

ARTICLE Surgical timing in traumatic spinal cord injury: current practice and obstacles to early surgery in Latin America

Alisson R. Teles 12.3^{III}, Miguel Bertelli Ramos 14, Orlando Righesso^{1,5} and Asdrubal Falavigna^{1,4,5}

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STUDY DESIGN: Cross-sectional.

OBJECTIVES: To evaluate current practice of Latin American spine surgeons regarding surgical timing in patients with traumatic spinal cord injury (tSCI) and to identify potential barriers for early surgery.

SETTING: Web-based.

METHODS: A web-based questionnaire was sent to members of AOSpine Latin America. Questions involved demographic features, familiarity with management of tSCI, and timing of surgery in various tSCI scenarios. The participants were also asked if they would like to operate earlier on patients with tSCI, indicating potential obstacles to early surgery.

RESULTS: A total of 307 surgeons answered the questionnaire. Early surgery (<24 h) is performed by 66.8% for ASIA A, 76.9% for ASIA B, and 76.9% for ASIA C/D injuries. For traumatic cauda equina syndrome (tCES), 85.2% performed surgery within 24 h. For traumatic central cord syndrome (tCCS) without osteoligamentous instability, only 31.5% performed surgery within 24 h and 41.2% follow-up on these patients, indicating surgery if no symptom improvement. Early surgery was performed always or in most cases by 50.4% and 41.8% of surgeons for incomplete and complete tSCI, respectively. The majority (85.4%) would like to operate earlier on patients with tSCI than they actually do. The most frequently perceived barriers to early surgery were difficulty of access to surgical implants (70.9%) and delay in patient transport to reference hospital for surgery (57.8%).

CONCLUSION: Latin American spine surgeons tend to operate earlier on patients with tCES and incomplete tSCI, then on those with complete tSCI and tCCS. The most reported obstacles for early surgery involved healthcare resources.

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INTRODUCTION

Traumatic spinal cord injury (tSCI) is a catastrophic event that affects patients' lives. Despite the recent advances in neuroprotective and neurodegenerative strategies, no pharmacological therapy has proved clinical efficacy to be implemented in routine clinical practice [1]. On the other hand, there is growing evidence demonstrating that timely surgical decompression and stabilization may improve neurological recovery by reducing secondary damage to the spinal cord [2–14]. In addition, potential benefits of early surgery include less complications, reduced length of hospital stay, and reduced costs [15, 16]. The concept of "time is spine" highlights this critical time window after the primary injury to the spinal cord during which secondary injury mechanisms may be minimized by therapies [17]. In fact, recent guidelines recommend surgical decompression and stabilization within 24 h of tSCI [18, 19].

Although early surgery is currently the only intervention that may improve neurological outcomes, it is estimated that only 39% of cervical and 45% of thoracic tSCI are operated within 24 h of injury in Canada [20]. Obstacles for early surgical intervention may be related to local healthcare resources or to patient variables, and they may vary in different healthcare systems and societies. International clinical practice variation and disagreement surrounding best practices in SCI have been previously investigated [21]. To date, there are no data regarding current practices in tSCI in Latin America. Identification of guideline adherence and obstacles for early surgery in tSCI may provide insights for education and address the needs for healthcare interventions in this continent.

Our goal was to evaluate current practice regarding surgical timing in patients with spine trauma with neurological involvement in Latin America. We also assessed potential barriers to early surgical intervention in this region.

METHODS

Portuguese and Spanish modified versions of a questionnaire published by Ter Wengel et al. [22] were used to evaluate surgical timing practices in patients with tSCI in Latin America. An e-mail request to participate in the survey was sent to members of AOSpine Latin America (AOSLA) with a cover letter explaining the objective of this study and an attached link to Survey Monkey. The Portuguese-language version was applied to Brazilian members. The link was available for 15 days, and reminders were sent three times in March 2019. Time to complete the questionnaire ranged from 5 to 10 min.

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¹Neurosurgery and Spine Program, Hospital Beneficente São Carlos, Farroupilha, RS, Brazil. ²Department of Neurosurgery, Hospital Mãe de Deus, Porto Alegre, RS, Brazil. ³McGill Scoliosis and Spine Group, Montreal, QC, Canada. ⁴University of Caxias do Sul, Caxias do Sul, RS, Brazil. ⁵Verti Spine Clinic, Caxias do Sul, RS, Brazil. ²⁶email: alisson.r.teles@amail.com

The electronic questionnaire contained topics regarding demographic features of participants (orthopedist versus neurosurgeon; spine fellowship; time of clinical practice; type of clinical practice), familiarity with

Table 1. General features of Latin American spine surgeons that participated in the survey (N = 307).

