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ORIGINAL ARTICLE

Epidural analgesia vs systemic opioids in patients undergoing laparoscopic colorectal surgery

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Abstract

Purpose A well-controlled pain is one of the most important targets of enhanced recovery after surgery (ERAS) protocols. Recent studies questioned the role of TEA (thoracic epidural analgesia) in support of less invasive techniques, in particular in laparoscopic mini-invasive surgery. The aim of this study is to compare patients undergoing laparoscopic mini-invasive colorectal surgery and receiving different analgesic techniques.

Methods Prospectively collected data entered in the electronic registry of POIS (Perioperative Italian Society) specifically designed for ERAS were reviewed. Patients undergoing colorectal laparoscopic surgery were divided in two groups according to TEA or parenteral opioid administration. In comparing TEA and opioid groups, propensity score weights were obtained. Postoperative pain control and time to readiness for discharge (TRD) were considered as primary endpoints of the study. Secondary endpoints were postoperative morbidity, PONV (postoperative nausea and vomiting), hours of mobilization, length of hospital stay (LOS), timing of fluid and solid re-assumption, and recovery of bowel function.

Results Fourteen Italian hospitals reported data on 560 patients (283 TEA, 277 opioid group). Patients of the opioid group were able to mobilize for a longer period than TEA group patients but presented a higher incidence of PONV. Pain intensity and TRD were similar in both groups. LOS was significantly reduced in TEA patients; also, this result was clinically irrelevant (5.7 ± 3.21 days TEA group vs 5.8 ± 2.92 opioid group).

Conclusion In patients undergoing laparoscopic colorectal surgery, TEA was not associated to a better pain control or to an improvement in postoperative outcome compared with opioid administration.

Keywords Epidural analgesia · Systemic opioids · Laparoscopic colorectal surgery

Introduction

Adequate postoperative pain control is a key item of enhanced recovery after surgery (ERAS) programs, fostering faster mobilization, coughing, and early recovery. Self-care is regained more readily without pain, and good analgesia with oral drugs is accepted worldwide as a discharge criterion [1].

The ERAS approach recommends thoracic epidural analgesia (TEA) as the gold standard technique for analgesia in patients undergoing open colorectal surgery [2]. In fact, when compared with parenteral opioids, TEA provides better analgesia during the first 72 postoperative hours, faster recovery of gastrointestinal function, and reduced postoperative cardiac and respiratory complications. A modulation of the inflammatory response seems responsible for the reduction in postoperative morbidity and mortality with TEA [3].

Nevertheless, the most recent ERAS guidelines for colorectal surgery state that TEA can be used in the context of laparoscopic colorectal surgery, but it is not recommended in that setting: spinal analgesia, wall blocks, or lidocaine intravenous infusion should be preferred [2]. It is even suggested

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that TEA has no beneficial impact on the length of hospital stay (LOS), contributing in some circumstances to prolong it.

A recent randomized study on patients undergoing laparoscopic colorectal surgery within an ERAS pathway showed that opioid patient-controlled analgesia (PCA) reduced postoperative morbidity and shortened LOS when compared with TEA [4]. The well-known advantages of TEA (optimal pain control, stress response reduction, immune system protection, postoperative ileus prevention) could be counterbalanced by the occurrence of hypotension, urinary retention, and delayed mobilization [5].

The aim of our retrospective study is to compare the effects of TEA and intravenous opioids in a large series of consecutive patients undergoing elective laparoscopic colonic surgery.

The primary endpoints of the study are postoperative pain control and time to readiness for discharge (TRD). Secondary endpoints are postoperative morbidity, incidence of postoperative nausea and vomiting (PONV), and recovery of mobilization, oral feeding, and bowel function.

Methods

This study is reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for conducting and reporting observational cohort studies [6].

Before starting the study, all the participating hospitals were involved in an ERAS pathway implementation program led by Perioperative Italian Society (POIS).

