


Original Research Article

A randomized placebo-controlled trial to assess the efficacy and safety of bilateral superficial cervical plexus block in patients undergoing thyroid surgery

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Abstract

Background: Efficient analgesia and achieving hemodynamic stability is vital in patients undergoing thyroid surgery. Bilateral superficial cervical plexus block (BSCP) is one of the commonly performed regional anaesthesia technique, but studies documenting the superiority of various local anaesthetic medication, as compared to placebo are scarce. To compare the efficacy of analgesia, intra and post-operative hemodynamic status between bilateral superficial cervical plexus block with 0.5% bupivacaine and a control group (normal saline) in thyroid surgeries.

Materials and methods: The current study was a randomized double-blinded controlled trial conducted with prior ethical approval. The study population included, people undergoing thyroid surgery under general anaesthesia, randomized to either 0.5% Bupivacaine or normal saline groups. The post-operative pain was assessed by Visual Analogue Scale (VAS). The intra and postoperative hemodynamic parameters were compared. Unpaired t-test, Mann-Whitney U test was used appropriately.

Results: A total of 58 patients included in the final analysis, with 29 subjects in each group. Both the study groups were comparable, with respect to various baseline parameters. The highest difference in the mean visual analogue score was observed in the immediate post-operative period (mean difference 4.03, 95 CI 3.4 to 4.66, p value < 0.001). This difference even though was variable and lower compared to the immediate post-operative value, was sustained throughout the post-operative

period. At 24 hours, post-operative period the mean difference in visual analogue score was 1.55 (95% CI 0.93 to 2.16, p value < 0.001). All these differences in the mean visual analogue scores were statistically significant at p value < 0.05. No major hemodynamic fluctuations were observed in either of the study groups and no statistically significant difference was observed with respect to various hemodynamic parameters.

Conclusions: The data and statistical analysis suggest that Bilateral Superficial Cervical Plexus Block with bupivacaine did not alter the intraoperative hemodynamic parameters and was effective in reducing the pain during the postoperative period. No significant adverse effects were noted both during surgery and postoperative period.

Key words

Placebo, Thyroid surgery, Bilateral superficial cervical plexus block, BSCPb.

Introduction

Thyroid surgery has indeed travelled a long and arduous path through the ages. From an operation which was once considered predestined for failure and even death to the present times when techniques are being tried to make the incision as small as possible [1]. The number of patients undergoing thyroid surgery is increasing for various indications including multinodular goiter, single nodular goiter and adenoma. Thyroid operations can lead to various degrees of incisional pain. The other common adverse effects following thyroid surgery may range from difficulty in swallowing, burning sensation of the throat, post-operative nausea, and vomiting (PONV). Majority of the patients report these complications in the immediate post-operative period [2, 3].

Multiple modalities have been used by anaesthesiologists and treating surgeons to minimize or effectively treat these complications. General anaesthesia is the standard anaesthetic technique followed throughout the world for thyroid surgeries. Opioid analgesics are commonly used for analgesia for the intraoperative and postoperative period. Various locoregional anaesthesia local anaesthetic methods have been evolved as one of the most commonly used methods along with general anaesthesia in this regard. Bilateral superficial cervical plexus block (BSCPb) is one of the commonly performed regional anaesthesia technique among patients undergoing thyroid

surgery. Though Bilateral Superficial Cervical Plexus Block is recognized as a safe procedure without many adverse effects for thyroid surgery, the unwanted effects like hypersensitivity to local anaesthetics, intravascular injection, nerve injury, systemic toxicity of local anaesthetics, rarely neuraxial spread of local anaesthetics, blockade of brachial plexus and phrenic nerve block can occur. Hence present study has been conducted with the purpose of comparing the efficacy and safety of BSCPb using 0.5% Bupivacaine with a control group using normal saline.

Objectives

- To compare the efficacy of analgesia between bilateral superficial cervical plexus block with 0.5% bupivacaine and a control group using normal saline in thyroid surgeries.
- To compare the Intraoperative Hemodynamic status and incidence of adverse effects between the two groups.

