Journal of Cardiovascular Disease Research

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 08, 2023

Betamethasone as an Adjuvant in Paravertebral Block, A Double Blinded Randomized Controlled Trial in Laparoscopic Cholecystectomy

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Received Date: 10/07/2023 Acceptance Date: 15/08/2023

Abstract

Background: Despite its wide use in thoracic procedures, effectiveness of unilateral paravertebral block for laparoscopic cholecystectomy yet to be studied widely. This study is to assess the effectiveness of PVB with additives for acute postoperative pain management. **Materials And Methods:** Eligible patients were divided into two groups randomly. One group received Ropivacaine alone and other group received Ropivacaine with betamethasone. Both groups were given USG PVB at T7 level and induced general anaesthesia. Primary outcome was to measure the duration of TPVB. Secondary outcome was to assess post of pain relief, intra operative hemodynamics and time to rescue analgesia. **Results:** The betamethasone-Ropivacaine group had a much more prolonged duration pain relief than the plain Ropivacaine group. The duration of analgesia was significantly prolonged in group receiving betamethasone -Ropivacaine thoracic paravertebral block. The amount of rescue analgesia, frequency of analgesics and total dosage of drugs were significantly lower with betamethasone Ropivacaine group when compared with Ropivacaine group. **Conclusion:** Betamethasone sodium phosphate with Ropivacaine in ultrasound guided thoracic paravertebral block provides significantly better analgesia postoperatively in laparoscopic cholecystectomy surgeries in comparison with plain Ropivacaine.

Keywords: Thoracic paravertebral block, Ropivacaine, Betamethasone, Laparoscopic cholecystectomy, particulate glucocorticoid.

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Introduction

Laparoscopic techniques offer major benefits to the patient such as minimized incision size and trauma with reduced postoperative discomfort, shortened recovery rates, and a lower incidence of postoperative wound infections. By the nature of minimally invasive surgery, the pain is often short, yet intense, and up to 80% of patients will require opioid analgesia at some stage peri- operatively. The use of regional techniques such as subdural, epidural, and more recently thoracic paravertebral block, are increasingly utilized as opiate-sparing techniques, particularly in laparoscopic techniques where larger incisions are required. Postoperative care of thoracic and upper abdominal surgical patients is a very important part

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of patient recovery and can be very challenging. Pulmonary complications are responsible for significant numbers of deaths and morbidity of patients undergoing thoracotomy.

The thoracic paravertebral space begins at T1 and extends caudally to terminate at T12. Most PVBs are therefore performed at the thoracic level. PVB is easier to learn and perform than thoracic epidural anaesthesia. Analgesia is comparable with that provided by a thoracic epidural, in terms of success rate and analgesic efficacy. PVB can be performed safely in fully anesthetized patients. There is less risk of neurological complications than with most other regional anaesthetic techniques.

The regression of sensory block, an important factor for analgesia duration, was well studied in epidural anaesthesia but nearly none was documented in paravertebral block. Our hypotheses were Perineural administration of betamethasone together with local anaesthetic would prolong the duration of TPVB blockade; and TPVB would provide superior post-operative analgesia as compared to surgeon infiltration.

Our study is here to focus on the balanced anaesthesia with adequate post-operative anaesthesia for lap surgeries favouring an earlier recovery and discharge from health care system.

Aim of the Study

Primary outcome -The number of dermatomes affected on the ipsilateral side as a measure of duration of TPVB, assessed at 15mins and every hourly till 12hrs.

Secondary outcomes

- Visual analogue scores measured on a 0 to 10 every 1 hour following surgery till 12 hours.
- Intra operative vitals
- The frequency and dosage of analgesics including oral and intravenous (IV) nonsteroidal anti-inflammatory agents (NSAIDs), and IV opioids up to 12hrs postop.
- Time of rescue analgesia
- Total dosage of analgesics
- Side effects such as dizziness, nausea, vomiting, drowsiness, hypotension.

Materials And Methods

This was a single centre, prospective, randomized, double-blind, and controlled study with an institutional approval from the Ethic Committee. This study was conducted during October 2021 to November 2022 at Government Rajaji Medical College, Madurai. 50 patients were enrolled in this study, divided into Group 1 and Group 2. Group 1 will receive ultrasound guided Thoracic Paravertebral Block would be injected with 0.5% Ropivacaine hydrochloride 14 ml + 0.9% normal saline 1 ml.

Group 2 will receive ultrasound guided Thoracic Paravertebral Block would be injected with 0.5% Ropivacaine hydrochloride 14 ml plus 1 ml-4mg betamethasone sodium phosphate.

