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Current use and timing of spinal surgery for management of acute spinal cord injury in North America: results of a retrospective multicenter study

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A multicenter retrospective study was performed in 36 participating North American centers to examine the use and timing of surgery in the treatment of acute spinal cord injury (SCI). The study was conducted to obtain information required for the planning of a randomized controlled trial of early compared with late decompressive surgery.

The records of all patients aged 16 to 75 years with acute SCI who were admitted to the 36 centers within 24 hours of injury over a 9-month period (August 1994 to April 1995) were examined to obtain data on admission variables, methods of diagnosis, use of traction, and surgical variables including type and timing of surgery.

A total of 585 patients with acute SCI or cauda equina injury were admitted to these centers, although approximately half were ultimately excluded because they did not meet inclusion criteria. Common causes for exclusion were late admission, age, gunshot wound, and an absence of spinal cord compression demonstrated on imaging studies. Thus, only approximately 50% of acute SCI patients would be eligible for inclusion in a study of acute decompressive procedures. Although 100% of patient underwent computerized tomography (CT) scanning, only 54% underwent magnetic resonance imaging, and CT myelography was performed in only 6%. Complete neurological injuries (American Spinal Injury Association Grade A) were present in 57.8%. Traction was applied in only 47% of patients with cervical injuries, of which only 42% demonstrated successful decompression by traction. Neurological deterioration occurred in 8.1% of patients after traction. Surgery was performed in 65.4% of patients. The timing of surgery varied widely: less than 24 hours in 23.5% of patients; 25 to 48 hours in 15.8%; 48 to 96 hours in 19.0%; and 5 days or longer in 41.7% of patients.

These data indicate that whereas surgery is commonly performed in patients with acute SCI, one-third of the cases are managed nonoperatively, and there is very little agreement on the optimum timing of surgical treatment. The results of this study confirm the need for a randomized controlled trial to

determine the optimum timing of surgical decompressive procedures in patients with SCI.

Key Words * acute spinal cord injury * timing of surgery * multicenter clinical study

The Surgical Treatment for Acute Spinal Cord Injury Study (STASCIS) group was formed in 1992 by the Spinal Cord Injury Committee of the Joint Section on Neurotrauma and Critical Care of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), the two largest neurosurgical specialty organizations in North America. In 1996, STASCIS was joined by the Joint Section on Spinal Disorders and Peripheral Nerves of the AANS/CNS. The principal aim of the STASCIS group was to conduct a randomized prospective controlled trial to examine the role and timing of decompressive surgery performed on the spinal cord and cauda equina of patients after acute spinal injury.

In the present paper we describe the methodology and results of the first STASCIS study, the aim of which was to assess in a retrospective study the use and timing of spinal surgery to treat patients with acute SCI in North America. This information was sought by the STASCIS group to design a protocol for a randomized, prospective trial of surgical decompression for acute SCI. The study was conducted in 1994 and 1995 among 36 North American centers. Although numerous individual surgical series were available from the literature,[5,34,35,38,45,51] very few studies provided an overall analysis of the use and timing of surgery in acute SCI in more than one center, especially with respect to surgical decompressive procedures. Exceptions to this were the National Acute Spinal Cord Injury Study-1 (NASCIS-1) and NASCIS-2[10,11,12] trials, which provided some information on the use of surgery, although important issues such as the exact type of surgery performed were omitted.[26]

CLINICAL MATERIAL AND METHOD

Clinical Coordinating and Statistical Centers

The clinical coordinating center for this study was the Division of Neurosurgery at the Toronto Hospital, University of Toronto, Toronto, Ontario, and the statistical center was the Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario, Canada. Specific reporting forms were developed for the recording of individual patient data.

Participating Investigators and Participating Centers

Through advertisements in the AANS and CNS newsletters and through membership in the Spinal Cord Injury Committee, 36 of the major SCI centers in North America were recruited into the study (Table 1), including 33 U.S. centers and three Canadian centers. There was a very wide representative geographic distribution, as well as a mixture of teaching and nonteaching hospitals.

