의학박사 학위논문

경부신경뿌리병증에 대한 별신경절 차단술에서의 스테로이드의 효과에 대한 연구

The effects of steroids on the stellate ganglion block for treating unilateral cervical radiculopathy

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의학과

주은영

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Korean Abstract

본 무작위 대조 시험은 일측 경부 신경뿌리병증 환자의 통증 관리를 위한 초음파 유도 성상 신경절 차단(SGB)시 스테로이드 유무에 따른 치료 효과 차이를 비교하기 위하여 시행되었다. 시험자는 덱사메타손 (DEXA, 1% 리도카인 5mL 와 덱사메타손 1mL(5mg) 혼합) 그룹과 생리식염수(NS, 1% 리도카인 5mL 와 생리식염수 1mL 혼합) 그룹에 무작위로 배정되었으며, 시술 전 및 시술 후 1 개월, 3 개월, 6 개월에 숫자 평가 척도(NRS), 경부 장애 척도(NDI), 전반적인 만족도(GPES)를 측정하였다. 연구의 1 차 목표는 시술 후 3 개월 시점에서 NRS 에 의해 측정된 통증 정도의 감소로 정하였다. 총 73 명의 환자가 DEXA 군(n = 37)과 NS 군(n = 36)으로 무작위 배정되었으며, 두 군 모두 시술 후 1 개월, 3 개월, 6 개월 시점에서 NRS 와 NDI 가 시술 전 보다 유의하게 감소하였다 (두 군 각각 $P < 0.05$). NRS, NDI 및 GPES 는 모든 시점에서 두 그룹 간 유의한 차이를 보이지 않았다. ($P = 0.210$, 0.180 및 0.751). 결론적으로, 일측 경부 신경 뿌리병증 환자에서 초음파 유도 SGB 에 스테로이드를 사용하는 것은 국소 마취제 단독 사용에 비해 추가적인 이점을 제공하지 않았으며, 국소 마취제 단독 사용만으로도 SGB 는 일측 경부 신경뿌리병증 환자의 통증을 최대 6 개월까지 효과적으로 감소시킬 수 있음을 확인하였다.

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Introduction

Cervical radiculopathy is a common condition characterized by the compression and inflammation of the nerve root in the cervical spine.[1] The process by which compression results in cervical radiculopathy can result in local ischemia affecting efferent conductivity and pain response. Among the various treatment modalities available, cervical epidural steroid injection (C-ESI) has long been widely used to relieve the symptoms of cervical radiculopathy. Stellate ganglion block (SGB) has been performed in patients with many kinds of chronic head, neck and arm pain, also with cervical radiculopathy. [2,3] A recent study suggest that SGB can provide pain relief comparable to C-ESI, with the added advantages of being less invasive and avoiding radiation exposure through the use of ultrasound guidance.[4] However, there is a lack of studies comparing the use of local anesthetics alone to the addition of steroids in SGB, notwithstanding the mounting evidence endorsing the efficacy of local anesthetics in pain interventions, such as epidural blocks.[5]

Consequently, this study aims to address this gap by evaluating whether the addition of steroids to SGB enhances its therapeutic efficacy compared to the use of local anesthetics alone for unilateral cervical radicular pain. The goal is to assess the benefits of using steroids in SGB, to provide a clearer understanding of the mechanisms behind the pain relief provided by SGB for cervical radiculopathy, and furthermore, to clarify the potential benefits of SGB as a safer and simpler alternative treatment for cervical radiculopathy.

Methods

Study Design and Participants

The Participants were enrolled from October 12, 2021, to March 9, 2023. Patients aged 20-70 years experiencing radiating pain in the unilateral upper extremity, with or without neck pain, and demonstrating unresponsiveness to conservative management, including medication and physical therapy, for a minimum duration of one month, were eligible for inclusion.

