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CLINICAL TRIAL REPORT

Hydromorphone is Noninferior to Dexamethasone as an Adjuvant to Ropivacaine for Transversus Abdominis Plane Block After Laparoscopic Colorectal Cancer Surgery: A Randomized, Double-Blind Trial

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Purpose: The transversus abdominis plane (TAP) block provides analgesia for laparoscopic colorectal cancer surgery. To extend block duration and provide adequate analgesia, adjuvants such as dexamethasone and hydromorphone have been used. This study hypothesized that hydromorphone is an effective adjuvant for local anesthetics, and it is noninferior to dexamethasone for the TAP block duration.

Patients and Methods: Eighty-one subjects undergoing laparoscopic colorectal cancer surgery were randomized to Group C (given TAP- block with 40 mL of 0.25% ropivacaine and saline), Group H (given TAP- block with 40 mL of 0.25% ropivacaine, 0.05mg/mL hydromorphone and saline), or Group D (given TAP- block with 40 mL of 0.25% ropivacaine, 0.25mg/mL dexamethasone and saline). The primary outcome was the first request time for patient-controlled intravenous analgesia (PCIA). Additional outcomes included visual analog scale (VAS) scores, total opioid use, side effects including nausea, vomiting, pruritus, and respiratory depression.

Results: Eighty subjects completed the study. Compared with Group C (428.6 ± 175.3 min), both Group D (546.1 ± 190.5 min; P = 0.032) and Group H (620.2 ± 185.3 min; P = 0.001) showed significantly prolonged first request time for PCIA. Moreover, the difference between the mean first request time for PCIA in Group H and Group D was 74.0 (95% confidence interval [CI], −37.7 to 185.7, P = 0.020 for noninferiority). The VAS score on coughing in Group D showed a significant decrease compared with Group C at 12 h post-operatively (P = 0.006). No significant differences were observed in other outcomes.

Conclusion: The addition of hydromorphone to ropivacaine in TAP block provided noninferior analgesia duration compared to dexamethasone for laparoscopic colorectal cancer surgery.

Keywords: hydromorphone, dexamethasone, transversus abdominis plane block, laparoscopic colorectal cancer surgery, postoperative analgesia

Introduction

Laparoscopic surgery is an effective treatment for colorectal cancer. Although it is characterized by less intraoperative blood loss, less postoperative pain, faster recovery of bowel function, and shorter hospital stay compared with traditional open surgery,[1,2] 30%-40% of patients suffer from severe pain in the absence of proper analgesia when undergoing laparoscopic surgery. This pain may affect postoperative recovery and quality of life.[3,4] Multimodal approaches, including patient-controlled intravenous analgesia with low-dose opioids, combined with transversus abdominis plane (TAP) block, can mitigate this pain. Ultrasound-guided TAP block has been reported to reduce pain scores and opioid

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consumption, as well as prolong the time to the first request for analgesia in colorectal surgery.[5–7] However, a single TAP block provides effective abdominal wall analgesia for only an average of 8 h and can be associated with rebound pain as the effect wears off, leading to unanticipated overnight sleep disturbance, increased consumption of opioids, and adverse outcomes in patients.[8] To enhance postoperative recovery and reduce opioid consumption, strategies have been explored to extend the benefits of peripheral nerve (including peripheral nerve, plexus, or fascial plane) blockade beyond the traditional maximum of 4h to 12h.[9–11]

Various adjuvants (dexamethasone, opioids, etc.) have been investigated to prolong the duration of local anesthetic. Dexamethasone, a corticosteroid with anti-inflammatory properties, has been widely used clinically based on evidence showing a 3-hour extension of TAP block duration and reduced opioid-related side effects.[12] However, safety concerns remain regarding its potential neurotoxicity and hyperglycemic effects.[13]

