain scores and postoperative nausea and vomiting. **Conclusions**: Although oxycodone preemptive analgesiadid not reduce the incidence of POD, it demonstrated effective analgesic properties and reduced postoperative adverse events. **Clinical Trial Registration**: The study was registered with the Chinese Clinical Trial Registration Center (ChiCTR2200064308, 02 October 2022).

Keywords

Delirium; Preemptive analgesia; Oxycodone

1. Introduction

Postoperative delirium (POD) is a prevalent neurological complication that affects elderly patients after surgery. Studies have shown that the incidence rate of POD in patients after major surgery is approximately 30% [1, 2]. POD is marked by brief fluctuations in cognition, attention and consciousness, which may occur during the first week after surgery or as soon as the patient is discharged from the hospital. The development of POD is associated with multiple factors during the perioperative period, with poor control of postoperative acute pain being a significant contributor [3]. As a primary treatment approach in clinical practice, opioid drugs are widely utilized to manage acute pain after major abdominal surgery (MAS) [4]. However, traditional opioid drugs are often accompanied by a range of side effects, including dizziness, sedation, nausea, constipation, vomiting, physical dependence, respiratory depression and tolerance, which still pose challenges for clinical doctors, patients, and their families [5].

Oxycodone, a semi-synthetic μ-receptor opioid, exhibits an additional stimulating effect on the on κ-receptor, which not only provides analgesic effects but also minimizes the incidence of adverse events, making it widely used in postoperative analgesia [6, 7]. A previous study demonstrated that the combination of intercostal nerve block and oxycodone could enhance the postoperative cognitive function in elderly patients undergoing radical resection of lung cancer [8]. Additionally, research by Gan *et al*. [9] demonstrated that using oxycodone for patient-controlled intravenous analgesia in elderly patients following total hip arthroplasty could reduce the incidence of postoperative cognitive dysfunction. Preemptive analgesia (PA) is a type of analgesic intervention administered prior to the onset of harmful stimuli to prevent central sensitization, mitigate incision-related inflammation, and reduce postoperative pain, opioid consumption, and associated side events [10]. Studies have shown that oxycodone provides superior control over visceral pain and lower opioid consumption compared to sufentanil following abdominal surgeries [11, 12]. Poor

pain management and postoperative opioids should still be risk factors for POD [13, 14]. However, there is currently a lack of evidence on the effect of preoperative usage of oxycodone on POD in elderly patients compared to other opioids.

In this study, we aimed to evaluate the efficacy of oxycodone PA compared to sufentanil in managing POD in older adult patients undergoing MAS. To achieve this objective, we conducted a randomized controlled trial (RCT) meticulously designed to assess the potential differences in pain management outcomes among the two analgesic approaches.

2. Materials and methods

2.1 Study design

This double-blind RCT was approved by the Jiaxing University Affiliated Hospital Ethics Committee (LS2022-KY-068, 28 April 2022) and registered with the Chinese Clinical Trial Registration Center (ChiCTR2200064308, 02 October 2022). The implementation of this study is based on the Helsinki Declaration and its amendments, with all patients or authorized individuals signing informed consent prior to enrollment. We reported this study following the Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines [15].

Eligible participants for this study included individuals aged 65 or above, classified according to the American Society of Anesthesiologists (ASA) with physical status levels ranging from I to III, who were scheduled to undergo elective abdominal surgery (including gastrointestinal, pancreas, liver, procedures) under general anesthesia. Exclusion criteria included the following: (1) a history of mental illness and surgery for severe head trauma; (2) a history of sedative-hypnotic drugs use or drug abuse; (3) visual or auditory impairment; (4) patients who cannot cooperate with delirium assessment.

An independent researcher who did not participate in this study prepared a computer-generated non-blocked random sequence in a 1:1 ratio, sealed it in an opaque envelope and numbered in sequence. This researcher kept this envelope until the subjects entered the operating room. At that point, an independent research nurse opened the envelope to obtain grouping information and prepared the study drug (diluted with saline to 5 mL) using identical syringes without participating in patient care or data collection. The group allocation was concealed from all the participating surgeons, anesthesiologists, nursing nurses and investigators.