Among the cohort, patients meeting the criteria of cervical radicular pain stemming from C3 to T1-level pathology as observed on magnetic resonance imaging (MRI) were considered for inclusion. Exclusion criteria encompassed patients with shoulder ailments, neck pain surpassing upper arm pain, non-radicular pain, prior cervical spine surgeries, red flag indicators (such as infection, malignancy, fracture, progressive neurological deficits, and cauda equina syndrome), or yellow flag indications (including inappropriate attitudes or beliefs about pain, maladaptive pain-related behaviors, and emotional disturbances).[6]

Additional exclusion criteria comprised patients presenting with bilateral symptoms or symptoms involving more than three levels, those in whom facet joint syndrome or myofascial pain syndrome could not be definitively ruled out, unavailability of pre-procedural MRI, coagulopathy, pregnancy, breastfeeding, hypersensitivity to steroids, as well as patients unable to articulate pain levels or functional impairments using the numeric rating scale (NRS) and neck disability index (NDI), respectively. Lastly, patients declining participation or failing to furnish written informed consent were also excluded.

The study adhered to the CONSORT guidelines for reporting. Written informed consent was acquired from all participants, and the study was conducted in accordance with the principles outlined in the Declaration of Helsinki.

Randomization and Blinding

Patients were randomized in a 1:1 ratio to the dexamethasone (DEXA) group and the normal saline (NS) group without risk stratification. Block randomization was employed to ensure an equal distribution of patients across each group. Block sizes were randomly permuted to enhance the unpredictability of the allocation process. Randomization was conducted by a researcher not engaged in patient diagnosis, utilizing a web-based program available at http://www.randomizer.org.

Both the operator and the patient were blinded to the procedure. The drug was prepared by researchers who were aware of the group to which the patient was assigned. However, the two operators

performing the procedure were blinded to this information. Additionally, the researchers who prepared the medication did not participate in the procedure or the outcome assessment beyond the preparation of the drugs. The outcome of each patient was assessed by an another blinded researcher at 1, 3, and 6 months after the procedure.

Outcome Assessments

The demographic characteristics and cervical MRI findings of the participants were documented. The primary endpoint of this study was to assess the NRS for pain intensity at the 3 months follow-up post-procedure. The secondary outcomes encompassed the comparative analysis of the NDI and rates of successful responders between the two study groups throughout the study duration. The assessment of outcome variables post-procedure was conducted by a blinded clinical instructor, unaware of participants' group assignments. Evaluations were conducted at 1, 3, and 6 months following the procedure. Pain intensity, functional status, and pre-injection medication were quantified using the NRS, and NDI respectively.[7,8] The NRS with a scale from 0 (no pain) to 10 (extreme pain) was used. Functional assessment was conducted utilizing the Korean adaptation of the NDI.[8] Patient satisfaction and perceived improvement were evaluated using the Global Perceived Effect of Satisfaction (GPES) questionnaire, rated on a 7-point Likert scale.[9] Additionally, multidimensional successful response was determined based on previously established criteria with slight modifications: it was defined as reduction of ≥50% (or ≥4 points) from baseline in NRS for pain intensity, with no increases from baseline in NDI, and a score of ≥4 points on the GPES scale, simultaneously.[7] Lastly, any complications were documented, and adverse events were evaluated during subsequent follow-up visits.

SGB procedures

Ultrasound-guided stellate ganglion block (SGB) was performed using an anterolateral approach with patients positioned supine and the neck slightly extended (Figure 1). The ultrasound transducer was positioned on the ipsilateral ventrolateral neck in a transverse orientation, approximately 1cm inferior to the cricoid cartilage on the side to be blocked. Utilizing ultrasonography, the C6 root was initially identified by scanning the lower transverse processes and the brachial plexus in the interscalene region. The transverse process of C6, characterized by its anterior tubercle, was readily discernible on ultrasound imaging and typically displayed a distinctive shape. The needle's target point was not the bone itself, but the plane between the lateral aspect of the longus colli muscle posteriorly and the prevertebral fascia covering the posterior aspect of the carotid sheath anteriorly.[10] Injection was then performed medial to this tubercle.[11] Patients in the DEXA group received an injection of 5 ml of 1% lidocaine combined with 5 mg (1 ml) of dexamethasone, while those in the NS group were administered a mixture of 5 ml of 1% lidocaine with 1 ml of normal saline.[10]

