Trakia Journal of Sciences, No 3, pp 250-258, 2014

Available online at:
http://www.uni-sz.bg
ISSN 1313-7050 (print) doi:10.15547/tjs.2014.03.006
ISSN 1313-3551 (online)

Original Contribution

COMPARISON OF THE USE OF THORACIC EPIDURAL ANALGESIA IN AWAKE PATIENTS VERSUS GENERAL ANESTHESIA UNDERGOING INTRA-ABDOMINAL SURGERY

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ABSTRACT

PURPOSE: Our goal was to compare the efficacy and side effects of thoracic epidural anesthesia or general anaesthesia during intra-abdominal surgery.

METHODS: A hundred twenty-five patients were randomized to receive thoracic epidural anesthesia in awake patients (Group TEA) or general anesthesia (Group GA) in a prospective, randomized study. Preoperatively, all patients received a thoracic epidural catheter. Bolus dose of bupivacaine with fentanyl, was given to Group TEA. Patient-controlled epidural analgesia was maintained with an infusion of bupivacaine with fentanyl in both groups just after the end of surgery.

RESULTS: Intraoperative mean arterial pressure values at 10,15,30,45 min, heart rate values at 5,10,15,30 min were significantly less in Group TEA in comparison to Group GA($P<0.05$). At 2 hours after operation, pain (resting and coughing) scores($P<0.0001$) and postoperative total analgesic consumption were significantly less ($P=0.008$) in Group TEA in comparison to Group GA. The length of hospital stay was significantly short($P=0.03$) and total hospital costs were significantly less($P=0.042$) in Group TEA than Group GA.

CONCLUSIONS: During intra-abdominal surgery, TEA in awake patients have better analgesic effect at two hours postoperatively, less analgesic consumption, shorter hospital stay and less hospital costs. However, clinicians must pay attention to intraoperative hypotension and bradycardia during use of thoracic epidural anesthesia in awake patients.

Key words: Awake epidural anesthesia, General anesthesia

INTRODUCTION

General anesthesia causes depression on mucociliary transport which may lead to serious respiratory complications (1). Thoracic Epidural Anesthesia (TEA) is a preferred technique after thoracic and major abdominal surgery as it provides the most effective analgesia (2). Advantages of TEA in awake patients over general anesthesia includes: Less hypertension and tachycardia as a result of reduced stress response, increase in intestinal motility as a result of more parasympathetic activity with the blockage of the sympathetic system, reduction in the loss of time between surgical procedures (3). Furthermore, TEA technique reduces the rate of postoperative pulmonary complications, provides early mobilization, and reduces opioid consumption and improved cough (4, 5).

We aimed to compare the quality of anesthesia, the efficacy of analgesia and the side effects of thoracic epidural in awake patients and general anesthesia in patients undergoing intra-abdominal surgery.

MATERIALS AND METHODS

One hundred and twenty five patients undergoing intra-abdominal surgery were included into a prospective, randomized, double-blinded study. The age range was between 21 and 83 including American Society of

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Anesthesiologists (ASA) physical status I, II or III.

After obtaining the approval of the local ethics committee and informed consent from the patients, we randomized the patients with a sealed envelope to choose either single or double digit. Single digit was referred to thoracic epidural (Group TEA; n=59), double digit was referred to general anesthesia (Group GA, n=66). The observers who collect visual analogue scale (VAS) scores and other data were blinded to the pain relief protocol. Caregivers (nurses and doctors) were not blinded, but they did not participate in data collection or data interpretation.

From 156 patients, 12 were excluded as 5 of them did not meet the inclusion criteria and 7 of them declined to participate. A total of 144 patients were randomized into two groups. Six patients did not receive allocated intervention and intervention was discontinued in 13 patients. A consort diagram is presented in **Figure 1**.

