

Cost-Effectiveness of Cervical Epidural Steroid Injections: A 3-Month Pilot Study

Global Spine Journal
2019, Vol. 9(2) 143-149
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DOI: 10.1177/2192568218764913
journals.sagepub.com/home/gsj



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Abstract

Study Design: Retrospective cohort.

Objectives: There are conflicting reports on the short- and long-term quality of life (QOL) outcomes and cost-effectiveness of cervical epidural steroid injections (ESIs). The present study analyzes the cost-effectiveness analysis of ESIs versus conservative management for patients with radiculopathy or neck pain in the short term.

Methods: Fifty patients who underwent cervical ESI and 29 patients who received physical therapy and pain medication alone for cervical radiculopathy and neck pain of <6 months duration were included. Three-month postoperative health outcomes were assessed based on EuroQol-5 Dimensions (EQ-5D; measured in quality-adjusted life years [QALYs]). Medical costs were estimated using Medicare national payment amounts. Cost/utility ratios and the incremental cost-effectiveness ratio (ICER) were calculated to assess for cost-effectiveness.

Results: The ESI cohort experienced significant ($P < .01$) improvement in the EQ-5D score while the control cohort did not (0.13 vs 0.02 QALYs, respectively; $P = .01$). There were no significant differences in costs between the cohorts. The cost-utility ratio for the ESI cohort was significantly lower (\$21 884/QALY gained) than that for the control cohort (\$176 412/QALY gained) ($P < .01$). The ICER for an ESI versus conservative management was negative, indicating that ESIs provide greater improvement in QOL at a lower cost.

Conclusions: ESIs provide significant improvement in QOL within 3 months for patients with cervical radiculopathy and neck pain. ESIs are more cost-effective compared than conservative management alone in the short-term. The durability of these results must be analyzed with longer term cost-utility analysis studies.

Keywords

cervical, epidural, injection, neck pain, radiculopathy

Introduction

Nearly two-thirds of all adult patients experience a significant episode of neck pain in their lives.¹⁻³ Cervical epidural steroid injections (ESIs) are a commonly used nonsurgical intervention typically administered for cervical radiculopathy and/or neck pain that is refractory to other conservative measures.⁴ ESIs are the most frequently performed procedures in pain clinics in the United States.⁴⁻⁶ They are performed under fluoroscopic guidance via the more commonly used interlaminar (IL) approach or alternatively via a transforaminal (TF) approach.⁴⁻⁶ Short- and long-term clinical effectiveness of ESIs is controversial.⁴⁻¹⁰ Studies have been published attesting to the clinical efficacy of both IL-ESIs and TF-ESIs in reducing pain and

improving quality of life.⁴⁻⁶ Yet the reported efficacy varies relative to many factors, including time, type, and route of injection. In a systematic review, Cohen et al⁴ reported on 45

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placebo-controlled studies on cervical and lumbar ESIs. Half of the studies included had significant positive effect on quality of life, but the effect usually lasted fewer than three months. Complications, though rare, include hypotension, neural injury, hemorrhage, infection, or infarction.¹¹ Nonetheless, Manchikanti et al¹² reported that the number of ESIs performed annually have continued to increase over the past decade.

Numerous studies support that cervical ESIs provide a short-term benefit in certain patients with neck pain.⁴ Several questions remain: (a) Which patients receive most benefit from ESIs and (b) are ESIs a cost-effective alternative to standard conservative management of physical therapy and medications? In the present study, we perform the first-ever cost-utility analysis of ESIs versus conservative management for patients with neck pain and cervical radiculopathy. We analyze 3-month health outcomes, calculate cost-utility ratios for both cohorts, and calculate the incremental cost effectiveness ratio (ICER) of ESIs versus conservative management. Our hypothesis was that ESIs would (a) result in clinical improvement that was not significantly different from conservative management alone, but at higher cost, and, therefore (b) ESIs would be less cost-effective than conservative management.

