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Comparison of Intraperitoneal Instillation Ropivacaine and Ropivacaine Plus Dexmedetomidine for Pain Relief After Laparoscopic Cholecystectomy Surgery

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Absract: ***Laproscopic Cholecystectomy surgery has CO2 insufflation causing raise in intra abdominal pressure and hypercapnia contributing pain and undesirable hemodynamic changes. Ropivacaineis amide type of local anaesthatic. Dexmedetomidine is selective α2agonist. The study was carried out in 60 patients allocated into two equal groups. Group A received ROPIVACAINE (0.2%) 30 ml+ 2ml NS and Group B received ROPIVACAINE (0.2%) 30 ml+ DEXMEDITOMEDINE (1mcg/kg) diluted in 2ml NS. In our study VAS scores in group B was reduced as compared to group A. Mean Duration for need of First Rescue analgesia in group A was 6.6 hours and was increased by adding Dexmedetomidine to 14 hours in group B. From the study, it was concluded that addition of Dexmedetomidine to Ropivacaine significantly increases the duration of postoperative analgesia without much side effects.***

Keywords: Laproscopic Cholecystectomy, Dexmedetomidine

1. Introduction

Pain is perfect misery, the worst of all evils and if excessive, overturns all patients‖

- John Milton

Pain is a protective mechanism designed to alert the body to potentially injurious stimuli. Laparoscopic cholecystectomy surgery is minimal invasive surgery having CO2 insufflation which causes increased abdominal pressure and hypercapnia. These may contribute to pain and undesirable hemodynamic changes. Administration of intraperitoneal local anaesthetics blocks the conduction of sensory afferent fibres for pain from peritoneum and viscera. Intraperitoneal instillation of local anaesthetic agents alone or in combination with opioids, ∝2 agonists such as clonidine and dexmedetomidine have been found to reduce postoperative pain following laparoscopic cholecystectomy surgery. Dexmedetomidine, ∝2 adrenergic agonist provides sedation, anxiolysis, analgesia and sympatholysis with minimal respiratory depression and cardioprotection, neuroprotection and renoprotection.

2. Aims and Objectives

With the advent of laparoscopic cholecystectomy surgical technique, previously major open surgery has been reduced to minimally invasive procedure, thereby improving patient comfort and reducing the duration of hospital stay. But still, inadequate postoperative pain relief is significantly prolonging the discharge. Moreover the adverse affect of analgesic agents itself can affect the early discharge.

With these objectives our aim was

1) To study the efficacy of intraperitoneal instillation of Ropivacaine with Dexmedetomidine and Ropivacaine for post operative analgesia after Laparoscopic cholecystectomy surgery.
2) To compare the efficacy of Ropivacaine and Ropivacaine with Dexmedetomidine.
3) To study the Adverse reactions and complications associated with the instillation. Postoperative pain was analyzed by below mentioned parameters.
   - Severity of postoperative pain by Numeric Visual Analogue Score (VAS)
   - Postoperative hemodynamic changes
   - Time to rescue analgesic
   - Sedation score
   - Post operative complication

Pharmacology

Dexmedtomidine

The α2 - adrenergic agonists provide sedation, anxiolysis, hypnosis, analgesia, and sympatholytic.

Ropivacaine

Ropivacaine is an amide type of local anesthetic. Ropivacaine HCl is chemically described as S - (-) - 1 - propyl - 2', 6' - pipecoloxylidide hydrochloride monohydrate. Itblock the generation and the conduction of nerve impulses, presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential.

3. Material and Methods

According to inclusion criteria patients were randomly assigned into two groups. Following written informed consent, 60 ASA (American Society of Anesthesiologists) I or II patients aged 18 - 70 years scheduled for elective laparoscopic cholecystectomy surgery under general anesthesia were recruited for the comparative study. The patients were assigned randomly into either of following two groups with each group including 30 patients.

