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Predicting early complications in patients with spinal gunshot wounds: A multicenter study

Guillermo A. Ricciardi [a,*], Juan P. Cabrera [b,c], Oscar Martínez [d], Javier Matta [e], Hugo Vilchis [f], Jeasson Javier Perez Ríos [g], Charles A. Carazzo [h], Michael Dittmar [i], Ratko Yurac [j,k], the AO Spine Latin America Trauma Study Group

[a] *Orthopaedics and Traumatology, Centro Médico Integral Fitz Roy, Acevedo 865, C1414, Buenos Aires, Argentina*
[b] *Department of Neurosurgery, Hospital Clínico Regional de Concepción, San Martín 1436, 4070022, Concepción, Bío Bío, Chile*
[c] *Faculty of Medicine, University of Concepción, Janequeo esquina, Av. Chacabuco S/N, Concepción, Bío Bío, Chile*
[d] *Hospital Universitario Dr. José E. González, Av. Dr. José Eleuterio González S/N, Mitras Centro, 64460, Monterrey, N.L., Mexico*
[e] *Hospital Militar Central, v. 3C No. 49 – 02, CP 110231, Bogotá, Colombia*
[f] *Unidad Médica de Alta Especialidad, Hospital de Traumatología y Ortopedia, Lomas Verdes IMSS, Avenida Lomas Verdes 52, Sta Cruz Acatlan, 53150, Naucalpan de Juárez, Méx., Mexico*
[g] *Clínica de Columna "Dr. Manuel Dufoo Olvera", Calz. San Juan de Aragón 285, Granjas Modernas, Gustavo A. Madero, 07460, Ciudad de México CDMX, Mexico*
[h] *Neurosurgery, University of Passo Fundo, São Vicente de Paulo Hospital, R. Teixeira Soares, 808 - Centro, Passo Fundo, RS, 99010-080, Brazil*
[i] *Centro Médico Puerta de Hierro, Av. Empresarios, Puerta de Hierro, 45116, Zapopan, Jal., Mexico*
[j] *Department of Orthopedic and Traumatology, Universidad del Desarrollo, Av Plaza 680, 7610658, Las Condes, Región Metropolitana, Chile*
[k] *Spine Unit, Department of Traumatology, Clínica Alemana, Av Vitacura 5951, Vitacura, Región Metropolitana, Santiago, Chile*

A R T I C L E I N F O

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A B S T R A C T

Introduction: There is a wide variation in the clinical presentation of spinal gunshot wounds ranging from isolated minor stable fractures to extremely severe injuries with catastrophic neurological damage.
Research question: we aim to analyze the risk factors for early complications and impact of surgical treatment in patients with spinal gunshot wounds.
Material and methods: This is a multicentre retrospective case-control study to compare patients with spinal gunshot wounds who had early complications with those who did not. The following matching criteria were used: sex (1:1), injury level (1:1) and age (±5 years). Univariate and multivariate analyses were performed using logistic regression.
Results: Results: Among 387 patients, 36.9 % registered early complications, being persistent pain (n = 32; 15 %), sepsis/septic shock (n = 28; 13 %), pneumonia (n = 27; 13 %) and neurogenic bladder (n = 27; 12 %) the most frequently reported. After case-control matched analysis, we obtained 133 patients who suffered early complications (cases) and 133 patients who did not as control group, not differing significantly in sex (p = 1000), age (p = 0,535) and injury level (p = 1000), while the 35 % of complications group required surgical treatment versus 15 % of the non-complication group ($p < 0.001$). On multivariable analysis, significant predictors of complications were surgical treatment for spinal injury (OR = 3.50, 95 % CI = 1.68–7.30), dirty wound (3.32, 1.50–7.34), GCS ≤8 (3.56, 1.17–10.79), hemodynamic instability (2.29, 1.07–4.88), and multiple bullets (1.97, 1.05–3.67).
Discussion and conclusion: Spinal gunshot wounds are associated with a high risk of early complications, especially when spinal surgery is required, and among patients with dirty wound, low level of consciousness, hemodynamic instability, and multiple bullets.