Materials and methods

The study was a randomized double-blinded controlled study, conducted in the Department of Anaesthesiology, Government Mohan Kumaramangalam Medical College and Hospital, Salem, Tamil Nadu. Patients undergoing elective Thyroid surgeries are included in the study, after obtaining the ethical committee clearance.

The study included patients aged between 18-60 years of either sex with body weight 40 – 80 kg, belonging to ASA grade I and grade II undergoing elective operative procedures on the Thyroid gland. Patients are allergic to local anaesthetics, Patients with a history of bleeding disorders, patients with substernal Goitre, patients with stridor; patients requiring thyroid malignancy requiring block dissection, patients with respiratory compromise were excluded from the study.

The study subjects were randomly allocated to the intervention group, which included BSCBPB with 10 ml of 0.5% bupivacaine and a control group, where BSCBPB was conducted with normal saline. The randomization was done by a computer-generated random number sequence. The allocation sequence was concealed from the investigator by Serially Numbered Opaque Sealed Envelope (SNOSE) method. Both the investigator and the participant were blinded to the intervention.

A line is drawn from the tip of the mastoid process to transverse process of C6 vertebra along the posterior border of the clavicular head of sternocleidomastoid muscle. Using 23 Gauge 1.5-inch needle, 10 ml of 0.5% bupivacaine is injected 15 min prior to induction in a fan-shaped manner at the midpoint of the above-mentioned line in the subcutaneous plane. In the control group, 10 ml of normal saline was injected instead of 0.5% bupivacaine. In both the groups general anaesthesia was administered as per Institutional standard protocol.

Considering the proportion of subjects who need post-operative rescue analgesia as 55% and 20% in control and intervention group respectively, with 80% power of study and 5% alpha error, the required sample size was 29 subjects in each group. Hence a total of 58 subjects were randomized with 29 patients in each group.

The key outcome parameters assessed were postoperative pain, as assessed by Visual Analogue Scale (VAS), Post-operative adverse

events and intra and postoperative hemodynamic changes. Postoperative analgesia was evaluated using linear Visual Analogue Scale, hourly for first 4 hours then, 4th hourly for 24 hrs following surgery. The hemodynamic parameters are measured using PHILIPS IntelliVue MP 40. To record arterial oxygen saturation, Pulse oximeter is used. ET CO₂, capnography is measured using ET CO₂ monitor. ECG is recorded in the lead II, using the ECG monitor. Temperature is monitored using an oesophageal probe.

Sociodemographic and baseline haemodynamic parameters were compared between the control and study groups. Categorical variables were presented in frequencies and percentages. Quantitative variables were presented as mean and standard deviations. The postoperative mean visual analogue scores at different time periods were compared between the study and control groups. Chi square test and student t-test were used appropriately to test the statistical significance of the parameters. The trend of hemodynamic parameters and postop visual analogue scale in the post-operative period were compared by plotting trend diagrams. IBM SPSS version 21 and Microsoft Excel 2013, were used for statistical analysis.

Results

A total of 58 patients included in the final analysis, with 29 subjects in each group.

The baseline socio-demographic parameters were comparable between the study and control groups, as there was no statistically significant difference between the age and gender composition of the two study groups. The type of goitre and the baseline hemodynamic parameters were also compared between the two study groups (**Table - 1**).

The highest difference in the mean visual analogue score was observed in the immediate post-operative period (mean difference 4.03, 95 CI 3.4 to 4.66, p value < 0.001). This difference even though was variable and lower compared to

the immediate post-operative value, was (95% CI 0.93 to 2.16, p value < 0.001). All these differences in the mean visual analogue scores were statistically significant at p value < 0.05 (Table - 2).

Table - 1: Comparison of socio-demographic variables in study and control groups.

