



Clinical Decision making for Neck Pain: Use of Clinical Prediction Rules and Current Evidence for Manual Therapy

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Objectives

- Discuss factors relating to clinical decision making for patients with neck pain, including indications and contraindications for the use of joint manipulation.
- Summarize the evidence for the effectiveness of cervical spine joint and soft tissue mobilization.
- Discuss in general terms the application, development, and validation of clinical prediction rules for establishing treatment effectiveness.
- Summarize the current status of clinical prediction rules as evidence for the effectiveness of thoracic manipulation for neck pain.
- Discuss recent studies on the effectiveness of cervical spine manipulation by physical therapists in the clinical setting.

Clinical Case

- Subjective presentation
- Objective findings
- Assessment
- Decision making re: treatment
 - ♦ Red or yellow flags
 - Contraindications, precautions for manual therapy (or save for later?)

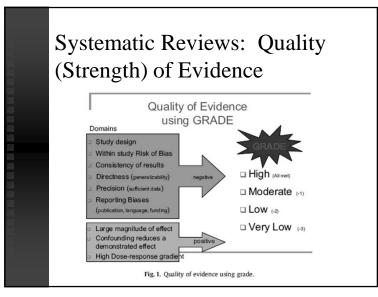
Evidence for Manual Therapy for Treatment of Neck Pain

Recent Systematic Reviews:

- Evidence for massage: Ezzo J, et al. Massage for Mechanical Neck Disorders. Spine. 2007;32(3): 353-362.
- Evidence for manual therapy for neck pain: Series of systematic reviews by the same authors:
 - Gross A, et al. Manipulation or mobilisation for neck pain: A Cochrane Review . *Man Therapy*. 2010;15:3315-333.
 - Miller J, et al. Manual therapy and exercise for neck pain: A systematic review. *Man Therapy*. 2010;15:334-354.
 - D' Sylva J, et al. Manual therapy with or without physical medicine modalities for neck pain: a systematic review. *Man Therapy*. 2010;15:415-433.

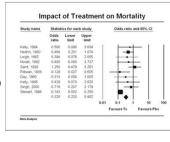
Systematic Review Methods

- Exhaustive search including MEDLINE, EMBASE, Cochrane Library, Manual Alternative and Natural Therapy, CINAHL, and Index to Chiropractic Literature (ICL)
- Inclusion criteria
 - Randomized controlled trials only
 - Acute, subacute, or chronic patients with diagnosis of mechanical neck pain, with or without cervical headaches, radiculopathy
 - Outcome of pain, function/disability, satisfaction, and/or global change
- Independent review by 2 authors
- Quality of methods were assessed using established Cochrane review criteria



Systematic Reviews: Forest Plots

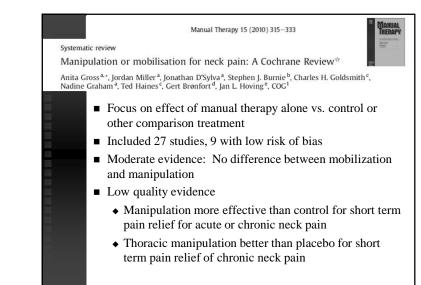
- Display of multiple study comparisons in one graph
- Shows point estimate (rectangle) and 95% CI for difference between treatments (exp. vs. control)
- Meta-analysis (when possible) gives overall weighted average shown by diamond with width of diamond indicating 95% CI

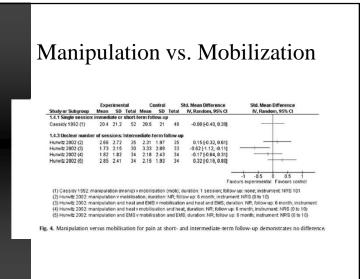


Vertical line in middle of graph = no difference

Evidence for Massage/Soft Tissue Mobilization (Ezzo 2007)

