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Methylprednisolone Therapy in Acute Traumatic Spinal Cord Injury: Analysis of a Regional Spinal Cord Model Systems Database

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BACKGROUND: The objective of this study was to assess the relationship between exposure to methylprednisolone (MP) and improvements in motor function among patients with acute traumatic spinal cord injury (TSCI). MP therapy for patients with TSCI is controversial because of the current conflicting evidence documenting its benefits and risks.

METHODS: We conducted a retrospective cohort study from September 2007 to November 2014 of 311 patients with acute TSCI who were enrolled into a model systems database of a regional, level I trauma center. We linked outcomes and covariate data from the model systems database with MP exposure data from the electronic medical record. The primary outcomes were rehabilitation discharge in American Spinal Injury Association (ASIA) motor scores (sum of 10 key muscles bilaterally as per International Standards for Neurological Classification of Spinal Cord Injury, range, 0–100) and Functional Independence Measure (FIM) motor scores (range, 13–91). Secondary outcomes measured infection risk and gastrointestinal (GI) complications among MP recipients. For the primary outcomes, multivariable linear regression was used.

RESULTS: There were 160 MP recipients and 151 nonrecipients. Adjusting for age, sex, weight, race, respective baseline motor score, surgical intervention, injury level, ASIA Impairment Scale (AIS) grade, education, and insurance status, there was no association with improvement in discharge ASIA motor function or FIM motor score among MP recipients: −0.34 (95% CI, −2.8, 2.1) and 0.75 (95% CI, −2.8, 4.3), respectively. Adjusting for age, sex, race, weight, injury level, and receipt of surgery, no association with increased risk of infection or GI complications was observed.

CONCLUSIONS: This retrospective cohort study involving patients with acute TSCI observed no short-term improvements in motor function among MP recipients compared with nonrecipients. Our findings support current recommendations that MP use in this population should be limited. (Anesth Analg 2017;124:1200–5)

Traumatic spinal cord injury (TSCI) is a devastating ailment. It affects nearly 12,400 new patients annually in the United States and has a relatively stable incidence.[1,2] These injuries often lead to profound and permanent disability, for which direct care costs can range from $1,100,000 to $4,700,000 over a patient's lifetime.[3,4]

Anesthesiologists, surgeons, and critical care providers continue to face the dilemma of glucocorticoid use in the management of acute TSCI. Early methylprednisolone (MP) therapy is considered to be one of the few treatments with potential clinical benefit for acute TSCI; however, its use is controversial.[5–9] The highest profile study supporting MP use was the Second National Spinal Cord Injury Study (NASCIS II), which identified a benefit in early motor function among one subgroup of recipients of MP therapy compared with placebo.[10] The results demonstrating benefit, identified in a subgroup analysis of those who received MP within 8 hours of injury, were not observed in a similar fashion in other studies.[6,11]

The most significant criticism of NASCIS II has been its reliance on a post hoc, subgroup analysis with an obvious selection bias to support the use of MP in TSCI.[7] Multiple subgroup analyses increase the likelihood of a type I error.[12] Possibly because individual clinical practice may lag behind current recommendations, MP is still used by some physicians despite the limited evidence supporting its therapeutic benefit in acute TSCI, as well as its potential for untoward side effects.[13,14] However, this clinical practice is changing.[15,16]

Steroid therapy in TSCI thus remains controversial largely because of the interpretation of the NASCIS II results and subsequent meta-analyses that have not demonstrated clear benefit of MP therapy in this patient population.[5,17] Most recent guidelines do not recommend routine administration of MP for TSCI.[18] Despite current evidence and guidelines, the combination of variability in patient selection, injury level, and injury severity, together with methodological deficiencies in study design and analysis, prevents at least some clinicians from reaching a definitive conclusion.[7,8] Medicolegal concerns regarding failure to administer MP further fuel these controversies. In light of

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these issues, we conducted a retrospective analysis of carefully collected motor outcomes that deliberately minimized secondary analyses in a single, high-volume trauma center.

We hypothesized that there would be no association between exposure to MP in the acute phase of injury and early improvements in motor function.

METHODS

Experimental Design

We conducted a retrospective cohort study to examine the association between MP exposure and discharge American Spinal Injury Association (ASIA) motor score and Functional Independence Measure (FIM) motor score after acute TSCI. The data for this analysis were drawn from 2 separate databases: the University of Washington electronic medical record (EMR, ORCA Powerchart, Cerner, Kansas City, MO) and the University of Washington Northwest Regional Spinal Cord Injury System (NWRSCIS) database.[19] All enrollees in the database undergo a standardized informed consent process. The University of Washington institutional review board approved this study (NWRSCIS IRB No. 32148).

