

Cite as: Hu J, Huang FY, Zhang HH, Huang SR. Oxycodone hydrochloride preemptive analgesia regimen in perioperative anesthesia management of burn patients undergoing tangential excision and skin grafting [J]. Chin J Clin Res, 2025, 38(12):1836-1840.

DOI: 10.13429/j.cnki.cjcr.2025.12.010

Oxycodone hydrochloride preemptive analgesia regimen in perioperative anesthesia management of burn patients undergoing tangential excision and skin grafting

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Abstract: Objective To investigate the effects of a preemptive analgesia regimen with oxycodone hydrochloride on vital signs, analgesic quality, pain mediators, and inflammatory factor levels in patients undergoing tangential excision and skin grafting during the perioperative anesthesia management period. **Methods** A total of 1 200 patients undergoing tangential excision and skin grafting at 910th Hospital of PLA Joint Logistic Support Force from June 2021 to June 2024 were selected as the study subjects and randomly assigned to two groups. Ultimately, 837 patients were included in the analysis, with 420 cases in the observation group and 417 cases in the control group. Patients in the observation group received an intravenous injection of 0.1 mg/kg oxycodone hydrochloride injection 10 minutes before anesthesia induction, while patients in the control group received an intravenous injection of 10 mL normal saline. The perioperative vital signs [mean arterial pressure (MAP) and heart rate], analgesic quality [Visual Analog Scale (VAS) score], pain mediator indicators (norepinephrine, 5-hydroxytryptamine), and inflammatory factor levels [interleukin (IL)-6, tumor necrosis factor (TNF)- α , and cortisol] were compared between the two groups. The Quality of Recovery-40 (QoR-40) scale was used to assess the quality of recovery 24 hours postoperatively, and the incidence of adverse reactions was recorded. **Results** Compared with the control group, patients in the observation group demonstrated better stability in MAP and heart rate during anesthesia induction and tracheal intubation ($P<0.05$). Within 24 hours postoperatively, the VAS scores, serum levels of norepinephrine, 5-hydroxytryptamine, IL-6, TNF- α , and cortisol in the observation group were significantly lower than those in the control group ($P<0.05$). The total score and all dimension scores of the QoR-40 in the observation group were significantly higher than those in the control group ($P<0.05$). The total incidence of adverse reactions in the observation group was significantly lower than that in the control group [9.05% (38/420) vs 21.34% (89/417), $\chi^2=24.58$, $P<0.01$]. **Conclusion** Oxycodone hydrochloride preemptive analgesia regimen can improve perioperative analgesic quality in burn patients undergoing tangential excision and skin grafting, stabilize vital signs during operation, reduce the release of serum pain mediators and the occurrence of adverse reactions, and promote postoperative recovery.

Keywords: Burn; Tangential excision and skin grafting; Oxycodone hydrochloride; Preemptive analgesia; Anesthesia management; Norepinephrine; 5-hydroxytryptamine; Interleukin; Tumor necrosis factor; Cortisol

Fund program: Program of Natural Science Foundation of Fujian Province (2023J01241)

Acute stress disorder, post-traumatic stress disorder, chronic pain, and depression are very common among survivors of severe burns, and anesthetic management can modulate these physiological responses and influence postoperative recovery [1]. It's very challenging to maintain adequate analgesia and appropriate sedation in patients undergoing tangential excision and skin grafting, during which high doses of anxiolytics and analgesics are often required. However, the rising levels of opioids and benzodiazepines offer little additional benefits while increasing the incidence and severity of adverse effects [2]. Oxycodone hydrochloride is currently the only pure opioid μ and κ dual-receptor agonist that blocks sensory pathways, reducing the body's sensitivity to noxious sensations, thereby achieving postoperative analgesia, known as preemptive analgesia [3]. In addition, oxycodone hydrochloride has a rapid onset, strong analgesic effect, and minimal impact on hemodynamics [4]. Based on the evidence, this study aimed to verify the efficacy of oxycodone hydrochloride preemptive analgesia regimen in perioperative anesthetic management for patients undergoing tangential excision and skin grafting.

1 Subjects and Methods

1.1 Study Subjects

Before randomization, informed consent was obtained from all the participants. Between June 2021 and June 2024, a total of 1200 patients with moderate to severe burns who were scheduled to undergo tangential excision and skin grafting at 910th Hospital of PLA Joint Logistic Support Force were enrolled in the study. This study was approved by the Medical Ethics Committee of our hospital (Approval No. [2021] 19). The inclusion criteria were: (1) age 18-65 years; (2) American Society of Anesthesiologists (ASA) classification II-III; (3) cardiac function I-II; (4) conscious and able to cooperate positively. The exclusion criteria were: (1) known or suspected allergy to anesthetic drugs; (2) combined with sinus bradycardia or myocardial dysfunction; (3) combined with malignant tumor or severe organ dysfunction. Patients were randomly assigned to the observation group or the control group using a computer-generated random number

sequence and sealed-envelope method. Among the 1200 initially enrolled subjects, 137 did not meet the inclusion criteria, 51 declined to participate, 175 dropped out, and 837 patients were finally included into the study. The flowchart of the Consolidated Standards of Reporting Trials (CONSORT) is shown in **Figure 1**. There were no significant differences between the two groups in terms of age, sex, body mass index (BMI), ASA classification, burn area, operation time, anesthesia time, time from admission to the post-anesthesia care unit (PACU) to extubation, or length of stay in the PACU ($P>0.05$). [**Table 1**]