2.2 Procedures

All patients did not receive preoperative medication. Standard anesthesia care was adopted, which included routine monitoring of the patient's electrocardiogram, blood oxygen saturation, blood pressure and bispectral index (BIS). Ten minutes before anesthesia induction, patients in the oxycodone group (group O) were administered intravenous oxycodone 0.1 mg/kg. In contrast, patients in the sufentanil group (group S) were administered intravenous sufentanil 0.1 μg/kg. The doses of oxycodone and sufentanil were determined based on opioid conversion guidelines and previous study [9, 16]. General anesthesia was then induced with propofol (1.5 mg/kg), sufentanil (0.5 μg/kg) and rocuronium (0.6 mg/kg), followed by tracheal intubation. The anesthesia was sustained using a dosage of 4–6 mg/kg/h of propofol and 0.2–0.6 μg/kg/min of remifentanil to ensure that the BIS index remained within the range of 40–60. During the surgery, rocuronium was administered to maintain the required muscle relaxation. For mechanical ventilation, adjust tidal volume 6–8 mL/kg to sustain the end-expiratory carbon dioxide level at 35–45 mmHg. When the systolic blood pressure is 20% higher or lower than the baseline, intravenous urapidil or ephedrine is administered for treatment. When the heart rate is below 50 beats per minute, administer atropine in a single dose. Administer ondansetron hydrochloride 4 mg 0.5 hours prior to the surgery end to prevent postoperative nausea and vomiting (PONV).

After the surgeries, all patients were transferred to either the post-anesthesia care unit (PACU) or the surgery intensive care unit (SICU) for recuperation. All patients received patient-controlled intravenous analgesia for postoperative pain management, consisting of sufentanil 100 μg and ondansetron hydrochloride 8 mg. The medication was diluted to 100 mL using saline, and a loading dose of 2 mL was administered 5 minutes before the surgery end. The postoperative analgesia was administered with a continuous infusion rate of 2 mL/h, a 2 mL bolus dose, a 20 min lockout interval and a maximum dose of 8 mL/h.

2.3 Outcomes measures

The primary outcome was POD incidence within 7 days post-surgery (or before discharge). The POD assessment was performed twice daily using the confusion assessment method (CAM) or CAM for the ICU (intensive care unit) (CAM-ICU) between 8:00–11:00 and 19:00–23:00 by a trained investigator who was not involved in other processes of this study. Both methods include the following four evaluation indicators: (1) Changes in mental state or fluctuations in consciousness levels during acute attacks; (2) Lack of concentration; (3) Confused thinking; (4) Changes in level of consciousness. If both features 1 and 2 are positive, and at least one of features 3 or 4 is positive, the diagnosis is delirium. Before using CAM or CAM-ICU, patients were initially evaluated using the Richmond Agitation-Sedation Scale (RASS). Further evaluation was performed for patients with RASS >-4. Subtypes of delirium were classified according to RASS score: hyperactive type (RASS >0), hypoactive type (RASS <0) and mixed type. The hypoactive and hyperactive types occur in an alternating pattern.

Second outcomes included postoperative opioid consumption, pain score during the 24-hour postoperative period, patient satisfaction score, complications (including PONV and respiratory failure), and length of hospital stay. Pain score was assessed by a numerical rating scale (NRS) ranged 0 to 10 (0 being painless and 10 being the most intense pain). Patient satisfaction score was assessed by a numerical rating scale ranged 0 to 10 (0 is the least satisfied, 10 is the most satisfied).

2.4 Sample size calculation

Based on our previous study, POD prevalence in older patients undergoing MAS was about 25% [17]. A recent RCT reported an occurrence rate of 34% [18]. As a result, we assumed a

POD incidence of 30% in the sufentanil group. According to a previous study [9], hydrocodone has been shown to reduce the incidence of POD by 20%. Consequently, we determined that a sample size of 114 participants would be sufficient to achieve 80% statistical power in detecting a 10% decrease in POD occurrence, using a 2-sided significance threshold of 0.05. Therefore, we intended to register 120 patients, with 60 assigned to each group. We anticipated a dropout rate of 5%.

2.5 Statistical analysis

The normality of continuous variable distribution was evaluated using the Kolmogorov-Smirnov test. Continuous variables were reported as either the mean (standard deviation (SD)) or the median (interquartile range), depending on their distribution. Categorical data were presented as frequencies and percentages and analyzed using the 2-tailed χ^2, or Fisher exact test, or Mann-Whitney U test. The study reported risk ratios (RR) and difference values with their corresponding 95% confidence intervals (CIs). All statistical tests were conducted using a two-sided approach, and a significance level of $p < 0.05$ was used to determine statistical significance. The statistical analyses were performed through SPSS version 29.0 (IBM, Armonk, NY, USA).