Cohort Designation

A retrospective cohort study was conducted using the University of Washington NWRSCIS database: a federally funded national database that has continually collected data since 1973 on patients with TSCI from multiple US centers. The University of Washington (through its affiliated level I trauma center, Harborview Medical Center) has been one of the contributing institutions for more than 40 years. During the study period, more than 80% of eligible patients admitted to Harborview Medical Center with traumatic spinal cord injuries were enrolled into the database.

Our EMR system enabled us to assess MP therapy for patients dating back to September 1, 2007. All patients included in the NWRSCIS database from that time until November 30, 2014, were eligible for inclusion. All patients enrolled in the database had received the standardized sensory and motor examinations required by the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) to provide classification of neurologic levels, as well as the ASIA Impairment Scale (AIS), which grades the severity (completeness) of the neurologic injury.[27] These comprehensive and standardized examinations were performed at the time of rehabilitation admission. Patients were excluded if more than 7 days had passed from their injury date until enrollment into the database.

The cohorts were defined by exposure to MP during the acute phase of injury. Specifically, patients were designated as MP recipients if there was a pharmacy record indicating they had received MP within 72 hours of admission. Because the earliest subjects in this cohort were enrolled in 2007, we assumed that if MP therapy was given, it was initiated in a fashion consistent with guidelines that support its use within 8 hours of injury.[9] Using a random 10% subsample of medical records as a quality control procedure, we confirmed that subjects identified as MP recipients were in fact given the medication within 8 hours of injury, both as a bolus and an infusion that completed 23 hours later. All patients in the random subsample received MP therapy as presumed with the exception of 1 patient. This was a transfer patient who started therapy approximately 10 hours after injury. The quality control procedure also confirmed that all patients with a pharmacy record indicating MP exposure had received this therapy and were not misclassified. Complete ISNCSCI and AIS neurologic examinations were performed in only about 75% of patients at the time of hospital admission, whereas complete exams were documented in all patients at the time of admission to the rehabilitation unit; thus, ASIA and FIM motor scores at rehabilitation admission were used for rehabilitation baseline scores. This comprehensive exam is typically performed on the day of admission/transfer to the inpatient rehabilitation unit. In a small number of cases, this examination is performed within the 72 hours before or after admission to the unit.

Outcomes

The first primary outcome was the discharge ASIA motor score. The ASIA motor score is a standardized examination based on a meticulously performed strength assessment, as defined by ISNCSCI.[20] It is calculated by summating motor grades (0–5 scale) recorded for 5 upper limb and 5 lower limb muscles bilaterally. The ASIA motor score ranges from 0 to 100. The second primary outcome was discharge FIM motor score. The FIM assessment measures motor and nonmotor domains of function: social cognition, communication, mobility, sphincter control, self-care, and locomotion. The FIM motor score component represents the sum of the 13 specific motor items of the FIM assessment. Each motor item has a maximal level score of 7. Total scores range from a minimum of 13 to a maximum of 91.

The a priori-defined secondary analyses were as follows. First, there was an analysis of whether age (older than or younger than 45 years) modified the effect of MP on the primary outcomes. Second, we determined whether there was an association with risk of infection (including surgical site infection [SSI] among the subset of patients undergoing surgery) and gastrointestinal (GI) complications among MP recipients as defined by International Classification of Disease code 9 (ICD-9) within 30 days of hospital admission. The following infections were included: bacteremia/fungemia, pneumonia, GI infection, urinary tract infection, skin/soft tissue infection, and severe sepsis. We conducted separate analyses on pneumonia, urinary tract infection, SSI, and "all infections."

Statistical Analyses

For MP-exposed and unexposed patients, univariate comparisons of demographic and injury characteristics were assessed using a χ^2 test for categorical variables and a 2-sample Student t test for continuous variables. Potential confounders were identified a priori based on whether they were associated with the primary exposure and the outcome of interest, yet they were not in the causal pathway of the exposure–outcome relationship.[21] In addition, some covariates identified in the literature to be associated with the outcome were adjusted for as precision variables.[22] All patients who satisfied inclusion criteria were used for

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analyses. Based on the number of eligible subjects, for the ASIA motor score, we had 90% power to detect an average difference of 5.2 points on this scale. With respect to the FIM motor score, we had 90% power to detect an average difference of 6.2 points. All hypothesis tests were 2 sided. Analyses were performed using Stata 11 (StataCorp 2009, Stata Statistical Software Release 11. College Station, TX: StataCorp LP).

