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Original Articles

Opioid Use Reduction in Failed Back Surgery Syndrome Patients at Three Months Utilizing Manual Spinal Decompression Manipulation

Ralph Kruse, DC, DIANM, FICC[1]

Maruti Gudavalli, PhD[1]

Casey Rogers, DC[2]

[1] Keiser University College of Chiropractic Medicine, West Palm Beach, Florida
[2]Birmingham VA Medical Center, Birmingham, Alabama

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ABSTRACT

Objective: Continued spinal pain and disability following spine surgery frequently results in continued or increased use of opioid pain medication. This study proposes to analyze the usage of opioids in patients with continued or recurring pain after spinal surgery treated with Cox Flexion Distraction Decompression Manipulation.

Design: Analysis of data collected during a multi-center prospective cohort study of Failed Back Surgery Syndrome patients seeking care from field Doctors of Chiropractic certified in Cox Flexion Distraction Decompression Manipulation. This study included patients who had undergone spinal surgery and chose to be treated with chiropractic care for symptoms in the same regions where surgery was performed.

Methods: This multi-center prospective cohort study of 59 Failed Back Surgery Syndrome patients treated by 21 chiropractors was designed to document clinical outcomes of manual spinal decompression manipulation interventions. Eleven of the 59 patients indicated they used opioids for their spinal pain and met the inclusion criteria for this study. Results of spinal pain and opioid use questionnaires administered at initial visits and following 3 months of care were collected and analyzed.

This study was approved by the Institutional Review Board (IRB000OC18MG72) of Keiser University.

Results: Eight of the 11 patients reported a reduction or discontinuation of opioid use for pain control related to the region of surgery; no change in opioid use was reported by 3 patients.

Conclusion: The results of this prospective study revealed a patient-reported reduction or discontinuation of opioid use during their initial three-month course of care.

Keywords: Chiropractic, Manipulation, Failed Back Surgery Syndrome, Post-Surgical Continued Pain, Opioids, Decompression

Trial Registration: ClinicalTrials.gov Identifier: CT05401682

INTRODUCTION

Spinal pain impacts millions of individuals and low back pain (LBP) is the leading cause of years lived with disability globally.[1] There are a variety of conservative and evidence-based treatments and prevention strategies recommended for managing spinal pain including education, exercise, thermotherapy, and manual therapies.[2] In some cases pharmaceutical interventions including non-steroidal anti-inflammatory drugs and opioids are recommended.[3] Utilization of spinal surgical procedures, especially lumbar, have also been trending upwards in recent years.[4-6] It is prudent to note that surgical interventions to the spine come with risks, including infection, vascular complications, and death. [7,8]

One specific complication from spinal surgery is Failed Back Surgery Syndrome (FBSS), also known as post-surgical spine syndrome or persistent spinal pain syndrome.[9,10] FBSS is defined by the International Association for the Study of Pain as "spinal pain (lumbar or cervical) of unknown origin either persisting despite surgical intervention or appearing after surgical intervention for spinal pain originally in the same topographical location."[11] FBSS pain may begin following the surgical intervention. Surgery may have also exacerbated the pain or it was insufficient in alleviating the original pain.[12] Previous reports state FBSS impacts between 10%-50% of the population undergoing spinal surgery.[13-15] Incidences of FBSS appears to have a wide range due to various pre-operative, operative, and post-operative factors.[16] The type of surgical intervention also plays a role in FBSS as some interventions, such as microdiscectomy appear to have a lower incidence.[17] FBSS may require additional surgical interventions or revisions, which increases medical costs and risks to the patient.[18]

Following surgical interventions a variety of medication may be prescribed including opioids and/or gabapentinoids.[19] More than 1 in 3 patients with chronic and persistent spinal pain continue to use opioids following a spinal fusion.[20,21] Previous studies have found that undergoing a spinal surgery revision was a predictor for continued opioid use.[22-24] Other studies have demonstrated that 77% of patients who were pre-operatively on opioids continued their utilization following lumbar surgery and nearly 40% of individuals who underwent an anterior cervical discectomy and fusion filled an opioid prescription post-

operatively.[25,26] These types of findings should alert providers and patients of the need for alternative options to achieve pain management post-operatively. Chiropractic interventions and spinal manipulation have demonstrated beneficial outcomes for patients with spinal pain following spinal surgery.[26,27] Additionally, patients with spinal pain who saw a chiropractor had half the incidence of filling an opioid prescription.[28,29] Cox Technic Flexion Distraction Decompression (CTFDD) is a form of spinal manipulation that has been shown to benefit post-surgical spine pain cases.[30,31] The purpose of this brief descriptive analysis of an observational study is to explore the usage of opioids in patients with continued or recurring pain after spinal surgery treated with CTFDD.

METHODS

Opioid use histories were obtained during the initial visit and at the 3-month follow up utilizing a questionnaire administered by the doctor. The form asked patients during the initial visit if they were currently taking any of the following opioid pain killers (yes/no):

Vicodin, Lortab, Norco, Hydrocodone, Codeine, Tylenol #3 or #4, Fentanyl, Duragesic, MS Contin, Percocet, Tylox, OxyContin, Oxycodone, Methadone Tramadol, Ultram, Dilaudid.

