Comparsion of ropivacaine alone and with dexmedetomidine in bilateral superficial cervical plexus block (BSCPB) for postoperative analgesia in thyroid surgeries: A prospective double blind study

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Abstract

Introduction: Superficial cervical plexus block is a mode of regional anaesthesia that is being used to provide intraoperative and postoperative analgesia for operations involving the neck including thyroid surgery. This study was done to assess the analgesic efficacy of ropivacaine (0.2%) with or without dexmedetomidine (1µg/kg) in bilateral superficial cervical plexus block (BSCPB) after completion of thyroid surgery.

Methods: This prospective study was conducted on 60 patients of ASA I-II, both sex, aged 18 to 60 yrs, who underwent thyroid surgeries under general anaesthesia. After completion of surgery they received BSCPB, by randomly divided into 2 groups (30 patients each): Group R – BSCP using 0.2% ropivacaine (19ml) + 1 ml NS. Group RD – BSCP using 0.2% ropivacaine (19ml) + dexmedetomidine (1µg/kg) +NS to make 20 ml solution, 10 ml were injected on each injection site. Vital Parameters, the cumulative consumption of rescue analgesic and VAS score were recorded on rest (R) at 0, 4, 8, 12, 24 hours postoperatively.

Results: Pain intensity using VAS score was significantly low in Group RD (at 0, 4 and 6 postoperatively) hrs as compared to Group R (P=0.013). The total rescue analgesic consumption was more in Group R (413.33±62.88mg) as compared to Group RD (370.00±53.50mg), (p<0.001). Mean Ramsay Sedation Score was significantly higher in Group RD as compared to Group R (P=0.015).

Conclusion: We conclude that dexmedetomidine in dose of 1 µg/kg may be used as an adjuvant to 0.2% ropivacaine for bilateral superficial cervical plexus block for thyroid surgeries, so as to prolong postoperative analgesia without added problems apart from low grade sedation.

Keywords: thyroid surgery, dexmedetomidine, ropivacaine, bilateral superficial cervical plexus block

1. Introduction

The common complaint of patients undergoing thyroidectomy is pain at the incision site and this pain after thyroid surgery is regarded as being of moderate intensity and of short duration. This postoperative pain is due to extensive tissue dissection and tension during the thyroid surgery. It leads to increased hospital stay and burden on patient as well as hospital care team.[1] Superficial cervical plexus block is a mode of regional anaesthesia that is being used to provide intraoperative and postoperative analgesia for operations involving the neck including thyroidectomy. Thyroidectomy under general anaesthesia and superficial cervical plexus block is becoming more popular as it is effective in reducing the use of supplementary opioids during the intraoperative period. [2] Ropivacaine is a long acting amide local anaesthetic agent pure S-enantiomer, unlike bupivacaine, which is a racemate, developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles.[3] Dexmedetomidine is a new generation highly selective alpha 2-adrenergic receptor agonist shown to have both sedative and analgesic effects. In a study by Nathalie Dieudonne et al used bupivacaine 0.25% with epinephrine 1:200,000 in Bilateral superficial cervical plexus block (BSCP), significantly reduce pain intensity in the postoperative period after thyroid surgery but do not provide optimal pain relief alone[4] Esmaeglu et al[5] and Rancourt et al[6] showed that Dexmedetomidine was safe when used as an adjuvant to local anaesthetic for brachial plexus block and posterior tibial nerve sensory blockade. Therefore the present study was plan to assess the analgesic efficacy of ropivacaine (0.2%) with or without dexmedetomidine (1mcg/kg) in bilateral superficial cervical plexus block (BSCP) after thyroidectomy. AIMS AND OBJECTIVES - To evaluate the effects of dexmedetomidine (1mcg/kg), adding to ropivacaine (0.2%) in bilateral superficial cervical plexus block in thyroid surgeries regarding effect on: Postoperative analgesia. To determine the adverse effects of study drugs and To study rescue analgesic requirement, sedation in patients, hospital stay and patient comfort.

2. Materials and Methods

After institutional ethical committee (IEC) approval, this prospective double blind comparative study was conducted in Department of Anaesthesiology of ENT operation theatre, at M.B. Hospital attached to RNT Medical College, Udaipur (Rajasthan) for a period of one year. Informed written consent was taken from each patient for participation in the
study. The present study was conducted on 60 patients of ASA Grade I & II of either sex, aged 18 to 60 years, having a euthyroid state, who underwent elective thyroid surgeries under general anaesthesia and after completion of surgery received bilateral superficial cervical plexus block. Exclusion criteria: Patient refusal for BSCP, Patient having severe respiratory, cardiac or renal disorders, Infection at the injection site. Allergy to drugs used, Morbid obesity (body mass index>35) and history of coagulation disorders.

