NEW YORK INSTITUTE OF TECHNOLOGY
College of Osteopathic Medicine

Constipation in Parkinson's Disease Improved by an Osteopathic Manipulative Medicine in a Repeated Measures Study

Saumya Valasareddi, OMS II, Melvin Mathai, OMS III, To Shan Li, D.O., Sheldon Yao, D.O., Jayme Mancini, Ph.D, D.O.

New York Institute of Technology College of Osteopathic Medicine

Saumya Valasareddi

Background
Methods
Results
Conclusion

TAP TO GO BACK TO KIOSK MENU

- Parkinson's disease (PD) patients suffer from a wide variety of symptoms including progressive motor and non-motor degeneration.
- One notable symptom, experienced by 80% of PD patients, is constipation. The factors contributing to constipation in PD includes autonomic nervous system (ANS) and enteric nervous system (ENS) dysregulation, bradykinesia and rigidity, pelvic floor muscle dyssynergic disorders, and restrictive pulmonary syndrome.
- The constipation in this disease is a very discomforting symptom that can result in hospitalization if severe.
- Osteopathic manipulative medicine (OMM) has been previously demonstrated to improve constipation in healthy subjects and in patients suffering from cerebral palsy, another central nervous system disorder.
- In this study, an OMM sequence was designed based on the pathophysiology of PD in attempt to provide relief for the patients.
- The goal of this study was to determine whether an OMM sequence can improve constipation severity and quality of life in PD subjects.

Hypothesis:

The OMM sequence will improve constipation severity in PD subjects.

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Methods

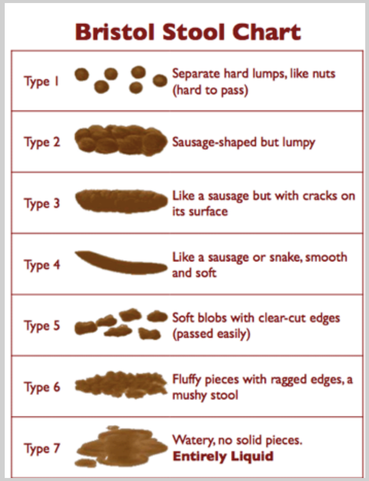
Determine an OMM sequence that related to the pathophysiology of PD:

- Literature reviews
- Clinical expertise
- The 5 osteopathic treatment models

Testing effectiveness:

- This study was IRB approved (BHS1065) in September 2015 and registered on registered on Clinicaltrials.gov#NCT02344485 .
- Inclusion criteria: medically diagnose PD, constipation diagnosis according to Rome III, over 40 years old
- Study design: repeated measures within-subject
  - each subject underwent measurements before, during, and after 4-week control-period, 4 weekly OMM treatments, and 2 weeks of no intervention
  - Advantageous when few subjects are available or with many confounding variables
- Measuring PD severity:
  - MDS-UPDRS
- Measuring constipation severity:
  - Wexner Cleveland constipation scoring system (WCCSS)
  - PAC-SYM and PAC-QOL
  - Bristol 7 type stool scale (measured colonic transit time by subjects and investigators from photos taken by subjects)

	Score
Frequency of bowel movements	
1–2 times per 1–2 days	0
2 times per week	1
Once per week	2
Less than once per week	3
Less than once per month	4
Difficulty: painful evacuation effort	
Never	0
Rarely	1
Sometimes	2
Usually	3
Always	4
Completeness: feeling incomplete evacuation	
Never	0
Rarely	1
Sometimes	2
Usually	3
Always	4
Pain: abdominal pain	
Never	0
Rarely	1
Sometimes	2
Usually	3
Always	4
Time: minutes in lavatory per attempt	
Less than 5	0



Detailed Research Hypothesis:

Mean survey constipation scores, colonic transit time and quality of life should improve after the 4 week OMM intervention as compared to the 4 week control period

