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Original Article

The effect of cervical parameters on interlaminar epidural steroid injection treatment outcomes in patients with cervical disc herniation

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ABSTRACT

Objectives: The aim of this study was to investigate the effect of cervical alignment parameters on outcomes of fluoroscopy-guided cervical interlaminar epidural steroid injection.

Patients and methods: This prospective observational clinical study included 63 patients (40 females, 23 males; mean age: 45.3±9.4 years; range, 24 to 69) with radicular pain due to central/paracentral cervical disc herniation between June 2022 and April 2023. Cervical anteroposterior, lateral, and oblique radiographs were taken before the procedure. The C7 slope, spinocranial angle (SCA), and cervical sagittal vertical axis (cSVA) were measured. Pain intensity was assessed using the Numerical Rating Scale (NRS) before and at three weeks and three months after the procedure. The disability and quality of life were evaluated with the Neck Disability Index (NDI) and the 12-item Short-Form Heath Survey (SF-12).

Results: Considering the outcomes at the three-month follow-up, there were moderate positive correlations between SCA and the improved NRS and NDI scores. Moderate negative correlations were determined between C7 slope and the improved NRS and NDI scores. There were also moderate negative correlations between cSVA and the improved NRS and NDI scores. Regarding the improvement in the physical component summary of SF-12, there was a moderate negative correlation with the C7 slope, a weak negative correlation with the cSVA, and a weak positive correlation with the SCA. The improved mental component summary of SF-12 was weakly positively correlated with SCA and weakly negatively correlated with C7 slope and cSVA.

Conclusion: The C7 slope, cSVA, and SCA are cervical alignment parameters affecting the success of cervical interlaminar epidural steroid injection treatment.

Keywords: Cervical radicular pain, cervical spine alignment, epidural injection, fluoroscopy, herniated disc.

Neck pain is a musculoskeletal complaint which concerns a significant part of the population and causes disability. Cervical radicular pain, which is one of the leading causes of neck pain, refers to pain involving the upper extremity due to damage or irritation of the cervical spinal nerve root.[1] The main causes of cervical radicular pain are disc herniation, cervical spondylosis, and spinal stenosis. Cervical interlaminar epidural steroid injection (ILESI) is an interventional pain management procedure specifically applied for radicular pain due to cervical disc herniation.[2,3] Although the exact mechanism of action of epidural steroids remains unclear, there are some prominent opinions on this subject. To illustrate, steroids can inhibit the synthesis and release of inflammatory mediators and also block nociceptive input and suppress neuronal activity when co-administered with local anesthetics.[2]

Atypical cervical alignment may be the underlying cause of many cervical disorders.[4] With increasing age, malalignment becomes more common, leading to pain and disability.[5] The main parameters involved in cervical alignment and balance are C7 and T1 slopes, spinocranial angle (SCA), and cervical sagittal vertical axis (cSVA).[4] With the change of

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cervical parameters, cervical discs are exposed to head weight at varying rates, resulting in thickening of the ligamentum flavum, disc degeneration, and increased intramedullary pressure.[5] Therefore, it may cause cervical disc herniation and radicular pain in the long term. Taken together, these parameters are associated with neck pain, impaired quality of life, and surgical outcomes and are considered as valuable assessment tools in cervical diseases and spinal surgeries.[6-9] From this point of view, it can be speculated that alignment parameters have the potential to affect interventional pain procedures.

Although several factors that may affect the success of treatment have been investigated so far, to the best of our knowledge, there is no study in the literature examining the effect of cervical alignment on the success of epidural steroid injection treatment. Therefore, this study aimed to investigate the effect of cervical alignment parameters on the outcomes of ILESI treatment for radicular pain due to cervical disc herniation.

PATIENTS AND METHODS

This prospective, observational clinical study was carried out in the outpatient clinics of the Pain Management Department of the Marmara University Training and Research Hospital between June 2022 and April 2023. Patients aged between 18 and 65 years with radicular pain due to central/paracentral cervical disc herniation and who did not respond to conservative treatments adequately were included in the study. Patients with previous cervical spinal surgery, foraminal herniation, cervical spinal stenosis, cervical fracture, torticollis or scoliosis, bleeding diathesis, systemic or local infection, and pregnant women were excluded from the study (Figure 1). Initially, 67 patients were included in the current study. Four patients were lost to follow-up, and the study was completed with 63 patients (40 females, 23 males; mean age: 45.3±9.4 years; range, 24 to 69) years. Written informed consent was obtained from each patient. The study was approved by the Marmara University Faculty of Medicine Ethics Committee (Date: 07.01.2022, No: 82) and was conducted in accordance with the principles of the Declaration of Helsinki.

