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CLINICAL TRIAL REPORT

Effect of General Anesthesia Combined with Transversus Abdominis Plane Block on Postoperative Sleep Disorders in Elderly Patients Undergoing Gastrointestinal Tumor Surgery: A Prospective, Randomized Controlled Trial

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Purpose: The aim of this study was to investigate the effect of general anesthesia combined with transversus abdominis plane block on postoperative sleep disorders in elderly patients undergoing gastrointestinal tumor surgery.

Methods: For elderly patients with gastrointestinal malignant tumors, we recruited 94 patients, aged 65–80, who were scheduled for radical laparoscopic surgery. Using the random number table method, the patients were randomly divided into two groups, the general anesthesia group (group GA) and the general anesthesia combined with transversus abdominis plane block group (group GT). The group GA received the sedation-aspiration complex general anesthesia regimen, while the group GT underwent bilateral transversus abdominis plane blocks (TAPB) after the same induction of anesthesia. Group GA was injected bilaterally with equal amounts of saline in the same way. Sleep was monitored using wearable devices on the first day before surgery (P1) and the first and third day after surgery (D1 and D3). The Pittsburgh Sleep Quality Index(PSQI) scale was used to assess sleepiness and the occurrence of post-operative sleep disorders (POSD) on P1, D1 and D3 nights, respectively.

Results: Compared to the group GA, the group GT showed a significant decrease in remifentanil use during surgery ($P<0.05$). At D1, the group GT showed an increase in the ratio of deep sleep to rapid eye movement sleep (REM), along with a significant decrease in the number of wakefulness ($P<0.05$). At D3, the proportion of REM continued to increase and PSQI scores were significantly lower at both D1 and D3 ($P<0.05$). In addition, the incidence of POSD and the visual analog scores (VAS) at 0.5h and 6h postoperative activity in D1 showed a decreasing trend ($P<0.05$). However, no significant differences were observed between the two groups in general condition, intraoperative condition, remedial analgesia and number of analgesic pump presses ($P>0.05$).

Conclusion: General anesthesia combined with transversus abdominis plane block reduces the dosage of opioids in abdominal surgery, especially gastrointestinal surgery, alleviates postoperative pain in elderly gastrointestinal oncology patients, improves sleep quality, and reduces the incidence of sleep disorders.

Keywords: transversus abdominis plane block, sleep disorders, elderly, gastrointestinal tumors, Pittsburgh sleep quality index

Introduction

Sleep is an integral part of human life activities and is a physiological phenomenon that is actively produced and regulated by the brain.[1,2] With age, the amplitude of circadian oscillations of bodily functions, including sleep, as well as melatonin levels, gradually decreases, and the efficiency of the suprachiasmatic nucleus of the hypothalamus decreases, a situation that can result in altered sleep patterns with age, which in the elderly population manifests itself in the following ways Increased percentage of light sleep time (N1 and N2), sleep fragmentation, and forward phase shift of circadian rhythms, etc. Also opioids, depression, chronic pain, and neurodegenerative changes can lead to predisposition to sleep disorders in elderly

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patients.[3,4] POSD is a common clinical phenomenon in surgical patients, which manifests itself as an abnormal quality of sleep for at least one day postoperatively or as behavioral abnormalities, such as sleep fragmentation, frequent nocturnal awakenings, difficulty falling asleep, sleep deprivation, early awakening, and sleep rhythm disorders.[5,6] Factors triggering POSD are manifold, mainly surgical trauma, pain, use of anaesthetics, age, environmental factors, preoperative comorbidities and type of surgery. Age is an important preoperative factor in perioperative sleep disorders, and its influence is mainly reflected in the changes in sleep structure during aging and the diminished ability to adaptively regulate sleep in response to environmental changes.[5] Therefore, based on the special needs and challenges of perioperative management of elderly patients, as well as the high prevalence of postoperative sleep disorders and the statistical significance of their associated complications in this age group, we chose the elderly patient population as the study population.

