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Intravenous Dexmedetomidine effect on shoulder pain in Laparoscopic Cholecystectomy under Spinal Anesthesia

Hend F. Hassan [1], Moshira S. Amer[1], Ahmed A. Rady[1], Ahmed Essam[1], Mohamed M. Hussien[1], Hesham A. Elmeligy*, M. EmadEsmat[2], Mohamed A. Maher[1], Ahmed I. Refaat[1].

[1] Anesthesia department, Theodor Bilharz Research Institute, Giza, Egypt.

[2] Surgical department, Theodor Bilharz Research Institute, Giza, Egypt.

Hend F. Hassan:
Affiliation: Anesthesia lecturer at Theodor Bilharz Research Institute.
Orchid ID: 0000- 0002-1469-0597.
Corresponding author: Moshira S. Amer.*
Affiliation: lecturer of anesthesia at Theodor Bilharz Research Institute.
Orchid ID: 0000-0003-3867-568X
Ahmed A. Rady Abbas:
Affiliation: Anesthesia lecturer at Theodor Bilharz Research Institute.
Ahmed M. Essam
Affiliation: Anesthesia lecturer at Theodor Bilharz Research Institute.
Mohamed M. Hussien:
Affiliation: Anesthesia lecturer at Theodor Bilharz Research Institute.
Orchid ID: 0000-0003-1353-5656.
Mohamed A. Maher:
Affiliation: Anesthesia assistant professor at Theodor Bilharz Research Institute.
Orchid ID: 0000-0003-0578-6930.
Ahmed I. Refaat:
Affiliation: Assistant professor of Anesthesia at Theodor Bilharz Research Institute.
HeshamA. Elmeligy:
Affiliation: Associate professor of Surgery at Theodor Bilharz Research Institute.
ORCHID ID: 0000-0002-1824-6602.
Mohamed E. Esmat:
Affiliation: Professor of General Surgery Theodor Bilharz Research Instiute.

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KEYWORDS
intravenous dexmedetomidine, shoulder pain, laparoscopic cholecystectomy and spinal anesthesia

ABSTRACT:

Introduction: Laparoscopic cholecystectomy (LC) is the commonly used surgical technique in acute and chronic cholecystitis. Regional anesthesia is not extensively used in such surgeriesdue to some limitations, mainly shoulder pain with no ideal alleviating method till now.Dexmedetomidine is aα2-adrenoreceptor agonist agent which has a promising results in controlling shoulder pain.

Aim: Assessing the effectiveness of IV dexmedetomidine on managing shoulder pain in patients undergoing laparoscopic cholecystectomy and receiving spinal anesthesia.

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Methods: Forty six ASA I, II patients whose age ranged from 18- 60 years oldundergoing elective LC were randomized into 2 groups, 23 patients in each group. All patients received spinal anesthesia. Dexmedetomidine group (D) received 1µg/kg loading dose of dexmedetomidine in 10 minutes followed by maintenance dose: 0.7 µg/kg/ hr. The control (C) group received similar doses of normal saline. For all patients, the highest degree of VAS was recorded, incidence of shoulder pain, rescue analgesic requirements, incidence of conversion to general anesthesia and intraoperative hypotensive, bradycardic and hypoxic episodes were recorded.

Results:IV dexmedetomidine significantly reduced shoulder pain in the D group than the C group. Incidence of shoulder tip pain in the D group was significantly lower (26.1 %) compared to (78.3%) in the C group. The incidence of patients required rescue analgesia in the D group (21.7%) was significantly lower than the C group (73.9%). Also the incidence of conversion to general anesthesia was significantly higher in the C group (52.2 %) than the C group (0.0%).The incidence of intraoperative hypotensive, bradycardic and hypoxic episodes were comparable in both groups.

Conclusion: Intravenous dexmedetomidine decreased the severity and the incidence of shoulder pain, rescue analgesic requirement and the incidence of conversion to general anesthesia in patients underwent laparoscopic cholecystectomy under spinal anesthesia.

Introduction:

Laparoscopic cholecystectomy (LC) is the most commonly used surgical technique in acute and chronic cholecystitis. Laparoscopic cholecystectomy is highly preferable than open procedure due to shorter recovery time, early ambulation , better cosmetic results , and a lower complication rates. General anesthesia (GA) has been the commonly used anesthetic technique for these patients despite its disadvantages, such as higher rates of postoperative nausea and vomiting (PONV), postoperative opioid analgesic requirement, airway instrumentation related complications and hemodynamic variability.(1,2).