At the three-month visit, the patients were asked via a survey form: "Was the use of opioid painkillers diminished or stopped during the duration of chiropractic care?" with "yes" and "no" options available.

RESULTS

Fifty-nine patients from 21 chiropractic clinics recruited between February 1, 2019 and July 31, 2019, who met the inclusion criteria were included in the overall study. Of those, 11 patients reported using opioids to control their pain and are included in this report.

Demographic characteristics of the patients (n=11) in this study are 8 females and 3 males, mean age and standard deviation (SD) of 65.73 (14.6) years old. The mean (SD) height is 168.4 cm (7.5) and mean (SD) weight is 87.5 (22.26) kg.

The patients received a mean (SD) of 15.2 (8.29) treatments during 67.4 (47) days. Questionnaires documented at three months of care a reduction in opioid use in 8 patients, an increase in opioid use in 0 patients, and no change in opioid use in 3 patients.

DISCUSSION

The described findings are consistent with prior reports noting reduced or no increase in opioid use following application of chiropractic care.[28,29,32] This brief descriptive analysis revealed no increase in opioid use and denoted a reduction or discontinuation of opioid medication in 8 subjects with FBSS receiving chiropractic care over a 3-month period. Although this cohort is a small population, findings are still of interest clinically for individuals that desire to use non-pharmacological approaches to manage spinal pain. Patients with FBSS require a nuanced approach to pain management which may include individual rehabilitation plans, interventions, and a combination of providers in a team, and

vary from person to person. These individuals may have undergone extensive surgical interventions and there may be numerous reasons why their surgery did not lead to a favorable outcome. FBSS patients require a systematic evaluation of common FBSS etiologies, including new-onset stenosis, recurrent disc herniations, epidural fibrosis, and pseudarthrosis.[33] In some cases additional imaging may be utilized to differentiate etiologies such as residual disc herniation versus epidural scar tissue.[34] For individuals with FBSS, these diagnoses may be the determining factor that drives the next step of spinal pain management. Once an etiology is determined, a multidisciplinary approach to treatment is most effective.[35] A prior retrospective study demonstrated that an intensive, interdisciplinary pain rehabilitation program consisting of cognitive-behavioral therapy and physical reconditioning provided an "effective therapeutic modality for patients with post-laminectomy syndrome who have failed spinal cord stimulation by decreasing pain levels and by increasing functional status and self-efficacy."[34] A multidisciplinary team consisting of psychology, primary care, and manual therapy is also beneficial in management for these cases.[9,36]

Given that prior chiropractic studies have reported benefit in FBSS cases, it would be prudent to include chiropractic services into these multidisciplinary teams.[26,27,35] Further investigation into specific chiropractic services, such as flexion distraction versus high velocity manipulation would be of value to better understand spinal pain management in FBSS cases. Larger cohort studies and randomized controlled trials would further evaluate the efficacy of chiropractic care for managing FBSS patients. Previous studies have demonstrated reduced opioid use risk in patients who sought chiropractic interventions.[31,32] It is the opinion of the authors that investigation into opioid use for individuals with FBSS and the role chiropractic interventions serve to reduce utilization would be a valuable addition to the existing literature. The authors believe that our study provides some promising findings regarding opioid use reduction and chiropractic interventions, specifically with that of CTFDD. A large population study exploring individuals with FBSS, current opioid use, and chiropractic interventions would be valuable for a better understanding of the relationship and the role spinal manipulation may have. Investigation into different approaches of spinal manipulation, such as thrust versus non-thrust, would also be of interest for individuals with FBSS and potential opioid use reduction and add to gaps in current literature that address this particular patient population.

CONCLUSION

Of the 11 patients reporting the use of opioids for FBSS at the onset of care, 8 reported a reduction or discontinuation of opioid use at 3 months of care. The results of this brief descriptive analysis show promise for the potential reduction of opioid use in Failed Back Surgery Syndrome patients, and the need for larger studies.

LIMITATIONS

The authors understand the limitations of this review to include the small cohort, lack of information regarding the type of surgery, length of time before presenting for chiropractic care after surgery, duration and dosage of opioid use, and lack of a control group.

COMPETING INTERESTS

The authors declare they have no competing interests.

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Portable Hip Clamshell Strength Assessment: Reliability and Validity

Takashi Nagai, ATC, PhD[1-3]
Nathan D. Schilaty, DC, PhD[2-6]
Corey M. Kunzer, DPT, ATC[3]
Allison Greer, PT, DPT, SCS[3]
Nathaniel A. Bates, PhD[2,3,7]
April L. McPherson, PhD[2,3,7-10]

[1] United States Army Research Institute of Environmental Medicine, Natick, MA
[2] Department of Orthopedic Surgery, Mayo Clinic, Rochester, MN
[3] Sports Medicine Center, Mayo Clinic, Rochester, MN
[4] Department of Neurosurgery & Brain Repair, University of South Florida, Tampa, FL
[5] Department of Medical Engineering, University of South Florida, Tampa, FL
[6] Center for Neuromusculoskeletal Research, University of South Florida, Tampa, FL
[7] Department of Orthopaedics, The Ohio State University Wexner Medical Center, Columbus, OH
[8] Emory Sport Performance and Research Center (SPARC), Flowery Branch, GA
[9] Emory Sports Medicine Center, Atlanta, GA
[10] Department of Orthopaedics, Emory University School of Medicine, Atlanta, GA

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ABSTRACT

Hip abduction and external rotation muscular strength deficits are associated with various musculoskeletal conditions such as balance loss (falls), osteoarthritis, and lower extremity ligament strains. To countermeasure, a clamshell hip resistance exercise is commonly included as a part of preventive or rehabilitative programs. A simple and portable clamshell strength device was developed in attempt to encourage widespread hip strength assessments in clinics.