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Methods – Outcome Measures

Scale	Quality Rated by Domain	Usage
Wexner Cleveland Constipation Scoring System (WCCSS) [31-35] 14 questions Total score range 0 to 30 (severe) Score ≥ 15 suggests constipation diagnosis	Severity: 1. BM frequency 2. Painful BMs 3. Incomplete evacuation 4. Straining or time spent attempting BMs 5. Laxatives or enemas required 6. Failed attempts 7. Incontinence/soiling 8. Difficulty withstanding urge 9. Bleeding	Non-PD studies Constipation Score ≥ 15 (p<0.05) compared to CTT, manometry, cinedefecography, & EMG. Accurately predicted 97.4% (p<0.0001) of cases.
Patient Assessment of Constipation- Symptom (PAC-SYM) [31-36] 12 questions total score range 0 to 48 (severe)	Symptoms: 1. abdominal 2. rectal 3. stool	Non-PD studies ES* per individual question[45]: small 0.2–0.5, moderate 0.5–0.8 large 0.8 Includes severity related to dyssynergistic constipation.
Patient Assessment of Constipation- Quality of Life (PAC-QOL) [31-36] 28 questions total score range 0 to 96 (worse) Associated with: abdominal pain (p<0.001) constipation severity (p<0.05)	Quality of life: 1. physical discomfort 2. worries and concerns 3. psychosocial discomfort 4. satisfaction	Non-PD studies Internally consistent Cronbach's α >0.80, reproducible (ICCs >0.70), except for satisfaction (ICC=0.66) Overall ES 1.77 Includes severity related to dyssynergistic constipation.
Bristol Stool Scale (Bristol) [37-40,48] Visual scale depicts types of stool total score range 1 to 7 Healthy mean 3.7 (±1.5)	CTT 1 (Slow transit/ constipation) to 7 (Fast transit/ diarrhea)	Correlated with stool water content (rho = 0.491, P<0.001) 81% healthy adults correctly rated with substantial accuracy (κ=0.78) & reliability (κ=0.72), moderate reliability for Type 2 (63%, κ= 0.57) Type 3 (62%, κ= 0.55)

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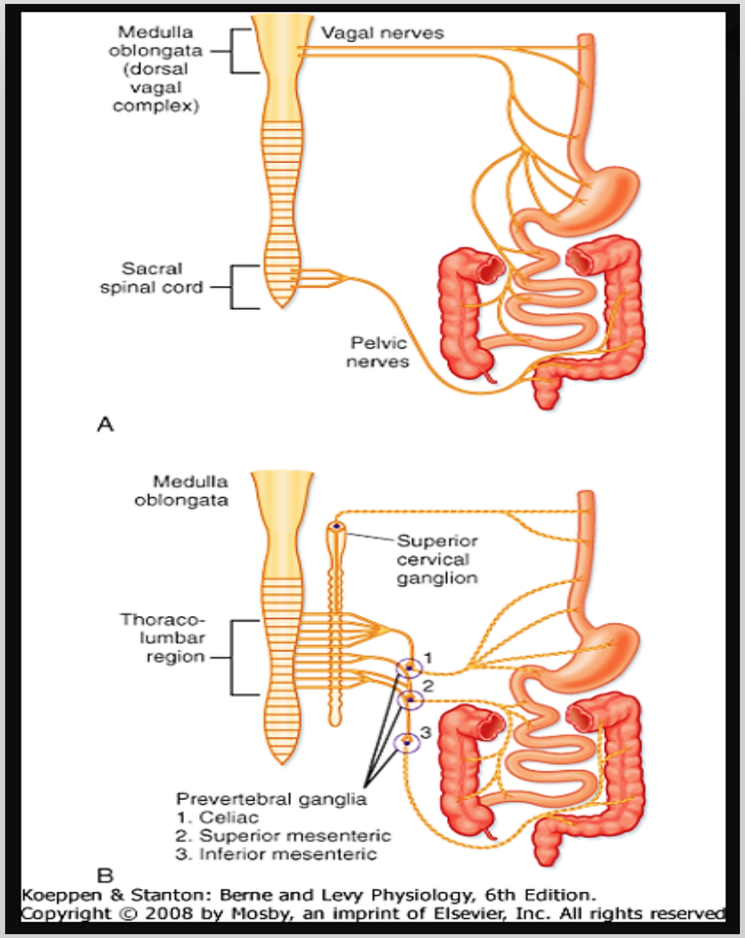
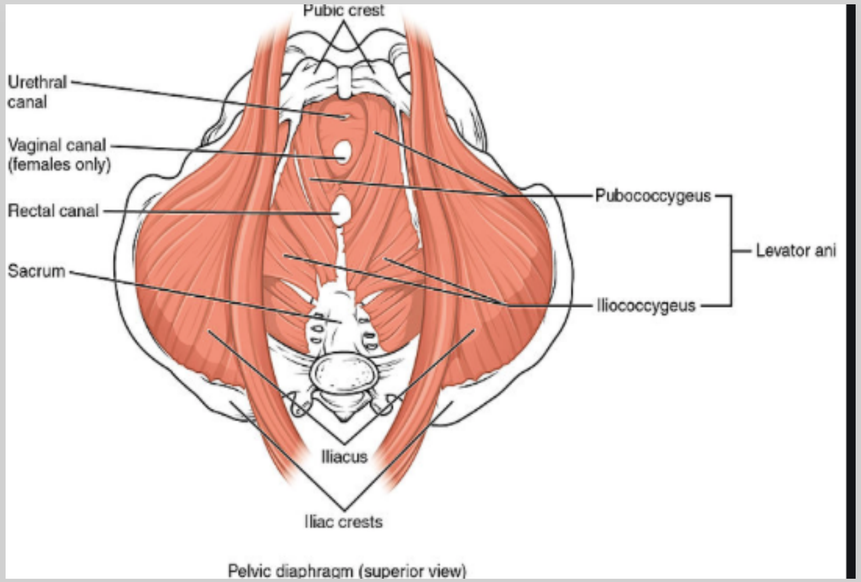
Methods – OMM Targets

- The OMM sequence took into account the osteopathic model for clinical decision making and physiologic factors such as the autonomic nervous system of the gut (which is affected in PD) and the pelvic floor muscles.