Study design

This study is a retrospective analysis of a prospectively collected Italian national database that included unselected patients undergoing elective colorectal surgery in 14 Italian hospitals between January 2016 and September 2017. These hospitals were affiliated with the POIS.

Since patients had to be treated according to an ERAS pathway, which was defined with the active contribution of the ERAS® Society, before the start of the study, all the hospitals were involved in a pathway implementation program led by POIS, consisting of education and audit meetings every 6 months for a 2-year period. Consecutive patients aged more than 18 years and undergoing laparoscopic colorectal resections were included in the study.

TEA patients received a continuous infusion of low-concentration local anesthetics (ropivacaine 0.2% or levobupivacaine 0.125%) and opioids (fentanyl 2 mcg/ml or sufentanil 0.5 mcg/ml) through a mid-thoracic epidural catheter.

Patients in the opioid group received intravenous morphine (by PCA, or at fixed intervals, or through an elastomeric pump). PCA devices were programmed in order to administer 1-mg boluses with 10-min lockout time and 4 mg/h maximum dosage. Elastomeric pumps were prepared with morphine 0.4 mg/ml and set at an infusion rate of 2 ml/h (19 mg/day). In the remaining cases, subcutaneous morphine was administered (3–5 mg every 4–6 h at fixed intervals).

The adherence to ERAS items is reported in Table 1. Intraperitoneal drainage placement was not recommended, but the decision on this issue was left to the attending surgeon. On the day of surgery, patients were mobilized out of bed and allowed to take liquids by mouth at will. Urinary catheter removal and oral feeding were planned on the first postoperative day (POD). Intravenous fluid infusion was stopped as early as possible, according to the oral feeding tolerance. NSAIDs (namely iv ketorolac 30 mg up to three times per day and/or iv paracetamol 1 g three/four times per the day) were administered as adjuvants in both groups in order to follow a multimodal analgesic regimen.

Data collection

Data were prospectively collected in a standardized electronic spreadsheet entailing 90 variables per patient. Every 3 months, the spreadsheets were submitted to a web-based password-protected data center managed by POIS, where all files were merged. Data collected included demographics, patient comorbidities, preoperative and intraoperative parameters, adherence to ERAS items, early recovery variables, and short-term postoperative outcomes.

Outcome measures

The primary endpoints of the study are postoperative pain control and TRD. The latter is defined according to standardized discharge criteria (see below) and measured as number of PODs. Previous consensus [7] defined TRD as a validated measure of postoperative recovery in colorectal surgery. Postoperative pain was quantified by the numeric rating scale (NRS) administered both at rest and during movement. The NRS is a segmented numeric version of the visual analog scale (VAS): the respondent selects a whole number on an 11-point scale (from 0 = "no pain" to 10 = "worst pain imaginable") that best reflects the intensity of his/her pain. The NRS is characterized by words describing pain severity at its extremes [8].

Discharge criteria were no clinical or laboratory evidence of postoperative complications or untreated medical problems, good pain control with oral analgesics, adequate oral food intake with no need for intravenous infusion, and recovery of bowel function defined as passage of flatus.

Secondary endpoints were postoperative morbidity, LOS, PONV occurrence, mobilization, timing of fluid and solid food re-assumption, and recovery of bowel function. According to previous studies, criteria to identify postoperative complications were a priori defined [9]. Postoperative complications were graded according to the Clavien–Dindo classification

