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ABSTRACT

A comparative study of post-operative analgesic efficacy of dexmedetomidine 25 µg versus dexamethasone 2 mg used as an adjuvant with 20 ml 0.25% ropivacaine in bilateral superficial cervical plexus block for thyroidectomy under general anaesthesia – a prospective randomized double blinded study

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ABSTRACT

Introduction: The bilateral superficial cervical plexus block (BSCPB) is effective for postoperative analgesia following thyroid surgeries. We compared the efficacy of dexmedetomidine and dexamethasone used as an adjuvant with 0.25% ropivacaine in BSCPB for thyroidectomy under general anaesthesia with regards to the duration of analgesia, total amount of rescue analgesic requirement, changes in intra and post operative haemodynamic parameters, VAS scores and adverse events, if any.

Methods: In this prospective double blinded study, 40 adults undergoing thyroidectomy were randomized into two equal groups and given BSCPB with 20 ml 0.25% ropivacaine with adjuvants as either dexmedetomidine 25 µg (Group A) or dexamethasone 2 mg (Group B), 10 ml on each side, after the induction of general anaesthesia. Visual analogue scale (VAS) was used for monitoring postoperative pain and the duration of analgesia. Postoperative haemodynamics parameters and any adverse events were recorded.

Results: The mean duration of analgesia in group A was slightly prolonged but statistically non-significant as compared to group B (15.39 ± 1.61 vs. 13.15 ± 2.11 hours;

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p>0.05). The postoperative VAS scores and haemodynamics were comparable for both the groups (p>0.05). Group B reported significant decrease in the incidence of PONV (p<0.05).

Conclusion: Although, dexamethasone offers a slight advantage of decreased incidence of PONV and cost effectiveness, BSCPB using ropivacaine with either dexmedetomidine or dexamethasone as an adjuvant imparted superior analgesia with stable haemodynamics and may be used as a pre-emptive analgesic technique in thyroid surgeries.

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A COMPARATIVE STUDY OF POST OPERATIVE ANALGESIC EFFICACY OF DEXMEDETOMIDINE 25 µg VERSUS DEXAMETHASONE 2 mg USED AS AN ADJUVANT WITH 20 mL 0.25% ROPIVACAINE IN BILATERAL SUPERFICIAL CERVICAL PLEXUS BLOCK FOR THYROIDECTOMY UNDER GENERAL ANAESTHESIA – A PROSPECTIVE RANDOMIZED DOUBLE BLINDED STUDY

Introduction-

Anaesthesia, by its definition, is a triad of analgesia, amnesia, and unconsciousness. Thyroid surgeries can cause mild to moderate incisional pain, which is usually of short duration.[1] Current methods of providing analgesia include paracetamol, non-steroidal anti-inflammatory drugs (NSAIDS), oral or parenteral opioids and regional anaesthesia techniques. Cervical plexus blocks (CPBs) have been employed frequently in various head and neck surgeries. CPBs confer apposite analgesia in a constricted space in the region of the neck.[3]

Superficial cervical plexus block

The superficial cervical plexus block consists of a bilateral injection of local anesthetic at the mid-point of the lateral border of the sternocleidomastoid (SCM) muscle producing surface anesthesia of the neck. It principally anaesthetizes the four superficial cutaneous branches of the cervical plexus, i.e., the lesser occipital nerve (C2, C3), the greater auricular nerve (C2, C3), the transverse cervical nerve (C3, C4) and the supraclavicular nerve (C3, C4).

The superficial CPB is practical, easier to learn and master, and accounts for only trivial complications.[4,5] Unilateral or bilateral superficial CPBs can be utilized for dispensing postoperative analgesia for a collection of head and neck surgeries such as thyroidectomy[2], minimally invasive parathyroidectomy and tympanomastoid surgery.

Superficial cervical plexus block administered bilaterally potentially reduces the amount of inhaled anaesthetics intra-operatively, [2] in turn, maintaining the haemodynamic parameters as well as minimizing analgesic requirements post-operatively without the conceivable major complications.[1, 13]

Minor complications of this technique comprise of infection, hematoma, accidental phrenic nerve blockade, local anaesthetic toxicity/ hypersensitivity and nerve injury.