Several attempts were made to use spinal anesthesia in laparoscopic cholecystectomy in an attempt to avoid the disadvantages of general anesthesia. They faced complications that limited its use: shoulder pain secondary to intra-abdominal carbon dioxide (CO_2) pneumoperitoneum, patient anxiety, pain, and discomfort, and inadequate sedation. (3)

Many studies(4, 5, 6),investigated the use of different drugs to manage complications of spinal anesthesia in laparoscopic cholecystectomy. No ideal drug is found yet that prevents intraoperative complications especially shoulder pain which is considered the most common cause of conversion from spinal to general anesthesia.

Dexmedetomidine is a selective α2-adrenoreceptor agonist that has sedating, analgesic, anxiolytic, and hemodynamic stabilizing properties with maintenance of the ventilatory drive (7). Thus, we designed a prospective study to investigate the effect of intravenous dexmedetomidine infusion on alleviating shoulder tip pain.

Methodology:

A randomized, controlled, double-blinded trial was performed at Theodor Bilharz Research Institute, Giza, Egypt, after approval of the research ethics committee. (PT :479)The study was registered before patient enrollment at the clinicaltrial.gov registry system. ID: NCT04115449.

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The study was conducted from December 2021 till November 2023. There were 2 years of interrupted enrollment of the patients due to the COVID-19 pandemic.

All patients had signed written informed consents before enrollment in the study. Online random number generator was used by a statistician to perform the randomization of the patients. An anesthesia resident who was not participating in the study was responsible for inserting patient codes into serially numbered, sealed and opaque envelopes. Another anesthesia resident not involved in the anesthetic management of the patients was responsible for unsealing the envelope & preparing the study drugs according to patients codes contained within each envelope. Then he gave it to the anesthetist in charge.

Forty-six patients ASA (American Society of Anesthiolgists) I or II, whose age ranged from 18 to 60 years old underwent elective laparoscopic cholecystectomy with pneumoperitoneum time 30 to 45 minutes and were recruited in the study and were divided into two groups either Dexmedetomidine group (D) or Control group (C). Each group contained 23 patients.

Patients were excluded from the study if they were diagnosed with glaucoma, had a body mass index (BMI)> 30 kg/m2, and were pregnant, lactating, or had any contraindication to spinal anesthesia. Furthermore, patients known to be allergic to bupivacaine &dexmedetomidine or treated with α2- adrenergic receptor antagonist agents, calcium channel blockers, angiotensin-converting enzyme inhibitors, and antidepressants were also ruled out from the study.

On admission to the operating theater, standard monitoring devices were applied: electrocardiogram(ECG), pulse oximetry, and noninvasive blood pressure monitor for each patient. Baseline measurements were recorded. Two intravenous (IV) lines were inserted, one of them 22 gauge(G) was specified for the infused drugs, and the other one 18 G for the required perioperative IV fluids. Patients were premedicated with 2mg midazolam IV and 4 mg ondansetron IV. Ringer's solution 500 ml was started as co-loading over 15 minutes.

In both groups; a 50 ml syringe was mounted on a syringe pump and attached to the 22 g cannula of all patients. In the Dexmedetomidine group (D), the syringe was prepared by adding dexmedetomidine to normal saline to achieve a concentration of 4 µg/ml. In the control group:only normal saline was used. To achieve blinding in both groups, the syringe pump rate was adjusted by the anesthesia resident responsible for checking patient code and drug preparation accordingly. The syringe pump rate was adjusted to administer 1µg/kg as a loading dose throughout 10 minutes then a maintenance dose of 0.7µg / kg/hr till the end of the procedure.

After finishing administration of the loading dose of the study drug in both groups, spinal anesthesia was performedin the lateral position through the L3–4 or L2-3 interspaces using a 25 G spinal needle. 4 ml (20mg) of hyperbaric bupivacaine 0.5% solution with 20 µg fentanyl was injected into the subarachnoid space. After the patient was turned to the supine position, the level of sensory block was assessed using a pinprick, and if patients had a sensory level below T4, it was considered a failed block and were precluded from the study. Insufflation of gas for pneumoperitoneum was done at the rate of 1.5 liters/min and the abdominal pressure was adjusted from 12- 14 mmHg. Supplementary oxygen at 4 liters/min was given to the patients with face masks.

