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Efficacy and safety of stellate ganglion block with different volumes of ropivacaine to improve sleep quality in patients with insomnia: a comparative study

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Abstract. – OBJECTIVE: The aim of this study was to compare the efficacy and safety of ultrasound-guided stellate ganglion block (SGB) with different volumes of 0.375% ropivacaine on sleep quality in patients with insomnia.

PATIENTS AND METHODS: A total of 80 patients who were selected to undergo SGB for the treatment of insomnia were enrolled. The patients were divided into saline control group, and low-volume (4 mL), medium-volume (6 mL), and high-volume (8 mL) ropivacaine injection groups according to the random table method. The treatment included 7 blocks with once every three days. The left and right stellate ganglions are alternately blocked. The onset and maintenance time of Horner syndrome, the degree of carotid artery dilation and blood flow velocity before and 20 minutes after the first block, the occurrence of complications such as drug crossing of the midline of the artery and hoarse throat were recorded, and the improvement of sleep disorders was evaluated with the Pittsburgh Sleep Quality Index Scale.

RESULTS: Horner syndrome occurred in 100% of all volumes of ropivacaine block. The ipsilateral internal carotid artery was dilated and was accompanied by increased blood flow. The degree of dilation and increase in blood flow were not affected by the volumes of drug injection. There were no serious complications in any group, but the incidences of hoarseness and dysphagia were higher in the medium- and high-volume groups than those in the low-volume group (all $p < 0.05$). Compared with the low- and medium-volume groups, the high-volume group had a faster onset of action, longer maintenance time, and the highest chance of the drug crossing the artery (all $p < 0.05$). Compared to those before the pre-block and in the control groups, insomnia was improved in all volume groups after the block with nonsignificant intergroup differences.

CONCLUSIONS: 4 mL of 0.375% ropivacaine for ultrasound-guided SGB is sufficient to improve the sleep quality of insomnia patients, whose overall risk is lower than block with 6 mL or 8 mL of ropivacaine.

Key Words:
Stellate ganglion block, Ropivacaine, Insomnia, Pittsburgh sleep quality index.

Introduction

In sensory signal transmission, ganglion cells serve as the principal neurons responsible for integrating and conveying information from peripheral sensory receptors to higher-order central nervous systems[1]. Stellate ganglion block (SGB), by injection of local anesthetics to block stellate ganglion nerve transduction, can regulate autonomic nerve function in the area innervated by stellate ganglion, leading to improved cerebral blood perfusion, reduced local reactive oxygen species (ROS), and synchronized melatonin secretion rhythm[2]. Several studies[3-5] have found that stellate ganglion block can improve sleep disorders, including insomnia, but its safety issue limits its wide application in the clinical treatment of sleep disorders.

The traditional hand palpation SGB procedure using surface landmarks typically adopted is the anterior paratracheal approach. The needle advances through the skin and muscles until seated on the Chassaignac tubercle (anterior tubercle of the transverse process of C6), where local anesthetic is injected. To ensure success, more than 10 mL of local anesthetics are usually used[6]. The adjacent structure of the needle advancement path is complex. Internal carotid artery, internal jugular vein, thyroid, vagus nerve, recurrent laryngeal nerve, phrenic nerve, and cervical brachial plexus

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vary among individuals, which leads to the unpredictable result of local anesthetic spread and the occurrence of adverse reactions such as recurrent laryngeal nerve block, brachial plexus block, superficial cervical plexus block and other adverse reactions[6]. Ultrasound-guided SGB can increase the success rate of the block, reduce the volume of local anesthetics injected, decrease the occurrence of complications, and greatly improve safety[2]. However, when performing ultrasound-guided SGB with the aim of treating sleep disorders, the ideal injection volume remains unclear.

As a long-acting amide local anesthetic, ropivacaine hydrochloride is one of the ideal local anesthetics for SGB due to its long duration of action, low central neurotoxicity, and cardiotoxicity[7]. Although some studies[8,9] have explored its appropriate dose in the treatment of other diseases, the optimal injection volume for the treatment of sleep disorders is still inconclusive. In this study, we compared the efficacy and safety of different doses of ropivacaine for ultrasound-guided SGB to improve the sleep quality of insomnia patients.