Ropivacaine, the long acting S-enantiomer of 1-propyl-2', 6'-pipecolocylidide, was chosen as it has a lower central nervous system (CNS) toxicity and cardiotoxic potential than the R-enantiomer. This is presumably because of slower uptake, resulting in lower blood levels for a given dose[6].

Dexmedetomidine, a new highly selective α2-agonist is the D-enantiomer of medetomidine. It is being used in premedication, as a component for balanced general anaesthesia and as an adjuvant in neuraxial anaesthesia as it provides stable hemodynamic conditions, good quality of intraoperative and prolonged postoperative analgesia with minimal side effects.[6]

Dexamethasone is a well-known corticosteroid with strong anti-inflammatory effects, started to be investigated for its analgesic efficacy. When used as an adjuvant in regional blocks, dexamethasone could reduce the incidence and severity of postoperative pain in adults by enhancing the block characteristics as well as provide antiemetic effect.

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Methods

This was a hospital based prospective, randomized, double blind study, conducted on the patients undergoing elective thyroidectomy surgeries. The study population was randomly divided into two groups with 40 patients in each group using computer generated tables of random numbers. Then, bilateral superficial cervical plexus block was performed after the induction of general anaesthesia (10 ml per side).

Group A (n= 40): Ropivacaine 0.5% 10 ml + 0.9% normal saline 9 ml + 25 µg dexmedetomidine made up to 1 ml (total volume 20ml)

Group B (n= 40): Ropivacaine 0.5% 10 ml + 0.9% normal saline 9 ml + 2mg dexamethasone made upto 1 ml (total volume 20ml)

Level of significance was set at $P \leq .05$.

Inclusion Criteria:

- Patients undergoing thyroid surgery under general anesthesia,
- Age between 16 – 60 years
- ASA physical status I and II.

Exclusion Criteria:

- Age < 16 and > 60 years
- ASA physical status III, IV, V and VI
- Patient refusing for procedure
- Patient with a known history of sensitivity and contraindications to drugs
- Psychiatric illness.
- Patients non-euthyroid at the time of surgery, patients with known coagulopathy, infection at the site of block
- Patients with substernal goitre and patients with stridor or respiratory compromise.

On arrival of the patient in the operation theatre, all standard ASA monitor were connected. Baseline pulse rate, oxygen saturation, electrocardiogram, blood pressure were recorded. An intravenous cannula of 18 or 20 G was secured.

Pre- anaesthetic medications included injections midazolam 0.02 mg/kg, fentanyl 2µg/kg and 1% xylocard 1ml along with preoxygenation with 100% oxygen. Induction of general anaesthesia was achieved with 2mg/kg propofol and vecuronium 0.1 mg/kg followed by tracheal intubation. Anaesthesia was maintained with inhalational agent sevoflurane (MAC 1.3-1.7), vecuronium 0.01mg/kg and a mixture of O2:N2O in the ratio 50:50.

After induction, the patient's head was placed facing away from the side to be blocked. With the anaesthesiologist standing at the head end of the patient, bilateral superficial cervical plexus block was performed. The site was painted with 5% Povidone – Iodine and spirit and draped.

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A 24-gauge needle was inserted into the mid-portion of the posterior border of the sternocleidomastoid muscle, between the landmarks of mastoid process and C-6 transverse process. Next, 5 ml of anaesthetic was injected subcutaneously, horizontally and the other 5 ml injected cephalad toward the tragus of ipsilateral ear and caudad toward the sternal notch in a "fan" fashion. The same technique was used to perform the block on the contralateral side and the time at which the bilateral superficial cervical plexus block was performed was noted.

Haemodynamic parameters, SpO2, respiratory gas monitoring was done continuously and recorded at 5 min intervals for the first 15 minutes and thereafter every 15 minutes until the end of surgery. Sevoflurane and nitrous oxide were discontinued at the end of the surgery. The neuromuscular blocking agent was reversed with an intravenous injection of 0.05 mg/kg neostigmine and 10 μg/kg glycopyrrolate, and patient was extubated after complete recovery. Post-operatively duration of analgesia was assessed using the Visual Analog Score

Post-operatively if VAS ≥4 was noted, then the rescue analgesics drugs were given in the order of decreasing priority:

- Tablet diclofenac 50 mg
- Injection diclofenac 75 mg IM
- Injection tramadol 100 mg slow IV

The total number of doses of rescue analgesics required in 24 hours were also taken into account.