* Corresponding author. Department of Orthopedic Surgery, Centro Médico Integral Fitz Roy, Argentina.
E-mail addresses: guillermoricciardi@gmail.com (G.A. Ricciardi), jucabrera@udec.cl (J.P. Cabrera), oamg67@hotmail.com (O. Martínez), jematta@yahoo.es (J. Matta), dr_hugovilchis@mac.com (H. Vilchis), jeasson62@gmail.com (J.J. Perez Ríos), cacarazzo@hotmail.com (C.A. Carazzo), dittmar@cdcolumna.com (M. Dittmar), ryurac@gmail.com (R. Yurac).

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1. Introduction

There is a wide variation in the clinical presentation of spinal gunshot wounds (SGW) ranging from isolated minor stable fractures to extremely severe injuries with catastrophic neurological damage (Bono and Heary, 2004; Jakoi et al., 2015; de Barros et al., 2014). SGW represents 17–21 % of all traumatic spinal injuries, being the third most common cause of spinal cord injury in the civilian population, after falls from heights and motor vehicle accidents (de Barros et al., 2014). Civilian victims are mainly young adult male patients with thoracic spinal injuries (Bono and Heary, 2004; Jakoi et al., 2015; de Barros et al., 2014; Jaiswal and Mittal, 2013).

It should be noted that several unique features differentiate the initial assessment and decision-making on SGW from other traumatic spinal injuries, such as determining its severity and prognosis should include a comprehensive description of projectile ballistics. Other variables requiring analysis in these cases are injury level, mechanical stability, dura-mater integrity, vertebral canal compromise, degree of tissue contamination, hollow viscous perforation, or associated non-spinal injuries (Jaiswal and Mittal, 2013).

In SGW several complications have been widely reported (de Barros et al., 2014; Jaiswal and Mittal, 2013; Sidhu et al., 2013). Some of them are related to penetrating trauma like sepsis, meningitis, or acute respiratory distress. Others are related to neurological damage, spinal injury causing instability or cerebrospinal fluid (CSF) leak, type of wound, projectile toxicity, and bullet migration. Finally, complications could be related to an associated spinal cord injury such as prolonged decubitus with pressure ulcers, pneumonia, among others (de Barros et al., 2014; Jaiswal and Mittal, 2013; Sidhu et al., 2013). Of note, pain is the most common complication after a SGW in long term follow-up patients (de Barros et al., 2014).

The most frequent surgical indications of SGW are neurological deterioration in patients with incomplete deficit, CSF leak, mechanical instability, toxicity, and risk of bullet migration (Bono and Heary, 2004; Jakoi et al., 2015; de Barros et al., 2014; Jaiswal and Mittal, 2013). However, the surgical treatment had been associated with higher complications rates compared to patients receiving conservative treatment (Sidhu et al., 2013). Therefore, this study aimed to analyze the risk factors for early complications and clinical impact of surgical treatment in patients with SGW.

2. Methods

This is a retrospective, multicenter, case-control, multivariate study of patients treated for SGW from registers of 12 Latin American institutions during the period from January 2015 to January 2022. This study was conducted in accordance with ethical standards and approved by the Ethics Committee (Approval number: OR23-00001) for multiple centers. Due to the retrospective nature of this study, informed consent was not deemed necessary. The ethical principles outlined in the Declaration of Helsinki were respected. All patients were anonymized with an identification number, and the investigators were blinded to their identity.

2.1. Study population

The study was conducted at every center enrolled according to the following inclusion and exclusion criteria:

- Inclusion criteria: adult patients (18–65 years old) with gunshot wounds to the spine who required either surgical or conservative treatment.
- Exclusion criteria: Patients with exclusive soft tissue injury.

