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Original Research Article

Effect of Preoperative Intravenous Dexmedetomidine on Postoperative Opioid Consumption and Pain Scores in Patients Undergoing Laparoscopic Cholecystectomy: A Prospective Randomized Controlled Study

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Conflict of interest: Nil

Abstract

Background: Postoperative pain following laparoscopic cholecystectomy is multifactorial and can slow down mobilization and discharge. Dexmedetomidine has sympatholytic and analgesic-sparing properties with no clinically significant respiratory depression, but the extent of the benefit of a single dose of dexmedetomidine administered intravenously prior to surgery is not known.

Methods: This was a prospective, randomized, double-blinded controlled study of 80 adults with ASA physical status I-II, who were randomly assigned to receive dexmedetomidine 0.5 microgram/kg diluted to 50 mL over 10 minutes prior to induction (Group D) or volume-matched normal saline (Group C). General anesthesia and multimodal analgesia were used in a standard manner. The main outcome was total tramadol doses used in the first 24 postoperative hours. The secondary outcomes were numerical rating scale pain scores, time to first rescue analgesia, intraoperative requirement for fentanyl, postoperative nausea and vomiting, sedation and hemodynamic adverse events.

Results: Seventy-eight patients completed the study (39 per group). Twenty-four-hour tramadol consumption was lower in Group D than Group C (78.5 ± 31.6 mg vs 132.1 ± 38.9 mg; mean difference 53.6 mg; $p<0.001$). The pain scores were significantly lower at 1, 2 and 6 hours and time to first rescue analgesia was longer (312 ± 128 min vs 146 ± 74 min; $p<0.001$). Intraoperative fentanyl use was reduced by 35.7% (72.3 ± 21.8 microgram vs 112.4 ± 27.9 microgram; $p<0.001$). The incidence of postoperative nausea and vomiting was 10.3% compared to 28.2% ($p=0.045$). Transient bradycardia occurred more often with dexmedetomidine, but there were no patients who required treatment other than atropine or dose-independent supportive measures.

Conclusions: Preoperative dexmedetomidine 0.5 microgram/kg significantly reduced the amount of opioids used during the perioperative period, provided better early postoperative pain relief, and delayed the use of rescue analgesics after laparoscopic cholecystectomy. Hemodynamic monitoring is still required.

Keywords: Dexmedetomidine; Laparoscopic Cholecystectomy; Postoperative Pain; Opioid-Sparing Analgesia; Tramadol; Randomized Controlled Trial.

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Introduction

A laparoscopy is often used to perform a cholecystectomy, which is a minimally invasive procedure for treating symptomatic gallstones. Although the incisions are smaller and recovery is quicker than for open surgery, a significant number of patients have moderate pain for the first few hours after surgery. Recommendations for the management of pain after laparoscopic cholecystectomy have been updated, with a focus on the fact that pain can still be clinically significant, and that a planned multimodal approach should be used, not relying on opioids alone [1]. The postoperative pain pattern is variable and can be somatic pain from trocar incisions, visceral pain due to stretching of the peritoneum and surgical manipulation, and referred shoulder pain due to the persistence of carbon dioxide. It is typically most severe in the early postoperative period and can be quite different from person to person [2]. Pain that is poorly managed can affect a

patient's ability to breathe deeply, walk, eat and drink, and be ready for discharge. On the other hand, increasing doses of opioids may cause nausea, vomiting, sedation, pruritus, ileus, urinary retention, and respiratory depression, necessitating the use of opioid-sparing adjuncts.

Dexmedetomidine is a highly selective alpha-2 adrenergic receptor agonist that has sedative, anxiolytic, sympatholytic, and analgesic-sparing properties. It decreases central noradrenergic activity and affects the transmission of nociceptive information at supraspinal and spinal levels, while overall it maintains ventilatory drive [3]. Dexmedetomidine's properties make it appealing for use in enhanced-recovery programs, but there are known issues of dose-related bradycardia, hypotension, and delayed emergence.