Inclusion Criteria

1. Age-20 – 70yrs
2. Both males and females
3. ASA-1,2,3

Exclusion Criteria

1. Patient refusal
2. Allergic to local anesthetics
3. Chronic pain management therapy patient
4. Pregnant ladies
5. Vertebral anomalies
6. Coagulopathies

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7. Patients on psychiatric drugs or cognitive disorders

Patients fitting the inclusion and exclusion criteria were selected for the study.
The procedure, objectives and potential side effects were explained to the patient and informed written consent was obtained.
History of the presenting condition, comorbid conditions and general physical examination was done.
The patients will be randomized into two equal groups and will be designated by sealed envelope selection.
The patients will be shifted to the Operating Room.
The use of anxiolytics and anti-emetics if required will be mentioned.
Standard monitoring of pulse oximetry, non-invasive blood pressure and electrocardiography will be monitored.
Both the groups will be given ultrasound guided thoracic paravertebral block in T7 level and induced general anaesthesia after confirmation of success of block with cold spirit at dermatome level.
General anaesthesia was induced with injection propofol 2-3 mg/kg and injection fentanyl 2mg/kg used for stress attenuation.
Paralysed with injection succinyl choline 2mg/kg and intubated with appropriate size tube and connected to circle absorber.
Group 1 -the patients in group Ropivacaine Thoracic Paravertebral Block would be injected with 0.5% Ropivacaine hydrochloride 14 ml + 0.9% normal saline 1 ml.
Group 2 -the patients in Ropivacaine Betamethasone thoracic paravertebral group would be injected or 0.5% Ropivacaine hydrochloride 14 ml + 4 mg betamethasone (1ml).
Evaluation of Pulse Rate, Blood Pressure and pulse oximetry every 15 minutes during the procedure till end of surgery and duration of analgesia till 24 hours after the procedure recorded.

Parameters Monitored

Vitals [heart rate, blood pressure, spo2] during and immediately after the thoracic paravertebral block administration till end of surgery was observed and recorded.
Dermatomes blocked with cold spirit analysed and recorded after 15mins block given and then after immediately after surgery and till 24 hours post operatively every one hour.
Then post operatively level of pain also assessed by the Visual analogue pain score from 2 hours after surgery and every hourly till 24 hours post injection monitored and recorded as the primary outcome.
As the secondary outcome

- Time of rescue analgesics
- Total frequency of analgesics
- Total dosage of analgesics
- Drowsiness
- Hypotension
- Nausea vomiting was monitored and recorded.

Any adverse incidents encountered during the procedure recorded.
Block failure cases, surgery exceeding more than 2 hours, surgeries converted to open procedures excluded from study.

Statistical Analysis

The information gathered from the selected cases was noted in the master chart. The collected data was analysed with IBM.SPSS statistics software 23.0 Version. To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical

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variables and the mean & S.D were used for continuous variables. To find the significant difference between the bivariate samples in Independent groups the unpaired sample t-test was used for normal data and Mann-Whitney U test for skewed data. To find the significance in categorical data Chi-Square test was used. In all the above statistical tools the probability value 0 .05 is considered as significant level.

Observations and Results

The demographic data like age, weight, sex and height were comparable to each other in both the groups.

The pain relief in Ropivacaine group at a mean VAS SCORE of 3 after 4 hours of surgery during the period of study compared with the VAS SCORE of 1 to the betamethasone Ropivacaine group. Thus the betamethasone-Ropivacaine group had a much more prolonged duration pain relief than the plain Ropivacaine group.

TABLE 1: COMPARISON OF PAIN RELIEF BY VAS SCORE

VAS	ROPIVACAINE		BETAMETHASONE		p value	Significance
	Mean	SD	Mean	SD		
1 hr	0.48	0.505	0.54	0.503	0.553	Not Significant
2 hrs	0.44	0.501	0.62	0.49	0.073	Not Significant
3 hrs	0.36	0.485	0.38	0.49	0.838	Not Significant
4 hrs	0.92	0.34	0.88	0.328	0.551	Not Significant
5 hrs	1.74	0.443	1.7	0.463	0.66	Significant
6 hrs	2.22	0.465	2.12	0.435	0.269	Significant
7 hrs	2.24	0.431	2.26	0.443	0.82	Significant
8 hrs	2.22	0.465	2.12	0.435	0.269	Significant
9hrs	2.24	0.431	2.26	0.443	0.82	Not Significant
10 hrs	2.22	0.465	2.12	0.435	0.269	Not Significant
11 hrs	2.24	0.431	2.26	0.443	0.82	Not Significant
12 hrs	1.74	0.443	1.7	0.463	0.66	Not Significant

