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Intraperitoneal Bupivacaine (0.25%) Alone or in Combination with Dexmedetomidine 1µg/kg for Post-Operative Analgesia in Patients Undergoing Laparoscopic Cholecystectomy: An Observational Study

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Abstract

Background and Aim

Laparoscopic cholecystectomy is conducted under general anaesthesia. Pain intensity remains high in initial hours. In search of analgesic technique which has minimal side effects this study was conducted to observe the effectiveness of intraperitoneal instillation of Bupivacaine (0.25%) alone or in combination with dexmedetomidine 1µgm/kg on post-operative pain following laparoscopic cholecystectomy.

Method

It was a prospective, observational study conducted in the young adult patients between 18-60 years of age, weighing 45-85 kg of ASA grades I-II who underwent laparoscopic cholecystectomy under general anaesthesia. Duration of analgesia was considered as primary outcome. VAS, 24 h analgesic requirement, changes in haemodynamic parameters (HR, SBP, DBP and MBP) and incidence of adverse events (nausea, vomiting, bradycardia, respiratory depression & shoulder pain) were considered as

secondary outcome. IM Diclofenac (75mg) was used as rescue analgesic when VAS ≥ 4.

Results

Demographically both the groups were comparable. Mean duration of analgesia in group BD was 7.454±0.454 h and 5.892±0.603 h in group B.(p=0.0001) VAS in group BD was lower when compared to group B throughout the study but was statistically significant at 30 min, 2 h, 3 h, 4 h, and 8 h (p<0.05). Mean number of doses of rescue analgesic was 2.4±0.48 in BD group and 2.72±0.44 in B group (p=0.019). There was no statistical difference in hemodynamic variables and side effects between the two groups.

Conclusion

Intraperitoneal instillation of dexmedetomidine with bupivacaine produces prolonged duration of analgesia and requires less number of analgesic doses as compared to bupivacaine alone in patients undergoing laparoscopic cholecystectomy with stable hemodynamics and minimal adverse effects.

Keywords

Laparoscopic cholecystectomy, Intraperitoneal instillation, Bupivacaine, Dexmedetomidine, Post-operative analgesia

Introduction

Technical and scientific advancements in the field of surgery necessitates several modifications in anaesthetic management. Cholecystectomy being increasingly performed by laparoscopic technique requires a different approach for pain management as compared to the traditional ones. Degree of pain after laparoscopic procedures have multifactorial influence including the volume of residual gas, type of gas used for pneumoperitoneum, pressure created by pneumoperitoneum and insufflated gas temperature. Also the irritation due to bile, pus or blood in peritoneal cavity may cause peritoneal or diaphragmatic irritation leading to pain. Different modalities have been proposed to relieve post-operative pain after laparoscopic surgeries like NSAIDs, epidural and intrathecal opioids, intrapleural local anesthetic, intercostal nerve blocks, intraperitoneal local anaesthetics & opioids, intraperitoneal saline, removal of insufflation of gas drains, low pressure abdominal insufflations, acetazolamide administration and use of N_2O in place of CO_2.[1,2,3]Intraperitoneal instillation of local anaesthetics blocks visceral afferent signals and modifies visceral nociception by affecting nerve membrane associated proteins and by inhibiting the release and action of prostaglandins, which stimulates the nociceptors and cause inflammation.[4]Also, addition of alpha 2 agonists such as clonidine and dexmedetomidine have been found to reduce post-operative pain following laparoscopic cholecystectomy & it is deemed to be safe, improves patients comfort, shortens the length of stay in the post-operative care unit and decreases the total analgesic requirement in the ward.[4,5,6]Dexmedetomidine cause local analgesia by enhancement of the hyperpolarization-activated cation channels, which prevents the nerve from returning to resting membrane potential.[7]Hence this study was done in our institute to evaluate the analgesic efficacy of intraperitoneal bupivacaine alone and bupivacaine with dexmedetomidine in laparoscopic cholecystectomy. Primary objective was the time of first rescue analgesic request & secondary objectives were Visual analogue score (VAS), number of doses of rescue analgesic (IM diclofenac) requirement, changes in hemodynamic variables and side effects (nausea, vomiting, respiratory depression).