Table 1 Perioperative ERAS intervention and definition of compliance

ERAS intervention	Definition of compliance
Preoperative preadmission education	Patient received preoperative multidisciplinary counseling including information on recovery goals and expectation about hospital stay
No mechanical bowel preparation	No preoperative oral solution for bowel cleansing. Intake of a preoperative maltodextrin-based drink
Carbohydrate loading	
No long-acting sedation	No long-acting sedating medication used before surgery
Intraoperative	
Antibiotic prophylaxis	Antibiotic prophylaxis completed prior to surgical incision
Epidural analgesia	Thoracic epidural analgesia prolonged until POD 3
Avoid fluid overload	Intraoperative fluid infusion rate 6 ml/kg/h
PONV prophylaxis	Multimodal pharmacologic prophylaxis administered
No abdominal or pelvic drainage	No resection-site drainage used
Active warming	Active patient warming during surgery
Thromboembolic prophylaxis	Thromboembolic disease prophylaxis with low-molecular-weight heparin
Avoidance of nasogastric tube	Nasogastric tube removed at the end of surgery
Postoperative	
Opioid-sparing multimodal analgesia	Use of opioid-sparing analgesic strategies
Oral liquids on POD 0	Patient receives oral liquids on the day of surgery postoperatively
Solid diet on POD 1	Patient receives solid food starting on POD 1
Early mobilization out of bed	Patient mobilized out of bed within the first 24 h after surgery
Early termination of IV fluid infusion	Termination of intravenous fluid infusion by POD 2
Early removal of urinary catheter	Removal of urinary catheter by POD 1

POD postoperative day, *PONV* postoperative nausea and vomiting, *IV* intravenous

[10]. Complications graded III–V were considered as major. A follow-up evaluation was performed 30 days after hospital discharge. Hospital readmission within 30 days after discharge for any postoperative complication was also recorded.

Statistical analysis

Statistical analyses were performed using STATA version 13.1 software (Stata Corp, College Station, TX, USA) and R (Core Team (2018) R—A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/).

Continuous data are reported as mean ± standard deviation; categorical data are reported as number (percentage).

All statistical tests were two-sided, and a p value < 0.05 was considered to indicate statistical significance.

In comparing TEA and opioid groups, propensity score weights were obtained for all of the variables reported in Table 2. The use of PSs as weights allows to control the influence of any single case by weighting its response based on its PS. The key of this analysis is the creation of weights based on PSs, and the advantage compared with matching is that all the individuals in the sample are used. PSs were estimated with logistic regression, which determines the probability of membership in the treatment or control group, given the specific set of selection variables included. Several treatment effects can be estimated with this method, and we chose the average treatment effect (ATE), which is the difference in the outcome variable between the average score for the individuals in the treatment group and the individuals in the control group. Weighted generalized linear regressions were performed using computed PSs as weights to verify the balance between groups. Eventually, the final analysis produced the outcome models using the PSs as weights in a univariate comparison of the two groups with the general linear model (linear regression, binomial, or Poisson as needed).

Results

We enrolled 560 consecutive patients undergoing laparoscopic colorectal resection. TEA was administered to 283 (51%) patients. Opioids were given to 277 (49%) patients: at fixed

Table 2 Demographics and preoperative variables

	TEA (283)	Opioids (277)	*p*
Male	159 (55%)	151 (54%)	0.819
Age	66.3 ± 11.6	67.6 ± 11.4	0.177
BMI	24.8 ± 4.3	25.7 ± 3.7	0.001
Weight loss > 5% in the last 6 months	19 (6.83%)	10 (3.61%)	0.088
MUST score 0	234 (83.5%)	254 (91.6%)	0.002
ASA 1–2	212 (75.7%)	144 (52.1%)	< 0.0001
ASA 3–4	64 (24.2%)	134 (47.8%)	< 0.0001
Diabetes	33 (11.6%)	26 (9.3%)	0.381
Independent mobilization	273 (98.2%)	275 (99.2%)	0.266
Preoperative HB	13.07 ± 1.8	13.14 ± 2.03	0.409
Malignant illness	225 (82.1%)	243 (89%)	0.009

Data are number of patients (%) or mean ± standard deviation

BMI body mass index, *MUST* Malnutrition Universal Screening Tool, *ASA* American Society of Anesthesiologists, *HB* hemoglobin

intervals in 101 (36%) patients, through a PCA in 43 (15%) patients, and through an elastomeric pump in 133 (48%) patients.