Objective: Examine test-retest reliability of hip clamshell strength using a portable device and validity with the hip abduction strength using the isokinetic dynamometer.

Methods: A test-retest reliability and validity study design at a sports medicine facility. Twelve young and healthy adults (8M/4F, 27.4yo, 180.1cm, 88.8kg) visited a sports medicine laboratory twice one week apart. Subjects performed maximum voluntary

isometric contractions using both a portable clamshell strength device and isokinetic dynamometer. Average peak forces (Newtons) in right and left muscular strength with a clamshell strength device and hip abduction peak torques (Newton-Meters: Nm) with a dynamometer. Reliability and validity was analyzed using the intraclass correlation coefficients (*ICC 3,1*) and Pearson correlation coefficient (*r*), respectively.

Results: Clamshell strength was moderately reliable (*ICC* = 0.593-0.820) and valid (*r* = 0.545-0.584).

Conclusion: The current study found that a portable and inexpensive clamshell strength device was reliable and valid. This result encourages more hip strength testing at point-of-care clinics.

Key terms: dynamometer, clamshell, gluteus medius, power, test-retest, reliability, validity

INTRODUCTION

Physical therapists, chiropractors, and physiatrists often incorporate a wide variety of resistance exercises for hip abductors and external rotators as a part of rehabilitation. The primary hip abductor muscles include the gluteus medius, gluteus minimus, and the tensor fasciae latae; and the primary hip external rotator muscle includes the gluteus maximus which also functions as the primary hip extensor muscle.[1] These hip muscles play an important role in providing balance, joint alignment, and dynamic stability of trunk, pelvis, and lower extremity joints (hip, knee, and ankle). Musculoskeletal modeling has demonstrated that muscular weakness in the hip abductors results in lateral pelvic tilt, increased vertical and lateral ground reaction forces, and increased knee abduction moments during drop vertical jump, which are the primary mechanism of non-contact anterior cruciate ligament (ACL) injury.[2] This contention was supported prospective investigations that found hip abduction and external rotation muscular weakness as a prospective risk factor of non-contact ACL injury and other lower extremity injuries in competitive athletes.[3,4] Furthermore, the lower leg musculature – especially hip abductors, hip extensors, and core muscles – lead to higher incidence of low back pain.[5,6]

Hip abduction strength weakness is associated with poor balance in individuals with chronic ankle instability[7] and predicts prospective inversion ankle sprains in young adults.[8] If not corrected, weak hip abduction muscles and alterations in movement patterns could compromise joint health and contribute to early progression of osteoarthritis in the medial patellofemoral and lateral tibiofemoral joints in older adults.[9] Clinically, hip abduction strength is assessed with an isokinetic dynamometer or a portable hand-held dynamometer (HHD). During HHD testing, subjects are usually in a side-lying position and raise their superior leg against a stationary dynamometer or examiner's hand to record the peak force; and the HHD hip abduction testing has been shown to have good to excellent test-retest reliability (intraclass correlation coefficient: *ICC* = 0.62-0.94) and validity against isokinetic dynamometer (Pearson correlation coefficient: *r* = 0.56-0.92).[10,11]

While it is seemingly simple to train and activate the hip abductors, blindly performing hip abductors for the maximum peak force could lead to hypertrophy of the tensor fasciae latae which is a hip internal rotator secondarily. This hypertrophy of the tensor fasciae latae and atrophy of the gluteus medius was reported in middle-aged adults with hip osteoarthritis.[12,13] Excess hip internal rotation with weaker hip abduction and extension strength was observed in young adults with the patellofemoral pain.[14] In an attempt to minimize the tensor fasciae latae activities and maximize the gluteus medius activities, physical therapists commonly use a hip resistance exercise called "clamshell". This exercise is performed in a side-lying position with the knee flexed at 90 degrees and the hip flexed around 45 degrees. The superior knee is then raised to an 'open' clamshell position while maintaining heel contact. Clamshell exercise has the highest muscle activation ratios of the gluteus medius/maximum over the tensor fascia latae.[15] Similarly, another study reported that the clamshell exercise with or without an elastic band around could the knees activate the gluteal muscles while maintaining lower activation of the tensor fascia latae muscle.[16]

Since performing a clamshell exercise is a novel task isolating the hip abductors and external rotators, clinicians and researchers expressed interests in quantifying the maximum clamshell hip strength. With a simple force transducer and two thigh cuffs (made of Velcro®) attached to each end of the force transducer, we have built a simple contraption to measure the maximum voluntary isometric contraction (MVIC) during a clamshell task. Because it is a novel device with no prior studies, the aim of this study was to establish basic reliability and validity of this clamshell testing device. Clinically, a simple clamshell device can be significant and used to test individuals' ability to perform clamshell MVIC within 5 minutes in attempt to inform surgical or rehabilitation outcomes. To our knowledge, this device is the only one that can quantify the peak force of the gluteus medius without too much involvement of the tensor fasciae latae. It is hypothesized that the clamshell strength device can be moderately reliable ($ICC > 0.6$) and valid ($r > 0.5$) based on the previous hip abduction study.[10,11,17]