Patients and Methods

Study Subjects

From September 2021 to June 2022, 80 patients aged 18-65 years, with an ASA grade of I to II, who underwent ultrasound-guided SGB due to insomnia, were selected. Inclusion criteria: (1) Diagnosis of insomnia was in line with the criteria of Advances in treating insomnia[10], and the Pittsburgh Sleep Quality Index (PSQI)[11] score was higher than 12 points. (2) The patients did not receive benzodiazepines, anti-anxiety drugs, Chinese herbal medicine, or other sleep medications before enrollment. Exclusion criteria: (1) Patients with a history of thoracic sympathetic nerve or stellate ganglion neurolysis. (2) Patients with coagulation dysfunction. (3) Patients with injection site or systemic infection. (4) Patients who were allergic to ropivacaine. (5) Patients with pregnancy or lactation. (6) Patients with cognitive dysfunction. This study was approved by the Medical Ethics Committee of the Third People's Hospital of Longgang District, Shenzhen (No. LGKCYLWS2021000034) and informed consent was obtained from every patient.

Grouping and Intervention

This study recruited a total of 80 patients. The patients were equally divided into four groups (20 patients per group) according to a random table method. Patients in the low-volume group received 4 mL of 0.375% ropivacaine injection during ultrasound-guided SGB each time. Patients in the medium-volume and high-volume groups received 6 and 8 mL of ropivacaine injection each time, respectively. Patients in the saline control received 8 mL of saline injection with the same procedures. SGB for treating sleep disorders requires multiple injections[3]. In this study, all patients underwent left SGB for the first time, and the contralateral side was injected with an interval of 3 days. The whole treatment included 7 SGBs with a duration of 18 days. In a blinded fashion, neither the patients nor the statisticians were privy to the treatment allocations; however, the clinicians administering the interventions were cognizant of the group assignments. There was no significant difference in general data among different groups ($p > 0.05$), as shown in Table I.

Ultrasound-Guided SGB

Ultrasound-guided SGB was performed 4 h before the habitual sleep time. Electrocardiogram, non-invasive blood pressure and pulse oxygen saturation were routinely monitored during the procedure. Oxygen was continuously delivered at a rate of 1-2 L/min. A compound solution of sodium chloride was infused peripherally. The patients were placed in a supine position with the neck extended and slightly rotated to the non-injection side. A linear ultrasound operating at a high-frequency range of 4-8 MHz was deployed. Under sterile conditions, according to the steps described in the literature[1], the short-axis plane was taken to slide up and down along the neck to identify C6 and C7 transverses, common carotid artery, internal jugular vein, longus colli muscle, and the vertebral body. The block needle (22G * 50 mm, Pajunk Sonoplex Needle) was inserted in an in-plane approach. After reaching the superficial cervical membrane of the long neck muscle, the specified volume of saline or 0.375% ropivacaine was injected under continuous observation. The injection pressure was kept lower than 20 psi and the maximal injection rate was 4 mL per 10 seconds. After the block, the patients received close monitoring for 30 minutes. The block was performed by the same anesthesiologist, and data were recorded by another anesthesiologist.

Outcome Measures

Sleep quality

The Pittsburgh Sleep Quality Index (PSQI) was used to evaluate changes in sleep quality,

Table I. Patients data.

Characteristic	Group NS (n = 20)	Group L (n = 20)	Group M (n = 20)	Group H (n = 20)	t/χ^2	p
Male/Female (case)	8/12	10/10	8/12	11/9	1.358	0.715
Age (years)	33.5 ± 2.1	34.4 ± 1.9	31.9 ± 2.7	35.6 ± 5.4	2.567	0.069
BMI ($kg \cdot m^{-2}$)	21.97 ± 1.8	23.45 ± 2.1	23.21 ± 1.9	22.19 ± 2.0	1.213	0.331
Education level (case)						
High school and below	7	5	6	4	1.883	0.93
University	12	14	12	14		
Master degree and above	1	1	2	2		
Fixed occupational schedule (presence or absence)	8/12	10/10	13/7	12/8	2.967	0.397
Prior treatment (case)						
None	20	20	20			
Traditional Chinese medicine	0	0	0			
Western medicine	0	0	0			
Smoking (presence or absence)	9/11	9/11	7/13	10/10	0.965	0.810
Drinking (presence or absence)	8/12	9/11	4/16	10/10	4.371	0.224

Patients in the low-volume (Group L), medium-volume (Group M), and high-volume group (Group H) received 4, 6 and 8 mL of 0.375% ropivacaine injection during ultrasound-guided SGB each time. Patients in the saline control (Group NS) received 8 mL of saline injection with the same procedures.

which was the main outcome measure of the current study. Sleep quality was evaluated the morning before and 1 month after the first SGB. The PSQI comprises 24 items measuring seven dimensions from 0 (best) to 3 (worst). Patients taking sleep medications were excluded. Only scores from the other six dimensions (subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, daytime dysfunction) were calculated with a total score range of 0 to 18 points.

