Section: Anesthesiology

Original Research Article

BILATERAL SUPERFICIAL AND DEEP CERVICAL PLEXUS BLOCK USING ROPIVACAINE &CLONIDINE FOR THYROID SURGERIES UNDER GENERAL ANAESTHESIA - (A PROSPECTIVE, RANDOMIZED, DOUBLE-BLINDED, PLACEBO-CONTROLLED STUDY FOR EVALUATING THE ANALGESIC EFFICACY OF (0.2%) ROPIVACAINE VS (0.2%) ROPIVACAINE & CLONIDINE)

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Abstract

Background: General anaesthesia is the preferred anaesthetic technique for thyroid surgeries. Tracheal stimulation due to endotracheal tube movement and surgery in the neck requires a deep plane of general anaesthesia, which may result in delayed recovery. In this study, we evaluated the intraoperative and postoperative analgesic efficacy of combined deep and superficial cervical plexus block using ropivacaine (0.2%) and ropivacaine (0.2%) with clonidine (2µg/kg) in bilateral superficial and deep cervical plexus block after general anaesthesia for thyroid surgeries. **Materials and Methods:** For this purpose, 60 patients undergoing elective thyroid surgery were randomized to receive a bilateral combined deep and superficial cervical plexus block (14 mL per side) with saline (Group 1; n=20), ropivacaine 0.2% (Group 2; n=20), or ropivacaine 0.2% plus clonidine two µg/kg (Group 3; n=20). With ultrasound guidance, a deep cervical plexus block was performed with a single injection (8 mL) at the C3 level. The superficial cervical plexus block consisted of subcutaneous injection (6 mL) behind the lateral border of the sternocleidomastoid muscle. **Result:** During surgery, the number of additional fentanil boluses was significantly reduced in Groups 2 and 3 compared with Group 1 (mean –A [133 µg], B [100 µg], C [100 µg]; $P < 0.05$). After surgery, the duration of analgesia was also significantly more in Groups 2 and 3 ($P < 0.05$) during the first 24 h. Adverse reaction status is considered statistically insignificant since $p > 0.05$ between the groups. **Conclusion:** A combined deep and superficial cervical plexus block effectively alleviates pain during and immediately after thyroidectomy.

INTRODUCTION

General anaesthesia is the preferred anaesthetic technique for thyroid surgeries. Tracheal stimulation due to endotracheal tube movement and surgery in the neck requires a deep plane of general anaesthesia, which may result in delayed recovery. Short-acting opioids can avoid this but may result in postoperative hyperalgesia. Postoperative pain is of moderate intensity after thyroid surgery.[1] Opioids or NSAIDs may be required during the first postoperative day. Opioids produce analgesia effectively but with side effects like nausea, vomiting, hypoventilation, urinary retention, and somnolence.[2] By reducing the dose of opioids, we can reduce the side effects, but the analgesia will also be less. So other methods like nonopioid analgesia, regional blocks, and local anaesthetic infiltration at the surgical site have been tried.[3]

Ropivacaine, a new long-acting amide local anaesthetic and pure S-enantiomer, provides an equipotent sensory block but a less intense and shorter motor block than bupivacaine in adults and children.[4] Studies in volunteers have shown that

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ropivacaine has a lower potential for central nervous and cardiac toxicity than bupivacaine due to its lower lipid solubility.[5] The maximum tolerated dose for central nervous system symptoms, which occur before cardiovascular symptoms, was higher after ropivacaine in most subjects.[6] Animal studies have confirmed that ropivacaine is less arrhythmogenic than bupivacaine. These positive properties appear to favour the use of ropivacaine as local anaesthesia.[7]

Several studies have shown that adding clonidine improves anaesthesia quality, reduces the anaesthetic agent's dose requirement, and provides better hemodynamic stability without adverse effects on fetal or maternal outcomes.[8,9] Danelli and colleagues reported that adding 50 µg of clonidine to 150 mg of ropivacaine for superficial cervical plexus block shortened the onset time and improved the quality of surgical anaesthesia in patients undergoing elective carotid endarterectomy. Moreover, adding clonidine 1 µg / kg to ropivacaine 0.75% prolongs the duration of postoperative analgesia by 3 hours.[10] Hence, this study was conducted to compare postoperative analgesia using ropivacaine (0.2%) and ropivacaine (0.2%) with clonidine (2 µg/kg) in bilateral superficial and deep cervical plexus block after general anaesthesia for thyroid surgeries.