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Methods – Osteopathic Clinical Decision-Making

Parkinson's disease Feature	Osteopathic Treatment Model & Factor addressed with OMM-sequence
ANS dysregulation: **Early α-synuclein pathology, Lewy body accumulation, and neuron loss in dorsal motor nucleus and vagus nerve** • **Decreased colonic blood flow** • **Slow transit constipation**	Neurologic Imbalance of parasympathetic and sympathetic nervous system activity Steps: 1. Suboccipital Release 3. Celiac, Superior Mesenteric, & Inferior Mesenteric Ganglion Inhibition 4. Bilateral T10-L2 Paraspinal Inhibition 5. Bilateral Sacroiliac Joint Gapping 6. Sacral Rock
Enteric nervous system degeneration: **α-synuclein pathology of interstitial cells of Cajal that are mechanosensory, mediate signals from motor neurons, and generate intrinsic electrical rhythmicity in phasic smooth muscles and motor neurons** • **Slow transit constipation**	Neurologic Irregular bowel peristalsis Steps: 7-8. Mesenteric Release of ascending & descending colon 9. Colonic Stimulation
Bradykinesia and rigidity **Central nervous system**	Biomechanical & Behavioral Decreased mobility and physical activity 4. Bilateral T10-L2 Paraspinal Inhibition 5. Bilateral Sacroiliac Joint Gapping 6. Sacral Rock
Restrictive pulmonary syndrome	Respiratory-Circulatory Decreased pumping mechanics of thoracic excursion and ventilatory diaphragm Step 2. Respiratory Diaphragm Release
Outlet obstruction secondary to dyssynergic disorders	Neurologic & Biomechanical Pelvic floor muscle tone and balance Steps: 5. Bilateral Sacroiliac Joint Gapping 6. Sacral Rock

Based on the listed pathophysiologic features of PD the following OMM sequence was determined to be optimal for the manage of constipation in PD patients:

1) Subooccipital Release
2) Respiratory Diaphragm Release
3) Celiac, Superior Mesenteric, and Inferior Mesenteric Ganglion Inhibition
4) Bilateral Sacroiliac Joint Gapping
5) Sacral Rock
6) Mesenteric release of Ascending colon
7) Mesenteric Release of Descending Colon
8) Colonic Stimulation

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Results:

- No subject experienced any worsening of constipation severity post treatment
- The mean Bristol stool rating improved from type 2 to type 3
- There were significant improvements in PD severity seen in the MDS-UPDRS
- There were significant improvements in constipation severity and quality of life as demonstrated by improved scores in the PAC-SYM and PAC-QOL

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Results:

Repeated outcome measure	4-Week Control period Mean (SD)	Post-OMM Mean (SD)	2-Weeks Post-OMM Mean (SD)(p value)
WCCSS	12.5 (1.8)	11.1 (1.7)	8.3 (1.5) (p<0.001)
PAC SYM	12.9 (3.0)	12.1 (2.2)	11.7 (3.8) (p=0.81)
PAC QOL	35.9 (5.9)	30.3 (4.3)	25.3 (4.0) (p=0.002)
Bristol Subject	2.9 (0.2)	3.1 (0.5)	3.0 (0.4) (p=0.74)
Bristol Investigator	2.4 (0.3)	2.9 (0.6)	3.0 (0.3) (p=0.14)

Table shows the average outcomes of the surveys and tests during the control period, immediately post-OMM, and 2 weeks after the OMM treatment.
There is an improvement in scores over time with the OMM.

