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Original Research Article

Efficacy of Dexamethasone or Dexmedetomidine as an Adjuvant to Levobupivacaine in Ultrasound Guided Superficial Cervical Plexus Block for Thyroidectomy Surgeries

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ABSTRACT

INTRODUCTION & BACKGROUND
Bilateral Superficial Cervical Plexus Blocks (BSCPB) with general anaesthesia (GA) has improved the quality of anaesthesia and post-operative analgesia in thyroidectomy surgeries. Adjuvants like dexmedetomidine, dexamethasone in combination with Local Anaesthetics (LA) improves the duration of post-operative analgesia. So we compared the intraoperative hemodynamics and post-operative analgesic efficacy of USG guided BSCPB with levo bupivacaine (20ml) 0.5% alone and dexmedetomidine (50mcg), dexamethasone (4mg) as adjuvants .We hypothesize that levobupivacaine with dexmeditomedine provides superior hemodynamic stability and analgesic efficacy compared to other 2 groups.

METHODOLOGY
After obtaining Institutional Ethical Committee approval, 45 patients of ASA 1 & 2 undergoing total thyroidectomy under GA were enrolled in this prospective randomized double blinded study. Patient refusal, allergy to study drugs, ASA class 3 and above were excluded.
Patients were randomly allocated into three groups (A, B & C) of 15 each using sealed envelope technique, to receive either of the 3 drug combinations for BSCPB:
A-Levo-bupivacaine 0.5% (20ml) with 1 ml NS
B-Levo-bupivacaine 0.5% (20ml) with dexmedetomidine (50 mcg)-diluted to 1ml with NS
C-Levo-bupivacaine 0.5% (20ml) with dexamethasone (4mg)
Data were analysed using SPSS 21 software. p value <0.05 was considered statistically significant

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RESULTS
There was statistically significant difference in peri-operative hemodynamics (p value 0.001), post-operative VAS, analgesic requirement ($p<0.001$) between group B compared to group A and C .None of the patients had any procedure or drug related adverse effects.

CONCLUSION
Dexmedetomidine (50mcg) as an adjuvant to levobupivacaine (20ml) 0.5% used in USG guided BSCPB provides stable peri operative hemodynamics and good post-operative analgesia following thyroidectomy surgeries.

KEYWORDS
Superficial Cervical Plexus Block, Levobupivacaine, Dexmedetomidine, Dexamethasone, thyroidectomy, general anaesthesia.

INTRODUCTION AND BACKGROUND

Thyroidectomies are done under general anaesthesia. Studies have reported that the mean pain score in the post-operative period ranged between 6.9 on a 1-10 visual analog scale-VAS.[1] Various methods are used to relieve the surgical pain such as parenteral analgesics and Bilateral Superficial Cervical Plexus Blocks(BSCPB).

Levobupivacaine, a S-enansiomer of Bupivacaine is relatively less cardiotoxic, better safety profile and preferable for nerve plexus blocks. Adjuvants such as Dexmeditomedine 50 µg[2] and Dexamethasone 4mg to 8 mg are known to prolong the duration of analgesia of local anaesthetic(LA), have anti-inflammatory actions and enhances patient satisfaction. Ultrasound (USG) guided BSCPB improves the analgesic quality with reduced volume of LA and fewer complications.[3]

So we wanted to evaluate the effectiveness of USG guided BSCPB with 0.5% Levo-bupivacaine alone and with Adjuvants like Dexmeditomedine 50 µg and Dexamethasone 4 mg on intraoperative hemodynamics and post-operative analgesia(POA). Dose selection were based on literature search for the same comparing benefits and side effects.[2,4]

The primary objectives of our study was to evaluate the intra-operative hemodynamics after GA and USG guided BSCPB along with duration of post-operative analgesia. Secondary objectives were to assess the 12 hours total analgesic consumption, any procedure or drugs related side effects or adverse events and to document the same and analyse. Our hypothesis is that Levobupivacaine 0.5% with Dexmeditomedine 50 µg gives better perioperative hemodynamicstability and prolonged post-operative analgesia with fewer side effects compared with plane Levobupivacaine 0.5% or Levobupivacaine with Dexamethasone 4mg.