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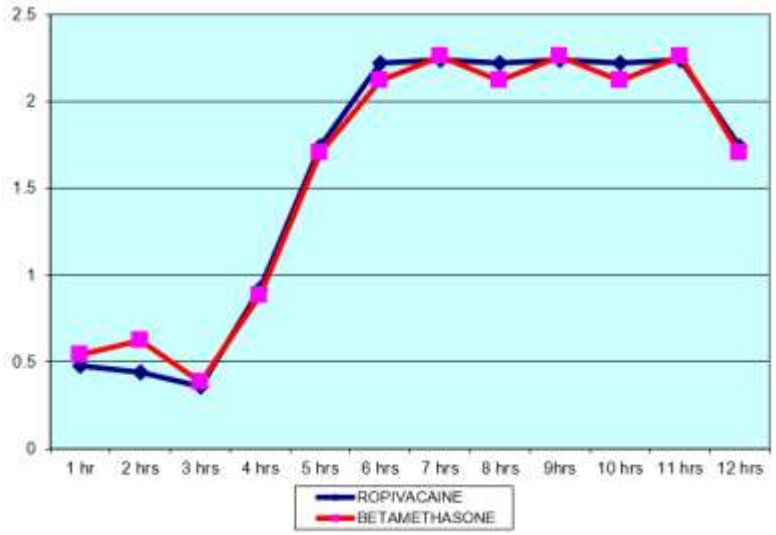

FIGURE 1: COMPARISON OF VAS SCORE

It is evident that after 4 hours of injection the difference in dermatomal blockade is statistically significant in Betamethasone- Ropivacaine group.

TABLE 2: COMPARISON OF DERMATOMES BLOCKED

DERMATOMES BLOCKED(ONSET AND TOTAL DURATION)	ROPIVACAINE		BETAMETHASONE		p value	Significance
	Mean	SD	Mean	SD		
15 mins	7.96	0.198	7.92	0.274	0.405	Not Significant
2 hrs	7.96	0.198	7.9	0.303	0.244	Not Significant
3 hrs	7.96	0.198	7.9	0.303	0.244	Not Significant
4 hrs	7.8	0.404	7.9	0.303	0.165	Not Significant
5 hrs	6.76	0.431	7.78	0.418	< 0.001	Significant
6 hrs	6.76	0.431	7.74	0.443	< 0.001	Significant
7 hrs	6.12	0.558	7.64	0.563	< 0.001	Significant
8 hrs	5.04	0.57	7.36	0.802	< 0.001	Significant
9hrs	4.32	0.587	7.28	0.809	< 0.001	Significant
10 hrs	3.6	0.728	7.24	0.87	< 0.001	Significant
11 hrs	2.66	0.479	7.1	0.995	< 0.001	Significant
12 hrs	1.72	0.454	6.64	0.631	< 0.001	Significant

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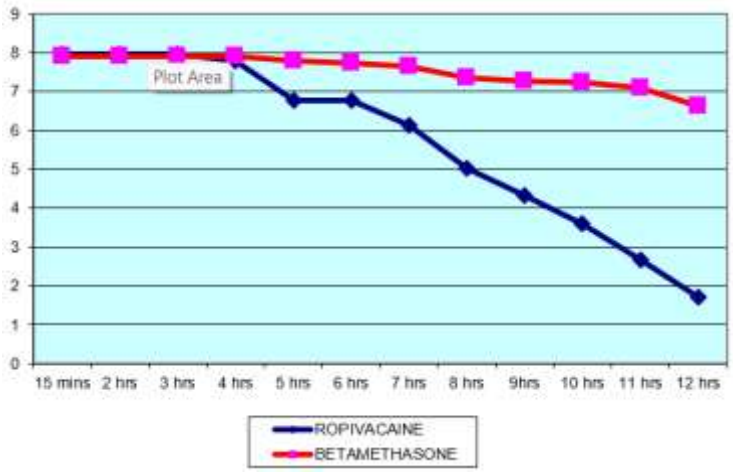

FIGURE 2: DERMATOMES BLOCKED (ONSET AND TOTAL DURATION)

The duration of analgesia was significantly prolonged in group receiving betamethasone - Ropivacaine thoracic paravertebral block.

TABLE 3: TOTAL ANALGESICS

Total dosage of analgesic	ROPIVACAINE	BETAMETHASONE
DOSAGE 1	0	49
1 & 2	23	1
1, 2 & 3	27	0
Total	50	50
P value	< 0.001 Significant	