PONV was assessed using a four-point scale 1= No nausea; 2= Mild nausea; 3= Severe nausea; 4= Retching and/or vomiting

The primary objective was to analyse duration of post-operative analgesia. The secondary objectives included total consumption of analgesic in 24 h**,** post-operative nausea and vomiting**,** haemodynamic changes peri-operatively (SBP, DBP, MAP, HR)**,** adverse effects like haematoma, intravascular injections, local anaesthetic toxicity, bradycardia, hypotension, sedation and post operative respiratory distress.

Results:

Both the groups were demographically comparable with respect to age, gender, weight, ASA status. The groups were also comparable regarding baseline hemodynamic parameters, mean duration of surgery and mean duration of anesthesia.

Figure-1 shows mean values of preoperative baseline parameters in both A and B groups. Mean values of all the baseline parameters were comparable in both the groups ($P > 0.05$).

Figure 1: Comparison of baseline hemodynamic characteristics

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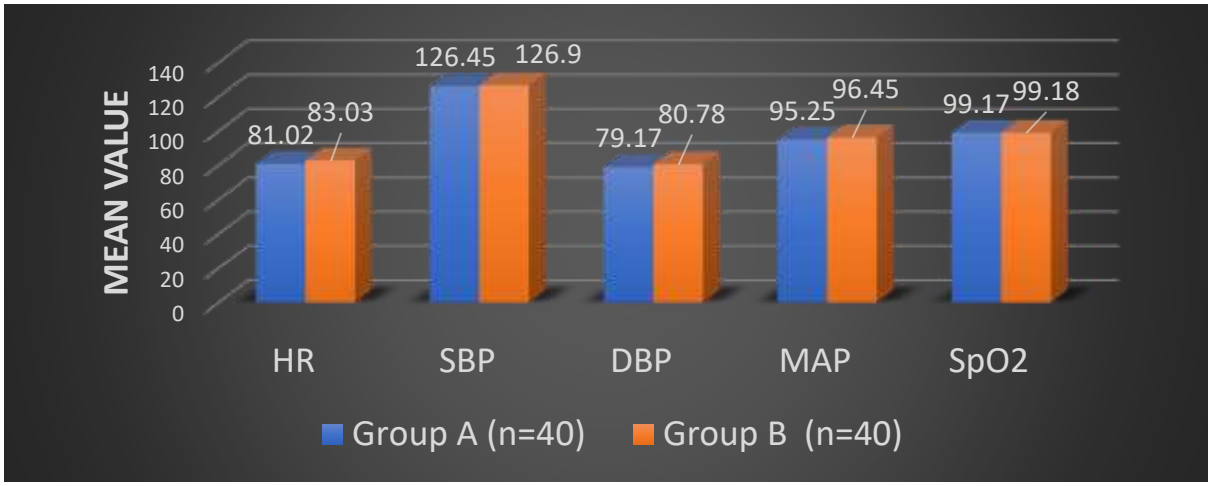

Figure-2 depicts the mean MAP intra-operatively. It was revealed that in group A, intraoperative mean MAP was lower in comparison to group B from the time duration of 30 mins to 90 mins.. The difference in MAP was comparable at 0 to 15 min duration.

Figure 2: Comparison of intraoperative mean arterial pressure (mmHg) among study groups