MATERIALS AND METHODS

This prospective randomized double blinded study was registered with CTRI (Vide-CTRI/2021/04/033253).After obtaining Institutional Ethical Committee clearance (Vide-FMMCIEC/CCM/328/2019), 45 cases of ASA 1 and 2 belonging to 18-70 years age, of either sex, scheduled to undergo thyroidectomy under GA(Euthyroid status) were included in this study. Patient refusal, ASA GRADE 3 and above, coagulopathy, block site infection, patients on analgesics for other pathologies, history of study drug reactions were excluded from the study. On the day prior to the surgery, the recruited patients underwent pre-anaesthetic evaluation, were explained about the study, Visual Analogue Scale (VAS) from 0-10 to obtain informed consent. They were kept NPO as per standard guidelines, pre-medicated with Tab Diazepam 10 mg on the night prior to surgery and Tab Ranitidine 150 mg with sip of water, 2 hours prior to surgery.

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On the day of surgery, the patients were reassessed for new symptoms, vitals and investigations before wheeling into the Operation Theatre (OR).Inside the OT, baseline vitals such as Heart Rate (HR), Noninvasive Blood Pressure (NIBP), Oxygen Saturation (SpO2) were recorded. A large bore I. V access was secured with 18 G cannula and I.V fluid RL was started. Patients were pre-oxygenated for 3 minutes with 100% O2, induced with Injection fentanyl 2mcg/kg, Inj propofol 2mg/kg and succinylcholine 1.5mg/kg after confirming adequate mask ventilation. Patients were intubated into trachea using an appropriate size cuffed endotracheal tube, pilot balloon inflated with air and bilateral equal air entry confirmed and secured with plasters. Anaesthesia was maintained with Intermittant Positive Pressure Ventilation (IPPV), Tidal Volume (Vt-8ml/Kg), EtCO2 (35-40 mmHg), Vecuronium bolus dose 0.1mg/kg and top up of 0.02mg/kg, and Oxygen : Nitrous Oxide (50:50) and Isoflurane to maintain 1 MAC depth.

Patients were randomized in the pre-operative period by sealed enveloped technique to receive one of the three study drug combinations (A, B, C)

A-Levo-bupivacaine 0.5% (20ml) with 1 ml NS
B-Levo-bupivacaine 0.5% (20ml) with dexmedetomidine (50mcg)-diluted to 1ml with NS
C-Levo-bupivacaine 0.5% (20ml) with dexamethasone (4mg). (Consort diagram)
Patients, Resident preparing the drug mixture, Consultant performing the block and resident recording the data were blinded.

The BSCPB was performed under USG guidance (HD11XE-PHILIPS Ultrasound machine) with 26G hypodermic needle using high frequency linear probe,with patient in supine position. Needle was placed above the scalene muscles and beneath the pre-vertebral fascia, where the drug was injected sub-fascially, deep to the posterior border of sternocleidomastoid muscle, at the midpoint and along its length above and below from the insertion point.[5-7] The block was performed by consultant familiar in using the ultrasound machine and technique of block. 10ml of study drug was injected on each side.

Intraoperatively HR, NIBP, SPO2, EtCO2 were monitored every 10 minutes till extubation. Inj. fentanyl 0.5mcg/kg given as top up when BP increased > 20% of the baseline, after ruling out lighter planes of anaesthesia. At the end of surgery patients were extubated with full reversal using 0.05mg/kg neostigmine and 0.02mg/kg glycopyrrolate and then transferred to postoperative ward.

Postoperative pain was assessed using 0-10 VAS at every 1hour for 1st 6 hours and every 2 hours for the next 6 hours. Inj PCT 1g i.v was used as rescue analgesic when VAS score >3 in all the groups and the time of administration noted.

Bradycardia was defined as HR < 60 and Inj Atropine 0.6 mg bolus I.V was given if it dropped to <50/min with fluid bolus.

Hypotension was defined as Systolic Blood Pressure (SBP) or mean arterial pressure (MAP) of <20 % of baseline and treated with Inj. Ephedrine 6 mg i.v bolus with fluid rush of 200 ml. Any drug or procedure related side effects were documented.