Table 2 reports on the characteristics of the two groups. The TEA group included more patients with ASA score I–II and fewer patients with malignant disease. Tables 3 and 4 report on the comparison of the two groups after propensity score balance with respect to Table 2 variables.

Preoperative counseling, bowel preparation, and premedication with long-acting drugs were applied similarly in the two groups, whereas preoperative carbohydrate loading, intraoperative warming, and PONV prophylaxis were more common in the TEA group. The nasogastric tube was removed at the end of surgery more often in the opioid group.

Blood transfusion rate, intraoperative fluid administration, conversion to laparatomy, and abdominal drain removal on POD 1 were similar between groups, while vasoactive drugs were intraoperatively administered more frequently in TEA patients.

NRS was similar in the two groups throughout the postoperative course. Notably, NRS values were always very low in both groups, indicating adequate pain control.

Prophylactic use of postoperative prokinetics was applied similarly, and bowel function was resumed in a comparable time span in the two groups. In the TEA group, more intravenous fluids were administered on PODs 1 and 2, oral intake of fluids and food occurred later, the urinary catheter was removed later, and the rate of intravenous infusion restart, nasogastric tube reinsertion, and PONV occurrence was lower.

Pain control with oral analgesics and ability to mobilize and accomplish self-care were acquired later in TEA patients. On the other hand, although postoperative complication rate, TRD, and readmission rate did not differ between groups, the length of hospital stay was shorter for TEA patients.

Patients in the opioid group were mobilized longer than TEA patients (Fig. 1).

No serious adverse event occurred in the TEA group.

Discussion

In our study, TEA and iv opioids did not differ with respect to postoperative pain control, morbidity, and TRD in a series of laparoscopic colonic surgery patients managed according to an ERAS pathway. In the opioid group, iv fluids stop and attainment of full self-care and full mobilization occurred earlier than in TEA patients.

Previous ERAS statements purported the importance of a TEA-based analgesic regimen, given its good analgesic properties and sparing effect on opiate consumption. Nevertheless, recent ERAS guidelines on abdominal surgery encompassed the evidence supporting the use of TEA in open surgery but underscores that TEA is poorly indicated in minimally invasive surgery [2–5]. A recent randomized study on patients undergoing laparoscopic colorectal surgery and managed within an ERAS pathway showed that both TEA and PCA opioid analgesia provided adequate postoperative pain control. However, more TEA patients needed vasopressor treatment during surgery and during the first POD. Moreover, the TEA group had higher morbidity and longer LOS compared with the opioid group [4]. The authors concluded that the use of TEA should not be considered an ERAS item in laparoscopic surgery.

In our series, a 3–4 ASA score was more common in the opioid group. There is no evidence about which analgesic regimen would be preferable according to the preoperative patient's conditions, and no guidelines clearly indicate if it is advisable to prefer TEA or an opioid-sparing technique in fragile patients. Any opioid-based analgesia regimen could theoretically increase the incidence of respiratory adverse events and postoperative delirium in such patients. Moreover, ASA 3–4 patients could present relative or absolute contraindications to central neuraxial blocks, such as platelet dysfunction, coagulopathy, or spine alterations.

Table 3 Surgery and ERAS adherence

	TEA (283)	Opioids (277)	*p*	*p* propensity
Preoperative counseling	97.88% (277)	95.67% (265)	0.138	0.104
No bowel preparation	87.63% (248)	83.7% (232)	0.184	0.141
Carbohydrate loading	92.58% (262)	65.34% (181)	< 0.001	< 0.001
Premedication	67.5% (191)	58.33% (161)	0.025	0.284
Intraoperative warming	99.29% (281)	97.47% (270)	0.087	0.039
PONV prophylaxis	84.81% (240)	51.62% (143)	< 0.001	< 0.001
Nasogastric tube removal at the end of surgery	91.4% (256)	98.1% (270)	0.02	< 0.001
Abdominal drain removal POD 1	63.6% (180)	68.95% (191)	0.181	0.366
Blood transfusion (patients)	2 (0.7%)	4 (1.4%)	0.325	0.892
Intraoperative infusion (ml/kg/h)	7.8 ± 3.88	9.87 ± 4.78	< 0.001	0.516
Laparotomic conversion	3.9% (14)	3.6% (13)	0.57	0.015
Vasoactive drugs	3.19% (9)	0.72% (2)	0.036	0.008
Type of surgery				
Right colectomy	27.8% (79)	38.5% (107)		
Left colectomy	43.46% (124)	38.55% (107)		
Total colectomy	1% (3)	1.4% (4)		
Rectum resection	26.4% (77)	21.2% (59)		