3. Results

3.1 Sample size and groupings

We recruited 223 patients from October 2022 to June 2023 (The first patient was recruited on 17 October 2022). Out of these, 187 patients met the eligibility criteria. Ultimately, 120 participants were randomly assigned to the study (60 in group O and 60 in group S). During the study, 8 patients were excluded for the following reasons: 5 patients withdrew their consent before surgeries; 1 patient refused to cooperate with postoperative evaluation and withdrew from the trials, and surgery was canceled for the other 2 patients. In the end, 112 patients finished the study and were subsequently incorporated into the data analysis (Fig. 1).

Of the 112 patients (57 and 55 were in groups O and S, respectively), 48 (42.9%) were women, and the mean (SD) age was 73.17 (3.88) years. Furthermore, 6 (10.5%) in group O and 4 (7.3%) in group S exhibited baseline impaired cognition (defined as a Mini-Mental State Examination $\leq$26). The baseline characteristics of both groups were comparable, with no statistically significant differences in the demographic data (Table 1).

Table 2 summarizes the intraoperative characteristics, with were generally similar between the two groups.

3.2 Primary outcome

The overall POD incidence was 18% among all patients, with 8 in group O and 12 patients in group S (Fig. 2), showing no statistically significant difference between the two groups (Risk ratio, 0.64; 95% CI, 0.28 to 1.45; $p = 0.282$). Also, the subtypes of POD were similar between group O and group S as follows: hyperactive delirium (50.0% *vs.* 41.7%), hypoactive delirium (25.0% *vs.* 33.3%), and mixed delirium (25.0% *vs.* 25.0%) (Table 3).

3.3 Secondary outcomes

Group O patients exhibited significantly lower postoperative opioid consumption compared to those in group S ($p < 0.001$, Fig. 3). Additionally, patients in group O reported lower postoperative pain score ($p < 0.001$, Fig. 4). Furthermore, patients in group O achieved higher satisfaction score and lower occurrence of PONV ($p < 0.001$, Fig. 5). Overall, patients in group O had a better postoperative experience, which is beneficial for postoperative recovery and in line with Enhanced Recovery After Surgery (ERAS) protocols. Notably, there were no incidents of respiratory failure among any of the patients (Table 3).

4. Discussion

The findings from our RCT illustrated that oxycodone PA was unrelated to a decreased POD incidence post-MAS in comparison to sufentanil. Nevertheless, patients treated with oxycodone require lower doses of intraoperative and postoperative opioids and exhibit lower postoperative pain scores.

A previous study demonstrated that the combination of intercostal nerve block and oxycodone could improve postoperative cognitive function [8]. Another RCT reported that employing oxycodone for patient-controlled analgesia in elderly patients following total hip arthroplasty could significantly lower the incidence of postoperative cognitive dysfunction [9]. Collectively, these studies suggest that oxycodone, as an adjuvant medication, improves postoperative cognitive function in elderly patients. However, there is still a lack of strong evidence on the impact of oxycodone on POD.

Our study failed to elucidate a significant difference in the primary outcome of PA between the two drugs evaluated. The differences between the current trial and previous studies may be partially attributed to differences in the choice of primary outcome and diagnostic tools. In Wang's study [8], only MMSE was used to calculate the incidence of cognitive impairment 24 hours post-surgery. This limited approach could easily result in missed diagnosis and failure to differentiate cognitive impairment classifications adequately. Gan's study [9], on the other hand, utilized both the MMSE and Montreal Cognitive Assessment to evaluate postoperative cognitive dysfunction (POCD) during the 7 days postoperative. However, the POCD definition does not adhere to the 2018 Recommendations for the nomenclature of cognitive alteration linked to anesthesia and Surgery [19]. In contrast, we relied on the widely accepted CAM and CAM-ICU to estimate the incidence of POD. In addition, we speculated that the lack of observed improvement in cognitive function of oxycodone in our study might be related to the route of administration. These two previous studies reported that continuous use of hydrocodone after surgery (intercostal nerve block and patient controlled intravenous analgesia), which could improve neurological inflammation [8, 9], while our study involved preoperative single dose administration.