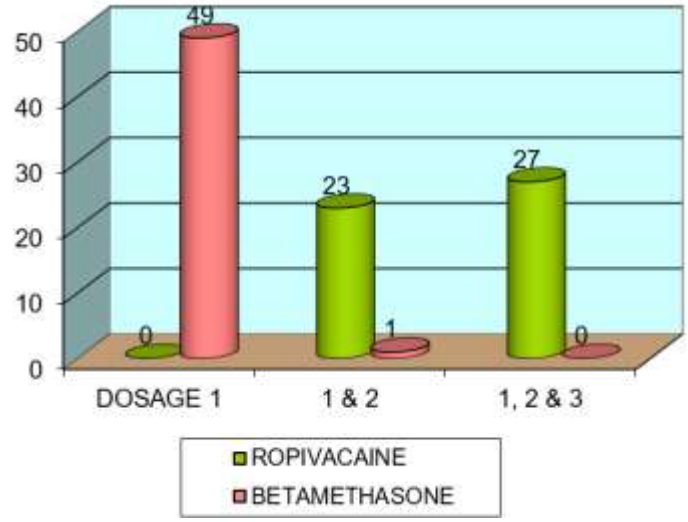

FIGURE 3: TOTAL DOSAGE OF ANALGESIC

The amount of rescue analgesia, frequency of analgesics and total dosage of drugs were significantly lower with betamethasone Ropivacaine group when compared with Ropivacaine group.

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TABLE 4: TIME OF RESQUE ANALGESIA

Time of Rescue analgesia (in hrs)	ROPIVACAINE	BETAMETHASONE
≤ 4	46	0
> 4	4	50
Total	50	50
Mean	4.1	7.94
SD	0.364	0.24
P value	< 0.001 Significant	

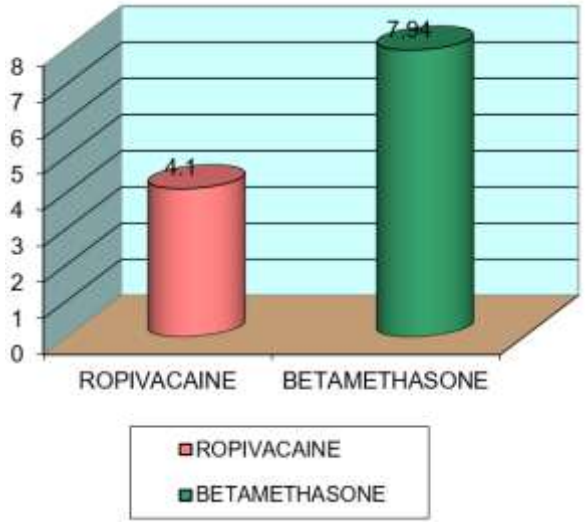

FIGURE 4: TIME OF RESQUE ANALGESIA IN HOURSE

Regarding adverse effects of the patients receiving Ropivacaine- nausea vomiting, dizziness and hypotension recorded slightly higher than betamethasone -Ropivacaine group.

TABLE 5: COMPARISON OF SIDE EFFECTS

Side effects	ROPIVACAINE	BETAMETHASONE
Nausea	2	1
Vomiting	2	1
Drowsiness	2	1
Hypotension	2	1
Dizziness	2	0
Total	10	4
P value	0.786 Not Significant	

Discussion

The vitals measured during the procedure and immediately after the procedure showed no significant variations from the baseline in both the ROPIVACAINE AND ROPIVACAINE-BETAMETHASONE GROUP. This suggests that the procedure is acceptably safe.

In the present study, the analgesia caused by particulate Betamethasone sodium phosphate with Ropivacaine was significantly better and sustained for an average of 8 hours after the injection when compared to the analgesia in those who received plain Ropivacaine alone.

The quick onset of analgesia and pain relief in the thoracic paravertebral block is explained by the presence of a significant concentration of local anaesthetic bathing the spinal neurons, causing noticeable pain relief.

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The prolonged duration was due to sustained release of particulate betamethasone for a long time.
On comparing both groups VAS SCORES after surgery that is immediately after surgery -2 hours after injection and every one hour after that till 12 hours,
The group that received betamethasone Ropivacaine showed a minimum mean VAS SCORE of 1-2 till 8 hours post operatively than with Ropivacaine group from 4 hours post operatively recorded a VAS scores of 3-4.
The onset of analgesia was comparable with both groups.
Intaoperatively hemodynamic stability is maintained better for both groups with good analgesia, less usage of opioids and good maintenance for lap surgeries.
Secondary outcome of the study shows that usage of rescue analgesics and dosage and frequency of analgesics such as opioids or NSAIDS was significantly lower in postoperative day 1 (8- 10 hrs postop) for betamethasone Ropivacaine group than Ropivacaine alone group.
Another important observation was the incidence of adverse effects nausea, vomiting, dizziness and hypotension was lower with betamethasone Ropivacaine group.
As laparoscopic procedures are day-care procedures the extended postoperative pain relief by Ropivacaine-betamethasone combinations allows patient to recover soon and reduce significant respiratory complications and earlier discharge.

Conclusion

Betamethasone sodium phosphate with Ropivacaine in ultrasound guided thoracic paravertebral block provides significantly better analgesia postoperatively in laparoscopic cholecystectomy surgeries in comparison with plain Ropivacaine.

CONFLICT OF INTEREST:

The authors report no conflicts of interest in this work.

FINANCIAL SUPPORT: NIL

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