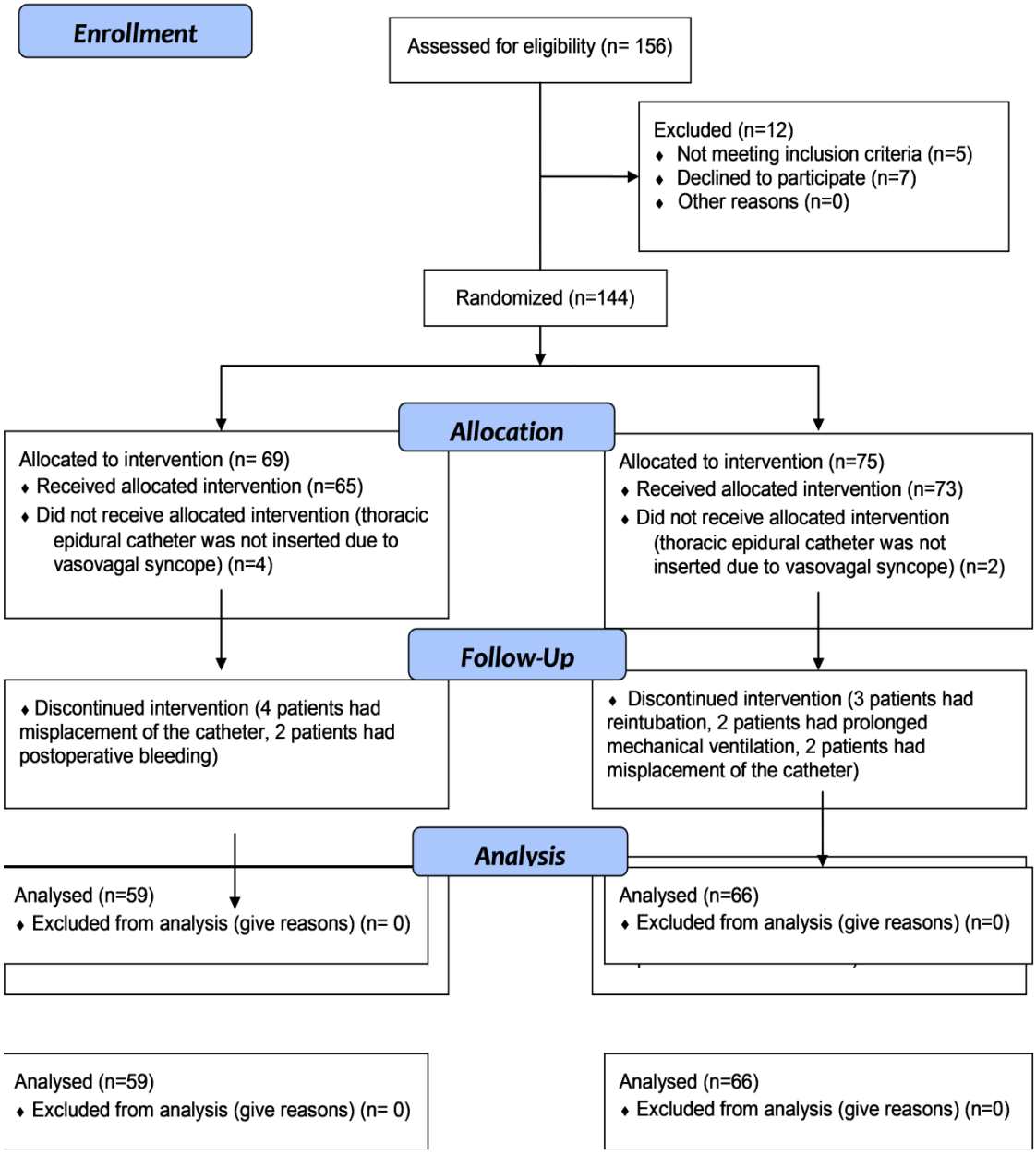

Figure 1. CONSORT 2010 Flow Diagram

We excluded the patients who do not agree to participate in the study or could not cooperate, chronic pain use of analgesic drugs, hypovolemia, platelet count<100.000/mm^3,

history of coagulopathy, renal or liver disease, history of allergy to study drugs and local or systemic infection.

Demographic data, age, sex, height, weight, body mass index, surgical procedures were recorded. Nineteen conditions were defined as significantly influencing survival in the study population and were given a weighted score based on the relative mortality risk. The sum of the weighted scores of all the comorbid conditions in cancer patients was then scaled to establish the Charlson comorbidity index. The weights range from 1–6 (0 if the comorbidity is absent) and four Charlson comorbidity index classes were defined as 0, 1–2, 3–4 and≥5 (6).