In this study, patients treated with oxycodone required lower intraoperative and postoperative opioids and had lower postop-

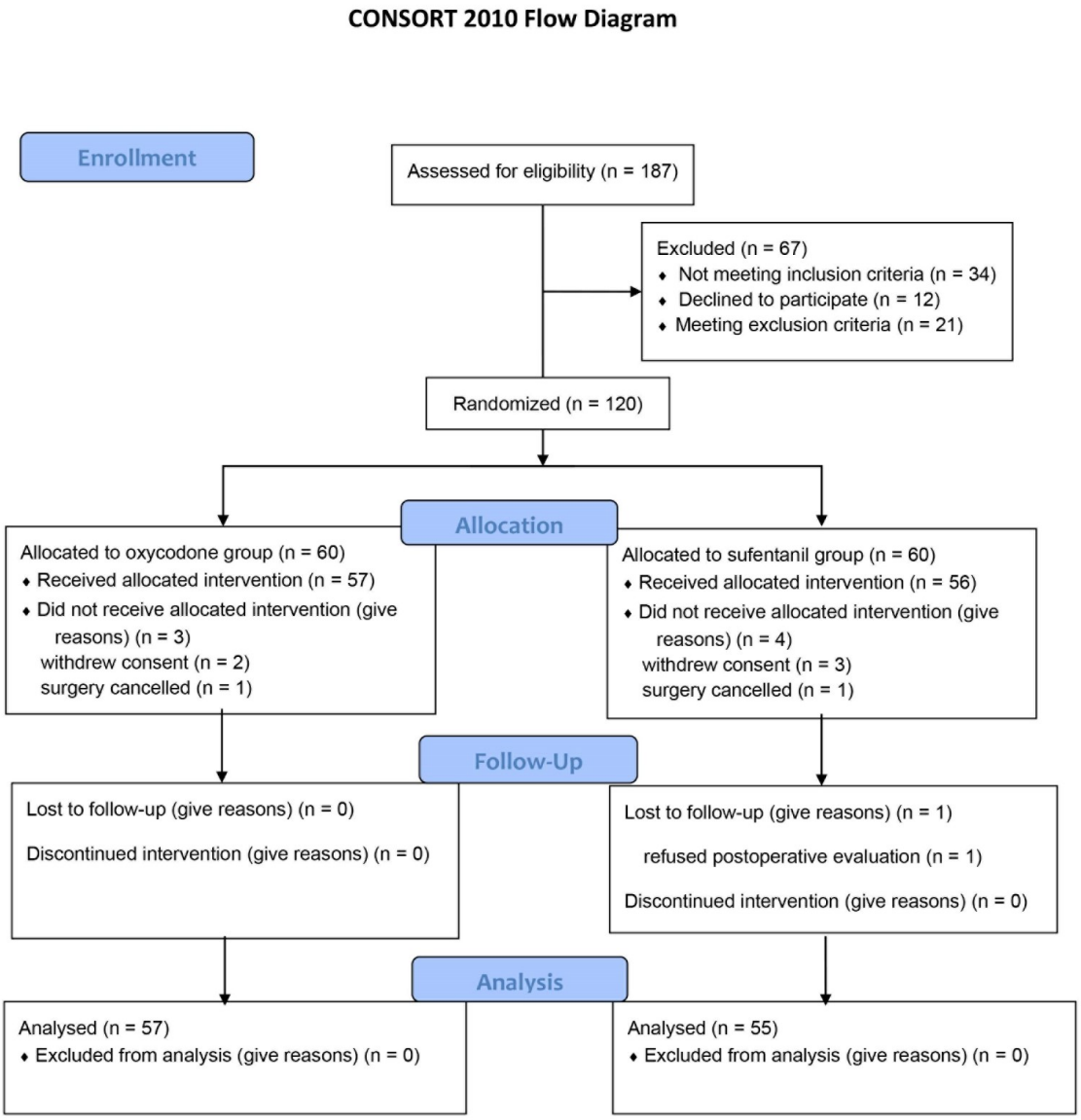

FIGURE 1. CONSORT 2010 flow diagram. CONSORT, Consolidated Standards of Reporting Trials.

TABLE 1. Characteristics of patients.