Inclusion Criteria

- ASA (American Society of Anesthesiologists) risk I, II & III
- Patients aged 18 - 70 years of either sex.
- Patients weight 25 - 70kg of either sex.
- Patients scheduled for elective laparoscopic surgery: laparoscopic cholecystectomy

Exclusion Criteria

- ASA grade IV, V
- Patient refusing to give consent.
- Patient having a preexisting cardiac, pulmonary or neurological disease.
- Patients who are not able to appreciate the VAS score.
- Patients on treatment with steroids, NSAIDS, opioids, α2 - adrenergic receptors antagonists, calcium channel blockers, angiotensin converting enzyme inhibitors before surgery.
- Uncontrolled systemic co morbidities.
- Allergy to drugs (K/C/O Hypersensitivity).
- Patients noted to have dysrhythmias on the electrocardiogram (ECG).

Group A: Ropivacaine (0.2%) 30 ml + 2ml NS Intraperitoneal instillation at the end of surgery.

Group B: Ropivacaine (0.2%) 30 ml + Dexmedetomidine (1mcg/kg) diluted in 2ml NS Intraperitoneal instillation at the end of surgery.

Before taking the patient to the operation theatre, he/she was explained the VAS (Visual Analogue Scale) scores for pain. At the end of the procedure these patients were randomly allocated to Group A or Group B. Group A received 30 ml 46 0.2% Ropivacaine + 2ml NS and Group B received 30 ml 0.2% Ropivacaine + Dexmedetomidine 1mcg/kg diluted in 2ml NS. Post - operative pain was assessed at 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 hrs. period post operatively. Patients were asked to rate the severity of pain with a Visual analogue scale ranging from 0 - 10 cm where 0 cm corresponds to no pain and 10 cm corresponds to worst conceivable pain and sedation score measured by Ramsey sedation score where score more than 3 considered as sedated. Post - Operative Nausea Vomiting (PONV) score along with hemodynamic variables (Systolic and diastolic blood pressure and pulse rate) were observed post operatively. Any time during the post - operative monitoring of pain score when the VAS (Visual Analogue Scale) score was more than 4, the patients were given Inj. Diclofenac Sodium as a rescue analgesic in the dose of 2mg/kg IV slowly. The time of first analgesic dose and the total number of analgesic doses required during 24 hours in the post - operative period were recorded. All patients were observed for minimum period of 24 hours post operatively.

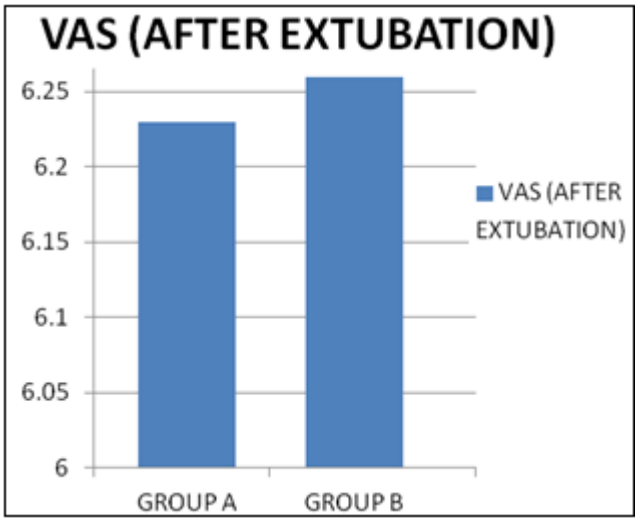
4. Observation and Results

1) Postoperative Assessment of Pain by Visual Analogue Scale (VAS)

Postoperatively the patients were assessed for pain utilizing the Visual Analogue Scale (Number Score). As from the data shown in table 1 and Graph 1 mean VAS in group A 6.23±0.89 and group B 6.26±1.45 is comparable and there is no statistical difference in pain scores between two groups immediately after extubation.