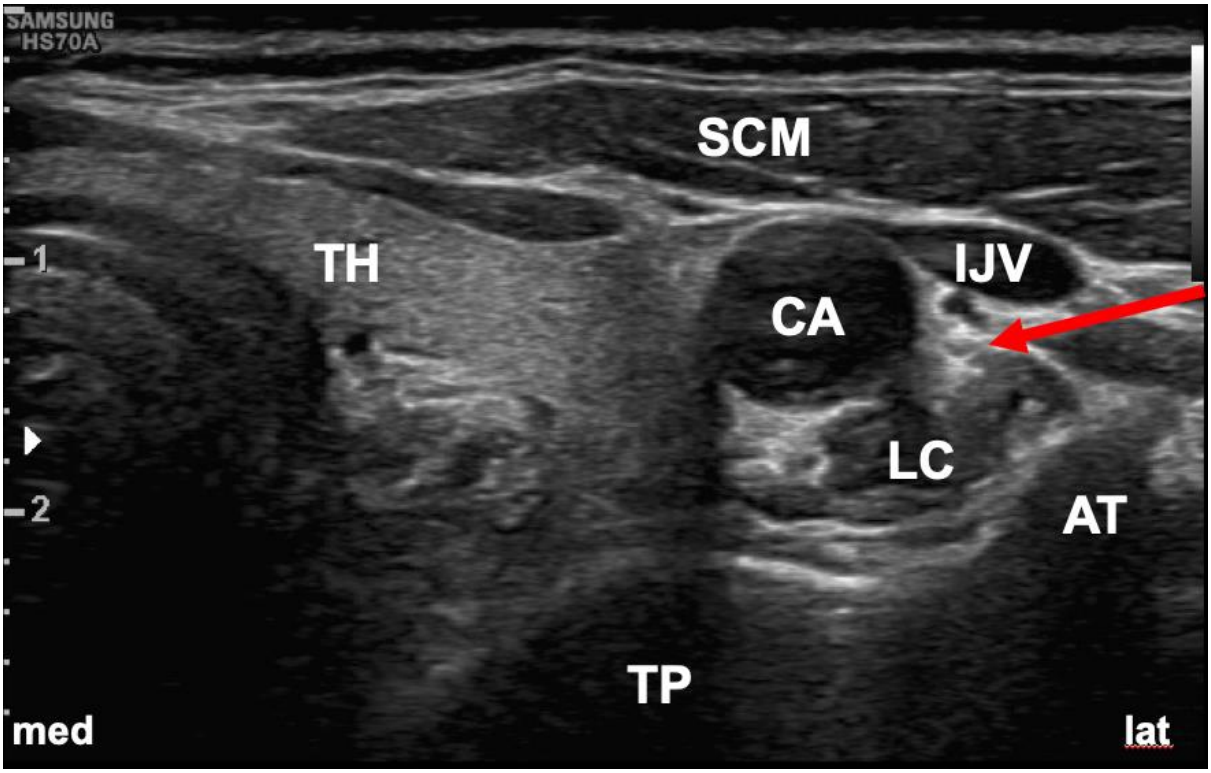

Figure 1. Ultrasonography imaging of Stellate ganglion block at C6 level.

Arrow indicates the direction of the needle's advancement and the spread of local anesthetics above the longus colli muscle. CA, carotid artery; LC, longus colli muscle; SCM, sternocleidomastoid muscle; TH, thyroid gland; TP, Transvers process; AT, Chassaignac's tubercle; med, medial; lat, lateral.

