

Meaningfulness of PROs: Clinician and Patient Perspectives

2020 DO-Touch.NET Annual Meeting and Educational
Seminar

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Disclosure Information

DO-Touch.NET Annual Meeting and Educational Seminar

Measuring the Impacts of OMM:

Patient-reported Outcomes in the Clinical Setting

Michael Dohm, MD, and Brian F. Degenhardt, DO

- We have no financial relationships to disclose.
- We will not discuss off-label use or investigational use in our presentation.



Learning Objectives

After attending, participants should be able to:

1. discuss the utility of patient-reported outcome measures in clinical practice,
2. explain how patient-reported outcomes can be used to improve health, and
3. outline methods for discussing patient-reported outcomes with patients.



Aim of Medicine

- To provide safe, effective, timely, patient centered, efficient and equitable care

Institute of Medicine, Crossing the Quality Chiasm, 2001



Our Questions -

- How many of our patients get better?
- Implication of unreliable diagnostic palpation?
- Is our inability to demonstrate reliability an important factor why outcomes are not as robust as we think they should be in pragmatic studies?
- Are we willing to improve the art of osteopathy and medicine by progressively engaging a 21st century scientific process to what we do?



George W. Northup, DO

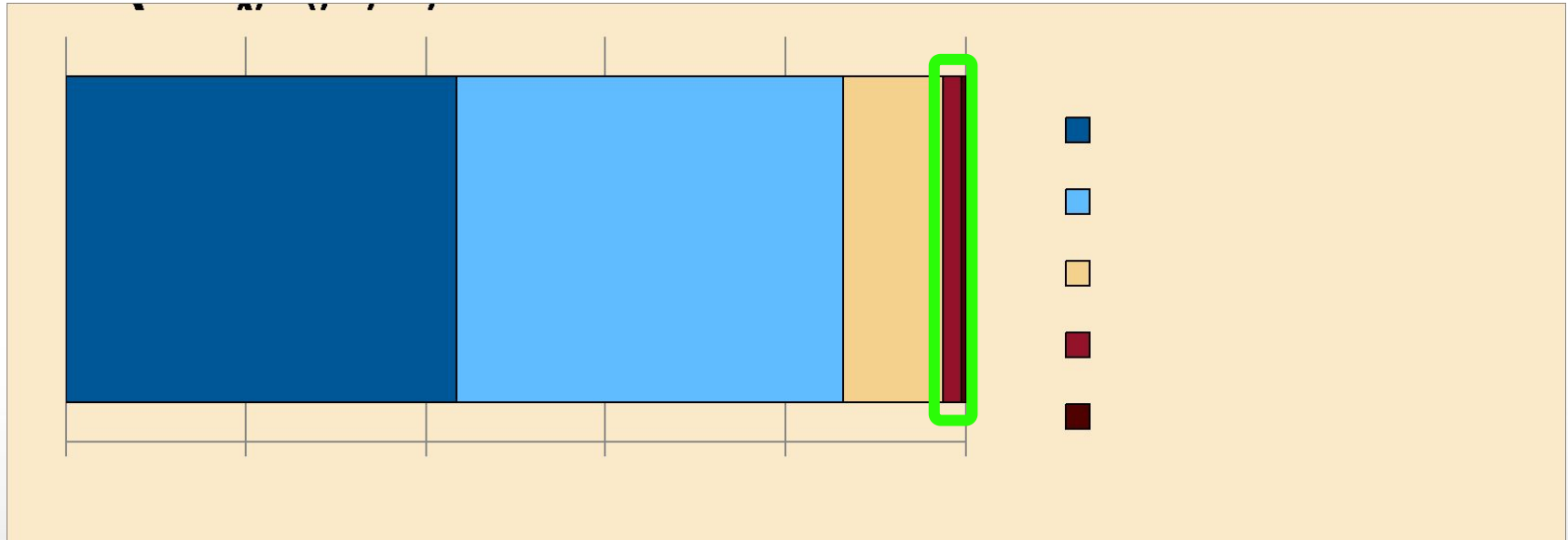
- Today, the practice of medicine needs as never before the guiding light of a fundamental philosophy. It needs to recognize the action and interaction of all body systems. It should apply known truths and explore new frontiers founded on the osteopathic profession's basic philosophy.... Dr Still did not say he was giving the world a philosophy that should act as a guide to the future. Rather, in his book, *The Philosophy of Osteopathy*, he stated his desire was "... to give the world a start in a philosophy that may be a guide to the future".



SAFETY



Patient Reported Response - Immediate AE



Adverse Events Defined

“Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease **temporally associated** with the use of a medical treatment or procedure that **may or may not be considered related** to the medical treatment or procedure.”