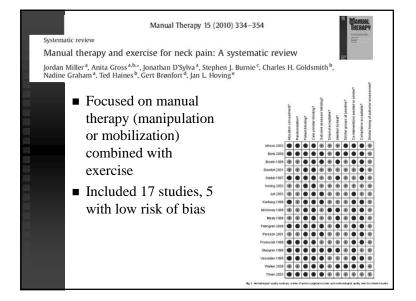
- 19 controlled trials found; all were relatively small, 12 were judged low quality
- Only 6 studies examined massage alone vs. a control; all 6 covered different types of massage
 - ◆ 2 studies included only one treatment
 - 1 study utilized self-administered massage
- Conclusion: Limited evidence of no benefit
- Limitations:
 - Many studies lacked details re: massage method and qualifications of practitioner
 - Disability outcomes rarely reported

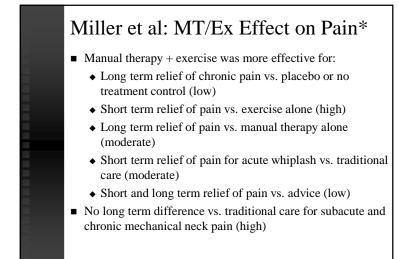




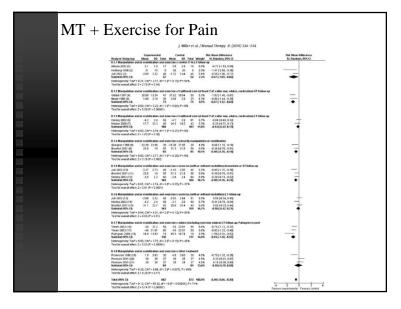
Gross et al: Summary

- Relatively few high quality trials, low sample sizes
- Mostly short and intermediate term results; no difference in long term results
- No indications of optimal dose
- Lack of quality evidence for whiplash associated disorders
- Benign, short term side effects (8 studies)





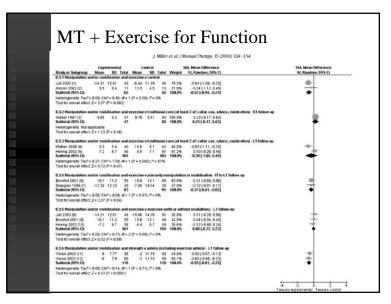
*Strength of evidence in parentheses



Miller et al: MT/Ex Effect on Function*

- Manual therapy + exercise was more effective for:
 - Long term functional improvement vs. placebo or no treatment control (low)
 - Long term functional improvement vs. manual therapy alone (low)
 - Long term functional improvement vs. exercise advice (very low)
- No short or long term difference versus:
 - Exercise only for subacute and chronic mechanical neck pain (high)
 - Traditional care for acute whiplash or for subacute and chronic mechanical neck pain (low)

*Strength of evidence in parentheses



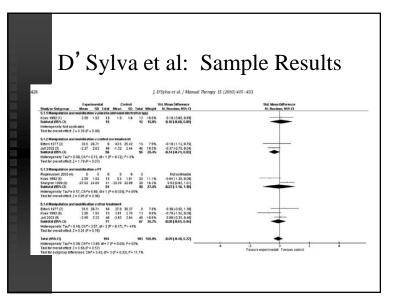
Miller J, et al. Manual Therapy + Exercise

- No significant differences for health related quality of life (5 studies)
- Significant differences in global ratings of change vs. waitlist (1 study) or traditional care (2 studies) but not vs. exercise only (3 studies)
- Moderate evidence shows reduced cost of care for MT+Ex (4 studies)

Miller J, et al. Further Research Needed:

- What is the best manual therapy technique?
- What is the best exercise approach?
- What is the optimal dose of manual therapy and exercise?
- Are there patient subgroups that would benefit more than others?