Materials and Methods

Demographic and Health Measurement Data

Electronic medical records of patients with cervical radiculopathy and neck pain were retrospectively identified between 2008 and 2014 using the corresponding International Classification of Diseases, Ninth Revision (ICD-9) codes. Current Procedural Terminology (CPT) codes were then used to narrow the search to patients who received at least 1 ESI for our intervention arm. Patient records were reviewed to identify patient demographic information and postoperative health resource utilization (eg, outpatient visits, medications) within a 3-month time frame. The patient population was divided into 2 cohorts: (a) patients who received an IL or TF ESI in addition to physical therapy and/or pain medication and (b) patients who received only physical therapy and/or pain medications, deemed the control cohort. Pain medication included narcotics, nonsteroidal anti-inflammatory drugs, neuropathic pain relievers, and anxiolytics. Specific dosages and frequencies of use were recorded. Physical therapy was analyzed as a 6-week, twice per week period, as per the standard at our institution and included various treatments aimed at reduced radicular symptoms, including massage and exercise. All patients had neck and radicular pain in one or both arms for fewer than 6 months at presentation. These symptoms were due to a variety of degenerative processes, including disc herniation, degenerative disc disease, spondylosis, and spinal stenosis. Patients were excluded if they were younger than 18 years, or had previous cervical spine surgery, prior cervical ESIs, myelopathy, nonspondylotic causes of radicular pain (eg, tumor, infection), neuromuscular disease (eg, multiple sclerosis, Parkinson's disease), or a workers' compensation claim.

Quality of life (QOL) scores including the Pain Disability Questionnaire (PDQ),^{13,14} Patient Health Questionnaire-9 (PHQ-9),¹⁵⁻¹⁷ and EuroQOL-5 Dimensions (EQ-5D)¹⁸⁻²⁰ were acquired via the institutional Knowledge Program. For all measures except the EQ-5D, a decrease in score represents improvement. This data has been systematically collected since 2009, in a prospective fashion, at the time of the patient visits. The Knowledge Program is a patient-derived outcome assessment tool that is embedded in our electronic medical record. The minimum clinically important difference (MCID) used for each questionnaire in a 1-year time frame was as follows: PDQ (26), PHQ-9 (5), and EQ-5D (0.1).²¹⁻²⁴ In the present study, the preoperative EQ-5D score and the postoperative EQ-5D score from the outpatient visit nearest the 1-year mark were recorded and converted to quality-adjusted life years (QALY) values using US valuation.

Direct Costs

Direct costs were defined as all hospital charges to the patient undergoing the procedure (ie, the cost of resources used for treating a particular illness).^{25,26} Medicare national payment amounts were used to estimate all direct cost data. The MS-DRG national Medicare payment amounts for hospitals were referenced in Ingenix's *DRG Expert*.²⁷ The American Medical Association online database and Center for Medicare and Medicaid Services were queued for CPT code Medicare national payment amounts based on the physician fee schedule using the corresponding author's institutional geographic region and practice.^{28,29} Diagnosis Related Group (DRG) and CPT code-associated costs were recorded in the year of surgery and then adjusted for inflation to 2017 dollars using US Census Bureau data on annual inflation changes. Other direct costs included physical therapy days, outpatient visits, and diagnostic imaging. These costs were recorded from the electronic medical records of patients. Any outpatient procedure performed outside of the home institution was not included. Pharmaceutical costs were estimated from the 2007 Red Book for medications and adjusted for inflation to 2017 US dollars.³⁰ Any other out-of-pocket costs covered by the patient were not accounted for because of the retrospective nature of this study.

Indirect Costs

Indirect costs were defined as the value of resources lost due to the surgery and postoperative recovery (ie, missed worked days).^{25,26} These costs are commonly estimated using a standard human capital approach, whereby the patient's reported gross-of-tax wage rate is multiplied by the total number of work-hours lost due to the surgery. In this retrospective study, wage rates were not available. Therefore, we used median annual household income averages based on the patients' zip code, converted these incomes into daily rates, and multiplied the rates by the patient self-reported days of missed work.³¹

Cost-Utility Ratio and ICER

Cost-utility ratios and ICERs have been the primary mathematical tools used in previous cost-effectiveness studies to compare the cost utilities of 2 treatments for a given diagnosis.²⁵ Cost-utility ratios are defined as the total cost divided by the QALYs gained from the intervention. The ICER is defined as the difference in total cost divided by the difference in QALYs gained between interventions, where total cost includes both direct and indirect medical costs.

