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Research Article

"COMPARATIVE EVALUATION OF DEXMEDETOMIDINE AND DEXAMETHASONE AS ADJUVANT WITH BUPIVACAINE IN ULTRASOUND GUIDED TAP BLOCK FOR POST OPERATIVE PAIN RELIEF IN PATIENTS UNDERGOING LAPAROSCOPIC CHOLECYSTECTOMY"

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A B S T R A C T

Background: Many adjuvants have been used to increase the duration and quality of local anaesthetics in different nerve block techniques. Aim of this study was to evaluate the relative efficacy of bupivacaine and dexmedetomidine versus bupivacaine and dexamethasone for post-operative analgesia using ultrasound-guided TAP block in laparoscopic cholecystectomies.

Objective-The primary objective was to compare quality of analgesia using Visual Analog Scale (VAS), duration of postoperative analgesia, whereas the secondary objective was to assess the requirement of rescue analgesia and reduction in 24 hour intra venous PCM/NASAID consumption, to compare hemodynamic parameters (heart rate, MAP, SPO2, and respiratory rate) and to measure adverse effect if any.

Methods: A prospective randomised controlled clinical study was conducted in 60 patients undergoing laparoscopic cholecystectomies. Participants were divided into two groups in which group 1 (DM) received 20 ml of 0.25% bupivacaine hydrochloride with 8 mg dexamethasone as TAP block and those in a group 2 (DA) received 20 ml of 0.25% bupivacaine hydrochloride with dexmedetomidine 1ug/kg as TAP block at the end of surgery. Postoperative pain was evaluated by Visual Analog Score for pain scoring at 0 min,30 min, 1 hr, 2 hr, 4 hr , 6 hr, 12 hr, 18 hr, and 24 hr postoperatively. Subjective assessment of duration of analgesia was done.

Results: Patients receiving USG guided TAP block with bupivacaine with dexmedetomidine as adjuvant (group 2) had significantly lower pain score when compared to patients with bupivacaine with dexamethasone as adjuvant(group1) at the postoperative 0 min (4.83vs 3.43, p=0.008), 15 min (5.30 vs 3.80, p=0.002), 30 min (5.27 vs 3.87, p=0.002), 1 hour (4.67 vs 3.87, p=0.34), 2 hour (4.53 vs 3.33, p=0.002), 4 hour (4.37 vs 2.67, p=<0.001), 6 hour (3.97 vs 2.70, p=0.002), 12 hour (3.80 vs2.83, p=<0.001), and 18 hour (3.37 vs 2.67, p=0.011). Requirement of first dose of rescue analgesia among patients of dexamethasone group was significantly earlier as compared to dexmedetomidine group (108.00 vs 422.00 min p=<0.001). Total dose of rescue analgesia used (gram of paracetamol iv) was less in dexmedetomidine group as compared to dexamethasone group (p=30 vs 16, p=0.13). No complications related to nerve block were observed.

Conclusion: Dexmedetomidine added to bupivacaine for TAP block in laparoscopic cholecystectomy prolongs the duration of postoperative analgesia, have lower Visual analogue score and less rescue analgesia requirement than dexamethasone added to bupivacaine.

INTRODUCTION

Laparoscopic cholecystectomy is a most common surgical intervention now a days which is performed in the day care unit[1]. Pain after laparoscopic cholecystectomy arises from port sites, pneumoperitoneum-inducedabdominal stretch, and hepatic bed disturbances due to cholecystectomy[2]. Painexperienced following laparoscopic cholecystectomy derives significantly from the anterior abdominal wall which has segmental innervation provided by nociceptor afferents in the transverses abdominis fascial plane[3]between the internal oblique and transversus abdominis muscle.

Although it is considered to be minimally invasive, pain intensity in the early postoperative period is still significant especially in the first 24 hours[4]. Proper pain control is essential for optimizing clinical outcomes and earlier ambulation after surgery. Multimodal analgesia management is utilized for pain observed in the postoperative period. For this purpose, Nonsteroidal Antiinflammatory Drugs (NSAIDs), paracetamol,

opioids, and other similar medications are utilized. Traditional pain management with opioids increases the incidence of side effects such as post-operative nausea and vomiting (PONV), constipation, urinary retention and excessive sedation resulting in respiratory depression[5].Precaution should also be taken with NSAID use due to possible side effects in elderly patients, patients with renal, cardiac, hematopoietic and liver failure, and in patients with positive history of gastrointestinal bleeding[6].