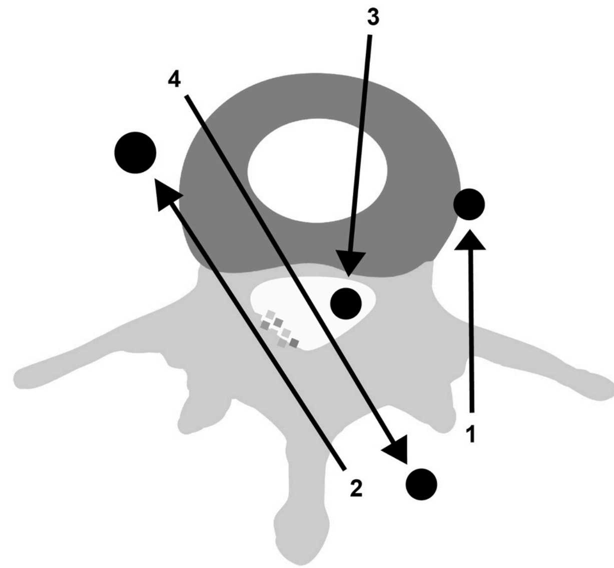

Fig. 1. Bullet trajectory according to the vertebral canal: 1) Non-penetrating; 2) Penetrating (tangential); 3) Penetrating; and 4) Transfixing. Adapted from Steverlynck et al.[9].

2.2. Study variables

Demographic and clinical characteristics were assessed, including age, sex, level of injury (cervical, thoracic, lumbosacral), bullet entry/exit, bullet trajectory, type of wound (clean/dirty), number of bullets and canal compromise, time to surgery, time from trauma to initial assessment, morbidity, Glasgow Coma Scale on arrival, hemodynamic status, concomitant injuries (count and types), abdominal organ perforation and neurological injury categorized according ASIA impairment scale (Kirshblum et al., 2014).

Early complications were considered as the primary endpoint – presence or absence – defining early complications those registered before of 90 days from the injury time and/or during the period from arrival to discharge. Complications were registered in numbers, percentages and classified in the following groups: clinical (systemic), related to the spine injury, related to the surgery, and others. Surgical complications were registered applying the Dindo-Clavien (DC) classification based on 5 grades according to the severity and type of intervention required to treat the complication (Dindo et al., 2004). The surgical treatment for the spinal injury was the main independent variable.

2.3. Matching

A matched case-control analysis was done. The control to case ratio was 1:1. The case group was defined as patients with a SGW who had at least 1 documented early complication. Controls were matched from patients with SGW who did not suffer any type of early complication, according to the following criteria: sex (1:1), age (±5 years) and injury level (1:1; cervical; thoracic and lumbosacral).

2.4. Definitions

Clean or dirty wound: SGW with concomitant visceral perforation or those injuries with significant soft tissue destruction as well as local tissue contamination were considered as dirty wounds (Mahmood et al., 2020).

Bullet trajectory: The bullet trajectory related to the vertebral canal was classified including, non-penetrating, penetrating (tangential), penetrant, or transfixing wounds according to the NOPAL classification (Fig. 1) (Steverlynck et al., 2001).

Table 1
Demographic and clinical characteristics of the patients (n = 387).