An infusion of 10 ml/kg Ringer's lactate solution was administered to all patients preoperatively in the operation room. Standard monitoring (non-invasive arterial blood pressure, heart rate (HR), periferic oxygen saturation (SpO_2), and ECG was applied. We recorded the first measurements as the initial value. For skin infiltration, 3 ml of 2% lidocaine (Jetmonal 2%, Adeka Pharmaceutical, Turkey) was applied in sitting position at the level of $T_{7–8}$ interspace. Epidural catheter was inserted with an 18-gauge Tuohy needle. A thoracic epidural catheter was moved 3 to 4 cm in the cephalad direction, then 3 ml of 2% lidocaine was applied as a test dose to exclude misplacement of the catheter. The misplacement of thoracic epidural was tested after insertion of the catheter by aspiration of blood or colored fluids to check for hemorrhage, insertion of the catheter into other cavities such as pleura or intravertebral foramen. Another sign of misplacement is lack of injection of fluids from the catheter. The epidural catheter was removed from all of the patients 24 hours after surgery. After preparation of a 0.25% solution of bupivacaine (Bustesin 0.5%, Vem Pharmaceutical, Turkey) with 1 μg/ml fentanyl (Fentanyl, Janssen, Janssen Pharmaceutica, Belgium) a bolus dose of 14 ml was given to Group TEA. In both groups, patient-controlled analgesia was maintained with an infusion of 0.125% bupivacaine with 1μg/ml fentanyl for 24 hours postoperatively. During operation and postoperatively, a VAS score greater than 4 required application of a bolus dose of 4 ml of analgesic solution from epidural catheter. If the VAS score less than 4 could not be achieved with single dose a second dose was administered. The operation was started when the sensory block reached the $T_{4–8}$ level, determined with the pinprick test. Patients breathed spontaneously with nasal oxygen (2-4 l/min) and upon starting the operation were sedated with an infusion of propofol 2 mg/kg/h (Propofol 1%, Fresenius Pharmaceutical, Turkey). Mean arterial blood pressure (MAP), HR and SpO_2 were measured in the 5, 10, 15, 30, 45, 60, and 90 min intraoperatively. Patients whose arterial blood pressure values are normal but the SpO_2 value is 90% or less were regarded as hypoxic. We planned to apply tracheal intubations in the presence of hypoxia and muscle relaxation insufficiency and to pass to general anesthesia. We reduced the propofol infusion dosage 1 mg/kg/h when MAP was 20% of the baseline value or lower or the respiratory rate dropped below 8 breath/min, and increased infusion of propofol 1 mg/kg/h when the MAP was 20% of the baseline value or greater. We terminated infusion of propofol for about 5 minutes before the end of surgery.

In the group GA, the standardized general anesthesia was induced with fentanyl of 2 μg/kg and sodium thiopental at a dose of 4 mg/kg (Pental, IE Ulugay Pharmaceutical Industry, Turkey). Neuromuscular blockade was achieved with intravenous rocuronium bromide at a dose of 0.6 mg/kg (Esmeron, Organon Pharmaceuticals, U.S.A.). Patients were intubated and were mechanically ventilated (mean tidal volume 8 ml/kg) with 67% nitrous oxide, oxygen and sevoflurane (2 - 2.5 MAC). Intravenous bolus doses of rocuronium were given 0.15 mg/kg as required. MAP, HR, SpO_2 was measured noninvasively in 5, 10, 15, 30, 45, 60, and 90 min intraoperatively. In both groups hypertension and tachycardia that was observed as; MAP greater that 20% of the baseline value and HR greater than 100 beats/min was treated with an additional analgesia of intravenous fentanyl at a dose of 1 μg/kg. All patients received intravenous doses of neostigmine 0.05 mg/kg (Neostigmine, Adeka Pharmaceutical, Turkey) and atropine 0.01 mg/kg (Atropin sulfate, Biofarma Pharmaceutical, Turkey) to reverse residual neuromuscular blockade.
We treated hypotension (MAP being 20% of the baseline value or lower) with infusion of a bolus of isotonic fluid solution and intravenous 10 mg of ephedrine bolus (Ephedrine, Osel Pharmaceutical, Turkey), bradycardia (decrease in HR below 50 beats/min) with intravenous atropine at a dose of 0.5 mg in both groups.