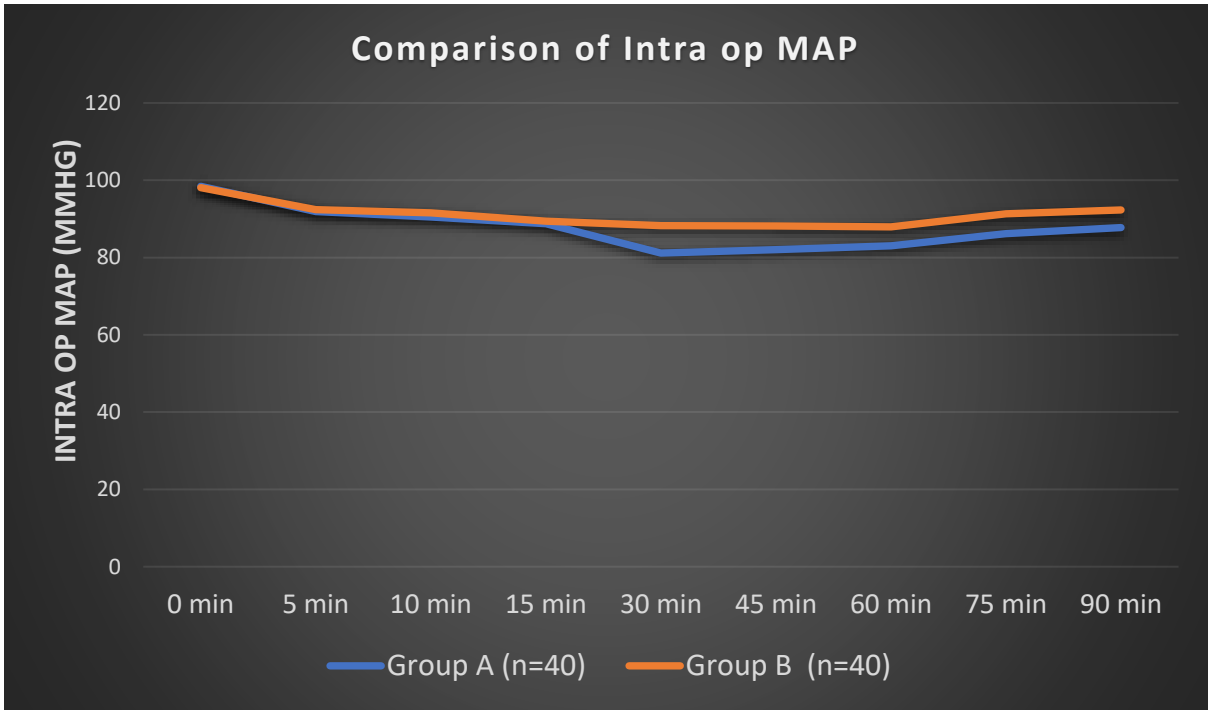

Figure-3 illustrate the changes in the mean HR intraoperatively in both the groups recorded from 0 min to 90 min. It was revealed that the readings were comparable in both the groups in the initial 15 minutes but was significantly lower in group A as compared to group B thereafter.

Figure 3: Comparison of intraoperative heart rate (beats/min) among study groups

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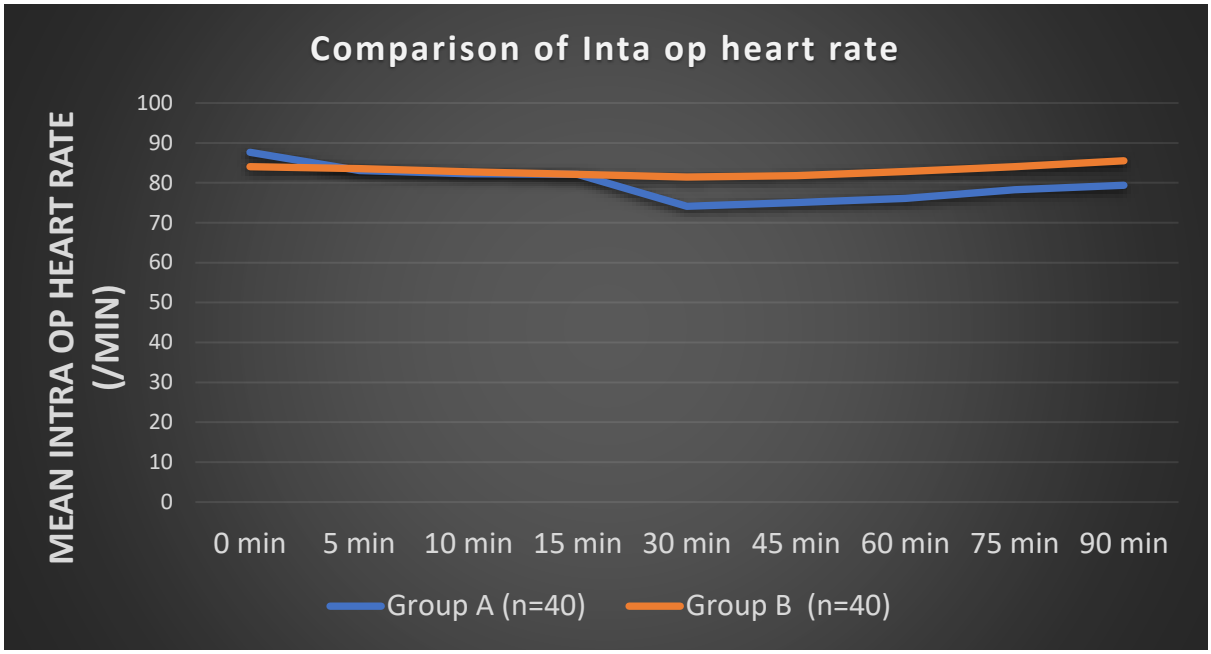