Statistical Analysis

The effect size was estimated as 0.3 based on previous studies that evaluated clinical effectiveness 1, 3, and 6 months after SGB.[7,12] The sample size was calculated to achieve the assumption of a type 1 error of 0.05 and a desired power of 80%. Anticipating a dropout rate of 30%, we aimed to recruit 36 participants per group to ensure that at least 31 participants would be available for analysis.

Categorical variables are presented as absolute numbers and percentages, while continuous variables are presented as means with standard deviations, 95% confidence intervals, or medians along with interquartile ranges. To compare data between groups, categorical variables were assessed using the $\chi 2$ test or Fisher's exact test, while continuous variables were analyzed using Student's t-test or Mann-Whitney U-test as deemed appropriate. All collected data were analyzed based on the intent-to-treat principle, irrespective of any loss to follow-up or dropout occurrences during the study period. Considering the anticipated loss of data during follow-up assessments, a linear mixed-effects model was employed to analyze and compare alterations in continuous variables (such as NRS, NDI, and GPES) and a generalized estimating equations was employed in categorical variables (such as responder analysis) from baseline to 1, 3, and 6 months post-procedure, both within and between the groups. Data were analyzed using IBM SPSS ver. 22 (IBM Corp., Armonk, NY), and $P < 0.05$ was considered statistically significant.

Results

In accordance with the CONSORT guidelines, 37 patients in the DEXA group and 36 patients in NS group were subjected to analysis (Figure 1). In the comparison of baseline characteristics between the two groups, no statistically significant differences were noted except for variations in gender distribution and duration of pain. (Table 1). DEXA group included a higher proportion of male patients and patients in DEXA group also exhibited a longer duration of pain. The pain intensity (measured by the NRS) significantly decreased from baseline in both the DEXA and NS groups up to 6months post-procedure (Table 2). There were no significant differences in NRS scores between the groups at 1, 3, and 6 months, while the NS group showed lower NRS scores without statistical significance (Figure 2). Changes in the NDI significantly decreased compared with baseline up to 6 months post-procedure in both groups, without any group differences. GPES scale was not significantly different between the two groups. The rate of successful responders, as determined by responder analysis, was similar in both the DEXA and NS groups at 1 and 3 months post-procedure, but the proportion of successful responders was higher in the NS group at 6 months (P=0.025).

