INFECTOLOGY

# A SCORING SYSTEM TO PREDICT THE RISK OF SURGICAL SITE INFECTIONS AFTER SPINAL SURGERY

SISTEMA DE PONTUAÇÃO PARA PREVER O RISCO DE INFECÇÕES LOCAIS DEPOIS DE CIRURGIA DA COLUNA

SISTEMA DE PUNTUACIÓN PARA PREDECIR EL RIESGO DE INFECCIONES LOCALES DESPUÉS DE CIRUGÍA DE LA COLUMNA

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## ABSTRACT

Objective: This retrospective clinical study was carried out to generate and cross-validate a scoring system for the identification of patients at risk of SSIs after spinal surgery. Methods: A retrospective study was conducted, which included patients who underwent spinal surgery. The potential variables for SSIs were extracted from the database, including preoperative, intraoperative and postoperative risk factors for univariate and multivariate regression analyses. Results: A total of 2347 patients were included in this retrospective clinical study. Postoperative SSIs were observed in 53 patients (2.2%). The multivariate logistic regression analysis revealed the following risk factors for SSIs after spinal surgery: diabetes mellitus (P=0.029), body mass index (P=0.008), low serum calcium concentration (P=0.012), low pre- and postoperative albumin (P=0.023, P=0.037), more than three operated segments (P=0.008), operation time of more than 180 minutes (P=0.019), estimated blood loss (P=0.011), low postoperative hemoglobin (P=0.017) and prolonged drainage time (P=0.025). Each of these factors contributed 1 point to the risk score. The predicted rates of incidence for the low-, intermediate-, high-, and extremely high-risk categories in the validation set were 1.4%, 12%, 41.6%, and 66.6%, respectively. Conclusions: Our scoring system allows for easy and validated risk stratification of SSIs after spinal surgery. **Level of evidence III; Cross-sectional Observational Study**.

Keywords: Surgical Wound Infection; Spine; Risk Factors; Risk Assessment.

## RESUMO

Objetivo: Este estudo clínico cruzado retrospectivo foi realizado para gerar e validar um sistema de pontuação para a identificação de pacientes com risco de ICL após cirurgia da coluna vertebral. Métodos: Foi realizado um estudo retrospectivo que incluiu pacientes submetidos à cirurgia de coluna vertebral. As possíveis variáveis para ICL foram extraídas do banco de dados, incluindo fatores de risco pré-operatórios, intraoperatórios e pós-operatórios para análises de regressão univariada e multivariada. Resultados: Um total de 2.347 pacientes foram incluídos neste estudo clínico retrospectivo. As ICLs pós-operatórias foram observadas em 53 pacientes (2,2%). A análise de regressão logística multivariada revelou os seguintes fatores de risco de ICL depois de cirurgia da coluna: diabetes mellitus (P = 0,029), índice de massa corporal (P = 0,008), baixa concentração sérica de cálcio (P = 0,012), albumina pré e pós-operatória baixa (P = 0,023, P = 0,037), mais de três segmentos operados (P = 0,008), tempo de cirurgia superior a 180 minutos (P = 0,025). Cada um desses fatores contribuiu com 1 ponto para o escore de risco. As taxas de incidência previstas para as categorias de risco baixo, intermediário, alto e extremamente alto no conjunto de validação foram 1,4%, 12%, 41,6% e 66,6%, respectivamente. Conclusões: Nosso sistema de pontuação permite uma estratificação de risco fácil e validada das ICLs depois de cirurgia da coluna. **Nível de evidência III; Estudo Observacional Transversal.** 

Descritores: Infecção da Ferida Cirúrgica; Coluna Vertebral; Fatores de Risco; Medição de risco.

# RESUMEN

Objetivo: Este estudio clínico cruzado retrospectivo se realizó para generar y validar un sistema de puntuación para la identificar pacientes en riesgo de IQL después de cirugía de columna. Métodos: Se realizó un estudio retrospectivo que incluyó pacientes sometidos a cirugía de columna. Las posibles variables de IQL se recopilaron de la base de datos, incluidos los factores de riesgo preoperatorios, intraoperatorios y posoperatorios para análisis de regresión univariados y multivariados. Resultados: Se incluyó un total de 2.347 pacientes. Las IQLs posoperatorias se observaron en 53 pacientes (2,2%). El análisis de regresión logística multivariante reveló los siguientes factores de riesgo de IQL después de cirugía de columna: diabetes mellitus (P = 0,029), índice de masa corporal (P = 0,008), baja concentración sérica de calcio (P = 0,012), albúrnina baja en el período pre y posoperatorio (P = 0,023, P = 0,037), más de tres segmentos operados

Study conducted at the Irkutsk State Medical University, Irkutsk, Russia.