TAPB is performed by injecting local anesthetic drugs into the fascial space between the transversus abdominis muscle and the internal oblique muscle and blocking the abdominal wall nerves that travel in this plane.[7] To achieve analgesia and anesthesia in the abdominal wall region, an ideal block and dosing regimen can produce analgesia for 15–20 hours.

Previous studies have shown that general anesthesia combined with TAPB significantly reduces intraoperative opioid use and improves patient prognosis.[8] However, its effectiveness in improving postoperative sleep quality in elderly patients has yet to be thoroughly investigated. In this study, we propose to evaluate the effect of general anesthesia combined with TAPB on patients' POSD in elderly patients undergoing gastrointestinal oncology surgery, with the aim of providing a valuable reference basis for clinical anesthesia.

Methods

Study Design and Participants

This single-center, prospective, double-blind, randomized controlled trial was formally approved by the Medical Ethics Committee of the Second People's Hospital of Changzhou Affiliated to Nanjing Medical University (No. 2023YLJSA030), and registered in the China Clinical Trial Registry (Registration No. ChiCTR2300075329). All patients and their families participating in the study have signed an informed consent form to ensure that each patient and their family fully understand the study and agree to participate in this study.

From August 2023 to March 2024, this study included elderly patients who were to undergo laparoscopic radical surgery for gastrointestinal malignant tumors at the Changzhou Second People's Hospital affiliated with Nanjing Medical University, with an age range of 65–80 years old, American Society of Anesthesiologists (ASA) classification I to II, body mass index (BMI) of 18–30 kg/m², and no restriction on gender. Patients who met the following criteria were excluded from the study: (1) preoperative PSQI scores higher > 7, (2) sleep apnea syndrome, (3) severe cardiac, cerebral, hepatic, and renal diseases, (4) long-term application of narcotic analgesics or sedatives, (5) patients with history of psychiatric disorders, such as anxiety and depression. During the course of the study, we excluded participants who changed surgical methods, had incomplete follow-up data, withdrew midway, failed or developed complications from TAPB treatment, and were transferred to the ICU after surgery.

Randomization and Blinding

All enrolled patients underwent laparoscopic radical surgery for gastrointestinal malignancies. Patient eligibility was assessed by a two-step screening with final enrollment and randomization. Initial screening, recruitment, final enrollment, and randomization were performed 1 day before surgery. Patients were assigned to either the group GA or the group GT by a computer-generated table of random numbers. Group assignments were sealed in sequentially numbered opaque envelopes. Patients, attending surgeons, data collectors, and individuals performing final statistical analyses were unaware of group assignments.

Anesthetic and Analgesic Techniques

Electrocardiogram (ECG), heart rate (HR), peripheral vascular oxygen saturation (SpO_2), blood pressure (BP), and Bispectral index (BIS) were routinely detected on admission, and oxygen denitrification was administered for 3 min

(oxygen flow rate of 6 L/min). The peripheral venous access was opened, and 8 $mL \cdot kg^{-1} \cdot h^{-1}$ of crystalloid or colloid fluid was infused intravenously, and under local anesthesia, the patients' intraoperative invasive arterial pressure was monitored by radial artery puncture catheterization. Anesthesia was induced in the GA group by the intravenous injection of midazolam 0.03 mg/kg, propofol 1.5–2.5 mg/kg, sufentanil 0.3–0.5 μg/kg, and rocuronium bromide 0.6–1.2 mg/kg, and after successful tracheal intubation, mechanical ventilation was implemented with an oxygen concentration of 60%, a tidal volume of 6–8 mL/kg, and a ventilation rate of 12–16 times/min. The partial pressure of end-expiratory carbon dioxide ($PETCO_2$) was maintained at 35–45 mmHg (1 mmHg = 0.133 kPa). For anesthesia maintenance, propofol and remifentanil were infused by inhalation of sevoflurane and target-controlled infusion, with initial effector compartment concentrations of 3 μg/mL and 4 ng/mL, respectively (adjusted intraoperatively according to the BIS value and hemodynamic dynamics), and myorelaxation was maintained with an intravenous infusion of cisatracurium 0.1 $mg \cdot kg^{-1} \cdot h^{-1}$. If the patient's blood pressure dropped more than 20% of the basal value or the systolic blood pressure <90mmHg during the operation, ephedrine 6mg was injected to elevate the blood pressure; if the heart rate was ≤50 beats/min, atropine 0.5mg was injected to increase the heart rate.

