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AIMS AND SCOPE

The primary aim of World Journal of Gastrointestinal Surgery (WJGS, World J Gastrointest Surg) is to provide scholars and readers from various fields of gastrointestinal surgery with a platform to publish high-quality basic and clinical research articles and communicate their research findings online.

WJGS mainly publishes articles reporting research results and findings obtained in the field of gastrointestinal surgery and covering a wide range of topics including biliary tract surgical procedures, biliopancreatic diversion, colectomy, esophagectomy, esophagostomy, pancreas transplantation, and pancreatectomy, etc.

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ORIGINAL ARTICLE

Retrospective Study

Analgesic effect of ultrasound-guided bilateral transversus abdominis plane block in laparoscopic gastric cancer

Ya-Ya Wang, Hua-Jun Fu

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Abstract

BACKGROUND

Postoperative complications are important factors affecting the survival time and quality of life of patients undergoing radical gastrectomy.

AIM

To investigate and compare the anesthetic effects of intravenous general anesthesia combined with epidural anesthesia or ultrasound-guided bilateral transversus abdominal plane block (TAPB) in gastric cancer patients undergoing laparoscopic radical gastrectomy.

METHODS

The clinical data of 85 patients who underwent laparoscopic radical gastrectomy in our hospital from December 2020 to January 2023 were retrospectively collected and divided into a TAPB group (n = 45) and epidural anesthesia group (n = 40) according to the different anesthesia and analgesia programs used. The TAPB group received general anesthesia combined with TAPB, and the epidural anesthesia group received general anesthesia combined with epidural anesthesia. The pain status, cognitive status, intestinal barrier indicators, recovery quality, and incidence of complications were compared between the two groups.

RESULTS

Compared with the epidural anesthesia group, the TAPB group's visual analog scale scores were significantly lower 6 h, 12 h, 24 h and 48 h after surgery (P <0.05). The incidence of postoperative cognitive dysfunction (POCD) in the TAPB group was significantly lower than that in the epidural anesthesia group, and the Mini-mental State Examination score 24 h after surgery was significantly higher in the TAPB group than the epidural anesthesia group (P < 0.05). The levels of diamine oxidase and plasma D-lactate were significantly lower in the TAPB group than the epidural anesthesia group 24 h after surgery (P < 0.05). The agitation score and the incidence of agitation during recovery were significantly lower in



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the TAPB group than epidural anesthesia group (P < 0.05). The total incidence of postoperative complications in the TAPB group was 4.44%, significantly lower than the 20.00% in the epidural anesthesia group (P < 0.05).

CONCLUSION

Compared with epidural anesthesia combined with general anesthesia, TAPB combined with general anesthesia had a good analgesic effect in laparoscopic radical gastrectomy and can further reduce the incidence of POCD and postoperative complications, improve the levels of intestinal barrier indicators, and improve postoperative recovery quality.

Key Words: Laparoscopic radical gastrectomy; Ultrasound-guided bilateral transversus abdominal plane block; Cognitive impairment; Intestinal barrier function

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Core Tip: As an important part of surgical treatment, anesthesia significantly impacts the incidence of postoperative complications. In this study, the anesthetic effects of intravenous general anesthesia combined with epidural anesthesia or ultrasound-guided bilateral transversus abdominal plane block (TAPB) in patients with laparoscopic gastric cancer were compared. The results showed that, compared with epidural anesthesia combined with general anesthesia, TAPB combined with general anesthesia had better analgesic effects in laparoscopic gastric cancer surgery and could further reduce the incidence of postoperative cognitive dysfunction and postoperative complications, improve the levels of intestinal barrier index, and improve the quality of postoperative recovery.