Injection technique

The patient was informed about the injection method before the intervention. The procedure was performed in the operating room. Standard monitoring, including electrocardiography, noninvasive blood pressure, and peripheral oxygen saturation, was employed, and an intravenous catheter was inserted.

The patients were required to lie down in a prone position with a pillow placed under the chest to elevate the shoulders and flex the spine. Following aseptic cleaning and dressing, local anesthesia was administered using 3 mL of 2% prilocaine subcutaneously. Following the use of C-arm fluoroscopy to visualize the C7-T1 space, the needle was advanced into the epidural space using an 18-gauge Tuohy needle (Egemen International®, İzmir, Türkiye) with a paramedian approach. Once the needle was placed immediately posterior to the ventrolaminar line in the contralateral oblique position, it was cautiously advanced, and access to the epidural space was confirmed using intermittent fluoroscopic imaging and the loss of resistance technique.[10]

The accuracy of needle tip positioning in the epidural area was verified by examining anteroposterior and contralateral oblique views, which showed the flow of contrast media across the epidural space. Afterward, a 5-mL medication was administered via injection into the epidural space (Figures 2a, b), consisting of 3 mL of dexamethasone (12 mg), 1 mL of 2% hydrochloride, and 1 mL of 0.9% saline. After a 3-h period of observation following the procedure, the patient was discharged with suggestions. The administration of all injections was carried out by an experienced pain medicine specialist.

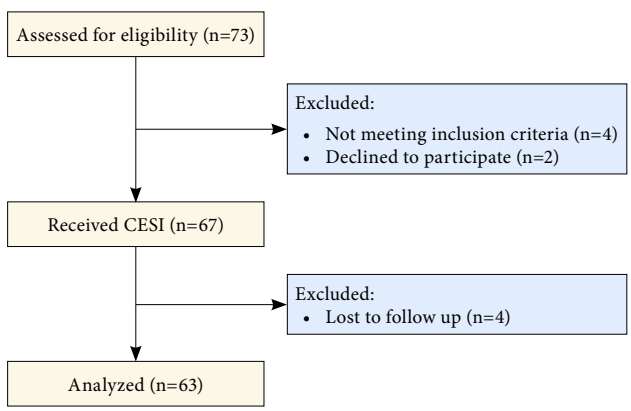

Figure 1. Flowchart for establishing the research population.
CESI: Cervical epidural steroid injection.