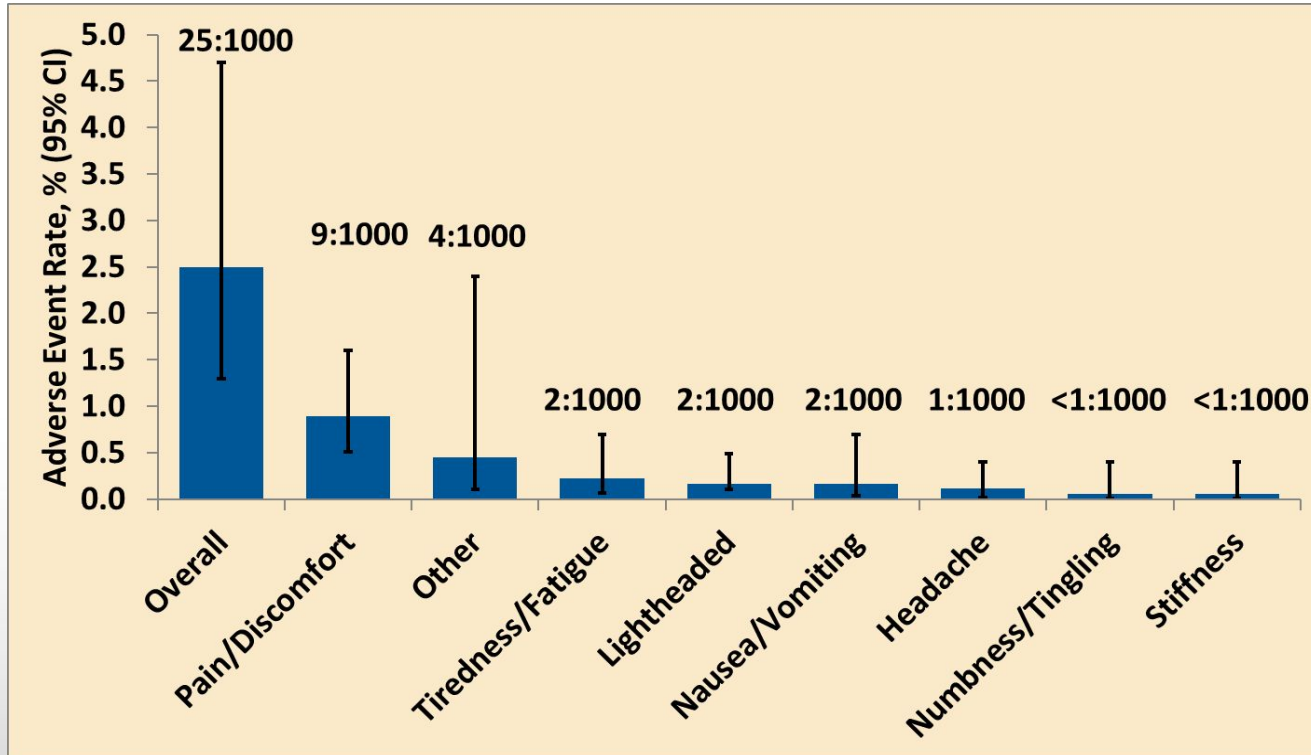


Adverse Events

- Number of Participants: 27/864
- Number of Office Visits: 44/1,817
- Number of Clinicians: 14/43
- Gender: 26 (96%) female, 1 (4%) male
- Age: mean (SD) 52.6 (15.7) years, range 21-90
- Ethnicity: 26 (96%) Not Hispanic/Latino or not specified
- Race: 26 (96%) White



Patient Reported Response - Immediate AE



Adverse Event Rate (Immediate): 2.5%

(4/157/1847)

Table.

Association of Demographic Characteristics and Incidence of Adverse Events Reported Immediately After Osteopathic Manipulative Treatment (N=1847 office visits)

Demographic Variable	Adverse Event (n=45)	No Adverse Event (n=1802)	OR (95% CI)	P Value
Gender, No. (%) female ^a	44 (97.8)	1380 (76.9)	13.9 (1.7-115.6) ^b	.01
Race/ethnicity, No. (%) ^c other	2 (4.4)	144 (8.1)	0.6 (0.1-4.8) ^d	.61
Age, y, mean (SD) ^e	46.8 (16.3)	51.2 (14.5)	0.8 (0.5-1.3) ^f	.35

^a Seven participants chose not to provide their gender; none had an adverse event.

^b OR comparing female with male patients.

^c Twenty-four participants chose not to provide their race and/or ethnicity; none had an adverse event.