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INTRODUCTION

Gastric cancer is the fifth most common malignant tumor in the world. According to incomplete statistics[1], the incidence of gastric diseases in China increases as the average population age increases. As the early symptoms of gastric cancer are not specific, it is mostly clinically diagnosed in the middle and late stages, and surgery is the main method of clinical treatment. Compared with traditional open surgery, laparoscopic radical gastrectomy causes less surgical trauma to patients and has a clearer intraoperative field of vision, which helps operators to perform more detailed lymph node dissection. Therefore, laparoscopic radical gastrectomy has become a standard surgical method for the treatment of some early and advanced gastric cancer patients^[2]. Previous studies have shown that^[3] postoperative complications are important factors affecting the survival time and quality of life of patients undergoing radical gastrectomy. Furthermore, anesthesia, as an important part of surgical treatment, significantly impacts the incidence of postoperative complications. In recent years, general anesthesia combined with epidural anesthesia has been applied in laparoscopic surgery with good analgesic effects^[4], effectively reducing the need for single opioid drugs. Ultrasound-guided bilateral transversus abdominal plane block (TAPB) provides analgesic effects by injecting a local anesthetic into the plane between the internal oblique and transversal abdominal muscles under the guidance of ultrasound, thus blocking sensory nerves that pass through this plane. With the advantages of fast onset and a good analgesic effect, TAPB has been widely used for auxiliary anesthesia and postoperative analgesia in patients undergoing abdominal surgery [5,6]. At present, there are few relevant literature reports comparing the application effects of epidural anesthesia and TAPB in laparoscopic radical gastrectomy. This study mainly analyzed and compared the effects of epidural anesthesia and TAPB on postoperative cognitive dysfunction (POCD), intestinal barrier function, and postoperative recovery quality in gastric cancer patients undergoing laparoscopic radical gastrectomy to provide a reference for the clinical selection of appropriate anesthesia programs.

MATERIALS AND METHODS

Clinical data

A retrospective study was conducted on the clinical data of 85 patients who underwent laparoscopic radical gastrectomy in our hospital from December 2020 to January 2023. Inclusion criteria: Patients undergoing elective laparoscopic radical gastrectomy, patients aged 18-65 years old, patients with grade I to II according to the American Society of Anesthesiologists (ASA), patients with a body mass index (BMI) of 18-24 kg/m², patients undergoing primary surgery, patients who received TAPB or epidural anesthesia, and patients with complete clinical data. Exclusion criteria: A history of



analgesic drug abuse, history of abnormal blood coagulation and chronic pain, infection at the puncture site, peripheral neuropathy, and incomplete clinical data. Eighty-five patients were divided into the TAPB group (n = 45) and epidural anesthesia group (n = 40) according to the different anesthesia and analgesia programs they received.

Anesthesia methods

All patients were forbidden to drink and eat for 8 h before surgery, and no drugs were used before the operation. Noninvasive blood pressure, electrocardiogram, oxygen saturation, and double-frequency index (BIS) were monitored after entering the operation room. Peripheral venous access was opened, and radial artery puncture and right internal jugular vein puncture and catheterization were conducted under local anesthesia.

Anesthesia methods for patients in the epidural anesthesia group were as follows: Before general anesthesia induction, the anesthesiologist conducted an epidural puncture and catheterization between T8 and T9 of the patients and adopted the posterior median approach. The oblique angle of the puncture needle was placed longitudinally parallel to the dural fibers, and the needle was slowly advanced. Advancement of the puncture needle was stopped when there was a characteristic resistance change when passing through the ligamentum flavum and dura mater. After cerebrospinal fluid was seen to flow out smoothly, excluding the possibility that the catheter entered the spinal canal and simultaneously verifying the location of the anesthesia plane and epidural catheter, 5 mL of 2% lidocaine was injected; then 4-6 mL of 1% ropivacaine was injected. Anesthesia induction was performed when the patient's vital signs were stable. The anesthesia induction method was as follows: 0.3-0.4 µg/kg sufentanil, 2 mg/kg propofol, 0.6 mg/kg rocuronium, and 0.5 µg/kg dextrometomidine were used for anesthesia induction, and tracheal intubation was performed after successful induction. For anesthesia maintenance, 4-10 mg/kg/h propofol was used for target-controlled infusion, and the BIS was maintained between 40 and 60. During the surgery, 1% ropivacaine (4-6 mL/h) was administered through an epidural catheter according to the patient's condition, and 0.1 mg/kg/h cisatracurium was intermittently administered to maintain the neuromuscular block. After pneumoperitoneum was stopped, the use of muscle relaxants was stopped, and the tracheal intubation was removed after reaching the indication for extubation. A patient-controlled intravenous analgesia (PCIA) pump was used after surgery. The drug formula for the injection was 100 µg sufentanil, 4.48 mg tropisetron, and sodium chloride diluted to 100 mL. The parameters were set to 2 mL/h, a single compression dose of 2 mL, and a locking time of 20 min.