TABLE 1
PARTICIPATING CENTERS AND INVESTIGATORS, NUMBERS AND AGE OF CASES

Center No.	Participating Center	Participating Investigator	No. of Cases	Mean Age (yrs)
1	University of Alabama, Birmingham, AL	M Hadley	10	37
2	Saint Joseph's Hospital, Phoenix, AZ	C Dickman, V Sonntag	4	30
3	Drew University, Los Angeles, CA	G Locke	6	31
4	University of California, Davis, Sacramento, CA	F Wagner	10	30
5	University of California, San Diego, San Diego, CA	L Marshall	20	32
6	Hartford Hospitals, Hartford, CT	H Onyuke	16	44
7	University of Florida, Jacksonville, FL	C Arce, W Faillace	17	46
8	University of Miami School of Medicine, Miami, FL	B Green, P Madsen	34	42
9	Orlando Regional Medical Center, Orlando, FL	D Behrmann	14	40
10	Neurological Institute of Savannah PC, Savannah, GA	F Wirth	13	34
11	Indiana University Medical Center, Indianapolis, IN	C Shapiro	10	38
12	University of Iowa, Iowa City, IA	P Hitchon, V Traynelis	14	43
13	University of Kansas Medical Center, Kansas City, KS	P Arnold	15	35
14	Henry Ford Hospital, Detroit, MI	R Nockels	14	41
15	Cooper Hospital/University Medical Center, Camden, NJ	S Neff	42	35
16	University of New Mexico, Albuquerque, NM	E Benzel, A Halliday	8	44
17	Mount Sinai Medical Center, New York, NY	N Perin	7	35
18	State University of New York, Syracuse, NY	R Martin	5	48
19	Victoria General Hospital, Halifax, NS	R Holness	14	40
20	McMaster University, Hamilton, ON	K Reddy	19	49
21	Sunnybrook Health Sciences Center, Toronto, ON	M Fazl	12	40
22	The Toronto Hospital, Toronto, ON	C Tator, M Fehlings	14	46
23	Oregon Health Sciences Center, Portland, OR	F Edmund	21	38
24	Temple University School of Medicine, Philadelphia, PA	R Narayan, W Young	11	51
25	Thomas Jefferson University, Philadelphia, PA	B Northrup	104	45
26	University of Philadelphia, Philadelphia, PA	P Marcotte	7	40
27	Allegheny General Hospital, Pittsburgh, PA	J Wilberger	10	38
28	Presbyterian University Hospital, Pittsburgh, PA	D Marion	9	36
29	Rhode Island Hospital, Providence, RI	F Harrington	15	40
30	Plains UC & Regina General Hospital, Regina, SK	C Ekong	12	45
31	Medical University of South Carolina, Charleston, SC	B Cuddy	20	31
32	Center for Neurological Disorders, PA, Ft Worth, TX	G Cravens	9	45
33	Ben Taub General Hospital, Houston, TX	A Valadka	15	34
34	Fairfax Hospital, Falls Church, VA	J Burgess	12	39
35	Medical College of Virginia, Richmond, VA	K Holloway	9	48
36	Froedtert Memorial Lutheran Hospital, Milwaukee, WI	D Maiman, J Hollowell	13	36
		total	585	40

Protocol Format

The participating investigators were asked in the fall of 1995 to record retrospectively the information on all patients with spinal cord or cauda equina injuries who were admitted to their centers within 24 hours of injury during the 9 month trial period (August 1994 to April 1995). Specific questions were posed to determine whether the patients would have been eligible for a planned trial of decompressive surgery according to a specific protocol that had been developed by STASCIS. This protocol would theoretically include all patients with spinal cord or cauda equina injury at all levels of the vertebral column, both neurologically complete (American Spinal Injury Association [ASIA] A) and incomplete (ASIA B-D) injuries. Investigators were asked to evaluate whether the obtained data on each patient would have conformed to a specific list of inclusion criteria (Table 2) which were almost identical to those used in the previous NASCIS protocols with respect to age, medical risk factors, and other variables,[10-12] and to "predict" retrospectively whether each patient would have been able to provide consent. In this way,

we attempted to evaluate the features of the planned protocol for a randomized, prospective trial.

TABLE 2	
DESCRIPTION OF INCLUSION AND EXCLUSION CRITERIA USED IN THE TRIAL*	
inclusion criteria	SCI or cauda equina injury of ASIA Grade A, B, C, or D at any vertebral level patient admitted to participating center w/ 24 hrs of injury spinal cord compression determined by MR, CT, or CT/myelogram aged 16–75 yrs
exclusion criteria	gunshot wounds & other penetrating injury cognitive impairment (including altered mental state due to alcohol or drugs) major uncertainty about the time of trauma & inability to determine TTIs pregnancy uncertain follow up, such as illegal aliens or overseas visitors multiple life-threatening injuries medically unstable patients including those w/ myocardial infarction w/ 3 mos previous neurological injury previous cerebrovascular disease with neurological deficit uncompensated congestive heart failure cancer AIDS ankylosing spondylitis criminals, under indictment, or incarcerated
* CT = computerized tomography; TTI = time-to-treatment interval.	