Nausea or vomiting was treated with intravenous metoclopramide at a dose of 10 mg (Metoclopramide, Yeni Pharmaceutical, Turkey). All of the patients were taken to the recovery room, postoperatively. First haemodynamic measurements in the recovery room were recorded as basal values. The haemodynamic parameters including MAP, HR and SpO_2 of patients were recorded at 1, 2, 4, 8, 16, 24 hours after operation.

We administered patient-controlled epidural analgesia (PCEA) with an infusion of 0.125% bupivacaine with 1µg/ml fentanyl at 0.1 ml/kg/h, bolus dose of 2 ml, a lockout period of 20 min and a total dose of 12 ml in both groups just after the end of surgery for 24 hours postoperatively.
We recorded our patients who were taken to the recovery room and who required intensive care (ICU). We also administered intravenous 1000 mg paracetamol (Perfalgan, Bristol-Myers Squibb Pharmaceutical, France) every 8 hrs to all patients.

Endpoints

The primary endpoint was pain at rest and on coughing. Pain intensity was measured at rest (VAS-R) and after coughing (VAS-C) using a VAS in which 0 cm is no pain and 10 cm is the worst pain imaginable. The pain was assessed by a blinded observer at baseline, 1, 2, 4, 8, 16, and 24. hours after surgery. Also, Addenbrooke's sedation scale (0=agitated; 1=awake; 2=arousable by voice; 3=arousable by tracheal suction; 4=unarousable by tracheal suction; 5=paralysed; 6=asleep) was performed at the same time points postoperatively. Nausea/vomiting was evaluated as 0=absent, 1=mild nausea, and 2=severe nausea and/or vomiting. A VAS-R score of 4 cm or less was considered to be an acceptable level of pain. We increased infusion dosage by 20% in patients whose VAS-R value was 4 or greater and reduced it in patients who had respiratory depression (rate, 8 breath/min) by 20%; postoperative total analgesic consumption was recorded. All changes related to pain relief were made by the pain service physicians who were not blinded to the type of analgesia that each patient receives.
Secondary end points we assessed the complications, such as hypotension, bradycardia, nausea and vomiting, respiratory depression, allergy for 24 hours. Also, 30-day postoperative mortality were recorded.

Statistical analysis was performed with SPSS (version 16.0; SPSS Inc, Chicago, IL). The sample size was determined as; for a clinically significant change in VAS-R value of 2 cm and a VAS-R standard deviation of 2 cm between groups with a confidence interval of 95% and 80% power, 21 patients needs to be included into each group (7). Results are expressed as means, standard deviations (SD) and ranges. Statistical significance was accepted if $P<0.05$. The compliance of the data of the continuous measurements to normal distribution were examined by Kolmogorov-Smirnov test. Pearson Chi-Square test or Fisher's Exact test was used for the evaluation of categorical data. Normally distributed variables were evaluated by Independent-Samples T test, and the variables without normally distribution were evaluated by Mann-Whitney U-test. The changes of the hemodynamic measurements according to time were compared with two-way ANOVA test between groups.

RESULTS

The MAP values were lower in Group TEA then Group GA. In comparison to basal values, MAP values at 5, 10, 15, 30, 45 min were significantly lower in the Group GA **(Table 2).**

The HR values were lower in Group TEA in comparison to Group GA. In comparison to basal values, the HR value at 5 min was significantly lower in Group GA **(Table 2).**

During the intraoperative period, we found that hypotension incidence was statistically significantly higher in 12 (20%) patients in Group TEA in comparison to Group GA of 2 (3%) patients (P=0.002).

During the intraoperative period, we found the bradycardia incidence statistically significantly higher in 8 (14%) patients in Group TEA than one (2%) of the Group GA (P=0.009).
At 2 hours after operation pain (resting and coughing) scores were significantly less in the Group TEA in comparison to Group GA. The VAS-R values was lower in Group TEA than in the Group GA **(Table 3**).