Opioids offer direct analgesic effects through μ-receptor activation, which may synergize with local anesthetics to modulate inflammatory pain pathways.[14] Hydromorphone, a hydrophilic opioid, exhibits a slower onset of analgesia and delayed systemic absorption compared with lipophilic opioids such as fentanyl. These pharmacological characteristics may contribute to prolonged analgesic duration and reduced systemic opioid-related side effects when hydromorphone is used as local anesthetic adjuvant. A previous study has confirmed that hydromorphone added to ropivacaine for brachial plexus blocks could increase block duration without adverse reactions, such as respiratory depression or excessive sedation.[15] However, no relevant studies have investigated its efficacy in TAP block, and there remains controversial regarding whether systemic absorption leads to an increase in opioid-related adverse effects. Therefore, we aimed to explore the potential benefits of hydromorphone as an adjuvant for TAP block, from both efficacy and side effects perspectives. Meanwhile, considering safety concerns associated with dexamethasone, we sought to identify safer and comparable alternatives. Accordingly, we designed a three-arm non-inferiority study to compare perineural hydromorphone with perineural dexamethasone, aiming to investigate the potential clinical value of perineural hydromorphone. We hypothesized that perineural hydromorphone would provide non-inferior analgesic duration to perineural dexamethasone.

Materials and Methods

Study Design

This was a randomized, double-blind, non-inferiority study. The ethical committee of Peking University Shougang Hospital, Beijing, China approved this study (reference number IRBK-2022-102-02) on 30 November 2022. The study was registered at www.chictr.org.cn (ChiCTR2200066907; December 21, 2022) and was performed in accordance with the Declaration of Helsinki. Patients were enrolled at Peking University Shougang Hospital in 2023 between January and July. Written informed consent was obtained from each participant before surgery.

The inclusion criteria were American Society of Anesthesiologists (ASA) classes I-III, ages between 18–70 years, and scheduled laparoscopic colorectal cancer surgery. Patients were excluded if they had significant respiratory, cardiac, hepatic, or renal diseases; a known allergy to the study drugs; injection site infection; chronic pain history; alcohol abuse; opioid dependence; body mass index greater than 35 kg/m2; or those with the psychiatric illnesses that would interfere with perception and assessment of pain. Before anesthesia, patients were taught to evaluate their pain intensity using the visual analog scale (VAS) score and to operate the patient-controlled analgesia machine.

Randomization and Blinding

Patients were randomized into three groups: the hydromorphone group (Group H), the dexamethasone group (Group D), and the control group (Group C). Randomization was performed using the statistical package SPSS to generate blocks of random numbers in groups of six individuals. Before the group assignment, a staff member who was not involved in the study opened the sealed opaque envelopes with the study group allocation and prepared the medication using unidentifiable syringes. The observers, anesthesiologists, and patients were blinded to the treatment-group assignment.

Anesthesia Protocol

On arrival to the operating room, all patients were monitored with non-invasive arterial pressure, electrocardiography, pulse oximetry, end-tidal carbon dioxide, and bispectral (BIS) index. General anesthesia was induced with intravenous sufentanil (0.4 μg/kg), propofol (2–3 mg/kg), and rocuronium (0.6–0.9 mg/kg). Tracheal intubation was facilitated with a tracheal tube of appropriate size. Anesthesia was maintained with remifentanil (0.05–0.2 μg/kg/min), sevoflurane (1–2%), propofol (2–4 mg/kg/h), and rocuronium as necessary. Drug doses were titrated by the anesthesiologist to maintain a BIS index within 40–60 and keep heart rate and mean arterial pressure within ± 20% interval of the preoperative values. The end-tidal carbon dioxide partial pressure was maintained within 35 to 40 mm Hg. 5 μg sufentanil and 5 mg tropisetron were administered approximately 30 min before emergence from anesthesia. At the end of the surgery, sugammadex (2–4mg/kg) was administered to reverse muscle relaxation. Extubation was performed once the spontaneous breathing and consciousness had returned. Patients were then transferred to the post-anesthesia care unit (PACU).