The following anesthesia method for patients in the TAPB group was applied. Before general anesthesia induction, the anesthesiologist placed the ultrasonic probe vertically on the anterior axillary line between the patient's iliac crest and costal margin, and identified the structures of the external oblique, internal oblique, transversal, and peritoneum of the abdomen. Using in-plane technology, a 20G puncture needle was placed in the middle of the transversus abdominis muscle and the internal oblique muscle of the abdomen. After no blood or air bubbles were extracted, 1 mL of sodium chloride was injected using water separation technology to prove that the needle tip was located at the transversus abdominal plane. Then 0.375% ropivacaine and $0.75 \,\mu$ g/kg dexmedetomidine were injected at a uniform rate, using 20 mL on each side. Anesthesia induction was performed after the block was completed. The methods of anesthesia induction and maintenance were the same as those of the epidural anesthesia group.

Observation indicators

(1) The general data of the two groups were compared; (2) The visual analog scale (VAS) was used to evaluate the degree of pain felt 6 h, 12 h, 24 h, and 48 h after surgery, with the score ranging from 0 to 10 points. The higher the score, the more severe the pain; (3) The occurrence of POCD 24 h and 72 h after surgery was recorded and compared between the two groups. The Mini-mental State Examination (MMSE) was used to evaluate the cognitive status of the two groups before and after surgery. A score of < 27 points indicated cognitive impairment, and the higher the score, the better the cognitive function; (4) Intestinal barrier function indexes, including diamine oxidase (DAO) and plasma D-lactate (D-LA), for the two groups were compared before and 24 h after surgery; (5) The agitation score and the incidence of agitation of the two groups during the recovery period were recorded and compared. An agitation score of 1 point indicated an inability to wake up, 2 points indicated excessive sedation, 3 points indicated sedation, 4 points indicated sedation and cooperation, 5 points indicated agitation with stimulation, 6 points indicated agitation without stimulation, 7 points indicated severe agitation, and 5 to 7 points indicated agitation during the awakening period; and (6) Postoperative complications were compared between the two groups.

Statistical analysis

The data obtained were analyzed and processed by SPSS23.0 software. Measurement data conforming to a normal distribution were expressed as the mean \pm SD and were compared by *t* test. Count data were expressed as cases or percentages, and the chi-square test was used for comparison. *P* < 0.05 was considered to be statistically significant.

RESULTS

Comparison of general data between two groups

There were no statistically significant differences in sex, age, BMI, ASA grade, operation time, or intraoperative bleeding between the two groups (P > 0.05), as shown in Table 1.

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Table 1 Comparison of general data between two groups							
Group	Gender (male/female)	Age (yr, mean ± SD)	BMI (kg/m², mean ± SD)	ASA grade (I/II)	Operation time (min, mean ± SD)	Intraoperative bleeding (mL, mean ± SD)	Sufentanil consumption (µg, mean ± SD)
TAPB group (<i>n</i> = 45)	25/20	59.56 ± 6.82	23.08 ± 0.58	23/22	148.52 ± 22.63	135.81 ± 22.56	25.36 ± 4.88
Epidural anesthesia group ($n = 40$)	23/17	59.08 ± 6.94	22.84 ± 0.65	21/19	150.97 ± 20.51	136.44 ± 22.79	27.12 ± 4.15
Statistical value	0.033	0.321	1.799	0.017	0.521	0.128	1.779
P value	0.857	0.749	0.076	0.898	0.604	0.899	0.079

BMI: Body mass index; ASA: American Society of Anesthesiologists; SD: Standard deviation; TAPB: Transversus abdominal plane block.

Comparison of VAS scores between two groups

Compared with the epidural anesthesia group, TAPB group patients' VAS scores were significantly lower 6 h, 12 h, 24 h, and 48 h after surgery (P < 0.05), as shown in Table 2.

Comparison of cognitive function between two groups

There was no statistically significant difference in MMSE scores between the two groups before surgery (P > 0.05). The incidence of POCD in the TAPB group was significantly lower than that in the epidural anesthesia group, and the MMSE score was significantly higher in the TAPB group than the epidural anesthesia group 24 h after surgery (P < 0.05), as shown in Table 3.

Comparison of intestinal barrier function indicators between two groups

There were no statistically significant differences in the preoperative DAO or D-LA levels of the two groups (P > 0.05). The DAO and D-LA levels 24 h after surgery in the TAPB group were significantly lower than those in the epidural anesthesia group (P < 0.05), as shown in Table 4.

