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ORIGINAL ARTICLE

Optimization of the mean arterial pressure and timing of surgical decompression in traumatic spinal cord injury: a retrospective study

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Study design: A retrospective comparative study.
Objectives: This study aims to investigate the extent to which early surgical decompression and maintenance of MAP ⩾85 mm Hg for 5 days postinjury affected neurological recovery utilizing internal controls for comparison of outcomes in patients with traumatic spinal cord injury.
Setting: Acute trauma center, Halifax, Nova Scotia, Canada.
Methods: We identified 94 cases of traumatic SCI. Follow-up data were available at an average of 26.7 ± 19.5, 115.0 ± 69.3, and 252.0 ± 152.8 days postinjury for 61, 48, and 47 patients, respectively. Neurological recovery was assessed using the American Spinal Cord Injury Association (ASIA) Impairment Scale (AIS).
Results: Patients with MAP <85 mm Hg for at least 2 consecutive hours during the 5-day period postinjury were 11 times less likely to have an improvement in the AIS grade when compared with patients with MAP ⩾85 mm Hg (P=0.006). This association was independent of early surgery or the severity of SCI. At a mean of 252.0 days postinjury, a significantly greater proportion of SCI patients treated with early surgical decompression (within 24 h) improved neurologically (P=0.031).
Conclusions: Our data demonstrated that there may be improved neurologic outcomes in patients with SCI who undergo early surgical decompression. Maintenance of MAP ⩾85 mm Hg for 5 consecutive days post-SCI was also associated with higher rates of AIS grade improvement at mean 26.7 days without a statistically significance difference at prolonged follow-up although a higher rate of neurological recovery persisted in patients with MAP ⩾85 mm Hg.
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INTRODUCTION

Traumatic spinal cord injuries (SCI) have a substantial economic and social impact on society.[1,2] There are about 250 000 individuals currently living with SCI in North America, with an annual incidence of 28–55 cases per million people.[3] The lifetime cost estimates are on the order of $500 000 to $2 million per individual, amounting to an overall annual health care cost of $7 billion in the United States.[4] Therefore, there is tremendous interest in the clinical community to investigate factors that alter the neurologic and functional outcomes of patients with acute SCI.[5]

Acute care for patients with SCI requires multifaceted management consisting of both medical and surgical interventions. The American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), the SCI Solutions Network, and the Consortium for Spinal Cord Medicine (CSCM) have published guidelines on the acute medical and surgical management of SCI.[6–9] A subset of these recommendations supported maintenance of the mean arterial pressure (MAP) between 85 and 90 mm Hg postinjury. Clinical evidence underlying this recommendation is derived from noncontrolled case series in which MAP was aggressively maintained ⩾85 mm Hg for 5–7 days post-SCI.[10–12] A more recent publication by Hawryluk *et al.* suggested that a greater proportion of patients with SCI and associated neurologic improvement was noted, when MAP was maintained for an average reading above 85 mm Hg.[13]

Human and animal studies suggest that early surgical decompression in acute cervical and thoraco-lumbar cord injuries improves neurologic outcome and aids recovery.[1,14–19] The most commonly used definitions of early surgery were either within 24 or 72 h postinjury.[17,19–24]

In this study, we aim to evaluate the role of such medical and surgical interventions in improving the clinical outcomes in SCI. This study provides description of the natural history of neurologic recovery in different SCI subtypes and highlights the impact of early surgical decompression (within 24 h) and maintenance of MAP ⩾85 mm Hg on neurologic outcome.

METHODS

Study sample

All trauma patients in the province of Nova Scotia with an injury severity score (ISS) >12 are prospectively identified through hospital admission records and entered into a centrally administrated registry. Queen Elizabeth II Health Sciences Center in Halifax represents level I trauma center for the province of Nova Scotia and receives all cases of traumatic SCI from different emergency departments across the province. Using the centralized trauma database,

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we identified patients coded as traumatic SCI presenting between 2006 and 2010. A retrospective chart review was then completed.

Timing to surgery and blood pressure parameters

Time to operative intervention was defined as the time between the initial call from the site of injury to emergency medical services (EMS) and the time of entering the operating room. In keeping with the evolving literature regarding the timing of surgical intervention,[14,20] we defined 'early' surgical decompression as surgery within 24 h postinjury and 'late' surgery being past 24 h.