Variable	N (%)
Specialty	
Neurosurgery	133 (43.3)
Orthopedics	174 (56.7)
Spine fellowship training	
No	77 (25.1)
Yes	230 (74.9)
Duration of clinical practice	
<5 years	82 (26.7)
5–10 years	73 (23.8)
11–15 years	44 (14.3)
15-20 years	41 (13.4)
>20 years	67 (21.8)
Type of clinical practice	
Public	39 (12.7)
Private	70 (22.8)
Public and private	198 (64.5)
Number of tSCI treated per year	
Zero	5 (1.6)
<5	63 (20.5)
5–10	101 (32.9)
10–20	74 (24.1)
20–30	31 (10.1)
>30	33 (10.7)
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management of tSCI, and preferred timing of surgical decompression in patients with complete tSCI, incomplete tSCI, traumatic cauda equina syndrome (tCES), and traumatic central cord syndrome (tCCS). In addition, the participants were asked if they would like to operate earlier on patients with tSCI, and to indicate potential barriers to early surgery in these patients.

Statistical analyses were conducted with SPSS. Data were presented as number and percentage. Group comparisons were conducted with a chisquare test.

RESULTS

A total of 307 AOSLA members answered the electronic questionnaire, with a response rate of 24.3% (n = 307/1261). Table 1 presents the general characteristics of the respondents. Most participants were orthopedic surgeons (56.7%), spine fellowship-trained (74.9%), 49.5% had more than 10 years of clinical practice in spine surgery, and most had a mixed practice including public and private (64.5%). Regarding experience with tSCI, only 5 (1.6%) answered that they do not treat spine trauma, and most of the participants treat up to 10 cases per year (53.4%).

Current practice on surgical timing in traumatic spinal lesions with neurological involvement

Figure 1 shows the current practice regarding surgical timing for unstable tSCI, spine fractures presenting with tCES, and tCCS. Regarding unstable tSCI, Latin American spine surgeons report having operated on patients with incomplete SCI earlier than on those with complete injuries. Indeed, 66.8% reported performing early surgery (<24 h) for ASIA A, 76.9% for ASIA B, and 76.9% for ASIA C/D injuries. For tCES, 85.2% reported a surgical timing of less than 24 h. For tCCS without osteoligamentous instability, in turn, only 31.5% operate these patients within 24 h. Conversely, 41.2% reported following up on these patients and indicate surgery if there is no improvement in symptoms.

For incomplete and complete tSCI, 29.3% and 38.3% of respondents never or rarely perform surgery in less than 24 h of trauma, respectively. Early surgery, in turn, was performed always or in most of the cases by 50.4% and 41.8% of surgeons for incomplete and complete tSCI, respectively (Fig. 2).

tSCI traumatic spinal cord injury



Fig. 1 Surgical timing regarding severity and type of initial neurological injury in Latin America (*N* = 307). ASIA American Spinal Injury Association, tCES traumatic cauda equina syndrome, tCCI traumatic central cord injury, ER emergency room.

Surgical timing in relation to severity and type of initial neurological injury

Factors associated with early surgery in traumatic spinal lesions with neurological compromise

Table 2 presents factors associated with early surgery (<24 h) in patients with traumatic spine injuries presenting with neurological





involvement. It is observed that fellowship-trained spine surgeons are more likely to operate within 24 h in patients with incomplete tSCI ASIA C/D and tCES patients (p < 0.001). Surgeons practicing in public hospitals are less likely to operate within 24 h in all clinical scenarios (p < 0.01). No effect on surgical timing was observed in any of the clinical scenarios according to specialty (neurosurgery versus orthopedics), duration of practice, and volume of SCI per year.

Barriers to early surgery in traumatic spinal cord injury in Latin America

A total of 85.4% of the respondents stated that they would like to operate earlier on patients with traumatic tSCI than they actually do (Fig. 3). The most frequently perceived obstacles that delay the timing of the surgery were difficult access to surgical implants (70.9%) and delay in patient transport to a reference hospital to have surgery (57.8%). Only 11.6% of the participants believe there is not enough scientific evidence to support benefits of early surgery (<24 h) in tSCI.