Comparison of postoperative recovery quality between two groups

The agitation score of the TAPB group was significantly lower than that of the epidural anesthesia group, and the incidence of agitation in the TAPB group was significantly lower than that of the epidural anesthesia group during the recovery period (P < 0.05), as shown in Table 5.

Comparison of postoperative complication rates between two groups

The total incidence of postoperative complications in the TAPB group was 4.44%, significantly lower than the 20.00% recorded in the epidural anesthesia group (P < 0.05), as shown in Table 6.

DISCUSSION

With the promotion and application of the concept of enhanced recovery after surgery in clinical practice in recent years, methods to reduce the incidence of complications, shorten the length of the hospital stay, and accelerate the recovery of patients after laparoscopic gastric cancer surgery have gradually become hot spots and the focus of clinical attention[7]. More and more anesthesia guidelines recommend the use of multi-mode analgesia programs in laparoscopic surgery. Multi-mode analgesia programs prevent the introduction of pain stimuli from various sources by using analgesic techniques and drugs with different mechanisms to block the transmission of pain signals and improve the postoperative recovery of patients[8,9]. Although PCIA can rapidly control breakthrough pain through impact doses in laparoscopic surgery, the opioids used tend to cause adverse reactions such as nausea, vomiting, and respiratory depression[10], which are not conducive to the postoperative recovery of patients and can affect the length of the patients' hospital stay. Therefore, it is of great significance to patient recovery and comfort to optimize anesthesia and analgesia programs.

Epidural anesthesia combined with general anesthesia is a commonly used anesthesia and analgesia program for abdominal surgery. However, studies have revealed[11] that epidural anesthesia has a failure rate of about 7%. It is also difficult to implement and requires a high level of clinical experience and operational skill in anesthesiologists. In recent years, the application of ultrasound technology in the clinical work of anesthesiology departments has been increasing, which promotes the clinical application of TAPB to a certain extent. Ultrasound-assisted visual operation makes TAPB a simple, safe, and effective local nerve block technique. Most studies[12,13] have shown that TAPB has a good blocking effect in abdominal surgery and can effectively reduce postoperative pain, reduce the dosage of analgesic drugs needed, and reduce inflammation. In a comparison of the anesthetic effects of TAPB and epidural anesthesia in laparoscopic radical gastrectomy, the VAS scores of patients in the TAPB group 6 h, 12 h, 24 h, and 48 h after surgery were significantly lower that lose in the epidural anesthesia group (P < 0.05), indicating that TAPB could further relieve the



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Table 2 Comparison of visual analog scale scores between two groups (points, mean ± SD)						
Group 6 h after surgery 12 h after surgery 24 h after surgery 48 h after surgery						
TAPB group ($n = 45$)	2.53 ± 0.44	2.31 ± 0.39	2.01 ± 0.31	1.32 ± 0.29		
Epidural anesthesia group ($n = 40$)	2.78 ± 0.39	2.69 ± 0.45	2.55 ± 0.37	1.92 ± 0.36		
<i>t</i> value	2.757	4.171	7.319	8.501		
<i>P</i> value	0.007	< 0.001	< 0.001	< 0.001		

SD: Standard deviation; TAPB: Transversus abdominal plane block.

Table 3 Comparison of cognitive function between two groups

Crown	Incidence of DOCD , n (%)	MMSE score		
Group	Incidence of POCD, <i>n</i> (%)	Before surgery	24 h after surgery	
TAPB group ($n = 45$)	2 (4.44)	27.94 ± 0.78	25.63 ± 1.25	
Epidural anesthesia group ($n = 40$)	9 (22.50)	27.82 ± 0.84	24.45 ± 2.97	
Statistical value	6.128	0.683	2.435	
<i>P</i> value	0.013	0.497	0.017	

TAPB: Transversus abdominal plane block; POCD: Postoperative cognitive dysfunction; MMSE: Mini-mental State Examination.