METHODS

Participants

A convenient sample of twelve participants (8M/4F) were recruited for the study (average age 27.4 ± 2.0 years, average height 180.1 ± 4.0 cm, and average weight 88.8 ± 23.8 kg). Subjects were included if they were recreationally active a minimum of three times per week for sixty minutes. Subjects were excluded 1) if they had a history of lower extremity musculoskeletal injury within two years, 2) if they were taking any medication or supplements known to affect performance, or 3) if they had a reported medical condition that could affect strength (e.g., acute infection, neurological, or cardiovascular disease). Anthropometric data were measured for each subject (height, weight) prior to testing. At each visit, subjects were asked to perform clamshell and HumacNORM hip abductor MVIC tests. The order of testing methods (clamshell and HumacNORM) and limbs (right and left limb) was randomized.

Study Design

This study was a test-retest reliability and validation study. All subjects reported to the sports medicine research laboratory two times (one week apart) for 30 minutes of strength testing (clamshell and HumacNORM dynamometer testing). The study was approved by the Mayo Clinic Institutional Review Board (IRB 17-001833).

Procedures

Subjects were instructed to warm up on a bicycle for five minutes. For the clamshell isometric strength testing, a custom device was built with Velcro® straps attached to a uniaxial load cell (MLP-300; Transducer Techniques, Temecula, CA; **Figure 1**). The load cell was placed in between the knees of the subjects with their body in a side-lying position with their knees at a 90° angle, but with their feet in line with the longitudinal axis of their body. The Velcro® straps were secured around the thighs proximal to the knee. Subjects were instructed to slowly open the hips in a clamshell motion, engage the load cell, and ramp up force to a maximum effort with the heels connected.

Figure 1. Hip abduction strength testing using HumacNORM isokinetic dynamometer (top) and clamshell strength testing using a clamshell strength device (bottom).

For HumacNORM isometric hip abductor strength testing, the HumacNORM dynamometer (CSMi, Stoughton, MA) was used. Subjects were positioned side-lying on the HumacNORM chair, which was set to a flat position. To limit extraneous movement, restraining straps were secured across the subject's non-testing leg (**Figure 1**). The dynamometer height was raised to align with the hip joint center and the chair was translated

to ensure the subject's hip joint center was aligned with the dynamometer arm. For familiarity, subjects completed one practice set at 50% perceived effort. The practice set was followed by a ten-second rest period before the isometric test began. Subjects completed a MVIC for five seconds followed by a twenty-second rest period. Two additional trials were completed. During all tests, the examiner verbally encouraged the subject to give their maximal effort. The setup and testing protocol were then repeated on the contralateral leg.

The peak force during the clamshell MVIC was recorded. The average of three peak forces were used for statistical analysis. The peak torque during the HumacNORM hip abduction strength data was recorded using the HumacNORM software (CSMi, Stoughton, MA), and the average of three torques were used for statistical analysis. The clamshell peak force data for session #1 and session #2 was used to calculate the intraclass correlation coefficients (*ICC 3,1*) to examine test-retest reliability for each limb (right and left). *ICC* values were interpreted as slight (0 to 0.2), fair (0.21 to 0.40), moderate (0.41 to 0.60), substantial (0.61 to 0.80), and almost perfect agreement (0.81 to 1.0) according to Landis and Koch[18]; while Portney and Watkins[19] interpret *ICC* as poor (less than 0.5), moderate (0.5 to 0.75), and good reliability (above 0.75). Both clamshell peak force data and the HumacNORM peak torque data was used to calculate bi-variate Pearson correlation coefficient (*r*) for validation. Significance was set at *P-value* less than 0.05. All statistical analyses were performed with IBM SPSS Statistics (v26; IMB Corp., Armonk, NY).

RESULTS

Descriptive statistics (means and standard deviations: SD) are shown in **Table 1**. Test-retest *ICC* (model: 3,1) for right and left clamshell strength were 0.820 and 0.593, respectively. These *ICC* values were interpreted as good and moderate reliability, respectively. When clamshell strength was compared with HumacNORM isometric hip abduction strength, Pearson correlation coefficients (*r*) were 0.584 and 0.545 for the right and left limb, respectively. These *r* values were statistically significant ($P = 0.003$ and $P = 0.006$), respectively. A scatter plot including all data points (clamshell vs. dynamometer) for both right and left limb on both days is shown in **Figure 2**.

	Clamshell #1 (Newtons)	Clamshell #2 (Newtons)	Test-Retest Reliability	Isometric Hip ABD (Nm)	Validity
	Mean ± SD	Mean ± SD	*ICC* (*95% CI*)	Mean ± SD	*r* (*P-value*)
Right	225.0 ± 57.0	243.5 ± 45.2	0.820 (0.489, 0.945)	112.5 ± 23.9	0.584 ($P = 0.003$)
Left	217.5 ± 56.7	234.4 ± 59.1	0.593 (0.060, 0.863)	105.4 ± 21.5	0.545 ($P = 0.06$)

Table 1. Descriptive statistics on clamshell strength and isometric hip abduction strength testing, test-retest reliability, and validity.