Figure-4 show the mean heart rate postoperatively in beats/minute for both groups A and B. The mean HR was slightly lower in group A as compared to group B for the entire post operative period but statistically significant increase in HR was seen in Group B at 16, 18 and 20 hours ($P < .05$).

Figure 4: Comparison of postoperative pulse rate (beats/min) among study groups

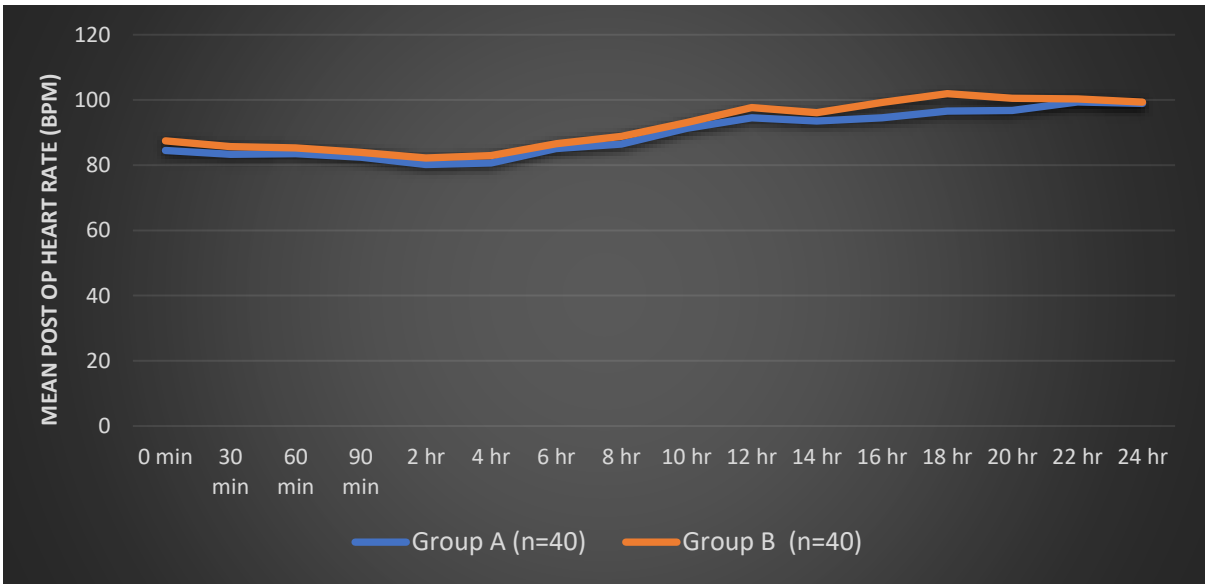

Figure- 5 show the mean VAS score in relation to time period in postoperative period. It is revealed that mean VAS score was comparable for the entire postoperative period in group A and B. The difference in mean VAS score was statistically non-significant ($P > .05$).