Table 4 Comparison of intestinal barrier function indicators between two groups (mg/L, mean ± SD)					
Group	DAO		D-LA		
Group	Before surgery	24 h after surgery	Before surgery	24 h after surgery	
TAPB group ($n = 45$)	4.64 ± 0.85	3.17 ± 0.72	5.28 ± 0.67	4.21 ± 0.44	
Epidural anesthesia group ($n = 40$)	4.52 ± 0.91	3.85 ± 0.64	5.09 ± 0.78	4.63 ± 0.32	
<i>t</i> value	0.628	4.578	1.208	4.978	
<i>P</i> value	0.531	< 0.001	0.230	< 0.001	

SD: Standard deviation; TAPB: Transversus abdominal plane block; DAO: Diamine oxidase; D-LA: D-lactate.

Table 5 Comparison of postoperative recovery quality between two groups					
Group Agitation score Incidence of agitation during the recovery period, <i>n</i> (%)					
TAPB group ($n = 45$)	4.21 ± 0.85	0 (0.00)			
Epidural anesthesia group ($n = 40$)	5.08 ± 0.66	5 (12.50)			
Statistical value	5.222	5.977			
<i>P</i> value	< 0.001	0.015			

TAPB: Transversus abdominal plane block.

postoperative pain of patients with gastric cancer. The reason for this is speculated to be because TAPB alleviates peripheral and central pain sensitization by inhibiting nociceptive stimuli such as skin incision and separation, helping to relieve pain. In addition, the 0.375% ropivacaine selected in this study can effectively guarantee the effectiveness and safety of TAPB in ultrasound-guided bilateral TAPB and meet the needs of analgesic plane.

POCD is one of the most common complications in patients who have undergone laparoscopic gastric cancer surgery and is related to many factors, such as age, underlying disease, surgical and anesthesia methods, and surgical time. Anesthetic drugs can act on multiple targets in the brain, thereby affecting brain function, and the choice of drug is an important factor leading to postoperative POCD in patients[14]. MMSE is a commonly used scale for evaluating cognitive



Table 6 Comparison of postoperative complication rates between two groups						
Group	Nausea and vomiting (cases)	Respiratory depression (cases)	Hypotension (cases)	Total incidence rate (%)		
TAPB group ($n = 45$)	2	0	0	4.44		
Epidural anesthesia group (<i>n</i> = 40)	5	0	3	20.00		
χ^2 value				4.936		
<i>P</i> value	0.026					

TAPB: Transversus abdominal plane block.

function in clinical practice. The results of this study showed that the incidence of POCD in the TAPB group was significantly lower than that in the epidural anesthesia group, and the MMSE score 24 h after surgery was significantly higher in the TAPB group than the epidural anesthesia group (P < 0.05). The results indicated that, compared with epidural anesthesia, TAPB improved the cognitive function of patients. It was speculated that TAPB allows anesthesiologists to observe the diffusion of anesthetic drugs and the degree of anesthesia through ultrasonic visualization, properly control the dosage of anesthetic drugs, effectively reduce the degree of damage to the nervous system, and thus reduce the incidence of postoperative POCD.

In the results of this study, the levels of DAO and D-LA in the TAPB group were significantly lower than those in the epidural anesthesia group 24 h after surgery (P < 0.05), indicating that compared to epidural anesthesia, TAPB can help improve the postoperative intestinal barrier index levels of patients and promote intestinal peristalsis. A possible reason for this may be that opioid drugs inhibit gastrointestinal function by activating the u and k receptors distributed in the gastrointestinal tract. Previous studies [15,16] have found evidence that opioids can lead to intestinal peristalsis disorders and even constipation. TAPB reduces the need to use opioids during the perioperative period; alleviates the adverse symptoms caused by opioids, such as nausea, vomiting, and decreased intestinal motility; promotes intestinal peristalsis; and improves the levels of intestinal barrier indicators in patients [17]. In addition, this study showed that the agitation score, the incidence of agitation during recovery, and the total incidence of postoperative complications were significantly lower in the TAPB group than the epidural anesthesia group (P < 0.05), further confirming the benefits of TAPB in improving the postoperative recovery quality of patients and reducing incidences of postoperative complications.

CONCLUSION

In summary, compared to the scheme of epidural anesthesia combined with general anesthesia, TAPB combined with general anesthesia has a good analgesic effect in laparoscopic gastric cancer surgery. It can reduce the incidence of POCD and postoperative complications, improve the level of intestinal barrier indicators, and improve postoperative recovery quality, and thus is worthy of clinical promotion and application. There were some limitations in this study. As it was a single-center retrospective study, there was no blank control group. It is hoped that the sample size can be further expanded in the future to analyze the effect of ultrasound-guided bilateral transversus abdominis plane block on the expected prognosis of patients with laparoscopic gastric cancer.