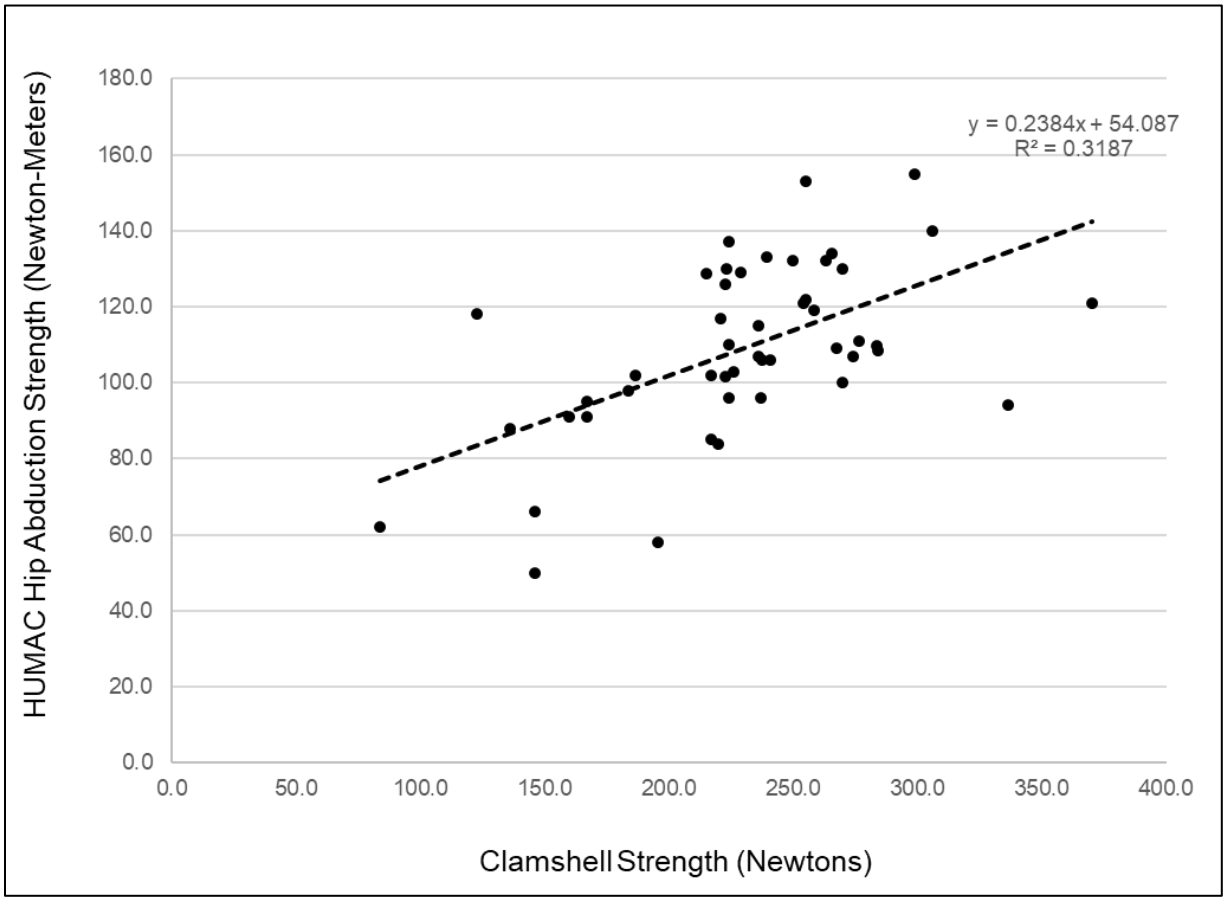

Figure 2. Correlation between clamshell strength and HumacNORM hip abduction strength (both right and left limbs during both visits were combined).

DISCUSSION

This study demonstrated moderate test-retest reliability of the clamshell hip strength and validity with HumacNORM isometric hip abduction strength. Thus, the hypothesis was mostly supported. Stated earlier, a few studies have established test-retest reliability with a simple hand-held dynamometer and concurrent validity with an isokinetic dynamometer machine in young healthy adults.[10,11,17] Test-retest reliability: *ICC* for hip abduction strength with HHD and Pearson correlation coefficient: *r* were 0.90 and 0.56, respectively.[10] Similarly, hip abduction strength by HHD was reliable (*ICC* = 0.88 & 0.90, right & left limb, respectively) and valid (*r* = 0.62 & 0.72, right & left limb, respectively).[11] Another hip abduction HHD reliability and validity study had *ICC* = 0.87-0.95 and *r* = 0.92-0.96.[17] The current reliability values of the clamshell device (*ICC* = 0.593 – 0.820) was slightly less than those studies while the current validity values (*r* = 0.545 – 0.584) were similar to two studies and lower than one study.