MATERIALS AND METHODS

This prospective, randomized, double-blinded, placebo-controlled study was done on 60 patients undergoing total thyroidectomy under general anaesthesia at Rajiv Gandhi Government General Hospital, Chennai, in 2016. An institutional ethical committee approved the study, and informed consent was obtained from all the patients.

Inclusion Criteria

Age: 18 years to 60 years, ASA I, II, Elective surgery, euthyroid state, and patients who have given valid informed consent were included.

Exclusion Criteria

Patients posted for emergency surgery, patients with difficult airways, pregnant females, H/O seizures and any neurological deficit, poor lung compliance such as pulmonary fibrosis, allergy to drugs used, patient refusal, and patients with severe cardiovascular, respiratory, renal, and hepatic diseases were excluded.

A thorough physical and clinical examination was done preoperatively, all the investigations were verified, and the airway was assessed. Patients were randomly assigned by closed envelope method into groups A (normal saline), B (Inj Ropivacaine 0.2%), and C (Inj Ropivacaine 0.2% and Clonidine 2 µgm/kg). The baseline heart rate, blood pressure and Spo2 were recorded, and all patients were preloaded with 10ml/kg of normal saline and premedicated with Inj Glycopyrrolate 0.2mg intravenously.

The patient received a combination of fentanyl, thiopentone, and atracurium injections and was intubated. An anaesthetist administered bilateral cervical plexus blocks under ultrasound guidance. The injection was unknown to the patient, surgeon, anaesthesiologist, and PACU assessing doctor. The superficial cervical plexus block was performed bilaterally using a 23G needle, blocking the main branches of the plexus. The deep cervical plexus block was performed under ultrasound guidance, with the C3 level marked. Blood pressure, Spo2 and heart rate were measured every 5 minutes, and Inj.Atracurium 0.1mg/kg was administered every 30 minutes. The duration of surgery was noted, and fentanyl requirements were monitored. Inj. Fentanyl 0.3µg/kg was given when the heart rate or the systolic blood pressure rises more than 20%.

At the end of the surgery, the patient was reversed with 50 mcg/kg of neostigmine with 10 mcg/kg of Inj Glycopyrrolate I.V. Thorough oral suctioning was done, and the patient was extubated after adequate neuromuscular recovery—a postoperative laryngoscope done for vocal cord movement assessment. The patient was shifted to PACU postoperatively. In PACU, the VAS score as a measure of postoperative pain, heart rate, blood pressure, and sedation score was measured every 30 minutes up to 6 hours and every 4 to 24 hours. For patient with VAS score > 4, rescue analgesia in the form of I.V paracetamol 10mg/kg i.v administered as first rescue analgesia. For the second rescue, tramadol, 100 mg I.M., was used, and the patient was observed for procedure-related complications and recorded.

Statistical Analysis

The data was analyzed using SPSS version 16 and Microsoft Excel 2007. Descriptive statistics were done for all data and were reported in terms of mean values and percentages. Suitable statistical comparison tests were done, and continuous variables were analyzed with the unpaired t-test. Categorical variables were analyzed with the Chi-Square and Fisher Exact Test, and a statistical significance was taken as $P < 0.05$.

RESULTS

Female predominance was reported in all groups, and most patients were 31-50 years old. Most patients in the saline and Ropivacaine group belong to ≤ 150 cm height. Maximum patients were found in the 51-60 kg weight category in all groups. The majority of the saline group 16 (80%), ropivacaine group 13 (65%) and ropivacaine + clonidine group 17 (85%) patients belonged to the MNG diagnosis group [Table 1].

The saline group, ropivacaine group and ropivacaine + clonidine group patients had a mean total fentanyl dose of 133, 100 and 100 mcg, respectively. By conventional criteria, the association between the intervention groups (saline group vs ropivacaine group and saline group vs ropivacaine + clonidine) and total fentanyl dose is considered statistically significant ($p<0.05$).

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The saline group, ropivacaine group and ropivacaine + clonidine group patients had a duration of analgesia of 66, 475.50 and 1068 minutes, respectively. By conventional criteria, the association between the intervention groups (saline group vs ropivacaine group, saline group vs ropivacaine + clonidine and ropivacaine group vs ropivacaine + clonidine) and duration of analgesia is considered to be statistically significant ($p<0.05$) [Table 2].