Figure 5: Comparison of postoperative VAS score among study groups

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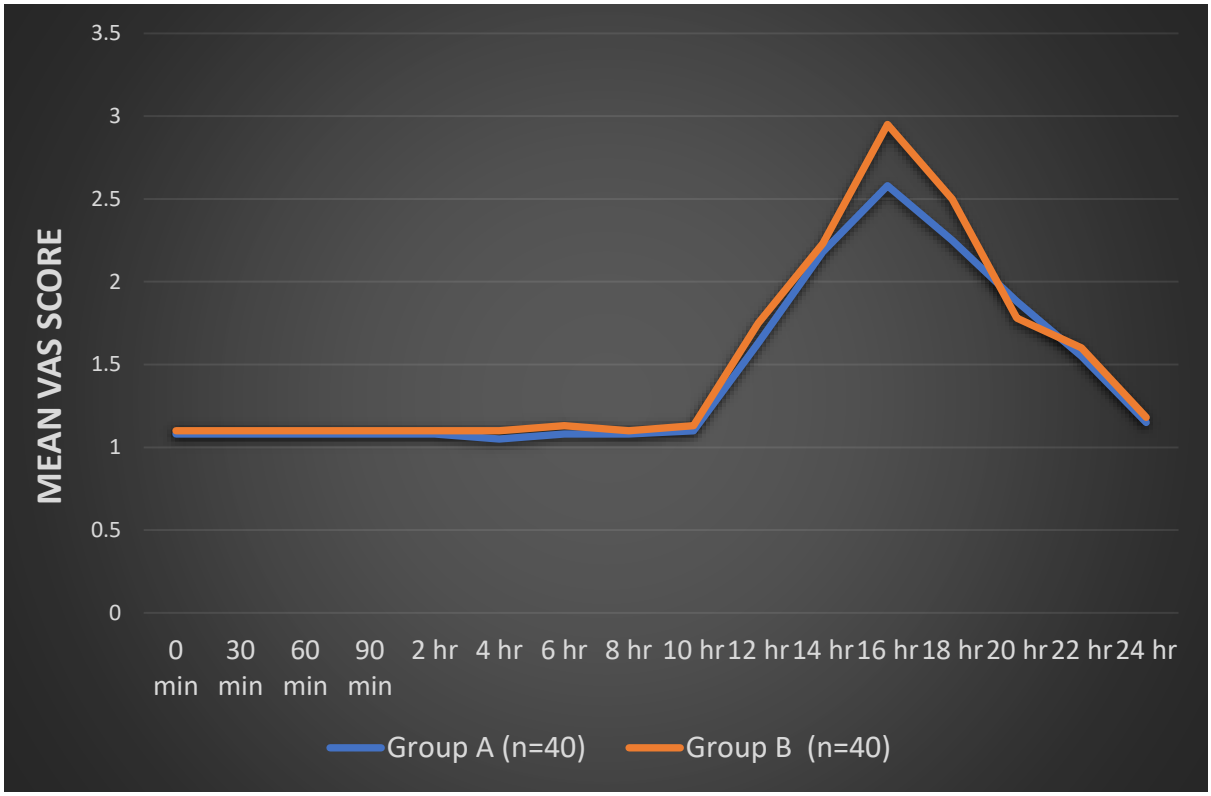

Table-1 shows the mean duration of analgesia in group A and B was (15.39 ± 1.61) hours and (13.15 ± 2.11) hours respectively. The mean duration of analgesia was slightly higher in group A as compared to group B but on applying unpaired student 't' test, this difference was statistically not significant ($P > .05$).

Table-1: Comparison of mean duration of analgesia (hours) among study groups

	Group A		Group B	
	Mean	SD	Mean	SD
Mean Duration of Analgesia	15.39	1.61	13.15	2.11
Median (Range)	15 (11-18)		13 (10-15)	
Result (p value)	0.120 (NS)			

The mean total analgesic dose for both the groups A and B was (53.13 ± 19.34) mg and (52.12 ± 19.31) mg respectively clearly showing a comparable demand of the rescue analgesic in both the groups (Table 2). The difference was found to be statistically non-significant. ($P > .05$).