Direct costs were added to indirect costs to obtain the total cost for each patient in each cohort. The preoperative utility score was used as a baseline for preoperative treatment health status (ie, initial EQ-5D score) for each cohort. The mean total cost was calculated and divided by the mean gain in QALY to obtain the cost-utility ratio for each cohort at the 3-month mark. The ICER was then calculated as the difference in the total cost for each intervention divided by the difference in QALY gains between the interventions. The resultant cost-utility ratios and ICER were then compared with the 3-month cost-effectiveness threshold (\$25 000/QALY gained) to assess for cost-effectiveness.²⁵ This ratio was derived from the standard 1-year threshold of \$100,000/QALY gained.²⁵

Statistical Analysis

Categorical data was assessed using Fisher's exact tests. Continuous data was assessed using the Student *t* test. All *P* values $\leq .05$ were considered statistically significant.

Results

Demographics

A total of 350 patients were initially identified, of which 79 were included. The rest were excluded for one of the following reasons: (a) lack of complete QOL data sets, (b) previous spine surgery, or (c) undergoing surgery within the 3-month time frame, which is common among patients presenting to our quaternary care center. Fifty patients who received an ESI in addition to physical therapy and/or pain medication (ESI cohort) and 29 patients who received physical therapy and/or pain medication alone (control cohort) were included based on the aforementioned inclusion criteria (Table 1). No statistically significant differences existed between the 2 cohorts for age, income, gender, ethnicity, body mass index, comorbidities, or diagnoses. All patients had preoperative symptoms of cervical radiculopathy (either unilateral or bilateral) and neck pain with symptoms present for less than six months prior to presentation. No patients had paralysis. All patients had 3 months of follow-up QOL data. For the ESI cohort (wherein some patients received more than 1 injection), more TF injections (47; 68.1%) were performed than IL injections (22; 31.9%). Patients in the ESI cohort received an average of 1.4 injections over the 3-month follow-up period. To decrease the potential for selection bias, we compared the 271 patients excluded with the 79 included and found no significant differences in age,

Table 1. Patient Demographics.

	ESI	Control	<i>P</i> ^a
n	50	29	
Age, years, mean \pm SD	52.5 \pm 10.2	56.8 \pm 9.7	.07
Male, n (%)	32 (64.0)	18 (62.0)	.87
Smoker, n (%)	19 (38.0)	8 (27.6)	.71
Diabetic, n (%)	0 (0.0)	3 (10.3)	.34
BMI, kg/m ² , mean \pm SD	29.1 \pm 5.9	28.9 \pm 5.6	.90
Caucasian, n (%)	47 (94.0)	28 (96.5)	.71
Opioid, n (%)	15 (30.0)	8 (27.6)	.82
Nonopioid analgesic, n (%)	38 (76.0)	18 (62.0)	.20
Physical therapy, n (%)	16 (32.0)	9 (31.0)	.15
Diagnosis, n (%)			
Spondylosis	16 (32.0)	11 (37.9)	.60
Disc herniation	21 (42.0)	10 (34.5)	.51
Spinal stenosis	4 (8.0)	6 (20.7)	.15
Degenerative disc disease	9 (13.2)	2 (5.3)	.13
ESI level, n (%)			
C4-5	29 (42.0)		
C5-6	24 (34.8)		
C6-7	16 (23.2)		
ESI approach, n (%)	22 (31.9)		
Interlaminar			
Transforaminal	47 (68.1)		

Abbreviations: BMI, body mass index; ESI, epidural steroid injection.

^aStatistical significance *P* < .05. Student's *t* test was used for categorical data and Fisher's exact test was used for noncategorical data.

gender, income, ethnicity, body mass index, comorbidities, diagnoses, number of ESIs, type of ESIs, medication use, or physical therapy use. We also followed patients out to 1-year follow-up and found none had undergone surgery.

Health-Related Outcomes and Costs

At 3 months' follow-up, the ESI cohort experienced both statistically significant (*P* < .01) and clinically relevant (>MCID) improvement in the EQ-5D score (and change in EQ-5D score) while the control cohort did not (0.13 vs 0.02 QALYs, respectively; *P* = .01). In addition, the final PDQ score for the ESI cohort was significantly (*P* = .05) lower than the control cohort. No other significant differences were found for the control cohort or between cohorts for any measures at either time point, including changes in scores (Table 2). No difference in outcomes was observed between patients receiving IL versus TF injections. We conducted a post hoc power analysis that verified that the present study was adequately powered to detect a clinically relevant significant difference in the QOL measures.