Preoperative hypotension was defined as a single-documented systolic blood pressure of <90 mm Hg, as described in the literature.[6] Hourly MAP measurements are routinely recorded in the ICU by cardiovascular telemetry using a pressure transducer connected to an arterial line. The ICU in our institution utilizes norepinephrine, as first line agent in the maintenance of hypertensive targets. This practice is derived from evidence extrapolated from a randomized controlled trial illustrating the lower frequency of adverse effects associated with norepinephrine, as compared with dopamine in the treatment of shock.[13] To rigorously examine the importance of MAP, we defined suboptimal MAP as measurements <85 mm Hg persisting constantly for >2 consecutive hours during the 5-day period postinjury. The 85 mm Hg cut-off is derived from a previous study by Vale and colleagues[10] arbitrarily targeting MAP >85 mm Hg in patients with SCI, reasoning that this MAP goal was the upper limit of normal for uninjured middle aged males. This also forms the basis of the clinical guidelines recommendation in respect to MAP support postinjury.[10–12]

Neurologic outcome and follow-up

The American Spinal Injury Association (ASIA) Impairment Scale (AIS) is a standardized neurologic assessment commonly used to define the extent and severity of SCI.[25–27] AIS assessments were performed at the initial admission to hospital, discharge from acute care, discharge from neurorehabilitation, and at follow-up after discharge from neurorehabilitation. Neurological improvement was defined as a change in AIS of $\geqslant 1$. Total ASIA motor score (AMS) represents the summation of motor scores derived from the AIS assessment, and correlates strongly with walking ability.[28] It was available from AIS assessments at initial admission and at discharge from acute care, with improvement in total AMS is defined as the difference between the two scores. When unavailable, AIS grades were derived based on documented neurologic examinations, including the key muscle groups that correspond to the ASIA levels and assessment of rectal tone, deep anal sensation, and sacral sensory sparing. Independent from the surgical team, the neurologic outcome (represented by all AIS assessment post-treatment) was evaluated by neurorehabilitation specialists.

Table 1 Demographic details of patients with SCI

Number of patients	94
Age range (y)	16–94
Mean age ± s.d. (y)	47.6 ± 20.7
Gender: Male:Female N (%)	74:20 (79:21)
Mechanism of Injury (%)	
MVC	26 (28)
ATV	11 (12)
Fall	45 (48)
Other	12 (13)
AIS grade (%)	
A	31 (33)
B	12 (13)
C	16 (17)
D	29 (31)
NA	6 (6)
Mean AMS ± s.d. (range)	44.9 ± 28.2 (0–99)
Mean ASS ± s.d. (range)	109.47 ± 56.6 (24–224)
Severity of injury N (%)	
Complete injury	31 (33)
Incomplete injury	61 (65)
NA	2 (2)
Site of cord injury N (%)	
Cervical cord	66 (70)
Thoraco-lumbar cord	28 (30)

Abbreviations: AIS, ASIA impairment scale; AMS, ASIA motor score; ASS, ASIA sensory score; ATV, all-terrain vehicle; MAP, mean arterial, pressure; MVC, motor vehicle collision; NA, not available.

Statistical analysis

Data analysis was performed using SPSS version 21.0. Results were either summarized as single proportions or as means with s.d. Differences of proportions of cases with SCI in study comparisons were assessed with the Pearson chi-squared test. For normally distributed data, two-sample student's *t*-test for independent samples. Alternatively, the Mann–Whitney U test was used. All levels of significance were two-tailed and set at $P<0.05$.

RESULTS

Descriptive data

A total of 164 cases with suspected SCI were identified. After excluding 6 deaths and 64 cases that were inappropriately coded as having SCI ($n=62$) or having incomplete medical records ($n=2$), 94 patients were included in the analysis. Table 1 provides SCI demographic features.

About 69% of patients were initially evaluated in an intermediate institution, which was associated with a significantly longer time-to-neurosurgical assessment when compared with patients directly transported to the trauma center (11.7 h ± 15.2 vs 2.2 h ± 2.7, $P<0.001$). Although prolonged transport through an intermediate institution was also associated with a greater time to surgical decompression compared to patients transported directly to the trauma center ((88.4 ± 158.2 h) vs (63.9 ± 76.6 h)), this difference was statistically insignificant ($P=0.85$).

