





Quality of life in people with spinal cord injuries in Tunja-Colombia

Qualidade de vida em pessoas com lesão da medula espinal em Tunja-Colombia

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ABSTRACT | BACKGROUND: Spinal cord injury (SCI) is a pathological condition that affects a person's performance in areas such as personal, social, economic, etc. In addition, it causes physical and functional changes that affect independence and functionality, which has an impact on quality of life (QoL). OBJECTIVE: To identify the factors associated with QoL in people with SCI in Boyacá - Colombia. MATERIALS AND METHODS: This is a cross-sectional design with a sample of 87 subjects selected using the snowball technique, for whom the WHOQOL-BREF test was used to assess QoL. The analysis was performed using descriptive statistics for the sociodemographic variables and, in the bivariate case, Pearson's chi-square test was used. In the multivariate case, negative binomial regression was used with the enter method, considering the theoretical and statistically significant variables. **RESULTS:** The mean age was 47.7 ± 14.4 years, with a predominance of men (69% - n=60); QoL was good in 74.7% (n=65) with a 95% CI (35.58%-83.85%). Protective factors included being male (OR=0.366, 95% CI [0.167-0.802]), marital status, having company (OR=0.324, 95% CI [0.131-0.800]), and risk factors: educational level (PR=5.052, 95% CI [1.095-23.319]), low socioeconomic status (PR=3.315, 95% CI [1.080-10.177]), and having a high disability (PR=3.145, 95% CI [1.144-8.649]). CONCLUSIONS: QoL, which is composed of different dimensions, is related to structural social determinants such as gender, socioeconomic status, educational level, and income, in addition to clinical determinants such as etiology and injury level.

KEYWORDS: Quality of Life. Protective Factors. Risk Factors. Spinal Cord Injuries. Cross-Sectional Studies.

RESUMO | FUNDAMENTOS: A lesão medular (LM) é uma condição patológica que afeta o desempenho da pessoa em áreas como a pessoal, social, econômica, etc. Além disso, causa alterações físicas e funcionais que afetam a independência e a funcionalidade, o que tem impacto na qualidade de vida (QV). OBJETIVO: Identificar os fatores associados à QV em pessoas com LM em Boyacá - Colômbia. MATERIAIS E MÉTO-DOS: Este é um estudo transversal com uma amostra de 87 indivíduos selecionados usando a técnica de bola de neve, para os quais o teste WHOQOL-BREF foi usado para avaliar a QV. A análise foi realizada usando estatísticas descritivas para as variáveis sociodemográficas e, no caso bivariado, foi usado o teste qui-quadrado de Pearson. No caso multivariado, foi usada a regressão binomial negativa com o método enter, levando em consideração as variáveis teóricas e estatisticamente significativas. **RESULTADOS:** A idade média foi de 47,7 ± 14,4 anos, com predominância de homens (69% - n=60); a QV foi boa em 74,7% (n=65) com IC 95% (35,58%-83,85%). Os fatores protetores incluíram ser do sexo masculino (OR = 0,366, IC 95% [0,167-0,802]), estado civil, ter companhia (OR=0,324, IC 95% [0,131-0,800]) e fatores de risco: nível de escolaridade (PR=5,052, IC 95% [1,095-23,319]), baixo status socioeconômico (PR=3,315, IC 95% [1,080-10,177]) e ter uma deficiência elevada (PR=3,145, IC 95% [1,144-8,649]). CONCLUSÕES: A QV, composta por diferentes dimensões, está relacionada a determinantes sociais estruturais, como gênero, status socioeconômico, nível educacional e renda, além de determinantes clínicos, como etiologia e nível da lesão.

PALAVRAS-CHAVE: Qualidade de Vida. Fatores de Proteção. Fatores de Risco. Lesões da Medula Espinal. Estudos Transversais.

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1. Introduction

According to the World Health Organization (WHO), quality of life (QoL) is "in terms of how individuals perceive their position in life within the context of the culture and value systems in which they live, as well as in relation to their goals, expectations, standards, and concerns. This is all influenced, of course, by their physical health, psychological state, level of independence, social relationships, environmental factors, and personal beliefs"1. QoL is, therefore, influenced by economic, social, and health factors. The presence of diseases has direct impact on it, with the physical, emotional, and social dimensions being the most affected. An example is spinal cord injury (SCI), which "refers to damage to the spinal cord as a result of trauma (car accident) or disease or degeneration (cancer)"2, an injury that in most cases leads to impairment of independence and function, resulting in dependence on the performance of various activities. The concept of health-related quality of life (HRQoL) is proposed to understand QoL with different functional changes, "which accounts for the dimensions of life affected by diseases, accidents, treatments, or health policies"3.