	Oxycodone (57)	Sufentanil (55)	*p* Value
Age, yr	72.58 (3.98)	73.78 (3.71)	0.101
Male/Female, n	31/26	33/22	0.548
Weight, kg	66.91 (6.69)	68.90 (5.05)	0.078
BMI, kg/m^2	23.86 (1.59)	23.57 (1.77)	0.369
Hypertension, n (%)	24 (42.1%)	25 (45.5%)	0.721
Diabetes, n (%)	13 (22.8%)	11 (20.0%)	0.717
MMSE $\leq$26, n (%)	6 (10.5%)	4 (7.3%)	0.743
ASA classification, n (%)			
I	3 (5.3%)	2 (3.7%)	
II	45 (78.9%)	48 (87.3%)	0.495
III	9 (15.8%)	5 (9.0%)	

Notes: Data are expressed as mean (standard deviation) or n (%).
Abbreviations: BMI, Body Mass Index; MMSE, Mini-Mental State Examination; ASA, American Society of Anesthesiologists.

TABLE 2. Perioperative surgical and anesthetic variables.

	Oxycodone (57)	Sufentanil (55)	*p* Value
Type of surgery, n (%)			
Gastrointestinal	43 (75.4%)	38 (69.0%)	
Pancreas	7 (12.3%)	8 (1.4%)	0.745
Others	7 (12.3%)	9 (1.6%)	
Length of anesthesia (min)	170.7 (18.4)	175.2 (17.9)	0.195
Length of surgery (min)	150.2 (19.7)	157.3 (20.8)	0.060
Blood loss (mL)	150 (100, 160)	120 (100, 180)	0.614
Blood transfusion, n (%)	3 (5.3%)	4 (7.3%)	0.714
Urine output (mL)	405.6 (104.0)	384.9 (100.0)	0.285

Notes: Data are expressed as mean (standard deviation), n (%) or median (interquartile range).

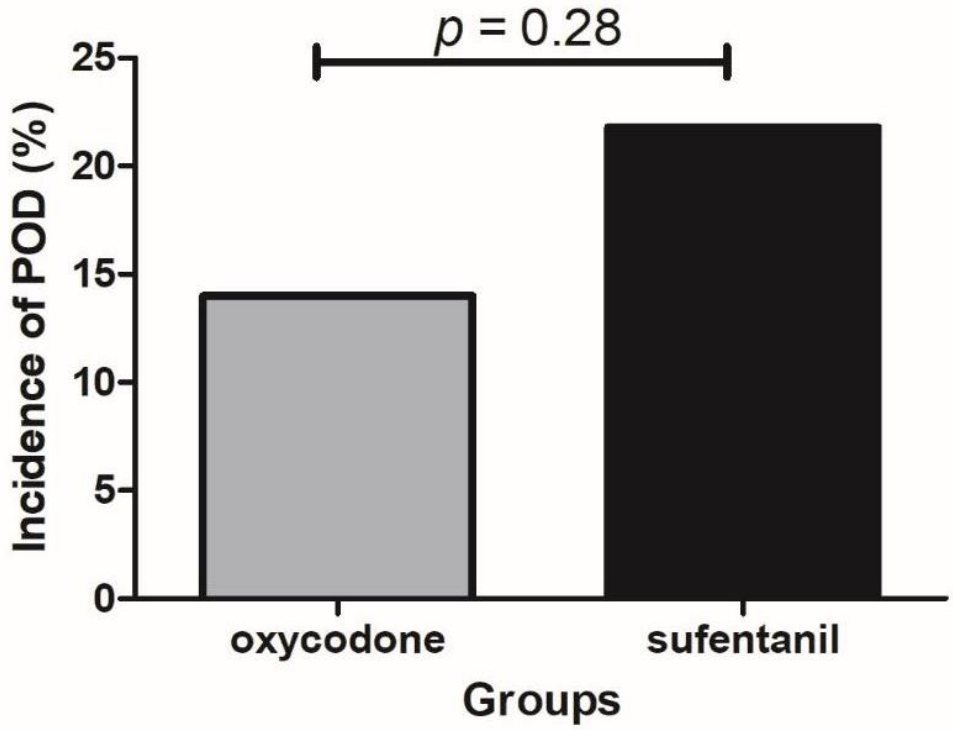

FIGURE 2. The incidence of POD between oxycodone and sufentanil groups. POD, postoperative delirium.