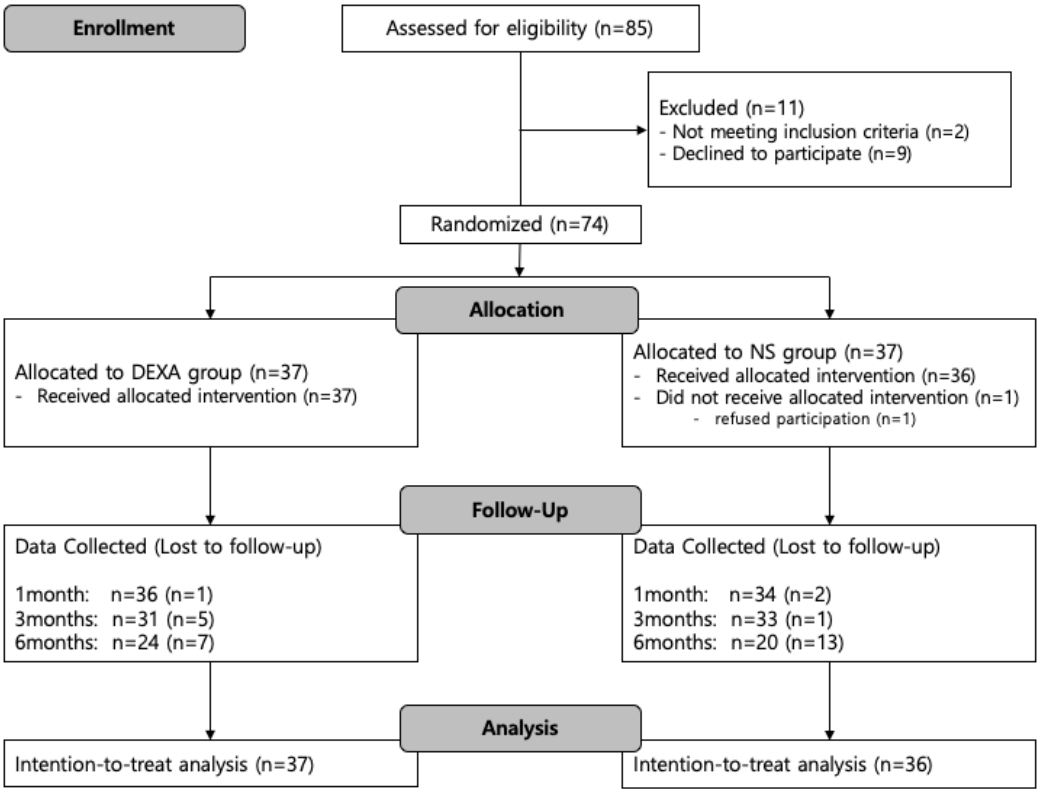

Figure 2. CONSORT flow diagram

Table 1. Baseline and interventional characteristics of the study subjects

Variables	DEXA (n=37)	NS (n=36)	P value
Age (years)	56.4 ± 11.4	55.5 ± 9.8	0.710
Sex			
Male/Female	26 (70.3)/11 (29.7)	14 (38.9)/22 (61.1)	0.014
Body mass index (kg/m^2)	24.1 (22.2, 27.1)	23.3 (22.4, 25.5)	0.588
Duration of pain (months)	5.0 (1.5, 12.0)	2.0 (1.5, 3.5)	0.020
Baseline pain intensity (NRS)	5.0 (4.0, 6.0)	5.0 (4.0, 6.0)	0.795
NDI (0-50)	13.7 ± 5.8	14.2 ± 4.7	0.705

Data are expressed as mean ± SD, median (Q1, Q3), or numbers (%). Baseline pain intensity refers to the worst unilateral radiating arm and/or neck pain. DEXA, dexamethasone; NDI, neck disability index; NRS, numeric rating scale; NS, normal saline.

Table 2. Changes in the adjusted predictions of pain intensity, physical function, and GPES after dexamethasone or normal saline injection while stellate ganglion block in patients with cervical radicular pain

Variables	Time	Estimated mean (95% CI)		Estimated Difference (95% CI)	P-value
		DEXA (n=37)	NS (n=36)		
Pain (NRS)	Baseline	4.9 (4.4 to 5.5)	5.0 (4.4 to 5.6)	0.0 (-0.8 to 0.8)	0.950
	1 month	3.0 (2.4 to 3.6) *	3.1 (2.5 to 3.8) *	0.1 (-0.7 to 1.0)	0.668
	3 months	2.5 (1.9 to 3.2) *	2.5 (1.9 to 3.1) *	0.0 (-0.9 to 0.8)	0.938
	6 months	2.9 (2.2 to 3.6) *	2.0 (1.2 to 2.7) *	-0.9 (-2.0 to 0.1)	0.070
NDI (0-50)	Baseline	13.8 (12.0 to 15.6)	14.2 (12.4 to 16.0)	0.4 (-2.2 to 3.0)	0.766
	1 month	8.8 (7.0 to 10.7) *	9.7 (7.8 to 11.6) *	1.0 (-1.6 to 3.6)	0.450
	3 months	7.1 (5.1 to 9.1) *	7.7 (5.7 to 9.6) *	0.5 (-2.2 to 3.3)	0.708
	6 months	8.9 (6.7 to 11.1) *	6.3 (4.0 to 8.6) *	-2.6 (-5.8 to 0.6)	0.112
GPES	1 month	5.1 (4.7 to 5.6)	5.1 (4.7 to 5.6)	-0.1 (-0.7 to 0.6)	0.876
	3 months	5.5 (5.0 to 6.0)	5.6 (5.2 to 6.1)	0.1 (-0.6 to 0.8)	0.800
	6 months	5.4 (4.9 to 6.0)	5.7 (5.1 to 6.3)	0.3 (-0.5 to 1.1)	0.486

NRS was used to assess the intensity of cervical radicular pain. NDI was used to assess physical function. A linear mixed-effect model was used for the statistical analysis. *P < 0.05 *vs.* baseline in each group. P values for interactions between group and time for NRS, NDI, and GPES = 0.210, 0.180, and 0.751, respectively.