Methods

This observational study was conducted after approval from the Institutional Scientific and Ethics committee from January 2019 to December 2019. Sample size (n=50) was calculated taking into consideration study performed by **Patel H et al(2016).**[6]The difference between two means was calculated with a confidence level of 95%, desired power 0.8 and variance 5. Minimum 48 samples were required (Epitools Software), but we considered 50 (n=25) samples for our study.Fifty young adult patients between 18-60 yrs of age of either sex, weighing 45-85 kg of ASA grade I-II who underwent laparoscopic cholecystectomy under general anaesthesia were included in the study. Exclusion criteria were patient refusal, need for bile duct exploration, insertion of a T-drain, acute cholecystitis, surgery related complication for example, bile spillage or conversion to open cholecystectomy, severe systemic disease (ASA III/IV), history of prolonged analgesics ingestion or history of intake of NSAIDS or steroids within 24 h before surgery. Patients were divided into two groups viz, group B (n=25)- who received 40 ml of 0.25 % bupivacaine & group BD (n=25) who received 40 ml of 0.25% bupivacaine with dexmedetomidine 1 µg/kgintraperitoneally. All the patients underwent thorough pre anaesthetic evaluation, written & informed consent was taken and they were explained about the numeric VAS (Visual Analogue Scale) score for pain.

As per institutional protocols, all the patients were premedicated with i.v.glycopyrrolate 0.2 mg, i.v.pentazocine 0.5 mg/kg and i.v.ondensetron 4 mg slowly. General anaesthesia was induced with i.v.propofol 2.0–2.5 mg/kg followed by i.v. succinylcholine 1.5 mg/kg to facilitate endotracheal intubation. Anaesthesia was maintained with 60% N_2O in oxygen with 0.5–1% Isoflurane. Intermittent boluses of i.v.atracurium were used to achieve muscle relaxation. Nasogastric tube was inserted. Minute ventilation was adjusted to maintain normocapnia.

Following removal of the gall bladder and achievement of haemostasis, surgeon was asked to instill 40 ml of study drug as per the group allocated, into the sub diaphragmatic suprahepatic surface of liver and gallbladder fossa. Patients were maintained in the right lateral trendelenburg position for 10-15 min. Anaesthesia was reversed and patients extubated.

Time of intraperitoneal instillation of study drug and duration of surgery were recorded and degree of postoperative pain was assessed using the VAS at 15 min, 30 min, 1 h, 2 h, 3 h, 4 h, 8 h, 12 h and 24 h post-operatively. At the same time intervals, hemodynamic variables like HR, SBP, DBP & MBP were also recorded. Those patients who had VAS $\geq$ 4 received a bolus of IM diclofenac (75mg) as rescue analgesic. Duration of analgesia (period between intraperitoneal instillation of study drug to time of 1st rescue analgesic); total rescue analgesic requirement within first 24 hrs and incidence of any adverse events such as shoulder pain, post-operative nausea and vomiting, respiratory depression were recorded. PONV was treated using i.v. ondansetron & patients with shoulder pain were given reassurance and i.v.pentazocine, if needed. Data collected from all the patients was compiled, compared and analysed using standard t – test and chi – square test. p-value>0.05 was considered as not significant and p-value <0.05 and <0.001 was considered as significant and highly significant respectively.

Results

Demographic profile and mean duration of surgery was statistically comparable between both the

groups. Mean value of all vital parameters (HR, systolic BP, diastolic BP, mean BP) were found to be statistically comparable between the groups at all-timeintervals.(Graph 1, graph 2, graph 3)Mean duration of analgesia was 7.45±0.454 h for group BD and 5.89±0.639 h for group B (p=0.0001). VAS in group BD was lower when compared to group B throughout the study and the difference was statistically significant at 30 min, 2 h, 3 h, 4 h, and 8 h (p<0.05). (Table 1) Mean number of doses of rescue analgesic was 2.4±0.48 in group BD and 2.72±0.44 in group B (p=0.019). (Table 2) Incidence of nausea and vomiting was 1 (4%) & 2 (8%) in group BD and 3 (12%) & 4 (16%) in group B respectively (p=0.960, p=0.960). Incidence of shoulder pain was 1 (4%) in group BD and 2 (8%) in group B. There was no incidence of bradycardia, hypotension and respiratory depression in any group. (Table 3)