Hemodynamic measurements in the form of Mean arterial blood pressure (MAP), heart rate (HR) and arterial oxygen saturation(SPO2) were recorded as follows; Baseline (T0) MAP was obtained as the mean of three successive readings with 2 minutes intervals and aless than 10% difference between them. T1 was recorded at the end of the loading dose. After spinal anesthesia, hemodynamic& SPO2 readings were recorded every 5 minutes till the end of the procedure. If the mean arterial pressure decreased (MAP) by 20% from the baseline, 15 mg ephedrine was given IV. If the heart rate decreased to 45 beats min, IV atropine 0.5 mg was administered. The number of intraoperative hypotensive, bradycardic, and hypoxic episodes were recorded.

Intraoperative shoulder pain was assessed using the visual analogue score (VAS). The degree of pain severity was

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categorized as follows;(1-3: mild pain), (4-6: moderate pain) and (7-10: severe pain). The highest degree of pain severity throughout the procedure was recorded for each patient. Rescue analgesic medications were given if the VAS ≥ 4 in the form of 25 µg fentanyl up to a maximum of 100 µg with a 3-minute interval between each dose. Persistent shoulder despite receiving maximum doses of rescue medication was managed by induction of general anesthesia and mechanical ventilation. Induction of general anesthesia was done by: a sleeping dose of propofol (1-2 mg/kg) and 0.5mg/kg of atracurium. Reversal of general anesthesia was done as usual anesthetic practice.

All patients were observedpost-operatively up to six hours after discharge from the post anesthesia care unit (PACU) to record the incidence of post-dural puncture headache & time of sensory regression of spinal anesthetic level(defined as the duration from administration of spinal anesthesia to two-segment sensory regression).

1ry outcome:

Effect of intravenous dexmedetomidine on the intensity of intraoperative shoulder pain assessed by Visual analogue score (VAS).

2ry outcomes:

- Incidence of shoulder pain in both groups.
- Incidence of conversion to GA.
- Intraoperative number of hypotensive (MAP<20% baseline) &bradycardic (HR<50) episodes.
- Intraoperative hypoxic (SPO2 <92%) episodes.
- Total rescue analgesic dose.
- Number of patients who received rescue analgesia.
- Spinal sensory regression time.
- Post-dural puncture headache.

Statistical analysis and sample size calculation:

Hamed et al. (2021) (8)found that the difference in shoulder tip pain VAS score between the dexmedetomidine group and the control group was 1.43 with a 1.21standard deviation. Based on these findings, a minimal sample size of 20 patients in each group was required to reject the null hypothesis at an alpha level of 0.05 and power of 95%. To compensate for the non-normality of data, the sample was increased by 15% to 23 patients in each group with a total sample size of 46 patients. The sample size was estimated using the NQuery statistical package, version 7.0, Los Angeles, CA.

Results:

Forty-six patients were enrolled and randomized as follows: 23 patients were allocated to the Dexmedetomidine group and 23 patients were allocated to the control group. (Figure 1).

The general characteristics of the patients regarding Age, Sex, ASA classification, and BMI showed no statistically significant difference. Although Length of surgery (LOF) was higher significantly in the C groupthan in the D group, yet both of them were in range of the predetermined length of surgery (Table 1):

Table (1) Demographic data and length of surgery:

		Group				
		D group		C group		p-value
Age	Mean ± SD	40.3 ±10.0		42.8±13.7		.496
Sex	Male (N&%)	3	13.0%	5	21.7%	.437
	Female(N&%)	20	87.0%	18	78.3%	
ASA	ASA I(N &%)	16	69.6%	11	47.8%	.134
	ASA II(N&%)	7	30.4%	12	52.2%	
BMI	18 < 25(N &%)	12	52.2%	13	56.5%	.767

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	25 ≥ 30(N &%)	11	47.8%	10	43.5%	
LOF	Minutes (Mean ± SD)	51.3 ± 8.7		56.5 ± 5.9		0.022