Table 1: VAS Immediately After Extubation

	VAS (After Extubation) Mean±SD	P Value
Group A	6.23±0.89	0.99
Group B	6.26±1.45	



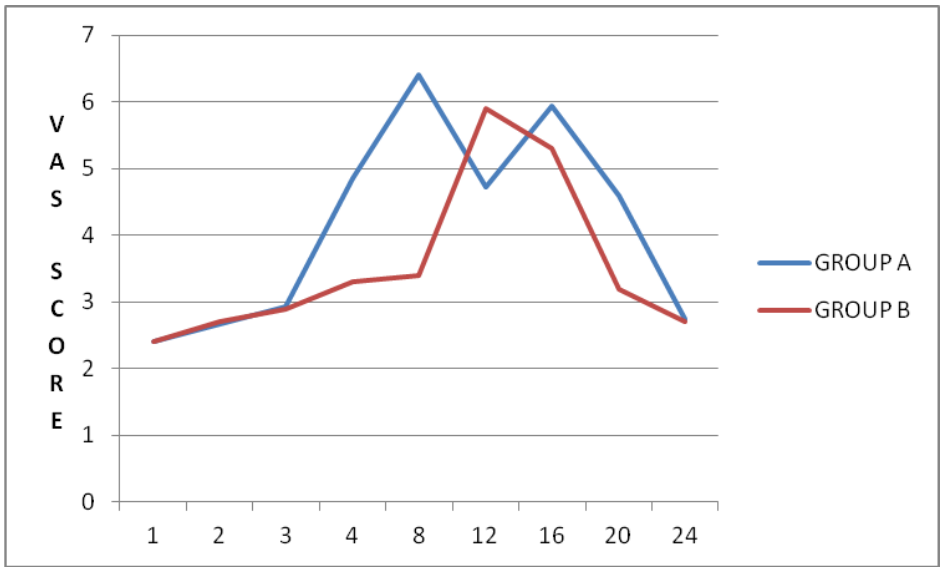
Graph 1: VAS Immediately After Extubation

Table 2 and Graph 2 shows the changes in VAS score at different time interval. In our study, there was statistically significant difference in VAS score in group A at 4, 8, 12 and 20 hours being 4.86±2.00, 6.4±2.13, 4.73±1.68, 4.6±1.91 hrs versus group B 3.3±0.8, 3.4±0.6, 5.9±2.4 and 3.2±1 respectively

Table 2: VAS Score Postoperative Period

VAS Score at interval	Group A Mean±SD	Group B Mean±SD	P Value	Significance
1	2.4±0.59	2.4±0.6	0.99	Not Significant
2	2.66±0.47	2.7±0.5	0.98	Not Significant
3	2.93±0.52	2.9±0.6	0.87	Not Significant
4	4.86±2.00	3.3±0.8	0.0005	Significant
8	6.4±2.13	3.4±0.6	0.017	Significant

12	4.73±1.68	5.9±2.4	0.03	Significant
16	5.93±1.97	5.3±2.3	0.28	Not Significant
20	4.6±1.91	3.2±1	0.002	Significant
24	2.75±0.45	2.7±0.4	0.88	Not Significant



Graph 2: VAS Score Postoperative Period

Table 3 and Graph 3 shows time of demand of 1st Analgesia. In our study, there was increased duration of analgesia in group B (14±2.25 hrs) compared to group A (6.66±1.66 hrs) which was statistically significant.

Table 3: First Rescue Analgesia

	Group A Mean±SD	Group B Mean±SD	P Value	Significance
First Rescue Analgesia	6.66±1.66	14±2.25	0.003	Significant