Discussion

Laparascopic cholecystectomy offers a number of advantages to the patient as compared to open procedure. As most of laparoscopic surgeries are conducted on day care basis, effective pain management plays a vital role in early discharge. Pain intensity usually peaks during the initial post-operative hours and then declines over the next two to three days. Inadequately treated pain may lead to splinting, loss of sighing and decrease in vital capacity, which may lead to post-operative pulmonary comorbidity. A wide variety of analgesic techniques are used to achieve adequate post – operative analgesia by various clinicians. Analgesic drugs delivered locally to peritoneal cavity may be of benefit post operatively for pain arising from peritoneum.[4,8,9]Intraperitoneal instillation of local anaesthetics blocks visceral afferent signals and modifies visceral nociception by affecting nerve membrane associated proteins and by inhibiting the release and action of prostaglandins, which stimulates the nociceptors and cause inflammation.[4]They can be used alone or in combination with various adjuvants like opioids[9] or alpha 2 agonists such as clonidine and dexmedetimidine.[2,4,6]

Antinociceptive effect of dexmedetomidine occurs at dorsal root neuron level, where it blocks the release of substance P in the nociceptive pathway and through action on inhibitory G protein, which increases the conductance through potassium channels[10]. Intraperitoneal administration of dexmedetomidine cause local analgesia by enhancement of the hyperpolarization-activated cation channels, which prevents the nerve from returning to resting membrane potential[7].

Various studies have already established the role of intraperitoneal local anaesthetics for post – operative analgesia following laparoscopic cholecystectomy.[3,11,12,13,14,15,16,17] Hence, in the present study we intended to evaluate the efficacy if intraperitoneal Dexmedetomidine as an adjuvant to Bupivacaine.

Both the groups were comparable in terms of demographic profile and duration of surgery. No statistical difference was observed in haemodynamic variables throughout the study duration. Duration of analgesia was significantly prolonged in group BD indicating the synergistic effect of Dexmedetomidine with Bupivacaine.VAS in group BD was lower when compared to group B throughout the study but was statistically significant at 30 min, 2 h, 4 h, and 8 h (p<0.05). similar results were observed by **Patel H et al (2016)**[6]and **Rapolu S et al (2016).**[2]IM diclofenac 75 mg was administered to the patients when VAS score

was more than 4. Total consumption of rescue analgesia was significantly lower in patients who received Dexmedetomidine, similar to results obtained by **Rapolu S et al (2016)[2], Sulekha D (2013)[3],Ali U et al (2017)[4]**and**Patel H et al (2016).[6]**

Conclusion

From the observations and analysis of the present study, it can be concluded that intraperitoneal instillation of dexmedetomidine with bupivacaine produces prolonged duration of analgesia and requires less number of analgesic doses as compared to bupivacaine alone in patients undergoing laparoscopic cholecystectomy with stable hemodynamics and minimal adverse effects.

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Tables and Graphs

Table - 1

Mean Visual Analogue Score

Time interval	Group BD (Mean±SD)	Group B (Mean±SD)	p value
Baseline (pre-op)	0.32±0.466	0.52±0.499	0.1500
15min	0.68±0.466	1.04±0.662	0.0310
30 min	1.16±0.366	1.76±0.906	0.0035
1 h	1.64±0.557	1.68±0.466	0.7843
2 h	2.08±0.483	1.48±0.640	0.0005
4 h	2.44±0.496	3.16±0.611	0.0001
8 h	2.88±0.711	3.64±0.557	0.0001
12 h	3.52±0.899	3.84±1.189	0.2887
24 h	4.92±0.796	5.16±0.966	0.3427

Table - 2

Total Analgesic Requirement (No. of doses)