Costs for each interlaminar and transforaminal injection, conducted under fluoroscopic guidance, were \$106.12 and \$233.62, respectively. Direct costs for the ESI cohort (\$1406.87) were not significantly higher than the costs for the control cohort (\$1194.57) (*P* = .34). Indirect costs for the control cohort (\$2446.31) were not significantly higher than those for the ESI cohort (\$1438.01), though there may have been a trend in the data (*P* = .15). The latter was not significant

Table 2. Quality of Life Outcomes.

	ESI	<i>P</i> ^a	Control	<i>P</i> ^a	<i>P</i> ^a (Between Cohorts)
PDQ					
Baseline	57.2 ± 29.7	.18	59.6 ± 32.6	.56	.75
3 months	47.9 ± 28.2		65.6 ± 35.2		.05 ^a
Change	7.0 ± 23.7	—	20.8 ± 37.7	—	.21
PHQ-9					
Baseline	6.5 ± 5.9	.53	6.1 ± 4.1	.90	.72
3 months	5.8 ± 5.5		6.3 ± 6.8		.75
Change	1.1 ± 4.1	—	0.1 ± 3.6	—	.38
EQ-5D/ QALY					
Baseline	0.60 ± 0.24	<.01 ^a	0.64 ± 0.20	.71	.57
3 months	0.73 ± 0.18		0.66 ± 0.20		.11
Change	0.13 ± 0.20	—	0.02 ± 0.17	—	.01 ^a

Abbreviations: EQ-5D, EuroQol 5-Dimensions; ESI, epidural steroid injection; PDQ, Pain Disability Questionnaire; PHQ, Pain Health Questionnaire; QALY, quality-adjusted life year.

^aSignificant value $P \leq .05$. Student's *t* test was used for data analysis.

Table 3. Medical Cost (in \$).

	ESI	Control	<i>P</i> ^a
Interlaminar ESI	106.12	—	—
Transforaminal ESI	233.62	—	—
Total direct costs	1406.87 ± 1023.50	1194.57 ± 888.26	.34
Indirect costs	1438.01 ± 2592.65	2446.31 ± 3611.27	.15
Total costs	2844.88 ± 2862.33	3558.66 ± 4000.05	.40

Abbreviations: ESI = epidural steroid injection.

^aSignificant value $P \leq .05$. Student's *t* test was used for data analysis.

likely because of the large standard deviation in indirect costs related to the wide range of missed work days, from 0 to 118 days. On average, however, the control cohort missed nearly double the number of work days (18.2 vs 10.4 days) as compared with the ESI cohort. The average overall costs were \$2844.88 and \$3558.66 for the ESI and control cohorts, respectively ($P = .40$) (Table 3).

Cost-Utility Ratios and ICER

The change in QALYs (Δ QALY) was calculated as the 3-month utility score minus the baseline utility score (Table 4). All patients had EQ-5D data at both the baseline and 3-month time points. The average 3-month Δ QALY for the ESI was significantly higher for the ESI cohort than for the control cohort (0.13 vs 0.02, respectively; $P = .01$). The 3-month cost-utility ratios for the ESI and control cohorts were \$21 884/QALY gained and \$176 412/QALY gained, respectively ($P < .01$). The ICER indicated that ESIs were the dominant treatment. A dominant treatment has a negative cost-effectiveness ratio and is not reported. This means that ESIs in addition to physical therapy and/or pain medication were more cost-effective than physical therapy and/or pain medications alone. That is, ESIs provided on average greater

Table 4. Cost-Utility Ratio and ICER (1-Year) Calculation.

Cohort	ESI	Control	<i>P</i> ^a
Δ QALY 3-month	0.13 ± 0.20	0.02 ± 0.18	.01 ^a
Cost/QALY gained	\$21 883.67/QALY gained	\$176 411.96/QALY gained	<.01 ^a
ICER 3-month	Dominated		—

Abbreviations: ESI, epidural steroid injection; ICER, incremental cost-effectiveness ratio ((cost of ESI minus cost of conservative management)/(Δ QALY ESI minus Δ QALY conservative management)); QALY, quality-adjusted life year.