All the data were entered in a dedicated format and subsequently analysed using SPSS 21 software. The following formula was used to obtain the sample size 'n', using BS Santhosh, Sripada Mehandale et al[8] as guide.

$$n = \frac{2(Z\alpha+Z\beta)\ 2\sigma 2}{(X1-X2)2}$$

$Z\alpha$=1.96(at 95% confidence interval)
$Z\beta$=1.281(at 90% power)
$X1\pm\sigma1$=29.6±17.8
$X2\pm\sigma2$=13.5±6.3

The collected data were analyzed by mean, standard deviation, ANOVA test and posthoc tukey tests.p value <0.05 was considered statistically significant.

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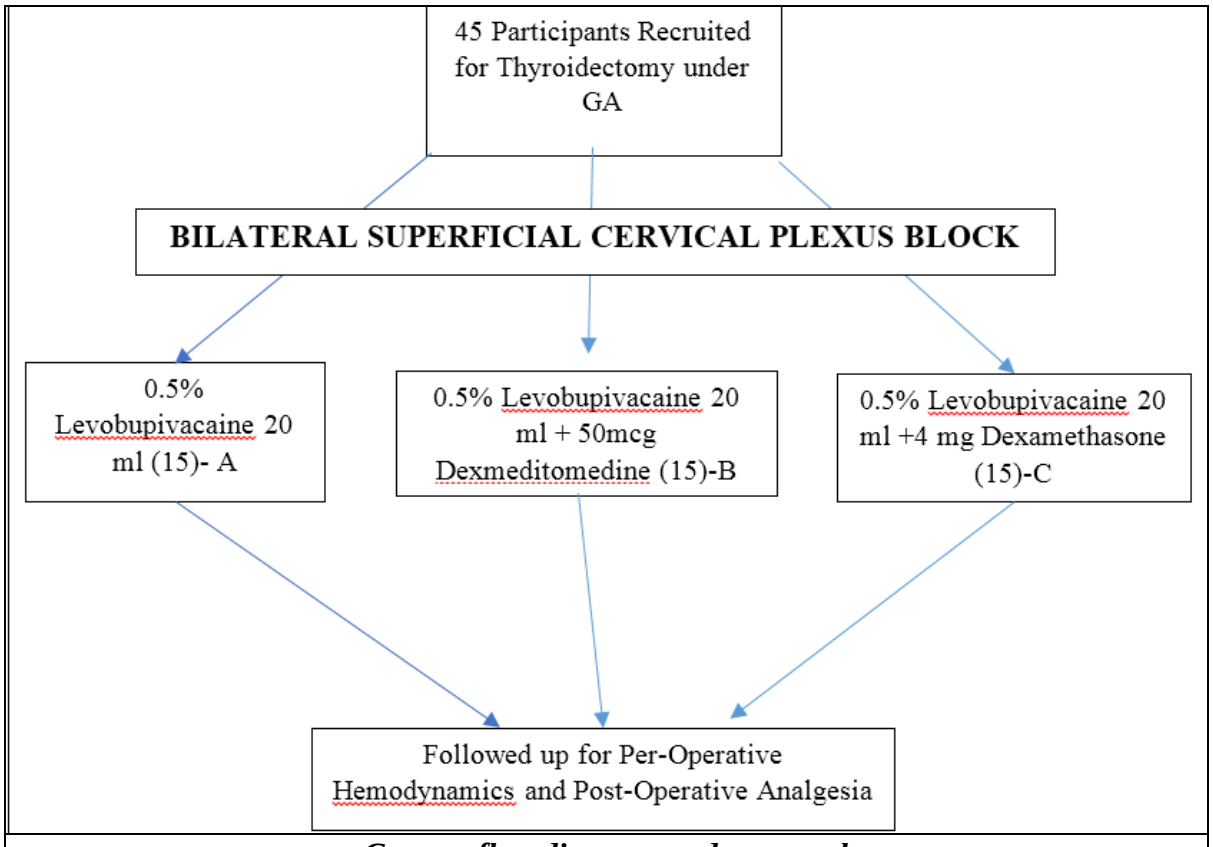
RESULTS

Demography were comparable between the groups. (Table 1) HR, SBP comparison at different time frames showed trend of statistically significant fall in Group B ($p<0.001$) compared to group A & C but were clinically insignificant(Graph 1 & 2). The time for 1st analgesic was the longest in group B at approx. 7 hours and shortest in Group A of approx. 2 hours($p<0.001$) (Graph 3).The VAS score was the least in Group B compared to other 2 groups($p<0.001$)Lesser in Group C compared to A ($p<0.001$)(Graph 4).All these differences were statistically significant and self-explanatory that group with highest post-operative analgesia(Group B) had least VAS compared to group C which was better than Group A. None of the patients had any drug or procedure related adverse events.