Changes in functionality involve adaptation processes, since SCI affects, among other things, physical health, which is a component of QoL as measured by the WHOQOL-BREF. This dimension is related to physical functions and bodily capabilities in the individual's daily life. Thus, it is associated with functional capacity and autonomy, which are affected by SCI as its sequelae limit mobility. In this sense, mobility, as a component of functionality, is important in all dimensions of QoL4.5, and SCI affects QoL in terms of participation and satisfaction. Better participation, in terms of frequency and limitations, is associated with better QoL, including areas such as social, leisure, and work activities. This is consistent with comparative analysis reports from countries with different levels of development, which show that lower QoL is associated with unemployment, country of residence, years of education, and time elapsed since injury. In addition, a longer time since injury is associated with better coping skills and performance (between 11 and 15 years)^{7,8}.

Thus, QoL is not only affected by the physical component of SCI; the presence of anxiety and depression are considered negative aspects, unlike community integration, social support from friends, and home adaptations, which are positive factors ^{9,10}. The purpose of this text is to identify the factors associated with QoL in people with SCI in Boyacá, Colombia.

At the national level, the National Administrative Department of Statistics (DANE) reports physical disabilities, including SCI, from the Registry for the Location and Characterization of Persons with Disabilities (RLCPD). Thus, for the period 2020-2024, 350,732 people were certified nationwide, with 54.2% having physical disabilities, followed by intellectual disabilities with 41.1%¹¹.

Regarding Tunja, the 2021 Health Situation Analysis (ASIS) reports 3,487 people with disabilities in 2020, equivalent to 1.93% of the population. Similarly, the highest proportion of cases involved nervous system disabilities (2,039-58.5%), followed by impairments affecting movement of the body, hands, arms, and legs, generally physical disabilities (1,573-45.1%), almost always due to traffic accidents or falls. These disabilities are predominant in adults and older people in rural areas, as well as in males and socioeconomic strata 1 and 2¹².

The contributions of the text lie in the study of a population group that has been little addressed regionally and nationally from the perspective of QoL, considering it from a multidimensional perspective: physical, psychological, environmental, and social relationships. This aspect highlights the complexity of addressing rehabilitation processes that must consider the domains of the International Classification of Functioning, Disability, and Health (ICF), such as bodily functions and structures, activities, and participation¹³. Therefore, QoL in people with SCI involves recognizing the importance of different family, institutional, and social entities in the care and rehabilitation process, which promotes mechanisms for inclusion in educational, family, economic, political, and other environments, ensuring human development and participation.

2. Method

This study used a cross-sectional design. The population consisted of individuals aged 18 years or older with SCI according to the SISPRO 2018 database of the city of Tunja (Boyacá, Colombia), with reduced mobility due to a disability, totaling 125 individuals. The sample was obtained using the EPIDAT software version 3.1, applying the formula for the mean, considering a dispersion for total QoL of 16.53¹⁴, an absolute precision of 3, a design effect of 1, and a confidence level of 95%. Thus, the sample size was 61 individuals; however, for this study, the sample size was 87 individuals, and the sampling technique used was snowball sampling.

Inclusion criteria were being over 18 years or older, belonging affiliated with the General System of Social Security in Healthcare (SGSSS), signing the informed consent, and having preserved higher mental functions. The exclusion criterion was having a medical diagnosis of impaired higher mental functions, which was determined by the pre-existing diagnosis during the investigation; no test was administered to evaluate it. The following variables were included: chronological age, sex, educational level, marital status, socioeconomic status (according to DANE, this is a classification of residential properties that must receive public services, divided into six strata: 1-Lowlow, 2-Low, 3-Medium-low, 4-Medium, 5-Mediumhigh, and 6-High)¹⁵, SGSSS affiliation, etiology, employment status, age at the time of injury in years, time elapsed since injury in months, quality of life, body image, disability, and functionality.