Currently transversus abdominis plane block is used for the management of pain in the postoperative period after various surgical procedures, namely open/laparoscopic appendicectomy, caesarean section, total abdominal hysterectomy, laparoscopic cholecystectomy, open prostatectomy, renal transplantation, and abdominoplasty among others[7,8,9]. The use of ultrasound imaging allows correct localization of injection site and visualization of local anaesthetic distribution, thereby leading to increased success and reduced complication rate[10].

TAP block to be a good choice of postoperative analgesia in laparoscopic cholecystectomy[7,8,11] as part of a multimodal strategy to optimize postoperative pain control. With the guidance of ultrasound or an anatomical landmark, local anaesthetic is injected into the neurovascular plane of the abdominal wall where the nerves from T6 to L1 are located.[12] Unfortunately, TAP block has limited duration of effect to the administered local anaesthetics (LA). Recently, adjuvant medications were added to LA to prolong the effect of TAP block. Dexmedetomidine and Dexamethasone are such adrugs used with bupivacaine and associated with prolongation of the LA effect.

Dexmedetomidine is a selective alpha-2 (α2) adrenergic agonist with both analgesic and sedative properties[13].Dexmedetomidine is notable for its ability to provide sedation without risk of respiratory depression. Its use with bupivacaine either epidurally or intrathecally associated with prolongation of sensory and motor nerve block.[14,15,16,17] Dexamethasone, a glucocorticoid, is now emerging as a new adjunct to LAs for prolonging the duration of action.[18,19]Dexamethasone acts locally on nociceptive C-fibers (through glucocorticoid receptors) to increase the activity of inhibitory channels, thus decreasing their activity[20].It also decrease the incidence of postoperative nausea and vomiting.

MATERIAL AND METHODS

After the institutional Ethics Committee approval and written informed consent, sixty American Society of Anaesthesiologist (ASA) physical status I/II patients of either sex, aged 18-60, scheduled to undergoing laparoscopic cholecystectomy were included in this study. Patients with a history of any known allergy for bupivacaine or dexmedetomidine, physical and mental conditions which may not allow postoperative pain measurement and patients giving negative consent to the procedure were excluded from the study. Patients were recruited and randomised into two groups using computer generated random number chart. One group to undergo USG guided TAP block with 0.25% bupivacaine with 8 mg dexamethasone as a adjuvant (Group I, n=30)and other group to undergo USG guided TAP block with 0.25%bupivacaine with dexmedetomidine 1ug/kg as a adjuvant of 30 each Patients were admitted one day prior to the scheduled surgery and examined, interviewed, written explained consent were taken. During the pre-operative anaesthetic assessment of patients, visual analogue scale (VAS) for pain assessment from 0 to 10, with 0 meaning no pain and 10 meaning the worst pain imaginable was explained to patients. No hypnotic medication was given on the evening before surgery. A peripheral iv line was placed. In the operating room, monitors were attached and baseline parameters, eg. heart rate, NIBP, oxygen saturation and ECG were recorded. After pre-oxygenation for 3 minutes, anaesthesia was induced with a standard anaesthetic protocol using midazolam 0.05 mg/kg, fentanyl 2mcg/kg, propofol 1.5-2 mg/kg. Tracheal intubation was facilitated by administration of iv vecuronium 0.1 mg/kg. Anaesthesia was maintained with O2 and nitrous oxide in the ratio of 40:60, inhalational agent, vecuronium bromide 0.02 mg/kg every 20-25 min. After 30 minutes of surgery, each patient received 1 gm iv paracetamol infused over 15 minutes intravenously. Throughout the laparoscopic surgery carbon dioxide pneumoperitoneum was established and maintained to a pressure maximum of 14 mm Hg and ETCO2 was maintained between 30-40 mm Hg. The surgical technique was identical in two groups. During surgery Ringer lactate solution was administered in maintenance dose.