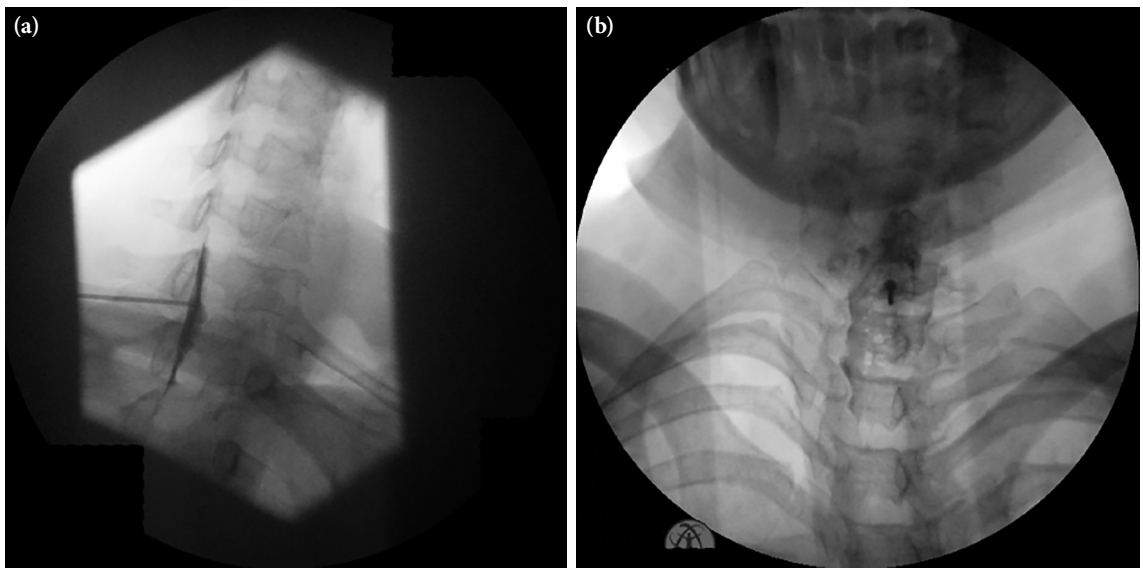

Figure 2. **(a)** Contrast spread on lateral imaging after cervical epidural injection. **(b)** Contrast spread on anteroposterior imaging after C7-T1 interlaminar epidural injection.

Data collection

Data including demographic and clinical characteristics of the patients were recorded. Cervical anteroposterior, lateral, and oblique radiographs were taken from all patients before the procedure. Radiographic images were obtained via a standard cervical X-ray series protocol and uploaded to the PACS (Picture Archiving and Communication System) at our institution. The cSVA and SCA were measured using a lateral radiograph, while the C7 slope was measured using an oblique radiograph.

The Surgimap software was used for radiological measurements of cervical alignment parameters. The C7 slope, SCA, and cSVA were measured.

The C7 slope is the angle between the horizontal line and the superior end-plate of C7. The SCA is the angle between the C7 slope and the straight line connecting the middle of the C7 end-plate and the middle of the sella turcica. The cSVA refers to the distance between the line running perpendicularly from the posterior superior corner of C7 to the cranial and the vertical line passing through the center of C2.[11] Since cSVA measurement provides information about cervical lordosis, C2-C7 cervical lordosis was not measured.

Outcome measures

In addition to collecting the demographic data of the study participants, prior to the treatment, as well as in the third week and third month after the procedure, the Neck Disability Index (NDI), the Numeric Rating Scale (NRS), and the 12-item Short-Form Health Survey (SF-12) were employed.

The NRS is a frequently used tool for assessing and monitoring the severity of pain. The pain scale is measured on an 11-point rating system, where 0 indicates the absence of pain and 10 represents the most severe pain one can imagine. Patients are requested to assess their pain on a scale ranging from 0 to 10. The physician obtained measurements at each visit by directly questioning the patient.

The NDI has emerged as a widely utilized tool for assessing self-reported impairment resulting from neck pain. The questionnaire comprises 10 sections. Each segment is evaluated using a rating scale ranging from 0 to 5, where a score of 0 indicates "no discomfort" and a score of 5 indicates "worst imaginable pain." The highest achievable score is 50. A higher score indicates greater patient-rated disability. Turkish validity and reliability study of this questionnaire was conducted,[12] and the Turkish version was filled by the patients.

The assessment of quality of life was conducted using the SF-12, a questionnaire specifically designed to measure health-related quality of life. The SF-12 consists of 12 items that evaluate eight different health domains, providing an evaluation of both physical and mental well-being. The SF-12

provides two summary scores: the mental component score (MCS) and the physical component score (PCS). A decrease in the questionnaire score indicates progression of disability. The questionnaire's validity and reliability were ensured,[13] and the Turkish version of the questionnaire was filled out by the patients.

Statistical analyses

Based on a similar previously conducted study, the sample size was determined to be 62 patients, as calculated using the G*Power version 3.1.9.6 software (Heinrich Heine University Düsseldorf, Düsseldorf, Germany). This calculation was based on a significant change in three-month NRS scores, accounting for a 10% dropout rate, an alpha error rate of 0.05, and a power of 80%.

Statistical analyses were performed using the IBM SPSS version 20.0 software (IBM Corp., Armonk, NY, USA). Continuous variables were expressed in mean ± standard deviation, while categorical variables were expressed in frequency and percentage. The Shapiro-Wilk test was used for the conformity of quantitative data to normal distribution. The changes over time with treatment for normally distributed data were analyzed using the repeated measures analysis of variance. Correlations between the measurements were analyzed using the Pearson correlation analysis. A p-value of <0.05 was considered statistically significant with a 95% confidence interval.