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http://dx.doi.org/10.1590/S1808-185120212003251045

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(P = 0,008), tiempo de cirugía mayor de 180 minutos (P = 0,019), pérdida de sangre estimada (P = 0,011), hemoglobina postoperatoria baja (P = 0,017) y tiempo de drenaje prolongado (P = 0,025). Cada uno de estos factores contribuyó con 1 punto a la puntuación de riesgo. Las tasas de incidencia previstas para las categorías de riesgo bajo, intermedio, alto y extremadamente alto en el conjunto de validación fueron 1,4%, 12%, 41,6% y 66,6%, respectivamente. Conclusiones: Nuestro sistema de puntuación permite una estratificación de riesgo fácil y validada de las IQLs después de la cirugía de columna. **Nivel de evidencia III; Estudio observacional transversal.** 

Descriptores: Infección de la Herida Quirúrgica; Columna Vertebral; Factores de Riesgo; Medición de Riesgo.

#### **INTRODUCTION**

Surgical site infections (SSIs) are among the most common nosocomial infections, accounting for 14 to 16% of nosocomial infections overall and 38% of nosocomial infections among surgical patients.<sup>1,2</sup> SSIs can lead to prolonged hospitalization, increased morbidity and mortality, increased surgery-related costs, and decreased quality of life.<sup>3</sup> According to data from the National Nosocomial Infections Surveillance System (NNIS), approximately 1.2% of patients who underwent laminectomy and 12.4% of those who underwent the surgical procedure of spinal fusion developed SSIs.<sup>4</sup> The rate of SSIs in the literature ranges from 0.2% to 12.0%, depending on the type of surgical procedure, the diagnosis, and the use of instrumentation.<sup>5,6</sup>

It is well known that the variability in infection risk is related to the nature of the procedure, with more complicated spinal surgical procedures having higher infection rates.<sup>7</sup> Besides surgery-related factors, certain patient characteristics are also associated with increased risk for SSIs.<sup>8</sup> It is difficult to predict, before surgery, which patients are at risk of developing SSIs. Knowing about the risk factors for SSI after spinal surgical procedures can help policy-makers to plan preventive strategies to reduce the incidence of SSI.

The NNIS risk index was developed in the early 1990s and has been used to predict the risk of SSI across a broad range of surgical procedures.<sup>9</sup> The NNIS risk index score, which ranges from 0 to 3, reflects how many of the following risk factors are present: American Society of Anesthesiologists (ASA) preoperative score of III or higher, an operation classified as contaminated or dirty, and an operation lasting for over three hours.<sup>10</sup> The NNIS risk index is a general score, and has been criticized for being overly simplistic as it does not consider specific aspects of spinal surgery. One component of the NNIS risk index – duration of the surgical procedure – cannot be determined prior to surgery, so the score cannot be used for preoperative preventive measures.

It is necessary to identify more procedure-specific risk factors for use in risk adjustment and in the application of preventive measures for individual patients. The aim of this retrospective clinical study was to generate and cross-validate a scoring system for the identification of patients at risk of SSI after spinal surgery.

## **METHODS**

#### Study design and participants

This clinical study was approved by the ethics committee (Protocol # 53/4) of Irkutsk State Medical University (Irkutsk, Russia) and informed consent was obtained from all the patients before their participation. This was a retrospective study that included patients who had undergone spinal surgery between June 2011 and March 2020. The inclusion criteria were: (1) a diagnosis of cervical or thoracic lumbar spinal degenerative disease, such as spinal stenosis, disc herniation and spondylolisthesis, and vertebral fracture; (2) different surgical approaches; (3) elective, non-emergency surgical procedures. Cases of spinal infections, tumor, tuberculosis, or spinal deformity, combined with multiple fractures of the extremities and open spinal injury were excluded from this clinical study.