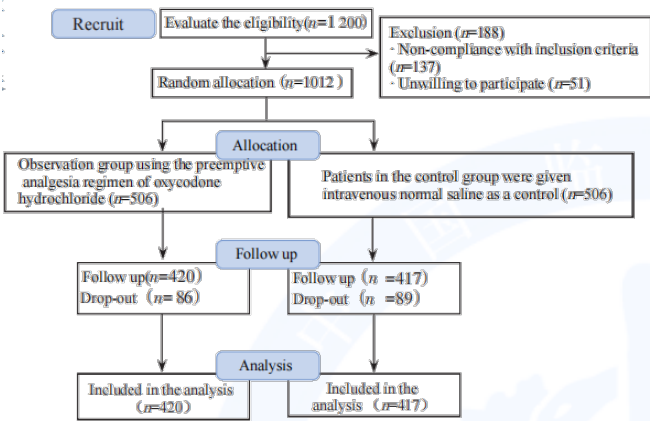


Fig.1 CONSORT flowchart

Tab.1 Comparison of general clinical data between two groups of patients ($\bar{X} \pm s$)

Items	Observation group (n=420)	Control group (n=417)	t/ χ^2 value	P value
Age (years)	39.21±11.39	39.46±12.14	0.31	0.76
Gender [n(%)]			1.08	0.30
Male	294(70.00)	278(66.67)		
Female	126(30.00)	139(33.33)		
BMI (kg/m ²)	22.56±2.17	22.60±2.24	0.26	0.79
ASA classification [n(%)]			1.65	0.20
Grade II	257(61.19)	273(65.47)		
Grade III	163(38.81)	144(34.53)		
Burn area (%)	17.51±6.73	17.27±6.91	0.51	0.61
Operation time (min)	89.43±14.58	88.76±16.07	0.63	0.53
Anesthesia time (min)	135.62±17.83	134.86±19.41	0.59	0.56
Time from entering PACU to extubation (min)	8.56±3.04	8.84±2.87	1.37	0.17
PACU stay time (min)	31.62±6.51	31.32±6.27	0.68	0.50

1.2 Anesthesia Methods

Ten minutes before anesthesia induction, patients in the observation group received an intravenous injection of oxycodone hydrochloride [Mindi (China) Pharmaceutical, batch No.: 122216] 0.1 mg/kg, while patients in the control group received an intravenous injection of 10 mL of normal saline. Anesthesia induction was performed by intravenous injection of midazolam (Jiangsu Enhua

Pharmaceutical, batch No.: TMS34E01) 0.05 mg/kg, fentanyl (Yichang Renfu, batch No.: AB40903021) 4 μ g/kg, propofol (Xi'an Libang Pharmaceutical, batch No.: 22412171) 2.0 ng/mL, or etomidate (Jiangsu Enhua Pharmaceutical, batch No.: YT211016) 0.2 mg/kg, and rocuronium bromide (Nanjing Hengdao Pharmaceutical, batch No.: 250602) 0.9 mg/kg. After achieving mandibular relaxation and loss of consciousness and spontaneous breathing, tracheal intubation was performed. Intermittent mechanical positive-pressure ventilation was applied with a tidal volume of 6–8 mL/kg, respiratory rate of 14–16 breaths/min, oxygen flow of 1.5 mL/kg, and an inspiratory-to-expiratory ratio of 1:2, maintaining end-tidal carbon dioxide partial pressure (PETCO₂) at 35–45 mmHg. Anesthesia was maintained intraoperatively with continuous propofol infusion at 3–4 mg/kg and remifentanyl (Yichang Renfu Pharmaceutical, batch No. AD5050131) at 0.08–0.1 μ g/(kg·min).

1.3 Indicators and Parameters

(1)Mean arterial pressure (MAP) and heart rate (HR) pre-operation, after anesthesia induction, after tracheal intubation, and 6h, 12h, and 24h postoperatively were recorded. (2) Visual Analogue Scale (VAS) was applied to assess perioperative pain [5]. (3) Venous blood samples (5 mL) were collected preoperatively and 24 hours postoperatively to measure serum levels of pain mediator indicators (norepinephrine, 5-hydroxytryptamine) and inflammatory markers, including interleukin-6 (IL-6), tumor necrosis factor-alpha (TNF- α), and cortisol. (4) The Quality of Recovery-40 Questionnaire (QoR-40) was used to evaluate patients' recovery 24 hours after surgery. The questionnaire includes 5 dimensions and 40 items. Each item is scored on a 5-point scale. The higher the score, the better the quality of recovery. (5) The occurrence of adverse effects was recorded, such as nausea, vomiting, dizziness, and respiratory depression (defined as a respiratory rate <8 breaths/min, oxygen saturation <90%, or PETCO₂ >50 mmHg.)

1.4 Statistical Analysis

Data were analyzed with SPSS 26.0. Continuous variables following a normal distribution were expressed as $\bar{x} \pm s$. Between-group comparisons were performed with independent-sample *t*-tests, while within-group comparisons used paired *t*-tests. Repeated-measured continuous variables were analyzed by two-way repeated-measures analysis of variance (ANOVA) followed by least significant difference (LSD) *t*-tests for pairwise comparisons. Categorical variables were expressed as *n* (%) and compared with χ^2 tests. A two-tailed significance level of $\alpha = 0.05$ was applied.

2 Results

2.1 Comparison of perioperative MAP and HR between the two groups

Preoperatively, there was no significant differences in MAP or HR between the two groups ($P>0.05$). After anesthesia induction, both MAP and HR decreased in both groups, followed by an increase after tracheal intubation. Significant differences were observed for group main effects, time main effects, and interaction effects in both MAP and HR ($P<0.01$). The observation group showed more stable MAP 6-24 hours after surgery, whereas the control group showed greater fluctuations. The two groups showed different temporal patterns of HR change postoperatively: it was more stable in the observation group, while the control group exhibited a significant increase 12-24 hours postoperatively. Within 24 hours after surgery, both groups gradually recovered to preoperative

levels [Table 2&3].

2.3 Comparison of levels of serum pain mediator indicators between the two groups before and after surgery

There was no significant difference regarding the levels of norepinephrine or 5-hydroxytryptamine between the two groups preoperatively ($P>0.05$). At 24 hours after surgery, levels of both indicators were significantly lower than their preoperative values in both groups, and the observation group showed significantly lower levels compared with the control group ($P<0.05$) [Table 5].