ARTICLE HIGHLIGHTS

Research background

Postoperative complications are important factors affecting the survival time and quality of life of patients undergoing radical gastrectomy. Choosing an ideal anesthesia and analgesia program is of great significance for ensuring good surgical effect and reducing the incidence of postoperative complications. Although patient-controlled intravenous analgesia (PCIA) can control the outbreak of pain in time, opioids can easily cause adverse reactions such as nausea, vomiting, and respiratory depression. Epidural anesthesia combined with general anesthesia is commonly used in abdominal surgery, and ultrasound-guided transversus abdominal plane block (TAPB) is also effective in reducing postoperative pain and reducing the amount of analgesic drugs required. At present, there are few reports on the application of these two schemes in radical gastrectomy.

Research motivation

PCIA has been the most frequently used analgesic regimen in laparoscopic surgery in the past. Although it can control the outbreak of pain in time through the impact dose, the opioids used can easily cause adverse reactions, such as nausea, vomiting, and respiratory depression, which are not conducive to the postoperative rehabilitation of patients. It is thus necessary to optimize the anesthesia and analgesia program. By comparing the effects of epidural anesthesia and TAPB



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on the incidence of postoperative cognitive dysfunction (POCD), intestinal barrier function, and postoperative recovery quality in patients with laparoscopic gastric cancer, we can gather data that should be helpful when choosing the most suitable anesthesia and analgesia scheme for clinical practice.

Research objectives

The main goal was to select a more appropriate surgical anesthesia/analgesia program for patients with gastric cancer. Multimodal analgesia can prevent the introduction of pain stimulation from many sources and thereby block the transmission of pain signals and improve postoperative rehabilitation. By comparing the effects of epidural anesthesia and TAPB on postoperative recovery quality and complications in patients with laparoscopic gastric cancer, we may find ways to reduce the need to apply opioids during perioperative period and accelerate postoperative rehabilitation.

Research methods

This was a retrospective study in which differences in postoperative pain, cognitive function, intestinal barrier function index, and incidences of agitation were observed between an epidural anesthesia group and an ultrasound-guided bilateral transversus abdominis plane block group. Cognitive dysfunction is one of the most common complications in patients undergoing laparoscopic gastric cancer surgery, and intestinal barrier function is an important indicator affecting postoperative intestinal peristalsis and recovery speed. By observing these indicators, we can obtain good reference data for future research.

Research results

Compared with patients in the epidural anesthesia group, patients in the ultrasound-guided TAPB group had less postoperative pain; significantly lower incidences of cognitive dysfunction, emergence agitation, and postoperative complications; and greater improvements in intestinal barrier function. The differences in the above indicators were statistically significant. However, the effects of the two anesthesia methods on the intraoperative vital signs of patients need to be further explored.

Research conclusions

In contrast to previous studies, this study used retrospective analysis to explore and compare the effects of epidural anesthesia and TAPB on cognitive dysfunction, intestinal barrier function, and postoperative recovery quality in patients with laparoscopic gastric cancer. It was concluded that, compared with epidural anesthesia combined with general anesthesia, TAPB combined with general anesthesia had a good analgesic effect in laparoscopic gastric cancer surgery patients. TAPB combined with general anesthesia helped to reduce the incidence of postoperative cognitive dysfunction, and the emergence agitation and concurrent tension, and had a good effect on improving the quality of postoperative recovery.

Research perspectives

Because this study was a retrospective analysis, the effects of the two anesthesia/analgesia regimens on the vital signs of a large sample of patients with gastric cancer needs to be analyzed in a prospective study.

FOOTNOTES

Author contributions: Wang YY initiated the project and designed the experiment, wrote the original manuscript, performed postoperative follow-up, and recorded data; Fu HJ conducted a number of collations, conducted clinical data collection and statistical analysis, and revised the paper; both authors have read and approved the final manuscript.

Institutional review board statement: This study was approved by the Ethics Committee of Shaanxi Provincial People's Hospital, and the Ethics Committee also agreed to waive the requirement for informed consent.

Informed consent statement: Patients were not required to give informed consent to the study because the analysis used anonymous clinical data that were obtained after each patient agreed to treatment by written consent.

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