Table 3 demonstrates the perceived barriers for early surgery in tSCI in Latin America stratified by surgical specialty, fellowship training, type of practice, duration of practice and number of tSCI treated per year. It is observed that neurosurgeons are more likely to report problems with spine implants compared to orthopedic surgeons (79.8% versus

Table 2. Early surgery (<24 h) for patients with traumatic spine injuries with neurological involvement stratified by characteristics of Latin American spine surgeons who participated in the survey (N = 307).

ASIA A	ASIA B	ASIA C/D	tCES	tCCS
66.7%	75.8%	77.5%	84.2%	33.9%
66.9%	77.7%	76.4%	86.0%	29.6%
0.970	0.714	0.835	0.672	0.453
68.2%	79.4%	80.8%	90.2%	32.4%
61.9%	68.3%	63.5%	68.3%	28.1%
0.349	0.064	0.004	<0.0001	0.534
51.4%	57.1%	54.3%	86.8%	23.5%
80.0%	91.7%	88.3%	90.0%	46.6%
65.4%	75.8%	77.5%	68.6%	28.0%
0.014	0.001	0.001	0.010	0.018
64.0%	73.3%	66.7%	81.3%	29.0%
68.2%	81.8%	84.8%	90.9%	36.5%
72.5%	85.9%	85.0%	87.5%	35.0%
65.8%	76.3%	73.7%	84.2%	21.1%
65.5%	70.7%	77.6%	82.8%	33.3%
0.915	0.368	0.075	0.547	0.529
75.95	82.8%	75.9%	84.5%	35.7%
61.1%	75.6%	77.8%	87.8%	34.5%
63.2%	75.0%	80.9%	86.8%	29.2%
83.3%	86.7%	80.0%	86.7%	32.1%
58.1%	64.5%	64.5%	74.2%	19.4%
0.072	0.228	0.475	0.454	0.541
	ASIA A 66.7% 66.9% 0.970 68.2% 61.9% 0.349 51.4% 80.0% 65.4% 0.014 64.0% 68.2% 72.5% 65.8% 65.5% 0.915 75.95 61.1% 63.2% 83.3% 58.1% 0.072	ASIA A ASIA B 66.7% 75.8% 66.9% 77.7% 0.970 0.714 68.2% 79.4% 61.9% 68.3% 0.349 0.064 51.4% 57.1% 80.0% 91.7% 65.4% 75.8% 0.014 0.001 64.0% 73.3% 68.2% 81.8% 72.5% 85.9% 65.8% 76.3% 65.5% 70.7% 0.915 0.368 75.95 82.8% 61.1% 75.6% 63.2% 75.0% 83.3% 86.7% 58.1% 64.5% 0.072 0.228	ASIA A ASIA B ASIA C/D 66.7% 75.8% 77.5% 66.9% 77.7% 76.4% 0.970 0.714 0.835 68.2% 79.4% 80.8% 61.9% 68.3% 63.5% 0.349 0.064 0.004 51.4% 57.1% 54.3% 80.0% 91.7% 88.3% 65.4% 75.8% 77.5% 0.014 0.001 0.001 64.0% 73.3% 66.7% 68.2% 81.8% 84.8% 72.5% 85.9% 85.0% 65.8% 76.3% 73.7% 65.5% 70.7% 77.6% 0.915 0.368 0.075 75.95 82.8% 75.9% 61.1% 75.6% 77.8% 63.2% 75.0% 80.9% 83.3% 86.7% 80.0% 63.2% 75.0% 80.9% 83.3% 86.7% 80.0%	ASIA A ASIA B ASIA C/D tCES 66.7% 75.8% 77.5% 84.2% 66.9% 77.7% 76.4% 86.0% 0.970 0.714 0.835 0.672 68.2% 79.4% 80.8% 90.2% 61.9% 68.3% 63.5% 68.3% 0.349 0.064 0.004 <0.001

Chi-square statistics. ASIA American spinal injury association, tCES traumatic cauda equina syndrome, tCCS traumatic central cord syndrome, tSCI traumatic spinal cord injury.

Bold values are the comparisons that reached statistically significant differences.



Fig. 3 Early surgery for traumatic spinal cord injury in Latin America. A Proportion of Latin American spine surgeons that would like to operate earlier on patients with traumatic spinal cord injury than they actually do and **B** perceived barriers to early surgery (N = 307).