Neurologic recovery in SCI

AIS assessments were performed at means 26.7 ± 19.5 days (at discharge from acute care), 115.0 ± 69.3 days (at discharge from neurorehabilitation), and 252.0 ± 152.8 days (at follow-up post-neurorehabilitation). During these follow-up periods, AIS grades were available for 61, 48, and 47 patients, respectively. The overall improvement rate in the AIS grade at means 26.7, 115 and 252 days postinjury was 20%, 31%, and 32%, respectively. About 21% of patients presenting with AIS grade A improved to other grades (B and C) at mean 26.7 days, whereas 40% and 33% of patients with AIS grades B and C, respectively, improved by $\geqslant 1$ grades. Although the difference in recovery rates between cervical and thoraco-lumbar cord injuries was not significant ($P>0.05$), patients with cervical cord injuries demonstrated higher rates of neurologic improvement compared with patients with thoraco-lumbar cord injury, which was sustained at means 26.7, 115.0, and 252.0 days. Of note, AIS grade A cervical cord injuries demonstrate a higher rate of improvement at mean 252.0 days (31%), when compared with thoraco-lumbar cord injuries with grade A (9%). Among patients with thoraco-lumbar cord injury, about 91% of cases with AIS grade A demonstrated no improvement at mean 26.7 days postinjury, with lack of significant improvement sustained at mean 252.0 days, compared with AIS grades B and C, all of whom improved by at least 1 grade at mean 252.0 days (Table 2).

Table 2 Ordinal AIS grade changes at mean follow-ups 26.7, 115, and 252 days (rows), compared with initial AIS grade at presentation (column)

Overall study sample

	26.7 days (n = 61)				*115 days (n = 48)*				*252 days (n = 47)*				
	A	B	C	D	A	B	C	D	A	B	C	D	E
A	19	3	2	0	14	2	2	0	13	2	0	1	0
B	0	6	1	3	0	2	3	4	0	0	1	6	0
C	0	0	6	3	0	0	3	4	0	0	1	4	0
D	0	0	0	18	0	0	0	14	0	0	0	18	1

Cervical cord injuries

	26.7 days (n = 39)				*115 days (n = 31)*				*252 days (n = 31)*				
	A	B	C	D	A	B	C	D	A	B	C	D	E
A	9	3	1	0	7	2	1	0	7	2	0	0	0
B	0	4	0	2	0	0	3	2	0	0	1	3	0
C	0	0	4	3	0	0	2	3	0	0	1	3	0
D	0	0	0	13	0	0	0	11	0	0	0	13	1

Thoraco-lumbar cord injuries

	26.7 days (n = 22)				*115 days (n = 17)*				*252 days (n = 16)*				
	A	B	C	D	A	B	C	D	A	B	C	D	E
A	10	0	1	0	7	0	1	0	6	0	0	1	0
B	0	2	1	1	0	2	0	2	0	0	0	3	0
C	0	0	2	0	0	0	1	1	0	0	0	1	0
D	0	0	0	5	0	0	0	3	0	0	0	5	0

Timing to surgical decompression

Surgical decompression was performed in 75 patients as opposed to 19 patients treated non-surgically. Of those who did not receive surgical decompression, 37% ($n=7$) were identified as having central cord syndrome. Data on the timing to surgical decompression were available in 56 cases, with 23 patients treated within 24 h (early decompression), and 33 patients after 24 h (late decompression). The average time from injury to surgical decompression was 13.4 ± 5.0 h (range, 5.6–20.9) and 127.7 ± 165.4 (24.1–212.5) h for the early and late groups, respectively. The proportion of patients with complete cord injury was equally distributed between the early (40.9%) and late (40.6%) surgery groups. Comparing all cases with SCI in the early and late surgery groups, there was no statistically significant difference in the rate of AIS grade improvement at means 26.7 (26.3 vs 16.7%, respectively, $P=0.44$) and 115.0 days (35.7 vs 27.8%, respectively, $P=0.63$). However, at mean 252.0 days, 47% of patients with SCI (including cervical and thoraco-lumbar cord injuries) in the early surgery group demonstrated significant improvement in AIS grade, compared with 13% of patients in the late surgery group ($X^2=4.7$, $P=0.031$). In cervical SCI, including both complete and incomplete injuries, subgroup analysis showed that 60% of patients in the early surgery group improved $\geqslant 1$ AIS grades at mean 252.0 days, compared with 20% in the late surgery group ($X^2=3.3$, $P=0.06$). Similarly, higher proportions of patients with cervical SCI in the early surgical group demonstrated improvement at 26.7 (33 vs 27%) and 115.0 days (50 vs 39%), although differences were not significant ($P=0.7$ and $P=0.6$, respectively). The proportion of complete injuries was equally distributed between the early and late surgery groups in cervical SCI ((33%) vs (29%), respectively, $P=0.76$).