First SGB Onset and Maintenance Time

When the symptoms of Horner syndrome, such as ptosis, miosis, increased skin temperature, and stuffy nose, appeared on the blocking side of the patient, the block was deemed successful[4], and the onset time and maintenance time were recorded.

Cumulative Rates of Complications of the Treatment Course

Complications, including local anesthetic poisoning, epidural anesthesia, brachial plexus or cervical plexus block, hematoma, hoarseness, and dysphagia during the whole treatment course were recorded.

Changes in Internal Carotid Artery Diameter and Blood Flow After the First SGB

The middle point of the left sternocleidomastoid muscle was selected, and the high-frequency linear array probe (4.0-8.0 MHz) was used to find the best observation place of the longitudinal and transverse section of the internal carotid artery. The Doppler ultrasound mode was adjusted to the blood flow mode, and the inner diameter and blood flow velocity were measured. During the block, the diffusion of the liquid was observed, and whether the liquid crossed the midline of the internal carotid artery was recorded. 20 minutes after the block, the internal carotid artery diameter and blood flow velocity were measured again.

Sample Size Determination

The main outcome measure of this study was sleeping quality improvement evaluated using the PSQI. We hypothesized that 4 and 8 mL of ropivacaine block resulted in similar efficacy in improving sleep quality. The average PSQI score after treatment was set at 8 points. The combined standard deviation was set as 2.0. The clinical significance of the difference between the two groups was set as 1.80 points. With $\alpha = 0.025$, $\beta = 0.2$, lost to follow-up ratio = 0.05, the sample size of each group was calculated to be 20 people based on a non-inferiority design.

Statistical Analysis

SPSS 23.0 (IBM Corp., Armonk, NY, USA) software was used for analysis. The measurement data were expressed as mean ± standard deviation. For intragroup before-after comparison, a pairwise *t*-test was used. For intergroup comparison, one-way ANOVA combined with post-hoc Bonferroni test was used for

comparison. Count data were compared using the Chi-square test. $p < 0.05$ (two-sided) was considered statistically significant.

Results

General Data

All the patients recruited completed the treatment and the follow-up. Table I shows the baseline data of the four groups. There was no significant difference in age, gender, body mass index (BMI), marital status, ASA Physical Status Classification, smoking, drinking or coffee consumption among groups.

Sleep Quality Measured as PSQI Score

There was no significant difference in each dimension and PSQI total score among the four groups before treatment (all $p > 0.05$). The scores of each dimension and total PSQI score were decreased after treatment except the saline treatment group, compared to those at baseline (all $p < 0.05$). No volume-associated changes in the scores of each dimension and total PSQI score were observed after SGB (all $p > 0.05$ for the pairwise comparison, Table II).

Onset and Maintenance Time of First SGB

No Horner syndrome appeared in patients receiving saline treatment. SGB was successful in all patients receiving ropivacaine injections. The onset time of SGB was decreased, and the maintenance time was prolonged (all $p < 0.01$) when the volumes of ropivacaine injection increased (Table III).

Cumulative Adverse Reactions and Complications

There were no major complications, such as local anesthetic poisoning, high epidural anesthesia, brachial plexus or cervical plexus block, and hematoma in the three groups. Ptosis less than 1/3 is considered mild, 1/3 to 1/2 is mild, and more than 1/2 is severe. The degree of ptosis was similar among the three ropivacaine injection groups ($p = 0.236$). Local anesthetics were more frequently observed across the common carotid artery in the high-volume group (both $p < 0.05$), and the incidence of hoarseness was higher in the high-volume group (both $p < 0.05$) compared to the other two groups (Table IV).

Ultrasound Findings

Before SGB, there was no significant difference in the internal diameter ($p = 0.329$) and blood flow ($p = 349$) of the internal carotid artery in each group. Injection of saline did not influence the internal carotid artery diameter ($p = 0.884$) and blood flow velocity ($p = 0.574$). In the ropivacaine injection groups, the internal carotid artery was dilated, and the flow rate was increased after SGB. There was no significant difference in the

Table II. PSQI scores before and after SGB in four groups (means ± standard deviations, n = 20 per group).