Multivariable Linear Regression Modeling

We used multivariable linear regression to examine the association between MP exposure and discharge ASIA motor and FIM motor scores. For the first primary analysis, we fit an unadjusted linear regression model with MP exposure as the primary independent variable, and rehabilitation discharge ASIA motor score as the dependent variable. The following were prespecified covariates that were added to the model: age, gender, weight, baseline rehabilitation admission ASIA motor score, injury level, AIS grade at rehabilitation admission, presence of surgical intervention, education level, and insurance status. The same model building procedure was then completed for the FIM motor outcome, except that rehabilitation admission FIM motor score was adjusted for instead of ASIA motor score. We used logistic regression to assess associations with infections: infection status was the dependent variable; exposure to MP was the independent variable. Covariates used for adjustment in the secondary outcomes analysis included: age, sex, race, weight, injury level, and surgical status (yes/no). The same procedure was used to measure associations with GI hemorrhage and GI ulceration.

RESULTS

During the study period, 383 patients were enrolled in the NWRSCIS database, 72 of whom (18.5%) were excluded because of admission to the hospital more than 7 days after injury. Of the 311 patients suitable for analysis, 293 (94%) were admitted to the hospital within 24 hours of injury. A total of 244 patients (78%) underwent surgical intervention for their injury. In the surgical cohort, the median time from hospital admission to surgery was 11.5 hours. A total of 160 (51.4%) were exposed to MP during the acute phase of their injury; 151 patients were not exposed to MP. Notable differences between groups were observed in AIS grade (grade A [most severe] injuries were more likely to receive MP therapy [$P < .01$]; patients with grade D injuries were less likely to receive MP therapy [$P < .01$]); surgical status ($P < .05$); racial subgroups (<.05); and insurance type (<.01) (Table 1).

Adjusting for age, sex, weight, race, rehabilitation admission ASIA motor score, surgical intervention, injury level, AIS grade, education, and insurance status, the difference in mean discharge ASIA motor score was −0.34 (95% CI, −2.8, 2.1) comparing MP recipients with nonrecipients. Similarly, adjusting for age, sex, weight, race, rehabilitation admission FIM motor score, surgical intervention, injury level, AIS grade, education, and insurance status, the difference in mean discharge FIM score was 0.75 (95% CI, −2.8, 4.3) comparing MP recipients to nonrecipients (Table 2).

No effect modification by age was observed; neither was there interaction between age of younger than 45 years and MP in the ASIA motor score model ($P = .54$), nor in the FIM motor score model ($P = .09$).

Finally, there was no association with increased risk among MP recipients of pneumonia (OR, 1.06, 95% CI, 0.56, 2.01) or any infection (OR, 0.84, 95% CI, 0.52, 1.36) compared with patients not exposed to MP (Table 3). Among all patients who underwent surgery (n = 244), there were 8 SSIs as identified by ICD-9 code. Seven SSIs occurred in nonrecipients; 1 SSI occurred in an MP recipient. After adjustment for age, sex, race, weight, and injury level, there was no significant difference in risk in SSI comparing MP recipients with nonrecipients (OR, 0.13, 95% CI, 0.015, 1.15). Based on ICD-9 codes, neither were there GI hemorrhage episodes in our cohort, nor were there any GI ulcers.

DISCUSSION

In this study of patients with acute TSCI, while adjusting for several potential confounders, we observed no association between exposure to MP and improved discharge ASIA motor score or FIM motor score. We also observed no differential response to MP therapy between patients younger than or older than 45 years of age (the mean age in our cohort). In addition, no association with increased risk for infection or GI complications within 30 days was observed between recipients of MP and nonrecipients.

The primary strengths of this study that extend and complement previous reports include a large sample size with detailed, high-quality covariate and outcomes data from a model systems database, as well as reliable exposure data that were verified with quality control procedures.

There are several limitations to this study. First, based on its observational design, this study is unable to control completely for potential confounders. Despite a robust database of covariates from which to control, there still exists the possibility of residual confounding within our models. We attempted to minimize this bias through thoughtful selection of covariates that were chosen in an a priori fashion and based on the SCI treatment literature.[10] Our results could also be biased by confounding by indication. As noted in the results and in Table 1, MP recipients were more likely to have had more severe injuries. Although theoretically, this leaves patients with more room for improvement, previous studies have shown that more severely injured patients tend to have less motor recovery.[23,24] As a result of this circumstance, the MP group may have actually had less opportunity for improvement, which could systematically bias our results. We attempted to control this by adjusting for injury severity in our model; however, there still exists the possibility that this adjustment was not sufficient to overcome confounding by indication.