Postoperatively, both groups received patient-controlled intravenous analgesia (PCIA), in which we used a mixture of oxycodone (0.8 mg/kg) and tropisetron (6 mg) diluted to 100 mL with saline. PCIA settings included a background dose of 2 mL/h, a single dose of 2 mL, and a lockout duration of 15 minutes. If remedial analgesia was required, 75 mg of diclofenac sodium lidocaine was injected intramuscularly.

Intervening Measure

After anesthesia induction was completed in patients of group GT, they were placed in supine position, and the probe was placed transversely under the raphe to find the paired rectus abdominis muscle images and white lines, followed by panning the probe along the edge of the ribs to the midclavicular line, which clearly showed the triple structure of the external abdominal obliquity, internal abdominal obliquity, and transversus abdominis muscle. Using the in-plane approach, the puncture needle was inserted into the superficial surface of the transversus abdominis muscle below the tendinous membrane of the internal oblique muscle, and after retracting without blood and gas, 30 mL of 0.25% ropivacaine was injected, and the contralateral TAPB was performed in the same way (Figure 1). Group GA was injected bilaterally with equal amounts of saline in the same way.

Clinical Data Collection

Intraoperatively, detailed records of fluid intake, bleeding, urine output, anesthesia time, operation time, anesthesia medication dosage, as well as remedial analgesia and the total number of analgesic pump compressions were recorded for

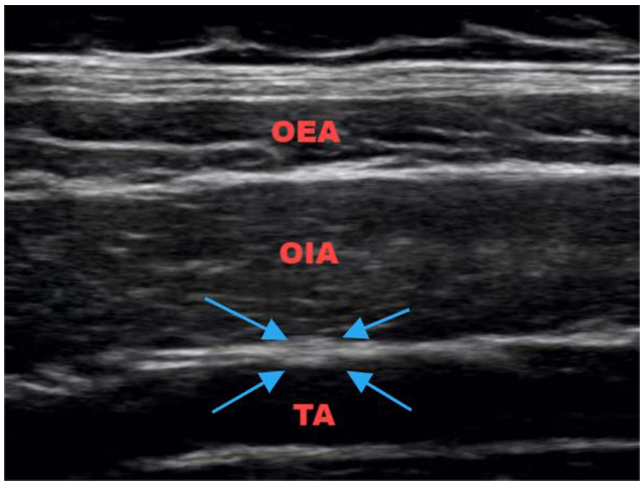

Figure 1 TAPB ultrasound schematic. The plane of local anesthetic injection is indicated by the arrow in the figure.
Abbreviations: OEA, obliquus externus abdominis; OIA, obliquus internus abdominis; TA, Transversus abdominis.

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48 hours after the operation. Sleep parameters, including the percentage of deep sleep, percentage of light sleep, percentage of REM, number of wakefulness, sleep continuity score, and sleep respiratory quality score, were monitored on P1 and D1, D3 nights (8:00 pm to 8:00 am the next day) using a wearable device (wireless smart band Honor 7, Honor Terminal Company Limited). At P1, D1 and D3 follow-up, subjective sleep quality was assessed using the PSQI[9] scale, which consists of 7 parts and 18 entries, with a total score ranging from 0 to 21, and the higher the score, the poorer the sleep quality. To screen for nonanxious and depressed patients, 1 day before surgery we assessed using the Hamilton Anxiety Scale (HAMA)[10] and the Depression Screening Scale (PHQ-9).[11] The same anesthesiologist responsible for PSQI scoring would record the patient's VAS[12] scores at 0.5h after extubation, and at 6h, 12h, and 24h postoperatively in the activity and rest states.