Table 1. *Patient characteristics on admission.*

Patients	Group TEA (n = 59)		Group GA (n = 66)		P
	Median	Quartile range	Median	Quartile range	
Age (years)	56.49 ± 13.17	27-83	56.98 ± 13.67	21-81	0.895
Sex-ratio (F/M)	18/41		16/50		0.432
Weight (kg)	71.27 ± 14.29	43-104	74.89 ± 13.34	53-108	0.936
Height (cm)	169.17 ± 9	142-85	170.82 ± 7.43	160-187	0.564
Body mass index (kg/m^2)	24.61 ± 4.5	16-36	25.8 ± 5.03	16-43	0.75
ASA classification (I/II/III)	38/15/6		34/22/10		0.339
Charlson Comorbidity Index					
0	38 (64.4)				0.145
1	15 (25.4)				0.334
≥ 2	6 (10.2)				0.405
Surgical procedure; n (%)					
Gastric resection	24 (40.7)		18 (27.3)		0.113
Small bowel resection	16 (27.1)		26 (39.4)		0.147
Large bowel resection	19 (32.2)		22 (33.3)		0.893
Unable to place the catheter	3 (5.1)		2 (3)		0.558
The postoperative cumulative local anesthetic consumption (mL)	164.07 ± 9.28		168.18 ± 7.75		0.008*
Duration of surgery (min)	120.34 ± 52.04	70-250	106.97 ± 38.19	75-220	0.102
Hospital stay (day)	6	5-20	8.5	5-16	0.031*
Cost (TL)	1805.98 ± 1418.64	792-5718	2547 ± 2423	751-1285.3	0.042*

Values are median (range), absolute numbers, or mean ± standard deviation
ASA; American Society of Anesthesiologists, TEA; Thoracic epidural anesthesia, GA; General anesthesia
*Comparison between groups, P < 0.05

Table 2. *Comparison of the MAP and HR values at basal and post-anesthesia induction period of the patients having abdominal operation under epidural anesthesia or general anesthesia.*

Variable	Basal	5	10	15	30	45	60	90
MAP (mmHg)								
Grup Epidural vs. Grup General (P value)	0.111	0.054	0.029[a]	0.018[a]	0.035[a]	0.042[a]	0.063	0.097
The comparation intragroup of postoperative Epidural (P value)	Δ	<0.37b	<0.0001[b]	<0.0001[b]	<0.0001[b]	<0.0001[b]	0.256	0.904
The comparation intragroup of postoperative General (P value)	Δ	0.013[c]	0.001[c]	<0.0001[c]	<0.0001[c]	0.001[c]	0.196	0.414
HR (beats/min)								
Grup Epidural vs. Grup General (P value)	0.371	0.001[a]	<0.0001[a]	0.001[a]	0.002[a]	0.052	0.119	0.086
The comparation intragroup of postoperative Epidural (P value)	Δ	0.011b	<0.0001[b]	<0.0001[b]	<0.0001[b]	<0.0001[b]	0.003[b]	0.64
The comparation intragroup of postoperative General (P value)	Δ	0.016c	0.843	0.327	0.487	0.182	0.408	0.45

Values are median (range), absolute numbers, or mean ± standard deviation
TEA; Thoracic epidural anesthesia, GA; General anesthesia
[a]Comparison between groups, P < 0.05
[b]Comparison to basal value in Group TEA, P < 0.05
[c]Comparison to basal value in Group GA, P < 0.05

Table 3. *The comparison of postoperative visual analog scale scores during rest (0 cm = no pain, 10 cm = worst pain imaginable) in both groups.*

Time (hours)	Visual Analogue Scala-R		Grup TEA vs. Grup GA (P value)	The comparation intragroup of postoperative TEA (P value)	The comparation intragroup of postoperative GA (P value)
	Group TEA (n = 59)	Group GA (n = 66)			
Basal	3.6 ± 1.8	5.5 ± 1.7	< 0.0001[a]	Δ	Δ
2	3.3 ± 2.3	4.7 ± 1.4	< 0.0001[a]	0.285	0.001[c]
4	3.4 ± 1.9	4 ± 1.5	0.035[a]	0.433	< 0.0001[c]
8	2.5 ± 1.7	3 ± 1.8	0.109	< 0.0001[b]	< 0.0001[c]
16	2.2 ± 1.3	2.5 ± 1.7	0.328	< 0.0001[b]	< 0.0001[c]
24	2.4 ± 1.3	2.3 ± 1.7	0.826	0.001[b]	< 0.0001[c]