	Group BD	Group B	p value
No. of doses Mean±SD	2.4±0.48	2.72±0.44	0.019

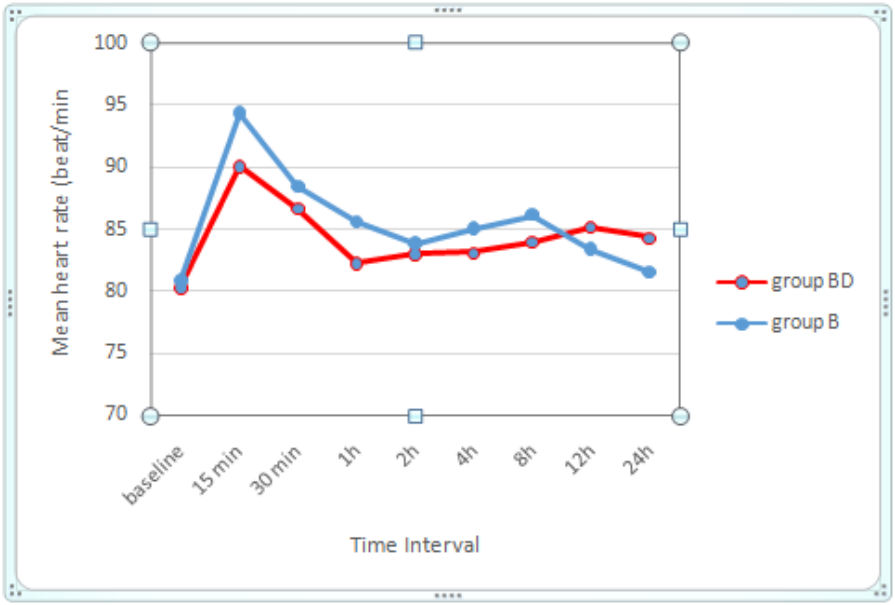
Table - 3

Incidence of Side Effects and Complications

S. No.	Side effects and complications	Group BD n (%)	Group B n (%)	p value
1	Nausea	1 (4)	3 (12)	0.960
2	Vomiting	2 (8)	4 (16)	0.960
3	Shoulder Pain	1 (4)	2 (8)	0.960
4	Hypotension	0	0	
5	Bradycardia	0	0	
6	Respiratory Depression	0	0	

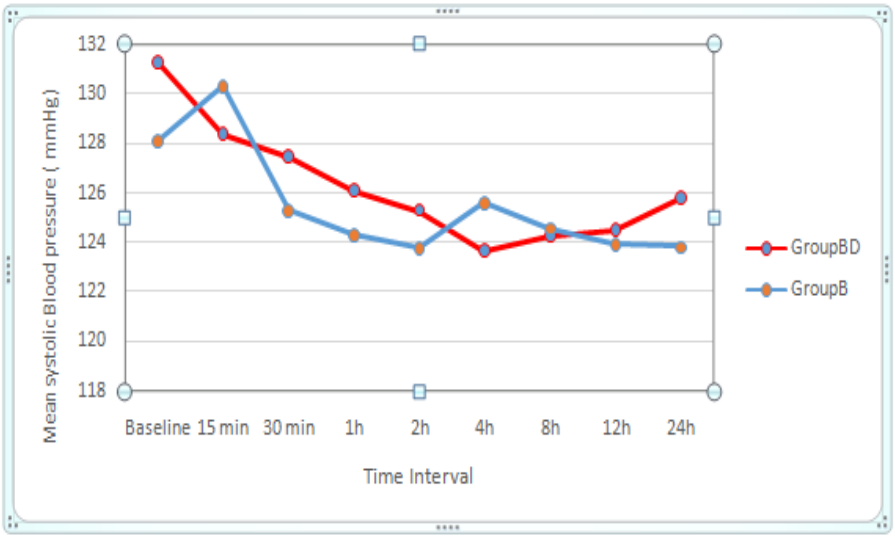
Graph - 1

Mean Heart Rate (bpm)



Graph - 2

Mean Systolic Blood Pressure (mmHg)



Graph - 3

Mean Diastolic Blood Pressure (mmHg)