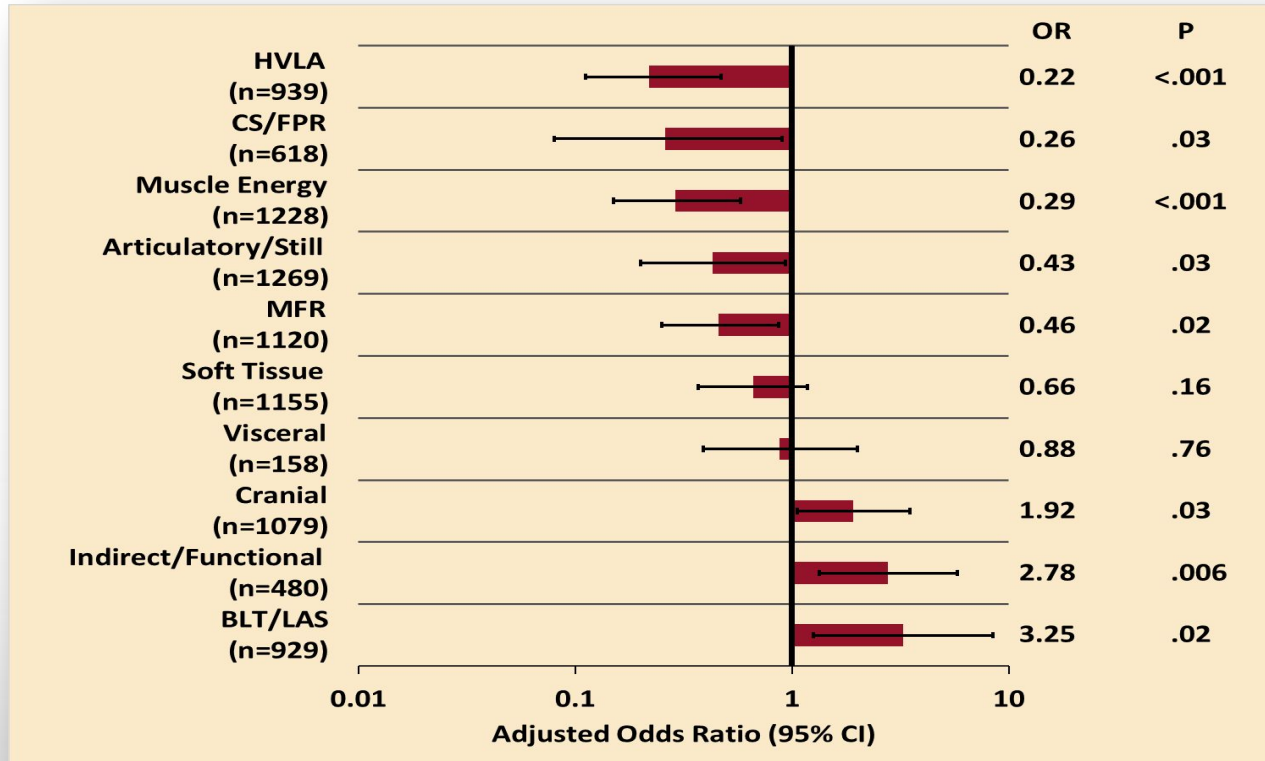
^d OR comparing other race/ethnicity patients with white patients.

^e Twenty-two participants chose not to provide their age; none had an adverse event.

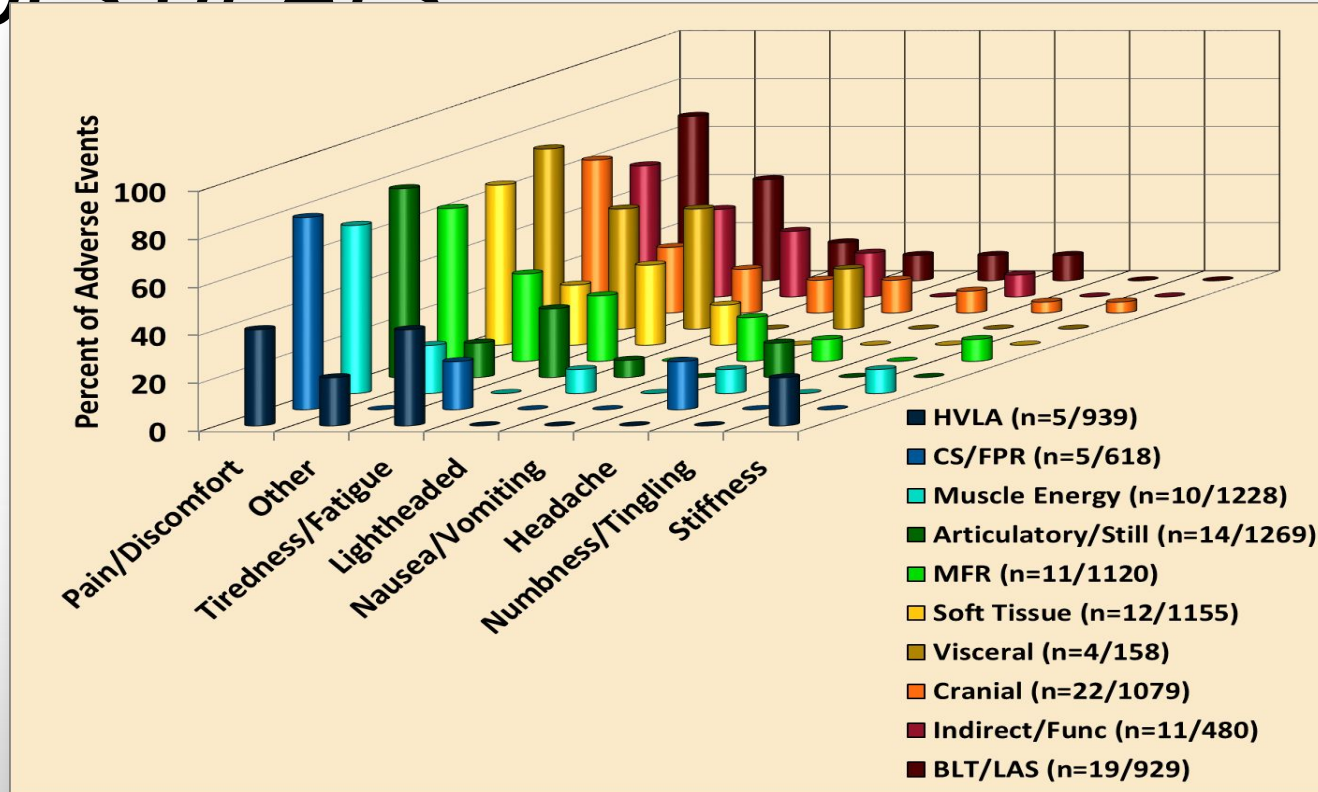
^f OR comparing the change in odds for a 10-year increase in age.