Variable		n (%)
Age; media ±SD (range)		32 ± 10.8 (18–71)
Sex	Female	54 (14)
	Male	333 (86)
Time from injury to admission (hours); median (range)		1 (0–96)
Referral from another center;	No	151 (39)
	Yes	159 (41.1)
Morbidities; median (range)		0 (0–3)
Injury level;	Cervical	86 (22)
	Thoracic	172 (44)
	Lumbosacral	129 (33)
Antibiotic prophylaxis;	No	25 (7)
	Yes	361 (93)
Bullet entry	Head	21 (5)
	Neck	72 (19)
	Thorax	159 (41)
	Abdomen	126 (33)
	Pelvis	8 (2)
	Multiple	1 (0.3)
Bullet exit	Head	2 (0.5)
	Neck	19 (5)
	Thorax	59 (15)
	Abdomen	37 (10)
	Pelvis	5 (1)
	Without bullet exit	264 (68)
Wound clean or dirty	Clean	304 (79)
	Dirty	82 (21)
Abdominal organ perforation	No	259 (67)
	Yes	127 (33)
Bullet location	Vertebral canal	57 (15)
	Vertebral body	33 (9)
	Posterior arch	26 (7)
	Disc	6 (2)
	Soft tissue	84 (22)
	Internal Organs	13 (3)
	Limbs	1 (0)
	Multiple locations	46 (12)
	None	120 (31)
Number of bullets; median (range)		1 (1–8)
AIS grade	A	184 (48)
	B	18 (5)
	C	45 (12)
	D	28 (7)
	E	81 (21)
	NT	20 (5)
Canal compromise	No	160 (41)
	Yes	226 (59)
Remains of splinters in the canal	No	228 (59)
	Yes	158 (41)
Bullet trajectory	Non penetrating	69 (18)
	Penetrating (tangential)	56 (15)
	Penetrant	81 (21)
	Transfixing	179 (46)
Hemodynamic instability	No	242 (63)
	Yes	144 (37)
Associated injuries	≤1	235 (61)
	2 or 3	103 (27)
	≥4	49 (13)
Glasgow coma scale	≤8	38 (11)
	>8	298 (89)
Treatment	Surgery	83 (21)
	Conservative	304 (79)

Hemodynamic instability: an abnormality of the circulatory system that results in inadequate organ perfusion and tissue oxygenation. For the purposes of the investigation, patients with a systolic blood pressure <90 mm Hg on arrival were considered (American College of Surgeons, 2018).

Associated injuries: other non-spinal penetrating injuries affecting the head, thorax, abdomen, or extremities were considered.

Table 2
Distribution of general complications (N = 143 patients).

Complications	n	%
Persistent pain	32	15 %
Sepsis/Septic shock	28	13 %
Pneumonia	27	13 %
Neurogenic bladder	25	12 %
Other	17	8 %
Wound infection	9	4 %
Cystitis/pyelonephritis	9	4 %
Pressure ulcers	9	4 %
Acute respiratory distress syndrome	7	3 %
Cerebrospinal fluid leak	7	3 %
Pleural effusion	6	3 %
Colonic perforation with abdominal sepsis	6	3 %
Gastrointestinal hemorrhage	5	2 %
Cutaneous fistula	4	2 %
Brachial plexopathy	4	2 %
Autonomic dysreflexia	3	1 %
Deep Venous Thrombosis	3	1 %
Meningitis	3	1 %
Spinal instability	2	1 %
Surgical site infection	2	1 %
Implant failure	2	1 %
Pyogenic spondylodiscitis	1	0,5 %
Pulmonary embolism	1	0,5 %
Pseudomeningocele	1	0,5 %
Multiple Organ Failure	1	0,5 %
TOTAL	215	100 %

Table 3
Distribution of 215 complications grouped from 143 patients.

Complications grouped	n	%
Clinical/Systemic	91	42 %
Spinal injury	71	33 %
Other	26	12 %
Penetrated trauma	23	11 %
Surgery	4	2 %
- DC Grade 1	2	50 %
- DC Grade 3	2	50 %

DC = Dindo-Clavien

2.5. Statistical analysis

Categorical variables were represented as counts, frequencies and analyzed by the Chi-Square method or Fisher's exact test. Numerical variables were described as mean or median, depending on normal or non-normal distribution, and its measure of dispersion as standard deviation (SD) and range values, respectively. Values of $p < 0.05$ were considered statistically significant. A multivariate binary logistic regression model was applied for the analysis of spinal injuries requiring surgical treatment and presence of early complications, including statistically significant variables from the bivariate analysis. SPSS Statistics 25 software (IBM, Armonk, NY) was used.