The instruments used were administered by research assistants who had been previously trained in the protocol and structure of the instruments directly to the participants. The assistants were students in their final semesters of Physical Therapy. Thus, the instrument contained a section on sociodemographic characteristics, measurement of the degree of spinal cord injury using the AIS (ASIA impairment scale)¹⁶, and the use of scales such as PICDF for body image, WHODAS 2.0 for measuring disability, and SCIM III for functionality.

Regarding QoL, the WHOQOL - BREF instrument proposed by the WHO and validated for Colombia was used. It consists of 26 questions divided into four dimensions: Physical Health Dimension (3, 4, 10, 15, 16, 17, 18), Psychological Health Dimension (5, 6, 7, 11, 19, 26), Environmental Dimension (8,9,12,13,14, 23, 24, 25), and Social Relationships Dimension (20, 21, 22). These are rated on a Likert scale from 1 to 5, with a total score of 100. For questions 3, 4, and 26 the scores are reversed so that 5 is always positive and indicates better QoL. The score is calculated over 24 questions as follows: total dimension score according to the highest score/ (total score minus the total number of questions in the dimension)* 100. QoL was categorized as follows: a score below 50 indicates poor QoL, and a score above 50 indicates good QoL17-22.

Data analysis was performed using Microsoft Excel version 365 for data entry and cleaning, and the statistical analysis was performed using the SPSS 26 statistical software. Qualitative variables were described by absolute and relative frequencies, and quantitative variables were described with means, medians, standard deviations, and interquartile ranges. Bivariate analysis was performed using Pearson's Chi-squared test. To control confounding and interactions, a multivariate model with the method of introducing theoretically important and statistically significant variables was performed using negative binomial regression, with 95% confidence intervals (CIs) and a type I error of 0.05.

This research was considered risk-free and in compliance with the ethical aspects of Resolution 8430 of 1993. It was approved by memo CB 494 of 10 December 2018 of the Bioethics Committee of the Universidad de Boyacá (University of Boyacá) for the microproject "Behavior from clinical aspects, functionality, body self-perception, disability, health-related quality of life, and central sensitization in people with spinal cord injury in the cities of Tunja, Duitama, Sogamoso, and Yopal 2018-2020".

3. Results

The mean age was 47.7±14.4 years with heterogeneous variability (CV=29.3%). Regarding gender, males predominated. The most common age group was 27 - 59 years. In terms of occupation, those with formal and informal resources were similar and more numerous than those without. Regarding marital status, single people predominate, and in terms of socioeconomic status, the middle class is the most common, with most affiliated with the SGSSS. The most common educational level is medium, followed by low. The most common etiology was traumatic, with incomplete injuries according to the AIS classification.

In addition, a positive body image predominated alongside high disability (measured using WHODAS 2.0; the "high" category includes moderate and severe ratings) and greater functionality (not perceived as positive). Variables associated with QoL were socioeconomic status, occupation, disability, and functionality, with the personal care dimension being significant (p=0.012) (Table 1).

 Table 1. General characteristics (to be continued)

		Total [—]		Quality of life				
Variables	Category			Bad		Good		<i>p</i> -Value
		n	%	n	%	n	%	
Age	≤ 26 years	9	10.3%	4	44.4%	5	55.6%	0.299
	27-59 years	61	70.1%	13	21.3%	48	78.7%	
	≥ 60 years	17	19.5%	5	29.4%	12	70.6%	
Sex	Woman	27	31.0%	10	37.0%	17	63.0%	0.091
	Man	60	69.0%	12	20.0%	48	80.0%	
Marital status	With company	35	40.2%	12	34.3%	23	65.7%	0.113
	Unaccompanied	52	59.8%	10	19.2%	42	80.8%	
Socioeconomic stratum	Half	48	55.2%	8	16.7%	40	83.3%	0.04*
	Low	39	44.8%	14	35.9%	25	64.1%	
Occupation	Without resources	28	32.2%	13	46.4%	15	53.6%	0.007**
	Non formal resources	29	33.3%	4	13.8%	25	86.2%	
	Formal resources	30	34.5%	5	16.7%	25	83.3%	
SGSSS	Contributory	53	60.9%	12	22.6%	41	77.4%	0.478
	Subsidized	34	39.1%	10	29.4%	24	70.6%	
Educational level	Low educational level	34	39.1%	12	35.3%	22	64.7%	0.114
	Medium educational level	39	44.8%	9	23.1%	30	76.9%	
	High educational level	14	16.1%	1	7.1%	13	92.9%	
Age of injury	≤12 years	8	9.2%	0	0.0%	8	100.0%	0.182
	13-17 years	6	6.9%	1	16.7%	5	83.3%	
	≥18 years	73	83.9%	21	28.8%	52	71.2%	