Immediate AE



Immediate AE - *Techniques and Types of AEs*

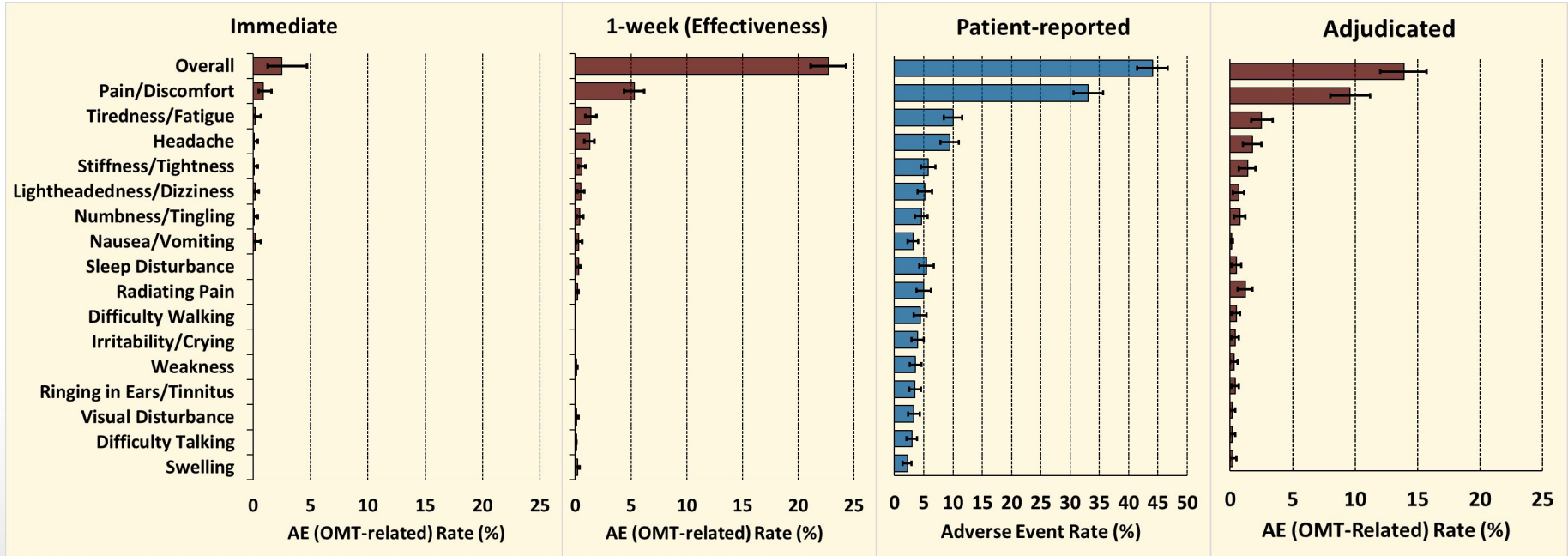


Adjudicated AE

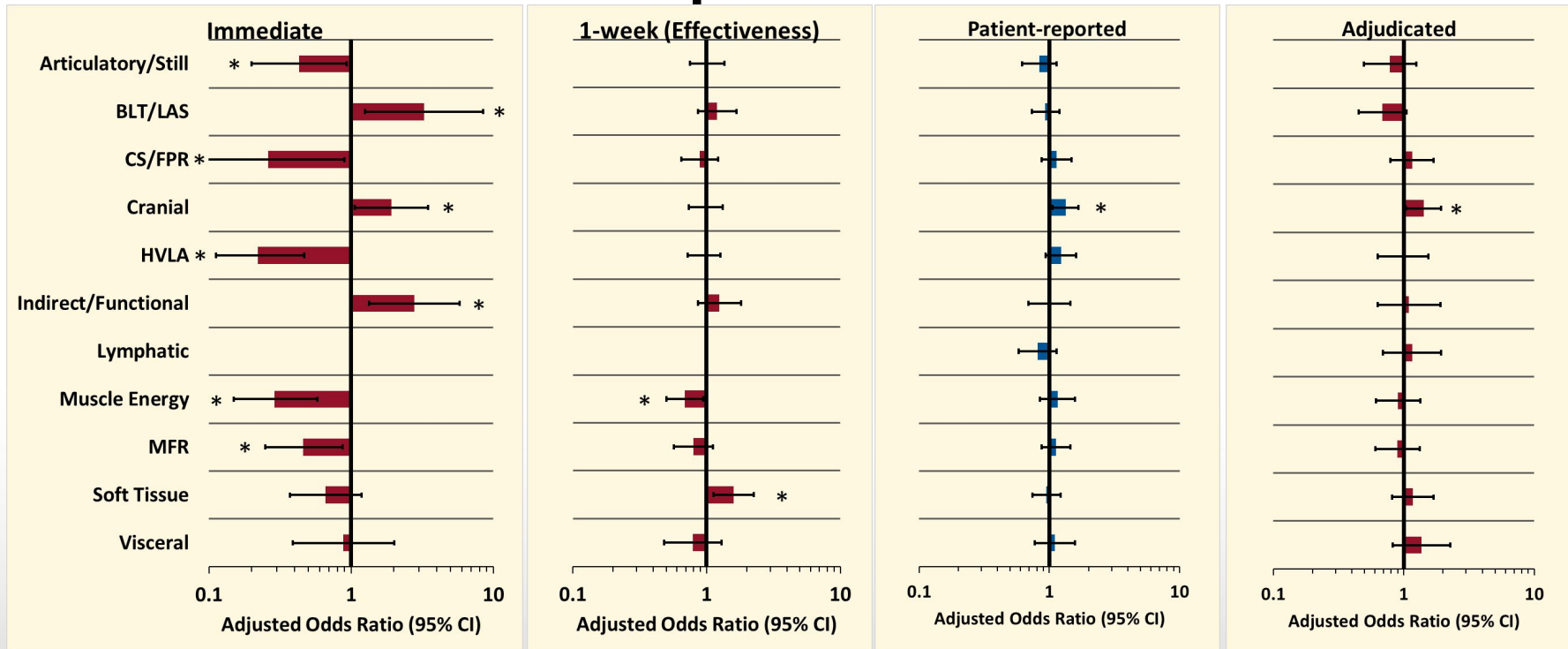
- 1303 patients participated, 899 from the US and 404 from Germany
- 541 (42%) patients had 1 or more AEs during week after OMT
- Adverse Event Rate: 41.5% (38.9%-44.2%)
- Adverse Event (OMT-Related) Rate: 13.9% (12.0%-15.7%)
 - Only 1 patient report of healthcare usage (a return visit to the treating clinician in the office) was an adverse event that was judged to be related to OMT.
- Adverse Event (OMT-Related or Undetermined) Rate: 29.9% (27.4%-32.3%)