3. Results

A total of 410 patients were initially included according to our selection criteria. Of them, 23 patients were excluded after a time from injury to initial assessment greater than 96 h (n = 20), and incomplete medical records (n = 3). Therefore, a study population of 387 patients were successfully included (Table 1). A total of 143 patients (36.9 %) registered at least one early complication. Persistent pain, visual analogue scale >5 and/or continuous analgesic consumption, in 32; (15 %); sepsis/septic shock in 28 (13 %); pneumonia in 27 (13 %); and neurogenic bladder in 27 (12 %) as the most frequently reported complications (Tables 2 and 3).

After case-control matching, we obtained 133 patients who suffered

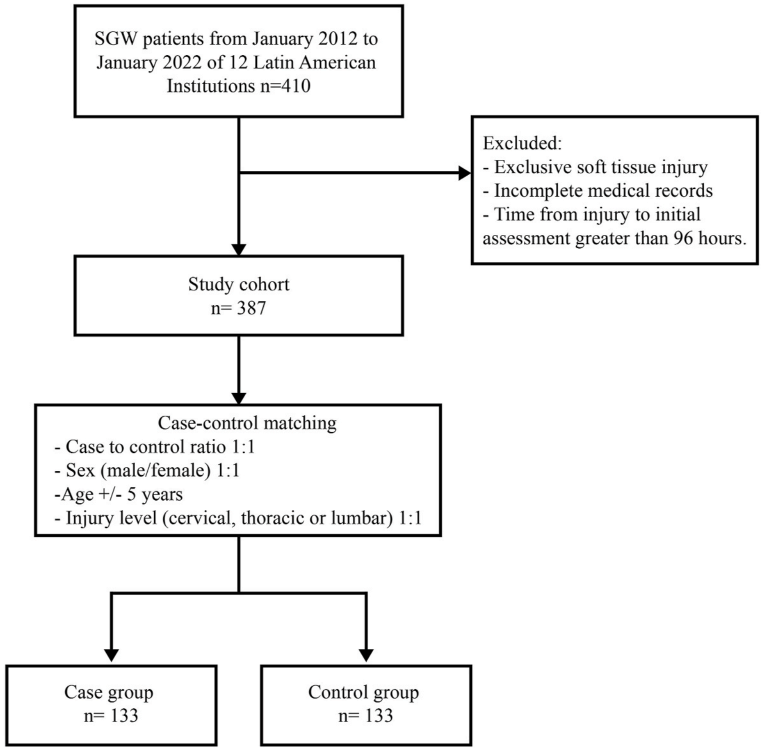

Fig. 2. Patients flowchart.

early complications (cases) and 133 patients who did not as control group (Fig. 2). Both groups did not differ significantly in terms of sex (p = 1000), age (p = 0,535) and injury level (p = 1000) (Table 4). Within surgical patients, time from injury to surgical intervention (hours) median was 36 h (range = 0–1608), without statically differences between case control groups (p = 0,115).

According to the bivariate analysis, statistically significant differences between the two groups have been observed for: 1) Type of wound "clean or dirty" ($p < 0.001$), 2) number of bullets (p = 0.002), 3) remains of splinter in the canal (p = 0.042), 4) bullet incidence (p = 0,005), 5) hemodynamic instability on arrival ($p < 0.001$); 6) Glasgow Coma Scale ≤8 ($p < 0.001$) and 7) spine injury surgical treatment ($p < 0.001$) (Table 4).

Spine surgery was associated with presence of early complications (OR = 3503; CI 95 % = 1680–7304; p = 0,001) according to our model. Nevertheless, other covariables also were related. According to our multivariate analysis "Dirty wounds" (OR = 3321; CI 95 % = 1502–7344; p = 0,003); number of bullets (OR = 1971; CI 95 % = 1058–3674; p = 0,033); Glasgow Coma Scale ≤8 on arrival (OR = 3566; CI 95 % = 1178–10,791; p = 0,024) and hemodynamic instability (OR = 2295; CI 95 % = 1078–3674; p = 0,031) were risk factors for early complications rates (Tables 4 and 5).

