Stanovisko výboru ČSIM k podávání kortikosteroidů u míšních traumat

1. Výbor ČSIM, vycházejíce z recentních údajů odborné literatury, nepovažují přínos rutinního podání kortikosteroidů u pacientů v akutní fázi míšního traumatu za průkazný. Použití kortikosteroidů v této indikaci by mělo předcházet pečlivé zvážení poměru přínosu a rizik v kontextu dané individuální situace.

2.Podání vysokých dávek kortikosteroidů může vést ke zvýšenému výskytu nežádoucích účinků: hyperglykémie, infekční komplikace, krvácení do gastrointestinálního traktu.

Východiska stanoviska:

1. Léčba kortikoidy u nemocných s akutním míšním traumatem byla doporučena na základě výsledků studií The National Spinal Cord Injury (NASCIS II-III). V žádné studii nebyl prokázán signifikantní příznivý efekt na neurologický výsledek mezi sledovanými skupinami.

2.Post-hoc analýza prokázala mírné zlepšení v motorickém ASIA (American Spine Injury Association) skore u nemocných s inkompletní míšní lézí a zahájením léčby do 8 hodin po úrazu.

3. Kritika kvality dat, statistických výsledků, interpretace a závěry studií, absence průkazu příznivého efektu v dalších studiích nepodporuje indikaci rutinního podávání kortikosteroidů u nemocných s akutním míšním traumatem.

4. Podávání kortikosteroidů ve vysokých dávkách je spojeno s vyšším výskytem nežádoucích vedlejších účinků. Rizika kortikosteroidní léčby převažují na potencionálním přínosem terapie.

Přehled studií: viz tabulka

TABLE 9.1 Summary of Reports on Treatment with Methylprednisolone after Acute Cervical Spinal Cord Injury*

Series (Ref No)	Description of Study	Evidence Class	Conclusions
Bracken et al, 1984 (11)	Multicenter, double-blind randomized trial comparing MP (2000 mg/d versus 100 mg/d for 11 d) in treatment of 330 ASCI patients (NASCIS I study).	III (study design, data presentation, interpretation and analysis flaws)	No treatment effect at 6 wk and 6 mo post-injury. No control group.
Bracken et al, 1985 (15)	1-yr follow-up of NASCIS I study.	III (study design, data presentation, interpretation and analysis flaws)	No significant difference in neurological recovery of motor or sensory function 1-yr post-injury.
Bracken et al, 1990 (14)	Multicenter, randomized, double-blind, placebo-controlled trial comparing MP with naloxone and placebo in treatment of 487 ASCI patients (NASCIS II study).	III (study design, data presentation, interpretation and analysis flaws)	Significant improvement in motor change scores ($P = 0.03$), and sensation change scores ($P = 0.02$) at 6 mo post-injury for patients treated with MP within 8 h of injury.
Bracken et al, 1992 (13)	1-yr follow-up of NASCIS II study.	III (study design, data presentation, interpretation and analysis flaws)	Significant improvement in motor changes scores 1 year post-injury for patients treated with MP within 8 h of injury ($P = 0.03$). Administration of MP detrimental if given more than 8 h after injury.
Galandiuk et al, 1993 (21)	Prospective assessment of 15 patients from 1990 to 1993 with retrospective review of 17 patients from 1987 to 1990 to assess differences in treatment outcome with MP compared with treatment without corticosteroids.	III	No difference in neurological outcome between two sets of patients. MP patients had immune response alterations, higher rate of pneumonia, and longer hospital stays than patients who did not receive corticosteroids.
Gerhart et al, 1995 (29)	Concurrent cohort comparison study (population-based) of 363 ASCI patients managed form 1990 to 1991 and 1993. 188 patients managed with NASCIS II MP compared with 90 patients with no MP.	III (Inadequate statistical power)	No differences in neurological outcome using Frankel classification between MP and No-MP patients. However, may be insufficient numbers of patients to show significant differences.
George et al, 1995 (28)	Retrospective review of 145 ASCI patients, 80 treated with MP compared with 65 who did not receive MP.	III	No difference in mortality or neurological outcome between groups despite younger age, less severe injury in MP-treated patients.
Gerndt et al, 1997 (30)	Retrospective review with historical control of 231 ASCI patients, 91 excluded. Comparison of medical complications among 93 MP patients compared with 47 who received no corticosteroid.	III	MP-treated patients had significant increases in pneumonia ($P = 0.02$), acute pneumonia ($P = 0.03$), ventilated days ($P = 0.04$), and ICU stay ($P = 0.45$), but no adverse effect on long-term outcome.
Poynton et al, 1997 (39)	Case-control analysis of 71 consecutive ASCI admissions. 63 available for 13 mo to 57 mo follow-up. 38 patients treated with MP compared with 25 referred > 8 hr after injury who received no MP.	III	Multiple factors influence recovery after SCI. No effect of MP or surgery on outcome.

Series (Ref No)	Description of Study	Evidence Class	Conclusions
Bracken et al, 1997 (16)	Multicenter, randomized double-blind trial comparing MP administered for 24 hr to MP administered 48 hr and TM in the treatment of 499 ASCI patients (NASCIS III study).	III (study design, data presentation, interpretation and analysis flaws)	48 MP patients had improved motor recovery at 6 wk and at 6 mo compared with 24 MP and 48 TM groups NS. When treatment initiated between 3 h and 8 h after injury, 48 MP had significant improvement of motor scores at 6 wk ($P = 0.04$) and 6 mo ($P = 0.01$). 48 MP was associated with high rates of sepsis and pneumonia. No control group.
Bracken et al, 1997 (17)	1-yr follow-up of NASCIS III study.	III (study design, data presentation, interpretation and analysis flaws)	Recovery rates equal in all 3 groups when treatment initiated within 3 h of injury. When treatment initiated between 3 h and 8 h, 24 MP patients had diminished recovery, 48 MP patients had increased motor recovery ($P = 0.053$).
Pointillart et al, 2000 (38)	Multicenter, prospective, randomized clinical trial of 106 ASCI patients treated with MP, nimodipine, neither, or both.	III (Inadequate statistical power)	No significant difference in neurological outcome at 1-yr follow-up between groups. Incomplete ASCI had significant improvement below level of injury compared to complete patients ($P < 0.0001$). Higher incidence of infectious complications among patients receiving corticosteroids (NS).
Matsumoto et al, 2001 (36)	Prospective randomized, double-blind study comparing incidence of medical complications among 46 ASCI patients, 23 treated with MP, 23 with placebo.	I	MP patients had higher incidence of complications (56.5% versus 34.8%). Respiratory complications ($P = 0.009$) and gastrointestinal bleed ($P = 0.036$) were most significant between groups. No data on neurological improvement.

*ASCI, acute spinal cord injury; NASCIS National Acute Spinal Cord Injury Study; MP, methylprednisolone; ICU, intensive care unit; SCI, spinal cord injury; TM tirilazad mesylate; NS, not significant.