Comparison on Adverse Event Rates



Comparison on Effect of Techniques



■ ■ ■ AE Severity Grading Scale (NCI)

- Common Terminology Criteria for Adverse Events (CTCAE) used for oncology drugs, generally not appropriate for otherwise healthy subjects.
- Grade refers to the severity of the AE
 - **Grade 1** Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; no intervention indicated
 - **Grade 2** Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL
 - **Grade 3** Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL
 - **Grade 4** Life-threatening consequences; urgent intervention indicated.
 - **Grade 5** Death related to AE.



<http://evs.nci.nih.gov/ftp1/CTCAE/About.html>



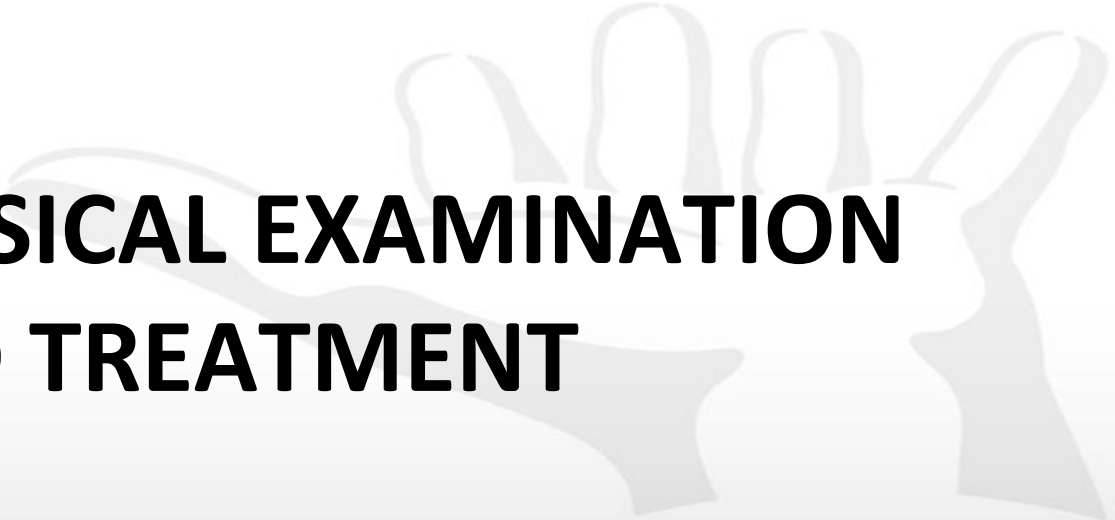
Consent Parameters



Conclusions

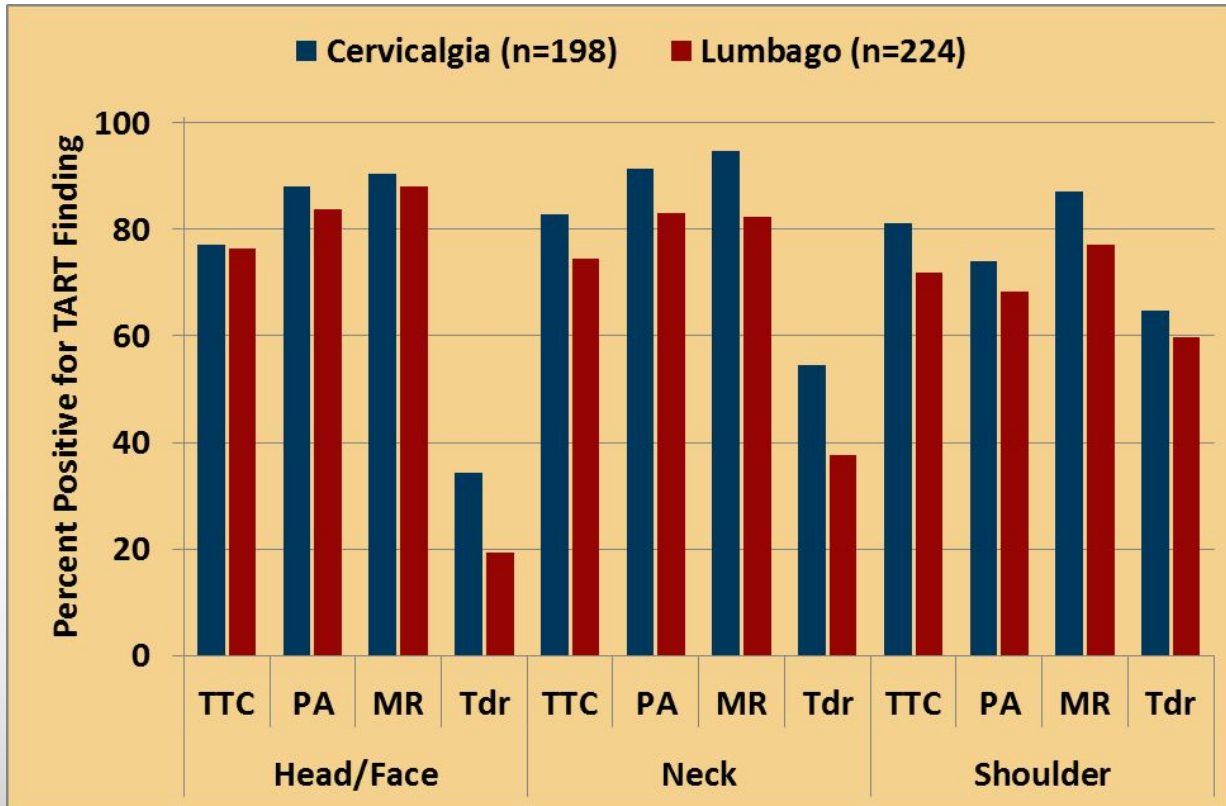
- Adverse events occur with all OMTs
- Most common immediate AE tend to fall into one of seven categories
- Immediate AE are infrequent and mild (2.5% rate)
- >80% report feeling better or much better
- Large numbers of office visits are needed to best estimate the incidence of AE following OMT
- Longitudinal data is needed to assess the true impact of OMT



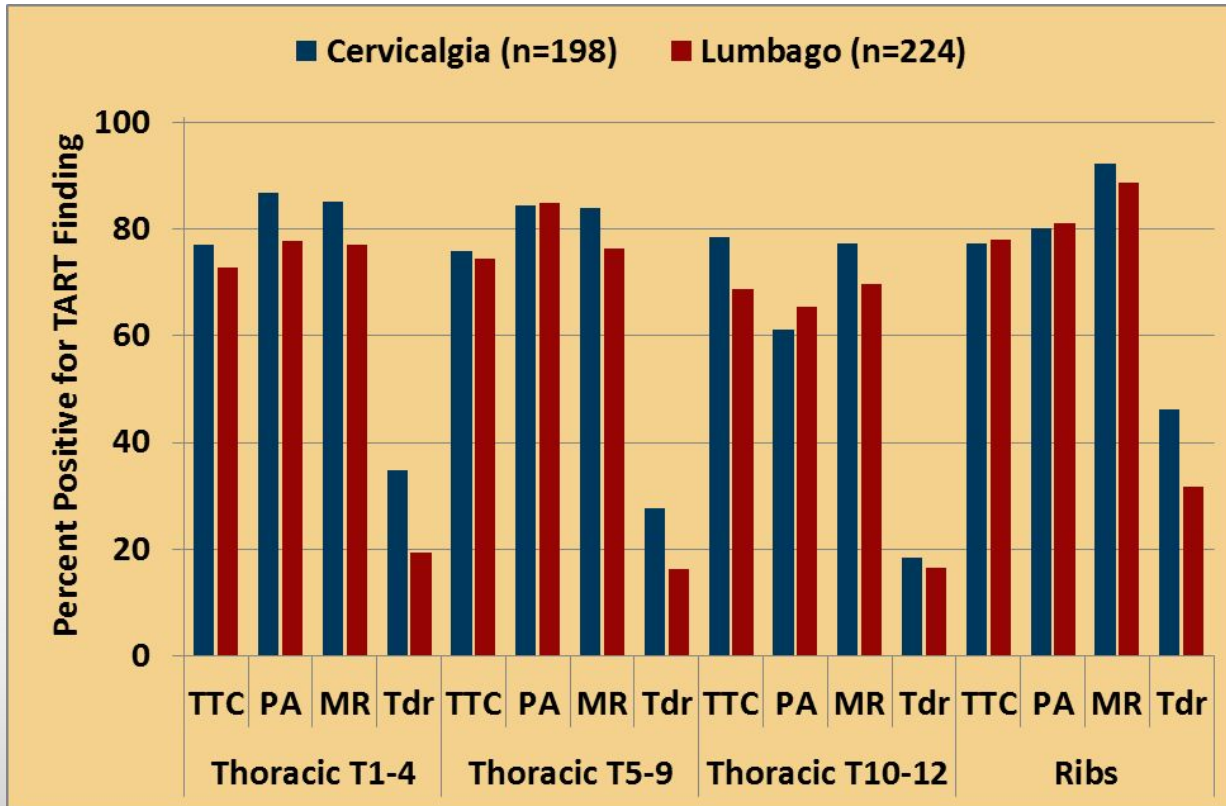
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PHYSICAL EXAMINATION AND TREATMENT