Manual Therapy 15 (2010) 415–433 Systematic review Manual therapy with or without physical medicine modalities for neck pain: a systematic review Jonathan D'Sylva^A, Jordan Miller^A, Anita Gross^{A,*}, Stephen J. Burnie^b, Charles H. Goldsmith^C, Nadine Graham^A, Ted Haines^C, Gert Bronfort^A, Jan L. Hoving^C, for the Cervical Overview Group. Manipulation, mobilization plus various physical medicine modalities were not more effective than various control group comparisons including modality alone, placebo, exercise, and education (low quality evidence) Mobilization, massage, heat, E stim and meds are more effective than meds alone for chronic neck pain (very low quality evidence) Manual therapy may be less costly than various alternative treatments (moderate quality evidence)



September, 2008 JOSPT Clinical Guidelines

INTERVENTIONS – CERVICAL MOBILIZATION/MANIPULATION: Clinicians should consider utilizing cervical manipulation and mobilization procedures, thrust and non-thrust, to reduce neck pain and headache. Combining cervical manipulation and mobilization with exercise is more effective for reducing neck pain, headache, and disability than manipulation and mobilization alone. (Recommendation based on strong evidence.)

JOSPT. 2008;38(9):A1-A34.

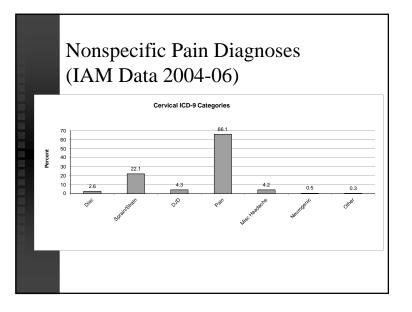
Challenges with Traditional Research on Manual Therapy for Spine Pain

- Spontaneous recovery: Some patients get better no matter what treatment
- Lack of examination/diagnostic tests with proven validity
- Wide array of manual therapy approaches; Different practitioners would not agree on:
 - ◆ Examination techniques
 - ◆ Findings or "diagnosis"
 - Manual therapy techniques
- →No way to agree on diagnostic categories or treatment approach

Result: Clinicians (and Researchers) Can't Agree on Pathology or Treatment

Patients with "nonspecific neck pain" of various causes are all randomized to manual therapy vs. other interventions, with no indication that manual therapy is even appropriate for the patient

- No 2 studies use the same manual therapy approach
 - If choice of technique is left up to the therapist ("eclectic approach"), then no 2 patients in a study receive the same technique!



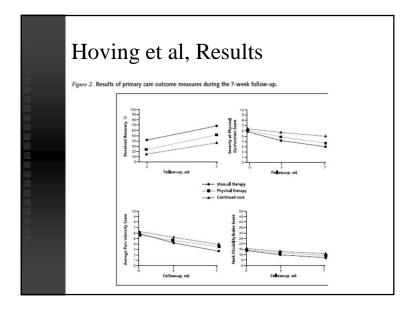
Example: Hoving et al, Ann Int Med 2002

- RCT; 183 patients with nonspecific neck pain
 - ◆ GP care education, NSAIDs
 - ◆ PT: Physical Therapy" exercise, modalities
 - ◆ MT: Manual Therapy PTs, DOs, DCs using own approach
- Outcomes
 - ♦ Pain
 - ◆ Neck Disability Index (NDI)
 - Global rating of perceived recovery "completely recovered" or "much improved"

*Hov ng J, et al. Manual Therapy, Physical Therapy, or Continued Care by a General Practitioner for Patients with Neck Pain . Ann Intern Med. 2002;136:713-722.

Hoving et al, 7 week outcomes

- Pain: Manual therapy was significantly better on pain VAS than PT or GP by 0.9, 1.5 on VAS
- Disability: Manual therapy was better, but differences not statistically significant
- Perceived recovery
 - $\bullet MT = 68.3\%$ NNT
 - $\bullet PT = 50.8\%$ - MT vs GP = 3- MT vs PT = 7
 - \bullet GP = 35.9%