Another limitation of this study is the absence of detailed ASIA motor scores before rehabilitation admission (ie, at hospital admission) for approximately 25% of patients. As a sensitivity analysis excluding patients without these examinations, we assessed the discharge ASIA motor score of MP recipients after adjusting for the earliest full neurologic examination per ISNCSCI from the acute care period of hospitalization (average of 1.9 days from hospital admission until this examination). The adjusted result of this analysis did not differ from the primary analysis: MP recipients,

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Table 1. Rehabilitation Baseline and Demographic Characteristics of Methylprednisolone Recipients and Nonrecipients

		No MP	MP
Number of patients		151	160
Sex			
	Male (%)	111 (73.5)	120 (75.0)
Race/ethnic group			
	White, Caucasian (%)	109 (72.2)	133 (83.1)*
	Black, African American (%)	21 (14.0)	7 (4.4)**
	American Indian, Alaska Native (%)	4 (2.6)	4 (2.5)
	Asian, Pacific Islander (%)	10 (6.6)	8 (5.0)
	Other race, multiracial (%)	6 (4.0)	6 (3.7)
	Declined/not known (%)	1 (<1)	1 (<1)
	Unknown (%)	0 (0)	1 (<1)
Height in inches (SE)		68.8 (0.3)	69.2 (0.2)
Weight in pounds (SE)		187.1 (4.5)	185 (3.0)
BMI (SE)		27.5 (0.5)	27.1 (0.4)
Age (SE)		44.8 (1.3)	42 (1.2)
Cause of injury			
	Automobile (%)	22 (14.6)	33 (20.6)
	Motorcycle (%)	17 (11.3)	13 (8.1)
	Fall (%)	52 (34.4)	60 (37.5)
	Bicycle (%)	11 (7.3)	14 (8.7)
	Water related (%)	2 (1.3)	7 (4.3)
	Other (%)	47 (31.1)	33 (20.6)*
Spinal surgery			
	Yes (%)	111 (74.0)	133 (83.1)*
Days from hospital admission to rehabilitation admission (SE)		21.9 (2.0)	17.8 (1.8)
Days on rehabilitation unit (SE)		34 (2.4)	39.8 (2.2)
Injury level			
	Cervical (%)	82 (54.3)	103 (64.4)**
	Thoracic (%)	52 (34.4)	42 (26.2)
	Lumbar (%)	13 (8.7)	12 (7.5)
	Sacral (%)	2 (1.3)	0 (0)
	Unknown (%)	2 (1.3)	3 (1.9)
AIS grade at rehabilitation admission			
	A (%)	40 (26.5)	72 (45.0)**
	B (%)	11 (7.3)	16 (10.0)
	C (%)	24 (15.9)	31 (19.3)
	D (%)	73 (48.3)	35 (22.0)**
	Unknown (%)	3 (2.0)	6 (3.7)
Insurance status			
	Private (%)	41 (27.2)	32 (20.0)
	Medicare (%)	19 (12.6)	7 (4.4)*
	Medicaid (%)	17 (11.3)	20 (12.5)
	Declined/not known (%)	5 (3.3)	2 (1.3)
	Other/unknown (%)	69 (45.6)	99 (61.8)**

Asterisk denotes statistically significant difference between 2 groups.
Abbreviations: AIS, American Spinal Injury Association Impairment Scale; BMI, body mass index; MP, methylprednisolone; SE, standard error of mean.
*P < .05; **P < .01.

−0.47 (95% CI, −4.58, 3.63) compared with nonrecipients, again indicating that MP recipients experienced no added benefit. Another possible limitation is that patients receiving MP may have had differential lengths of stay on the rehabilitation unit, and thus differential opportunities for improvement. However, when we adjusted our analysis for length of stay on the rehabilitation unit, there was again no difference from the primary findings.