Tab. 2 Comparison of perioperative MAP between two groups ($\bar{x} \pm s$)

Group	Pre-operation	After anesthesia induction	After tracheal intubation	6h postoperatively	12h postoperatively	24h postoperatively
Observation group (n=420)	101.37±7.52	94.81±7.52 ^a	95.32±6.81 ^a	94.36±7.14 ^a	97.62±8.73 ^a	99.51±7.43 ^a
Control group (n=417)	100.86±6.94	99.45±7.07	103.64±7.44	99.15±6.98	101.27±7.35	105.62±8.34
$F_{\text{group/time/interaction value}}$	15.52/42.65/18.90					
$P_{\text{group/time/interaction value}}$	<0.01/<0.01/<0.01					

Note: Compared with the control group, ^a $P<0.05$.

Tab.3 Comparison of perioperative heart rates between two groups ($\bar{x} \pm s$)

Group	Pre-operation	After anesthesia induction	After tracheal intubation	6h postoperatively	12h postoperatively	24h postoperatively
Observation group (n=420)	86.24±18.47	78.58±20.59 ^a	84.27±17.05 ^a	80.33±16.19 ^a	82.26±17.76 ^a	81.93±15.94 ^a
Control group (n=417)	86.48±20.15	83.62±18.51	94.50±19.53	88.46±19.45	90.22±16.41	88.40±15.66
$F_{\text{group/time/interaction value}}$	12.85/35.18/14.63					
$P_{\text{group/time/interaction value}}$	<0.01/<0.01/<0.01					

Note: Compared with the control group, ^a $P<0.05$.

Tab. 4 Comparison of perioperative VAS scores between two groups ($\bar{x} \pm s$)

Group	Pre-operation	6h post-operation	12h post-operation	24h post-operation
Observation group (n=420)	2.86±0.91	2.59±0.79 ^{ab}	2.20±0.73 ^{ab}	1.63±0.50 ^{ab}
Control group (n=417)	2.83±0.95	2.75±0.90 ^b	2.64±0.85 ^b	2.23±0.57 ^b
$F_{\text{group/time/interaction value}}$	18.73/156.42/25.89			
$P_{\text{group/time/interaction value}}$	<0.01/<0.01/<0.01			

Note: ^a $P<0.05$ compared with the control group at the same time point; ^b $P<0.05$ compared with the pre-operation period in the same group.

Tab.5 Comparison of serum pain mediator levels between two groups before and after surgery ($\bar{x} \pm s$)

Group	Norepinephrine (μg/L)		Serotonin (μmol/L)	
	Pre-operation	24 h post-operation	Pre-operation	24 h post-operation
Observation group (n=420)	544.28±89.51	203.17±50.66 ^a	0.90±0.21	0.33±0.14 ^a
Control group (n=417)	541.93±87.24	296.45±57.83 ^a	0.91±0.20	0.49±0.17 ^a
t value	0.38	24.83	0.71	14.89
P value	0.701	< 0.01	0.48	< 0.01

Note: Compared with the pre-operation, ^a $P<0.05$.

2.4 Comparison of levels of serum inflammatory factors between the two groups before and after surgery

Preoperatively, there was no significant difference between the two groups in serum levels of IL-6, TNF- α , and cortisol ($P>0.05$). At 24 hours postoperatively, levels of these factors significantly elevated compared with preoperative values in both groups, and the observation group showed significantly lower levels than the control group ($P<0.05$) [Table 6].

2.5 Comparison of 24-hour-postoperative QoR-40 Questionnaire results between the two groups

At 24 hours postoperatively, the total QoR-40 scores and scores for each dimension were significantly higher in the observation group when compared with the control group ($P<0.05$) [Table 7].

2.6 Comparison of adverse events between the two groups

In the observation group, 21 patients experienced nausea and vomiting, 13 experienced dizziness, and 4 experienced respiratory depression. In the control group, 38 patients experienced nausea and vomiting, 34 experienced dizziness, and 17 experienced respiratory depression. The overall incidence of adverse events was significantly lower in the observation group than in the control group [9.05% (38/420) vs 21.34% (89/417), $\chi^2 = 24.58$, $P<0.01$].

Tab.6 Comparison of serum inflammatory factor levels before and after surgery between two groups ($\bar{x} \pm s$)

Group	IL-6 (mg/mL)		TNF- α (mg/mL)		Cortisol (μ g/L)	
	Pre-operation	24 h post-operation	Pre-operation	24 h post-operation	Pre-operation	24 h post-operation
Observation group (n=420)	3.40 \pm 0.81	4.52 \pm 1.67 ^a	1.72 \pm 0.51	2.59 \pm 1.09 ^a	174.22 \pm 36.89 ^a	207.33 \pm 41.59 ^a
Control group (n=417)	3.46 \pm 0.79	6.61 \pm 2.01 ^a	1.69 \pm 0.44	3.72 \pm 1.18 ^a	176.48 \pm 35.38 ^a	252.42 \pm 44.55 ^a
t value	1.09	15.89	0.89	14.20	0.86	15.23
P value	0.27	<0.01	0.37	<0.01	0.37	<0.01

Note: Compared with the pre-operation, ^aP<0.05.