Table 3. Perceived barriers to early surgery in Latin America stratified by characteristics ($N = 307$).					
	Spine implants	Patient transport	OR, anesthesia, or ICU	Insurance	No scientific evidence
Specialty					
Neurosurgery	79.8%	53.5%	28.1%	30.7%	7.9%
Orthopedics	64.3%	61.0%	44.2%	26.6%	14.3%
P value	0.006	0.217	0.007	0.464	0.106
Spine fellowship					
Yes	69.2%	56.4%	34.1%	28.9%	12.8%
No	77.2%	63.2%	49.1%	26.3%	7.0%
P value	0.238	0.359	0.038	0.700	0.226
Type of practice					
Public	70.6%	52.9%	44.1%	14.7%	11.8%
Private	63.3%	66.7%	31.7%	30.0%	16.7%
Both	73.6%	55.7%	37.9%	30.5%	9.8%
P value	0.322	0.277	0.468	0.167	0.354
Years of practice					
<5 years	71.6%	58.2%	41.8%	25.4%	11.9%
5–10 years	72.6%	62.9%	43.5%	32.3%	6.5%
11–15 years	70.0%	55.0%	25.0%	32.5%	7.5%
15-20 years	71.8%	56.4%	38.5%	30.8%	10.3%
>20 years	68.3%	55.0%	33.3%	23.3%	20.0%
P value	0.988	0.907	0.328	0.744	0.166
tSCI patients treated	d				
Zero	75.0%	75.0%	100%	50.0%	25.0%
<5 annually	67.3%	58.2%	41.8%	23.6%	16.4%
5–10 annually	72.4%	55.2%	35.6%	26.4%	12.6%
10–20 annually	73.8%	60.0%	32.3%	32.3%	7.7%
20–30 annually	69.2%	61.5%	38.5%	30.8%	7.7%
>30 annually	67.7%	54.8%	35.5%	29.0%	9.7%
P value	0.967	0.952	0.153	0.812	0.626

Chi-square statistics. OR operative room, ICU intensive care unit, tSCI traumatic spinal cord injury.

Bold values are the comparisons that reached statistically significant differences.

64.3%, p = 0.006). On the other hand, orthopedic surgeons were more likely to report difficulty in accessing the OR, anesthesia or ICU than neurosurgeons (44.2% versus 28.1%, p = 0.007). Hospital facilities were also pointed out as an obstacle to perform early surgery more frequently by surgeons who did not undergo fellowship training in spine surgery (49.1% versus 34.1%, p = 0.038).

DISCUSSION

In this survey, we identified current surgical practices for spine trauma in patients presenting with neurological impairment to the emergency department in Latin America. Overall, a clear distinction of surgical timing was observed according to the severity (*i.e.* ASIA score) of neurological impairment among Latin American spine surgeons. There is a tendency to operate earlier on patients with

371

372

Table 4. Surveys regarding the preferred/ideal and actual reported timing of surgery in various scenarios of traumatic spinal cord injury.

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Authors	Sample	Region	Surgery <12 h	Surgery <24 h			
Preferred/ideal surgical timing							
Fehlings et al. [23]	971	Worldwide	Cervical ASIA A: 65%	Cervical ASIA A: 85%			
			Cervical ASIA B/C/D: 87.5%	Cervical ASIA B/C/D: 80-96%			
			Thoracic ASIA B/C/D: 62%	Thoracic B/C/D: 85%			
			tCMS: 69%	tCMS: 90%			
			tCCS: N/Aª	tCCS: N/A ^a			
Glennie et al. [20]	31	Canada	Cervical A/B: 55%	Cervical A/B: 93%			
			Cervical C: 33%	Cervical C: 70%			
			Cervical D: 17%	Cervical D: 50%			
			Thoracic A/B/C/D: 49%	Thoracic A/B/C/D: 91%			
Wengel et al. [22]	88	Netherlands	ASIA A: 31%	ASIA A: 57%			
			ASIA B: 55%	ASIA B: 75%			
			ASIA C/D: 57%	ASIA C/D: 78%			
			tCCS: 25%	tCCS: 44%			
Actual surgical timing							
Werndle et al. [24]	79	UK	ASIA A: 29%	N/A ^a			
			ASIA B/C/D: 61%	N/A ^a			
Glennie et al. [20]	31	Canada	Cervical A/B: 27%	Cervical A/B: 56%			
			Cervical C: 13%	Cervical C: 52%			
			Cervical D: 6.5%	Cervical D: 32%			
			Thoracic A/B/C/D: 21.5%	Thoracic A/B/C/D: 71%			
Teles et al. (current article)	307	Latin America	ASIA A: 32%	ASIA A: 67%			
			ASIA B: 45%	ASIA B: 77%			
			ASIA C/D: 45%	ASIA C/D: 77%			
			tCES: 62.1%	tCES: 85.2%			
			tCCS: 16%	tCCS: 31.5%			

ASIA American Spinal Injury Association, tCMS traumatic conus medullaris syndrome, tCCS traumatic central cord syndrome, tCES traumatic cauda equine syndrome.