A third limitation is that the FIM motor score was used to measure changes in function. The FIM assessment tool is not as sensitive to changes in function as other instruments developed specifically for use with the SCI population, such as the Spinal Cord Independence Measure III, and changes in FIM scores can demonstrate a ceiling effect when used on patients with minimal neurologic impairment.[25]

Despite these limitations, the results of this study add important context to this clinical dilemma and should be viewed as a complement to other studies with randomized designs, carefully adjusted observational studies, and metaanalyses combining both designs. A meticulous recent meta-analysis by Evaniew et al[5] (which included 4 randomized controlled trials and 17 observational studies) observed no improvements in long-term motor function among MP recipients compared with nonrecipients. The meta-analysis did observe a short-term gain in function among MP recipients; however, the confidence of this estimate was limited given that the improvement stemmed largely from the ad hoc secondary analysis from NASCIS II. In part because of the criticisms of NASCIS II and NASCIS III,[7] the present study deliberately tried to

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Table 2. Methylprednisolone and Rehabilitation Baseline and Discharge ASIA Motor and Functional Improvement Measure Scores

	No Methylprednisolone (n = 151)		Methylprednisolone (n = 160)	
	Baseline	Discharge	Baseline	Discharge
ASIA Motor Score | mean (SE)	59.7 (2.29)	69.2 (2.18)	44.5 (2.14)	53.6 (2.29)
FIM Motor Score | mean (SE)	30.8 (1.26)	59.8 (1.76)	25.1 (1.10)	53.1 (1.83)
	Methylprednisolone Versus No Methylprednisolone			
	Mean difference in discharge motor scores		95% CI	*P*
ASIA motor score	−0.34		−2.86, 2.17	.78[a]
FIM motor score	0.75		−2.83, 4.35	.67[b]

Abbreviations: ASIA, American Spinal Injury Association; CI, confidence interval; FIM, functional independence measure; MP, methylprednisolone; SE, standard error of mean.

[a]Linear regression with discharge ASIA motor score as dependent variable, methylprednisolone as independent variable, adjusted for sex, race, age, weight, rehabilitation admission ASIA motor score, rehabilitation admission AIS grade, injury level, surgery, education, and insurance status (no methylprednisolone = reference group).

[b]Linear regression with discharge FIM motor score as dependent variable, methylprednisolone as independent variable, adjusted for sex, race, age, weight, rehabiliation admission FIM motor score, rehabiliation admission AIS grade, injury level, surgery, education, insurance status (no methylprednisolone = reference group).

Table 3. Methylprednisolone Exposure and 30-Day Risk of Infection

Infection Within 30 Days	No MP (n = 151)	MP (n = 160)	Adjusted OR (95% CI)[a]
Pneumonia	23	27	1.06 (0.56–2.01)
Urinary tract infection	3	4	0.94 (0.19–4.65)
Any infection[b]	80	84	0.84 (0.52–1.36)

Abbreviations: CI, confidence interval; OR, odds ratio; MP, methylprednisolone. No methylprednisolone = reference group.

[a]Adjusted for age, sex, race, weight, injury level, and surgery.

[b]Includes primary bacteremia, fungemia, pneumonia, gastrointestinal infection, urinary tract infection, skin/soft tissue infection, surgical site infections, and severe sepsis, as identified by ICD-9 code, within 30 days of admission.

limit the number of outcomes under study. Consequently, we are cautiously optimistic regarding the validity of our results, especially when viewed in the context of other studies employing a randomized design yet failing to observe a benefit from MP exposure in their primary analyses. Conversely, our results demonstrate no association with specific risks of MP therapy related to infectious complications or GI hemorrhage.

Although our results do not resolve the controversy of MP therapy for TSCI, they demonstrate clinicians' persistence in using MP despite guidelines to the contrary, and they also suggest next steps to determine the reasons why. For example, future studies should not only include such early baseline neurologic assessments, but also SCI-specific outcome tools (eg, SCIM III) to better assess clinical benefit from therapies such as surgery or steroid treatment. Steroid therapy appears to be applied in a differential way in patients with different injury grades in our institution. It is previously reported that motor score recovery is more likely to be observed in grade D injuries than in grade A injuries.[23,24] This is contrary to our observations that more severely injured patients were more likely to receive MP treatment. Also, despite its declining use, MP continues to be a treatment option left to physician discretion on a case-by-case basis. TSCI refers to a wide range of disease states, the outcome for which can be influenced by its etiology, injury severity, injury level, physiologic reserve, genetic determinants, and other factors. Thus, the efficacy of glucocorticoids in specific subsets of patients remains unanswered and warrants properly designed randomized clinical trials. Until then, it is possible that steroid therapy will continue to be applied with discretion, despite evidence that it is not beneficial, by compassionate physicians anxious to provide any shred of hope to a traumatized patient and family.

In conclusion, this retrospective cohort study of patients with acute traumatic spinal cord injuries observed no short-term improvements in motor function among MP recipients compared with nonrecipients. No increased risk of infection or GI complications within 30 days was observed among MP recipients. Our findings support current beliefs that MP use in this population lacks beneficial effects with respect to motor score improvements.

DISCLOSURES

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