CI, confidence interval; DEXA, dexamethasone; NS, normal saline; NRS, numeric rating scale; NDI, neck disability index; GPES, global perceived effect of satisfaction

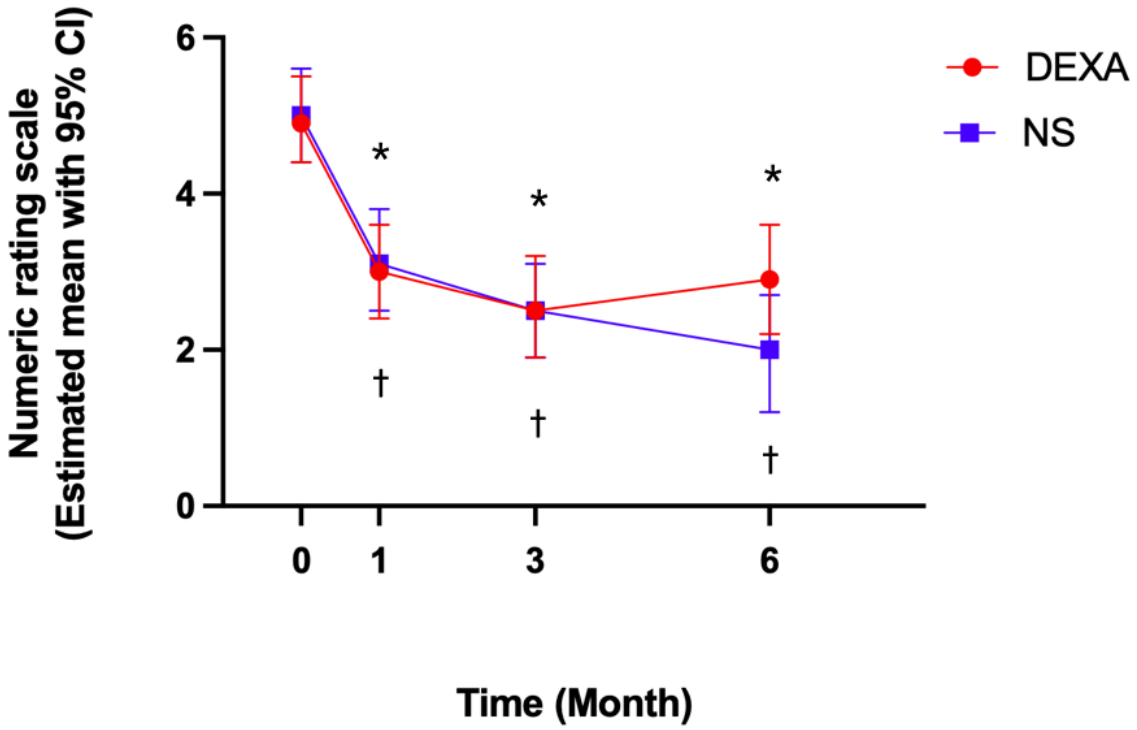

Figure 3. Changes in pain intensity over 6 months after stellate ganglion block.

The numeric rating scale significantly decreased from baseline to 6 months in each group (*P <0.05 vs. baseline at 1, 3, and 6 months in DEXA group; †P <0.05 vs. baseline at 1,3, and 6 months in NS group), with no differences between the groups (P=0.668, 0.938 and 0.070, respectively).