Observation Outcomes

Primary outcome: the incidence of postoperative sleep disorders in the two groups. Secondary outcomes: PSQI scores of P1, D1 and D3; sleep parameters monitored by P1, D1 and D3 using wearable smart bracelets; the situation of VAS scores in the 24h postoperative period; the number of effective presses of analgesic pumps in the 48h postoperative period, and the situation of remedial analgesia in the ward.

Sample Size

In this study, PASS 17.0 software was used to estimate the sample size, and the main outcome was the incidence of POSD in D1. Based on the pre-test, the incidence of POSD in D1 was 64% and 30% in the GA and GT groups, respectively. A two-sided test was set with α=0.05 and 1-β=0.9, and a minimum of 43 patients were required in each group. Considering a 10% dropout rate, the plan was to recruit at least 47 subjects in each group.

Statistical Analysis

SPSS software version 26.0 was used for analysis in this study, and $P<0.05$ was considered statistically significant. The measurement variables are represented as mean±standard deviation (SD), and countable data are represented by case number or percentage. The *t*-test of independent samples was used for pairwise comparisons between groups, and the analysis of variance of repeated measurement data was used for intra- and inter-group comparisons at different time points. During data processing, we will eliminate data that are too biased and lack practical significance.

Results

We initially evaluated 102 patients for eligibility to participate in this study, of which 6 patients did not meet the inclusion criteria and 2 patients declined to participate. The remaining 94 patients were enrolled in the study. Subsequently, 1 patient changed the surgical procedure, 1 withdrew midway, 3 were lost to postoperative visits, and 2 were transferred to the ICU; a total of 7 cases were excluded. Finally 87 cases were included in the statistical analysis, 44 cases in the group GA and 43 cases in the group GT (Figure 2).

There were no significant differences between the two groups in terms of gender, age, BMI, preoperative anxiety and depression assessment, and type of surgery ($P>0.05$), as shown in Table 1. In the group GT, we did not observe any record of adverse reactions, including but not limited to infection, hematoma formation, nerve damage, and local anesthetic toxicity, which ensured the safety of the operation.

Compared with the group GA, the use of remifentanil during the operation was significantly lower in the group GT ($P<0.05$). However, there was no significant difference between the two groups in terms of operation time, anesthesia time, propofol, sufentanil and ephedrine dosage, as well as fluid intake, bleeding, urine output, number of analgesic pump presses and remedial analgesic needs ($P>0.05$) (Table 2).

In terms of sleep parameters captured by the smart band, compared to the group GA, the proportion of both deep sleep and REM increased in the group GT in D1 ($P<0.05$), and the number of wakefulness decreased ($P<0.05$). In D3, the proportion of REM was still higher in the group GT ($P<0.05$). There was no significant difference between the two groups in each sleep parameter of P1 and the number of wakefulness, sleep continuity and sleep breathing quality scores ($P>0.05$) (Figure 3).