Table-2: Comparison of mean total analgesic dose of Diclofenac (mg) among study groups

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	Group A		Group B	
	Mean	SD	Mean	SD
DOSE OF RESCUE ANALGESIC	53.13	19.34	52.12	19.31
Median (Range)	50 (0-90)		50 (0-90)	
Result (p value)	0.817 (NS)			

Table 3 depicts the adverse events observed in patients in both group A and B. The incidence of hypotension was observed in both the groups, but it was statistically non-significant ($P > .05$). The incidence of nausea and vomiting was observed to be lower in group B as compared to group A and the difference was statistically significant ($P < .05$). No incidence of intravenous injection, Horner's syndrome or local anaesthetic toxicity was observed in any of the groups.

Table-3: Frequency of adverse events among study groups

	Group A (n=40)		Group B (n=40)		Result (p value)
Adverse events	No.	%	No.	%	
Hypotension	9	22.50	9	22.50	.789 (NS)
Nausea	11	27.50	3	7.50	.039 (S)
Vomiting	8	20.00	1	2.50	.034 (S)
Horner's syndrome	0	0	0	0	-

Discussion-

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Thyroidectomy is linked with mild to moderate incisional pain bracketed with pain in the neck region, reportedly 6.9 ± 1.7 on visual analog scale (VAS). Peripheral nerve blocks like cervical plexus blocks are remarkably safe and adept at providing analgesia in the perioperative period. In fact, Kolawale et al.[9] examined and proved success of bilateral superficial cervical plexus block in thyroidectomy, obviating the need of administration of general anaesthesia altogether.

Dexmedetomidine and dexamethasone have been used safely as adjuvant to bupivacaine and levobupivacaine[12] without any neurological side effects. An animal study done by Brummet et al.[10] showed that high-dose dexmedetomidine (25-40 μg/kg) on perineural administration did not damage axons or myelin sheaths and could even reduce the bupivacaine-induced acute perineural inflammation. Peripheral dexamethasone with local anesthetics, on the other hand, prolongs the analgesic duration of peripheral nerve blocks by suppressing transmission in thin unmyelinated C-fibers, a local vasoconstrictive effect, and anti-inflammatory actions[14] and plays a significant role in decreasing PONV [11].

In this study, we have investigated and compared the post-operative analgesic efficacy of dexmedetomidine 25 μg and dexamethasone 2mg used as an adjuvant with 20 ml 0.25% ropivacaine in bilateral superficial cervical plexus block in patients undergoing thyroidectomy under general anaesthesia with regards to the duration of analgesia, total amount of rescue analgesic requirement and changes in haemodynamic parameters, if any.

The rationale for choosing 0.25% concentration was supported by the study done by Andrieu et al.[8] & Goulart et al.[18]. They found that increasing the concentration of ropivacaine from to 0.5% or 0.75% failed to tweak the duration of analgesia, suggesting that the risk of increased total dose of LA can be avoided.

A study conducted by Okmen et al.[7] gauged the influence of volume of the drug irrespective of its concentration and concluded that the block was more efficacious when the total volume of the study drug 0.25% bupivacaine was higher (20 ml vs 10 ml). Further increment in the total volume of the drug, as shown by Shih et al.[1] & Karthikeyan et al.[17] failed to illustrate an advancement in the primary outcome variables. Hence, we decided to use standard volume of study drug, 20 ml of 0.25% ropivacaine with dexmedetomidine or dexamethasone as it is adequate, as used by kr Raiger L et al.[15]

The demographic profile and anthropometric measurements, i.e., age, gender, weight, and ASA physical status between two groups of our study were comparable (p >0.05).

The baseline parameters and mean duration of surgery (group A: 97.55 ± 30.76 min and group B: 94.80 ± 29.23 min) and anaesthesia (group A: 109.25 ± 27.30 min and group B: 108.68 ± 28.62 min) were almost similar in both groups and had no statistical significance (P > .05) like all other studies[7,8,11,16-18].

VAS scores were monitored for first 24 hours after discharge from PACU. The VAS scores were comparable and statistically non-significant for the entire duration of 24 hours of the postoperative period (P > .05) which correlates with the comparable duration of analgesia seen

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in both group A and group B. Whenever the VAS was ≥ 4, time was noted and tablet diclofenac 50 mg orally or inj. diclofenac sodium 75mg IM was given as rescue analgesia. The mean duration of analgesia in group A (15.39 ± 1.61 hours) as compared to group B (13.15 ± 2.11hours) was slightly prolonged but the difference was statistically non-significant (*P;*.120).