^aSignificant value $P \leq .05$. Student's *t* test was used for data analysis.

QOL improvement at equivalent or lower cost compared to conservative management alone within a 3-month time frame.

Discussion

This study represents the first cost-utility analysis of cervical ESIs for patients with cervical radiculopathy and neck pain. The rapid growth in use of ESIs by multiple medical and surgical specialties necessitates consideration of costs and effectiveness.⁴⁻⁶ In a review of ESI use in the Medicare population, Manchikanti et al¹² found that, from the year 2000 to 2011, ESIs increased 130% per 100 000 Medicare beneficiaries (whereas the number of beneficiaries increased only 18%), with cervical/thoracic ESIs increasing 123% for interlaminar approach and 142% for transforaminal approach.

Despite the increase in their use, few studies have actually examined the effectiveness of cervical ESIs in providing pain relief, thereby questioning their cost-effectiveness.⁴⁻⁶

In the present study, we conducted a cost-utility analysis comparing cervical ESIs (plus physical therapy and/or pain medication) to physical therapy and/or pain medication alone to assess whether ESI use is cost-effective in the short term (3-month follow-up). We found that ESIs were more cost-effective than physical therapy and pain medication alone. All patients either subsequently underwent surgery or were lost to follow-up, thereby preventing us from analyzing durability of QOL improvement greater than 3 months. The major difference in costs between cohorts was related to patient missed work days, of which the ESI cohort had about half as many work days missed as compared with patients in the control cohort (10.44 vs 18.24 days, respectively; $P = .15$). From our data, this seems to be the largest advantage of the ESIs, in that they help to return the patient to work and, thus, avoid incurring significant indirect costs. Physical therapy use was nearly equivalent in both cohorts (16 [32%] vs 9 [31%] patients, respectively; $P = .93$). Opioid and nonopioid medication use was also nearly equivalent in both cohorts ($P = .82$ and $.2$, respectively). No difference in specific medication type was noted between cohorts.

In 1996, Bush and Hillier³² analyzed patients that received serial ESIs ($n = 68$) for cervical radiculopathy who had ongoing symptoms for more than 4 weeks (average 2 months duration) and were considered surgical candidates. They

reported that all 68 patients no longer required surgery at the average follow-up time of 7 months, since they all showed marked improvement in their symptoms (subjective assessment) due to the ESIs. In their study the average patient had 2.5 injections, whereas in the present study the average was 1.3 injections per patient. There have been several subsequent studies that have showed excellent clinical outcomes (based on subjective clinician assessment and pain scores) in two-thirds of patients using either interlaminar or transforaminal ESIs; several other studies with study designs similar to the present study reported that less than one-fourth of patients experienced improved symptoms or avoided surgery after receiving ESIs.^{4-6,33-37} Benyamin et al⁵ conducted a systematic review of 3 randomized control trials of cervical IL-ESIs and found level I evidence for their effectiveness in treating radiculopathy secondary to a herniated disc and level II evidence for their effectiveness for patients with stenosis, discogenic pain, and failed neck surgery syndrome. This effectiveness was assessed as pain relief on the visual analogue scale and found to be durable in both the short term (<6 months) and long term (>6 months). Diwan et al⁶ conducted a systematic review and identified 9 studies between 1966 and 2011 that analyzed cervical IL-ESIs for axial discogenic pain, herniated disc, or spinal stenosis. The authors found evidence for significant short-term pain relief (ie, <6 months) in patients receiving an ESI only with a preoperative diagnosis of disc herniation. Thus, studies have found evidence that cervical IL-ESIs are useful for pain relief, but very few have used validated QOL measures outside of the VAS to quantify this pain relief.

Our QOL outcomes results agree with those of Benyamin et al⁵ and Diwan et al.⁶ In contrast to those studies wherein patients received 1 to 4 injections during the 1-year follow-up, the majority of our patient sample only had 1 ESI (average 1.4 injections/cohort), which is due to our more-focused 3-month time period. This was expected given general guidelines for how many ESIs patients should receive within 3 months, 6 months, or 1 year. Thus, 1 injection alone can lead to significant improvement in the short term. In addition, the prior reviews have included studies only analyzing interlaminar injections whereas the present study has a patient population that received mostly transforaminal injections. This allows us to conclude that either approach leads to significant QOL improvement. For cervical TF-ESIs, only a few studies (level III evidence) have been published that show benefit, while some studies have suggested that TF-ESIs lead to greater risk of complications than IL-ESIs.^{10,11,36,38} There was no significant difference in cost-effectiveness of IL versus TF approach.