#### Variables and definitions

SSIs include superficial and deep infection. The definition of SSI comes from the guidelines published by the U.S. Centers for Disease

Coluna/Columna. 2021;20(3):212-6

Control and Prevention. In this study, SSI was specified as acute spinal infection within 30 days after lumbar spinal surgery. Patients who met one of the following criteria were diagnosed as having an SSI: (1) a wound presenting symptoms or signs of redness, swelling, fever, pain, tenderness on palpation and/or purulent drainage; (2) a positive abscess drainage culture; (3) a positive culture for fluid or tissue harvested from revision surgery; (4) confirmation by histopathologic and radiologic examinations; (5) SSI diagnosed by the surgeons and recorded in the medical records.

The potential variables for SSIs were extracted from the database. These include (1) preoperative factors (sex, age, body mass index, hypertension, diabetes mellitus, white blood cells, red blood cells, thrombocyte, total protein, hemoglobin, albumin, globulin, serum calcium, serum potassium, glycated serum protein), (2) intraoperative factors (number of operated segments, ASA (American Society of Anesthesiologists) classification, duration of operation, estimated blood loss, surgical procedure, allogenic blood transfusion) and (3) postoperative risk factors (white blood cells, red blood cells, thrombocyte, total protein, hemoglobin, albumin, globulin, serum calcium, serum potassium, glycated serum protein, drainage time) for univariate and multivariate regression analyses.

#### Statistical analysis

The continuous data were reported as the mean±SD and the differences between groups were analyzed using t tests. The categorical data are presented as a proportion percentage and were analyzed using the  $\chi^2$  test or Fisher's exact test. The covariates with *P*<0.05 in the univariate analysis were subsequently included in a multivariate binary logistic regression model. The variables that remained significant in the multivariate analysis were used to construct a scoring system to classify the patients into groups, according to their risk of SSI. The Hosmer-Lemeshow test was used to check the goodness-of-fit of the model and the predictive value of the multivariate model was expressed using the *c*-statistic. Statistical significance was defined as *P*<0.05. Statistical analysis was performed using SPSS 22.0 (IBM Corp. Armonk, NY) and Microsoft Office Excel 2016 (Microsoft Corp., Redmond, Washington).

#### RESULTS

A total of 2347 patients were included in this retrospective clinical study, following the inclusion and exclusion criteria. Of these, 998 (42.5%) were diagnosed with intervertebral disk herniation, 674 (28.7%) with different types of spinal spondylolisthesis, 427 (18.19%) with spinal stenosis and 248 (10.5%) with vertebral fracture. Postoperative SSIs were observed in 53 patients (2.2%) (46 – superficial SSIs and 7 – deep incisional SSIs): 38 males and 15 females, with an average age of  $56.5 \pm 11.3$  years.

Of these, the surgical procedures were as follows: 23 (43.3%) lumbar interbody fusion, 12 (22.6%) open transforaminal lumbar interbody fusion (O-TLIF), 3 (5.6%) minimally invasive transforaminal lumbar interbody fusion (MI-TLIF), 5 (9.5%) direct (lateral) lumbar interbody fusion (D(L)LIF), 3 (5.6%) anterior lumbar interbody fusion (ALIF), 9 (11.3%) thoracic spine fusion, and 21 (39.6%) posterior cervical fusion. A further 110 patients who had undergone spinal surgery during the same period, without any postoperative adverse events, were included in this retrospective clinical study for comparative analysis.

#### Preoperative risk factors for SSIs

Table 1 shows the preoperative characteristics of patients with and without SSIs. The univariate analysis revealed the following preoperative adverse risk factors for SSIs: diabetes mellitus (P=0.031), body mass index (P=0.016), low total protein (P=0.042), low hemoglobin (P=0.012), low albumin (P=0.004) and decreased serum calcium concentration (P=0.007).

#### Intraoperative risk factors for SSIs

Table 2 shows the results of the univariate analysis of intraoperative risk factors for SSI. The factor analysis included number of operated segments, ASA classification, duration of operation, estimated blood loss, surgical procedure and allogenic blood transfusion. There were statistically significance differences in the number of operated segments (P=0.003), ASA classification (P=0.044), duration of operation (P=0.027) and type of surgical procedure (P=0.035).

## Postoperative risk factors for SSIs

Table 3 shows the postoperative characteristics of patients in the two groups. The univariate analysis revealed the following

Table 1. Univariate analysis of preoperative risk factors for SSIs after spinal
surgery.