Ingeborg BMJ 2003: F/U on Hoving Study

Cost Analysis

■ Manual Therapy \$402

■ Standard PT \$1167

■ GP

\$1241

Alternative to Diagnosis on Pathology: Classification Approach

- Classification an alternative to "Diagnosis" (which nobody can agree on anyway!)
 - ◆ Diagnosis a process to determine the underlying cause (i.e., "tissue at fault") of a patient's illness or discomfort
 - Classification a process of categorizing patients according to treatments for which they have been shown to respond favorably

Comments on Hoving et al

- Sample was "nonspecific neck pain whose clinical presentation did not warrant further diagnostic screening"
- All groups tended to get better over 7 weeks
- Manual therapy group did significantly better at less cost, but differences in pain, disability were not as great as we would hope
 - Are there subgroups that benefit more?
 - Can we identify them?
- If you wanted to incorporate these results into your practice, what would you do?
 - PT, chiropractic, and osteopathic methods used
 - No details on manual therapy techniques

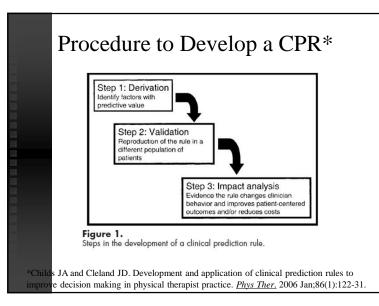
Diagnosis vs. Classification Diagnosis categories (traditional, biomechanical) C6-7 herniated disc Right C5-C6 facet FRS left Treatment based classification categories* (Decreased) Mobility Centralization Conditioning and Exercise Tolerance Pain Headaches (Cervicogenic)

Clinical Prediction Rule

- Method developed for diagnostic tests
- Administer a variety of history and objective diagnostic tests, followed by the gold standard
- Determine which of the exam findings are the best predictors for that diagnosis
- Examples:
 - CPR for cervical radiculopathy (Wainner, et al. *Spine*, 2003; 28:52-62.)
 - Ottawa Ankle Rules (JAMA, 1993, 1994)
 - CPR for deep vein thrombosis in orthopaedic outpatients. Riddle DL. *Clin Orthop.*

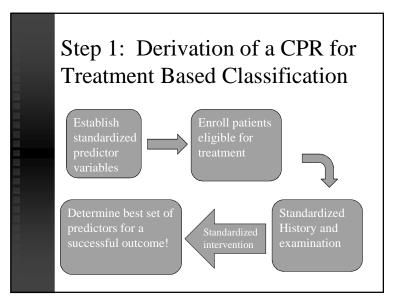
Types of CPRs

- Diagnostic: probability that a patient has a particular condition
- Prognostic: likely outcome of patients with a specific condition
- Interventions: which patients are likely to respond to a type or set of intervention(s)



Step 1: Derivation of a CPR for Treatment Based Classification

- Clinicians and researchers brainstorm potential and standardize a set of predictor variables
 - May be from history or examination
 - ◆ Ideally need 10-15 patients per predictor
- Enroll patients; blinded examiner administers standardized history and examination
- Apply the reference criterion
 - In diagnostic studies, the gold standard for diagnosis, such as an MRI
 - In treatment studies, it is a pre-defined favorable response to a standardized intervention, such as spinal manipulation



Step 1 for CPR: Data Analysis

- Analyze which predictor "diagnosed" which patients were most likely to benefit from treatment
- For each predictor, calculate:
 - Sensitivity and specificity (want close to 1)
 - Likelihood ratios
 - Positive predicts + response to treatment (higher above 1, the better)
 - Negative predicts unfavorable response to treatment (farther below 1, the better)
- Use multivariate regression analysis to "identify the most parsimonious set of predictor variables" (Childs and Cleland)

Step 2 for CPR: Validation

- Must be done before clinical implementation!
 - When you do an analysis with many predictors, some may be significant just by chance
 - This is unlikely to happen again when the study is repeated (i.e., validated)
 - Validation is also necessary to use the CPR in a different patient population and/or to show that it can be applied by various clinicians
- For diagnosis CPR, can repeat step 1 in a different sample to see if the same predictors emerge
- For treatment CPR, step 2 and 3 may be combined