^aNumerical data not available.

incomplete tSCI or tCES than on those with complete tSCI (Figs. 1 and 2). Indeed, surgery within 24 h was performed in 67% for ASIA A, 77% for ASIA B, 77% for ASIA C/D, and 85% for tCES. Similarly, prior surveys regarding surgical timing for tSCI also showed that early surgery is more often preferred and performed for incomplete rather than for complete lesions - when these were analyzed separately [20, 22-24]. Table 4 details the ideal and actual reported surgical timing for tSCI in other surveys. Although different practices are reported regarding neurological impairment, current clinical practice guidelines (2017) do not make a distinction on surgical timing recommendations in regards to neurological level (i.e. cervical, thoracic or lumbar) and injury severity (i.e. ASIA score) in tSCI [19]. Although it is still controversial, recent studies have suggested that functional and neurological outcomes may be even better with ultra-early decompression (<12 h or less) [10, 25, 26]. Interestingly, a high proportion of Latin American spine surgeons (45%) reported that they operate within 12 h of injury on patients with incomplete tSCI.

We also evaluated the surgical timing of Latin American spine surgeons for two specific entities: tCES and tCCS. The frequency of early surgery within 12 h and 24 h was even higher for tCES compared to tSCI. (Fig. 1). Similarly, Fehlings et al. [23] showed that 69.4% and 89.6% of surgeons prefer to operate on patients with traumatic conus medullaris syndrome (tCMS) with sphicnteric dysfuntion within 12 and 24 h, respectively (Table 4). CES is usually recognized as a surgical urgency. However, while the current evidence supports improved functional outcomes of surgery

within 48 h for patients with CES, the benefits of earlier surgery (<24 h) are more controversial [27-32]. Of note, the traumatic etiology is usually not addressed separately in these studies. For tCCS without osteoligamentous instability, in turn, we observed a heterogeneous practice among Latin American spine surgeons, with only 31.5% of surgeons performing surgery within 24 h, 41.2% reporting that they do not operate during the same hospital stay, following-up these patients and performing surgery if there is no improvement in symptoms or deterioration. Ter Wengel et al. [22] as well as Fehlings et al. [23] also showed a heterogeneous and less urgent approach for these patients (Table 4). Not only the timing of surgery, but also the surgical management itself are controversial for tCCS without osteoligamentous instability, since patients can improve from baseline status during follow-up. In fact, a recent meta-analysis did not show superiority of the surgery versus conservative management as well as superiority of early over late surgery when this modality of treatment is chosen [33]. A clinical trial (NCT01485458 in ClinicalTrials.gov) evaluating early (<24 h) versus delayed surgery for cervical tSCI grade ASIA C without bone injury in patients with cervical canal stenosis is underway, which may help to guide future management. Despite the controversy and low quality of evidence, early surgery (<24 h) may be offered as an option for patients with acute tCCS according to recent AOSpine clinical practice guidelines [19].

According to the World Bank list of economies of June 2019, the majority of Latin American countries is considered middle-income,

including the most populous ones. A very representative fraction of the countries' populations is covered by public healthcare, being generally complemented by private healthcare [34, 35]. By covering a large portion of the population, public health services may be more subject to lack of advanced resources in the setting of tSCI (e.g. transport, ICU, dedicated spine surgeon, OR), potentially delaying the management. This can obviously vary among countries and even among regions of each country [36, 37]. Disparity among public and private health practices among patients with tSCI was observed in Latin America: surgeons practicing in public hospitals were less likely to operate on spine trauma with neurological involvement within 24 h (Table 2). Surprisingly, we did not identify any association between practice (public versus private) and self-reported obstacles to early surgery. Possibly our study lacks power to detect statistically significant differences in this issue. Of note, the majority of surgeons reported a mixed practice including the public and private sector, and only 12.7% working only in the public healthcare system. We believe that this issue has to be better evaluated taking into consideration the differences of healthcare systems among Latin American countries.