2.1 Group allocation
Total 65 cases were assigned for the study, out of which 5 cases did not meet the inclusion criteria and hence they were excluded. This study was conducted on a study population of 60 patients who were randomly divided using opaque sealed envelope technique into 2 groups of 30 patients each.

Group R - BSCP using 0.2% ropivacaine (19ml) + 1 ml normal saline to make 20 ml solution, 10 ml on each injection site.
Group RD - BSCP using 0.2% ropivacaine (19ml) + dexmedetomidine (1mcg/kg) + normal saline to make 20 ml solution, 10 ml on each injection site.

2.2 Basis of Sample size
The sample size is calculated on the basis of previous study of G Andrieu et al[7] to improve postoperative analgesia and sufentanil requirement with ropivacaine plus clonidine group as compared with ropivacaine and normal saline group respectively. We carried out a pilot study in which we used ropivacaine or ropivacaine with dexmedetomidine (1mcg/kg). In this study the mean cumulative dose of rescue analgesia (RA) used in first 24 hrs with 4 mg/kg tramadol intravenous in the Ropivacaine group (Group R); while it was 1 mg/kg tramadol intravenous in the Ropivacaine plus Dexmedetomidine group (Group RD). The Standard Error was 0.75 for the study to have a Power of 80% with a type alfa error of < 0.05, 50 patients were required in two groups. To compensate for drop outs, we decided to include 30 patients in each group. Double Blindness: Two anesthesiologists were involved in the study. Drugs were prepared by one anesthesiologist who was not involved further in the study. Another anesthesiologist conducting the study administered all block and recorded data in all patients who was unaware of group allocation. Patients, nursing staff and surgeon were unaware of group allocation too.

2.3 Pre Anaesthetic Assessment & Anaesthesia
All patients in this study were subjected to detailed pre-anaesthetic evaluation which included: - Present complaints, history, complete general physical examination and routine investigations were done as a protocol of the required procedure. All patients were given oral ranitidine 300 mg, metoclopramide 10 mg, and lorazepam 1 mg at night before surgery. Intravenous cannulation was done and midazolam 2 mg i.v. was given. Patients were operated under general anaesthesia by the use of a standardized procedure. Routine monitoring (ECG, non-invasive blood pressure, pulse rate, oxygen saturation and temperature) was used. Patients were premedicated with glycopyrrolate (0.01mg/kg), tramadol (2mg/kg), ondansetron (0.1mg/kg) intravenously before induction. After induction with intravenous thiopentone 5mg/kg and atracurium 0.5 mg/kg, intubation was done with a cuffed endotracheal tube and anaesthesia was maintained with O2+N2O (50-50 ratio), propofol 100-200mcg/kg/min and atracurium 0.1mg/kg intermittently intravenous. After completion of surgery BSCP was given and anaesthesia was reversed by Inj. Neostigmine 0.5 mg/Kg and Glycopyrrolate 0.01 mg/Kg and extubation was done after full recovery and adequate oro-pharyngeal suctioning.

2.4 Block Procedure
After thyroidectomy and before reversal bilateral superficial cervical plexus block was given with ropivacaine 0.2% or ropivacaine plus dexmedetomidine (1mcg/kg) as per study group. The total volume used was 20ml (10 ml on each side). The block was performed in the following manner:- After cleaning with antiseptic, a line drawn from the tip of the mastoid process to the transverse process (Chassaignac’s tubercle) of the C6 vertebra, along the posterior border of the clavicular head of the sternocleidomastoid muscle. The site of needle insertion was marked at the midpoint of the line

![Fig 1: Point of Infiltration](image)

(Fig. 1). The branches of the superficial cervical plexus emerge behind the posterior border of the sternocleidomastoid muscle. Local anaesthetic was injected along the posterior border of the sternocleidomastoid muscle 2–3 cm below and above the needle insertion site by a “fan” technique with superior- inferior needle redirection, using a 1.5-inch 25-gauge needle. The depth of needle insertion was 1.0–1.5 cm to avoid the risk of deeper block or inadvertent vascular injection. Orientation of patient to time, place and person was assessed. Parameters like pulse rate (PR), mean blood pressure (BP) and oxygen saturation (SPO2) were recorded before blockade, after blockade, before shifting patient to postoperative ward and thereafter at 4, 8, 12 and 24 hrs. The primary outcome was the cumulative consumption of intravenous tramadol (2 mg/kg) over 24 hours in all groups. Pain score was measured using a 10 points (0-10) Visual Analogue Scale (VAS), where: 0 = no pain and 10 = worst pain imaginable. The VAS was recorded on rest (R) at 0, 4, 8, 12, 24 hours postoperatively (0 hours - the time when patient shifted from operation theatre to ward). Time for first rescue analgesic when VAS>3 was also noted. Secondary outcome included complications of procedure of block and drugs used in block like sedation, hypotension, bradycardia, headache, hyperasthesia, urinary retention, pleural puncture,
pneumothorax, haematoma, etc. Injection tramadol (2mg/kg) intravascular was given as a rescue analgesic, when the patient complaint of pain (VAS>3) any time after surgery.