Since previous reliability studies had the same subject position and targeted the same hip muscles between hip abduction HHD and isokinetic dynamometer testing, the current study is slightly different during clamshell testing. That could explain slightly lower reliability and validity. In addition, it is interesting to note that the current subjects exhibited better

clamshell strength (Visit #1: 221.3 ± 55.7 Newtons, Visit #2: 238.9 ± 51.6 Newtons, paired t-test *P-value*: 0.051) while HumacNORM hip abduction strength values were almost identical between visits (Visit #1: 108.6 ± 23.5 Nm, Visit #2: 109.2 ± 22.4 Nm, paired t-test *P-value*: 0.921). Further research is warranted to determine if a clamshell task is more complex to learn and perform consistently than a hip abduction strength task with the gold standard isokinetic dynamometer machine. More practice trials or visits will likely help to learn and optimize clamshell strength.

The idea of building a simple, low-cost clamshell strength device is essential for building large databases across many clinics as well as for tracking patients or athletes for their progress after interventions or training. Currently, the gold standard isokinetic dynamometer is expensive as well as bulky, making it difficult for small clinics to invest in the dynamometer machine (>$50,000 USD). In addition, aligning the dynamometer and a patient's joint center can be time consuming (especially, when a clinician is not a frequent user), limiting frequent usage at point-of-care. Therefore, HHD provides a simple and inexpensive alternative way to quantify a patient's strength for clinical use. The current clamshell strength device cost was ~$1,800 USD and built by our research members in one hour. Therefore, technically, anyone can make the same clamshell device. This device only measures hip strength (a combination of hip abduction and external rotation muscles) which is uniquely targeting the gluteus medius and maximus and less tensor fasciae latae at the same time,[17,18] instead of testing these muscles separately with the hip abduction, extension, and external rotation testing.

Clinical significance of the hip musculature, the gluteus medius in particular, was mentioned in the introduction and varied from ACL injury[3], loss of balance[7], and ankle sprain injury[8] among young athletes, to osteoarthritis progression[9] and low back pain[5,6] in older individuals. Furthermore, older individuals with a total hip replacement surgery exhibit weaker hip abduction strength. This hip abduction strength is strongly correlated with physical activity score and functional tests.[20,21] Interestingly, even among individuals with a total knee replacement surgery, hip abduction strength plays a critical role in functional tests such as lateral step and tandem gait tests more than other factors (demographics, anthropometric measures, and knee extensor strength).[22] Needless to say, hip strengthening exercises have been introduced in most conditioning programs for athletes or rehabilitation programs post-injuries/-operations. Simple and reliable devices (like the one developed for this study) that provide immediate clamshell strength values would help clinicians and researchers to establish an easy-to-follow clinical guideline for their patients' safe return-to-work/sports/duty. Integration of a simple, reliable, and portable device - such as the hip clamshell strength device presented herein - would provide another objective outcome for both clinicians and researchers to help determine the effectiveness of care (e.g., limitations of activities of daily living, performance, and rehabilitation prescription in the reduction of pain). With the large number of problems associated with deficient hip muscle strength (i.e., ACL injury, ankle instability, lower extremity injury, low back pain, osteoarthritis progression), it would be ideal to collect data on commonly overlooked stabilization and postural lateral hip muscles.

CONCLUSION

The current study investigated a simple and portable hip clamshell strength device and found moderate reliability and validity. Since the clamshell testing can examine individuals' ability to activate their hip abductors and external rotators without excessive activation of the tensor fascia latae muscle, it is clinically significant to monitor the clamshell strength periodically during rehabilitation. The device also provides an inexpensive, yet reliable and valid, alternative to an isokinetic dynamometer.

LIMITATIONS

This study was limited by a relatively small sample size that consequently caused large variability between days and devices. More subjects will likely help improve reliability and validity values. The current study was a pilot study with just one examiner; therefore, inter-rater reliability is largely unknown. However, we are confident that reliability and validity values will be similar to the current results because an examiner only provides verbal encouragement. The clamshell force transducer is located between the knees, and the examiner does not hold or touch the device during testing. This contrasts greatly from the HHD held/pushed by an examiner. In other words, as long as the examiner knows basic subject setup (side-lying with their knee and hip bend and heels connected), the clamshell task is the same.

COMPETING INTERESTS

The authors declare no conflict of interest. The views expressed in this manuscript are those of the authors and do not reflect the official policy of the Department of Army, Department of Defense, or the U.S. Government.

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A Rare Combination of Unilateral Transient Vocal Cord, Soft Palate, and Tongue Palsies and Numbness following Chiropractic Manipulation to the Cervical Spine: A Case Report

Ofer Baruch, DC, DIANM[1]

[1] Institute for Pain Medicine, Sourasky Medical Center, Tel Aviv

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ABSTRACT

Background: Multimodal chiropractic therapies are well known to reduce pain, improve range of motion and assist with functional rehabilitation of cervical spine dysfunction syndromes. Amongst the critical known contributing risks associated with cervical spinal manipulation are injuries to the vertebral and carotid arteries. Osteoarthritis or rheumatologic arthritides with associated osteophytosis or syndesmophytosis are not considered major risk factors for adverse events such as neuropraxia or vascular dissection.