At the end of surgery, following skin preparation, TAP blocks were performed under dynamic ultrasound guidance (Broadband linear array ultrasound probe was placed in the axial plane across the mid-axillary line midway between costal margin and iliac crest. Following identification of the three different layers of the abdominal wall, block needle (23-G) was inserted in plane until its tip was located in between the internal oblique and transverses abdominis muscles. After careful aspiration injection of study medication was performed and hypoechoic layer was detected on ultrasound.patients were given bilateral USG guided TAP block either with bupivacaine 0.25% 20 ml with dexmedetomidine (Group 2-DA) or bupivacaine 0.25% 20 ml with dexamethasone (group 1-DM). The anaesthesiologist who administered the TAP block and the investigator who assessed its outcome were blinded to the drug used. Thereafter residual neuromuscular block was antagonised by neostigmine and glycopyrrolate iv. Tracheal extubation was done once the patients were wide awake. Postoperative pain was evaluated by Visual Analog Score (VAS) for pain scoring just after extubation, at 15 minutes, at 30 minutes, at 1 hour, at 2 hours, at 4 hours, at 6 hours, at 12 hours, at 18 hours, and at 24 hours postoperatively. Duration of analgesia, rescue analgesia consumption and the occurrence of nausea, vomiting, respiratory depression, sedation (measured by Ramsay Sedation Score) or any other adverse effects like any sign of local anaesthetic toxicity, site of injection of TAP block for detection of hematomas or local infections was observed. All these measurements and recordings were done by the anaesthetist or nurse who was blind to the group of the patient.

Sample size estimation- sample size of 30 patients was required in each group which was determined using power calculation data obtained from earlier similar study, where $\alpha=0.05$ and $\beta=0.8$. P value <0.05 was considered statistically significant.

Statistical analysis-Continuous variables were expressed as the mean ± standard deviation. Normally distributed continuous variables were compared between multiple groups using one-way analysis of variance for inter-group comparisons. Categorical variables were compared using the

Chi-square test or Fisher's exact test as appropriate. All analyses were two-tailed, and P<0.05 was considered to indicate a statistically significant difference.

RESULTS

All the patients scheduled for laparoscopic cholecystectomy fulfilling the inclusion criteria were invited to participate in the study. Both groups were comparable regarding demographic data and operative characteristics.

Table 1 Between Group Comparison of Demographic variables

SN	Demographic Variables	Group I (n=30)	Group II (n=30)
1-	Age (years)	36.27±6.84	40.77±8.17
2-	BMI (kg/m^2)	23.91±2.47	22.88±2.36
3-	ASA-I	73.3 %	66.7 %
	ASA-II	26.7 %	33.3 %

Table 2 Between Group Comparison of Pain (VAS Score) at different time intervals (Mann-Whitney U test)

SN		Group I			Group II			Mann-Whitney U test	
		Md	Mean	S.D.	Md	Mean	S.D.	'Z'	'p'
1-	0 min	5.00	4.83	2.09	3.00	3.43	1.63	2.660	0.008
2-	15 min	5.50	5.30	1.78	4.00	3.80	1.69	3.038	0.002
3-	30 min	5.50	5.27	1.68	4.00	3.87	1.43	3.101	0.002
4-	1 hour	4.50	4.67	1.49	4.00	3.87	1.41	2.124	0.034
5-	2 hour	4.00	4.53	1.46	3.00	3.33	1.32	3.049	0.002
6-	4 hour	4.00	4.37	1.19	3.00	2.67	1.54	4.030	<0.001
7-	6 hour	4.00	3.97	1.16	3.00	2.70	1.49	3.073	0.002
8-	12 hour	4.00	3.80	0.76	3.00	2.83	1.32	3.571	<0.001
9-	18 hour	3.00	3.37	0.93	3.00	2.67	1.21	2.554	0.011
10-	24 hour	3.00	2.93	1.26	3.00	2.43	1.25	1.299	0.194

Table 2 depicts that Pain score of patients of Group II was found to be significantly lower as compared to that of Group I at all the periods of observation except at 24 h.

Table 3 Between Group Comparison of Doses of Rescue analgesia required

SN	Variables	Group I (n=30)		Group II (n=30)		Total (N=60)	
		No.	%	No.	%	No.	%
1-	No rescue analgesia reqd.	5	16.7	15	50.0	20	33.3
2-	Single dose	20	66.7	14	46.7	34	56.7
3-	Two doses	5	16.7	1	3.3	6	10.0
	χ^2=8.725(df=2); p=0.013						

Table 3 represents that Out of 60 patients enrolled in the study, one-third (n=20; 33.3%) did not require any rescue analgesia and only 10% required >1 dose (two doses), rest required single dose of rescue analgesia. Proportion of patients not requiring rescue analgesia was significantly higher in Group II as compared to Group I (50.0% vs. 16.7%).

Table 4 Between Group Comparison of Duration of First dose of Rescue Analgesia (minutes)

Group	No. of patients	Min.	Max.	Mean	S.D.
Group I	25	0.00	240.00	108.00	70.36
Group II	15	30.00	1080.00	422.00	302.23
Total	40	0.00	1080.00	225.75	244.00

Table 4 shows out of 30 patients in each group, rescue analgesia was required to 25 patients of Group I and 15 of Group II. Difference in mean duration of requirement of first dose of rescue analgesia among patients of Group I (108.00±70.36 min) was significantly earlier as compared to Group II (422.00±302.23 min).