Discussion

This study demonstrates that the efficacy of ultrasound-guided SGB with dexamethasone combined with the local anesthetic did not significantly differ from that of using the local anesthetic alone in patients with unilateral cervical radicular pain during the 6 months' follow-up.

Cervical radiculopathy is a relatively common neurological disorder resulting from nerve root dysfunction, commonly attributed to chemical irritation or compression within the neural foramen. The leading causes of include cervical disc herniation and cervical spondylosis.[13] The exact process by which compression or neuropraxia leads to cervical radiculopathy is not fully understood; however, both mechanisms can induce local ischemia, affecting efferent conductivity and pain response.[1] Shigeru et al. reported venous congestion, vascular insufficiency, and inflammation as important factors contributing to the manifestation of radiculopathy.[14] SGB has been extensively investigated for its efficacy in treating various pain conditions. It is known to be effective for chronic pain in the head, face, neck, upper limbs or upper chest.[15] The mechanism through which SGB induces analgesia is multifactorial, likely involving both peripheral and central mechanisms. Sympathetically mediated pain can be alleviated after SGB by inhibiting sprouting and new nerve growth through sympathetic modulation.[15] SGB also exhibits the ability to hinder the reflex pathway in the spinal cord, diminish the excitability and sensitivity of sympathetic nerves, promote the resolution of local vasoconstriction, enhance regional blood flow, alleviate ischemia and hypoxia, inhibit neurotransmitters like norepinephrine and substance P, modulate initial inflammatory reactions, suppress proinflammatory cytokines such as interleukin 1β (IL-1β), tumor necrosis factor-alpha, and IL-6, and support the process of nerve regeneration.[16-18] Previous study has reported a significant reduction in pain index (visual analog scale, VAS) 15 days after performing SGB in patients with cervical radiculopathy.[19] Another study comparing the effects of SGB with C-ESI has shown that SGB has comparable treatment effects in patients with cervical radiculopathy.[12] In this study, SGB also demonstrated pain reduction and functional improvement up to 6 months in patients with cervical radiculopathy. It appears likely that the sympathetic nerve blockade induced by SGB appears to enhances blood flow to the nerve roots implicated in cervical radiculopathy and also helps reduce inflammation.[19]

Corticosteroids have been used as adjuncts in peripheral nerve and epidural blocks with the aim of enhancing to the analgesic effects of local anesthetics and prolonging their efficacy through mechanisms such as direct reduction of pain transmission and anti-inflammatory action. However, the analgesic effect of corticosteroids in peripheral nerve blocks remains controversial.[20-23] Currently, there is increasing evidence suggesting that local anesthetics alone may be as efficacious as steroids in managing chronic neck pain, whether associated with disc herniation or pain originating from facet joint

pathology.[24,25] Furthermore, recent systematic review and meta-analysis, including high-quality and homogeneous randomized controlled trials, have indicated that the additional use of steroids in performing C-ESI for chronic neck pain management does not yield significant additional benefits.[5] Corticosteroids are recognized for their anti-inflammatory properties, which are attributed to the inhibition of prostaglandin synthesis and the reduction of inflammatory mediators such as IL-1, tumor necrosis factor-alpha, and phospholipase A2.[26,27] Corticosteroids, on the other hand, have been reported to exert direct neurotoxic effects on peripheral nerve tissues, and prolonged use may impact the immune status of patients, potentially increasing the risk of postoperative infection in patients undergoing surgical treatment.[28-30] Additionally, studies have reported that dexamethasone reduces blood flow to the normal nerve and dorsal root ganglia.[31] In this study, application of SGB for treating cervical radiculopathy yielded comparable outcomes regardless of the addition of steroids to local anesthetics. These findings suggest that the mechanism by which SGB alleviates pain in cervical radiculopathy patients primarily arises from increased blood flow to the nerve root. While local anesthetics also have anti-inflammatory properties, the additional anti-inflammatory effects from the use of steroids may be minimal.[32] Previous study has reported that the reduction in blood flow in the dorsal root ganglion and hindpaw caused by the application of nucleus pulposus to the nerve root is an important pathologic mechanism in the development of radicular pain associated with herniated disc.[33] Additionally, animal studies have reported that one of the therapeutic mechanisms of nerve root infiltration is related to increased nerve root blood flow, and that sympathetic ganglion block is associated with increased intraradicular blood flow.[34]