Tab.7 Comparison of QoR-40 scores between the two groups 24 hours after surgery (point, $\bar{x} \pm s$)

Items	Observation group (n=420)	Control group (n=417)	t value	P value
Physical comfort	54.71 \pm 4.07	39.82 \pm 6.22	41.008	< 0.01
Emotional state	39.83 \pm 4.50	30.05 \pm 3.76	34.107	< 0.01
Self-care ability	20.74 \pm 2.57	18.04 \pm 3.95	11.729	< 0.01
Psychological support	30.41 \pm 3.06	24.25 \pm 2.45	32.135	< 0.01
Pain	30.62 \pm 3.18	21.04 \pm 3.29	42.834	< 0.01
Total score	176.31 \pm 16.45	133.20 \pm 19.67	34.404	< 0.01

3 Discussion

In this study, moderate to severe burn patients were defined as those with second-degree burns covering less than 29% of total body surface area or third-degree burns covering less than 10% of total body surface area [7]. During surgery and wound care, patients undergoing tangential excision and skin grafting experience intolerable pain, which is influenced by both the depth of the burn and the sensory input from the burn area [8]. Oxycodone hydrochloride primarily acts on the central nervous system and smooth muscle, and it also provides certain analgesic effects on visceral organs [4]. In the meantime, oxycodone hydrochloride does not induce euphoria, gastrointestinal motility inhibition, or respiratory depression, and various analgesic strategies including preemptive analgesia have been applied in clinical practice in recent years [9]. Preemptive analgesia refers to blocking the sensory pathways through anesthesia pre-operation to reduce the body's sensitivity to harmful sensations, thereby achieving the purpose of postoperative analgesia [3].

This study demonstrates that intravenous administration of oxycodone hydrochloride at 0.1 mg/kg 10 minutes before anesthesia induction can effectively enhance perioperative analgesia and improve overall recovery quality 24 hours postoperatively in patients undergoing tangential excision and skin grafting, without significant adverse effects. Significant differences in MAP and HR were observed between the observation and control groups, indicating that preemptive analgesia with oxycodone hydrochloride provides more stable hemodynamics, which is consistent with the findings of Yanan Bian et al. [10]. This study also noted a significant decrease in MAP and HR following anesthesia induction, indicating that whether MAP and HR are within normal range should be carefully monitored. Close attention should be paid to parameters including baseline values, decline rates and duration and heart index to decide whether active intervention should be applied. During the operation, although these parameters remained normal, we should still monitor the patients' various parameters and take action according to the clinical presentation. Notably,

oxycodone hydrochloride attenuated the increases in MAP and HR following tracheal intubation, indicating that preemptive analgesia using intravenous injection of oxycodone hydrochloride at 0.1 mg/kg is safe.

Oxycodone hydrochloride has dual μ - and κ -receptor agonist effects and is widely used for postoperative analgesia. Its pharmacological characteristics are similar to morphine and shows a significant analgesic effect [11]. In this study, the preemptive analgesia regimen patients undergoing tangential excision and skin grafting, and VAS scores at all postoperative time points were significantly lower in the observation group compared with the control group. During anesthesia, extubation, stimulation from pain and surgery, the body produces more renin-angiotensin, aldosterone, adrenaline, cortisol, and catecholamines, the excessive levels of which could trigger the stress response and hinder the recovery [12]. Serum levels of pain mediator indicators, such as norepinephrine and 5-hydroxytryptamine, serve as important indicators of stress intensity. This study demonstrated that at 24 hours postoperatively, these indicators were significantly lower in the observation group than in the control group, consistent with the findings of Zhang et al. [13], indicating that preemptive analgesia with oxycodone hydrochloride can reduce stress hormone levels and mitigate excessive stress responses induced by surgery.

The QoR-40 questionnaire is a valid, reliable, and clinically acceptable tool for assessing recovery quality after surgery and anesthesia and is comparable to the VAS and the Patient Health Questionnaire-9 (PHQ-9) [14]. In this study, at 24 hours postoperatively, both the overall and category-specific QoR-40 scores were significantly higher in the observation group than that of the control group, proving that preemptive analgesia with oxycodone hydrochloride can facilitate early postoperative recovery and reduce pain. In addition, the overall incidence of adverse events in the observation group was 9.05%, significantly lower than the 21.34% in the control group, which is consistent with the findings of Yiming Xu et al. [15]. This indicates that preemptive analgesia with oxycodone hydrochloride can also reduce perioperative adverse events related to anesthesia, such as nausea,

vomiting, dizziness, and respiratory depression.

In conclusion, preemptive analgesia with oxycodone hydrochloride can improve perioperative pain management, stabilize hemodynamics, reduce the release of serum pain mediators and the incidence of adverse events, and promote postoperative recovery in patients undergoing tangential eschar excision and skin grafting, showing great clinical value. However, this study has certain limitations and potential biases. First, the QoR-40 questionnaire assessment was not performed preoperatively or on postoperative days 2 and 3. In addition, as a single-center study, the findings require further validation and more precise analysis in future research.

Conflict of Interest The authors declare no competing interest

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Submission received:2025-04-08/ Revised: 2025-08-09

· 论 著 ·

盐酸羟考酮超前镇痛方案在烧伤削痂植皮患者围手术期麻醉管理中的应用

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摘要: **目的** 探究在烧伤削痂植皮患者围手术期麻醉管理中使用盐酸羟考酮超前镇痛方案对患者生命体征、镇痛质量、疼痛介质及炎症因子水平的影响。 **方法** 选择中国人民解放军联勤保障部队第九一〇医院 2021 年 6 月至 2024 年 6 月共 1 200 例烧伤削痂植皮患者作为研究对象, 随机分为两组, 最终纳入分析 837 例, 其中观察组 420 例, 对照组 417 例。观察组患者于麻醉诱导前 10 min 静脉注射盐酸羟考酮注射液 0.1 mg/kg, 对照组患者静脉注射生理盐水 10 mL, 比较两组患者围手术期生命体征[平均动脉压(MAP)和心率]、镇痛质量[视觉模拟评分(VAS)]、疼痛介质指标(去甲肾上腺素、5-羟色胺)及炎症因子[白细胞介素(IL)-6、肿瘤坏死因子(TNF)- α 和皮质醇]水平, 采用 40 项恢复质量评分量表(QoR-40)评估患者术后 24 h 的恢复质量并记录患者不良反应发生情况。 **结果** 与对照组患者相比, 观察组患者在麻醉诱导和气管插管过程中表现出更好的 MAP 和心率稳定性($P<0.05$)。术后 24 h 内, 观察组 VAS 评分、血清去甲肾上腺素、5-羟色胺、IL-6、TNF- α 和皮质醇水平均明显低于对照组($P<0.05$)。QoR-40 量表评分总分及各维度评分均明显高于对照组($P<0.05$)。观察组患者不良反应总发生率明显低于对照组[9.05%(38/420) vs 21.34%(89/417), $\chi^2=24.58$, $P<0.01$]。 **结论** 盐酸羟考酮超前镇痛方案可以改善烧伤削痂植皮患者围手术期镇痛质量, 稳定手术中生命体征, 减少血清疼痛介质的释放和不良反应的发生, 促进术后恢复。

