**Baseline Physical Exam Predicts Final
Self-Reported Pain outcomes from a Randomized
Trial on Chronic Cervicogenic Headache**

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Presenter Disclosures

No relationships to disclose

Spinal Manipulative Therapy and CHA

- Self-reported outcomes (SO) for evaluating treatment effect:
  - Reported extensively in systematic reviews of RCTs for CHA
    - (Hurwitz 1996, Vernon 1999, Bronfort 2001, Astin 2002, Bronfort 2004, Lenssinck 2004, Fernandez-de-Las-Penas 2005 & 2006)
  - Include pain intensity, headache index, frequency, duration, and improvement.
- Objective outcomes commonly used by physicians:
  - Not established as primary outcomes in CHA clinical trials.

Objectives of analysis project

- CHA clinical trials use self-reported outcomes.
- We have tertiary PE data:
  - 73 RCT subjects (2 with no baseline PE, 5 with no SO f/u)
  - Two treatment doses (1/week & 2/week for 8 wks)
  - Unblinded DCs performing attention control PEs
  - 35 SMT
  - 38 Light Massage (LM)
- What could baseline objective PE measures reveal and how do they predict six month self-reported CHA subjective outcomes (SO)?
  - We investigate for associations using forwards and backwards stepwise regression.

Self-reported Subjective Outcomes (SO)

- Modified Von Korff scales (0-100)
  - CHA Pain
  - CHA Disability
  - Neck Pain
  - Neck Disability
- Number of CHA headaches in the last 4 weeks
- Related CHA disability days in the last 4 weeks

Standardized PE (8 minutes)

- Active cervical range of motion
  - Inclinometric evaluation
  - Associated pain (0-10 scale)
- Motion and static palpation of the spine
  - Cervical region
  - Upper thoracic region
- Algometric pain threshold evaluated over articular pillars/ transverse processes

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Stepwise regression

- All PE variables were assessed individually to see if they predicted each SO change from baseline
  - Chosen PE variables were then placed into stepwise regression models
- Forwards selection
  - We started with the best PE variable in the model
  - The remaining chosen PE variables were reassessed and the best of these was added to the model (repeat)
- Backwards elimination
  - We started with all the chosen PE variables in the model
  - The worst PE variable was eliminated from the model and a new model was generated (repeat)
- All regressions were adjusted for baseline randomization variables

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Table 1.—Baseline Participant Characteristics*

	(n = 73)
Socio-demographic information	
Age (years)	36 ± 11
Gender (female)	59 (81%)
Migraines	21 (29%)
Treatment group assignment	
SMT for 16 treatment visits	16 (22%)‡
SMT for 8 treatment visits	19 (26%)
LM for 16 treatment visits	19 (26%)‡
LM for 8 treatment visits	19 (26%)
Treatment expectation differences (SMT – LM)	
Optimal # txs out of 16 possible to resolve my LBP	-1.6 ± 4.2
Confidence tx will resolve my LBP	0.1 ± 1.0

SMT – spinal manipulative therapy; LM – light massage.
*notation is (mean ± sd) or n (%) as appropriate.
†100-point visual analog scales with lower scores favorable.
‡Two subjects did not receive a baseline attention physical exam

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Table 2.—Self-reported subjective headache outcomes (unadjusted)*

	(n = 73)		
	baseline	Week 24	Change from baseline
Cervicogenic headaches			
Pain intensity†	54.2 ± 16.9	38.0 ± 22.1	-16.2 ± 23.5
Functional disability†	45.2 ± 22.3	25.0 ± 22.2	-19.7 ± 25.0
Number (last 4 wk)	15.9 ± 8.1	8.5 ± 7.1	-7.4 ± 8.8
Disability days (last 4 wk)	5.1 ± 5.2	2.6 ± 4.4	-2.5 ± 4.5
Neck			
Pain intensity†	56.4 ± 21.5	41.6 ± 24.8	-14.9 ± 29.1
Functional disability†	42.6 ± 22.6	26.3 ± 25.2	-16.3 ± 25.7

SMT – spinal manipulative therapy; LM – light massage.
*notation is (mean ± sd) or n (%) as appropriate.
†100-point visual analog scales with lower scores favorable.