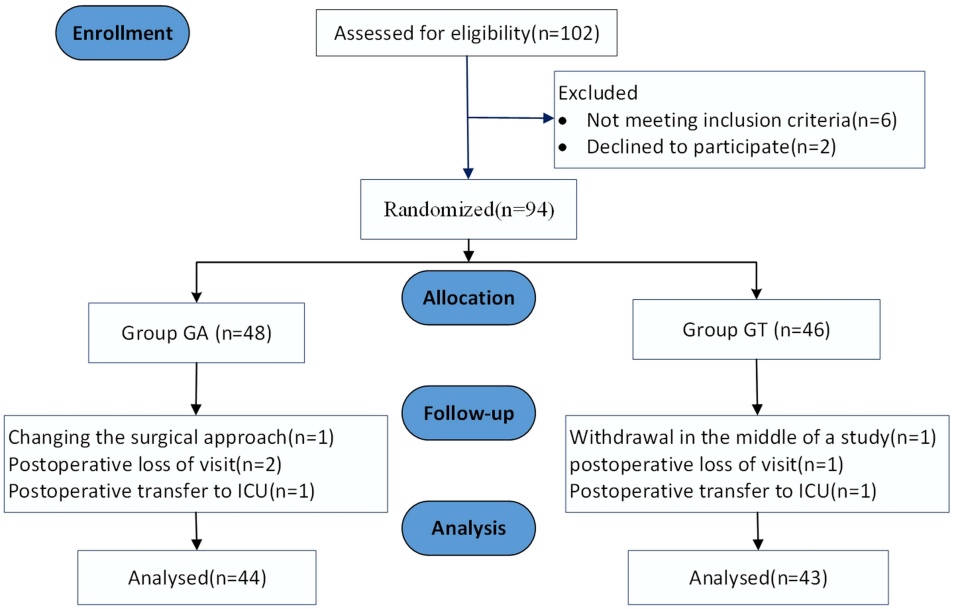

Figure 2 Flow chart of included population.

The patient's perioperative PSQI score and incidence of POSD were assessed by a specialized anesthesiologist. Compared with the group GA, the group GT showed a significant decrease in D1 and D3 PSQI scores (P<0.05) and a decrease in the incidence of D1 POSD (P<0.05). There was no significant difference between the two groups in P1 PSQI scores and the incidence of D3 POSD (P>0.05) (Table 3).

Comparing the VAS scores of the two groups of patients at each time point during the 24h postoperative period, the VAS scores at 0.5h and 6h postoperative activity were decreased in the group GT (P<0.05), and no significant difference was observed in the VAS scores at 6h and 12h postoperative activity and at rest at all postoperative time points (P>0.05)(Figure 4).

Discussion

Normal human physiological sleep is divided into non-rapid eye movement (NREM) and REM, and the NREM and REM cycles are repeated 4–6 times per night, each lasting 90–100 minutes. NREM is divided into three stages, N1, N2, and N3, which account for 2%-5%, 45%-55%, and 15–20% of the total sleep time, respectively, while REM accounts for 20–25% of the entire total duration of sleep.[13,14] High-quality sleep is essential for maintaining normal physical and mental health, and the prevalence of POSD is high in patients undergoing major surgery and in elderly patients.[15] POSD can weaken the immune system, increase the risk of cardiovascular disease, and interfere with postoperative recovery, leading to anxiety, depression, postoperative delirium, or prolonged cognitive decompensation.[5,15] Studies have found

Table 1 Patient Baseline Profile Characteristics

Characteristic	Group GA (n=44)	Group GT (n=43)	P value
Gender, M/F	20/24	17/26	0.475
Age, mean±SD, y	70.91±3.69	70.49±3.61	0.572
BMI, mean±SD, kg/m^2	23.24±2.12	23.82±1.35	0.137
Anxiety scores, mean±SD, score	3.09±1.36	3.00±1.00	0.724
Depression scores, mean±SD, score	1.36±1.12	1.56±0.98	0.393
Type of surgery, n(%)			0.460
Radical surgery for gastric tumors	21(47.73)	18(41.86)	
Radical surgery for intestinal tumors	23(52.27)	25(58.14)	

Abbreviation: BMI, body mass index.