Characteristic	Group A	Group B	Group C	p value
Sex(female/Male)	8/7	7/8	9/6	
Weight(kg)	50.43+/-9	51.07+/-6	51.22+/-3	.053
Height(cm)	159.43+/-9.15	160.67+/-8.90	164.8+/-0.76	.076
BMI(Kg/m^2)	24.07+/-2.87	24.85+/-2.58	25.54+/-2.33	.08
Duration of surgery(h)	2.0+/-0.3	1.98+/-0.44	2.20+/-0.55	<.001
Thyroid status(euthyroid)	15	15	15	

Table 1: Distribution of weight, height, bmi, sex, duration of surgery, thyroid status in 3 groups

Values shown for age, weight, duration of surgery are mean ± SD. The values shown for sex and thyroid status are the number of patients



Consort flow diagram-study protocol

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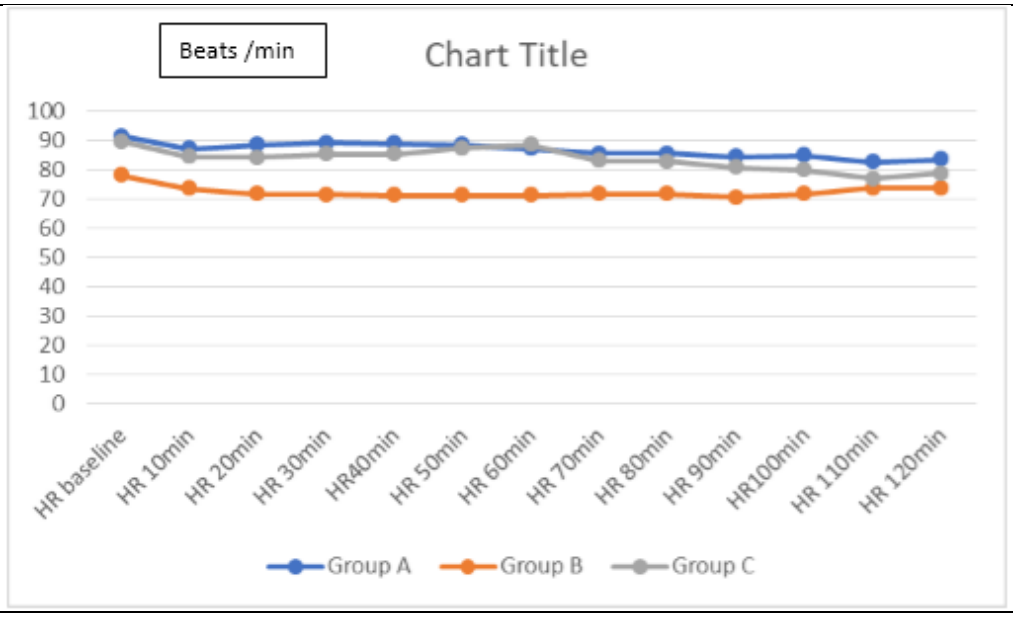
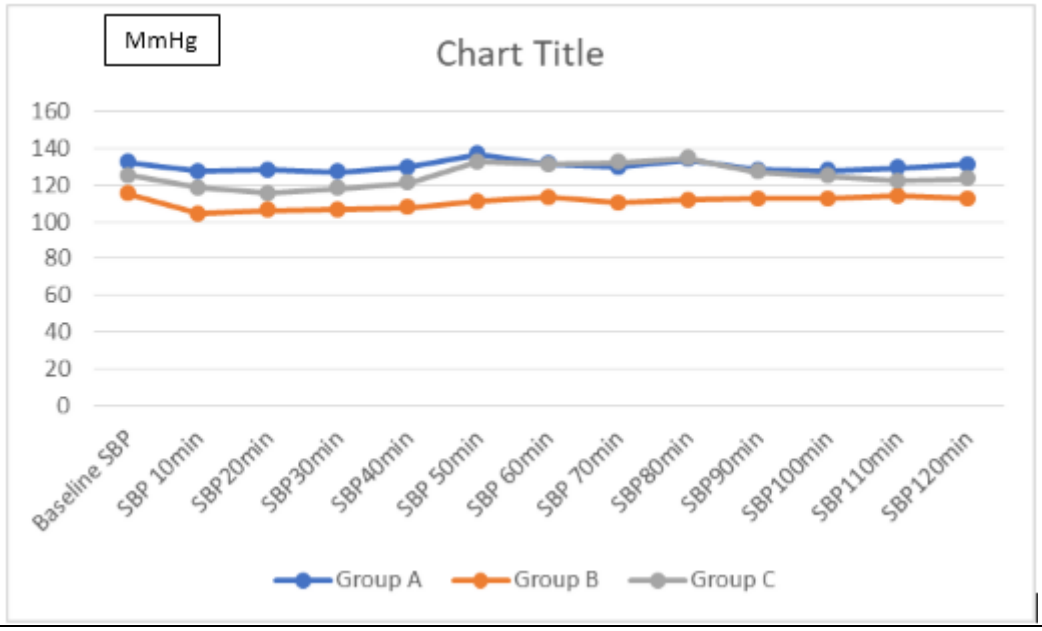