This study includes some limitations. First, this study included patients with cervical radiculopathy due to different pathogenesis such as herniated intervertebral disc, disc degeneration, and cervical spondylosis. The variance in pathophysiology such as inflammation due to differences in etiology may have implications on the differential efficacy of treatment modalities. Further research is warranted to explore the pathophysiology underlying cervical radiculopathy affected by the SGB and adjunct steroid therapy. Second, control over the medications taken by patients and the data collection process were not achieved. The baseline NRS of the patients participating in the study was around 5, and similar types of pro re nata (PRN) medications were prescribed by the same practitioner. Therefore, the impact may not be significant, but it cannot be completely ruled out that these patients might have received other medications or procedures from another physician. Future studies controlling for these factors are needed if possible. There is also a limitation of the impact of patients lost to follow-up. In the NS group, the number of patients lost to follow-up at 6months was higher than in the DEXA group. Although statistical methods were used to adjust for this, it may have resulted in a lower NRS in the NS group, albeit not statistically significant. The final limitation is the difference in gender ratio between the two

groups. Despite employing block randomization, the proportion of women was higher in the NS group. Previous studies have indicated that women exhibit higher prevalence of pain and greater pain after invasive procedures. Additionally, women demonstrate enhanced sensitivity to experimentally induced pain, although the differences in response to analgesic medications between genders are inconsistent, making it difficult to draw general conclusions.[35] In this study, we were unable to analyze treatment effects separately for each gender due to an insufficient sample size for dividing the groups accordingly. Therefore, the potential influence of gender differences on treatment effects cannot be entirely excluded and the extent of such influence remains unclear. Further research focusing on qualitative variables affecting sex differences in pain treatment response is needed.

In conclusion, the addition of steroids does not clearly demonstrate an additional therapeutic effect in SGB treatments for patients with unilateral cervical radiculopathy. Using only local anesthetics, SGB can serve as an alternative treatment, demonstrating pain reduction in patients with unilateral cervical radiculopathy for up to 6months. Therefore, it may be considered as one of the treatment options that can be easily performed without the risk of serious complications or the use of steroids in patients with cervical radiculopathy.

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English abstract

Objective: This randomized controlled trial investigates the effectiveness of ultrasound-guided stellate ganglion blocks (SGB) using local anesthetics with and without steroids for managing unilateral cervical radicular pain.

Methods: Participants were randomly allocated to the Dexamethasone (DEXA, 5mL of 1% lidocaine mixed with 1ml (5mg) of dexamethasone) group and Normal saline (NS, 5mL of 1% lidocaine mixed with 1ml of normal saline) group. The numeric Rating Scale (NRS), neck Disability Index (NDI), Global Perceived Effect of Satisfaction (GPES) were documented at 1, 3, and 6 months following the procedure. The primary endpoint of the study was defined as the reduction in pain intensity measured by NRS at 3 months post-procedure.

Results: A total of 73 patients were randomly allocated to the DEXA group (n = 37) and the NS group (n = 36). In both groups, there was a significant reduction in NRS and NDI from baseline at 1, 3 and 6 months post-procedure ($P < 0.05$, respectively). NRS, NDI, and GPES were not significantly different between the groups at all time points ($P = 0.210$, 0.180 and 0.751, respectively).

Conclusion: For treating unilateral cervical radicular pain, the use of steroids in Ultrasound-guided SGB did not provide additional benefits over local anesthetics alone. Using only local anesthetics, SGB can effectively reduce pain in patients with unilateral cervical radiculopathy for up to 6 months.

Keywords: Cervical radiculopathy, Stellate Ganglion Block, Corticosteroids