At 0 hours, saline group, ropivacaine group, and ropivacaine + clonidine group patients had a mean VAS score of 5.75, 0.00 and 0.15, respectively. Patients with the saline group, ropivacaine group and ropivacaine + clonidine group had a mean VAS score of 3.15, 1.96 and 1.78, respectively.

By conventional criteria, the association between the intervention groups (saline group vs ropivacaine group and saline group vs ropivacaine + clonidine) and VAS score 0-24 hours is statistically significant ($p<0.05$). By conventional criteria, the association between the intervention groups (ropivacaine group vs ropivacaine + clonidine) and VAS score between 2-18 hours is statistically significant ($p<0.05$) [Figure 1].

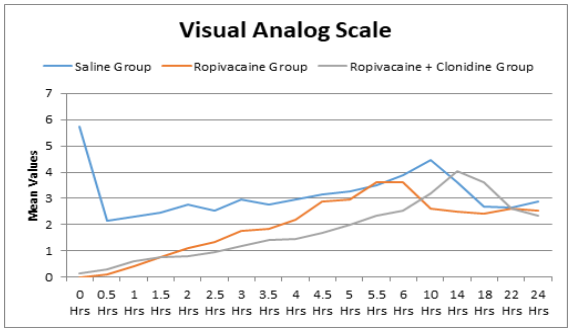

Figure 1: VAS score between groups

At 0 hours, saline group, ropivacaine group, and ropivacaine + clonidine group patients had a mean postoperative heart rate of 100.25, 78.95 and 76.15 bpm, respectively. The association between the intervention groups (saline group vs ropivacaine group and saline group vs ropivacaine + clonidine) for postoperative heart rate 0-24 hours was reported as statistically significant ($p<0.05$). Also, the association between the ropivacaine group vs ropivacaine + clonidine and postoperative heart rate between 0.5-24 hours was found statistically significant ($p<0.05$) [Figure 2].

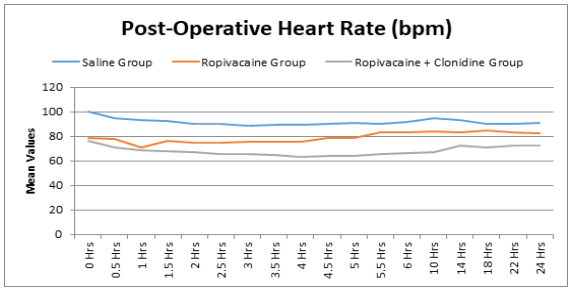

Figure 2: Postoperative heart rate between groups

The mean postoperative SBP, DBP and MAP at 0 hours were reported for saline group 141.95, 93.00, 109.32 mmHg, Ropivacaine group 122.55, 77.30, 92.38mmHg and for Ropivacaine + Clonidine group it was found 118.30, 76.5, 90.47 mmHg. The intervention groups (saline group vs ropivacaine group and saline group vs ropivacaine + clonidine) and postoperative SBP, DBP and MAP 0-24 hours postoperatively were statistically significant ($p<0.05$). The intervention groups (ropivacaine group vs ropivacaine + clonidine) and postoperative SBP, DBP, MAP between 2-24 hours postoperatively were also reported statistically significant ($p<0.05$) [Figure 3-5].