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Table 2 Patient Perioperative Data Characteristics

Characteristic	Group GA (n=44)	Group GT (n=43)	P value
Duration of surgery, mean±SD, min	170.34±16.08	174.30±17.10	0.269
Duration of anesthesia, mean±SD, min	199.77±21.02	200.12±16.57	0.933
Consumption of anesthetic drugs			
Propofol, mean±SD, mg	470.91±55.11	476.63±45.51	0.600
Remifentanil, mean±SD, mg	1.02±0.13	0.94±0.10	0.001
Sufentanil, mean±SD, ug	41.59±4.91	42.26±4.05	0.493
Ephedrine, mean±SD, mg	10.16±5.94	9.70±4.58	0.686
Intraoperative fluid input volume, mean±SD, mL	1902.95±228.98	1867.67±181.74	0.429
Intraoperative blood loss, mean±SD, mL	103.64±13.22	99.42±9.95	0.097
Urine output, mean±SD, mL	592.95±72.96	576.28±68.35	0.275
Effective number of analgesic pump presses, mean±SD, times	1.68±1.25	1.40±0.88	0.221
Postoperative remedial analgesia, n (%)	15(34.09)	8(18.60)	0.102

that intraoperative opioids, as well as postoperative pain, can lead to decreased sleep quality after falling asleep, such as shorter sleep duration, reduced sleep efficiency, and reduced sleep depth.[16] In addition, it has also been shown that POSD may enhance patients' pain perception by affecting pain modulation pathways, and that lack of sleep can lower pain thresholds and make patients more sensitive to the perception of pain.[17,18] Our study was conducted on patients who underwent laparoscopic radical surgery for gastrointestinal malignant tumors with intraoperative Bilateral TAPB was performed before surgery, and patients' preoperative and postoperative sleep was carefully evaluated using the PSQI scale and the smart band honor 7. We found that TAPB can improve POSD, reduce the use of opioids, improve patients' comfort, and has important clinical value in pain management in gastrointestinal oncologic surgery.

Polysomnography is the gold standard for the diagnosis of sleep-related diseases and a commonly used means of sleep monitoring, but its complexity, accessibility, and impact on subject comfort are all shackles to its further