In thoraco-lumbar cord injuries, the early surgery group included 7 patients compared with 9 patients in the late group. At mean 27.7 days postinjury, the AIS grade improved in only 14% ($n=1$) with early surgery compared with none in the late surgery group ($P=0.2$). The rate of improvement increased to 29% ($n=2$) in the early surgery group at mean 252 days with no improvement in the late surgery group ($P=0.15$).

Cardiovascular management

Approximately 47% of all patients with SCI in our cohort were admitted to the intensive care unit, and 98% of these patients had serial MAP recordings. MAP measurement was performed in 84% and 36% of complete and incomplete SCI, respectively. In patients without MAP monitoring, 50% had AIS grade D on admission. Among those patients with serial MAP measurement, 82% ($n=41$) failed to meet the MAP goal of not <85 mm Hg for over any 2-h period during the 5-day duration post-SCI (Table 3). Failure to meet the targeted MAP goal was associated with lack of improvement in the AIS grade at mean 26.7 days postinjury, compared with patients with MAP $\geqslant 85$ mm Hg. Among patients with MAP <85 mm Hg, 89% failed to demonstrate improvement in the AIS grade at mean 26.7 days, compared with 43% with MAP $\geqslant 85$ mm Hg ($P=0.006$, Fisher's Exact $P=0.018$). The odds ratio for no neurologic improvement at mean 26.7 days in patients with MAP <85 mm Hg was 11.1 (95% CI, 1.6–75.6) with a relative risk of 2.1 (95% CI, 1.1–6.0).

The rate of mean total AMS improvement at mean 26.7 days postinjury was significantly higher in patients with SCI with MAP $\geqslant 85$ mm Hg, compared with patients with MAP <85 mm Hg ((22.5 ± 30.9) vs (3.1 ± 23.2), respectively, $P=0.048$). Although there was no significant difference between the two MAP groups at later follow-up periods, a higher total AMS persisted in patients with MAP $\geqslant 85$ mm Hg (Table 3).

In subgroup analysis of patients with cervical SCI, the difference in neurologic outcome between the two MAP groups was also prominent, with 83% of patients with cervical SCI failing to show AIS grade improvement when associated with MAP <85 mm Hg, compared with 12% of cases with MAP sustained at $\geqslant 85$ mm Hg. However, this difference did not reach our threshold for significance ($P=0.051$; OR 7.5, CI 95% 0.9–66.1).

When allowing for interaction between MAP <85 mm Hg and other variables including age, early surgery, and an initial systolic blood pressure <90 mm Hg, a similar observation was encountered with MAP <85 mm Hg being significantly associated with lack of neurologic improvement at average 26.7 days (OR $=0.045$, 95% CI, 0.01–0.78, $P=0.033$), but not at 115.0 and 252.0 days. In this multivariate analysis, age, early surgery, and an initial systolic blood pressure <90 mm Hg were not significantly associated with AIS grade improvement ($P>0.05$).

DISCUSSION

Natural history of SCI

We found that about one in five patients with SCI and AIS grade A improved into grade B or C at mean 26.7 days. Our series reflects a higher rate of AIS grade A improvement (21%), compared with the improvement rate of 10–15% previously reported in the literature.[4] In addition, one in three patients with complete cervical injuries improved, whereas only one in eleven with complete thoraco-lumbar SCI cases improved. Only one in fourteen patients with cervical AIS grade D converted to grade E at mean 252.0 days, indicating that

Table 3 Neurologic outcome in patients with different MAP parameters 5 days postinjury or surgical decompression