Risk factors	SSI group (n = 53)	Non-SSI group (n = 110)	Р
Sex, n (%)			0.992
Male	38 (71.6)	82 (74.5)	
Female	15 (28.3)	18 (16.3)	
Age, (years)	56.5±11.3	56.2±10.8	0.853
Body mass index, (kg/m <sup>2</sup> )	28,5±5.7	22.6±4.1	0.016
Arterial hypertension, n (%)	19 (35.8)	47 (42.7)	0.614
Diabetes mellitus, n (%)	12 (22.6)	21 (19)	0.031
White blood cells, (×10 <sup>9</sup> /l)	7.1±3.7	6.9±2.5	0.319
Red blood cells, (×10 <sup>12</sup> /l)	4.2±0.7	4.4±0.5	0.128
Thrombocyte, (×10 <sup>9</sup> /l)	215.7±69.9	213.4±67.7	0.937
Total protein, (g/l)	65.7±6.4	67.5±5.8	0.042
Hemoglobin, (g/l)	122.6±17.5	131.9±16.5	0.012
Albumin, (g/l)	38.8±3.8	41.4±3.7	0.004
Globulin, (g/l)	25.7±5.3	26.1±4.8	0.447
Serum calcium, (mmol/l)	2.27±0.16	2.39±0.11	0.007
Serum potassium, (mmol/l)	3.89±0.49	4.01±0.38	0.088
Serum glucose, (mmol/l)	5.88±2.37	5.48±2.41	0.154
Glycated serum protein, (mmol/l)	2.08±0.39	2.13±0.26	0.215

 Table 2. Univariate analysis of intraoperative risk factors for SSIs after spinal surgery.

Risk factors	SSI group (n = 53)	Non-SSI group (n = 110)	Р
Number of operated segments, n	2.1±1.1	1,4±0.7	0.003
ASA classification	2.4±0.5	2.3±0.5	0.044
Duration of operation, (minutes)	156.8±62.5	131.5±47.7	0.027
Estimated blood loss, (ml)	619.8±359.9	571.3±221.5	0.118
Type of surgical spinal procedure, n (%)			0.035
O-TLIF	12 (22.6)	26 (23.6)	
MI-TLIF	3 (5.6)	37 (33.6)	
D(L)LIF	5 (9.5)	10 (9.1)	
ALIF	3 (5.6)	5 (4.5)	
Thoracic spine fusion surgery	9 (11.3)	13 (11.8)	
Posterior cervical spine fusion surgery	21 (39.6)	19 (17.3)	
Allogenic blood fusion, n (%)			0.627
+	14 (26.4)	22 (20)	
	39 (73.5)	88 (80)	

postoperative risk factors for SSIs: serum concentrations of thrombocyte (P=0.017), hemoglobin (P=0.009), albumin (P=0.001), calcium (P=0.006) and drainage time (P=0.001).

# Multivariate logistic regression analysis

All related pre- intra- and postoperative risk factors resulting from the univariate analyses were included in the logistic regression model (Table 4). The multivariate logistic regression analysis revealed the following risk factors for SSI after spinal surgery: diabetes mellitus (P=0.029), body mass index (P=0.008), low serum concentration of calcium (P=0.012), low pre- and postoperative albumin (P=0.023, P=0.037), more than three operated segments (P=0.008), operation lasting more than 180 minutes (P=0.019), estimated blood loss (P=0.011), low postoperative hemoglobin (P=0.017) and prolonged drainage time (P=0.025). The Hosmer-Lemeshow test confirmed a good overall model fit ( $\chi^2$ =5.447, P=0.634). The model was highly discriminatory in our study population, with a c-statistic of 0.637 (P<0.001).

# A scoring system for SSIs after spinal surgery

Despite the differences in the logistic regression coefficients, which ranged from 0.719 to 1.376 for SSIs after spinal surgery procedures, respectively, for the sake of simplicity, one point was assigned for each of the risk factors. The resulting scores were built for SSIs after spinal surgery. Because only seven of the patients had ten points, the following four risk groups were established: low risk (0 points), intermediate risk (1-4 points), high risk (5-8 points), and extremely high risk (more than 8 points). In this retrospective study, the distribution of the patients according to the scoring system for SSIs was as follows: low risk – 35 (66.1%), intermediate risk – 12 (22.6%), high risk – 5 (9.4%), and extremely high risk – 1 (1.8%) (P=0.004) (Table 5).