TABLE 3. Primary and secondary outcomes.

	Oxycodone (57)	Sufentanil (55)	Risk Ratio (95% CI)	*p*
Incidence of POD, n (%)	8 (14.0%)	12 (21.8%)	0.64 (0.28–1.45)	0.282
Subtype of POD, n (%)				
Hyperactive	4 (50.0%)	5 (41.7%)		
Hypoactive	2 (25.0%)	4 (33.3%)		0.912
Mixed	2 (25.0%)	3 (25.0%)		
Postoperative opioid consumption, μg	56.4 (5.1)	62.4 (6.9)		<0.001
Postoperative pain score	2 (1, 2)	3 (2, 3)		<0.001
Satisfaction score	8 (8, 9)	7 (6, 8)		<0.001
Incidence of PONV, n (%)	9 (15.8%)	19 (34.5%)		0.029

Notes: Data are expressed as mean (standard deviation), n (%) or median (interquartile range).
Abbreviations: POD, postoperative delirium; PONV, postoperative nausea and vomiting; CI, confidence interval.

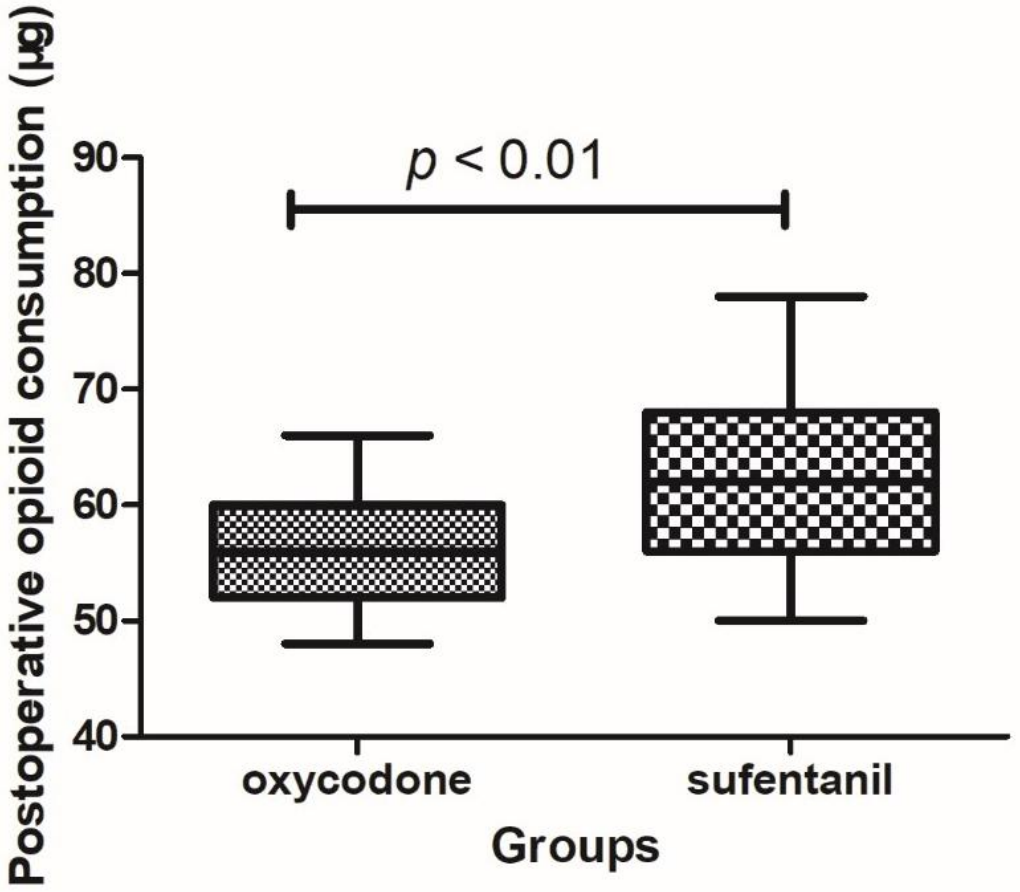

FIGURE 3. The postoperative opioid consumption between oxycodone and sufentanil groups.