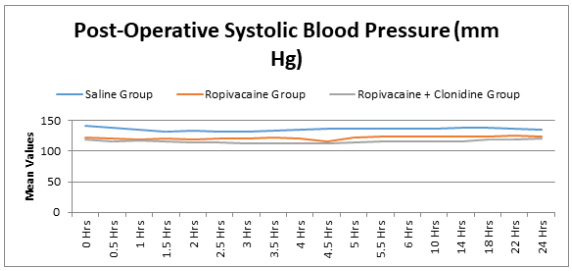

Figure 3: Postoperative systolic blood pressure between groups

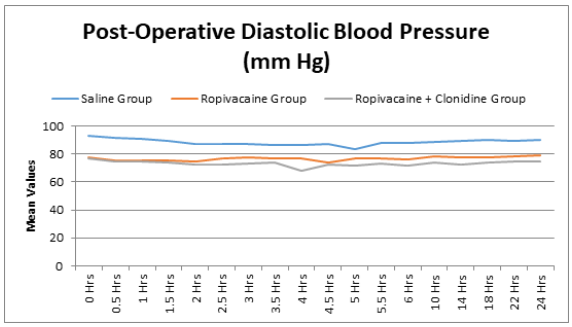

Figure 4: Postoperative diastolic blood pressure between groups

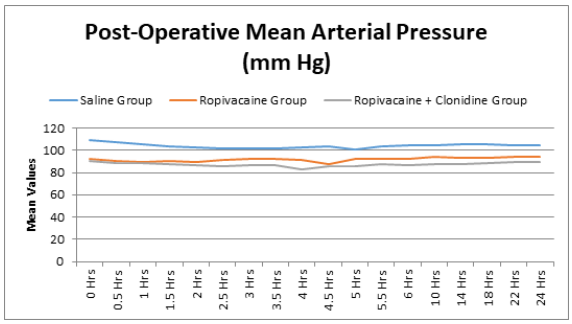

Figure 5: Postoperative mean arterial pressure between groups

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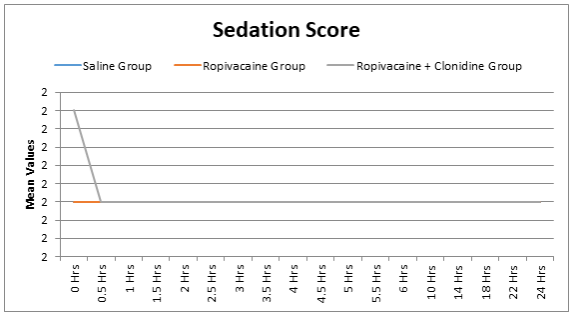

Figure 6: Sedation score between groups

At 0 hours, the saline group, ropivacaine group and ropivacaine + clonidine group patients had a mean sedation score of 2.00, 2.00 and 2.05 points, respectively. Between 0-24 hours, saline group, ropivacaine group and ropivacaine + clonidine group patients had a mean sedation score of 2.00, 2.00 and 2.00 points, respectively. The association between the intervention groups and sedation score 0-24 hours postoperatively was found statistically not significant since ($p>0.05$) [Figure 6].

Rescue analgesia - 1 Rescue

The saline group, ropivacaine group and ropivacaine + clonidine group patients had a mean first rescue analgesia time of 66.00, 475.50 and 1068 minutes, respectively. By conventional criteria, the association between the intervention groups and first rescue analgesia time is considered statistically significant ($p<0.05$).

Rescue analgesia - 2 Rescue

The saline group, ropivacaine group and ropivacaine + clonidine group patients had a mean second rescue analgesia time of 768.00, 0.00 and 0.00 minutes, respectively. By conventional criteria, the association between the intervention groups and second rescue analgesia time is considered statistically significant ($p<0.05$) [Table 3].

There was no significant difference in the duration of surgery between the three groups ($p>0.05$). The saline group, ropivacaine group and ropivacaine + clonidine group patients had an incidence of adverse reactions of 25%, 5% and 15%, respectively. By conventional criteria, the association between the intervention groups and adverse reaction status is considered statistically insignificant ($p<0.05$) [Table 4].

Table 1: Demographic data of the groups

		Saline Group	Ropivacaine Group	Ropivacaine + Clonidine Group
Gender	Male	2 (10%)	1 (5%)	0
	Female	18 (90%)	19 (95%)	20 (100%)
Age group (years)	≤ 20	0	0	1 (5%)
	21-30	2 (10%)	5 (25%)	3 (15%)
	31-40	8 (40%)	8 (40%)	6 (30%)
	41-50	8 (40%)	4 (20%)	7 (35%)
	51-60	2 (10%)	3 (15%)	3 (15%)
Height (cms)	≤ 150	10 (50%)	11 (55%)	7 (35%)
	151-160	9 (45%)	8 (40%)	13 (65%)
	151-170	1 (5%)	1 (5%)	0
Weight (kgs)	≤ 50	2 (10%)	5 (25%)	5 (25%)
	51-60	17 (85%)	14 (70%)	12 (60%)
	61-70	1 (5%)	1 (5%)	2 (10%)
	71-80	0	0	1 (5%)
Diagnosis	MNG	16 (80%)	13 (65%)	17 (85%)
	SNT	2 (10%)	1 (5%)	2 (10%)
	R SNT	2 (10%)	4 (20%)	1 (5%)
	L SNT	0	1 (5%)	0
	D G	0	1 (5%)	0