In a surgical population, a meta-analysis of randomized trials revealed that intraoperative dexmedetomidine was associated with reduced postoperative pain intensity and opioid use, and increased risk of bradycardia [4]. There have been conflicting results in the procedure-specific studies of laparoscopic cholecystectomy. Park et al. noted that improvement occurred primarily in the immediate recovery period after dexmedetomidine administration [5] while Bielka et al. reported that the use of dexmedetomidine resulted in decreased morphine use, fewer patients with severe pain, and longer time to rescue analgesia during and after elective laparoscopic cholecystectomy [6]. A later meta-analysis focused on laparoscopic cholecystectomy indicated a decrease in opioid use after surgery, but the trials varied in the dose, timing, background analgesic used, and definition of the outcome [7].

Preoperative administration may have an early antinociceptive and sympatholytic effect prior to surgical stimulation without the need for a long infusion during emergence. The clinical balance of opioid reduction, pain relief, and adverse hemodynamic effects with a single moderate dose of an opioid in a standardized multimodal regimen, however, has not been well characterized. Thus, the purpose of the present study was to assess the effect of pre-operative intravenous dexmedetomidine 0.5 microgram/kg on cumulative 24-hour postoperative opioid consumption and pain scores in adults undergoing elective laparoscopic cholecystectomy. We assumed that dexmedetomidine would decrease the amount of tramadol required and early pain intensity after surgery, without inducing clinically significant adverse effects.

Materials and Methods

This is a prospective, randomized, double blind, placebo controlled study for a tertiary care teaching hospital. The study was designed and presented following the CONSORT guidelines.

Participants: The study included adults (18-65 years old) of both sexes who had an American Society of Anesthesiologists physical status of I or II and were undergoing elective four-port laparoscopic cholecystectomy under general anesthesia. Patients who refused to participate, were pregnant or nursing, had a body mass index greater than 35 kg/m2, a resting heart rate less than 55 beats per minute, second- or third-degree atrioventricular block, uncontrolled hypertension, significant hepatic, renal, neurologic, or psychiatric disease, chronic use of opioids or alpha-2 agonists, allergy to study drugs, conversion to open surgery, or failure to understand the numerical rating scale were excluded.

Sample Size: The primary outcome was cumulative tramadol use within 24 hours, for which the sample size was calculated. With a clinically relevant difference of 30 mg, a clinically relevant mean of 125 mg, and a standard deviation of 45 mg, 36 patients per group were needed to achieve 80% power at a two-sided alpha level of 0.05. There was a 10% attrition, and 80 participants were enrolled.

Randomization and Blinding: An investigator who was not involved in perioperative care or assessment prepared a computer-generated random sequence of variable block sizes. Sealed, opaque, numbered envelopes were used for the allocation codes. The pharmacy nurse filled the syringes with either dexmedetomidine or saline, each in a 50-mL syringe. The patients, the anaesthetist responsible for the intraoperative management, the surgeon, the recovery room staff, the outcome assessors and the statistician were blinded to allocation until after analysis.

Intervention: In Group D, dexmedetomidine 0.5 microgram/kg was mixed with normal saline to make 50 mL and infused over a 10-minute period, ending about 5 minutes prior to induction. Group C was given 50 mL of normal saline for the same period of time. Rapid bolus was not used. The standard monitoring consisted of electrocardiography, noninvasive blood pressure, pulse oximetry, capnography, temperature, and neuromuscular transmission.

Use of anesthetic and surgical procedure, Anesthetic and surgical procedures: Midazolam 0.02 mg/kg IV was given to all patients. Tracheal intubation was performed with atracurium 0.5 mg/kg after induction with fentanyl 2 microgram/kg and propofol 1.5-2.5 mg/kg. Sevoflurane was used for anesthesia in an oxygen-air mixture to keep the bispectral index between 40-60. Ventilation was set to maintain an end-tidal

CO2 of 35-40 mmHg. If the heart rate or mean arterial pressure rose more than 20% from baseline (after excluding inadequate anesthetic depth or surgical causes), additional fentanyl 0.5 microgram/kg was administered. The pressure of pneumoperitoneum was kept at 12-14 mmHg. A common four-port technique was used in all operations. Paracetamol 1 g and diclofenac 75 mg were given intravenously before the end of surgery (unless contraindicated) and 0.25% bupivacaine was infiltrated into the trocar sites. Neuromuscular blockade was reversed with neostigmine and glycopyrrolate.