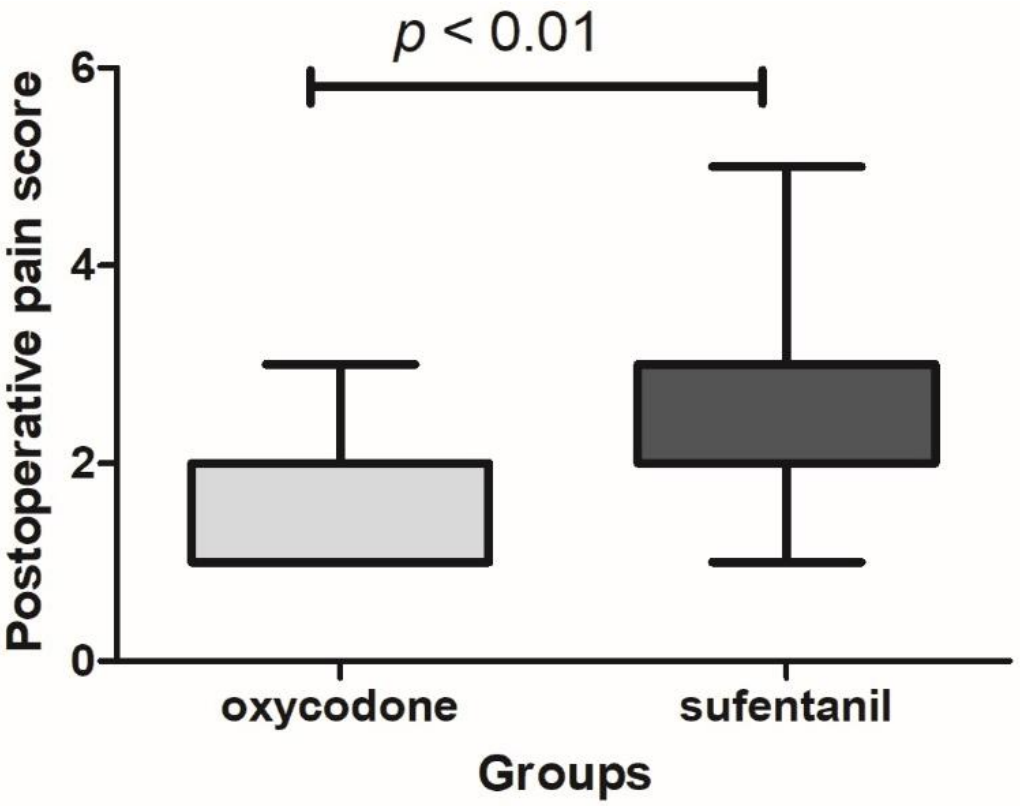

FIGURE 4. The postoperative pain score between oxycodone and sufentanil groups.