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Results:

Variable	Mean (SD) of Variable			p-value
	4-Week Control-period	4-week OMM-intervention period	2-Weeks Post-OMM	
Hydration (oz./day)	27.1 (9.7)	29.7 (13.4)	31.9 (16.5)	0.38
Caffeinated beverage (oz./day)	8.6 (6.4)	8.8 (4.8)	9.0 (6.6)	0.97
Yogurt (days/wk)	3.0 (2.3)	2.7 (1.9)	2.1 (2.3)	0.10
Cheese (days/wk)	3.3 (1.7)	2.9 (1.7)	3.0 (2.3)	0.40
Sauerkraut (days/wk)	0.3 (0.4)	0.0 (0.0)	0.0 (0.0)	0.14
Tempeh (days/wk)	0.1 (0.4)	0.0 (0.0)	0.0 (0.0)	0.40
Kimchi (days/wk)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	---
Pickle (days/wk)	0.4 (0.5)	0.3 (0.5)	0.2 (0.6)	0.45
Sour Cream (days/wk)	0.2 (0.4)	0.3 (0.5)	0.7 (1.3)	0.34
Alcohol (days/wk)	0.7 (1.1)	1.0 (1.4)	1.0 (2.2)	0.71
Probiotic (doses/wk)	0.0 (0.0)	0.0 (0.0)	0.0 (0.0)	---
Prunes (days/wk)	3.0 (2.9)	3.0 (3.3)	2.7 (3.5)	0.74
PT/OT (min/wk)	13.0 (15.9)	13.0 (15.9)	13.0 (15.9)	1.00
Aerobic Exercise (mins/wk)	167.3 (61.7)	168.6 (88.5)	150.0 (78.9)	0.45
Osmotic Laxatives (doses/wk)	3.2 (4.8)	2.8 (4.8)	3.0 (4.6)	0.38
Stool Softener Docusate (days/wk)	0.4 (1.0)	0.5 (1.1)	0.4 (1.1)	0.48
Suppository/Enema (days/wk)	0.1 (0.3)	0.2 (0.6)	0.6 (1.5)	0.38
Mineral Oil (days/wk)	0.2 (0.6)	0.3 (0.8)	0.0 (0.0)	0.34

<u>Physical exercise</u>

Parkinson's disease Center Programs	Other Aerobic Exercise
• Physical therapy • Tai Chi • Yoga • Rocksteady non-contact boxing	• cycling • walking • raking

<u>Laxatives</u>
- Polyethylene glycol
- Mineral oil
- Senacot
- Aloe vera
- Lactulose

<u>Stool softeners</u>
- docusate

<u>Suppositories</u>
- Glycerin

<u>Enemas</u>
- Fleetz

<u>Nutrition</u>
- Prunes
- Fruit juice
- Fiber
- Tamarind extract Israel
- Medical marijuana
- Fig

** NOTE: medical marijuana effects the enteric nervous system, immune system and reduces muscles spasticity

These tables show the other variables involved in constipation severity throughout the study- Including diet, exercise, medication, etc. There was no significant change in their usage.

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Results

- Subjects experienced a 7% improvement in quality of life with this OMM sequence in addition to their existing management which continued through treatment.
- This is one of the first studies to use an OMM sequence to provide constipation relief to PD patients
- Variables such as hydration, cheese, sauerkraut, tempeh, kimchi, etc were consistently measured and had no significant change throughout the course of the study.

ASSOCIATION LOGO

OTHER LOGO OR IMAGE

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Conclusion:

- This OMM treatment once a week significantly improved constipation severity and quality of life in PD patients.
- OMT techniques were determined based on PD features and the osteopathic treatment model related to that feature
- Limitations of the study:
  - Lack of blinding
  - Inability to isolate pharmaceutical and nutraceutical effects
  - Relying solely on the subject self reporting of hydration, diet, etc

References

Agachan, Feran, et al. "A Constipation Scoring System to Simplify Evaluation and Management of Constipated Patients - Semantic Scholar." *Undefined*, 1 Jan. 1996,
"Bristol Stool Chart." *Bristol Stool Chart · Faecal · Continence Foundation of Australia*
"Constipation & Nausea." *Parkinson's Foundation*, 23 Aug. 2018
Verbaan D, Marinus J, Visser M, van Rooden SM, van Hilten JJ. Patient-reported autonomic symptoms in Parkinson's disease. Neurology. 2007;69(4):333-341.
Hou JG, Lai E. Non-motor symptoms of Parkinson's disease. Int J Gerontol. 2007;1(2):53-64.
Pfeiffer RF. Gastrointestinal dysfunction in Parkinson's disease. Lancet Neurol. 2003;2(2):107-116. https://doi.org/10.1016/S1474-4422(03)00307-7
Mathers SE, Kempster PA, Lees AJ. Constipation and paradoxical puborectalis contraction in anismus and Parkinson's disease: A dystonic phenomenon? J Neurol, Neurosurg, and Psychiat. 1988;51:1503-1507
Kuijpers HC, Bleijenberg G, de Morree H. The spastic pelvic floor syndrome large bowel outlet obstruction caused by pelvic floor dysfunction: a radiological study. Int j Colorectal Dis. 1986;1(1):44-8
Version 8.25 from the Textbook OpenStax Anatomy and Physiology Published May 18, 2016
Vrees MD, Weiss EG. The evaluation of constipation. Clinics in Colon Rectal Surg 2005 18(2): 65-75
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