Table 1. General characteristics (conclusion)

	Category	Total ⁻						
Variables				Bad		Good		<i>p</i> -Value
		n	%	n	%	n	%	-
Etiology	Traumatic	56	64.4%	14	25.0%	42	75.0%	0.934
	Non traumatic	31	35.6%	8	25.8%	23	74.2%	
AIS	Incomplete injury	58	66.7%	15	25.9%	43	74.1%	0.862
	Complete injury	29	33.3%	7	24.1%	22	75.9%	
Body Image – PICDF ²³	Good assessment BI	73	83.9%	17	23.3%	56	76.7%	0.327
	Poor assessment BI	14	16.1%	5	35.7%	9	64.3%	
Disability- WHODAS 2.0 ²⁴	Low	35	40.2%	3	8.6%	32	91.4%	0.003**
	High	52	59.8%	19	36.5%	33	63.5%	
Functionality – SCIM III ²⁵	More	73	83.9%	14	19.2%	59	80.8%	0.003**
	Lower	14	16.1%	8	57.1%	6	42.9%	

Source: the authors (2021).

In terms of QoL, a mean score of 62 ± 14.43 was reported, with the highest scoring dimensions being psychological health and environment, while the lowest scoring dimension being physical health. Overall, 74.7% of people with SCI reported good QoL (Table 2).

Table 2. Global and item QoL and dimensions (to be continued)

Quality of Life Item	Average (d.e)	Minimum	Máximum	Me (RI)	95% CI
HRQoL.1 How would you rate your quality of life?	3.33(0.79)	1	5	3(1)	(3.17-3.5)
HRQoL.2 How satisfied are you with your health?	3.21(0.79)	1	5	3(1)	(3.04-3.38)
HRQoL.3 To what extent does (physical) pain prevent you from doing what you need to do?	3.22(1.31)	1	5	3(2)	(2.94-3.5)
HRQoL.4 Do you need any medical treatment to function in your daily life?	3.17(1.44)	1	5	3(2)	(2.87-3.48)
HRQoL.5 How much do you enjoy life?	3.68(1.03)	2	5	4(2)	(3.46-3.9)
HRQoL.6 To what extent do you think your life has meaning?	3.89(1.06)	1	5	4(2)	(3.66-4.11)
HRQoL.7 Do you have the ability to concentrate?	3.82(0.92)	1	5	4(1)	(3.62-4.01)
HRQoL.8 Do you feel safe in your daily life?	3.77(1.02)	1	5	4(2)	(3.55-3.99)
HRQoL.9 Is the physical environment around you healthy?	3.98(0.95)	2	5	4(2)	(3.77-4.18)
HRQoL.10 Do you have enough energy for your daily life?	3.61(0.99)	1	5	4(1)	(3.4-3.82)
HRQoL.11 Are you able to accept your physical appearance?	3.93(1.04)	1	5	4(2)	(3.71-4.15)
HRQoL.12 Do you have enough money to meet your needs?	2.84(1.06)	1	5	3(1)	(2.61-3.06)
HRQoL.13 Dou you have available the information you need in your daily life?	3.54(1.02)	1	5	4(1)	(3.32-3.76)

^{*}Significance level at 0,05. **Significance level at 0,01. PICDF - body image for people with physical disabilities.

Table 2. Global and item QoL and dimensions (conclusion)