All patients were connected to patient-controlled intravenous analgesia (PCIA) for postoperative pain management, which contained 2ug/kg sufentanil in 100 mL 0.9% normal saline. The PCIA program consisted of a background infusion of 1mL/h, a bolus volume of 2 mL, and a lockout period of 8 min. Pain at rest and on movement (coughing) was assessed using VAS scores for all patients at 6, 12, 24, and 48 h postoperatively. The PCIA was pressed to any patient who had a VAS rest score ≥ 4. Specifically, the patient's first request time for PCIA was recorded. If the postoperative VAS rest score was ≥ 4 after three times of continuous pressing of the PCIA, 50 mg pethidine was administered intramuscularly by a nurse. Nausea and vomiting were recorded using a five-stage verbal descriptive scale (0 = none, 1 = mild nausea, 2 = moderate nausea, 3 = vomiting once, 4 = vomiting more than once) in the 48h postoperatively. Intravenous tropisetron (5 mg) or metoclopramide (10 mg) was administered if the patient vomited.

Intervention

Bilateral ultrasound-guided TAP blocks were performed immediately after induction of anesthesia in all patients by three senior anesthesiologists with more than 5 years of regional anesthesia experience. A junior anesthesiologist was also present to assess the ultrasound image quality together. A high frequency linear ultrasound probe was placed in the axial plane across the mid-axillary line midway between the iliac crest and subcostal margin. Three muscle layers of the obliquus externus abdominis, obliquus internus abdominis, and transversus abdominis muscles were clearly visible in the image. The 21G × 100 mm needle was inserted between the internal oblique and transversus abdominis muscle using an in-plane technique. After careful aspiration to exclude vascular puncture, a test dose of 1 mL of saline was used to separate the plane between the internal oblique and transversus abdominis muscles, which appeared as a hypoechoic space when viewed with ultrasound and then, followed by insertion of the full dose of 20mL local anesthetic. This procedure was repeated on the opposite side of the midline, giving a total volume of 40 mL. If the patient was randomly assigned to Group C, then 40 mL of 0.25% ropivacaine was used. If the patient was randomly assigned to Group H, then 40 mL of 0.25% ropivacaine, 0.05mg/mL hydromorphone, and saline were used. The dose of hydromorphone was converted from the equipotent dose of morphine reported in a previous study.[16] If the patient was randomly assigned to Group D, they received a total 40 mL volume of 0.25% ropivacaine, 0.25mg/mL dexamethasone, and saline; this dose of dexamethasone was commonly used in clinical practice.[12] An independent assessor not involved in the block operation performed a pinprick test (pinprick to the abdominal wall) to assess sensory function when the patient was fully awake in the PACU. A patient's reported response of having no sensation or pinprick not being felt indicated a successful TAP block.

Outcomes

The primary outcome was the first request time for PCIA. Secondary outcomes included VAS scores at rest and on coughing at 6, 12, 24, and 48h postoperatively; total opioid use (all opioids were converted into sufentanil equivalents for comparison); incidence of nausea, vomiting, pruritus, and respiratory depression (respiratory rate less than 8/min); time to pass flatus and pelvic drain removal; patient satisfaction with pain management; hospital length of stay; and surgical

complications including bleeding requiring transfusion, surgical site infection, intra-abdominal abscess, anastomotic leak, and ileus requiring nasogastric tube insertion (NGT).

Statistical Analysis

This three-arm noninferiority study was designed to determine whether Group H achieved a longer duration of TAP block compared with Group C and to verify whether Group H's analgesia duration would be noninferior to that of Group D in laparoscopic colorectal cancer surgery. The first request time for PCIA, as determined from a preliminary study of 10 patients per group (Group C, 482 ± 193.5 min; Group H, 701 ± 206.8 min; Group D, 591 ± 182.7 min) was used to determine the sample size. First, we calculated a sample size based on a superiority test between Group H and Group C. A sample size of 18 patients per group was detected, with an alpha level of 0.025 and a power of 80%. Then, we conducted another sample size calculation based on a noninferiority test between Group H and Group D. Based on the difference in means of 110 min and the noninferiority margin of 60 min (derived from < 1/2 of 142.2 minutes, the lower limit of the 95% confidence interval from a previous meta-analysis[12]), a sample size of 22 patients per group was required, with an alpha level of 0.025 and a power of 80%. Of the two sample sizes above, we chose the larger one. Considering a loss rate of 20%, a total of 81 patients were enrolled in the study. The sample size was calculated using power analysis and sample size calculation software (PASS, version 2023, NCSS, USA).