Values are median (range), absolute numbers, or mean ± standard deviation
TEA; Thoracic epidural anesthesia, GA; General anesthesia
[a]Comparison between groups, P < 0.05
[b]Comparison to basal value in Group TEA, P < 0.05
[c]Comparisonto basal value in Group GA, P < 0.05

The VAS-C values was lower in Group TEA than in Group GA **(Table 4).**

Table 4. *The comparison of postoperative visual analog scale scores during coughing (0 cm = no pain, 10 cm = worst pain imaginable) in both groups.*

Time (hours)	Visual Analogue Scala-C		Grup TEA vs. Grup GA (P value)	The comparation intragroup of postoperative TEA (P value)	The comparation intragroup of postoperative GA (P value)
	Group TEA (n = 59)	Group GA (n = 66)			
Basal	4.8 ± 1.3	7.3 ± 1.5	< 0.0001[a]	Δ	Δ
2	4.2 ± 1.2	5.6 ± 2.1	< 0.0001[a]	0.285	0.016[c]
4	4.1 ± 1.8	5.3 ± 2.6	0.002[a]	0.433	0.016[c]
8	4.1 ± 1.2	4.7 ± 2.1	0.036[a]	< 0.0001[b]	0.004[c]
16	3.5 ± 1.2	3.9 ± 2	0.17	< 0.0001[b]	< 0.0001[c]
24	3 ± 1.3	2.8 ± 1.6	0.518	0.001[b]	< 0.0001[c]

Values are median (range), absolute numbers, or mean ± standard deviation
TEA; Thoracic epidural anesthesia, GA; General anesthesia
[a]Comparison between groups, P < 0.05
[b]Comparison to basal value in Group TEA, P < 0.05
[c]Comparison to basal value in Group GA, P < 0.05

We found that the cumulative local anesthetic consumption for twenty-four hours in Group TEA was statistically significantly lower than Group GA **(Table 1).**

Addenbrooke's sedation scales were similar at basal, and at 2, 4, 8, 16 and 24 hours after operation (P=0.057; P=0.094; P=0.099; P=0.084; P=0.141; P=0.134, respectively).

During the postoperative twenty-four hours, we did not detect hypotension, bradycardia, or allergy in any of our patients. We did not find

the nausea and vomiting incidences statistically significant in 4 (6.8%) patients in Group TEA and in 8 (12.1%) patients in Group GA (P=0.312). Two patients with vomiting received intravenous metoclopramide treatment.

We did not detect any transfer to intraoperative intubations or general anesthesia in none of the patients in Group TEA. While none of the

patients Group TEA needed ICU stay postoperatively, three patients (4.5%) in Group GA were desaturated in the recovery room and were taken to intensive care unit for close monitoring for respiratory depression with 40% facial mask oxygen support. The ICU was not required in any of our patients in Group TEA, but 7 of 66 patients (10.6%) required an ICU stay (P=0.01). The mechanical ventilation was not required in any of our patients in Group TEA, but 4 of 66 patients (6.1%) of them were administered mechanical ventilation in Group GA (P=0.055).

Pulmonary complication did not develop in any of the patients of Group TEA, but the pneumonia which developed in four patients (6.1%) in the Group GA was not statistically significant (P=0.055). Urinary retention could not be assessed, since patients routinely had Foley catheters inserted at the time of surgery.
Mortality was not observed in either of our study groups.

DISCUSSION

General anesthesia with or without neuromuscular blockade leads to a reduction in residual functional capacity. Residual neuromuscular blockade is a predictor of postoperative pulmonary complication, causing alveolar hypoventilation and gastric regurgitation with consequent bronchoaspiration (8). Elrazek et al. (9) applied the awake TEA method in two patients for whom cholecystectomy and sigmoid colon operations were planned and reported that the haemodynamic and respiratory parameters were stable and sufficient muscle relaxation was provided. Savas et al. (10) reported that sufficient surgical conditions were provided and there was no need for general anesthesia in any of the cases. In another study, intubation was not required in any of the patients in the laparoscopic cholecystectomy operations which were performed under awake epidural anesthesia and the haemodynamics were stable (11). In our study, intraoperative hypoxia did not develop in any patients, and intubation, passing to general anesthesia and ICU were not required either.