Awareness and education are important in clinician's adherence to healthcare guidelines [38]. However, we acknowledge that specific clinical practice guidelines should be implemented in Latin America in order to improve tSCI care, and these guidelines have to take into consideration the barriers for early surgery presented in each region. As the evidence for early surgery continues to improve [14], it is important to better educate health professionals that manage SCI. In our study, fellowship-trained spine surgeons were more likely to operate patients with incomplete tSCI ASIA C/D and tCES within 24 h, compared to surgeons who did not have a spine fellowship. Similar findings were identified among Dutch surgeons with spine specialization who more often preferred to operate tSCI patients within 24 h, regardless of injury severity (i.e. ASIA score), when compared to their non-specialized colleagues [22].

A mismatch of ideal versus actual timing of performing surgery for this population was observed in other international surveys (Table 4) [20, 22–24]. In Latin America, the majority of spine surgeons (85.4%) reported that they would like to operate earlier on their patients with tSCI (Fig. 2). On the other hand, a similar survey with 88 Dutch neurosurgeons showed that 62.5% (55/88) would not perform surgery for any type of tSCI in a more urgently than they actually do [22]. This discrepancy may be explained by the differences in healthcare systems and society.

Several studies have investigated reasons for surgical delay in tSCI in developed countries. Thompson et al. [39] observed that surgical delay in tSCI (>24 h after injury) was mainly healthcarerelated such as delay in transfer to the SCI center, delay before surgical plan completion (i.e. image exams), and waiting time for the operating room in the province of Quebec, Canada. In their analysis of 93 tSCI cases, no patient-related factors such as severity of trauma (i.e. Injury Severity Score), severity of injury (i.e. ASIA score) or age were related to surgical delay. Similar findings were reported by other authors [40, 41]. Glennie et al. [20] evaluated reasons for surgical delay in Canada. They identified the following reasons: lack of operating room availability (52%), delayed transport of patients from place of injury or other centers to the SCI center (28%), medical condition of patient (7%), lack of specialized operating room nursing teams (3%), and lack of surgeon availability on call (3%). Surprisingly, the most commonly reported obstacle for early surgical intervention among Latin American spine surgeons was access to spine implants, being pointed by more than 2/3 of them. Also, 37.3% reported having issues with OR availability, anesthesiology or ICU (Fig. 3). Interestingly, there were different complains according to surgical specially; in general neurosurgeons were more likely to report difficulty with spine implants than orthopedists, and orthopedists were more likely to report lack of OR availability (Table 3). It is possible that the historical differences in spine practice between these specialties still have an impact on current implant availability for neurosurgery programs.

We acknowledge that this survey presents limitations. First, despite the relatively large sample size, the participants may not represent the entire contingent of orthopedic surgeons and neurosurgeons that deal with acute SCI in the continent. However, our results certainly provide a baseline assessment and will be important for future comparisons. Second, the reported surgical timing might not always correspond to the actual timing in daily practice [20]. However, the present survey reflects the opinion of Latin American spine surgeons on current practice. In fact, there is a need to establish clinical registries in Latin America in order to gather better information on current practices for spine injuries [42].

CONCLUSIONS

This survey identified current practice regarding surgical timing in patients with spine trauma presenting with SCI, CES, and CCS. Latin American spine surgeons clearly have different approaches according to severity of injury (i.e. ASIA score). They tend to operate earlier on patients with CES and incompete tSCI, compared to patients with complete tSCI and tCCS. Spine fellowship-training was associated with a higher likelihood of indicating early surgery for incomplete tSCI and tCES. Besides education, professionals working in public health systems were less likely to operate within 24 h. We identified healthcare resources obstacles for early surgery for SCI in Latin America such as access to spine implants, OR, anesthesia team and ICU.

DATA ARCHIVING

The data and analyses performed in this study are available from the corresponding author on request.

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AUTHOR CONTRIBUTIONS

ART contributed to designing the study, elaboration of questions, statistical analysis, data extraction and interpretation and writing of the report. MBR contributed to data interpretation, confection of tables and figures, and writing of the report. OR contributed to designing the study, elaboration of questions, data interpretation, and provided feedback on the report. AF: contributed to designing the study, elaboration of questions, data interpretation of questions, data interpretation, and provided feedback on the report.

COMPETING INTERESTS

Alisson R. Teles received consulting fees from Medtronic, outside the submitted work.

STATEMENT OF ETHICS

We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

ADDITIONAL INFORMATION

Correspondence and requests for materials should be addressed to Alisson R. Teles.

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374