The analysis was performed using SPSS, version 26 (IBM, Armonk, NY, USA) and SAS version 9.4 (SAS Institute, USA). Depending on the data's distribution, continuous variables were presented as means ± standard deviations (SD) or medians and interquartile range (IQR, Q1- Q3), while categorical variables were presented as numbers or percentages. One-way ANOVA was used to compare normally distributed data, whereas the Kruskal–Wallis test was used for non-normally distributed data. Post hoc analysis was performed using the Mann–Whitney *U*-test with Bonferroni correction for multiple comparisons. The chi-square test and Fisher's exact test were used for categorical data. The first request time for PCIA between Group H and Group D was evaluated using a one-sided *t* test in SAS. If the lower limit of 95% confidence interval (CI) for the difference in mean first request time for PCIA between Group H and Group D was greater than the predefined noninferiority margin of −60, it was considered that Group H is noninferior to Group D. P values <0.05 were considered statistically significant.

Results

A Consolidated Standards of Reporting Trials (CONSORT) flow diagram of patient randomization and exclusion is shown in Figure 1. Eighty patients were enrolled in the study. One patient in Group C was discontinued from the study due to a surgery-related complication. The patient received reoperation on the day after laparoscopic colorectal cancer surgery. There were no significant differences among the groups in baseline demographic characteristics (age, sex, and body mass index), ASA status, duration of surgery or type of surgical incision (Table 1).

Comparison of the Primary Outcome of the Three Groups

The first request time for PCIA was significantly longer in Group D (546.1 ± 190.5 min) and Group H (620.2 ± 185.3 min) than in Group C (428.6 ± 175.3 min) (overall P = 0.002; D vs C, P = 0.032; H vs C, P = 0.001; D vs H, P = 0.176). We then conducted a noninferiority test for Group D and Group H. The difference between the mean first request time for PCIA in Group H and Group D was 74.0 (95%confidence interval [CI], −37.7 to 185.7, P = 0.020), with the lower limit of the 95% CI above the predefined noninferiority margin of −60 (Table 2).

Comparison of Additional Outcomes

VAS scores at rest did not show significant difference among the three groups over time (Figure 2A). There was a statistical difference in VAS scores on coughing among groups at 12 h post-operatively (P = 0.022), mainly it was significantly lower in Group D (2.0 ± 1.1cm) compared to Group C (2.4 ± 0.9 cm; P = 0.006) (Figure 2B). VAS scores on coughing at any other time point were not significantly different (Figure 2B). There was no difference in opioid consumption among the groups at any time points: postoperative 6h, 12h, 24h or 48h (P = 0.160, 0.496, 0.497 and