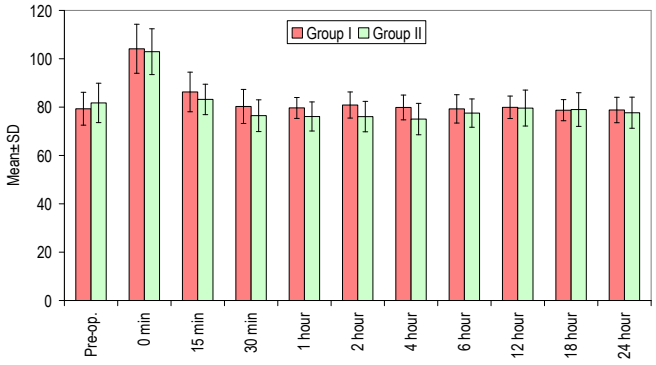

Figure 1 Comparison of histogram of Mean Heart Rate

Figure 1 shows that Mean heart rate of patients of Group I was found to be higher as compared to Group II at all the periods of observation except at pre-op. (baseline) and at 18 hour. Difference in mean heart rate of patients of Group I and Group II was found to be statistically significant only at periods of observation during 30 min to 4 hour (30 min, 1 hr, 2 hr& 4 hr).

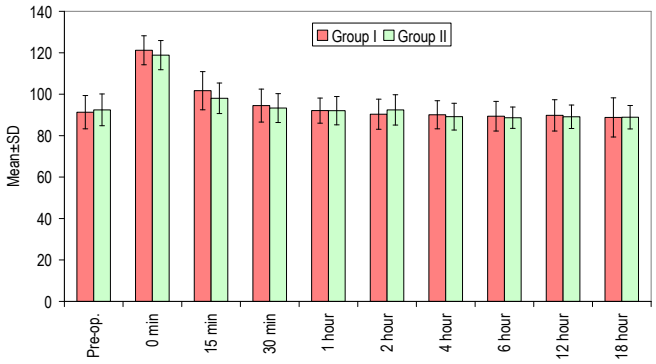

Figure 2 comparision of histogram of Mean Arterial Pressure (mm Hg) at different time intervals

Figure 2 represents that Mean arterial pressure of patients of Group I was found to be higher as compared to that of Group II at all the periods of observation except at baseline, 2 hr and 18 hr. Mean arterial pressure of patients of above two groups was found comparable at all the periods of observation except at 15 min

Table 5 between Group Comparison of Complications

SN	Complications	Total (N=60	Group I (n=30)		Group II (n=30)		Significance of difference	
			No.	%	No.	%	χ^2	'p'
1-	Nausea	10	3	10.0	7	23.3	1.920	0.166
2-	Vomiting	6	2	6.7	4	13.3	0.741	0.389
3-	Respiratory despression	3	0	0.0	3	10.0	3.158	0.076

Table 5 shows that patients of Group II as compared to Group I showed higher incidence of complications like nausea (23.3% vs. 10.0%), Vomiting (13.3% vs. 6.7%) and Respiratory depression (10.0% vs. 0.0%) but between group difference for none of the above complications was found to be statistically significant

DISCUSSION

TAP block has been shown to reduce postoperative pain score and analgesia requirement resulting in early ambulation and discharge after a lot of abdominal surgeries (laparoscopic cholecystectomy, colectomy, appendicectomy, hysterectomy, caesarean section nephrectomy etc)[21]

There are many benefits of adequate postoperative analgesia-it includes a reduction in the postoperative stress response, a reduction in postoperative morbidity and in certain types of surgeries postoperative analgesia does yield an improved surgical outcome[22,23,24]Other benefits of effective regional analgesic techniques include reduced pain intensity, decrease in the incidence of side effects from analgesics and improved patient comfort.[25]

Carney *et al*[26] did a study of 50 females undergoing elective total abdominal hysterectomy who were randomized to undergo TAP block with ropivacaine (n=24) versus placebo (n=26). They concluded that TAP block, provided superior analgesia when compared to placebo block up to 48 postoperative hours after elective total abdominal hysterectomy

Many studies have found that the addition of dexmedetomidine to Local Anaesthesia in central neuraxial blocks and in peripheral nerve blockades in human was a safe and effective way to potentiate the Local Anaesthesia effect and reduce the required analgesics.