	MAP status	
	<85 mm Hg n = *41*	*⩾85 mm Hg* n = *9*
Severity of SCI		
Complete *N*	22	4
NA *N*	1	1
Timing of surgery		
Early	15	4
Pre-hospital SBP		
<90 mm Hg *N*	7	2
Lack of neurologic improvement in SCI % (n)		
At 26.7 d ($n=35$)	89% (25/28)	43% (3/7)
At 115 d ($n=27$)	73% (16/22)	40% (2/5)
At 252 d ($n=25$)	71% (15/21)	25% (1/4)
Total AMS improvement in all cases mean ± s.d. (n)		
At 26.7 d ($n=26$)	3.1 ± 23.2 (22)	22.5 ± 30.9 (4)
At 115 d ($n=21$)	2.7 ± 11.0 (17)	7.8 ± 26.7 (4)
At 252 d ($n=13$)	15.5 ± 21.6 (12)	42.0 ± (1)
Lack of neurologic improvement incervical SCI		
At 26.7 d ($n=23$)	83% (15/18)	40% (2/5)
At 115 d ($n=17$)	54% (7/13)	50% (2/4)
At 252 d ($n=15$)	58% (7/12)	33% (1/3)

Abbreviations: AMS, ASIA motor score; MAP, mean arterial pressure; NA, not available.

patients with AIS grade D rarely improve to baseline (that is, AIS grade E). Our data also demonstrate a high recovery rate in patients with SCI and AIS grade B: 100% of these patients converted to AIS grades C or D, which is in keeping with previous reports of a significant recovery of substantial motor strength in patients with sacral sparing (that is, AIS grade B).[29,30]

Timing of surgery

The recent Surgical Timing in Acute Spinal Cord Injury Study (STASCIS) study demonstrated significant improvement in the AIS grades of patients with traumatic SCI after 'early' surgical decompression (24 h of injury).[20] About 20% of patients treated early showed 2 or more AIS grade improvements, compared with 9% in the late surgery group (OR = 2.6, 95% CI: 1.1–6.0). Factors that could contribute to late surgical decompression include delayed transportation to level I trauma centre. Our findings suggest that patients assessed at an intermediate institution were fivefold delayed in their arrival to trauma centre. Early surgery (<24 h) was significantly associated with a higher rate of neurologic improvement in SCI, compared with late surgery (⩾24 h) (47 vs 13%, respectively). Interestingly, this difference was statistically significant only at mean 252 days postinjury, which is consistent with the results of STASCIS demonstrating increased rate of neurologic improvement at mean 4 months, and suggests that neurologic improvement as a result of early surgery might be more prominent at ⩾4–6 months postinjury.

Cardiovascular management

Augmentation of MAP in the initial management of SCI has been recommended by the AANS/CNS, the SCI Solution Networks, and the CSCM.[6–9,31,32] The first investigation to suggest an effect of MAP on outcome was by Levi and colleagues,[11] utilizing intravenous fluids, dopamine, and dobutamine to maintain MAP >90 mm Hg in 50 patients with acute cervical SCI. The authors included cases with complete SCI, as well as severe hemodynamic deficits (defined by pulmonary and systematic vascular resistance), which were found to have worse neurological outcomes. However, they were unable to account for the potential confounding effect of late surgical decompression and severe SCI, which could account for worse neurologic outcomes. Vale and colleagues[10] administered fluids, dopamine, and norepinephrine to maintain an arbitrarily selected MAP >85 mm Hg for an average of 7 days, reasoning that this MAP goal was the upper limit of normal for uninjured males aging between 15 and 30 years. The authors reported high rates of neurologic recovery and suggested a role of increased MAP in improved neurologic outcomes. The duration of hypertensive treatment in the literature is variable, as two studies instituted a 7-day treatment duration,[10,11] whereas one study maintained hypertensive treatment for 5 days postinjury.[12] This time window was chosen on the basis of traumatic spinal cord studies suggesting that spinal cord edema peaks between 3 and 5 days,[33] which prompted us to retrospectively evaluate the MAP measurements in this study within 5 days postinjury.