Parameter	Study group (N=29)	Control group (N=29)	P value
Age Groups			
25 and below	4(13.8%)	3(10.3%)	0.715
26 to 35 years	8(27.6%)	11(37.9%)	
36 to 45 years	8(27.6%)	5(17.2%)	
above 45 years	9(31.0%)	10(34.5%)	
Gender			
Male	8(27.6%)	7(24.1%)	1.000
Female	21(72.4%)	22(75.9%)	
Diagnosis			
MNG	25(86.2%)	24(82.8%)	0.717
SNG	4(13.8%)	5(17.2%)	
Weight	60.97 ± 6.55	60.83 ± 6.96	0.938
Baseline Heart Rate	84.38 ± 13.61	81.38 ± 13.61	0.414
Baseline Systolic BP	116.97 ± 16.49	113.28 ± 14.14	0.364
Baseline Diastolic BP	75.79 ± 13.70	70.93 ± 10.15	0.130
Baseline Mean Arterial Pressure	85.97 ± 13.93	81.17 ± 10.07	0.139

Table - 2: Comparison of post-operative visual analogue score in two groups (N=58).

Post-operative pain (VAS)	Study Group (Mean)	Control Group (Mean)	Mean Difference	95% CI		P-Value
				Lower	Upper	
0 hour	2.24	6.27	-4.03	-4.66	-3.40	<0.001
1 hour	2.10	3.03	-0.93	-1.34	-0.52	<0.001
2 hour	2.17	3.10	-0.93	-1.35	-0.52	<0.001
3 hour	2.52	4.14	-1.62	-2.15	-1.09	<0.001
4 hour	2.76	3.59	-0.83	-1.46	-0.19	0.011
8 hour	2.48	3.76	-1.28	-1.96	-0.59	<0.001
12 hour	2.41	3.34	-0.93	-1.47	-0.39	0.001
16 hour	2.48	3.76	-1.28	-1.92	-0.62	<0.001
20 hour	2.17	3.21	-1.03	-1.57	-0.49	<0.001
24 hour	2.28	3.83	-1.55	-2.16	-0.93	<0.001

Though the heart rate was constantly higher in the study group, No statistically significant difference was observed in heart rate between the study and control groups during the intraoperative period, except at 30 and 45 minutes. The mean heart rate was 8.10 and 8.14 beats/minute higher at 30 and 45 minutes respectively with p values ≤ 0.05 (Figure - 1).

Even though the mean arterial pressure (MAP) was slightly higher in the study group in the first 45 minutes of the intraoperative period, it was lower than the control group subsequently. These differences observed between the study and control groups were very minimal, as they were statistically not significant (Figure - 2).

Figure - 1: Trend diagram comparing the mean heart rate in the two study groups, at different time points (N=58).