Data are number of patients (%) or mean ± standard deviation. p propensity: values obtained after propensity score analysis

PONV postoperative nausea and vomiting, *POD* postoperative day

In order to avoid possible biases related to preoperative variables, we performed a propensity weighted analysis, considering all the data included in Table 2.

Preoperative carbohydrate drink administration and PONV prophylaxis were more frequent in the TEA group, and this could explain the lower intraoperative fluid administration in these patients.

Indeed, it has been shown that fasting from midnight before surgery increases insulin resistance and patient's discomfort and potentially decreases intravascular volume, especially in patients receiving bowel preparation [11].

In a rigorous ERAS pathway, intraoperative fluid therapy should aim to maintain a near-zero fluid balance [12].

TEA patients received more iv crystalloids in the early postoperative course and had prolonged iv infusions. TEA is usually associated with systemic vasodilation and possible hypotensive episodes in the first postoperative hours, especially in patients treated with an intraoperative fluid restrictive approach [13].

In our study, TEA is not associated with better postoperative pain control. Both TEA and iv opioids were effective in obtaining good analgesia. This result is in agreement with the data reported by Hubner et al. [4], although other studies and reviews reported better pain control with TEA, in particular in the first PODs [14].

As expected, the opioid group presented more PONV and more need for restarting iv fluid administration. Early mobilization and attainment of full self-care are key components in ERAS protocols. Yet, TEA side effects such as urinary retention, arterial hypotension, and paraesthesia could explain why our patients receiving opioids were able to mobilize longer than TEA patients. This apparent advantage observed in patients receiving opioids was not associated with a reduction in LOS. These results are in agreement with a recent randomized trial by Fiore et al. [15], in which staff-directed facilitation of early mobilization led to an increase of out-of-bed activities during hospital stay but not to a better outcome.

In our study, postoperative morbidity, TRD, and LOS were comparable in the two groups. In a previous study, TEA was not able to offer an independent contribution to improve short-term postoperative outcome after minimally invasive colorectal resection within a comprehensive ERAS pathway [16].

It should be noted that several loco-regional techniques could offer the same analgesic effectiveness of TEA with less invasiveness and technical difficulty. Notable examples are loco-regional blocks such as the transversus abdominis block (TAP) [5, 17–19]. Niraj et al. found similar postoperative analgesia levels following laparoscopic colorectal surgery when comparing TEA and four quadrants of TAP block [20, 21]. According to a recent meta-analysis, the TAP block should be considered part of a multimodal approach to anesthesia and enhanced recovery in patients undergoing abdominal surgery [22]. Nevertheless, TEA remains the first choice in patients undergoing open abdominal surgery and could be the preferred technique in patients with severe respiratory and cardiovascular disease [23].