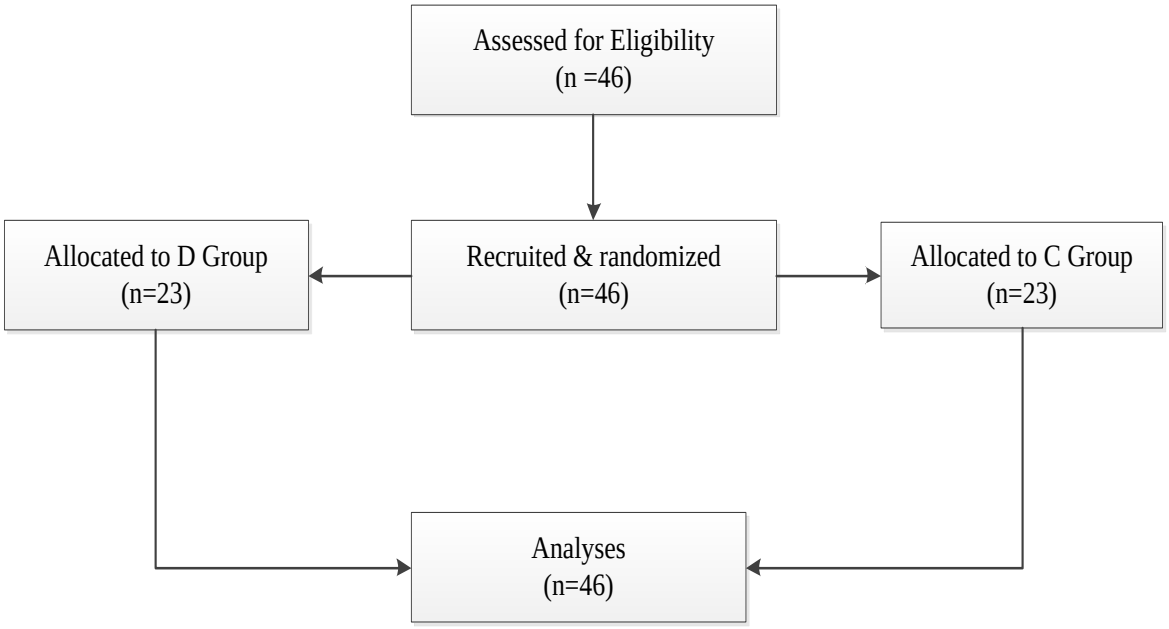

Figure (1): flow chart

Regarding the effect of dexmedetomidine on intraoperative (IO) shoulder pain intensity. The number of patients experiencing moderate(0.0%) and severe(4.3%) shoulder tip pain in the D groupwere statistically significantly lower than in the C group (21.7%), (43.5%) respectively with P value< 0.001. Also, the number of patients experiencing no shoulder painwas statistically significantly higher in the Dgroup (78.3%) than in the C group (26.1%) respectively with P value < 0.001.(Table 2)

Table (2): Effect of IV dexmedetomidine on Incidence and severity of shoulder pain:

			Group		P value
			D group	C group	
Shoulder Pain	No	N&%	18 (78.3%)	6 (26.1%)	< 0.001
	Mild	N& %	4 (17.4%)	2 (8.7%)	
	Moderate	N&%	0 (0.0%)	5 (21.7%)	
	Severe	N &%	1 (4.3%)	10 (43.5%)	

Evaluation of the rescue analgesic requirements showed that the D group had a significantly lower incidence of patients who required rescue analgesia (21.7%)compared to (73.9%) in the C group with a p-value < 0.001.

Also, the total dose of rescue analgesic requirement was higher significantly in the C group compared to the D group. This was shown through that the percentage of patients in the D group who required double and maximum doses

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(17.4% and 4.3% respectively) of rescue analgesia was significantly lower compared to (26.1% and 47.8% respectively) in the C group with p-value < 0.001. Table 3

Table (3): Rescue analgesic requirements:

			Group		
			D group	C group	P value
Fentanyl.IO	No	N & %	18 (78.3%)	6 (26.1%)	< 0.001
	Yes	N &%	5 (21.7%)	17 (73.9%)	
Fentanyl (µg).IO	50	N & %	4 (17.4%)	6 (26.1%)	< 0.001
	100	N& %	1 (4.3%)	11 (47.8%)	

Incidence of conversion to general anesthesia was significantly lower in the D group as it had zero percentage of converted patients compared to 52.2% in the C group with P value < 0.001. Table 4