Agarwal *et al*[27]indicated in their study that analgesia time was prolonged up to 8 hrs when they added 100 ug dexmedetomidine to bupivacaine in a supraclavicular block.

Almarakbi *et al*[28]stated that in a study in which they added dexmedetomidine to bupivacaine in TAP block in abdominal hysterectomy, the first time to analgesic administration was significantly longer than in the group that dexmedetomidine (470 min and 280 min, respectively) and total 24 h morphine consumption was significantly lower in this group (19 mg and 29 mg, respectively).

Brummett *et al*[29,30]have reported that perineural administration of high-dose dexmedetomidine in combination with bupivacaine enhanced LA blockade in rats without inducing neurotoxicity.

There are two possible mechanisms to explain the effect of prolonging the duration of postoperative analgesia in this. Firstly, some researchers believed that dexmedetomidine, by the action of α2 receptor, induced vasoconstriction, which might contribute to prolong the period of analgesia.[17,31]Secondly, Eledjam and his colleagues compared adding clonidine and epinephrine to local anesthetics and suggested that clonidine plays a role through α2-receptor agonists rather than by the action of vasoconstriction[32]. Similar to clonidine, dexmedetomidine may take effect through α2-receptor agonists.

Various studies have demonstrated the beneficial effect of adding dexamethasone to LAs to prolong their duration of action. Shrestha *etal*[33] added 8 mg of dexamethasone to a mixture of lidocaine and bupivacaine for supraclavicular brachial plexus block. This resulted in a faster onset of action and longer duration of analgesia without any adverse effects. Parrington *et al*[34] added 8 mg of dexamethasone to 30 mL mepivacaine 1.5% during supraclavicular brachial plexus blockade. The dexamethasone group showed a longer duration of analgesia. 332 (225-448 min) versus 228 (207-263 min) min in the control group, whereas the onset times of sensory and motor blockade were similar in both groups. Ammar *et al*[35]compared the efficacy of dexamethasone as an adjunct to bupivacaine in TAP block. They concluded that addition of dexamethasone increases the duration of analgesia as compared to addition of saline (placebo). Prolongation of the block duration is due to the anti-inflammatory effect of dexamethasone. Others suggests a direct effect on nerve membrane rather than an anti-inflammatory action, as the corticosteroids were able to inhibit ectopic neural discharge originating in experimental neuromas.[36] Modulation of pain signals in the spinal cord has been suggested as intrathecal betamethasone produced rapid analgesia for pelvic and perineal cancer pain that lasted for 5 days[37.] Triggering vasoconstriction and antiallergic activity of topical steroids have been suggested through action on specific glucocorticoid receptors.[38,39] Steroids potentiate the action of local anaesthetics through modulation of the function of potassium channels in the excitable cells.

In the present study, the addition of dexmedetomidine or dexamethasone to bupivacaine in TAP block was compared. Pain score of patients of Group II (dexmedetomidine group) was found to be significantly lower as compared to that of Group I (dexamethasone group) at most of thethe periods. Requirement of rescue analgesia was higher in dexamethasone group than dexmedetomidine group and proportion of patients not requiring rescue analgesia was significantly higher in group with dexmedetomidine as compared to group with dexamethasone (50.0% vs. 16.7%). Difference in mean duration of requirement of first dose of rescue analgesia among patients of dexamethasone group (108.00±70.36 min) was significantly earlier as compared to dexmedetomidine group (422.00±302.23 min).

The major finding of our study was that addition of dexmedetomidine to bupivacaine in TAP block provides prolonged post-operative analgesia and better pain control in comparison the addition of dexamethasone to bupivacaine.

The present study has certain limitations-like investigator's inability to objectively quantify and evaluate postoperative pain which being a subjective experience can be amajor limiting factor in estimating and comparing the treatment options, inability to assess dexmedetomidine or dexamethasone plasma concentration among study patients to determine whether its action was related to systemic absorption or pure local effect and sample size which may reduce the power of study and may increase margin of error.

CONCLUSION

Dexmedetomidine added to bupivacaine for TAP block in laparoscopic cholecystectomy prolongs the duration of postoperative analgesia, have lower Visual analogue score and less rescue analgesia requirement than dexamethasone added to bupivacaine. Both the dexmedetomidine and dexamethasone may be considered as adjuvants for postoperative analgesia in TAP block. However multimodal approach can be used to provide a more complete postoperative analgesia with minimal side effects.

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