关键词: 烧伤; 削痂植皮; 盐酸羟考酮; 超前镇痛; 麻醉管理; 去甲肾上腺素; 5-羟色胺; 白细胞介素; 肿瘤坏死因子; 皮质醇

中图分类号: R614 文献标识码: A 文章编号: 1674-8182(2025)12-1836-05

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Abstract: **Objective** To investigate the effects of a preemptive analgesia regimen with oxycodone hydrochloride on vital signs, analgesic quality, pain mediators, and inflammatory factor levels in patients undergoing tangential excision and skin grafting during the perioperative anesthesia management period. **Methods** A total of 1 200 patients undergoing tangential excision and skin grafting at 910th Hospital of PLA Joint Logistic Support Force from June 2021 to June 2024 were selected as the study subjects and randomly assigned to two groups. Ultimately, 837 patients were included in the analysis, with 420 cases in the observation group and 417 cases in the control group. Patients in the observation group received an intravenous injection of 0.1 mg/kg oxycodone hydrochloride injection 10 minutes before anesthesia induction, while patients in the control group received an intravenous injection of 10 mL normal saline. The perioperative vital signs [mean arterial pressure (MAP) and heart rate], analgesic quality [Visual Analog Scale (VAS)]

DOI:10.13429/j.cnki.cjcr.2025.12.010

基金项目: 福建省自然科学基金项目(2023J01241)

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出版日期: 2025-12-20



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score], pain mediator indicators (norepinephrine, 5-hydroxytryptamine), and inflammatory factor levels [interleukin (IL)-6, tumor necrosis factor (TNF)- α , and cortisol] were compared between the two groups. The Quality of Recovery-40 (QoR-40) scale was used to assess the quality of recovery 24 hours postoperatively, and the incidence of adverse reactions was recorded. **Results** Compared with the control group, patients in the observation group demonstrated better stability in MAP and heart rate during anesthesia induction and tracheal intubation ($P<0.05$). Within 24 hours postoperatively, the VAS scores, serum levels of norepinephrine, 5-hydroxytryptamine, IL-6, TNF- α , and cortisol in the observation group were significantly lower than those in the control group ($P<0.05$). The total score and all dimension scores of the QoR-40 in the observation group were significantly higher than those in the control group ($P<0.05$). The total incidence of adverse reactions in the observation group was significantly lower than that in the control group [9.05% (38/420) vs 21.34% (89/417), $\chi^2=24.58$, $P<0.01$]. **Conclusion** Oxycodone hydrochloride preemptive analgesia regimen can improve perioperative analgesic quality in burn patients undergoing tangential excision and skin grafting, stabilize vital signs during operation, reduce the release of serum pain mediators and the occurrence of adverse reactions, and promote postoperative recovery.

Keywords: Burn; Tangential excision and skin grafting; Oxycodone hydrochloride; Preemptive analgesia; Anesthesia management; Norepinephrine; 5-hydroxytryptamine; Interleukin; Tumor necrosis factor; Cortisol

Fund program: Program of Natural Science Foundation of Fujian Province (2023J01241)

急性应激障碍、创伤后应激障碍、慢性疼痛和抑郁在严重烧伤幸存者中非常普遍,麻醉管理能够调节这种生理反应并影响术后恢复^[1]。在烧伤削痂植皮患者中维持镇痛和适当的镇静是极具挑战性的,通常需要高剂量的抗焦虑药物和镇痛药物。然而,不断增加的阿片类药物和苯二氮草类药物的剂量几乎没有额外的益处,而且会增加不良反应的发生率和严重程度^[2]。盐酸羟考酮是目前唯一的纯阿片类药物 μ 、 κ 双受体激动剂,可阻断神经感觉通路,降低机体对有害感觉的敏感性,从而达到术后镇痛的目的,称为超前镇痛^[3]。同时,盐酸羟考酮起效快,镇痛作用强,对血流动力学影响小^[4]。基于以上证据,本研究拟验证盐酸羟考酮超前镇痛方案在烧伤削痂植皮患者围手术期麻醉管理中的应用效果,现将相关研究结果报告如下。

1 对象与方法

1.1 研究对象 在随机化之前,均获得了所有参与者的书面知情同意。2021年6月至2024年6月期间,共有联勤保障部队第九一〇医院1 200例择期行削痂植皮术的中度至重度烧伤患者入组本研究。本研究已通过联勤保障部队第九一〇医院医学伦理委员会审核批准(院医伦[2021]19号)。纳入标准:(1) 年龄18~65岁;(2) 美国麻醉医师协会(American Society of Anesthesiologists, ASA)分级Ⅱ~Ⅲ级;(3) 心功能Ⅰ~Ⅱ级;(4) 意识清醒,能够积极配合。排除标准:(1) 已知或疑似对麻醉药物过敏;(2) 合并窦性心动过缓或心肌功能障碍;(3) 合并恶性肿瘤或严重器官