2.5 Ramsay sedation score
As dexmedetomidine is known to have sedative effect, the level of post-operative alertness and sedation was assessed using Ramsay Sedation Score

1. Anxious or restless or both, 2 - Cooperative, orientated and tranquil,
2. Responding to commands, 4 - Brisk response to stimulus,
3. Sluggish response to stimulus, 6 - No response to stimulus.

Consort Flow Chart

2.6 Statistical Analysis: Statistical analysis was performed using Microsoft (MS) Excel Software with SPSS version 21. The continuous data was analyzed by ANOVA test and Chi-Square test for categorical data was used. Pain scores and analgesic consumption were reported as median and range. Differences were considered significant at p<0.05.

3. Results

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group R (n=30)</th>
<th>Group RD (n=30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>41.53 ± 14.17</td>
<td>40.93 ± 13.67</td>
<td>0.93</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>59.47 ± 4.67</td>
<td>55.23 ± 4.07</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>SEX F</td>
<td>28</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>M</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Demographic Characteristics of the Patients

Table 1 shows no statistical significant difference was found in between the groups. Both groups were comparable with respect to age, weight and sex (P >0.05). Pain intensity using VAS score was significantly low in Group RD at 0, 4 and 6 postoperative hours as compared to Group R (P=0.013). VAS Score was low in group RD at 8 post-op hour as compared to Group R but statistically not significant (p=0.62).

<table>
<thead>
<tr>
<th>Time interval (hrs)</th>
<th>Group R (n=30)</th>
<th>Group RD (n=30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.83 ± 0.38</td>
<td>0.10 ± 0.31</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>4</td>
<td>0.97 ± 0.18</td>
<td>0.57 ± 0.50</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>6</td>
<td>2.43 ± 0.50</td>
<td>1.60 ± 0.62</td>
<td>0.0139</td>
</tr>
<tr>
<td>8</td>
<td>0.76±0.44</td>
<td>0.70 ± 0.47</td>
<td>0.62</td>
</tr>
<tr>
<td>12</td>
<td>0.00</td>
<td>0.00</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Comparison of visual analogue score (VAS) on rest and at varied time interval in between the groups

(Test applied: T test) (P<0.05 is significant)
Figure 2 and 3 shows Rescue analgesic was required early in Group R (387.0±24.0 minutes) as compared to Group RD (424.8±35.4 minutes) and the total rescue analgesic consumption was also more in Group R (413.33±62.88mg) as compared to Group RD (370.00±53.50mg) which was statistically significant (p<0.001). In Group RD only 1 patient (3.33%) required higher dose (5 doses) of rescue analgesic while 4 patients (13.33%) in Group R required 5 doses. In Group RD 19 patients (63.33%) required 4 doses of rescue analgesic as compared to Group R in which 22 patients (73.33%) demanded 4 doses of rescue analgesic in 24hrs. Similarly, 10 patients (33.33%) in Group RD and 4 patients (13.33%) in Group R required 3 doses in 24hrs.

Table 3: Number of Rescue Doses in 24 hours

<table>
<thead>
<tr>
<th>No. of Rescue Doses</th>
<th>Group R (n=30)</th>
<th>Group RD (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>13.33%</td>
</tr>
<tr>
<td>4</td>
<td>22</td>
<td>73.33%</td>
</tr>
<tr>
<td>5</td>
<td>4</td>
<td>13.33%</td>
</tr>
</tbody>
</table>

Mean Ramsay Sedation Score was significantly higher in Group RD as compared to Group R (P=0.015).

**Discussion**

In present study we found that both groups were comparable in respect to pulse rate, mean arterial pressure and respiratory rate measured postoperatively at varied time intervals. (P>0.05), Our study was comparable with Santosh BS et al [9] (2018) who observed no significant differences in regard to post-operative hemodynamics at any point of time in between both groups (Ropivacaine v/s Ropivacaine + dexmedetomidine) during bilateral superficial cervical plexus block.