Case Presentation: A 59-year-old male presented to an outpatient chiropractic clinic with a chief complaint of daily headaches and numbness of the right hand at night. History and review of symptoms obtained by the chiropractor at the initial appointment were devoid of any pertinent red flags or relevant medical history. Physical examination indicated appropriateness of spinal manipulative therapy as management of neck pain and headaches. 10 minutes following treatment, the patient developed dysphasia and dysarthria and was evaluated in the emergency department. He underwent extensive CT, MRI, and laryngoscopy diagnostic procedures to rule out the possibility of a stroke, vertebra-basilar-insufficiency (VBI), or space occupying lesion. The imaging revealed a right sided vocal cord palsy, severe anterior vertebral osteophytosis, multiple levels of canal stenosis, disc disease, and post-traumatic vertebral end-plate degeneration likely caused by multiple neck injuries earlier in life. He was treated with IV corticosteroids as well as occupational and speech therapies, which improved his swallowing and speech except for mild hoarseness.

Conclusion: The risks for spinal manipulation especially in the cervical region should include osteophytosis and degenerative processes that may affect the surrounding neural and vascular soft tissues. Given the rarity and extremely low incidence of adverse effects related to cervical spine manipulation, it would be reasonable to assume that this type of adverse effect could have happened in association with any activity of daily living demanding a fast head or neck rotation. More research is needed on post-traumatic spinal and juxta-spinal degeneration and their effects on different soft tissues and function with the goal of improving clinical safety and practical procedures within chiropractic clinics.

Key words: chiropractic, manipulation, vocal cord palsy, recurrent laryngeal nerve, glosso-pharyngeal, vagus, hypoglossal, Tapia syndrome

INTRODUCTION

Different management strategies exist for neck pain and dysfunction syndromes and no single modality can address all issues. Instead, a multimodal patient-centered approach is recommended where modalities such as exercise and manual therapy can be used in addition to a thorough patient-specific explanation including possible underlying reasons for the condition and potential work practice and self-management strategies.[1]

Neck pain has been defined based on anatomic landmarks, severity, or duration of pain as well as reason for onset such as trauma, work-related, or unknown/idiopathic.[2] Neck pain is a common complaint amongst adults globally.[1-4] Neck pain affects women more frequently than men; however, the prevalence in both sexes follows similar trajectories, with peak incidence around 50 years of age and declining thereafter.[4] In 2017, the global age-standardized prevalence and incidence rate of neck pain were 3551.1 and 806.6 per 100,000, respectively.[4] Like other painful spinal conditions, thoughts, negative emotion, and problems with sleeping can be related to persistent neck pain, and if present, may present yellow flags that should be considered in the management strategy.[5]

Cervical radiculopathy may include a component of neck pain and is a common clinical diagnosis classified as a disorder of a nerve root and most often is the result of a compressive or inflammatory pathology from a space-occupying lesion such as a disc herniation or spondylotic spurs, also known as cervical osteophytes.[6-7] The average annual incidence rate of cervical radiculopathy is 83 per 100,000 for the population in its entirety, with an increased prevalence occurring in the fifth decade of life (203 per 100,000).[8] The location and pattern of symptoms may vary, depending on the nerve root level affected, and can include sensory and/or motor alterations if the dorsal and/or ventral nerve root is involved.[9]

Although patients with cervical radiculopathy may have complaints of neck pain, the most frequent reason for seeking medical assistance is arm complaints. Patients usually present with complaints of pain, numbness, tingling, and weakness in the upper extremity, which often result in significant functional limitations and disability, as was the case with this patient.[10,11]

Conservative therapies have been shown effective for alleviating pain and reducing disability when a multimodal approach is used such as manual therapy, traction, soft tissues release, stretches, and rehabilitation exercises.[12-14]

CASE PRESENTATION

A 59-year-old Caucasian male presented to an outpatient chiropractic clinic with a chief complaint of intermittent nocturnal numbness to the right hand, which prevented him from sleeping through the night. In addition, he complained of occasional daytime neck pain with radiation down his right arm. He also complained of occasional non-specific migraines. At intake, the patient denied previous injuries, trauma, or surgery to the cervical spine. Contributing social history factors included a highly stressful business management lifestyle and chronic and heavy smoking of one pack of cigarettes daily for 3 to 4 decades. He also reported being easily tired and experiencing fatigue.

Additional inquiries about the patient's past medical history at a hospital setting later revealed heavy drinking habits, borderline diabetes and hypertension, and that his history included an active sport lifestyle during adolescence and active military service as a combat airborne rescue member. The patient elaborated that his military service required intense physical activity such as lifting, pulling, and holding injured combat pilots and additional activities that required repetitive loading to the shoulder girdle, neck, and lower back.

Further inquiry about previous injuries, prior hospitalizations, and imaging also revealed a remarkable water-skiing accident 15 years prior to the chiropractic visit, which resulted in him being thrown onto the water at very high speed over his right side, where he felt a sudden physical blow and stretch to the right side of his back, shoulder, and neck. The patient further indicated that due to his past combat rescue experience that forced him to cope with pain and discomfort, he negated the accident's resultant discomfort and pain in his neck and back and did not seek any examination or treatments. Unfortunately, details of this later information were not disclosed by the patient at initial presentation to the chiropractic clinic.

Examination

Physical examination revealed a mesomorphic body type with anterior head carriage, robust neck musculature at the suboccipital region bilaterally, the upper trapezius regions, and the left sternocleidomastoid (SCM), in addition to hypotrophic right sided levator scapulae and splenius capitis. A slight head tilt to the right was noted along with an elevated right shoulder, a slight left curve of the cervical spine and a slight right sided curve of the thoracic spine between the shoulder blades were noted. Orthopedic and neurological examinations were unremarkable, and cervical spine range of motion was generally limited, most notably in bilateral lateral flexion, flexion, and extension. Numerous joint restrictions were revealed along the cervical spine.