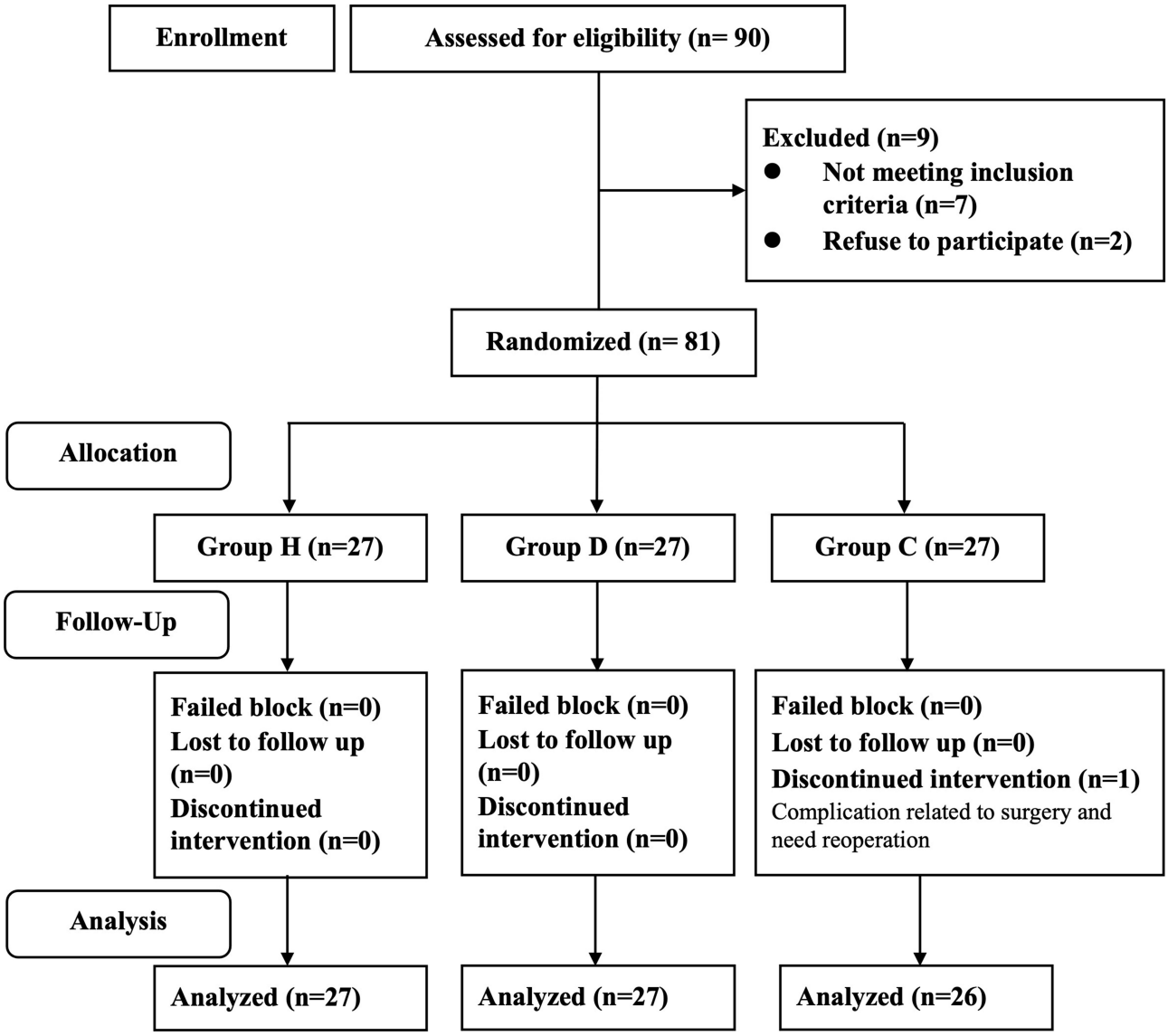

Figure 1 Flow diagram of patient data distribution.

0.443, respectively; Table 2). The number of patients experiencing nausea and vomiting was similar among the three groups (P = 0.468; P = 0.339; Table 3). No pruritus or respiratory depression was observed in patients.

The time to pass flatus, time to pelvic drain removal, length of hospital stays, patient satisfaction with pain management, and surgical complications did not show significant differences among the groups (Table 3).

Discussion

Our findings suggested that the addition of hydromorphone or dexamethasone to TAP block prolonged the first request time for PCIA after laparoscopic colorectal cancer surgery. The effect of hydromorphone on prolonging TAP blockade time was non-inferior to the dexamethasone group. Additionally, we demonstrated that perineural dexamethasone reduced pain scores on coughing at 12 h post-operatively.

Hydromorphone is chemically similar to morphine, and it is considered to have some advantages based on analgesia and relevant side effects (nausea, vomiting, respiratory depression, and itch).[17] In our study, the analgesia of TAP block was prolonged by 3 h with the addition of hydromorphone (0.05mg/mL). This was partially consistent with what was found in a recent study performed by El Sherif et al,[16] which demonstrated that the addition of morphine to bupivacaine

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Table 1 Baseline Demographics of Study Subjects