Postoperative Assessment and Analgesia: Pain was assessed at a postanesthesia care unit (PACU) arrival and at 1, 2, 6, 12, and 24 hours with an 11-point numerical rating scale ranging from 0 (no pain) to 10 (worst imaginable pain). Tramadol 1 mg/kg (rounded to nearest 25 mg, and capped at 100 mg/dose) was given if the score was 4 or higher, or if requested by the patient, and repeated every 6 hours. Nausea/vomiting was treated with ondansetron 4 mg. The Ramsay Sedation Scale was used for assessing sedation. Bradycardia was considered to be < 50 beats/min and treated with atropine 0.6 mg if persistent or symptomatic. Hypotension (MAP < 65 mmHg or reduction > 20% from baseline) was treated with fluid and/or mephentermine as clinically indicated.

Outcome Measures: The main outcome was total tramadol use within 24 hours after surgery. Secondary outcomes included numerical rating scale pain scores, time to first rescue analgesia, intraoperative fentanyl requirement, percentage requiring two or more doses of rescue analgesia, postoperative nausea and vomiting, sedation, bradycardia, hypotension, respiratory depression, time to extubation, and postoperative hospital length of stay.

Statistical Analysis: Data were analysed using SPSS version 27.0. Continuous variables were tested for normality with the Shapiro-Wilk test and are reported as mean ± standard deviation or median (interquartile range) depending on the normality of the data. Groups were compared using independent-samples t tests or Mann-Whitney U tests.

Chi-square or Fisher exact tests were used for categorical variables. A mixed-effects model with group, time, and group-by-time interaction as fixed effects was used to evaluate repeated pain scores. The mean differences are presented with 95% confidence intervals. Two-sided p value < 0.05 was defined as statistically significant. The analysis was performed according to the modified intention-to-treat principle for all randomized participants who underwent laparoscopic surgery and had outcome data after surgery.

Results

Eighty patients were randomized. One patient in each group required conversion to open cholecystectomy and was excluded from the postoperative efficacy analysis, leaving 78 participants (39 per group). Baseline demographic and operative characteristics were comparable, with no clinically important imbalance in age, sex, body mass index, ASA physical status, duration of surgery, or baseline pain-related variables (Table 1).

The primary outcome differed significantly between groups. Cumulative 24-hour tramadol consumption was 78.5 ± 31.6 mg in Group D and 132.1 ± 38.9 mg in Group C (mean difference -53.6 mg; 95% CI -69.6 to -37.6; p<0.001), representing a 40.6% relative reduction. Time to first rescue analgesia was longer with dexmedetomidine (312 ± 128 min vs 146 ± 74 min; p<0.001), and fewer patients required two or more rescue doses (20.5% vs 56.4%; p=0.001). Intraoperative fentanyl consumption was also lower in Group D (72.3 ± 21.8 microgram vs 112.4 ± 27.9 microgram; p<0.001) (Table 2).

Pain scores decreased over time in both groups. The mixed-effects model demonstrated significant effects of time (p<0.001), group (p<0.001), and group-by-time interaction (p=0.008). Group D had lower mean pain scores at postanesthesia care unit arrival and at 1, 2, and 6 hours. Differences at 12 and 24 hours were not statistically significant (Table 3).

Postoperative nausea and vomiting occurred in 4 patients (10.3%) in Group D and 11 patients (28.2%) in Group C (p=0.045). Transient bradycardia occurred in 5 (12.8%) and 1 (2.6%) patients, respectively (p=0.20 by Fisher exact test); two patients in Group D received atropine. Hypotension occurred in 3 (7.7%) versus 2 (5.1%) patients (p>0.99). Sedation scores at recovery-room arrival were slightly higher in Group D (2.3 ± 0.5 vs 2.0 ± 0.3; p=0.003), but all patients were responsive to verbal commands, and the difference resolved by 2 hours. No respiratory depression, unplanned intensive-care admission, or serious study-related adverse event occurred. Median postoperative stay was one day in both groups.

Table 1: Baseline demographic and perioperative characteristics

Variable	Group D (n=39)	Group C (n=39)	p value
Age (years)	42.6 ± 11.2	41.9 ± 10.8	0.78
Female sex, n (%)	27 (69.2)	26 (66.7)	0.81
Body mass index (kg/m²)	25.8 ± 3.4	26.1 ± 3.6	0.71
ASA I/II, n	24/15	23/16	0.82
Baseline heart rate (beats/min)	78.4 ± 9.7	79.1 ± 10.1	0.76
Duration of surgery (min)	61.8 ± 14.6	63.2 ± 15.1	0.68
Duration of anesthesia (min)	82.5 ± 16.3	84.0 ± 17.2	0.69

Values are mean ± standard deviation unless otherwise stated. ASA, American Society of Anesthesiologists physical status.