Graph 1: Heart rate at various intervals

X axis corresponds to time interval of measurement and Y axis corresponds to Heart Rate in beats/minute



Graph 2: SBP at various intervals

X axis corresponds to time interval of measurement and Y axis corresponds to Systolic Blood Pressure in MmHg

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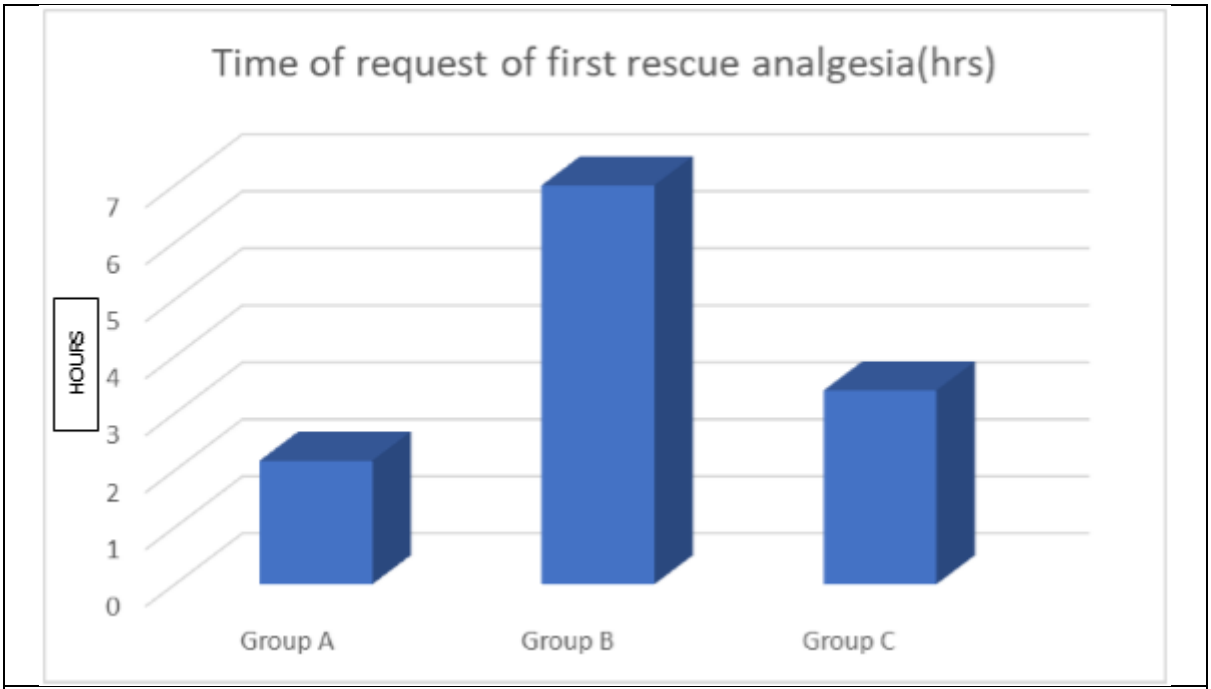
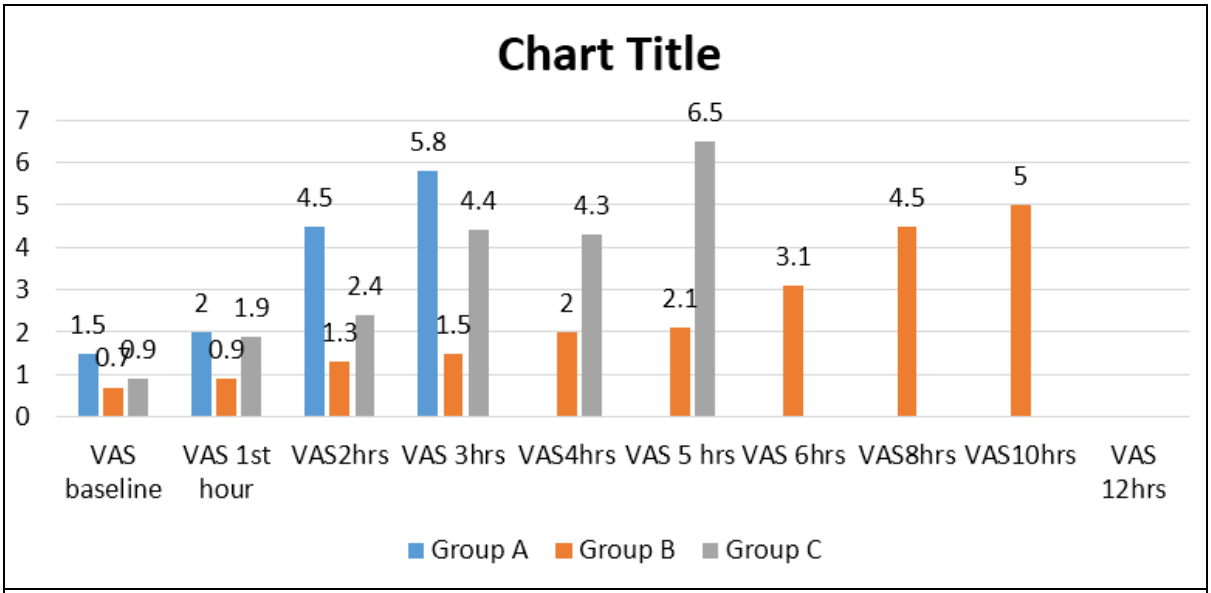