RESULTS

The mean duration of symptoms was 21.2±5.8 (range, 3 to 84) months. The mean body mass index of the patients was 27.9±3.5 kg/m^2 (Table 1). There was a statistically significant difference between baseline, three-week, and three-month NRS, NDI, and SF-12 scores (p<0.001; Table 2).

Considering the relationship between cervical alignment parameters and the improvement in clinical scores at the three-month follow-up, there were moderate positive correlations between SCA and the improved NRS (r=0.587, p=0.001) and NDI (r=0.555, p=0.001) scores. In contrast, moderate negative correlations between C7 slope and the improved NRS (r=–0.632, p=0.001) and NDI (r=–0.496, p=0.001) scores were determined. There were also moderate negative correlations between cSVA and the improved NRS (r=–0.641, p=0.001) and NDI (r=–0.505, p=0.001) scores.

In addition, with regard to the improvement in the SF-12 PCS scores, there was a moderate negative correlation with the C7 slope (r=–0.520, p=0.001), a weak negative correlation with the cSVA (r=–0.463, p=0.001), and a weak positive correlation with the SCA (r=0.458, p=0.001).

Finally, the improved SF-12 MCS scores were weakly positively correlated with SCA (r=0.380,

TABLE 1
Demographic and clinical characteristics of patients (n=63)

Variables	n	%	Mean±SD
C7 slope (angle)			29.3±3.5
SCA (angle)			76.3±3.6
cSVA (mm)			25.9±4.3
Age (year)			45.3±9.4
Sex			
Female	40	63	
Male	23	37	
Symptom duration (month)			21.2±5.8
BMI (kg/m^2)			27.9±3.5
Pre-NRS			7.9±1.3
Pre-NDI			29.3±3.5
Pre-PCS-12			30.9±3.7
Pre-MCS-12			33.9±5.3

SD: Standard deviation; SCA: Spinocranial angle; cSVA: Cervical sagittal vertical axis; BMI: Body mass index; Pre: Before treatment; NRS: Numerical rating scale; NDI: Neck disability index; PCS-12: SF-12 physical component summary; MCS-12: SF-12 mental component summary.

TABLE 2
Changes in NRS, NDI, and SF-12 subscale scores of patients over time

	Mean±SD	*p*
Pre-NRS1	7.9±1.3	
NRS week 32	3.5±2.2	<0.001*[a]
NRS month 33	5.5±2.5	
Pre-NDI1	21.5±4.7	
NDI week 32	14.3±6.6	<0.001*[b]
NDI month 3 3	17.5±6.7	
Pre-PCS-121	30.8±3.7	
PCS-12 week 3 2	37.8±4.4	<0.001*[c]
PCS-12 month 33	33.3±3.7	
Pre-MCS-121	34.0±5.2	
MCS-12 week 32	36.9±5.6	<0.001*[d]
MCS-12 month 33	35.1±5.8	

NRS: Numerical Rating Scale; NDI: Neck Disability Index; SF-12: 12-item Short-Form Heath Survey; SD: Standard deviation; Pre: Before treatment; PCS-12: SF-12 physical component summary; MCS-12: SF-12 mental component summary; [a] Post-hoc tests: 1-2, 1-3 significant; [b] Post-hoc tests: 1-2, 1-3, significant; [c] Post-hoc tests: 1-2, 1-3 significant; [d] Post-hoc tests: 1-2, 1-3 significant; * p<0.001.

TABLE 3
Correlation of clinical measurements with cervical sagittal alignment parameters at the three-month follow-up

	C7 slope		SCA		cSVA	
	r	*p*	r	*p*	r	*p*
NRS improvement	−0.632	0.001	0.587	0.001	−0.641	0.001
NDI improvement	−0.496	0.001	0.555	0.001	−0.505	0.001
PCS-12 improvement	−0.520	0.001	0.458	0.001	−0.463	0.001
MCS-12 improvement	−0.332	0.011	0.380	0.002	−0.421	0.001

SCA: Spinocranial angle; cSVA: cervical sagittal vertical axis; NRS: Numerical Rating Scale; NDI: Neck Disability Index; PCS-12: SF-12 physical component summary; MCS-12: SF-12 mental component summary.

p=0.002), while they were weakly negatively correlated with C7 slope (r=−0.332, p=0.001) and cSVA (r=−0.421, p=0.011; Table 3).