Groups		Daytime Function	Sleep Disorders	Sleep Efficiency	Sleep Time	Time to Fall Sleep	Sleep Quality	Overral Score
Group NS	Before	2.65 ± 0.47	2.75 ± 0.43	2.80 ± 0.40	2.65 ± 0.47	2.65 ± 0.47	2.70 ± 0.46	16.10 ± 1.30
	After	2.70 ± 0.46	2.75 ± 0.43	2.80 ± 0.40	2.65 ± 0.47	2.70 ± 0.46	2.70 ± 0.46	16.20 ± 1.21
Group L	Before	2.70 ± 0.46	2.75 ± 0.43	2.90 ± 0.30	2.65 ± 0.47	2.65 ± 0.47	2.85 ± 0.35	16.35 ± 1.19
	After	1.00 ± 0.45*#	0.90 ± 0.30*#	0.85 ± 0.36*#	0.90 ± 0.30*#	0.85 ± 0.36*#	0.95 ± 0.21*#	5.4 ± 0.74*#
Group M	Before	2.65 ± 0.47	2.70 ± 0.46	2.65 ± 0.47	2.51 ± 0.32	2.65 ± 0.47	2.80 ± 0.40	16.25 ± 1.37
	After	0.95 ± 0.38*#	0.85 ± 0.36*#	0.90 ± 0.30*#	0.85 ± 0.36*#	0.90 ± 0.30*#	1.05 ± 0.38*#	5.7 ± 1.14*#
Group H	Before	2.60 ± 0.49	2.60 ± 0.49	2.80 ± 0.40	2.49 ± 0.36	2.65 ± 0.47	2.80 ± 0.40	16.30 ± 1.27
	After	1.00 ± 0.32*#	0.75 ± 0.43*#	0.85 ± 0.36*#	0.95 ± 0.21*#	0.90 ± 0.30*#	1.05 ± 0.38*#	5.5 ± 0.80*#

Patients in the low-volume (Group L), medium-volume (Group M), and high-volume group (Group H) received 4, 6 and 8 mL of 0.375% ropivacaine injections during ultrasound-guided SGB each time. Patients in the saline control (Group NS) received 8 mL of saline injection with the same procedures. *, compared with the same group before administration, $p < 0.05$; #, compared with the NS group at the same time point, $p < 0.05$.

internal diameter and blood flow velocity of the internal carotid artery among the three-volume groups (all $p > 0.05$, Table V).

Discussion

Four ganglions are located in the cervical spine level and are upper, middle, lower, and cervicothoracic ganglions. In most cases, the lower cervical sympathetic ganglion and the first thoracic sympathetic ganglion fuse into one oval ganglion, usually called 'stellate ganglion', located in the front of the transverse process of the C7 vertebra or the front of the neck of the first rib, and extends to the gap between C7 and T1[12].

Visualization technology improves the success rate of SGB and can reduce complications by decreasing the volume of local anesthetic used[13]. Examining the optimal volume remains a topic of considerable discussion among clinicians[14]. By prevertebral fascia staining at C6, a study[15] found that 2 mL of local anesthetic is sufficient to spread to the C7-T1 level. However,

Table III. Onset time and maintenance time of the three groups (means ± standard deviations, n = 20 per group).

Groups	Onset time (min)	Maintenance time (min)
Group L	2.10 ± 0.84	248.05 ± 14.23
Group M	1.57 ± 0.55**	289.50 ± 11.20***
Group H	1.19 ± 0.38***$^{\#\#\#}$	331.85 ± 13.46***$^{\#\#\#}$
F	24.49	404.40
p	< 0.001	< 0.001

Patients in the low-volume (Group L), medium-volume (Group M), and high-volume group (Group H) received 4, 6 and 8 mL of 0.375% ropivacaine injections during ultrasound-guided SGB each time. Onset time $^{**}p < 0.01$ *vs.* Group L, $^{***}p < 0.001$ *vs.* Group L, $^{\#\#\#}p < 0.001$ *vs.* Group M.

Table IV. Cumulative incidences of adverse reactions among groups (%, n = 20*7).

Groups	Group L	Group M	Group H	χ^2	*p*
Ptosis of the upper eyelids	140 (100%)	140 (100%)	140 (100%)		
None	0 (0.00%)	0 (0.00%)	0 (0.00%)		
Slight	75 (53.57%)	81 (57.86%)	71 (50.71%)	5.540	0.236
Mild	60 (42.86%)	47 (33.57%)	60 (42.86%)		
Severe	5 (3.57%)	12 (8.57%)	9 (6.43%)		
Stuffy nose	140 (100%)	140 (100%)	140 (100%)		
Hoarseness	42 (24.29%)	56 (40.00%)	82 (58.57%)***$^{\#\#\#}$	***=23.160	0.000
				$^{\#\#\#}$=9.659	0.000
Difficulty swallowing	10 (7.14%)	11 (7.86%)	30 (21.43%)***$^{\#\#\#}$	***=11.667	0.001
				$^{\#\#\#}$=10.315	0.001
Crossing the middle artery	11 (7.86%)	43 (30.71%)	80 (57.14%)***$^{\#\#\#}$	***=77.509	0.000
				$^{\#\#\#}$=19.850	0.000

Patients in the low-volume (Group L), medium-volume (Group M), and high-volume group (Group H) received 4, 6 and 8 mL of 0.375% ropivacaine injections during ultrasound-guided SGB each time. $^{***}p < 0.001$ *vs.* Group L, $^{\#\#\#}p < 0.001$ *vs.* Group M.