Characteristic	Group H (n=27)	Group D (n=27)	Group C (n=26)	P value
Age (years)	53.1±12.3	58.4±9.7	59.4±6.2	0.052
Sex				0.795
Male	18 (66.7)	17 (63.0)	15 (57.7)	
Female	9 (33.3)	10 (37.0)	11 (42.3)	
Body mass index, kg m^{-2}	23.3±3.4	24.1±3.8	23.8±3.4	0.671
ASA status				0.818
I	2 (7.4)	3 (11.1)	1 (3.9)	
II	20 (74.1)	21 (77.8)	20 (76.9)	
III	5 (18.5)	3 (11.1)	5 (19.2)	
Duration of surgery (min)	162.4±47.5	169.8±62.5	176.2±73.8	0.723
Type of surgical incision				
Low midline vertical incision	27 (100.0)	27 (100.0)	26 (100.0)	–

Note: Data are reported as mean ± SD or number (%).
Abbreviation: ASA, American Society of Anesthesiologists.

Table 2 The First Request Time for PCIA and Total Opioid Consumption of Three Groups

	Group H (n=27)	Group D (n=27)	Group C (n=26)	P value
The first request time for PCIA (min)	620.2±185.3†#	546.1±190.5*	428.6±175.3	0.002
Total opioid consumption (ug)				
6h	8.2±1.4	9.9±4.6	9.9±4.0	0.160
12h	19.7±4.4	22.8±9.5	24.0±11.1	0.496
24h	41.2±8.9	45.5±22.8	48.7±22.9	0.497
48h	82.0±16.8	85.2±28.6	93.5±31.1	0.443

Notes: Data are reported as mean ± SD. †P = 0.001 vs corresponding data of Group C. *P = 0.032 vs corresponding data of Group C. # The mean difference (95% confidence interval [CI]) between Group H and Group D was 74.0 (−37.7 to 185.7), P = 0.020.
Abbreviation: PCIA, patient-controlled intravenous analgesia.

in TAP blocks prolonged the time to first request of analgesia by nearly 4 hours. However, two previous studies showed that the addition of fentanyl to TAP block was not found to prolong the duration of analgesia, which was inconsistent with the finding of our research.[9,18] We hypothesized that this discrepancy lies in the distinct physicochemical properties of these opioids. Fentanyl, due to its high lipophilicity, potentially diffuses into peripheral adipose tissues, which may reduce its bioavailability at neural targets. In contrast, both hydromorphone and morphine, being hydrophilic, may result in slower diffusion through perineural sheaths. This delayed tissue penetration may contribute to prolonged analgesic duration.

This was the first study to compare perineural hydromorphone to perineural dexamethasone for use in TAP blocks and found perineural hydromorphone prolonged the first request time for additional analgesic by 74 minutes compared to the dexamethasone group. There have been multiple published studies comparing perineural opioids to the control but none