Song ZG et al.[14] had similar observations while comparing the postoperative analgesic effects in response to either dexamethasone or dexmedetomidine as local anaesthetic adjuvants in perineural blocks. Hassan AH et al.[12,] in their study compared dexmedetomidine and dexamethasone as adjuvants to levobupivacaine for bilateral superficial cervical plexus block and observed that the addition of dexmedetomidine to levobupivacaine resulted in the duration of analgesia being significantly longer compared to dexamethasone added to the levobupivacaine group (232.34 versus 303.55 min; $P < .05$).

In conclusion, it is expressed that dexmedetomidine and dexamethasone, both provide post-operative analgesia of longer duration and better quality when added to levobupivacaine, bupivacaine or ropivacaine as evidenced by Song ZG et al.[14], Hassan AH et al.[12], Elbahrawy K et al.[11], Banu P et al.[13] and our study.

The mean total analgesic dose, tablet or injection diclofenac, given in first 24 hours in Group A (53.13 ± 19.34 mg) was statistically non-significant and comparable to the mean total analgesic dose given in Group B (52.12 ± 19.31 mg), $P > .05$. This is also reflected in other studies namely Cai et al.[16], Karthikeyan et al.[17], Okmen et al.[7] & Goulart et al.[18].

PONV was assessed using a four-point scale previously used by Shih et al.[1] and Goulart et al.[18]. Severe PONV was defined as grades 3 and 4; and rescue antiemetic, inj. ondansetron 8mg was administered. Other studies, like Cai et al.[16] and Elbahrawy et al.[11] also evaluated PONV using a 10-point scale and administered rescue anti-emetics when score became ≥4.

In our study, it was observed that the incidence of nausea was 27.50% in Group A while the incidence of nausea was 7.50% in Group B ($P < .05$). The incidence of vomiting was found to be 20% in Group A while in Group B, it was found to be 2.50% ($P < .05$). Therefore, the incidence of nausea/vomiting demonstrated a statistically significant decrease with the use of dexamethasone as an adjuvant, as compared to dexmedetomidine.

Studies conducted by Shih et al.[1], Cai et al.[16], Karthikeyan et al.[17] and Goulart et al.[18] testified that the use of bilateral superficial cervical plexus block significantly reduces the incidence of PONV. Reducing the level of general anaesthesia required and the dosage of opioids along with prolonged postoperative analgesia are important strategies for reducing the incidence of PONV, which were all achieved.

The groups were comparable with regards to pre-operative pulse rate, mean arterial pressure, systolic and diastolic blood pressure and oxygen saturation ($P > .05$).

Although, group A had statistically lower SBP, DBP and MAP as compared to group B, the frequency of hypotension was comparable for both the groups (Group A: Group B :: 9 : 9) (*P*

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> .05) suggesting that both dexmedetomidine and dexamethasone are haemodynamically stable when used as adjuvants for peripheral nerve blocks.

The post operative heart rate, SBP and DBP were found to be statistically non-significant (*P* > .05) for the initial 14 hours however there was a statistically significant difference in the vital parameters at 16, 18 and 20 hours as the analgesic effect of the block began to wear off. Other anticipated side effects like Horner's syndrome and others were not noted in our study, as observed by Okmen et al.[7].

Conclusion-

From this study, we observed that superficial cervical plexus block performed bilaterally using ropivacaine with dexmedetomidine or dexamethasone as an adjuvant, in patients undergoing thyroidectomy results in prolonged yet comparable duration of analgesia in the postoperative period, along with comparable dose of rescue analgesics and VAS scores. Despite dexmedetomidine and dexamethasone being comparable adjuvants, dexamethasone appears to be slightly more propitious with regards to decreased incidence of PONV and cost effectiveness of the drug.

From our study, we conclude that superficial cervical plexus block administered bilaterally using ropivacaine with either dexmedetomidine or dexamethasone as an adjuvant imparted superior analgesia and decreased opioid usage without potential side effects or complications and may be used as a pre-emptive analgesic technique in thyroid surgeries.

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