	Qual	lity of Life	Item		Average (d.e)	Minimum	Máximum	Ме	(RI)	95% CI
	HRQoL.14 To what extent are you able to carry out activities n your free time?		3.3(1)		1	5	3	(1)	(3.09-3.51)		
HRQoL.15 Are you able to move from one place to another?			3.4(1.22	2)	1	5	3	(1)	(3.14-3.66)		
HRQoL.16 How satisfied are you with your sleep?			3.64(0.9	6)	1	5	3	(2)	(3.44-3.85)		
HRQoL.17 How satisfied are you with your ability to perform activities of daily living?			3.44(1.0	1)	1	5	3	(1)	(3.22-3.65)		
HRQoL.18 H	Haw satisfied	are you wit	h your ability	to work?	3.13(1.1	2)	1	5	3	(2)	(2.89-3.36)
HRQoL.19 F	How satisfied	are you wit	th yourself?		3.72(0.9	1)	1	5	4	(1)	(3.53-3.92)
HRQoL.20 H relationship		are you wit	th your persor	nal	3.75(0.8	7)	1	5	4	(1)	(3.56-3.93)
HRQoL.21 F	low satisfied	are you wit	th your sex life	?	2.85(1.1	5)	1	5	3	(2)	(2.61-3.09)
HRQoL.22 How satisfied are you with the support you get from your friends?			3.62(0.9)	2)	1	5	4	(1)	(3.43-3.82)		
HRQoL.23 How satisfied are you with the conditions of the place where you live?			3.84(0.8	6)	1	5	4	(1)	(3.66-4.02)		
HRQoL.24 How satisfied are you with the access you have to health services?			ou have to	3.63(0.9	3)	1	5	4	(1)	(3.43-3.83)	
HRQoL.25 H	How satisfied	are you wit	th your transp	ortation?	3.06(1.2	2)	1	5	3	(2)	(2.8-3.32)
HRQoL.26 How often do you have negative feelings, such as sadness, hopelessness, anxiety, depression?			, such as	3.38(1.0	3)	1	5	3	(1)	(3.16-3.6)	
QoL Global					62.25(14.	43)	25.96	95.19	61.54	(23.08)	(59.17-65.32)
Physical health				59.32(19.	72)	14.29	100.00	60.7	1(25)	(55.12-63.52)	
Psychologic	al health				68.39(17.3)		29.17	100.00	66.67	(29.16)	(64.7-72.08)
Social relationships			60.15(18.	61)	16.67	100.00	58.3	3(25)	(56.19-64.12)		
Environment		62.36(16.	07)	31.25	96.88	62.5(18.75)	(58.93-65.78)			
(n/%)	Physical	health	Psycholog	ical health	Social relatio	nships	Enviro	nment	Glo	bal	(95%) CI
Good	59	67.8	71	81.6	48	55.2	66	75.9	65	74.7	65.58-83.55
Bad	28	32.2	16	18.4	39	44.8	21	24.1	22	25.3	16.15-34.42

Source: the authors (2021).

 $\mbox{\it RI}$ - interquartile range, $\mbox{\it Me}$ - median, $\mbox{\it CI}$ - confidence Interval.

From the multivariate analysis, the following protective factors (PF) for QoL were identified: being male (protective factor of 2.73 [1/0.366]) and having companionship (protective factor of 3.08 [1/0.324]). In addition, the following risk factors (RF) were identified: having a low level of education conferred a risk of 5.052 for poor QoL, belonging to a low socioeconomic status conferred a risk of 3.315, and having a high level of disability conferred a risk of 3.145 (Table 3).

Table 3. Multivariate model with negative binomial regression

_				95% Wald confidence Interval for RP		
Parameter		Sig.	RP	Lower	Upper	
Age	Lower 26	0.097	8.094	0.686	95.511	
	27 - 59	0.119	3.517	0.722	17.125	
	Upper 60		1			
Occupation	Without resources	0.111	2.867	0.785	10.472	
	Non formal resources	0.845	0.901	0,318	2.555	
	Formal resources		1			
Educational level	Low	0.038*	5.052	1.095	23.319	
	Medium	0.136	3.082	0.701	13.556	
	High		1			
Sex	Man/Woman	0.012*	0.366	0.167	0.802	
Marital status	With company / Unaccompanied	0.015*	0.324	0.131	0.8	
Stratum	Low/Medium	0.036*	3.315	1.08	10.177	
SGSSS	Subsidized/ Contributory	0.079	0.5	0.231	1.082	
Etiology	Traumatic/ Non traumatic	0.784	0.848	0.261	2.756	
AIS	Incomplete/ Complete	0.114	2.24	0.825	6.087	
Body Image	Bad/Good	0.144	2.258	0.756	6.738	
Disability	High/Low	0.026*	3.145	1.144	8.649	
Functionality	Lower/More	0.767	1.152	0.452	2.931	
Time of injury in years		0.335	0.971	0.913	1.031	
Age of injury		0.393	1.022	0.972	1.074	

Source: the authors (2021).