Table 3. –Baseline Physical Exam Scores

	(n = 73)
Cervical Active ROM (Inclinometer)	
Rotation: min R or L (Normal 80° - shoulder)	73 ± 12
Flexion (Normal 60°)	58 ± 12
Extension (Normal 75°)	56 ± 14
Lateral Bending: min R or L (Normal 45°)	40 ± 9
Cervical Active ROM (Pain: 0 – 10)	
Rotation†: max R or L	1.8 ± 2.4
Flexion†	1.3 ± 2.1
Extension†	1.1 ± 2.0
Lateral Bending†: max R or L	2.5 ± 2.6
Sitting Rotation Endplay Restriction	
C_{0-1} to C_{2-3}: L or R	66 (90%)
C_{3-4} to C_{5-6}: L or R	59 (81%)
C_{6-7} to $C_7 T_1$: L or R	31 (42%)
T_{1-2} to T_{3-4}: L or R	42 (58%)
Pain Pressure Threshold (kg)	
C_2: min R or L	2.9 ± 1.0
C_{4-5}: min R or L	3.0 ± 1.2
C_7: min R or L	3.6 ± 1.6
Orthopedic Tests for midline pain (Pain: 0 – 10)	
Compression†: max R or L	1.3 ± 2.1
Distraction†: max R or L	0.3 ± 0.9

SMT – spinal manipulative therapy; LM – light massage; ROM – range of motion.
*notation is (mean ± sd) or n (%) as appropriate.
†10-point pain scale with 0 indicating no pain and 10 indicating highest pain conceivable.

Table 4. – PE's that predict subjective outcome change from baseline*
(Table only shows textured p-values when the p-value from linear model is <.20)

*All listed models include covariates for age, presence of migraine, treatment and dose group, difference in expected number of treatments necessary between modalities, difference in expected success with treatment modality, baseline HA pain, and baseline # HA in addition to baseline subjective outcome being predicted.
†Number of headaches and number of days with headache are over the past four week

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CGH Pain model

- Every Kg of PPT at C4-C5 at baseline PE predicts a
  - 4.9 point improvement 95%CI(.6, 9.2) in CGH pain
  - This is statistically significant
- Every 10 degrees of restriction of extension at baseline PE predicts a
  - 3.3 point improvement 95%CI(-0.7,7.3) in CGH pain
- On average at 24 weeks on a 0-100 MVK pain scale after adjusting for each other, baseline CGH pain, and randomization variables using backwards or forwards sw linear regression
- NB:
  - Estimates are 6.7 and 5.3 respectively in those receiving SMT suggesting an interaction effect between PE and tx group

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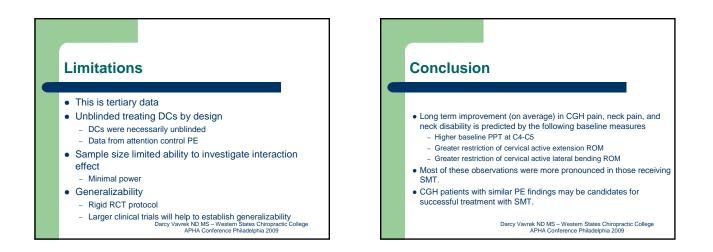
Neck Pain model

- Every Kg of PPT at C4-C5 at baseline PE predicts a
  - 7.5 point improvement 95%CI(2.5,12.6) in neck pain
  - This is statistically significant
- Every 10 degrees of restriction in lateral bending at baseline PE predicts a
  - 7.7 point improvement 95%CI(0.0, 15.4) in neck pain
- On average at 24 weeks on a 0-100 MVK pain scale after adjusting for each other, baseline neck pain, and randomization variables using backwards or forwards sw regression
- NB:
  - Estimates are 5.7 and 16.1 respectively in those receiving SMT suggesting an interaction effect between lateral bending and tx group.

Neck Disability model

- Every Kg of PPT at C4-C5 at baseline PE predicts a
  - 5.9 point improvement 95%CI(1.2,10.6) in neck disability
  - This is statistically significant
- Every 10 degrees of restriction in lateral bending at baseline PE predicts a
  - 9.0 point improvement 95%CI(1.7, 16.2) in neck disability
  - This is statistically significant
- On average at 24 weeks on a 0-100 MVK disability scale after adjusting for each other, baseline neck disability, and randomization variables using backwards or forwards sw regression
- NB:
  - Estimates are 5.8 and 13.0 respectively in those receiving SMT suggesting an interaction effect between lateral bending and tx group.

Limitations

- This is tertiary data
- Unblinded treating DCs by design
  - DCs were necessarily unblinded
  - Data from attention control PE
- Sample size limited ability to investigate interaction effect
  - Minimal power
- Generalizability
  - Rigid RCT protocol
  - Larger clinical trials will help to establish generalizability

Conclusion

- Long term improvement (on average) in CGH pain, neck pain, and neck disability is predicted by the following baseline measures
  - Higher baseline PPT at C4-C5
  - Greater restriction of cervical active extension ROM
  - Greater restriction of cervical active lateral bending ROM
- Most of these observations were more pronounced in those receiving SMT.
- CGH patients with similar PE findings may be candidates for successful treatment with SMT.

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