DISCUSSION

In the present study, we investigated the effect of cervical alignment parameters such as C7 slope, cSVA, and SCA on the outcomes of ILESI for radicular pain due to cervical disc herniation. With the change of cervical parameters, cervical discs are exposed to weight of the head at varying degrees, resulting in thickening of the ligamentum flavum, disc degeneration, and increased intramedullary pressure.[5] In the long term, this may adversely affect the treatment of radicular pain due to cervical disc herniation. Our study also supports this notion by showing that correlations exist between the treatment outcomes and varying cervical parameter values.

According to Dubousset's[14] theory, known as the "cone of economy," the body adapts to changes in balance to regulate the center of gravity over as narrow a perimeter as possible. Considering the cervical spine, it has been suggested that, in the presence of malalignment, the cervical spine would increase in curvature as a compensatory mechanism to protect the center of gravity of the head in a narrow range. This change, which refers to hyperlordosis of C1-C2, attempts to optimize the craniocervical alignment.[15] The presence of correlations between C1-C2 lordosis and cSVA measurements indicates that these parameters are related to each other.

In a meta-analysis, Azimi et al.[4] reported a significant difference in cSVA measurements in the healthy and symptomatic population and concluded that this value was higher in the symptomatic group. They also showed that cSVA values were between 4.5 and 53.3 mm, although these values are recommended to remain below 40 mm. Oe et al.[5] reported that cSVA increased with age and that cervical spinal alignment was impaired in advanced age. Tang et al.[16] associated high postoperative cSVA values with unsuccessful surgical outcomes. Iyer et al.[6] defined preoperative high cSVA values as a predictive factor for neck disability. In the present study, we found a lower reduction in pain scores after epidural injections, as the cSVA value increased. Neck disability was also negatively affected. The patients were evaluated in terms of SF-12 PCS and MCS scores during follow-up. We observed a weak negative correlation between cSVA values and the improvement in those SF-12 subscale scores. As a result, the rate of recovery in the physical and mental states after epidural injection decreased in patients with high cSVA scores.

The C7 or T1 slope indicates the degree of thoracic kyphosis and is typically associated with increased cervical lordosis. The increased C7 slope value above the average values is associated with cervical hyperlordosis. Le Huec et al.[17] proposed the following formula: SCA=90° - C7 slope + sella turcica tilt. Accordingly, SCA and C7 slope are negatively correlated with each other, and the SCA value decreases in cervical hyperlordosis.

A review of the literature reveals that T1 and C7 slopes are strongly correlated with each other. Since it is difficult to visualize the T1 vertebra and to measure it on radiographs, it is recommended to measure the C7 slope.[18,19] Therefore, we measured the C7 slope in our study. Ling et al.[7] reported the mean value for the C7 slope as 20° and concluded that it should remain below 40°. Azimi et al.[4] found that the T1 slope ranged from 12.8° to 42.6° in their systematic review. Knott et al.[20] also reported that the T1 slope would be considered normal between 13° and 25° and that, in cases above 30°, it could be an indicator of cervical malalignment

accompanied by thoracolumbar deformity. Chen et al.[21] reported that the T1 slope increased with age, while Sharma et al.[22] reported that the high T1 slope was associated with increased development of kyphosis after laminectomy. Altogether, higher C7 slope may affect negatively the treatment results. In the present study, as the C7 slope increased, the success of epidural injection treatment decreased. Our results are consistent with the literature. Considering the treatment results, the increase in the C7 slope value also had a negative effect on neck disability. In addition, SF-12 subscale scores were also evaluated at three weeks and three months of follow-up. Accordingly, we observed moderate and weak negative correlations between the C7 slope and the improvement in SF-12 PCS and MCS scores, respectively. In other words, if the C7 slope is low, the SF-12 PCS and MCS scores tend to decrease more.