Step 3: Conduct Impact Analysis

- Assess impact of using CPR in clinic
- 3 Methods
 - Compare outcomes pre/post implementation
 - Randomized controlled designs (better)
 - Randomize each patient to CPR or non-CPR
 - Randomize different clinics to follow CPR or non-CPR approach
- Patients positive on the rule should have:
 - Better response to treatment than those not selected when given the experimental treatment
 - Worse response to treatment when given the control treatment

able 4. evels of Evidence for Clinical Prediction Rules ⁴⁵			
Level	Requirements		
I	At least one prospective validation in a different population plus one impact analysis demonstrating change in clinician behavior with beneficial consequences		
II	Validation in one large prospective study, including a broad spectrum of patients and clinicians, or in several similar settings that differ in geographical location and experience levels of clinicians		
	Validated in only one narrow prospective sample		
IV	Derived but not validated, or validated only in split samples or large retrospective databases or by statistical techniques		

Evidence for Effectiveness of Thoracic Spine Manipulation for Neck Pain

Development of CPR for Neck Pain



- Cleland, et al. Phys Ther. 2007; 87(1):9-23.
- Subjects: Ages 18-60, primary c/o neck pain, Neck Disability Index ≥ 10%
- Standardized history and examination
- Standardized treatment
 - ◆ 3 Thoracic thrust manipulations (2 visits)
 - ♦ Cervical ROM exercise
 - ♦ Maintain usual activity

CPR for Neck Pain (cont.)

- Success = "a great deal better" per global measure within 2 visits
- 42/78 (54%) success rate by this criteria



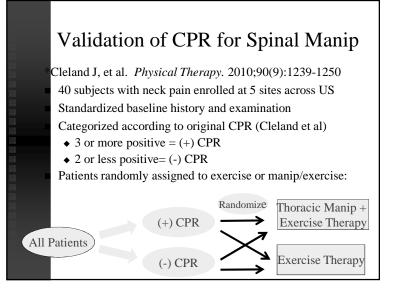
CPR for Neck Pain (cont.)

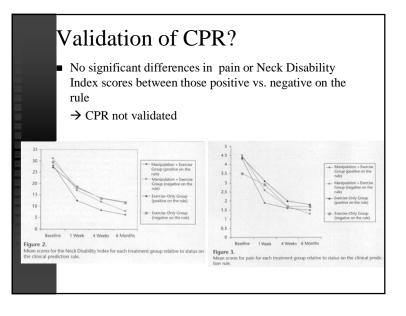
• Factors predicting success:

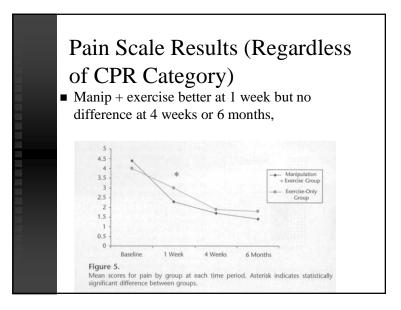
- ♦ Neck pain < 30 days
- ♦ No sxs distal to shoulder
- Looking up does not aggravate
- \bullet FABQPA < 12
- Decreased upper thoracic kyphosis
- ◆ Cervical Extension < 30 deg
- 86% success if 3/6 are present

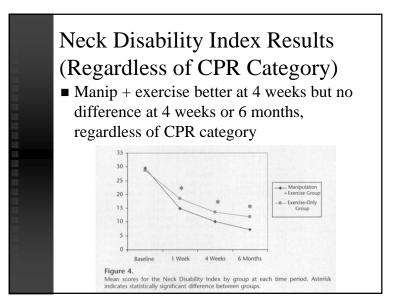
Cleland et all (2007) Alone: Weak Evidence

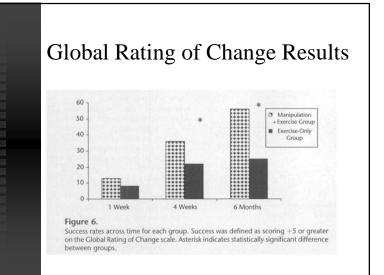
- Some patients in any cohort with neck pain will get better spontaneously
- Significant predictors (baseline findings) may be:
 - Simply predicting those with natural recovery
 - ♦ Chance findings
- Need a follow-up study to validate the clinical prediction rule











Conclusions: Cleland et al, 2010

- CPR not validated
- Thoracic manipulation plus exercise more effective than exercise alone for the treatment of neck pain.