Graph 4: Comparison of time of request of first resque analgesic

X axis corresponds to Group and Y axis corresponds to Time Interval in Hours



Graph 5: Comparison of vas scores at various intervals

X axis corresponds to time interval in hours and Y axis corresponds to VAS scoring

DISCUSSION

Bilateral superficial Cervical Plexus Block(BSCPB) is known to prevent perioperative fluctuations of hemodynamics due to Endotracheal intubation, surgical manipulation of the thyroid gland and imparts good post-operative analgesia according to Aweke Z et al.[9] They used 0.25% Bupivacaine and showed that the median pain score and time for 1st analgesic supplementation was statistically longer in the Bupivacaine group than the Control group.We preferred Levo-Bupivacaine as it had lesser cardiac toxicity compared to Bupivacaine.[10]

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Addition of adjuvants like Dexmeditomedine and Dexamethasone added to LA are known to prolong the action of LA. Dexmedetomidine being α2 agonist has central sympatholytic role, lowers the plasma catecholamine levels and hemodynamic fluctuations due to surgical stress. The perineural dexmedetomidine activates Na-K pump leading to membrane hyperpolarization,[11-13] reduces the peak amplitude of action potential in a concentration dependent manner and prolongs the duration of blockade.[14] Marhofer D et al observed that peri-neural Dexmeditomedine prolongs duration of LA more than systemic administration.[15]

The peri-neural Dexamethasone has anti-inflammatory action, vasoconstriction and decreased nociceptive C fibre activity via Glucocorticoid receptors activity, direct inhibition of K channel activity, thus prolonging the action of LA.