Cost-utility analyses of ESIs do not exist in the cervical spine literature. However, in the lumbar spine, both Price et al³⁹ and Straus et al⁴⁰ agreed that ESIs do not provide good economic value via the cost/QALY ratio. The former conducted a double-blind randomized controlled trial (n = 228) of patients receiving up to 3 lumbar ESIs or placebo over 1-year follow-up and found transient improvement in QOL scores (Oswestry Disability Index and Short-Form 6 Dimensions until 6 weeks post-ESI when scores returned to baseline.

The latter was a literature review that listed specific costs for ESIs and, through a cost-minimization perspective, concluded that fluoroscopy did not provide added value in conducting ESIs. In contrast, Whyne et al⁴¹ conducted a cost-effectiveness study (n = 39) of ESIs (2 per patient) for lumbar radiculopathy and found that, in a 12-week period, they were cost-effective (based on a threshold of \$50 000/QALY gained and EQ-5D used for outcomes). Thus, in agreement with our results, ESIs can provide short-term cost-effective improvement in QOL for patients. Relative to the long-term, Manchikanti et al⁴² conducted a cost-utility analysis of caudal ESIs for patients with lumbar disc herniation, low back pain, spinal stenosis, and postsurgery syndrome. All patients (n = 480) experienced significantly improved QOL outcomes at the final follow-up. The authors calculated 1-year cost-utility ratios of \$2206/QALY gained for disc herniation, \$2136/QALY gained for axial or discogenic pain, \$2155/QALY gained for spinal stenosis, and \$2191/QALY gained for postsurgery syndrome. However, these costs only included the ESI and outpatient visits over the 1-year period. In contrast, we included comprehensive direct (medication, physical therapy, and imaging) and indirect (missed workday) costs to the patient, which is the standard for cost-effectiveness analyses. The authors concluded that ESIs were cost-effective but did not compare ESIs to a separate intervention, which is important in understanding the more cost-effective treatment options. In addition, the authors did not specify where they derived QALY values, but rather reported a numeric pain scale and Oswestry Disability Index.

The authors also acknowledge limitations that must be considered when interpreting the results of the present study. First, obtaining a control cohort retrospectively proved difficult because of the higher likelihood of undergoing surgery or an ESI within 2 months of initial presentation to our tertiary care institution. However, our power analysis confirmed that our sample size was sufficient to detect significant differences in the QOL measures between the cohorts. Despite our focus on patients with less than 6 months of neck or arm pain, it is worthwhile to note that many patients that undergo cervical ESIs are often refractory to other conservative treatment or have chronic symptoms. Second, not all of the indirect costs were measured, as the calculations that were used do not take into account family member or other caregiver losses (eg, jobs, wages). Third, because of the retrospective nature of this study, specific medication dosage, frequency, and compliance could not be controlled among patients within or between cohorts. However, no significant difference existed in type of medication, dosage or frequency within or between cohorts. Finally, our cost calculations used Medicare national payment amounts, which may not accurately reflect the costs that all patients will incur (ie, any patient not on Medicare). Despite these limitations, the present study uses methodologies that are in line with those of previous cost-utility analyses. The present study represents the first to analyze both cost-effectiveness and QOL outcomes following cervical spine ESIs. The costs calculated are comprehensive and, in addition to the outcome measures

used, generalizable across hospitals wishing to conduct longer or prospective analyses.

Conclusion

Cervical ESIs lead to significant improvement in QOL within 3 months for patients with cervical radiculopathy and neck pain. ESIs are the more cost-effective option in the short term due to lower costs and greater overall improvement in QOL than conservative management alone. Lower costs are related to the fewer missed work-days in the short term following ESIs. The durability of these results must be analyzed with longer term cost-utility analysis studies.

Authors' Note

Institutional review board approval #13-319 was obtained prior to initiation of this study.

Acknowledgments

Neurological Institute Knowledge Project.


Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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