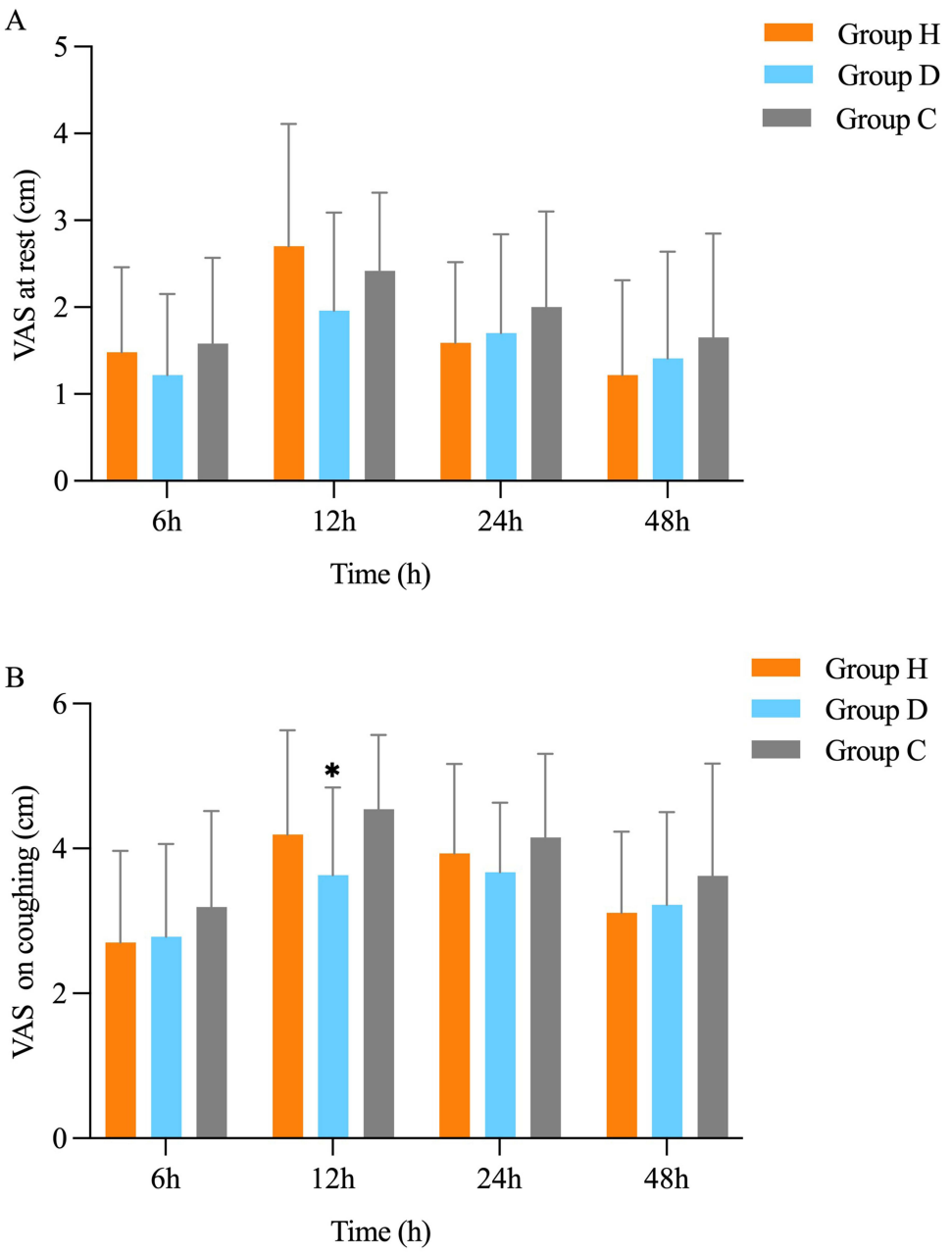

Figure 2 VAS scores at rest (**A**) and on coughing (**B**) over time for patients. Data are reported as means ± SD. *P = 0.006 vs corresponding data of Group C.
Abbreviation: VAS, visual analog scale.

to the perineural dexamethasone. Only a meta-analysis that made indirect comparisons and its results showed that fentanyl combined with local anesthetic for peripheral nerve block was not superior to dexamethasone, which did not conflict with our findings.[19] Contrary to the study by El Sherif et al,[16] our analysis suggested that perineural hydromorphone did not reduce postoperative pain scores or opioid consumption. This could be due to the use of background PCIA infusion. El Sherif et al used PCIA with no background infusion, whereas we applied PCIA with continuous low-dose background infusion, which may mitigate intergroup differences in VAS scores and opioid consumption, as continuous opioid delivery reduced breakthrough pain.[20] While clinically relevant, this design choice and the small sample size limited the ability to detect minor differences in analgesic effects among groups. Future larger trials could explore adjuvant effects in the context of no background infusion PCIA. However, in this study, while hydromorphone

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Table 3 Perioperative Outcomes of Study Subjects