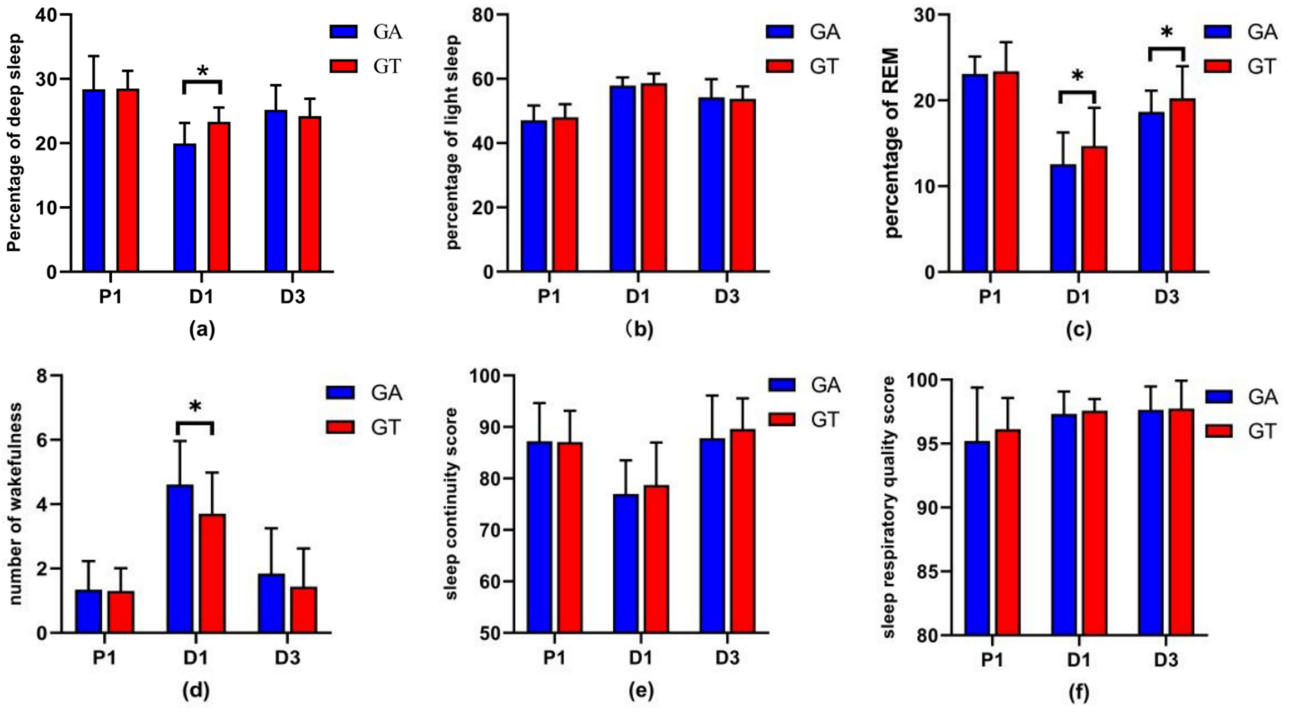

Figure 3 Sleep parameters captured by the wearable smart band ((**a**):percentage of deep sleep; (**b**):percentage of light sleep; (**c**):percentage of REM; (**d**):number of wakefulness; (**e**):sleep continuity score; (**f**):sleep respiratory quality score). *P<0.05 versus the Group GA.
Abbreviations: REM, rapid eye movement; P1, first day before surgery; D1, first day after surgery; D3, third day after surgery.

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Table 3 Patient PSQI Scores and Incidence of POSD

	PSQI, mean±SD, score			POSD, n (%)		
	P1	D1	D3	P1	D1	D3
Group GA(n=44)	4.43±1.021	7.77±1.395	6.02±1.229	—	26 (59.09)	10 (22.73)
Group GT(n=43)	4.37±0.976	6.26±1.498	4.88±1.349	—	13 (30.23)	5 (11.63)
P value	0.781	<0.001*	<0.001*	—	0.002*	0.067

Notes: *P<0.05 versus the Group GA.
Abbreviations: PSQI, Pittsburgh Sleep Quality Index; POSD, postoperative sleep disorders; P1, first day before surgery; D1, first day after surgery; D3, third day after surgery.

development and application. Studies have confirmed that wearable devices can objectively monitor the body's activity level and sleep, that they are easy to operate, and that they can monitor postoperative sleep in real time and objectively, which can meet the needs of clinical sleep monitoring.[19] The smart bracelet Honor 7 used in this study is based on the TruSleepTM sleep monitoring algorithm (TruSeenTM 2.0) with heart rate and motion sensors, which is validated by the University of Bern in Switzerland. With high-precision monitoring capability, it can accurately differentiate between deep sleep, light sleep, REM and awakening states, and its accuracy is as high as 96.3% when benchmarked against professional polysomnography monitors. With a PSQI score of 7, the sensitivity and specificity of assessing sleep disorders were 98.3% and 90.2%, respectively (Kappa=0.89, P<0.01)[20], which justifies the subjective assessment of sleep with the PSQI scale. Therefore, in this study, we used the PSQI scale and wearable smart band honor 7 to comprehensively assess the sleep of elderly patients undergoing surgery for gastrointestinal tumors from both subjective and objective aspects.

The results of this study showed that the group GT had a higher proportion of deep sleep and REM and a lower number of wakefulness at D1, a higher proportion of REM at D3, and lower PSQI scores at D1 and D3, in addition to a significantly lower incidence of POSD at D1, which suggests that general anesthesia in combination with a TAPB can effectively improve POSD in elderly patients undergoing surgery for gastrointestinal tumors. In the present study, we demonstrated that intraoperative remifentanil use in the GT group was significantly lower than that in the GA group, probably because TAPB provided additional intraoperative analgesia, patients' intraoperative pain perception was reduced, and opioid requirements were reduced accordingly. One previous study demonstrated that[21] normally, adenosine levels peak during sleep and promote sleep, and that opioids may reduce the pontine reticular formation of the basal forebrain and the anaphase region of the anterior cerebral plexus by either blocking the release of adenosine or by promoting the degradation of adenosine and anaphase regions of the basal forebrain, thereby interfering with sleep. Previous reports have shown that one way in which opioids affect sleep is through μ-opioid receptors on GABAergic neurons located in the ventrolateral prefrontal cortex (VLPO), and that, in isolated brain slices, opioids hyperpolarize the membrane potential in the VLPO and inhibited the firing of these sleep-promoting neurons.[22,23] One researcher demonstrated that patients with intraoperative remifentanil had significantly lower quality of sleep, with a 72.3%