Hawryluk and colleagues retrospectively identified 100 patients with SCI, with MAP data and neurologic outcomes being available in 71 patients.[13] The study sample was divided into three outcome groups including patients with no neurologic improvement ($n=35$), patients with 1 AIS grade improvement ($n=23$) and patients with >1 AIS grade improvement ($n=13$). During the 5-day period postinjury and whilst targeting a MAP of at least 85 mm Hg, all three groups were found to have an average MAP >85 mm Hg. However, patients lacking neurologic improvement had a higher proportion of MAP values below 85 mm Hg. There was a high proportion of patients with AIS grade A in the no-improvement group (23 out of 35 patients, 66%), which was statistically greater than patients improving by 1 AIS grade and >1 AIS grades with complete injuries constituting 13% and 23% of these groups, respectively. The authors excluded patients with AIS grade A ($n=29$), demonstrating similar results but without accounting for the higher proportion of patients with AIS grade D (48%) in the group improving by 1 AIS grade ($P=0.016$). Exclusion of complete injuries from outcome analysis resulted in the reduction of sample size down to 45 patients subdivided into the three outcome groups. Our study suffers similar limitations in relation to a small sample size and smaller numbers of patients available for comparison in different MAP groups, which represents one of the limitations of retrospective studies

Inotrope-driven hypertensive treatment post-SCI is not entirely benign. According to one multi-centre randomized study of patients with shock, dopamine was significantly associated with a higher rate of arrhythmic complications compared to norepinephrine.[34] However, few studies described dopamine and phenylephrine as the most commonly used first-line agents in SCI with adverse events including ventricular tachycardia occurring in about two-thirds of patients.[35–37] Our study demonstrated that SCI cases failing to meet the foregoing MAP goals were 11 times less likely to exhibit neurologic recovery (defined as AIS grade ⩾1), which was independent of confounding factors such as the severity of SCI and late surgical decompression. Patients with MAP ⩾85 mm Hg had a statistically significant seven-fold improvement in their total AMS, compared with patients with MAP <85 mm Hg. The difference in AIS grade was significant only at 1 month postinjury; although the difference in outcomes was not significant at subsequent follow-up (mean 115 and 252 days),

there was a higher rate of lack of neurologic improvement in SCI cases with MAP < 85 mm Hg. These data suggest that neurologic recovery maybe associated with hypertensive treatment post-SCI, regardless of the severity of SCI or timing of surgical decompression. In addition, these results are based on a strict definition of MAP being no less than 85 mm Hg for any 2-h period over 5 days post-SCI. A randomized controlled trial is currently randomizing patients into two groups of MAP maintained ⩾ 85 mm Hg for 7 days postinjury using inotropes or MAP ⩾ 65 mm Hg. The results are expected to shed light on whether normotensive blood pressure targets are noninferior to current clinical practice of induced hypertension.

Study limitations

This study suffers from small numbers available for assessment of clinical outcomes that generally reflect the shortcomings of retrospective studies encountered by other investigators.[13] Furthermore, we stress that the reader should interpret these data critically, as patients either lost for follow-up or at incomplete follow-up can not be inferred to have done better or worse than the population we presented. This potential source of bias calls for cautious interpretation of the results and signals the need for randomized controlled trials. Furthermore, AIS grade assessment in 48–72 h postinjury has been shown to be a predictor of neurological recovery.[5–7] However, these data were not available in retrospect, which poses an important limitation in assessing neurological recovery in this cohort but also represented a critical area in which the standards of care on our institution have been impacted significantly after this review. We also found retrospectively that MAP augmentation period was 2 days shorter than clinical guidelines recommendation (7 days), which highlights the value of auditing clinical practice in order to ensure successful implementation of clinical guidelines. Since this review, we instituted changes in our facility to include strict monitoring of MAP and extension of treatment duration to 7 days. The 85 mm Hg cut-off is arbitrary and derived from a study by Vale[10] targeting MAP > 85 mm Hg, reasoning that this was the upper limit of normal. Although we recognize that such cut-off is not based on strong evidence, it also forms the basis of the clinical guidelines recommendation.[10–12]

CONCLUSION

This study suggests that early surgical decompression can be associated with improved neurologic outcome in SCI, emphasizing the role of urgent transportation in achieving timely surgical decompression. These data also support the hypothesis that maintaining a MAP ⩾ 85 mm Hg maybe associated with higher rates of neurologic recovery at mean 26.7 days, with no statistical significance at prolonged follow-up periods although a higher rate of neurological recovery persisted in patients with MAP ⩾ 85 mm Hg. Indeed, a small sample size and considering the nature of a retrospective review represent a common challenge to research this area and call for multicentre prospective registries or randomized controlled trials.

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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