4. Discussion

Gunshot wounds continue to be one of the main causes of spinal cord injury and account for the third cause in civilian population (Bono and Heary, 2004; Jakoi et al., 2015). The National Spinal Cord Injury Statistical Center (NSCISC) described a peak of acts of violence (mainly gunshot wounds) between 1990 and 1999, declining to 14 % since 2013 to the present (Farmer et al., 1998; National Spinal Cord Injury Statistical Center, 2013; Spinal Cord Injury, 2016). On the other side, an increasing incidence of low-velocity SGW in low-income countries was described (de Barros et al., 2014; Villarreal-et al., 2022). Despite epidemiological differences, patients with SGW still represent a significant therapeutic challenge worldwide. SGW could be a life-changing event, especially in multiple trauma patients and those with neurological damage (McCunniff et al., 2017; Gjolaj and Eismont, 2015). It should be noted that, gunshot wounds may also include minor spinal injuries that are presumably much higher and underestimated among databases (Gjolaj and Eismont, 2015).

The initial assessment of SGW should be guided by a multidisciplinary team, addressing the Advance Trauma Life Support protocol, and including: emergency physicians, trauma, general and spine surgeons (Bono and Heary, 2004; Jakoi et al., 2015; de Barros et al., 2014; Escamilla et al., 2018). Associated injuries may have priority over SGW and spinal cord injury (de Barros et al., 2014). Antibiotic therapy for 48–72 h with broad-spectrum antibiotics should be immediately initiated in all cases (Bono and Heary, 2004; Jakoi et al., 2015; de Barros et al., 2014; Gjolaj and Eismont, 2015; Escamilla et al., 2018; Quigley and Place, 2006). The definitive treatment of spinal injury depends on multiple variables, and the amount of evidence to support surgical treatment remains unclear (Sidhu et al., 2013; Escamilla et al., 2018; Klimo et al., 2010; Platt et al., 2022). Surgical indications are: spinal mechanical instability; incomplete and/or progression over time of neurologic impairment; the presence of bullet fragments or any identifiable compressive cause in the vertebral canal; infection; the presence of persistent dural leaks; and metal toxicity (Bono and Heary, 2004; Jakoi et al., 2015; de Barros et al., 2014; McCunniff et al., 2017; Gjolaj and Eismont, 2015; Escamilla et al., 2018). SGW are usually described as stable injuries, so if mechanical instability is suspected it should be carefully evaluated with X-ray and computed tomography (de Barros et al., 2014; Escamilla et al., 2018).

The risk and benefits of surgical treatment is still a matter of debate (Sidhu et al., 2013; Nwosu et al., 2017; Bumpass et al., 2015). It is well known, that gunshot wounds to the spine have a high rate of complications (Sidhu et al., 2013; Nwosu et al., 2017). The last decade published case series, described an overall rate of complications between 36 and 45 % (Villarreal-et al., 2022; McCunniff et al., 2017; Escamilla et al., 2018; Nwosu et al., 2017; Bumpass et al., 2015; Beaty et al., 2014; Abbas et al., 2019; Gutierrez et al., 2020; Eftekhary et al., 2016; Sajid et al., 2020; Joseph, 2017; Ge et al., 2022). Bumpass et in a retrospective study

Table 4
Comparison according to the presence of complications.