More Evidence for T-Manip for Acute Neck Pain



Gonzalez-Inglesias J, et al. Thoracic spine manipulation for management of patients with neck pain: An RCT. JOSPT. 2009;39(1): 20-27.

- ◆ Patients (n=45): Mechanical neck pain < 1 mo. Duration
- ◆ Treatment:
 - ◆ 5 visits heat/electrotherapy vs. 5 visits heat/electrotherapy (3 with T-manip)
- Results: Manip significantly more effective for pain, disability, and ROM at 4 weeks

More Evidence for T-Manip for **Chronic Neck Pain**



- Mun Cheung Lau H et al, The effectiveness of thoracic manipulation on patients with chronic mechanical neck pain - RCT. Man Ther. 2011;16:141-147.
 - N = 120 patients with neck pain > 3 mos.
 - ◆ Randomized to thoracic manip vs. infrared heat + education
 - Outcomes at end of treatment, 3 and 6 mos: Pain, disability, posture, ROM
 - Results: Pain, disability, ROM, posture all significantly better for manipulation group at 3 and 6 mos.

Systematic Review on Thoracic Manipulation for Neck Pain*

- 6 RCTs included; PEDro scores 6-7 out of 10
- Subjects primarily had acute or subacute pain
- Results: Significant, large effect sizes in favor of manipulation (vs. various control) for pain, ROM, and functional measures.
- Conclusion: "Thoracic spine thrust manipulation may provide short-term improvement in patients with acute or subacute mechanical neck pain. However, the body of literature is weak, and these results may not be generalizable."

Cross KM, et al. J Orthop Sports Phys Ther 2011;41(9):633-642.

Physical Therapy

Critical Appraisal of Clinical Prediction Rules That Aim to Optimize Treatment Selection for Musculoskeletal Conditions Tasha R. Stanton, Mark J. Hancock, Christopher G. Maher, Bart W. Koes

- Reviewed 18 articles related to 15 different CPRs published through April 2009
- Only one CPR (lumbosacral manipulation) had been validated, and those results were not confirmed by other authors
- CPRs do not provide strong evidence at this point in time

PhysTher. 2010;90:843-854.

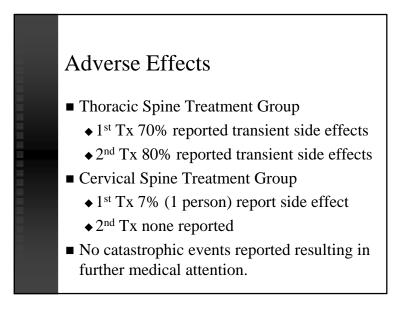
What About Cervical Spine High Velocity Low Amplitude ("Thrust") Manipulation?

T Spine Thrust Vs. C Spine Thrust in Patients With Acute Neck Pain: An RCT*

- RCT enrolling subjects who met the CPR for thoracic manipulation
- Subjects randomized to receive 2 sessions consisting of:
 - ◆ 3 T-spine manipulations + exercise, or
 - ◆ 1 mid cervical spine manipulation+ exercise

*Puentedura EJ, et al. JOSPT. 2011;4:208-220.