Table 2: Total fentanyl dose and duration of analgesia between groups

		Saline Group	Ropivacaine Group	Ropivacaine + Clonidine Group	P-value
Total fentanyl dose (mcg)	100	1 (5%)	20 (100%)	2 (100%)	<0.0001
	120	6 (30%)	0	0	
	140	12 (60%)	0	0	
	160	1 (5%)	0	0	
Duration of analgesia (minutes)	≤ 300	20 (100%)	3 (15%)	0	<0.0001
	301-600	0	14 (70%)	0	
	601-900	0	1 (5%)	7 (35%)	
	901-1200	0	1 (5%)	8 (40%)	
	1201-1500	0	1 (5%)	5 (25%)	

Table 3: Rescue analgesia between groups

Rescue Analgesia (minutes)		Saline Group	Ropivacaine Group	Ropivacaine + Clonidine Group	P-value
1 Rescue	≤ 300	20 (100%)	3 (15%)	0	<0.0001
	301-600	0	14 (70%)	0	
	601-900	0	1 (5%)	7 (35%)	
	901-1200	0	1 (5%)	8 (40%)	
	1201-1500	0	1 (5%)	5 (25%)	

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2 Rescue	Not Required	0	20 (100%)	20 (100%)	<0.0001
	301-600	8 (40%)	0	0	
	601-900	10 (50%)	0	0	
	901-1200	2 (10%)	0	0	
	1201-1500	0	0	0	

Table 4: Duration of surgery and adverse reactions between groups

		Saline Group	Ropivacaine Group	Ropivacaine + Clonidine Group	P-value
Duration of surgery (minutes)	≤ 90	6 (30%)	3 (15%)	4 (20%)	>0.05
	91-120	7 (35%)	6 (30%)	4 (20%)	
	121-150	5 (25%)	11 (55%)	8 (40%)	
	151-180	2 (10%)	0	4 (20%)	
Adverse reactions	Nil	15 (75%)	19 (95%)	17 (85%)	>0.05
	PONV	5 (25%)	1 (5%)	1 (5%)	
	Hypotension	0	0	0	
	Bradycardia	0	0	1 (5%)	
	Sedation	0	0	1 (5%)	

DISCUSSION

In our study, female predominance was reported in all groups; most patients were 31-50 years old. Most patients in the saline and Ropivacaine group belong to ≤ 150 cm height. All groups found maximum patients in the 51-60 kg weight category. The majority of the saline group 16 (80%), ropivacaine group 13 (65%) and ropivacaine + clonidine group 17 (85%) patients belonged to the MNG diagnosis group. These findings in the present study follow earlier reported studies.[11]

The intervention groups (saline group vs ropivacaine group and saline group vs ropivacaine + clonidine) and postoperative mean Heart rate, SBP, DBP and MAP 0-24 hours postoperatively were statistically significant ($p<0.05$). The intervention groups (ropivacaine group vs ropivacaine + clonidine) and postoperative mean Heart rate SBP, DBP, MAP between 2-24 hours postoperatively was also reported statistically significant ($p<0.05$). Eisenach et al. reported a decrease in MAP and heart rate within 15–30 min after injection of clonidine in the epidural space with insignificant effect.[12] In our study, the MAP and heart rate in the ropivacaine + clonidine group were less compared to plain ropivacaine. However, none of the patients required intervention as the hemodynamic parameters were not below the defined criteria.

The association between the intervention groups and sedation score 0-24 hours postoperatively was statistically insignificant since ($p>0.05$). Lee et al. noted significant sedation when 2 mcg/kg clonidine was added to caudal bupivacaine and concluded that the sedative effects in children reflected the improved quality of analgesia offered by clonidine.[13] Other studies have shown the absence of significant sedation with clonidine at 2 mcg/kg in the caudal space.[14]