We therefore designed a study to compare the analgesic efficacy of perineural dexamethasone and dexmedetomidine as adjuvant to levo-bupivacaine 0.5% along with plane Levo-bupivacaine in USG guided BSCPB. Keplinger et al observed that adjuvant dose of dexmeditomidine at 150mcg caused deep sedation or post block paraesthesia in 1/3rd of the patients and suggested reducing dosage to 100mcg or less for regional anaesthesia.[2] Thus a dose of 50mcg for Dexmeditomedine and 4 mg for Dexamethasone was preferred in our study.

BSCPB performed using anatomical landmarks as guide were associated with variable success rate and conflicting results as the site and technique of drug deposition were variable. We used USG approach which had the advantage of visualizing the plexus beneath the posterior border of Sterno-Cleido Mastoid Muscle, preventing intra-vascular injection and visualizing the drug spread across the plexus.

Elbahrawy K, et al observed that adding 8mg dexamethasone either I.V or to 0.2% Ropivacaine for BSCPB for thyroidectomies under GA prolonged POA with statistically lower mean pain scores at 6th and 8th h post operatively in the ropivacaine group than I.V group.[16] In our study, Levobupivacaine 0.5% with Dexamethasone 4mg gave POA of around 3 hours duration. This finding could be attributed to lower dose of Dexamethasone used in our study.

Santhosh et al studied the effect of 0.5mcg/kg dexmedetomidine as adjuvant on duration and quality of analgesia produced by BSCPB with 20ml 0.5% ropivacaine in patients undergoing thyroidectomies concluded prolonged POA and lower VAS scores at 12 and 24h post operatively.[9] On the contrary, in our study, Dexmeditomedine 50µg added to Levobupivacaine produced POA of 7 hours approximately. Such gross variation can be explained probably due to the pharmacodynamics of drugs or duration of surgeries.

Comparison of time of request of first rescue analgesia (hrs) between the three groups showed that Group B group had the highest value of approx 7 hours and Group A had the least value of 2.167 hours which was statistically significant ($p < 0.001$).This showed that addition of dexmeditomidine (50mcg) to 20ml 0.5% levobupivacaine significantly prolonged POA compared to plain levobupivacaine/addition of dexamethasone. Similar results were seen with Steffen et al and Karthikeyan VS et al using levobupivacaine in BSCPB($p < 0.001$) and also with clonidine as an adjuvant to bupivacaine in BSCPB ($P < 0.002$).[17-18]

Comparison of intraoperative hemodynamics revealed that HR, SBP and DBP were least in group B and highest among group A which was statistically significant,($p < 0.001$) at most time intervals. This showed that addition of dexmeditomedine as adjuvant to Levobupivacaine in BSCPB reduced peri-operative hemodynamic fluctuations and prolonged POA.

The results of our study was in contrast to that discussed by Herbland A et al[3] who evaluated 111 patients, divided into 3 groups to either not receive BSCPB, receive before or after the surgery. Inj Morphine was given when numeric pain scale was 4 or greater. There was no significant differences in terms of requirement of morphine, pain score and intraoperative opioid consumption. They concluded that BSCPB did not prevent postoperative pain after thyroidectomy. But the limitations to this study was BSCPB was performed by 2-point technique (caudal and rostral directions)[19] causing patchy block and inadequate analgesia .

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Comparatively our study was superior due to the fact that ultrasound guided technique helped in direct visualization of plexus, deposition of LA's in their vicinity; avoiding inadvertent nerve injuries, and preventing intra-vascular injections. It also allowed assessment of adequate local anaesthetic spread thereby improving quality of analgesia, avoiding drug and procedure related adverse events.

Another factor contributing in reducing drug related complications were taking precautions in the optimal drug dosage and combination to attain therapeutic targets.

Confounding factor could be be pain due to throat irritation secondary to endotracheal intubation.[20]

To conclude, Dexmedetomidine -50mcg as an adjuvant to levobupivacaine 0.5%-20ml to BSCPB provided better postoperative analgesia compared to dexamethasone-4mg and plain Levo-Bupivacaine along with clinically stable peri-operative hemodynamics(though statistical difference existed). There were also no procedure or drug related adverse events.

Limitation of the study were lack of follow up for 24 hours, lack of pain assessment with neck movement as the surgical site was covered with dynaplast restricting the movement, need of bigger number of participants for more accurate results and analysis.

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