功能障碍。使用计算机生成的随机数序列和密封信封技术将患者随机分为观察组和对照组,在1 200例烧伤削痂植皮患者中,137例不符合纳入标准,51例不愿参加,175例脱落,最终837例患者参与了本研究,随机对照试验报告统一标准(Consolidated Standards of Reporting Trials, CONSORT)流程图如图1所示。两组患者在年龄、性别、身体质量指数(body mass index, BMI)、ASA分级、烧伤面积、手术时间、麻醉时间、入麻醉后监测治疗室(post-anesthesia care unit, PACU)至拔管时间及PACU停留时间等方面差异无统计学意义($P>0.05$)。见表1。

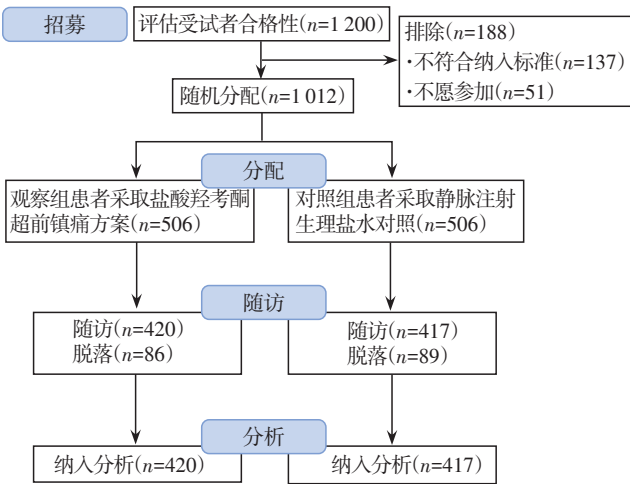


图1 CONSORT流程图

Fig.1 CONSORT flowchart

1.2 麻醉方法 观察组患者于麻醉诱导前10 min静脉注射盐酸羟考酮注射液[明蒂(中国)制药,批号:122216]0.1 mg/kg,对照组患者静脉注射生理盐水

10 mL。麻醉诱导:静脉注射咪达唑仑(江苏恩华药业,批号:TMS34E01)0.05 mg/kg、芬太尼(宜昌人福,批号:AB40903021)4 μg/kg、丙泊酚(西安力邦制药,批号:22412171)2.0 mg/kg或依托咪酯(江苏恩华药业,批号:YT211016)0.2 mg/kg、罗库溴铵(南京恒道医药,批号:250602)0.9 mg/kg进行麻醉诱导。待下颌松弛,意识和自主呼吸消失后,行气管插管。间歇机械正压通气,潮气量 6~8 mL/kg,呼吸频率 14~16 次/min,氧流量 1.5 mL/kg,吸呼比 1:2,维持呼气末二氧化碳分压(end-tidal carbon dioxide partial pressure, P_{ET}CO₂)35~45 mmHg。术中等速静脉泵注丙泊酚 3~4 mg/kg 和瑞芬太尼(宜昌人福药业,批号:AD5050131)0.08~0.1 μg/(kg·min)。

1.3 观察指标 (1)记录患者在手术前、麻醉诱导后、气管插管后及术后 6 h、12 h、24 h 等不同时间点的平均动脉压(mean arterial pressure, MAP)和心率。(2)采用视觉模拟评分(Visual Analogue Scale, VAS)评估患者围术期疼痛程度^[5]。(3)分别于手术前、术后 24 h 采集患者静脉血 5 mL,测定血清疼痛介质指标(去甲肾上腺素、5-羟色胺)及炎症因子[白细胞介素(interleukin, IL)-6、肿瘤坏死因子(tumor necrosis factor, TNF)-α和皮质醇]水平。(4)采用 40 项恢复质量量表(Quality of Recovery-40, QoR-40)评估患者术后 24 h 的恢复质量:包括 5 个维度,共 40 个项目,每个项目都以 5 分制进行评分,得分越高,恢复质量越好^[6]。(5)记录患者不良反应发生情况,如恶心呕吐、头晕、呼吸抑制。呼吸抑制:呼吸频率<8 次/min,血氧饱和度<90%,P_{ET}CO₂>50 mmHg。

1.4 统计学方法 采用 SPSS 26.0 软件处理数据。符合正态分布连续变量表示为 $\bar{x} \pm s$,两组间比较采用

成组 *t* 检验,组内比较采用配对 *t* 检验;重复测量连续变量对比采用两因素重复测量方差分析及两两比较的 LSD-*t* 检验。分类变量以例(%)表示,比较采用 χ^2 检验。检验标准为 $\alpha=0.05$,双侧检验。

2 结 果

2.1 两组患者围手术期 MAP 和心率比较 手术前两组患者 MAP 和心率均具有可比性($P>0.05$)。麻醉诱导后两组患者 MAP 和心率均有所降低,气管插管后均升高。两组 MAP、心率在组间主效应、时间主效应、交互效应上均有统计学意义($P<0.01$)。观察组术后 6~24 h 的 MAP 更平稳,对照组波动较大。两组患者的心率随时间变化的模式不同(观察组术后心率控制更稳定,对照组术后 12~24 h 心率回升更明显)。在术后 24 h 内,两组患者 MAP 和心率逐渐恢复至手术前水平。见表 2、表 3。

表 1 两组患者一般资料比较 ($\bar{x} \pm s$)
Tab.1 Comparison of general data between two groups of patients ($\bar{x} \pm s$)

项目	观察组 (<i>n</i> =420)	对照组 (<i>n</i> =417)	<i>t</i> / χ^2 值	<i>P</i> 值
年龄(岁)	39.21±11.39	39.46±12.14	0.31	0.76
性别[例(%)]				
男	294(70.00)	278(66.67)	1.08	0.30
女	126(30.00)	139(33.33)		
BMI(kg/m ²)	22.56±2.17	22.60±2.24	0.26	0.79
ASA 分级[例(%)]				
Ⅱ级	257(61.19)	273(65.47)	1.65	0.20
Ⅲ级	163(38.81)	144(34.53)		
烧伤面积(%)	17.51±6.73	17.27±6.91	0.51	0.61
手术时间(min)	89.43±14.58	88.76±16.07	0.63	0.53
麻醉时间(min)	135.62±17.83	134.86±19.41	0.59	0.56
入 PACU 至拔管时间(min)	8.56±3.04	8.84±2.87	1.37	0.17
PACU 停留时间(min)	31.62±6.51	31.32±6.27	0.68	0.50