In our study, the ropivacaine group had a significantly longer mean analgesia duration than the saline group, with a significant increase of 409.50 minutes (7.20 times or 86%). The ropivacaine + clonidine group also significantly increased, with a 34% increase of 1002 minutes (16.18 times or 34%). The ropivacaine + clonidine group had a 55% increase in analgesia duration, with a significant difference of 592.50 minutes (2.25 times or 55% increase). In the study by Aunac S et al., there is a reduction in analgesic requirements with combined superficial, deep cervical plexus block after general anaesthesia with 0.5% ropivacaine and 0.5% ropivacaine and clonidine. Additional fentanyl boluses were reduced during surgery in groups 2 and 3. Postoperative analgesic requirements were also reduced in groups 2 and 3, correlating with our study's findings.[1]

Susmita Chakraborty et al,[15] studied the effect of clonidine in bupivacaine-induced supra-clavicular block. They concluded that clonidine significantly prolonged the analgesic duration without any important side effects other than sedation. In our study, the addition of clonidine significantly prolonged analgesia duration by 1002 minutes compared to the saline group of 66 minutes. In Herbland et al. study, BSCPB was done by two-point injection with ropivacaine 0.75% without any adjuvants. The postoperative block recedes rapidly even though the analgesia lasts longer than the control group.[16] In our study, since we used clonidine as an adjuvant, the duration of analgesia lasts longer than group B and the control group, even though we used 0.2% ropivacaine.

In our study, the mean VAS score between 0-24 hours was significantly higher in the saline group compared to the ropivacaine group, with a 1.19-point increase. The saline group had a 44% increase, while the ropivacaine group had a 9% increase. Patients in the saline, ropivacaine, and ropivacaine + clonidine groups had mean VAS scores of 5.75, 0.00, and 0.15, respectively. In a study by Andrieu et al., at the time of entry in PACU, the pain scores were 5 for saline, 3 for the ropivacaine group, and 3 for the ropivacaine and clonidine group. Pain scores were reduced in all three groups during the first day after surgery, and our study results are consistent with these results.[17]

In our study, the ropivacaine group had a longer first rescue analgesia time (7.20 times) than the saline group, with a mean difference of 409.50 minutes. The ropivacaine + clonidine group had a longer first

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rescue time of 1002.00 minutes and a 55% increase. There was no need for second rescue analgesia in the ropivacaine and ropivacaine + clonidine groups, and this difference is significant ($p<0.0001$). In Negmi H et al. study, morphine use in PACU is significantly higher in the control group than in the BSCPBs group. Eighteen patients received morphine in the control group compared to 6 in the BSCPBs group, and this is comparable to our study.[18]

In our study, the mean total fentanyl dose was significantly higher in the saline group than in the ropivacaine group and ropivacaine + clonidine group, with a mean difference of 33 mcg (1.33 times or 25% increase), and this difference is significant ($p<0.0001$). In Andrieu et al. study where BSCPBs were performed, the intraoperative total fentanyl dose was reduced in group RC and R compared with group Saline, which is comparable to our study's results.[17] Rita Pal et al,[19] studied the duration of postoperative analgesia in total thyroidectomy patients with BSCPBs with bupivacaine and clonidine. Duration of analgesia is significantly more in the bupivacaine plus clonidine group than in the bupivacaine group. Total fentanyl use in the postoperative period is also significantly less in the bupivacaine plus clonidine group. In our study, the total intraoperative fentanyl consumption is significantly more in the control group than the ropivacaine group and ropivacaine plus clonidine group.

The saline group, ropivacaine group and ropivacaine + clonidine group patients had an incidence of adverse reactions of 25%, 5% and 15%, respectively. By conventional criteria, the association between the intervention groups and adverse reaction status is considered statistically insignificant ($p>0.05$). In the Aunac S et al. study, three patients in the control group and each in the ropivacaine group and ropivacaine plus clonidine group had nausea and vomiting, which is not statistically significant, consistent with our study results.[1]

CONCLUSION

Our study has shown better postoperative analgesia with Bilateral combined superficial and deep cervical plexus block with ropivacaine (0.2%) and clonidine (2 mcg/kg) than in patients with ropivacaine (0.2%) alone in patients undergoing total thyroidectomy. We also found a reduced intraoperative opioid requirement, postoperative rescue analgesia requirement and lower VAS score without any significant increase in adverse effects. So, we conclude that bilateral superficial and deep cervical plexus block with ropivacaine (0.2%) & clonidine is an effective and useful method to manage postoperative pain in total thyroidectomy patients.

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