4.1 Visual Analogue Score (VAS)

We found that the mean VAS score in Group RD at 0hr, 4hr and 6hr post-operatively was 0.10±0.31, 0.57±0.50 and 1.60±0.62 respectively which was low as compared to Group R (0.83±0.38, 0.97±0.18 and 2.43±0.50) (P=0.04) which was statistically significant. VAS Score was low in group RD at 8 post-op hour (0.70±0.47) as compared to Group R(0.76±0.44) but statistically not significant (P=0.62). Our study also comparable with observations of Santosh BS et al [9] who found that patients given Ropivacaine 0.5%+ dexmedetomidine (Group D) had significantly lower VAS as compared with patient given Ropivacaine 0.5% +saline (Group C) in bilateral superficial cervical plexus block (BSCB). On admission to PACU, Group D had significantly lower VAS score than control group. VAS scores for pain at 0, 2, 4 and 6 hr were comparable, whereas at 12 hr they were better in Group D, though statistically not significant. At 24 hr, VAS scores were significantly higher in Group C.

4.2 Duration of Analgesia

In our study, mean duration of analgesia was 7.08±0.59 hours in group RD as compared to 6.45±0.40 hours in group R which was statistically significant (P<0.001). This result was comparable with Arun S et al [10] (2016) who also found in their study (using dexmedetomidine as an adjuvant to 0.75% ropivacaine in axillary brachial plexus block) that the duration of analgesia was significantly prolonged in group D (774.67 ± 10.74 (min)) when compared with group R (607.33 ± 13.62min. Our findings were also comparable to the results by Santosh BS [9] et al (2018) who observed that
The duration of analgesia was nearly double when dexmedetomidine 1 µg/kg was added to 0.5% ropivacaine for BSCPB. The duration was 1696.2 min in Group D vs 967.8 min in Group R which was statistically significant (p < 0.001). The present study is conducted with a concentration of 0.2% ropivacaine. Duration of analgesia was more in both the above mentioned studies as compared to the present study since the concentration used were 0.75% and 0.5% respectively.

4.3 Rescue Analgesic
In our study, we found that post-operatively rescue analgesic dose requirement was low in Group RD as compared to Group R. In Group RD only one patient (3.33%) required higher dose (5) of rescue analgesic (inj. Tramadol 2 mg/kg i.v) while 4 patients (13.33%) in Group R needed 5 doses. In Group RD, 19 patients (63.33%) required 4 doses of rescue analgesic as compared to Group R in which 22 patients (73.33%) demanded 4 doses of rescue analgesic in 24 hrs. Similarly, 10 patients (33.33%) needed 3 doses of rescue analgesic in Group RD while 4 patients (13.33%) in Group R needed 3 doses in 24 hrs. Mean total dose of rescue analgesic in Group RD was significantly lower (370.00±53.50 mg) as compared to group R (413.33 mg) (P <0.001). The decreased requirement of rescue analgesic in Group RD indicates that dexmedetomidine has additional analgesic properties. It appears to exert analgesic effects at the spinal cord level and at supra spinal sites. Other mechanisms for analgesic effect are activation of α2a receptors, inhibition of the conduction of nerve signals through C and Aδ fibers, and the local release of encephalin.

4.4 Sedation Score
In our study we found that patient in group RD were more sedated postoperatively at 0 hour (at time of shifting) as compared to group R with mean Ramsay sedation score being 2.90±0.31 and 2.00±0.00 respectively with significant P value <0.001. For subsequent observation at varied time intervals i.e. at 4.6, 8 and 12 hrs postoperatively, the Ramsay Sedation score was found to be higher in Group RD as compared to Group R (P<0.001). The increased Ramsay sedation score in the group RD may be due to the sedative property of α2 receptor agonist i.e. dexmedetomidine. Our result was comparable with study done by Lin Yu-Nan et al[10]. Also comparable with observations of Sharma B et al[11] who found that the difference in the sedation scores in both groups was statistically significant till 4 hr post-operatively, with p = 0.000 at 2 hr and p = 0.005 at 4 hr in dexmedetomidine group.

5. Conclusion
Present study suggested that ropivacaine 0.2% with dexmedetomidine 1 µg/kg produces significantly higher duration of analgesia and post-operative rescue analgesic requirement was less as compared to ropivacaine 0.2% alone when used in bilateral superficial cervical plexus block for thyroid surgeries. Patient in group ropivacaine with dexmedetomidine were also more sedated (Grade 2-3) as compared to ropivacaine alone. Therefore, we conclude that dexmedetomidine in dose of 1 µg/kg may be used as an adjuvant to 0.2% ropivacaine for bilateral superficial cervical plexus block for thyroid surgeries, so as to prolong postoperative analgesia without added problems apart from low grade sedation.

6. Acknowledgment
Nil

7. References