There is a limited number of studies evaluating SCA measurement, which is one of the cervical parameters, in the literature. However, in one of the limited number of studies, Le Huec et al.[17] reported that a mean range of 83°±9° for SCA was normal. Jouibari et al.[23] compared 25 patients with nonspecific neck pain and 25 asymptomatic individuals and found no significant difference in the SCA measurements. They measured the angle as 75.6° in those with neck pain and 75.92° in asymptomatic individuals. Nonspecific neck pain covers a wide range of diseases. In the present study, we included patients with radicular pain due to disc herniation and focused on a more specific group to establish a more objective relationship with cervical alignment parameters. The SCA was lower in patients who did not benefit from epidural injections, which is one of the factors affecting the success of treatment. In this context, our results are contradictory to those of Jouibari et al.[23] In addition, we observed a weak positive correlation between the SCA and improved NDI, SF-12 PCS and MCS scores after cervical epidural injections.

Cervical epidural injections can be administered with an interlaminar or transforaminal approach, and their superiority to each other has not been proven yet.[24] However, there are more comprehensive and well-designed studies in the literature on interlaminar injections.[1,24] In addition, the transforaminal approach has a greater risk of developing complications, which may lead to fatal outcomes.[1] Therefore, we prefer the interlaminar approach in epidural injections for cervical radicular pain in our clinic. Cervical interlaminar epidural injections are administered at the C6-7 or C7-T1 level, where the adipose tissue is larger, and the epidural area is wider.[25] Thus, the risk of dural puncture can be reduced. In our clinic, we also perform procedures from the C7-T1 level. In the present study, cervical disc herniation and the compressed spinal nerve root were not detailed, as injections given from the C7-T1 interval is distributed up to the C2 level.[26,27] Lee et al.[27] reported that an injectable volume of 5 mL reached up to the C2 level. Goel and Pollan[26] also reported that even a 2-mL volume was sufficient to reach the C3 level. In our clinical practice, we inject a total volume of 5 mL, including 12 mg/3 mL of dexamethasone, 1 mL of 2% lidocaine, and 1 mL of 0.9% saline for cervical ILESIs. Therefore, irrespective of the level of cervical disc pathology, we believe that the 5 mL total volume given from the C7-T1 interval would reach the C2 level.

Some authors have advocated that foraminal stenosis reduces the success of cervical epidural injection treatment.[28,29] In our study, we included only patients with central/paracentral disc herniation and excluded patients with foraminal stenosis to eliminate the effect of foraminal stenosis on treatment success.

Nonetheless, there are some limitations to the present study. First, cervical parameters were unable to be re-measured in the post-injection follow-ups. Due to ethical concerns such as unnecessary radiation exposure and high cost, an approval for radiographic measurements during follow-up could not be granted. Therefore, it is unknown whether the alignment parameters change in patients who benefit from the injection. Of note, in such a benefit situation, it would be difficult to establish a cause-and-effect relationship between the injection and the change in parameters. In patients who comply with their exercises and have an improvement in cervical alignment, the primary reason for the reduction of pain may not be the injection, but may be the change in this alignment. Second, exercise is of utmost importance in treating cervical radicular pain, regardless of whether epidural injections are performed.[30] In our clinic, we also provided an exercise program to patients who underwent cervical epidural injections. However, not all patients accepted or had the opportunity for supervised exercise with a physiotherapist. Therefore, the adherence to this exercise program at home could not be reliably assessed in the absence of direct observation. Another limitation

of the current study was the absence of a control group. As stated, the patients included in the study and receiving injections were those who had not benefited from previous conservative treatments. Therefore, ethical concerns arise from following chronic pain individuals without treatment to establish a control group.

In conclusion, the results suggest that the C7 slope, cSVA, and SCA are the main cervical parameters affecting the outcomes of cervical ILESI treatment. However, further studies in which cervical parameters are re-measured with radiographs during follow-up are warranted to shed more light on the relationship between cervical epidural injections and cervical parameters.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: The conceptualization of the study was carried out by: S.K., R.I., S.S.; The study design was developed by: S.K., R.I., S.S., O.H.G.; The literature review was conducted by: S.K., R.I., R.S., S.S.; Data collection was performed by: S.K., R.I., R.S.; Data analysis and interpretation were undertaken by: S.K., R.I.; The original draft of the manuscript was written by S.K., R.I., R.S.; Contributed to the review and editing of the manuscript, supervision of the study was provided: S.S., O.H.G. All authors have read and approved the final version of the manuscript.

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