Table (4): Incidence of conversion to GA:

			Group		P value
			D group	C group	
Conversion to GA.	No	N&%	23 (100.0%)	11 (47.8%)	<0.001
	Yes	N&%	0 (0.0%)	12 (52.2%)	

Regarding the relation between intraoperative shoulder pain and BMI, the following was noticed: patients with low BMI (18< 25) had a statistically significant higher incidence of intraoperative shoulder pain in the C group (84.6%) than those of the D group (25%) with p value < 0.05 (Table 5). Patients with high BMI (25≥ 30) had a higher incidence of shoulder pain in the C group (60%) than in the D group (18.1%) with no statistical significant difference. (Table 6)

Table 5: Effect of dexmedetomidine on shoulder pain in patients with BMI (18<25):

			Group: BMI (18< 25)		P value
			D group	C group	
Shoulder pain	Yes	N&%	3 (25%)	11 (84.6%)	0.009
	No	N&%	9 (75%)	2 (15.4%)	

Table 6: Effect of dexmedetomidine on shoulder pain in patients with BMI (25 ≥30):

			Group: BMI (25 ≥30)		P value
			D group	C group	
Shoulder pain	Yes	N&%	2 (18.1%)	6 (60%)	0.12
	No	N&%	9 (81.8%)	4 (40%)	

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Intraoperative events showed the following; one patient (4.3 %) in the D group experienced abdominal discomfort and intraoperative nausea and vomiting versus 2 (8.7%) patients in the C group. No p-value was obtained due to the small number of cases within the groups.

Regarding other intraoperative parameters; the D group had 2(8.7%) bradycardic episodes and 1(4.3 %) hypoxic episode compared to 1(4.3%) bradycardic episode and 0 (0.0%) hypoxic episode in the control group. No p values were obtained due to the small number of cases within the groups. Although the D group showed a lower percentage of hypotensive episodes 2 (8.7%), compared to 3 (13.0%) in the C group, there was no significant difference between the 2 groups. (P value: 1.000).

Postoperative events and complications in the form of;Time of spinal regression (TOF) werehighersignificantly in the D group (2.3 ± .4 Hr) compared to (1.9 ± .3 Hr) in the C group with P value (<0.001). There was no incidence of post-spinal headache in both groups.

STATISTICAL METHODS:

Statistical analysis was done using IBM SPSS® Statistics version 26 (IBM® Corp., Armonk, NY, USA). Numerical data was demonstrated as mean ±standard deviation or median &interquartile range as suitable. Qualitative data was demonstrated as frequency and percentage. Pearson's Chi-square test or Fisher's exact test was used to assess the relation between qualitative variables.

Comparison of quantitative variables between the two groups was done using either the Student t-test for normally distributed data or the Mann-Whitney test for the abnormally distributed numerical data. All statistical tests were two-tailed. A p-value < 0.05 was considered significant.

Discussion:

This current study showed that intravenous dexmedetomidine infusion is considered a good choice for reducing the severity of intraoperative shoulder pain in patients scheduled for Laparoscopic cholecystectomy and receiving spinal anesthesia.One patient showed severe pain in the D group compared to 10 patients in the C group

Furthermore, it leads to a substantial reduction in the incidence of shoulder pain, as well as a reduced need for rescue analgesics. In the dexmedetomidine group, only **21.7 %** of patients **e**xperienced referred shoulder pain in contrast to **73.9 %** in the control group. These outcomes have crucial implications for improving the overall patient experience during laparoscopic cholecystectomy.

It is well shown in the literature that intraoperative shoulder pain in patients receiving regional anesthesia is a quite troublesome problem and is by far considered the main leading cause of conversion to general anesthesia.**(4)** The incidence of conversion from regional anesthesia to GA due to unbearable shoulder pain was 7%–43% for LC. (5, 9)

The current study showed that even though shoulder pain occurred in only 5 patients in the dexmedetomidine Group, none of them needed conversion to GA and was only managed by reassurance and rescue analgesia. However, in the control group, 52.2 % of patients receiving spinal anesthesia were converted to GA due to severe shoulder pain not relieved by rescue medications. This marked difference highlights the potential of dexmedetomidine use in reducing the need for conversion to general anesthesia, which can be advantageous in terms of both patient safety and procedure efficiency.