表 2 两组围手术期 MAP 比较 ($\bar{x} \pm s$)
Tab.2 Comparison of perioperative MAP between two groups ($\bar{x} \pm s$)

组别	手术前	麻醉诱导后	气管插管后	术后 6 h	术后 12 h	术后 24 h
观察组(<i>n</i> =420)	101.37±7.52	94.81±7.52 ^a	95.32±6.81 ^a	94.36±7.14 ^a	97.62±8.73 ^a	99.51±7.43 ^a
对照组(<i>n</i> =417)	100.86±6.94	99.45±7.07	103.64±7.44	99.15±6.98	101.27±7.35	105.62±8.34
<i>F</i> _{组间/交互} 值	15.52/42.65/18.90					
<i>P</i> _{组间/交互} 值	<0.01/<0.01/<0.01					

注:与对照组比较,^a $P<0.05$ 。

表 3 两组围手术期心率比较 ($\bar{x} \pm s$)
Tab.3 Comparison of perioperative heart rates between two groups ($\bar{x} \pm s$)

组别	手术前	麻醉诱导后	气管插管后	术后 6 h	术后 12 h	术后 24 h
观察组(<i>n</i> =420)	86.24±18.47	78.58±20.59 ^a	84.27±17.05 ^a	80.33±16.19 ^a	82.26±17.76 ^a	81.93±15.94 ^a
对照组(<i>n</i> =417)	86.48±20.15	83.62±18.51	94.50±19.53	88.46±19.45	90.22±16.41	88.40±15.66
<i>F</i> _{组间/交互} 值	12.85/35.18/14.63					
<i>P</i> _{组间/交互} 值	<0.01/<0.01/<0.01					

注:与对照组比较,^a $P<0.05$ 。

2.2 两组 VAS 评分比较 两组 VAS 评分组间主效应、时间主效应、交互效应均有统计学意义 ($P<0.01$)。术后各时间点,两组患者均较手术前明显降低,且术后各时间点比较,观察组患者均明显低于对照组患者 ($P<0.05$)。见表 4。

2.3 两组手术前后血清疼痛介质水平比较 手术前两组患者血清去甲肾上腺素、5-羟色胺水平差异无统计学意义 ($P>0.05$);术后 24 h,两组患者均较手术前明显降低,且组间比较,观察组患者均明显低于对照组患者 ($P<0.05$)。见表 5。

2.4 两组手术前后血清炎症因子水平比较 手术前两组患者 IL-6、TNF- α 和皮质醇水平差异均无统计学意义 ($P>0.05$);术后 24 h,两组均较手术前明显升高,且在组间比较中,观察组均明显低于对照组 ($P<0.05$)。见表 6。

2.5 两组患者术后 24 h QoR-40 量表评分比较 术后 24 h,观察组患者 QoR-40 量表评分总分及各维度评分均明显高于对照组患者 ($P<0.05$)。见表 7。

2.6 两组患者不良反应发生情况比较 观察组发生恶心呕吐 21 例,头晕 13 例,呼吸抑制 4 例;对照组发

生恶心呕吐 38 例,头晕 34 例,呼吸抑制 17 例。观察组不良反应总发生率低于对照组 [9.05% (38/420) vs 21.34% (89/417), $\chi^2=24.58, P<0.01$]。

表 4 两组围术期 VAS 评分比较 ($\bar{x}\pm s$)
Tab.4 Comparison of perioperative VAS scores between two groups ($\bar{x}\pm s$)

组别	手术前	术后 6 h	术后 12 h	术后 24 h
观察组 ($n=420$)	2.86 \pm 0.91	2.59 \pm 0.79 ^{ab}	2.20 \pm 0.73 ^{ab}	1.63 \pm 0.50 ^{ab}
对照组 ($n=417$)	2.83 \pm 0.95	2.75 \pm 0.90 ^b	2.64 \pm 0.85 ^b	2.23 \pm 0.57 ^b
$F_{\text{组间/时间/交互}}$ 值		18.73/156.42/25.89		
$P_{\text{组间/时间/交互}}$ 值		<0.01/<0.01/<0.01		

注:与同时点对照组比较,^a $P<0.05$;与同组手术前比较,^b $P<0.05$ 。

表 5 两组患者手术前后血清疼痛介质水平比较 ($\bar{x}\pm s$)
Tab.5 Comparison of serum pain mediator levels between two groups before and after surgery ($\bar{x}\pm s$)

组别	去甲肾上腺素 ($\mu\text{g/L}$)		5-羟色胺 ($\mu\text{mol/L}$)	
	手术前	术后 24 h	手术前	术后 24 h
观察组 ($n=420$)	544.28 \pm 89.51	203.17 \pm 50.66 ^a	0.90 \pm 0.21	0.33 \pm 0.14 ^a
对照组 ($n=417$)	541.93 \pm 87.24	296.45 \pm 57.83 ^a	0.91 \pm 0.20	0.49 \pm 0.17 ^a
t 值	0.38	24.83	0.71	14.89
P 值	0.70	<0.01	0.48	<0.01

注:与同组手术前比较,^a $P<0.05$ 。

表 6 两组手术前后血清炎症因子水平比较 ($\bar{x}\pm s$)
Tab.6 Comparison of serum inflammatory factor levels before and after surgery between two groups ($\bar{x}\pm s$)