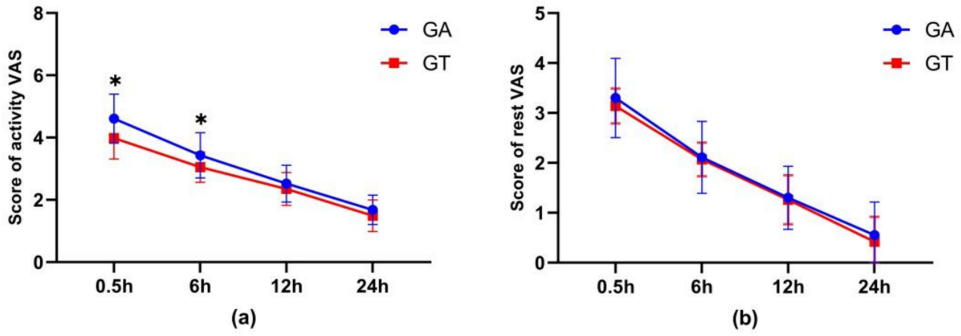

Figure 4 Patients' activity VAS and rest VAS scores at different postoperative time points. ((**a**):Score of activity VAS; (**b**):Score of activity VAS). *P<0.05 versus the Group GA.

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reduction in REM sleep period, which is consistent with the findings of the present study.[24] Therefore, it can be hypothesized in this study that the effect of general anesthesia combined with TAPB to improve POSD in elderly patients undergoing gastrointestinal oncologic surgery may stem from the reduction in intraoperative remifentanil use.

In addition, VAS scores at 0.5h and 6h of postoperative activity were significantly lower in the group GT than in the group GA in this study. Numerous studies found that pain patients experienced longer delays in falling asleep, woke up more often during the night, and had a shorter duration of sleep, lower sleep efficiency, and less deep sleep;[25,26] Kapustin and others confirmed that pain patients spent more time and experience more sleep fragmentation, altered NREM sleep, REM sleep and wakefulness periods, and altered delta power during NREM sleep.[27,28] Therefore, it can be speculated in this study that the ameliorative effect of TAPB on POSD may also be related to postoperative pain relief in patients.

This study has some limitations because its sample only included patients aged between 65 and 80 years, and further stratification is needed in the future to explore the effects of TAPB on POSD in patients of different ages; secondly, the postoperative follow-up time in this study was only 3 days, which may not fully reflect the long-term effects and complication rates, and prolonging the follow-up time may be more helpful in assessing the effects of general anesthesia combined with transversus abdominis plane block on the patients with sleep disorders and its long-lasting effects; furthermore, this study did not adequately control for other factors that may affect sleep quality, such as postoperative medication use, postoperative complications, noise, light, and turnover in the ward at night, which are potential factors that may affect the accuracy and reliability of the results.

Conclusion

In conclusion, general anesthesia combined with transversus abdominis plane block can reduce the dosage of opioids in abdominal surgery, especially gastrointestinal surgery, alleviate postoperative pain in elderly gastrointestinal tumor patients, improve the quality of sleep, and reduce the incidence of sleep disorders.

Data Sharing Statement

Data supporting the results of this study are available from the corresponding author (Yimin Hu) upon request.

Statement of Ethics

This study was conducted in accordance with the Declaration of Helsinki, and approved by the Medical Ethics Committee of the Second People's Hospital of Changzhou Affiliated to Nanjing Medical University (No. 2023YLJSA030). All patients and their families have signed an informed consent form.

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Disclosure

The authors report no conflicts of interest in this work.

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