In their study where they compared the epidural anesthesia and epidural-general anesthesia, Borghi et al. (12) reported the hypotension incidence as 18% in the epidural anesthesia group and 22% in the epidural-general anesthesia group; but they assessed the hypotension and bradycardia incidences among these groups as statistically insignificant. Baburajan et al. (13) reported that the sufficient surgical conditions were provided for patients to whom laparotomy was applied under awake TEA, but moderate hypotension was observed. Kurtoglu et al. (14) compared the awake thoracic epidural group and general group and found the bradycardia incidence statistically significantly high in the epidural group. Rigg et al. (15) compared the epidural anesthesia and the general anesthesia methods in their planned series with 915 cases in major abdominal surgery, detected a significant decrease in systolic blood pressure and HR in the epidural group. In the literature, it is underlined that in patients for whom the epidural anesthesia method is applied, the agents which spread to the upper thoracic area may lead to hypotension and thus the patients' blood pressures should be more closely observed after each local anesthetic injection (16). We are of the opinion that in our study, the reason why we detected intraoperative hypotension and bradycardia incidences in the group in which the awake TEA method was applied statistically significantly higher than the general anesthesia group is a result of widespread sympathetic blockade.
Baburajan et al. (13) reported that with the awake thoracic epidural method, sufficient analgesic activity is provided and there is no need for analgesic supplement. In other literatures, similar results were reported (8, 11, 13). In our study, in three patients in the epidural group and in seven patients from the general group the intraoperative fentanyl was required and this difference was not regarded as statistically significant.

Baburajan et al. (13) reported that sufficient postoperative analgesia was provided with a continuous epidural infusion method. In another study, the sufficient analgesic was obtained with postoperative epidural pain treatment (14). In the literature, the VAS values of the groups to which the awake TEA method was applied were found to be statistically significantly low (15, 16). In our study, we found the VAS (resting and coughing) values of the first two hours of the Group TEA statistically significantly low, but at all other times the observed difference was not statistically significant. We found that the cumulative local anesthetic consumption for twenty-four hours of the Group TEA was statistically significantly lower than the Group GA.

In epidural anesthesia, less postoperative nausea and vomiting were observed when compared to general anesthesia (3) The lack of airway manipulation and the decrease in the risk of pulmonary complications such as hypoxemia, atelectasis and pneumonia may increase the preference for epidural anesthesia (3, 11, 17). Rigg et al. (15) compared the epidural group and the control group (epidural analgesia after general anesthesia) in a major abdominal surgery series with 915 cases; and found the respiratory failure rate in the epidural group statistically significantly low (23% versus 30%).

In our study, intraoperative hypoxia did not develop in any of our patients in the Group TEA, but three patients (4.5%) from the Group GA who were desaturated in the recovery room were taken to ICU for close follow-up and were applied three hours of oxygen. It was reported that postoperative pneumonia developed in only one patient with the under awake epidural anesthesia method in abdominal operations in other series (10). In our study, pulmonary complication was not observed in any of the patients in the Group TEA; however, four patients (6.1%) in the Group GA developed pneumonia.

Patients are mobilized earlier and the duration of hospital stay decreases with the epidural anesthesia and analgesia methods, which provide effective postoperative analgesia (18).

Nonetheless in other series, the duration of hospital stay of the epidural anesthesia group was found to be significantly lower than the general anesthesia group (14, 17). In our study, we found the duration of hospital stay of the Group TEA to be statistically significantly lower than the Group GA. Grass et al. (17) reported that the cost of healthcare reduces with the epidural anesthesia method.

In their series in which they compared the awake TEA and general anesthesia methods, Son et al. (19) found the hospital costs of the epidural group (32.284.8±1209.4 versus 80.883.2±3956.9 won) to be significantly lower than the general anesthesia group. In our study, in parallel with the literature, we found the hospital cost of the Group TEA to be significantly lower than the Group GA.

CONCLUSION

During intra-abdominal surgery, TEA in awake patients have a better analgesic effect at two hours after operation, less analgesic consumption, shorter hospital stay and less hospital costs. However, clinicians must pay particular attention to intraoperative hypotension and bradycardia during use of TEA in awake patients.

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