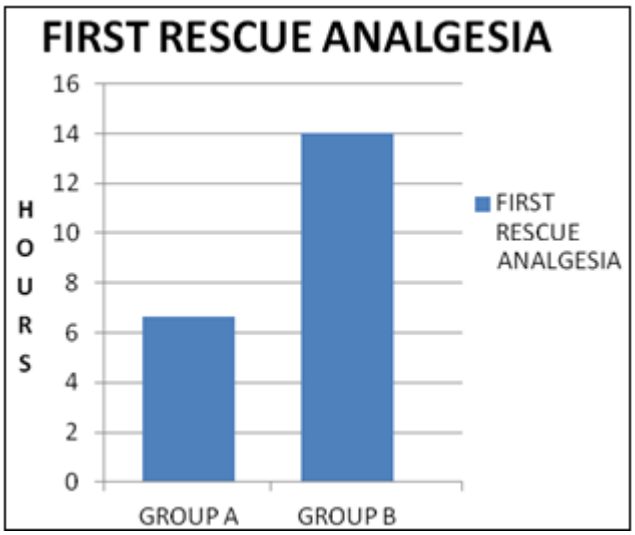
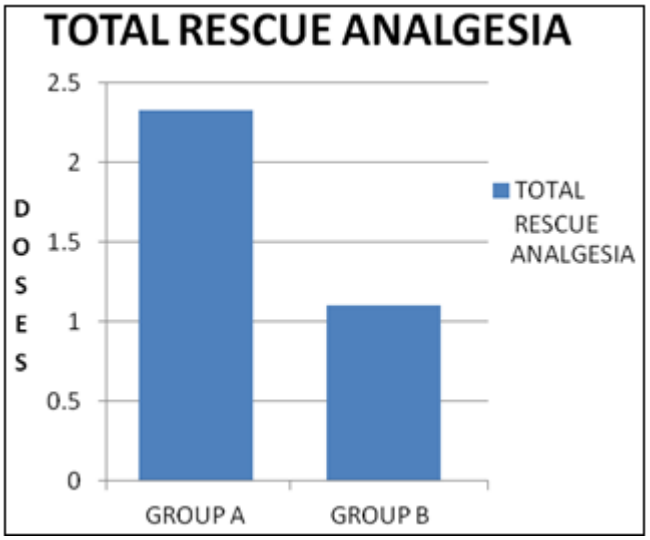


Table 4 and Graph 4 show Total rescue analgesia. In our study, there is decreased need of analgesia in Group B (1.1±0.3) than Group A (2.33±0.41).

Table 4: Total Rescue Analgesia

	Group A Mean±SD	Group B Mean±SD	P Value	Significance
Total Rescue Analgesia	2.33±0.41	1.1±0.3	0.0005	Significant



Graph 4: Total Rescue Analgesia

2. There was no difference in hemodynamic variables and complications in both groups.

5. Discussion

Laparoscopic cholecystectomy surgery, also called minimally invasive surgery is a modern surgical technique. Postoperative pain is reduced compared with open traditional surgeries, but effective analgesic treatment after laparoscopic cholecystectomy surgeries have remained a clinical challenge. Patients undergoing laparoscopic cholecystectomy surgery tend to expect a painless postoperative period because of common beliefs about this type of surgery. Pain is main reason for staying overnight in hospital on the day of surgery and pain is the dominant complaint and the primary reason for prolonged convalescence after laparoscopic cholecystectomy surgery. So, it is an essential task to provide adequate post operative

analgesia. For that we can use various analgesics (Opioids & non - opioids) via various routes, example Oral, Intravenous, Neuraxial blockage, Intraperitoneal instillation etc.

In addition, growing evidence suggests that treatment of postoperative pain should be multimodal and opioid sparing to accelerate recovery and avoid potential side effects. The rationale for intraperitoneal administration of drugs for treatment of the pain which follows laparoscopic cholecystectomy surgery is that the small incisions at the abdominal wall cause visceral component of the pain and shoulder pain. With this in mind, many authors have tried to diminish pain via the peritoneal route.

Intraperitoneal local anaesthetic is likely to blockade free afferent nerve endings in peritoneum. Systemic absorption of local anaesthetic from the peritoneal cavity may also play a part in reduced 68 nociception although this would expected to occur after any local anaesthetic technique. Along with local anaesthetic (e. g. Ropivacaine), use of Dexmedetomidine ($\propto 2$ agonist) as an adjuvant in laparoscopic cholecystectomy surgery is deemed to be safe, improve patient's comfort, shorten the length of stay in the post operative care unit and decrease the total analgesic requirement in the ward.

In our prospective, comparative study, after obtaining permission from the Institutional Ethics Committee with ref. no EC/Certi/106/2018, B. J. Medical College & Civil Hospital, 60 patients belonging to ASA Grade I and II were selected randomly into two Groups by computer generated random number sequence for the study. They were scheduled to undergo elective laparoscopic cholecystectomy procedure in B. J. Medical College & Civil Hospital, Ahmedabad from August 2018 to August 2019.