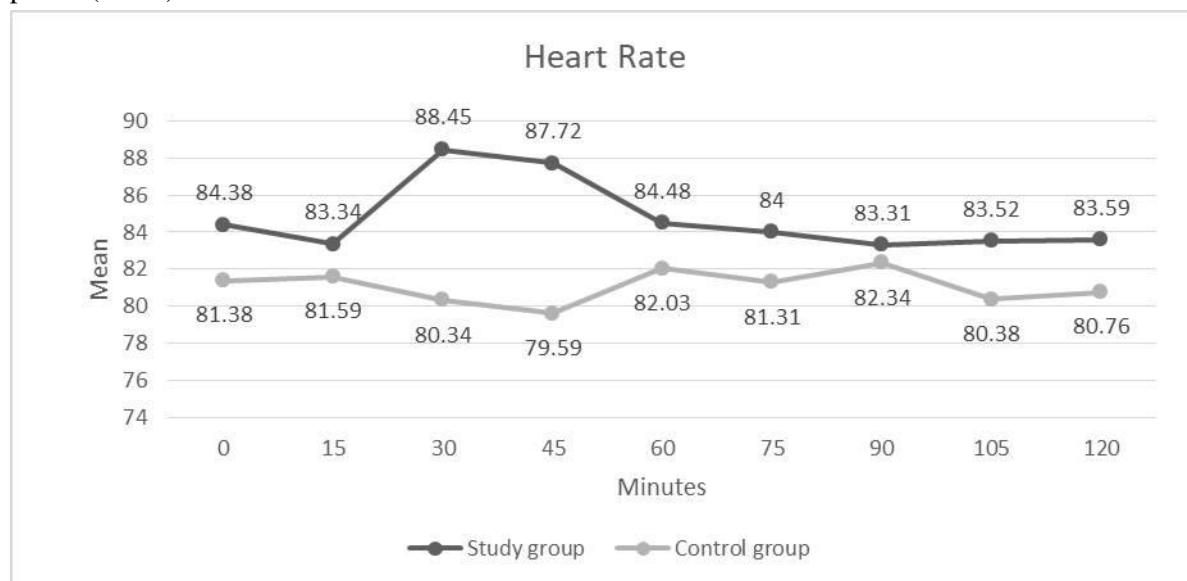
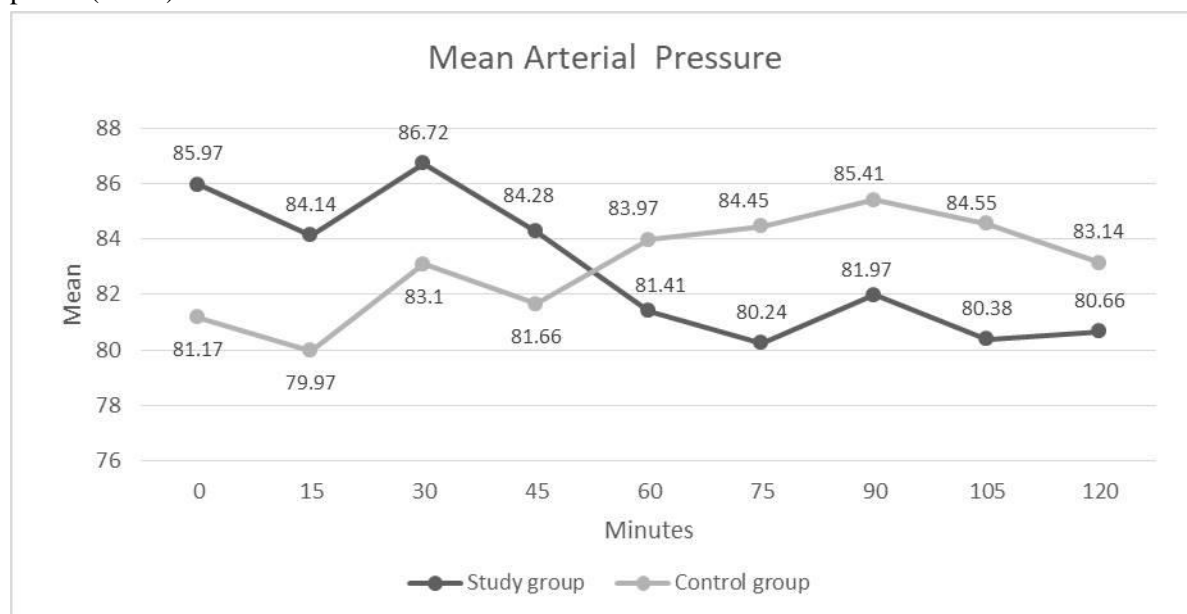


Figure - 2: Trend diagram comparing the mean MAP in study and control groups at different time points (N=58).



Even though the systolic blood pressure was slightly higher in the study group in the first 45 minutes of the intraoperative period, it was lower than the control group subsequently. These differences observed between the study and control groups were very minimal, as they were statistically not significant (**Figure - 3**).

Though the diastolic blood pressure was slightly higher in the study group in the first 45 minutes

of the intraoperative period, it was lower than the control group subsequently. These differences observed between the study and control groups were very minimal, as they were statistically not significant (**Figure - 4**).

Discussion

Post-operative pain in thyroid surgery is traditionally managed with parenteral opioids. Though it produces better analgesia, it has many

undesirable effects like respiratory depression, excessive sedation, paralytic ileus, nausea, vomiting and tolerance. In patients posted for elective thyroid surgery, usually, the thyroid hormone levels are brought to normal, by optimal therapy. In spite of this preoperative medication and optimisation of thyroid hormone levels before surgery, excessive release of thyroid hormones may occur during the surgery. This results in unwanted hemodynamic changes like tachycardia, hypertension, dysrhythmia and

fatal thyroid storm. Adequate depth of general anaesthesia is vital in preventing these adverse consequences. Use of other adjuvant locoregional anaesthetic methods like BSCPB may be highly useful in this regard [4]. When local anaesthetics are used to perform BSCPB, it reduces the general anaesthetic requirements and blunts the adverse effects of excessive stimulation of thyroid gland during thyroid surgery and maintains stable intraoperative hemodynamic parameters.