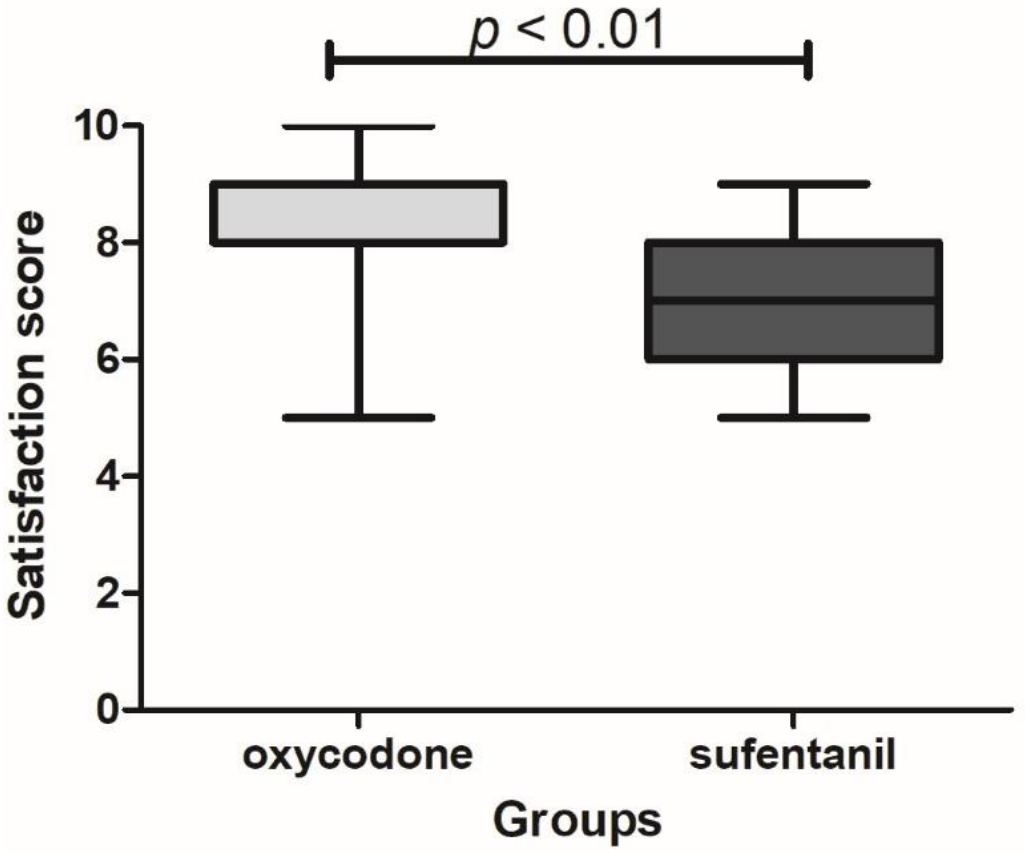

FIGURE 5. The satisfaction score between oxycodone and sufentanil groups.

erative pain scores. These results indicated that compared to pure μ-receptor agonist, oxycodone has a more potent analgesic effect. Oxycodone is believed to influence the κ-opioid receptor, suggesting a distinct pharmacological profile compared to sufentanil. It has been proposed that κ-opioid receptors located on peripheral nerves in the gut play an essential role in anti-nociception within the visceral pain system [20]. Additionally, the analgesic effect of oxycodone correlates with the plasma concentration, indicating a peripheral effect potentially mediated via κ-receptors [21]. Furthermore, administering oxycodone PA before surgery also played an essential role in intraoperative analgesia, which is consistent with previous studies [10, 22].

The incidence of PONV in group O was lower than in group S, which may be mainly due to the reduced opioid consumption. As one of the main postoperative adverse events of opioid drugs, PONV continues to pose a challenge for healthcare workers, patients, and their families [23]. To advance the implementation of ERAS, various strategies have been explored to reduce the occurrence of PONV, such as opioid-free anesthesia and opioid-reduced anesthesia [24, 25]. Thus, oxycodone PA might become an optional perioperative analgesic strategy in ERAS protocol. In addition, our findings indicated that Group O achieved a higher postoperative satisfaction score, suggesting that oxycodone may serve as a promising adjuvant analgesic compared to traditional opioids, especially for elderly patients undergoing MASs. However, further high-quality clinical trials are required to validate these findings.

It is essential to acknowledge that our study had several limitations. First, we enrolled a relatively small sample size and only focused on elderly patients undergoing MASs. Therefore, verifying these results in more extensive clinical studies encompassing various surgical procedures will be necessary. Secondly, while we calculated the incidence of POD and its subtypes, we lacked data regarding the onset, duration and severity of POD. Thirdly, the oxycodone dosage was determined based on the conversion of opioid doses, however, the optimal dose requires further investigation. Additionally, we did not evaluate the potential impact of other variables, such as perioperative hydration status and sleep disorders, on the incidence of POD. Lastly, our study focused solely on patients who underwent MAS, and our evaluation was limited to the hospitalization period. Future research should include a broader range of surgeries, patient populations and long-term cognitive outcomes.

5. Conclusions

Our research indicates that while oxycodone does not reduce the incidence of POD, it improves pain control, patient satisfaction and postoperative recovery. Future research may focus on evaluating different oxycodone administration schemes or combining them with non-pharmacological interventions aimed at reducing the occurrence of POD.

AVAILABILITY OF DATA AND MATERIALS

The datasets supporting the conclusions of this article are supplemented along with the article. Further inquiries about the datasets can be directed to the corresponding author on reasonable request.

AUTHOR CONTRIBUTIONS

DHY—Conceptualization, Methodology, Writing-original draft. YFS—Project administration, Resources, Supervision. YJC and KL—Formal analysis, Investigation, Validation. QHS—Project administration.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was obtained from the Ethics Committee of Affiliated Hospital of Jiaxing University (LS2022-KY-068). Written informed consent was obtained from a legally authorized representative for anonymized patient information to be published in this article.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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