RESULTS

Number of Cases and Age of Patients

Table 1 shows that 585 patients with acute SCI or cauda equina injury were admitted to the 36 centers during the 9 month study interval. The maximum number of patients admitted to a single center was 104 and the minimum was four. The overall mean age was 40 years.

Vertebral Level of Injury

Overall, 64.5% of the injuries were cervical (C1 to C7-T1), 18.7% were thoracic (T1-11), 11.0% were thoracolumbar (T11-12 to L1-2), and 5.8% were lumbosacral (L2-S5) (Table 3). In some centers there was a much higher incidence of cervical injuries, most likely due to the greater involvement of orthopedic spinal surgeons in those centers who had more responsibility for managing patients with noncervical injuries.

TABLE 3
VERTEBRAL LEVEL AND SEVERITY OF INJURY (ASIA GRADE) AND METHOD OF IMAGING*

Center No.	Level of Injury				ASIA Grade				Imaging Study		
	Cer-vical	Tho-racic	Thoraco-lumbar	Lumbo-sacral	A	B	C	D	CT	CTM	MR
1	10	0	0	0	4	2	3	1	10	0	10
2	3	0	1	0	4	0	0	0	4	0	3
3	6	0	0	0	4	0	0	2	3	0	2
4	8	2	0	0	8	0	1	1	9	0	6
5	12	5	2	1	8	0	8	4	18	0	6
6	9	4	2	1	7	6	3	0	15	0	8
7	10	4	3	0	10	0	4	3	15	4	4
8	18	14	2	0	21	4	7	2	34	1	19
9	13	1	0	0	7	4	0	3	10	0	10
10	6	4	2	1	7	4	1	1	12	1	2
11	7	1	1	1	1	1	0	8	10	0	10
12	6	3	2	3	5	0	5	4	13	0	13
13	8	3	3	1	6	0	3	6	15	0	15
14	11	1	1	1	7	0	3	4	13	4	10
15	24	5	2	1	8	2	17	15	42	5	26
16	1	2	4	1	2	2	0	3	8	0	1
17	16	1	0	0	2	2	0	3	7	1	2
18	3	0	1	1	2	0	1	2	5	0	0
19	10	1	3	0	7	1	1	5	8	2	3
20	9	5	5	0	6	8	4	1	18	3	1
21	5	1	2	4	1	1	4	6	11	0	4
22	12	2	0	0	6	2	4	2	14	1	14
23	14	2	3	2	8	0	3	10	17	0	4
24	10	0	0	1	1	0	4	6	11	0	11
25	69	17	12	6	42	10	27	25	70	1	66
26	4	3	0	0	6	1	0	0	7	0	2
27	4	2	4	0	7	0	0	3	10	0	10
28	5	4	0	0	6	0	0	3	8	0	6
29	13	1	1	0	3	3	4	5	11	4	10
30	10	0	0	2	5	0	6	1	6	4	0
31	11	4	1	2	9	0	3	8	11	3	3
32	5	1	3	0	1	1	4	3	8	0	7
33	12	0	2	1	6	2	2	5	14	1	5
34	4	6	1	1	7	0	2	3	12	0	4
35	6	2	0	1	4	1	3	1	3	0	9
36	5	6	0	0	9	0	4	0	12	0	10
total	369	107	63	33	247	57	131	149	494	35	316

*CTM = CT myelography.

Severity of Neurological Injury

Based on the ASIA neurological grading system,[2] 42.2% of the injures were Grade A, or complete SCI, 9.7% were Grade B, 22.6% were Grade C, and 25.5% were Grade 4 (Table 3). In general, the distribution of ASIA grades was similar among the various centers, although some appeared to admit an unusually high percentage of Grade A injuries, whereas other centers admitted a higher percentage of patients with neurologically incomplete injuries.