Several studies have employed multiple drugs to alleviate shoulder pain problem with varying results i.e. midazolam, opioids, and other agents like ketamine and propofol. (4, 6, 10) & up to the knowledge of the authors, there is no consensus on using a specific drug or technique in managing shoulder tip pain in laparoscopic cholecystectomy.

Recent advances in pain management emphasize the importance of preemptive analgesia, which seeks to prevent central neural hyper-excitability before the initiation of nociceptive input. (11) The use of dexmedetomidine as a preemptive analgesic in this study appears to align with this concept. As dexmedetomidine has a role in modulating, inhibiting transmission and perception of pain (12) its role as a pre-emptive analgesic drug needs to be evaluated.

A notable finding in this study, thatthere was a higher incidence of shoulder pain among patients with lower BMI (18<25) in comparison to a lower incidence of shoulder pain

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in patients with higher BMI (25 ≥ 30) in both groups. This observation is consistent with a study done by *XinYou Li1*, et al. (13) that examined the risk factors for postoperative shoulder pain in laparoscopic surgeries conducted under general anesthesia.

The suggested explanation is that patients with higher BMI may have abdominal characteristics, such as weaker abdominal muscles and a fatty abdominal wall, that are more accommodating to pneumoperitoneum. This accommodation may reduce the rapid increase in intra-abdominal pressure and the consequent stretching of the peritoneum, ultimately causing less irritation to the phrenic nerve. Patients with lower BMI, who tend to have tighter abdominal muscles, are more susceptible to rapid peritoneal irritation and resulting referred shoulder pain. (13) Further studies are recommended to verify this finding and explore possible causes.

In addition to its effect on alleviating shoulder pain, the current study showed that dexmedetomidine had a Safe hemodynamic profile which is one of the main concerns of using dexmedetomidine with spinal anesthesia.We noticed a very low incidence of hypotensive and bradycardicepisodes in the present study. Other studies using intravenous dexmedetomidine as an adjuvant to spinal anesthesia reported that it had a negative effect and a less favorable hemodynamic profile. (14, 15, 16) Bhana N, et al reported that the incidence of hypotension and bradycardia due to dexmedetomidine usage were 30 and 9%, respectively, in a study done on 401 patients. (17).

This hemodynamic stable profile in the current study may be attributed to thepreoperative administration of ondansetron for prophylaxis against nausea and vomiting, as several previous studies have supported the notion that preoperative ondansetroninjection significantly reduces the rates of hypotension and bradycardia-induced by spinal anesthesia, (18, 19, and 20).

Importantly, the study highlighted that effective sedation was achieved in the dexmedetomidine group without compromising respiratory function shown in the absence of hypoxic episodes in the D group. Additionally, the study reported, urine retention and incidence of postdural puncture headache were comparable between groups. These outcomes demonstrate the overall efficiency, safety, and tolerability of the intravenous dexmedetomidineinfusion as an adjuvant in spinal anesthesia.

The main limitation of our study is that we couldn't compare many postoperative parameters as 50 % of patients in the control group were converted to GA.

In conclusion, this study offers valuable insights into the management of intraoperative shoulder pain during laparoscopic cholecystectomy under spinal anesthesia. The use of intravenous dexmedetomidine appears to be an efficient drug in reducing the incidence and intensity of shoulder pain, potentially obviating the need for conversion to general anesthesia. While the study has limitations, its findings provide a foundation for further research to refine the management of shoulder pain during laparoscopic cholecystectomy.

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List of abbreviations:

µg	:	microgram
BMI	:	Body mass index
C group	:	Control group
Co2	:	Carbon dioxide
D group	:	Dexmedetomidine group
ECG	:	Electrocardiogram.
G	:	Gauge
GA	:	General anesthesia
gm	:	Grams
Hr	:	hour
HR	:	Heart rate
IO	:	Intraoperative
IV	:	Intravenous
kg	:	kilogram
L	:	Liter
LC	:	Laparoscopic cholecystectomy
LOF	:	Length of surgery
MAP	:	Mean arterial blood pressure
min	:	minutes
ml	:	milliliter
PACU	:	Post anesthesia care unit
PONV	:	Post-operative nausea and vomiting
Spo2	:	Arterial oxygen saturation
TOF	:	Time of spinal regression
VAS	:	Visual analogue score