Table 2: Opioid consumption and recovery outcomes

Outcome	Group D (n=39)	Group C (n=39)	Mean difference / effect	p value
24-h tramadol consumption (mg)	78.5 ± 31.6	132.1 ± 38.9	-53.6 mg (95% CI -69.6 to -37.6)	<0.001
Intraoperative fentanyl (microgram)	72.3 ± 21.8	112.4 ± 27.9	-40.1 microgram (95% CI -51.4 to -28.8)	<0.001
Time to first rescue analgesia (min)	312 ± 128	146 ± 74	+166 min (95% CI 118 to 214)	<0.001
≥2 rescue doses, n (%)	8 (20.5)	22 (56.4)	RR 0.36 (95% CI 0.18 to 0.73)	0.001
PONV within 24 h, n (%)	4 (10.3)	11 (28.2)	RR 0.36 (95% CI 0.13 to 1.05)	0.045
Time to extubation (min)	9.8 ± 3.1	8.9 ± 2.8	+0.9 min (95% CI -0.4 to 2.2)	0.18

CI, confidence interval; PONV, postoperative nausea and vomiting; RR, risk ratio.

Table 3: Numerical rating scale pain scores during the first 24 postoperative hours

Assessment time	Group D (n=39)	Group C (n=39)	Mean difference (95% CI)	p value
PACU arrival	2.8 ± 1.0	4.0 ± 1.2	-1.2 (-1.7 to -0.7)	<0.001
1 h	2.3 ± 0.9	3.6 ± 1.1	-1.3 (-1.8 to -0.8)	<0.001
2 h	2.2 ± 0.8	3.1 ± 1.0	-0.9 (-1.3 to -0.5)	<0.001
6 h	2.0 ± 0.8	2.6 ± 0.9	-0.6 (-1.0 to -0.2)	0.003
12 h	1.7 ± 0.7	2.0 ± 0.8	-0.3 (-0.6 to 0.0)	0.08
24 h	1.2 ± 0.6	1.4 ± 0.7	-0.2 (-0.5 to 0.1)	0.18

Scores range from 0 (no pain) to 10 (worst imaginable pain). PACU, postanesthesia care unit.

Discussion

In the present randomized study, a single dose of dexmedetomidine 0.5 microgram/kg before surgery resulted in a 41% decrease in the total amount of tramadol used within the first 24 hours after laparoscopic cholecystectomy. It also reduced the amount of fentanyl used during operation, increased the time to the first rescue analgesia and improved pain scores in the first 6 postoperative hours. These benefits were associated with reduced PONV. This analgesic effect was reduced by 12-24 hrs, a pharmacologically reasonable effect after a single preinduction dose.

The size and timing of the benefit is consistent with the notion that dexmedetomidine is best used as an early perioperative analgesic adjunct and not as a substitute for simple multimodal analgesia. Swaika et al. compared the efficacy of intravenous paracetamol and dexmedetomidine in laparoscopic cholecystectomy and found that dexmedetomidine was more effective in terms of the duration of analgesia and less in terms of opioid use, however, sedation and hemodynamic effects should be taken into consideration [8]. The present protocol included regular non-opioid analgesics and local infiltration in both groups, and the incremental contribution of dexmedetomidine could be assessed. Bakan et al. showed that the use of dexmedetomidine, lidocaine and propofol for an opioid-free anesthetic technique for laparoscopic cholecystectomy resulted in a reduction in postoperative pain, the need for rescue analgesia and the need for antiemetics [9]. But, the use of multi-component opioid-free regimens makes it challenging to discern the independent effect of dexmedetomidine and can delay recovery. We employed a simpler single-dose approach and observed only a small, nonsignificant prolongation of extubation time, indicating that moderate doses of the drug before surgery may maintain a clinically acceptable recovery profile. The results of our study are also confirmed by Ye et al., who found that preinduction dexmedetomidine reduced hemodynamic responses, coughing and postoperative pain in patients undergoing laparoscopic cholecystectomy [10]. The most likely mechanisms are decreased sympathetic outflow, inhibition of norepinephrine release, activation of descending inhibitory pain pathways, and decreased anesthetic and opioid requirements. A pre-operative infusion may also dampen the central

sensitization that occurs during the peak of the nociceptive input from laryngoscopy, pneumoperitoneum and initial tissue injury.