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Recent RCT: Cervical Manip More Effective than Cervical Mobilization*

- Multicenter RCT enrolling patients with neck pain
- Randomized to receive one visit for:
 - ◆ Bilat. thrust manip to C1-C2 and T1-T2, or:
 - ◆ Bilat. grade IV mobilization to C1-C2 and T1-T2
- Results: Thrust manipulation showed significantly greater improvement in pain, NDI
- Caution: Only 48 hour follow-up
- No adverse events reported
 - *Dunning JR, et al. JOSPT, in press

Risk for Cervical Manipulation

- Transient side effects from cervical manipulation (Cagnie B. *Man Ther*. 2004;9(3):151-156.)
 - Survey of 465 patients following PT, DO, or DC manipulation
 - ♦ 61% had at least one side effect (neck pain, radiating pain, HA, dizziness, blurred vision)
 - ♦ Most lasted 4-24 hours

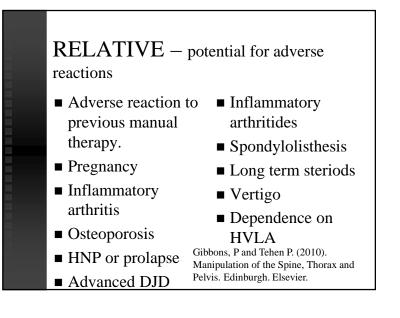
Risk for Thoracic Spine Manipulation

- Transient in nature, not catastrophic.
- Recent literature demonstrates that there is greater likelihood for transient side effects.
- Thoracic manipulation causes greater risk of side effects but does not carry the catastrophic risk?

Risk of Serious Injury

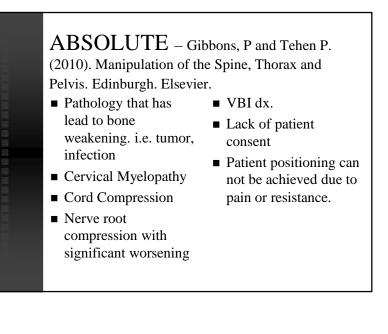
- Thrust manipulation risk estimates
 - ◆ Risk of serious complications estimated at 6 in 10 million (Hurwitz, Spine, 1996)
 - Risk of death at 3 in 10 million
 - Haldemann (Spine, 1999) documented 115 cases of vertebral artery occlusion leading to CVA after chiropractic manipulation leading to ischemia and CVA

Risks in Perspective			
Procedure	Risk / 10,000	Complication	
LS Manip	0.001	Cauda Equina	
Cervical Manip	0.006	Death or stroke	
Exercise	0.007	Death	
NSAIDs	100-300	GI Bleed	
C Spine Surgery	15.6	Varied	
Disc Surgery	1.6-1.7	Vascular perforation	
Disc Surgery	3.8	Visceral injury	
Fusion	1700	Various	
Lumbar surgery	20-30	Death	



Clinical Opinion

- Even though overall risks are small, the potential for spinal cord or vertebral artery injury is there
- Cervical spine manipulation has not been shown to be more effective than more gentle mobilization techniques (Gross A, et al. Manipulation or mobilisation for neck pain: A Cochrane Review. Man Ther 2010;15(5): 315-33)
- For this reason, mobilization techniques are often preferred and are recommended DPT faculty and other experienced clinicians
- If manipulation is performed, avoid extremes of ROM



Conclusions

- Thoracic spine manipulation may be a reasonable alternative to cervical spine manipulation for the treatment of neck pain
- No currently validated clinical prediction rule to identify a subset of subjects with better prognosis for manipulation.

Stay tuned: Future Research

- Limited, early evidence suggests that Cspine manipulation may be more effective than mobs or T-spine manipulation in the short term.
- Will C-spine manipulation prove to be effective in the long term to reduce chronic pain and disability?

Take Home

- CPR approach does not require complex biomechanical examination and analyses to decide on treatment approach
- These studies suggest that thoracic manipulation is more effective for neck pain than exercise or modalities alone, but no subgroup has been identified that would respond more favorably.
- Mechanism for improvement is unknown
 - Just because we don't know why it works, doesn't mean we can't use it!
 - There are a lot of "recovering biomechanists" in the PT world!