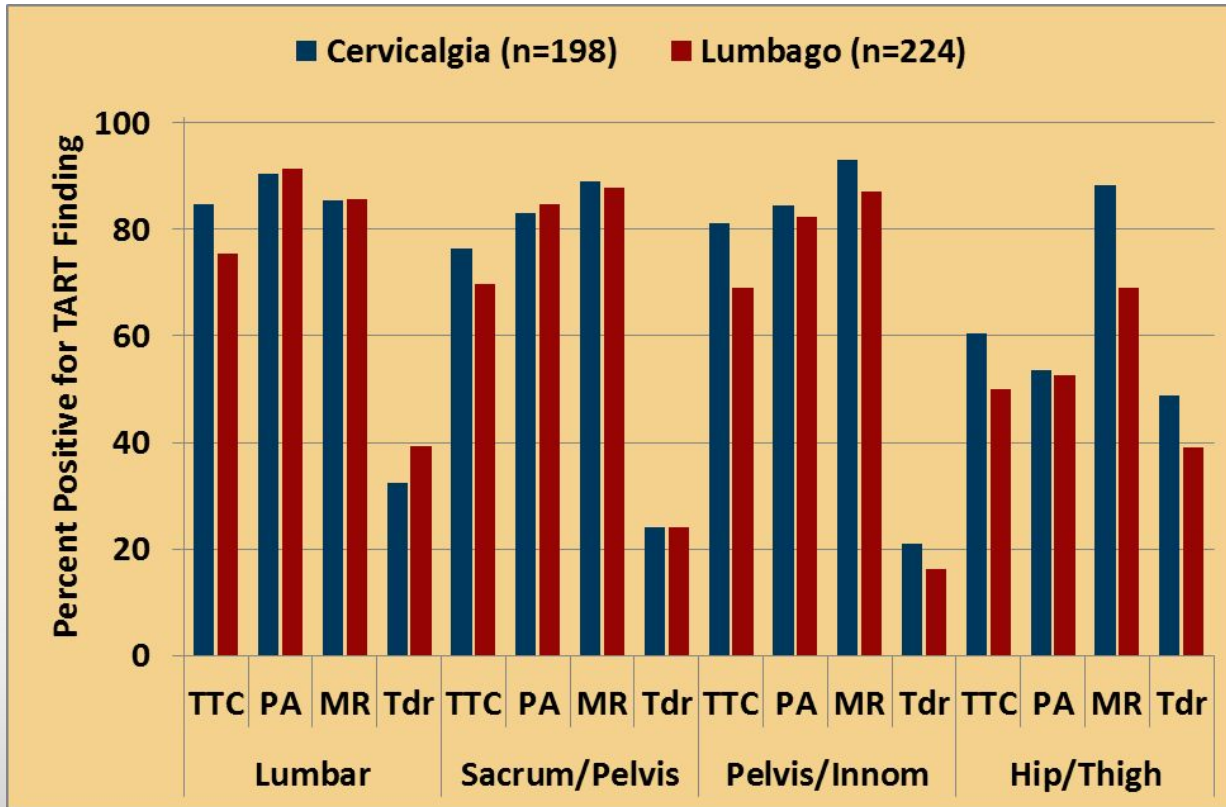
Diagnosis and TART Findings



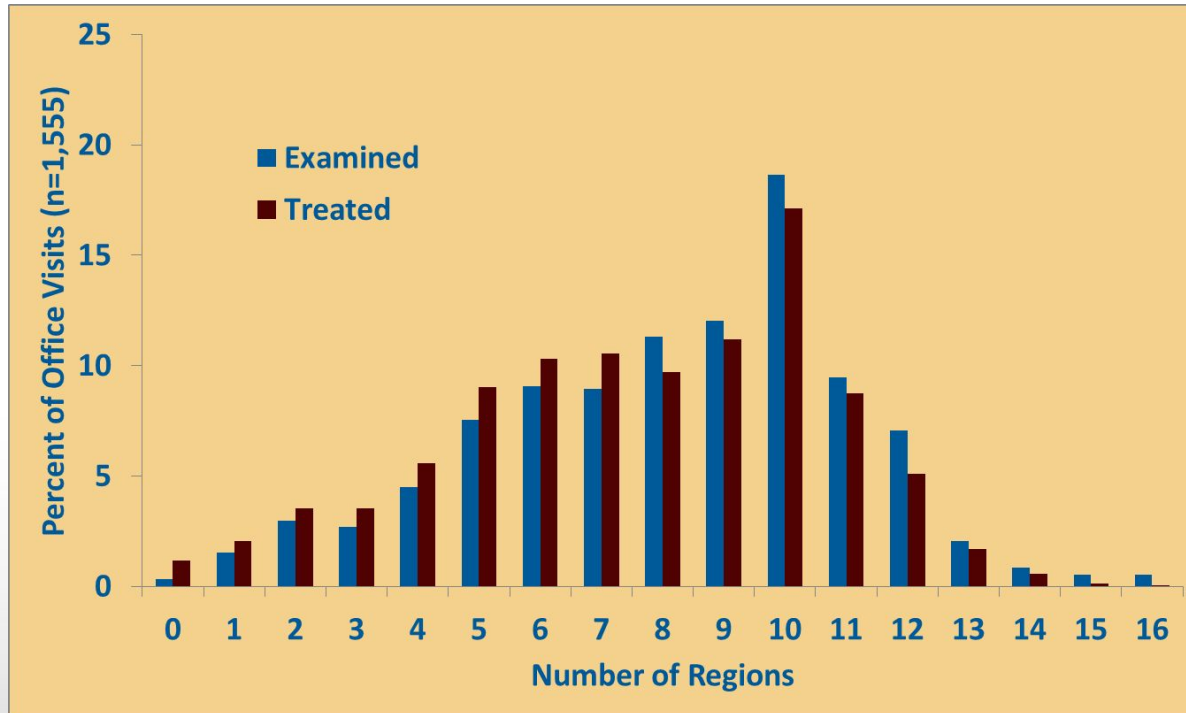
Diagnosis and TART Findings



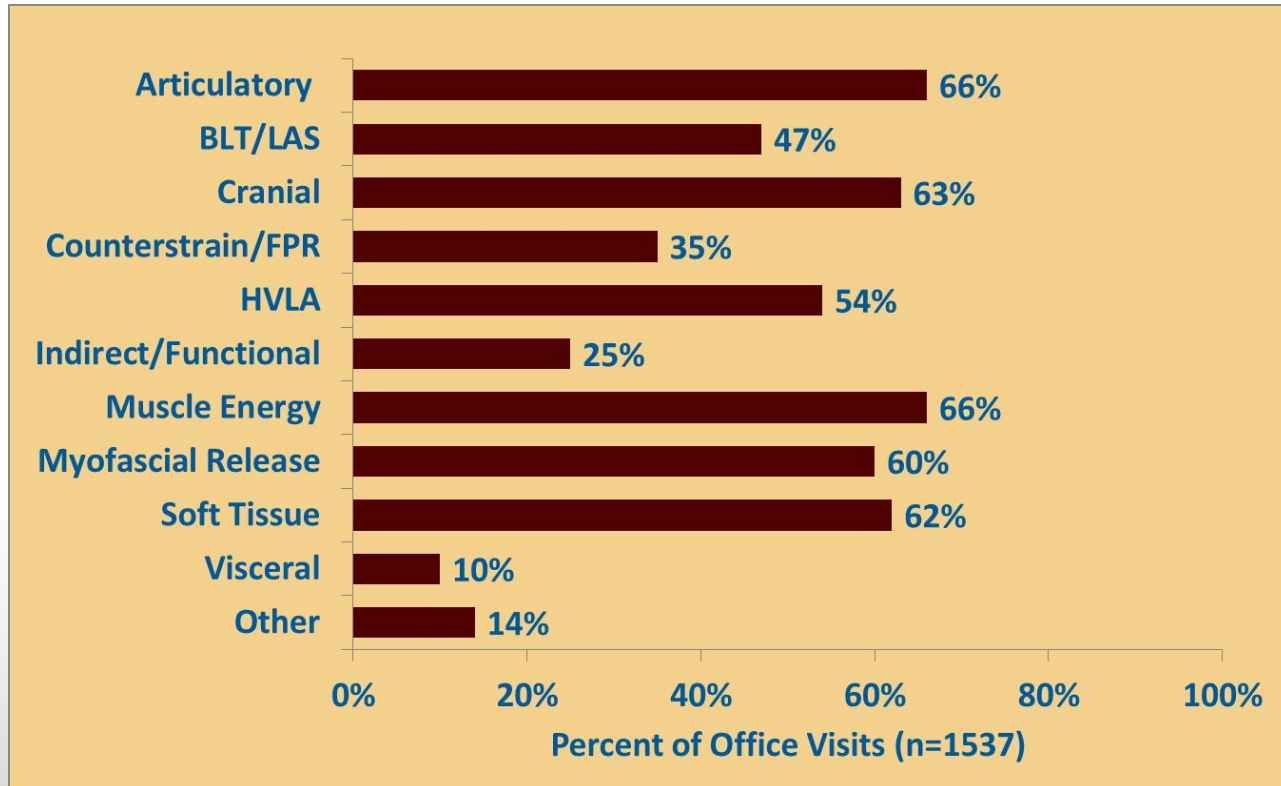
Diagnosis and TART Findings



OMT Techniques



OMT Techniques



Evidence-based References

- Kaiser G, Degenhardt BF, Menke JM, Snider KT. Characteristics and Management of Pediatric Patients Seen in an Osteopathic Manipulative Medicine Clinic. J Am Osteopath Assoc. Feb. 2020
- Johnson JC, Degenhardt BF. Who Uses Osteopathic Manipulative Treatment? A Prospective, Observational Study Conducted by DO-Touch.NET. J Am Osteopath Assoc. Dec. 2019
- Degenhardt BF, Johnson JC, Brooks WJ, Norman L. Characterizing adverse events reported immediately after osteopathic manipulative treatment. J Am Osteopath Assoc. 2018;118(3):141-149. doi:10.7556/jaoa.2018.033