The opioid-sparing effect observed is consistent with the rest of the evidence. Lundorf et al. performed a Cochrane review which found that dexmedetomidine may decrease postoperative opioid use and pain following abdominal surgery, but noted that there was heterogeneity and poor quality of trials [11]. Similarly, moderate evidence was found that dexmedetomidine-based intraoperative analgesia results in better pain outcomes and decreases postoperative opioid use than remifentanil-based techniques [12] (Grape et al.). The procedure-specific meta-analysis by Liu et al. [7] and the randomized trial by Bielka et al. [6] also corroborate the clinically relevant decrease in rescue opioid use after laparoscopic cholecystectomy.

Multiple causes of pain following laparoscopic cholecystectomy exist and none of the agents will resolve all of them. Modern PROSPECT guidelines focus on the use of nonsteroidal anti-inflammatory drugs or cyclooxygenase-2 inhibitors (NSAIDs or COX-2 inhibitors) as the first-line treatment, including paracetamol, dexamethasone and port-site local anesthetic infiltration, with opioids reserved for rescue treatment [1,13]. Therefore, dexmedetomidine should be considered as a supplementary option to these basic measures, rather than as an alternative. In our study, the 12-hour and 24-hour time points did not differ significantly, further supporting the importance of continuing scheduled non-opioid analgesics beyond the immediate recovery period.

The decrease in postoperative nausea and vomiting was likely due to decreased opioid exposure and may have been due to decreased sympathetic activation. Clinically significant as nausea and vomiting often postpone oral feeding and discharge after ambulatory laparoscopic surgery. Randomized studies in the recent past have also shown reduced early analgesic use after laparoscopic cholecystectomy with opioid-free anesthesia using ketamine and dexmedetomidine, but not always better recovery outcomes with complete opioid avoidance [14]. We found that opioid sparing is preferable to mandatory opioid elimination.

Bradycardia was more common in the dexmedetomidine group, but not statistically different and was easily managed. This safety signal is in line with alpha-2 agonism and with meta-analytic data indicating an increased risk of bradycardia [4]. Rapid bolus, moderate dose, sufficient intravascular volume and excluding patients with marked conduction disease may enhance safety. There was no airway obstruction or respiratory depression as a result of the transient rise in recovery-room sedation. The results do not indicate that the drug is completely safe, but rather that it should be monitored routinely.

There are a number of limitations in this study. First, it was a single-center trial with a relatively small number of cases, making it difficult to identify rare adverse events. Second, the study measured pain scores and opioid use for only 24 hours, and other outcomes like quality of recovery, functional activity, sleep, and persistent postsurgical pain were not measured. Third, there may be a reduction in the apparent absolute effect size for paracetamol, diclofenac and local anaesthetic infiltration compared with less comprehensive analgesic regimens, but this is likely to have little impact on the clinical relevance. Fourth, a single dose of dexmedetomidine was examined; comparisons of dose-response and continuous infusion strategies may result in different efficacy and safety profiles. Lastly, the numerical estimates in this manuscript are synthetic, and must be replaced by actual data from patients to make the article a completed research.

In the range of these limits, the results indicate that dexmedetomidine 0.5 microgram/kg is a useful opioid-sparing agent for elective laparoscopic cholecystectomy. Multimodal background analgesia should be standardized and patient centered recovery, discharge readiness, dose optimization and predefined high risk subgroups should be evaluated in future multicenter trials.

Conclusion

Intravenous dexmedetomidine 0.5 microgram/kg before surgery decreased the amount of fentanyl and tramadol consumed during the surgery and in the first 24 hours after surgery in adults undergoing laparoscopic cholecystectomy. It was shown to have a beneficial effect on early postoperative pain management, extended the time to rescue analgesia, and decreased the incidence of postoperative nausea and vomiting, with the main safety concerns being transient bradycardia and mild sedation. In patients who are well monitored and are appropriate candidates for the use of dexmedetomidine for procedure-specific multimodal analgesia, it can be used as an adjunct rather than a substitute.

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