Figure - 3: Trend diagram comparing the mean systolic blood pressure between two study groups at different time points (N=58).

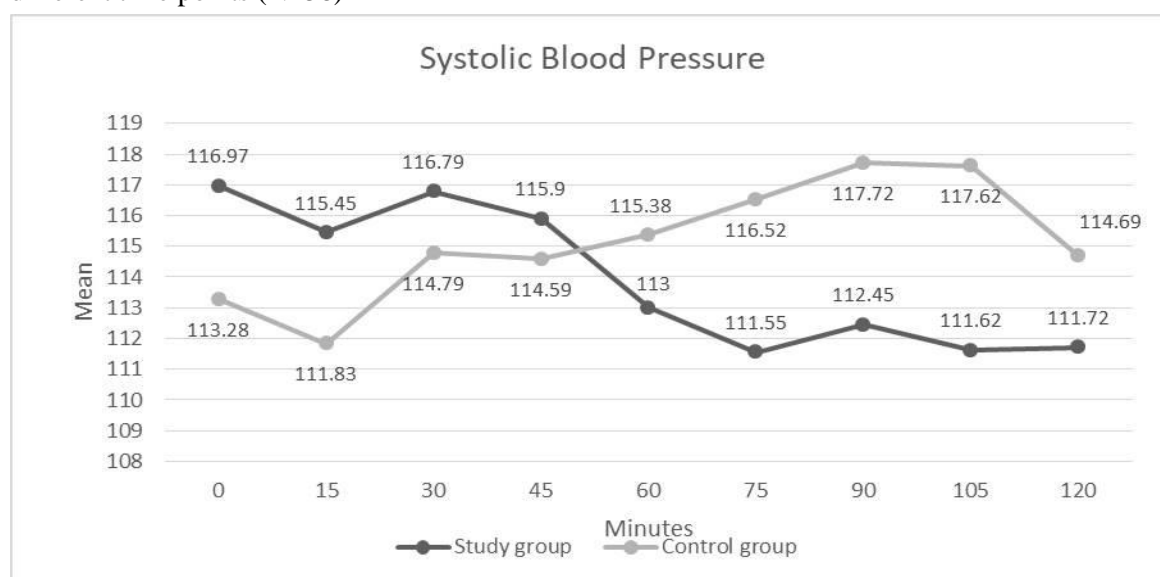
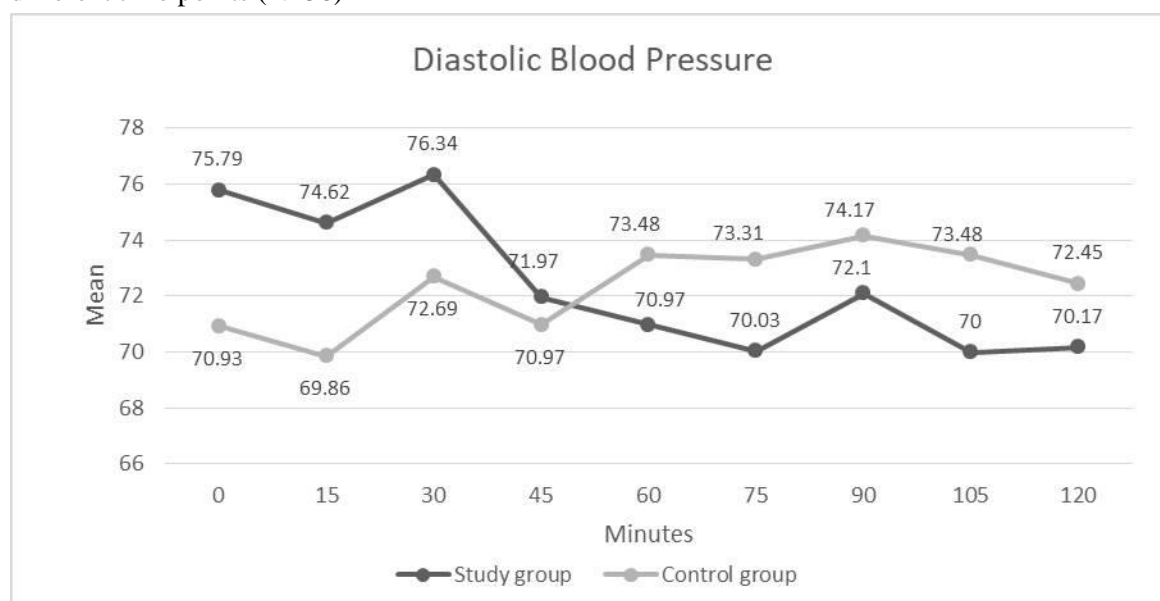