组别	IL-6 (mg/mL)		TNF- α (mg/mL)		皮质醇 ($\mu\text{g/L}$)	
	手术前	术后 24 h	手术前	术后 24 h	手术前	术后 24 h
观察组 ($n=420$)	3.40 \pm 0.81	4.52 \pm 1.67 ^a	1.72 \pm 0.51	2.59 \pm 1.09 ^a	174.22 \pm 36.89 ^a	207.33 \pm 41.59 ^a
对照组 ($n=417$)	3.46 \pm 0.79	6.61 \pm 2.01 ^a	1.69 \pm 0.44	3.72 \pm 1.18 ^a	176.48 \pm 35.38 ^a	252.42 \pm 44.55 ^a
t 值	1.09	15.89	0.89	14.20	0.86	15.23
P 值	0.27	<0.01	0.37	<0.01	0.37	<0.01

注:与同组手术前比较,^a $P<0.05$ 。

表 7 两组术后 24 h QoR-40 量表评分比较 (分, $\bar{x}\pm s$)
Tab.7 Comparison of QoR-40 scores between two groups 24 hours after surgery (point, $\bar{x}\pm s$)

项目	观察组 ($n=420$)	对照组 ($n=417$)	t 值	P 值
身体舒适度	54.71 \pm 4.07	39.82 \pm 6.22	41.01	<0.01
情绪状态	39.83 \pm 4.50	30.05 \pm 3.76	34.11	<0.01
自理能力	20.74 \pm 2.57	18.04 \pm 3.95	11.73	<0.01
心理支持	30.41 \pm 3.06	24.25 \pm 2.45	32.14	<0.01
疼痛	30.62 \pm 3.18	21.04 \pm 3.29	42.83	<0.01
总分	176.31 \pm 16.45	133.20 \pm 19.67	34.40	<0.01

3 讨论

本研究纳入的中度至重度烧伤患者的定义为烧伤面积小于体表面积 29% 的 II 度烧伤或烧伤面积小于体表面积 10% 的 III 度烧伤^[7]。在手术和伤口护理过程中,烧伤削痂植皮患者承受着难以忍受的疼痛,

而疼痛的感觉取决于烧伤的程度和烧伤区域的感觉输入^[8]。盐酸羟考酮主要作用于中枢神经系统和平滑肌,对内脏器官也有一定的镇痛作用^[4]。同时,盐酸羟考酮不会引起欣快感、胃肠运动和呼吸抑制,近年来超前镇痛等多种镇痛方式在临床上得到应用^[9]。超前镇痛是指术前通过麻醉阻断神经感觉通路,降低机体对有害感觉的敏感性,从而达到术后镇痛的目的^[3]。

本研究表明,麻醉诱导前 10 min 静脉注射盐酸羟考酮注射液 0.1 mg/kg,能够有效提高烧伤削痂植皮患者围术期的镇痛效果和术后 24 h 的整体恢复质量,且无明显不良反应。本研究观察组的 MAP 和心率与对照组差异有统计学意义,说明盐酸羟考酮超前镇痛提供了更稳定的血流动力学,与边雅楠等^[10]的研究结果基本一致。同时,本研究还观察到,麻醉

诱导后患者 MAP 和心率显著降低,临床上应观察 MAP 和心率是否在正常范围内,密切关注患者基线值、下降速度与持续时间、心脏指数等指标,并决定是否进行积极干预;而在手术过程中,数值保持在正常的临床范围内,但仍需密切关注患者各项指标,并根据临床表现采取干预措施。值得注意的是,盐酸羟考酮减弱了气管插管后 MAP 和心率的增加。以上结果均表明,使用静脉注射 0.1 mg/kg 盐酸羟考酮进行超前镇痛是安全的。

盐酸羟考酮具有 μ 、 κ 受体的双重激动作用,广泛应用于术后镇痛,作用特征与吗啡相似,镇痛效果显著^[11]。在本研究中,超前镇痛方案应用于烧伤削痂植皮患者,观察组患者 VAS 评分在术后各时间点均较对照组患者下降更明显。在麻醉、拔管、疼痛和手术等的刺激下,机体分泌的肾素血管紧张素、醛固酮、肾上腺素、皮质醇和儿茶酚胺会增加,其水平过高会刺激机体的应激反应,不利于患者恢复^[12]。血清去甲肾上腺素、5-羟色胺等疼痛介质的水平是反映应激强度的重要指标。本研究显示,观察组患者术后 24 h 上述指标均明显低于对照组患者,与 Zhang 等^[13]的研究结果基本一致,说明盐酸羟考酮的超前镇痛作用可降低患者应激激素水平,从而抑制手术等引起的过度应激反应。

QoR-40 是一种衡量麻醉和手术后恢复质量的有效、可靠且临床可接受的指标,可与 VAS 评分和躯体症状问卷(Patient Health Questionnaire-9, PHQ-9)相媲美^[14]。在本研究中,观察组术后 24 h QoR-40 整体及所有类别的评分均明显高于对照组,证实盐酸羟考酮超前镇痛可促进患者术后早期恢复,减轻疼痛。此外,观察组患者不良反应总发生率为 9.05%,明显低于对照组的 21.34%,与徐毅明等^[15]的研究结果基本一致,证实盐酸羟考酮超前镇痛还可减少围手术期麻醉引起的不良反应,如恶心呕吐、头晕及呼吸抑制等。

综上所述,盐酸羟考酮超前镇痛方案可以改善烧伤削痂植皮患者围手术期镇痛质量,稳定循环,减少血清疼痛介质的释放和不良反应的发生,促进术后恢复,值得临床借鉴应用。同时,本研究也具有一定的局限性和偏倚性。首先,术前或术后第 2 天和第 3 天未使用 QoR-40 问卷进行评估。此外,由于是单中心设计,研究结果有待进一步讨论和未来更精确地分析。

利益冲突 所有作者均声明不存在利益冲突

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收稿日期:2025-04-08 修回日期:2025-08-09 编辑:王娜娜