*RP>1. Dependent variable - Quality of life; **RP<1. Model - (Intercept), age, employment status, educational level, sex, marital status, socioeconomic stratum, SGSSS, etiology, AIS, body image, disability, functionality personal care, functionality breathing and sphincter management, functionality mobility, time of injury in years, age of injury. a. set to zero because this parameter is redundant. b. set to the displayed value.

Regarding the dimensional analysis, the following was found: a) Physical health dimension: there is a 3.31 lower risk (CI 0.127-0.719) if the person is accompanied (1/0.302), a risk of 2.862 if they belong to a low socioeconomic status (CI 1.425-5.749), and a risk of 2.504 if they have a high level of disability (CI 1.167-5.373); b) Psychological health dimension: there is a risk of 6.523 if they have a complete injury according to AIS (CI 2.087- 20.385) and a risk of 1.054 if the age at injury is less than 12 years (CI 1.013-1.098); and d) Environment dimension: there is a risk of 10.250 if they are between 27 and 59 years old (CI 2.172- 48.377) and a risk of 4.106 if they belong to a low socioeconomic status (CI 1.330-12.677).

4. Discussion

People with SCI in Tunja report a good QoL, identifying female gender and living with others as protective factors. On the other hand, low socioeconomic status, low educational level, and high disability, understood as greater impairments and limitations, are identified as risk factors.

QoL considers human performance dimensions (physical, social, environmental, and psychological) that are influenced by socio-demographic and clinical variables. Therefore, a good QoL in people with SCI requires medical accompaniment, social support, and friends as part of the adaptations that favor the subject's autonomy and independence in the social world. Angulo et al.¹⁰ report factors that coincide with those of this study in Tunja, such as age, gender, occupation, especially in relation to low economic income. With increasing age, there is a negative relationship with QoL and well-being. In addition, aging does not significantly affect the perception of QoL; however, the longer the time since the injury, the better the environmental adaptations.

Anshu and Sundaravadhanan²⁶ point out that physical health is one of the most important domains of QoL, and in the case of the people of Tunja, high disability is a risk for good QoL. This is reinforced by the presence of a complete SCI, considering that the degree of improvement depends on the severity of the initial motor deficit. This is in line with Gándara-Sambade et al., who state that better improvement in walking with robotic devices is more evident when high AIS scores, incomplete injury, time elapsed postinjury, patient characteristics, and early rehabilitation are considered, while etiology, injury severity, age, and gender are less predictive of improvement²⁷.

In terms of gender, Laxe and Borda mention that being a woman favors greater tissue preservation in the event of injury due to the effects of progesterone. They also experience more chronic pain, which increases with age, as well as higher rates of depression, suicide, and neurogenic bladder and bowel among other complications, not just physical. For example, women have lower rates of return to work or work fewer hours, are less likely to be served by rehabilitation services, and require professional carers (men are cared for by family or wife)²⁸.

In contrast to what Kumar and Gupta²⁹ described, people in Tunja showed an association between QoL and age, marital status, AIS, and time and age at injury. In this vein, Mashola and Mothabeng¹⁴emphasize the importance of support from Friends and families for good QoL. This includes driving skills, which contribute to independence in activities of daily living³⁰.

5. Conclusions

The QoL in people with SCI in Tunja is perceived to be good, with body image not being associated with it. This study suggested that the level of disability and functionality can be a risk or protective factor, depending on whether they enable the person to perform activities. In addition, suffering from complete SCI and lacking financial resources can affect QoL. Limitations of the study include the fact that the sample is specific to Tunja, a Colombian city characterized by low crime rates, tranquility, and a low cost of living, with one of the lowest inflation rates in the country. Furthermore, it is mediumsized (between 100,000 and 500,000 inhabitants; Tunja reports 189,000 inhabitants in 2025). These characteristics may influence the perception of quality of life, so studies in other population groups are needed to obtain a broader perspective.

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Authors' contributions

The authors declared that they have made substantial contributions to the work in terms of the conception or design of the research; the acquisition, analysis or interpretation of data for the work; and the writing or critical review for relevant intellectual content. All authors approved the final version to be published and agreed to take public responsibility for all aspects of the study.

Competing interests

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