Table 4 Postoperative recovery and pain control

	TEA (283)	Opioids (277)	*p*	*p* propensity
NRS day 0	1.73 ± 1.69	2.07 ± 2	0.102	0.874
NRS day 1	1.98 ± 1.66	2.27 ± 1.95	0.158	0.896
NRS day 2	1.77 ± 1.77	1.8 ± 1.86	0.966	0.267
NRS day 3	1.02 ± 1.35	1.21 ± 1.54	0.231	0.535
NRS day 4	0.71 ± 1.35	0.75 ± 1.37	0.913	0.517
TRD	5.26 ± 2.97	5.52 ± 2.67	0.188	0.108
Endovenous infusion POD 1 (ml)	1553.24 ± 694	1131.41 ± 693	< 0.001	< 0.001
Endovenous infusion POD 2 (ml)	785.85 ± 890	514.91 ± 738	0.001	< 0.001
Oral fluids (POD)	0.47 ± 0.88	0.43 ± 0.77	0.985	< 0.001
Food (POD)	1.67 ± 1.35	1.49 ± 0.99	0.314	< 0.001
Stop endovenous infusion (POD)	2.3 ± 2.2	1.62 ± 1.35	< 0.001	< 0.001
Restart endovenous infusion	7.14% (20)	16.3% (45)	0.001	0.025
Repositioning nasogastric tube	4.96% (14)	8.66% (24)	0.082	0.058
PONV first 24 h	4.26% (12)	10.11% (28)	0.007	0.011
Preventive use of postoperative prokinetics	13.1% (37)	24.19% (67)	0.001	0.144
Removal bladder catheter (POD)	1.54 ± 2.26	1.4 ± 0.87	0.064	< 0.001
Recovery of bowel function (POD)	1.87 ± 0.98	1.83 ± 0.88	0.681	0.289
Pain control with oral analgesics (POD)	3.14 ± 1.54	2.96 ± 1.40	0.208	0.035
Ability to mobilize and self-care (POD)	3.18 ± 1.82	2.4 ± 2.2	< 0.001	< 0.001
Postoperative complications	18.32% (52)	18.08% (50)	0.944	0.626
Length of hospital stay (POD)	5.7 ± 3.21	5.8 ± 2.92	0.538	0.007
Total length of hospital stay	6.5 ± 4.2	6.9 ± 3.3	0.075	0.109
Readmission rate	2.31% (7)	2.67% (7)	0.732	0.258

Data are number of patients (%) or mean ± standard deviation. p propensity: values obtained after propensity score analysis

POD postoperative day, *NRS* numeric rating scale, *PONV* postoperative nausea and vomiting, *TRD* time ready for discharge

A limitation of our study is that participating hospitals could differ in the degree of ERAS pathway implementation, and a potential selection bias cannot be ruled out.

The major strengths of our study are the access to a dedicated database to assess the adherence to ERAS items and the use of a validated indicator of short-term recovery such as the TRD [1].

In conclusion, in our series, TEA, despite its higher invasiveness and its related risk of potential serious side effects, presented similar effects on pain control and short-term postoperative outcomes as iv opioids.

Our results support the statement of the most recent ERAS guidelines in colorectal surgery, indicating how TEA can be used but is not recommended in laparoscopic colorectal surgery [2].

In our opinion, future large randomized trials should investigate the possible role of less invasive loco-regional techniques to achieve adequate pain control, rapid mobilization, and fast discharge in the setting of laparoscopic colorectal surgery within an ERAS pathway and an opioid-sparing strategy.

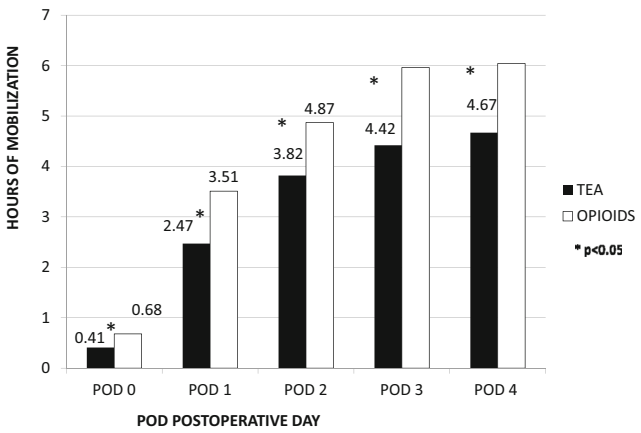

Fig. 1 Hours of mobilization of TEA and opioid groups

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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