Variables		Complications		P value
		Yes (n = 133)	No (n = 133)	
Age; media (SD; range)		32 (10; 18–65)	31 (10; 18–60)	0.535
Sex; n (%)		16 (14)	16 (14)	1.000
		117 (86)	117 (86)	
Time from injury to admission (hours); median (range)		1 (0–84)	1 (0,3–72)	0.833
Morbidities; n (%)	0	84 (65)	70 (54)	0.142
	1–2	41 (32)	52 (40)	
	>2	4 (3)	8 (6)	
Injury level; n (%)	Cervical	36 (27)	36 (27)	1.000
	Thoracic	58 (44)	58 (44)	
	Lumbosacral	39 (29)	39 (29)	
Antibiotic prophylaxis; n (%)	No	12 (9)	8 (6)	0.361
	Yes	121 (91)	124 (94)	
Bullet entry; n (%)	Head	13 (10)	5 (4)	0.225
	Neck	26 (20)	33 (25)	
	Thorax	52 (39)	52 (39)	
	Abdomen	40 (30)	40 (30)	
	Pelvis	1 (0,8)	3 (2)	
	Multiple	1 (0,8)	0 (0)	
Bullet exit; n (%)	Head	1 (1)	1 (0,8)	0.292
	Neck	6 (5)	10 (8)	
	Thorax	18 (14)	19 (14)	
	Abdomen	13 (10)	5 (4)	
	Pelvis	1 (1)	0 (0)	
	Without bullet exit	94 (71)	97 (73)	
Wound clean or dirty; n (%)	Clean	86 (63)	116 (88)	**<0.001**
	Dirty	49 (37)	16 (12)	
Abdominal organ perforation; n (%)	No	90 (68)	95 (72)	0.446
	Yes	43 (32)	37 (28)	
Bullet location; n (%)	Vertebral canal	25 (19)	18 (14)	0.314
	Vertebral body	10 (8)	14 (11)	
	Posterior arch	11 (8)	9 (7)	
	Disc	3 (2)	1 (0,8)	
	Soft tissue	30 (23)	25 (19)	
	Internal Organs	7 (5)	3 (2)	
	Limbs	0 (0)	1 (0,8)	
	Multiple locations	20 (15)	19 (14)	
	None	27 (20)	42 (32)	
Number of bullets; median (range)		1 (1–8)	1 (1–3)	**0.002**
AIS grade; n (%)	A	69 (53)	64 (49)	0.061
	B	6 (5)	8 (6)	
	C	12 (9)	21 (16)	
	D	11 (9)	6 (5)	
	E	19 (15)	27 (21)	
	NT	13 (10)	4 (3)	
Canal compromise; n (%)	No	45 (34)	58 (44)	0.092
	Yes	88 (66)	74 (56)	
Remains of splinters in the canal; n (%)	No	63 (47)	79 (60)	**0.042**
	Yes	70 (53)	53 (40)	
Bullet incidence; n (%)	Non penetrating	24 (18)	34 (26)	**0.005**
	Penetrating (tangential)	25 (19)	19 (14)	
	Penetrant	40 (30)	19 (14)	
	Transfixing	43 (32)	60 (46)	
Hemodynamic instability; n (%)	No	70 (52)	100 (76)	**<0.001**
	Yes	63 (48)	32 (24)	
Associated injuries; n (%)	≤1	74 (56)	82 (62)	0.162
	2 or 3	34 (26)	37 (28)	
	≥4	25 (19)	14 (10)	
Glasgow coma scale ≤8; n (%)	Yes	29 (26)	5 (5)	**<0.001**
	No	84 (70)	98 (95)	
Treatment; n (%)	Surgery	47 (35)	20 (15)	**<0.001**
	Conservative	86 (65)	113 (85)	

Table 5
Multivariate logistic regression analysis for risk factors of complications.

Variable	OR	95 % C.I.		
		Lower	Upper	p value
Spinal surgical treatment	3.50	1.68	7.30	0.001
Dirty wound	3.32	1.50	7.34	0.003
GCS ≤8	3.56	1.17	10.79	0.024
Hemodynamic instability	2.29	1.07	4.88	0.031
Number of bullets	1.97	1.05	3.67	0.033

Abbreviations: GCS = Glasgow Coma Scale; OR = Odds ratio; C.I. = confidence interval.

of 159 patients, had 45 % of patients who experienced at least 1 documented complication from their gunshot injury (Bumpass et al., 2015). Additionally, they estimated 24 % patients who suffered short-term complications (before 2 weeks post-injury) and 33 % with long-term complications (2 weeks postinjury). In our study, we had 36.9 % of patients who suffer almost 1 early complication (90 days postinjury) after a SGW, in line with the figures described above.