 Table 3. Univariate analysis of postoperative risk factors for SSIs after spinal surgery.

Risk factors	SSI group (n = 53)	Non-SSI group (n = 110)	Р
White blood cells, (×10 <sup>9</sup> /l)	11.1±3.5	12.2±3.1	0.077
Red blood cells, (×10 <sup>12</sup> /l)	3.3±0.5	3.4±0.4	0.135
Thrombocyte, (×10 <sup>9</sup> /I)	221.7±93.3	189.7±68.5	0.017
Total protein, (g/l)	54.6±8.1	54.5±7.9	0.691
Hemoglobin, (g/l)	95.2±21.1	107.3±17.7	0.009
Albumin, (g/l)	38.8±3.8	41.4±3.7	0.004
Globulin, (g/l)	21.9±5.6	22.3±4.8	0.121
Serum calcium, (mmol/l)	2.09±0.17	2.18±0.13	0.006
Serum potassium, (mmol/l)	3.88±0.51	3.96±0.37	0.205
Serum glucose, (mmol/l)	6.51±1.92	6.45±1.74	0.088
Glycated serum protein, (mmol/l)	1.67±0.25	1.74±0.31	0.114
Drainage time (days)	2.89±1.03	2.36±0.92	0.001

 Table 4. Multivariate logistic regression analysis of risk factors for SSIs after spinal surgery.

Risk factors	Odds ratio [95% Confidence interval]	Regression coefficient	Р
Body mass index	1.19 [1.04–1.77]	0.905	0.008
Diabetes mellitus	2.18 [1.07-4.61]	0.719	0.029
Preoperative serum calcium	0.01 [0.001-0.39]	0.884	0.012
Preoperative serum glucose	1.12 [1.01-1.35]	1.225	0.072
Preoperative albumin	0.76 [0.55-0.99]	1.105	0.023
Number of operated segments	2.27 [1.47-3.51]	1.376	0.008
Duration of operation	1.29 [1.02-1.84]	1.145	0.019
Estimated blood loss	1.09 [1.01-1.07]	0.914	0.011
Postoperative hemoglobin	0.87 [0.77-1.01]	0.931	0.017
Postoperative albumin	0.68 [0.35-0.97]	0.768	0.037
Drainage time (days)	1.39 [1.04-2.08]	0.856	0.025

#### Discrimination

The final models discriminated the development sets with the areas under the receiver operating characteristic (ROC) curve. The area under the ROC curve was 0.727 (0.654-0.793) for the multivariate logistic regression model and 0.724 (0.655-0.787) for the simplified score for SSIs after spinal surgery (Figure 1). To evaluate the performance of the models, the observed versus predicted incidence rates in the validation set were compared. The predicted incidence rates for the low-, intermediate-, high-, and extremely high-risk categories in the validation set were 1.4%, 12%, 41.6%, and 66.6%, respectively. There were no statistically significant differences between the observed and predicted incidence rates for SSIs in the validation set (P>0.05).

 
 Table 5. A scoring system to predict the risk of surgical site infections after spinal surgery.

Risk groups	Risk scores	n (%)	n (%)	Odds ratio [95% Confidence interval]I	Р
Low	0	67 (60.9)	1 (1.4)	1 [-]	-
Intermediate	1-4	25 (22.7)	3 (12)	2.11 [1.48-3.89]	0.034
High	5-8	12 (10.9)	5 (41.6)	5.67 [2.53-10.93]	0.004
Extremely high	>8	6 (5.4)	1 (66.6)	33.74 [15.31– 69.87]	0.002

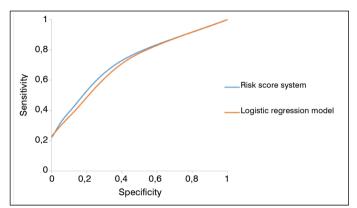


Figure 1. ROC curves for prediction of SSIs after spinal surgery in the development sets.