Inclusion and Exclusion Criteria

Based on the inclusion and exclusion criteria shown in Table 2, 62.1% of the 550 cases for whom this information was available met the inclusion criteria on admission and would have been eligible for

consideration for the planned study, whereas 37.1% would have been excluded (Table 4). The most frequent reasons for exclusion from the study were admission more than 24 hours postinjury, age, and the presence of gunshot wounds (Table 4). Absence of spinal cord compression, as determined by evaluation of available imaging studies on admission, would have excluded 18 patients, and presence of a concomitant head injury would have lead to exclusion of another 18 patients. It should be noted that absence of spinal cord compression based on imaging studies performed after admission resulted in the exclusion of many additional patients at a later stage.

TABLE 4	
INCLUSION CRITERIA ON ADMISSION IN 550 PATIENTS*	
	No. of Patients (%)
meets inclusion criteria	
yes	346 (62.9%)
no	204 (37.1%)
reasons for not meeting criteria	
late admission	64
age	37
gunshot wounds	37
no cord compression on imaging	18
head injury	18
medical/surgical factors	8
presence of alcohol	7
ankylosing spondylitis	2
total	204
* Data not available for 35 patients.	

Provision of Consent

It was the opinion of the staff of the participating centers that 510 (89.8%) of the 568 patients for whom this information was available would have been able to provide consent with respect to participation in the study, whereas 58 patients (10.2%) would not have been able to provide consent. These latter patients included those with head injuries, excess levels of alcohol, and other factors.

Imaging Studies

Although 100% of the patients underwent computerized tomography scanning, only 54% underwent magnetic resonance (MR) imaging (Table 3). As expected, computerized tomography myelograms were infrequently obtained (6%). The use of MR imaging varied significantly among centers, with some performing MR imaging in 90% or more of cases, whereas others performed it in only 10 to 20% of cases.

Overall Inclusion Rate Based on Imaging and Admission Eligibility

Data obtained from imaging studies performed prior to traction were available regarding the presence of spinal cord compression or deformation in 459 patients; in 303 (66%) there was cord compression or deformation patients whereas in 156 (34%) there was none. Thus, if the planned prospective study included only those patients who met all the inclusion criteria outlined in Table 2, and who were not excluded for any of the listed reasons for exclusion shown in Table 4 (omitting the 18 cases shown not to have cord compression on admission imaging studies and who would have been excluded on the basis of this finding), the eligibility rate would be 66%. By multiplying the rate of imaging study-detected spinal cord compression (66%) by the rate of potential eligibility (66%), one can deduce an approximate overall

inclusion rate of 44%. It is likely that this figure is a slight underestimation of the true inclusion rate because some patients may have been excluded based on more than one criterion. Accordingly, we estimate a true inclusion rate of approximately 50% based on the available data in this study.

Use of Traction

There was information on the use of traction in 173 cases of cervical cord injury, and traction was applied in 47% of cases. In the opinion of the participating investigators, spinal cord deformation persisted after traction in 43% of cases in which it was applied. The participants reported neurological deterioration during traction in 14 patients (8.1%). Information is not available regarding the severity of neurological deterioration and whether the deficits were temporary or permanent.

Incidence, Type, and Timing of Surgical Treatment

Information was requested on the use of surgical treatment in these 585 patients and information was available for 583 patients; 65.4% (381) underwent surgical treatment, and 34.6% (202) did not. Decompressive surgery was performed in 68.2% of those receiving surgical treatment, whereas fusion was performed in 85.7%. The majority of the patients underwent both decompressive surgery and spinal fusion. Data obtained on the timing of surgery were available for 374 of the 381 surgical cases. Surgery was performed at 24 hours or less postinjury in 23.5% (88) of patients, 25 to 48 hours postinjury in 15.8% (59), 48 to 96 hours postinjury in 19.0% (71) and 5 days or more postinjury in 41.7% (156) of patients (Table 5).

TABLE 5				
TIME FROM TRAUMA TO SURGERY IN 374 PATIENTS				
	Timing of Surgery			
	< 24 Hrs	25–48 Hrs	48–96 Hrs	> 5 Days
no. of patients (%)	88 (23.5)	59 (15.8)	71 (19.0)	156 (41.7)

DISCUSSION

The epidemiological features of these patients--age, level and severity of injury and other admission variables--were similar to those reported in other SCI patient populations.[31,32,41,44,46,48] For example, in this trial approximately two-thirds of the cases had sustained cervical injuries and approximately 60% were incomplete neurological injuries; these data are in keeping with other large series of SCI patients admitted to SCI units in North America in which neurosurgeons play a significant role.