Several complications have been described in patients whose suffered SGW, related to associated lesions, vertebral and spinal cord injury. Neurogenic bladder seems to be the most common, followed by genitourinary infections and chronic pain (Sidhu et al., 2013). In our cohort, persistent pain (15 %) was the lion's share of complications, followed by sepsis/septic shock (13 %), pneumonia (13 %) and neurogenic bladder (12 %).

Greater complication rate in surgical patients was previously reported (Jakoi et al., 2015; Sidhu et al., 2013; Escamilla et al., 2018; Nwosu et al., 2017). A decade before, Sidhu et al. conducted a systematic review and summarized the results of 15 studies, arriving at the conclusion that complication rates were greater in the operative group of patients suffering SGWs. Nevertheless, the overall strength of evidence for an effective recommendation was very low (Sidhu et al., 2013). In an attempt to expand knowledge on this topic, in our study, we have estimated that spinal surgery was a risk factor for the presence of early complications (90 days) in patients who underwent SGW.

We described, through a multivariate analysis, other factors associated with suffering complications after SGWs (dirty wounds, a GCS ≤8, hemodynamic instability, and number of bullets). Some of these factors were previously mentioned in the literature (Bono and Heary, 2004; Jakoi et al., 2015; de Barros et al., 2014; Jaiswal and Mittal, 2013; Sidhu et al., 2013).

Dirty wounds have already been widely described as a cause of infectious complications (Dindo et al., 2004; Quigley and Place, 2006; Lin et al., 1995; Kumar et al., 1998; Rabinowitz et al., 2012). Commonly, "dirty wounds" were defined as those SGW associated with perforation of a hollow viscus, or those resulting from high-velocity firearms (Bono and Heary, 2004; Jakoi et al., 2015; de Barros et al., 2014; Lin et al., 1995; Kumar et al., 1998; Rabinowitz et al., 2012). There is a uniform consensus that a 48-h course of broad-spectrum antibiotics should be administrated as soon as possible to prevent deep infections of the spine. As well, there is no need for routine bullet removal or surgical debridement (Lin et al., 1995; Kumar et al., 1998; Rabinowitz et al., 2012).

To be unconscious (a GCS score of 8 points or lower) or to have hemodynamic instability (systolic blood pressure of 90 mmHg or lower) also were risk factors for complications in our retrospective study. Both factors were considered relevant physiologic parameters in multiple trauma patients on arrival (Pape et al., 2014).

Previously, Initial neurological injury was described as a risk factor for suffering complications, as more severe neurological damage could be associated with higher rate of complications (Bumpass et al., 2015). We have not found statistically significant differences between patients, with or without, documented early complications and the severity of initial neurological injury.

Finally, we do not believe that the surgical treatment of spinal injury is solely responsible for the higher rate of complications. Our results show a statistically significant association between suffering complications and variables that define a more complex clinical scenario (multiple bullets, dirty wounds, unconsciousness, hemodynamic instability). Although surgical treatment may play a role in increasing the risk of complications, it was not the only factor. Many of the risk factors mentioned above are related to the primary injury of penetrating trauma and have a significant physiological impact. Multi-center prospective cohorts are needed to accurately assess the risk of complications in this patient population.

4.1. Limitations

Our study has several limitations, which include the retrospective nature of data collection and a sizeable percentage of missing data for some variables. Additionally, the sample is difficult to compare due to the data being obtained from various countries. On the other hand, we conducted a multicenter case-control study that improved knowledge of the risk of surgical treatment of SGW, an important issue with an uncertain amount of evidence even today.

5. Conclusions

Spinal gunshot wounds are associated with a high risk of early complications. Surgical treatment should not be dismissed in comparison to conservative treatment for spinal injuries. This study suggests that the patients who experienced more complications were typically a more severe and complex group, more likely to have multiple, dirty gunshot wounds, hemodynamic instability and unconsciousness. In this complex clinical scenario, surgical management of spinal injuries was necessary and was likely to be involved in, but not necessarily the main cause of, complications.

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Declaration of competing interest

The authors have no conflicts of interest to declare.

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