#### DISCUSSION

As already noted, SSIs after spinal surgery lead to increased morbidity, secondary surgical procedures, hospital readmissions, poorer clinical and radiological outcomes, and increased costs.<sup>11-13</sup> Many previous clinical studies have reported the prevalence and risk factors of SSIs after spinal surgery. Liu et al.,14 conducted a large-scale single-institution retrospective study including 2715 patients who underwent lumbar fusion surgery, and demonstrated that the prevalence of SSIs was 2.4%. The authors of that study also reported that diabetes mellitus, preoperative serum calcium, serum glucose, albumin, number of fused segments, surgical duration, estimated blood loss, postoperative hemoglobin, albumin and drainage time were significant risk factors for SSIs. A systematic review and meta-analysis by Fei et al.,15 included 12 studies. They reported that diabetes mellitus, prolonged operative times (>3 hours), body mass index (>35 kg/m<sup>2</sup>), posterior approach, and the number of intervertebral levels (≥7) are associated with an increased risk of SSIs after spinal surgery. According to a meta-analysis Peng et al.,<sup>16</sup> which included 26 observational studies, diabetes mellitus, body mass index (>30 kg/m<sup>2</sup>), arterial hypertension,  $\geq$ 3 hours operative

time and transfusion were closely associated with a remarkable increase in the risk of SSIs after spinal surgery procedures. Following previous clinical studies, the prevalence of SSIs after spinal surgery in our study, based on our study population of 2347 patients, was 2.2%. Our result concerning the risk factors of SSIs is consistent with those of previous studies.

Few articles have been designed to create a scoring system for predicting the risk of SSIs after different surgical procedures. Gervaz et al.,<sup>17</sup> illustrated a simple clinical score based on four preoperative variables (obesity, contamination class, ASA classification and open surgery), which was clinically useful in predicting the risk of SSIs in patients undergoing colorectal surgery. In a similar article Alavi et al.,<sup>18</sup> reported a simple risk score for predicting SSIs in inflammatory bowel disease. The authors of that clinical study showed that preoperative factors, including weight loss, smoking, emergent surgery and ASA classification >2, are strong predictors of SSIs. Moreover, operative time and wound class are important intraoperative predictors. Among these systems, the NNIS basic risk index is one of the most widely used to predict the risk of SSIs.<sup>19</sup> The NNIS basic SSI risk index consists of the following three criteria: ASA classification, wound class; and duration of operation. Unfortunately, the NNIS basic SSIs risk index might be not suitable for spine surgery.

To the best of our knowledge, no studies have been designed to develop a scoring system to predict the risk of SSIs after spinal surgical procedures. Our scoring system was based on the logistic regression model. For the risk stratification for SSIs, a scoring system classified the patients after spinal surgery into four groups - low, intermediate, high and extremely high. A scoring system to predict the risk of SSIs after spinal surgery discriminated the development sets with an area under the ROC curve of 0.724, which is similar to the logistic regression model. The scoring system did not show any statistically significant differences between the observed and predicted incidence rates in the validation set, indicating that the system performed well. Patient and disease parameters data are routinely available, which might have implications for selecting risk-adapted procedures to improve surgical safety. Since only the body mass index can be identified in the preoperative period, patients with obesity (>25 kg/m<sup>2</sup>) might be referred to surgeons with more experience, in order to reduce operation times and intraoperative blood loss. Also, if one or more of their other risk factors occurs intraoperatively or postoperatively, it is necessary to pay close attention to the signs and symptoms, conducting laboratory tests and radiological examinations in the postoperative period to ensure early detection and treatment of SSIs.

#### Limitations

This study has some limitations. First, as with other retrospective studies, inherent selective bias is inevitable, although we used a prospectively collected database. Second, data were acquired from hospitals and centers located in Russia, which use varying degrees of equipment and may not be generalizable. Broader representation would enhance the generalizability of the results to nonparticipating hospitals and surgeons.

#### CONCLUSIONS

Our scoring system allows for easy and validated risk stratification of SSIs after spinal surgery. This stratification might help in the selection of risk-adapted procedures to reduce the rates of SSI and improve surgical safety. A multicenter randomized controlled trial study with a large series would help validate this scoring system.

All authors declare no potential conflict of interest related to this article.

**CONTRIBUTION OF THE AUTHORS:** Each author made significant individual contributions to this manuscript. IAS: writing, data collection and analysis, intellectual concept, preparation of the whole research project and review; VAB: data collection and analysis; MAS: statistical analysis and review; EBB: review and intellectual concept.

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