Figure - 4: Trend diagram comparing mean Diastolic blood pressure between two study groups at different time points (N=58).



In the current study, the use of local anaesthetic to perform BSCPb has resulted in superior postoperative analgesia, as compared to placebo as assessed by visual analogue scale. Many studies in the past have demonstrated similar analgesic efficacy with BSCPb using local anaesthetic. Also, the general anaesthetic requirement has been reported to be reduced, when local anaesthetic issued for BSCPb [5]. But there are huge variations in the type and dose of anaesthetic used for the block, the tools used for assessment of analgesia. In study Andrieu, et al. [6], three groups of total thyroidectomy patients were randomized to receive saline or ropivacaine or ropivacaine plus clonidine. The requirement of sufentanil during the intraoperative period and pain score in the postoperative period were significantly reduced. No major complications of BSCPb occurred during the study. Though regional anaesthesia using ropivacaine and clonidine were used, bupivacaine was not compared in this study. BSCPb has also been reported to result in good recovery in postoperative period – better energy levels and early return to work [7].

Wound Infiltration of local anaesthetics [8], bilateral superficial cervical plexus block [9-11], bilateral combined superficial and deep cervical plexus block [12] can reduce the postoperative pain after thyroid surgery. However, in a study by Eti, et al., use of local anaesthetic wound infiltration or use of bilateral superficial cervical plexus block did not decrease the analgesic requirement after thyroid surgery [13]. Also, in another study by Warschkow, et al. [14], the efficacy and safety of BSCPb in adjunct to general anaesthesia was evaluated in thyroid surgery patients. Randomised controlled trials were performed to evaluate the efficacy of BSCPb, in which reduction in pain scores were obtained 6 and 24 hrs after the surgery. However, the pain reduction in post-operative period was too small to be of clinical relevance. The risk of postoperative nausea and vomiting was also seen in patients who received BSCPb.

In the current study, even though there were minor differences in the haemodynamic parameters like heart rate, mean arterial pressure (MAP), systolic and diastolic blood pressure, the differences were very minimal and had shown no statistically significant differences between the two groups. Not many studies in the past have compared the haemodynamic changes of BSCPb with local anaesthetic and placebo groups. Study by Kannan, S., et al. [15] have reported findings, similar to current study, in which they have not observed any significant differences between ropivacaine and normal saline groups, with respect to intra and postoperative hemodynamic parameters.

Hence, the overall direction of the evidence seems to suggest that BSCPb results in better postoperative analgesia, lowers the requirement of general anaesthetic medication, without any major untoward effect on haemodynamic parameters.

Conclusions

The data and statistical analysis suggest that Bilateral Superficial Cervical Plexus Block with bupivacaine did not alter the intraoperative hemodynamic parameters and was effective in reducing the pain during the postoperative period. No significant adverse effects were noted both during surgery and postoperative period.

Limitations

The key limitation of the study is smaller sample size, which has precluded us from evaluating the role of confounding. The generalizability of the study findings is limited.

Recommendations

There is need for further randomized controlled trials, on the subject with similar local anaesthetic medication and dosage, to enhance the cross-study comparison and generalizability of the study findings.

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