Outcome	Group H (n=27)	Group D (n=27)	Group C (n=26)	P value
Nausea	6 (22.2)	9 (33.3)	9 (34.6)	0.468
Vomiting	4 (14.8)	1 (3.7)	2 (7.7)	0.339
Pruritus	0 (0)	0 (0)	0 (0)	–
RR<8	0 (0)	0 (0)	0 (0)	–
Days to pass flatus	3 (2–4)	3 (2–3)	3 (2–4)	0.712
Days to pelvic drain removal	7 (6–8)	8 (7–9)	10 (7–12)	0.075
Length of hospital stay (days)	19±6	18±5	21±8	0.093
Patient satisfaction in 48h	8 (7–9)	9 (8–9)	8 (7–9)	0.294
Surgical complication				
Bleeding requiring transfusion	0 (0)	0 (0)	0 (0)	–
Surgical site infection	0 (0)	0 (0)	0 (0)	–
Intra-abdominal abscess	0 (0)	0 (0)	0 (0)	-
Anastomotic leak	1 (3.7)	1 (3.7)	0 (0)	0.394
Ileus requiring NGT	0 (0)	0 (0)	0 (0)	-

Note: Data are reported as mean ± SD, median IQR (Q1 - Q3) or number (%).
Abbreviations: RR, respiratory rate (breaths/min); NGT, nasogastric tube insertion.

was noninferior to dexamethasone as a TAP block adjuvant statistically, the clinical benefit was modest in terms of pain scores and opioid consumption.

The risks of adverse effects and neurotoxicity should be considered for all local anesthetic adjuncts. Perineural dexamethasone can produce an increase in postoperative blood glucose concentration, with a mean increase of 0.2 mmol/L.[21] However, other theoretical concerns, including neurotoxicity, delayed wound healing, and postoperative systemic or wound infection were not demonstrated in systematic reviews.[22–24] Similarly, we did not find related adverse effects in the dexamethasone group. A meta-analysis reported that compared with anesthetic, dexamethasone used in TAP block reduced the incidence of postoperative nausea and vomiting by nearly 72%.[25] In comparison, this effect was much weaker in our study. This could be attributed to the administration of antiemetics, some publication bias, and heterogeneity in meta-analyses. No clinically significant differences in the adverse effects were observed in the hydromorphone group. The neurotoxicity of hydromorphone has rarely been reported, and there is no evidence from available studies that hydromorphone use causes neurotoxic effects in patients with normal renal function.[26] Given this, hydromorphone may be considered as an alternative adjuvant to dexamethasone with local anesthetics. Nevertheless, the adverse events in this study were exploratory, and these findings should be interpreted cautiously.

Our study has several limitations. First, we did not assess blood hydromorphone concentrations and thus could not determine whether its effect was partially due to systemic absorption or purely local. Second, the sample size of this study was small. The superiority of hydromorphone over dexamethasone and rare complications related to perineural opioid use need to be confirmed by a larger sample size. Third, we evaluated satisfaction at 48h postoperatively and found no difference among the three groups. However, the analgesic duration of TAP block in all patients was within 24h. In this study, a 24-hour satisfaction score would more likely to reflect the patient's satisfaction with pain treatment. Fourth, we did not conduct the long-term follow-up to evaluate delayed adverse effects or persistent pain, which may restrict the safety interpretation. Fifth, this study was a single-center design, and the selective inclusion and exclusion criteria may limit its external validity. Finally, given the cost difference, perineural hydromorphone's benefit needs to be reevaluated in laparoscopic colorectal cancer surgery prudently.

Conclusion

In this single-center randomized trial, TAP block with hydromorphone demonstrated statistical noninferiority to dexamethasone in prolonging the first analgesic request time for patients undergoing laparoscopic colorectal cancer surgery. However, the clinical relevance of a mean difference of 74 minutes should be interpreted with caution, as secondary outcomes (pain scores, opioid consumption, adverse effects) were largely similar across groups. These results show that hydromorphone may be an alternative for patients in whom dexamethasone is relatively contraindicated, rather than as a routine replacement for dexamethasone in TAP block.

Given the single-center design and limited sample size, further research is warranted to confirm the mechanism of action and generalizability of these findings.

Data Sharing Statement

We intend to share individual deidentified participant data and the datasets generated during and/or analyzed in this study. Study protocol and statistical analysis plan can be made available. The data will be released immediately upon manuscript publication and retained for a long time; upon reasonable request, they can be accessed via the corresponding author's email.

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Disclosure

The authors declare that there are no conflicts of interest in this work.

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