This retrospective study was undertaken in attempt to define the feasibility of conducting a prospective randomized controlled trial of the timing and effectiveness of decompressive surgery of the spinal cord. Although pharmacotherapy using methylprednisolone has been proven to be effective in improving neurological deficits in patients with acute SCI, the results of the North American[12,13] and Japanese[40] trials in large numbers of patients have shown only a minimal amount of improvement. Modest neurological improvement was also seen when treating patients with GM-1 ganglioside in a trial in a small number of patients.[28] Thus, further studies of other drugs and other treatments must be undertaken to enhance the neurological recovery. There is evidence from experimental studies in laboratory models that early decompressive surgery improves neurological

recovery.[8,15,17,19,21,23,30,33,39,41,42,43] For example, in the laboratory of one of the authors (C.H.T.), removal at 2 hours of an extradural clip that compressed the spinal cord produced better neurological recovery than removal at 4 hours.[30] In some clinical studies in patients who have undergone decompressive surgery, promising results have been demonstrated,[6,53,54] although results of other studies have failed to show a benefit from early decompressive compared with later decompressive surgery.[5,26,34,35,38,49-51] Findings from several studies have failed to show improved recovery in those patients who underwent surgery compared with those receiving nonoperative treatment.[24,45,52] For example, in a study by one of the authors (C.H.T.), the outcome in 116 patients who underwent operative treatment (decompressive surgery in 75, fusion in 41) was compared with the outcome in 92 who did not undergo surgery, and there was no difference in neurological recovery between the two groups.[45] However, it should be noted that, with one exception, none of these studies was a randomized controlled trial in which patients were allocated to surgical or nonsurgical groups or to early or late surgery. The exception was the study by Vaccaro, et al.,[49] reported in 1997, in which patients were randomly allocated to an early-surgery or late-surgery group. In this study, only a small number of patients were studied: the early-surgery group, defined as undergoing surgery within 72 hours of injury, contained 34 patients (mean time to surgery 1.8 days); and the late-surgery group, defined as undergoing surgery more than 5 days after injury, contained 28 patients (mean time to surgery 16.8 days). There was no difference in neurological outcome between the two groups. The other shortcoming in this study was the low rate of follow up (approximately one-third of the patients were lost to follow-up reviews).

The authors of several other studies have reported improved neurological outcome in patients who underwent late decompressive surgery days, weeks, or months postinjury,[3,7,9,14,22,34,36] but none of these studies was a randomized controlled trial. Traction has also been reported to improve neurological outcome, especially if applied early,[1,16,18,29] but none of these studies reporting on traction was a randomized controlled trial. However, the authors of several studies did not find any neurological benefit in patients who underwent spinal reduction procedures,[20,32,52] with the possible exception of patients who suffered bilateral facet dislocation.[4] Furthermore, early spinal reduction procedures performed prior to imaging studies have become controversial because neurological deterioration has been reported after traction primarily in patients with large disc herniations.[25,27] It should be noted that the present study demonstrated an 8% rate of neurological deterioration due to traction. Unfortunately, data are not available regarding the severity and permanence of these deficits.

In the present study, we found that approximately 66% of patients with acute SCI are undergoing surgical treatments, and as noted above, there is no definite proof that the treatment yields improved neurological recovery. It should be noted that many of the authors claim that surgery enhances early mobilization and reduces length of hospital stay, but there is no definite proof. Furthermore, the effect of surgery, especially early surgery, on the rate of complications such as pneumonia or deep venous thrombosis is controversial.[37,55]

Findings from the present study showed a lack of consensus among centers concerning the optimum timing of surgical treatment, and only a minority of patients underwent surgery within 24 hours of trauma. Even this interval may be too late to reverse some of the secondary injury mechanisms identified after SCI.[47] The only therapeutic window established in humans is the 8-hour trauma-to-treatment window reported in the NASCIS-2 study in which methylprednisolone was used.[12]

We have shown that only approximately 50% of patients currently admitted to spinal cord centers in

North America would be eligible for inclusion in a randomized controlled trial of early compared with late decompression performed by using traction or surgery. This was based on inclusion of only those patients admitted within 24 hours of trauma. Thus, a randomized trial to study early decompressive surgery at a shorter therapeutic window time, such as 8 hours based on the NASCIS-2 results, would require a public education campaign and specific instructions to first aid personnel and emergency physicians to encourage much earlier referral to spinal cord treatment centers.

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