VAS Score: Table 2 and Graph 2 of our study show postoperative VAS Score group A at 4, 8, 12 and 20 hours being 4.86±2.00, 6.4±2.13, 4.73±1.68, 4.6±1.91 hrs versus group B 3.3±0.8, 3.4±0.6, 5.9±2.4 and 3.2±1 respectively. In our study we measured postoperative VAS Score up to 24 hours.

Our study results were comparable with study done by B. Ahmed et al [4]. who compared antinociceptive effect of dexmedetomidine or meperidine 70 with bupivacaine to bupivacaine alone 54 intraperitoneally after laparoscopic gynaecological surgery found that intraperitoneal instillation of meperidine or dexmedetomidine in combination with bupivacaine significantly decreases postoperative VAS Score. Chiruvella et al [8] in there study of comparison between ropivacaine and ropivacaine plus dexmedetomidine in laparoscopic hysterectomy showed patients given ropivacaine plus dexmedetomidine had significantly lesser VAS in 24hrs post operatively as compared to group ropivacaine.

DEMAND FOR FIRST ANALGESIA: Table 3 and Graph 3 of our study show demand for 1st analgesia postoperatively there was increased duration of analgesia in group B (14±2.25 hrs) compared to group A (6.66±1.66 hrs) which was statistically significant.

Our results were comparable with study done by B. Ahmed et al [4]. who compare antinociceptive effect of dexmedetomidine or meperidine with bupivacaine to bupivacaine alone 71 intraperitoneally after laparoscopic gynaecologic surgery found that intraperitoneal instillation of meperidine or dexmedetomidine in combination with bupivacaine significantly decreases postoperative analgesia requirement. Chiruvella et al [8] in their study of comparison between ropivacaine and ropivacaine plus dexmedetomidine in laparoscopic hysterectomy showed patients given ropivacaine plus dexmedetomidine had a significantly late demand for first rescue analgesia as compared to group ropivacaine. Acharya et al [1] in their study comparing ropivacaine plus dexmedetomidine versus ropivacaine alone for intraperitoneal instillation in laparoscopic hysterectomy found significantly late demand for first rescue dose for analgesia in the group receiving ropivacaine plus dexmedetomidine.

TOTAL RESCUE ANALGESIA: Table 4 and Graph 4 of our study show Total rescue analgesia need postoperatively, decreased need of analgesia in Group B (1.1±0.3) than Group A (2.33±0.41). Chiruvella et al [8] in there study of comparison between ropivacaine and ropivacaine plus dexmedetomidine in 72 laparoscopic hysterectomy showed patients given ropivacaine plus dexmedetomidine had significantly lesser number of total rescue analgesia requirement as compared to group ropivacaine.

In our study, In group A patients, nausea & vomiting was found in 15 patients and 13 patients in group B. Chiruvella et al [8] in there study of comparison between ropivacaine and ropivacaine plus dexmedetomidine in laparoscopic hysterectomy showed patients given ropivacaine plus dexmedetomidine had significantly lesser shoulder pain and nausea vomiting when compared to group ropivacaine.

In our study, there were no significant hemodynamic changes in both groups,

6. Summary

The following parameters were recorded and compared. VAS score: -

1) The mean VAS score in Group A is 4.86 at 4 hours, 6.4 at 8 hours, 4.73 at 12 hours and 4.6 at 20 hours while in Group B is 3.3 at 4 hours, 3.4 at 8 hours, 5.9 at 12 hours, 3.2 at 20 hours.
2) 1st DEMAND OF ANALGESIA: - The mean duration for 1st demand of analgesia in Group B is 14 hrs & whereas in Group A, it is 6.66 hrs.
3) TOTAL RESCUE ANALGESIA: - The mean number of total rescue analgesia given in 24 hrs in Group B is 1.1 whereas in Group A, it is 2.33.

Limitation of the present study is the post - operative pain, which is a subjective experience and can be difficult to quantify objectively and compare when comparing various treatment options.

7. Conclusion

From our study, we conclude that at the end of procedure Intraperitoneal instillation of Dexmedetomidine to Ropivacaine through ports produces prolonged duration of analgesia, hemodynamic stability compared to Ropivacaine alone And there is Less number of rescue analgesics required in post - op 24 hours when Dexmedetomidine is supplemented.

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