Table V. Internal carotid artery diameter and blood flow changes before and after SGB in four groups (means ± standard deviations, n = 20 per group).

Groups		D (mm)	FV (mL/min)
Group NS	Before	4.53 ± 0.35	234.38 ± 24.40
	After	4.64 ± 0.30	238.80 ± 16.10
Group L	Before	4.70 ± 0.35	238.54 ± 26.40
	After	5.09 ± 0.42***	269.30 ± 33.73***
Group M	Before	4.69 ± 0.33	236.21 ± 25.70
	After	5.12 ± 0.33***	267.25 ± 33.58***
Group H	Before	4.72 ± 0.41	240.69 ± 28.10
	After	5.11 ± 0.37***	270.41 ± 34.60***

Patients in the low-volume (Group L), medium-volume (Group M), and high-volume group (Group H) received 4, 6 and 8 mL of 0.375% ropivacaine injections during ultrasound-guided SGB each time. ***, compared with the same group before administration, $p < 0.001$. FV: flow velocities.

even with 4 mL of local anesthetics, SGB block failure still occurred. This study investigated the appropriate volume of 0.375% ropivacaine for SGB by observing the block effect and adverse reactions in insomnia patients.

The results showed that Horner syndrome appeared in all patients from three ropivacaine injection groups after SGB and the increased volume of ropivacaine injected was accompanied by a decreased onset time and prolonged maintenance time. The changes in the diameters of the common carotid artery 20 minutes after the block confirmed the effect. There were no serious complications, such as local anesthetic poisoning, which confirmed the effectiveness and safety of all three injection schemes with different volumes of ropivacaine. Continuous ultrasound imaging during SGB showed that the probability of local anesthetics crossing the artery in the high-volume (8 mL) group was significantly higher than in the other two groups, indicating that the probability of unwanted diffusion of 8 mL of local anesthetic injection was greater. The risk of hoarseness and dysphagia was also higher in patients receiving 8 mL of ropivacaine compared to the other two groups. Taken together, the results indicated that SGB using 8 mL of ropivacaine is not a good choice.

The effectiveness of SGB in improving sleep quality has been previously confirmed[14]. This study also found that SGB can improve insomnia from various dimensions, which was consistent with the results of other scholars[16,17]. However, no study has explored the appropriate volume for SGB. The current study found that the improvement of sleep quality by SGB did not increase with the increase of local anesthetic volume. Considering the success rate, sleep improvement effect, and complications of different volumes of 0.375% ropivacaine SGB, we recommend 4 mL of injection volume for SGB, which is consistent with the conclusions of similar studies[8,9].

Limitations

This study has several limitations. The research scheme ignores the potential influence of technical factors such as the anatomical variation of the patients. The neck structure of the patients included in this study did not show great variation under ultrasound, which did not bring greater difficulty to the procedure. When the patient's BMI and other factors affect the operation, in order to ensure the effect, increasing the injection volume seems to be more suitable. However, increasing injection volume may increase the risk of complications. Therefore, clinicians should weigh the pros and cons in clinical practice. In addition, most patients had effective improvement in all dimensions of PSQI one month after SGB, but long-term follow-up was not conducted in this study.

Conclusions

In summary, an ultrasound-guided satellite ganglion block using 4 mL of 0.375% ropivacaine for the treatment of insomnia is sufficient to achieve ideal efficacy with high safety.

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Authors' Contributions

WL and YL designed the experiments. YL and LZ carried out most of the experiments. YS, JZ, and YS analyzed the experimental results. ZLu and HWa wrote the manuscript. WL, YL, LZ, YS, JZ, YS, Hwa, and ZLu participated in the discussion of this project. All authors contributed to the article and approved the submitted version.

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Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Availability of Data and Materials

The data used or analyzed during the current study are available from the corresponding author upon request.

Informed Consent

The patients/participants provided their written informed consent to participate in this study.

Ethics Approval

The study was reviewed and approved by the Medical Ethics Committee of the Third People's Hospital of Longgang District, Shenzhen (No. LGKCYLWS2021000034).

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