Treatment

Informed consent was obtained and the patient was positioned supine on a chiropractic table. Light palpation and stretch were applied initially to the posterior aspects of the cervical spine and diversified adjustment of slight rotation posterior-to-anterior and right lateral to left medial vectors were applied to the right sided upper and middle cervical spine. The patient was made apprehensive by the noise produced from the numerous cavitations and asked the chiropractor about the necessity of such a maneuver. The rationale of improving biomechanics and function were explained by the chiropractor, and upon the patient's consent, further spinal manipulation in the opposite direction, left to right, was applied to the same dysfunctional segments. The patient sat and stood up independently post treatment without any difficulty.

Upon checking out at the front desk, he began feeling dyspnea, saliva accumulation in his mouth, dysphagia, and shortness of breath. Ten minutes later, when taking a taxi back to his business, he noticed dysarthria and hoarseness. He canceled his business schedule and went to the nearest hospital emergency room (ER). At the ER he was examined for suspected vascular brain injury, resulting in a head CT scan, the finding of which were unremarkable. He was given corticosteroid injections to reduce possible inflammation in the cervical region and released from care, with instructions to rest and return the next day for a follow-up examination (this practice is not uncommon in this small rural ER). Upon his return for the follow-up examination, his symptoms had worsened, including dysesthesia and deviation of the tongue to the right side. He was referred then to an ear nose and throat (ENT) specialist who performed laryngoscopy and diagnosed right vocal cord palsy, right deviated tongue, left deviated uvula and suspected injury of cranial nerves (CN) IX, X, XI, and XII post chiropractic treatment. The patient was then referred to a neurologist for further diagnosis, treatment, and rehab. As a part of the neurology examination, he underwent additional head and neck CT to include flair technique and subsequent MRI of the head to rule out intra-cranial hemorrhage, thrombus, or another space-occupying lesion. He was hospitalized for additional neurological evaluation and administered corticosteroids via IV infusion. His follow-up examination two days post chiropractic treatment revealed all the above and in addition, weakness of the right levator scapulae and upper trapezius, but no weakness of serratus anterior. The patient was also diagnosed with loss of gag reflex and softening of the soft palate on the right. He underwent a second opinion in another hospital neurology department which re-affirmed the injuries of CN IX, X, XI, and XII and termed it "palsy due to chiropractic manipulation".

Post treatment follow-up

At the several hospitals where he was examined and treated, the patient underwent extensive diagnostic studies of CT and MRI post chiropractic treatment. He received multiple intra-venous (IV) corticosteroids, along with rehabilitation and training aimed at restoring ability to perform activities of daily living, with an emphasis on speech and swallowing therapy. His symptoms improved slowly over several months.

Post treatment imaging findings

X-rays of the cervical and thoracic spine revealed:

- Moderate bilateral acromioclavicular (AC) joint arthrosis, cervicothoracic rotatory scoliosis apexed right at T5 and left at C5-6, reversed lordotic curve of mixed traumatic and degenerative nature found at the levels of C3-C6 with resultant multiple level osteophytes, and anterior vertebral body traumatic wedge of C5
- The tracheal air shadow deviated to the left at C6-C7

Cervical spine CT and MRI axial, sagittal, and coronal views revealed:

- C1-2 moderate calcification of the transverse ligament (**Figure 1**)
- C1-2 right side 3-millimeter osteophytes at the lateral end plates of C2's superior articular facet and C1's inferior articular facet
- C1-2 posterior arch calcification and soft tissue buckling producing osseus and soft tissue canal stenosis of 11 millimeters (normal = 17mm) **(Figure 1)**
- C1 old partial compression fracture and arthrosis at right lateral mass at its medial section
- Hypertrophy of bilateral sub-occipitals, the left upper trapezius region, and the left sternocleidomastoid muscles
- Hypotrophy was noted at the right levator scapulae and splenius capitis
- C3-4 bilateral narrowed inter-vertebral foramen (IVF) and spinal canal stenosis of 8.7 millimeters (normal = 12mm), and traction osteophytes at the anterior right sided vertebral body 9 millimeters long **(Figure 2)**
- C4-5 canal stenosis of 9.6 millimeters (normal = 12mm) with a large right antero-lateral traction/traumatic induced 14 millimeter osteophyte just behind the epiglottis. Right vocalis muscle supporting the right vocal cord is laterally loosened at its front and buckled medially at its posterior origin (**Figure 3**)
- C5-6 severe disc degeneration with concomitant old calcified posterior disc protrusion and resultant spinal stenosis of 7 millimeters (normal = 12), bilateral IVF narrowing and multiple anterior osteophytes 7.5 millimeters long
- C6-7 moderate narrowing of IVF bilaterally, antero-lateral left 7 millimeter and right 9 millimeter long osteophytes
- Enlargement of the subclavian vein and iodized thyroid lobes

Figure 1
C1-2 transverse ligament calcification (white arrow) and stenosis due to soft tissue buckling and posterior arch calcification (black arrow)

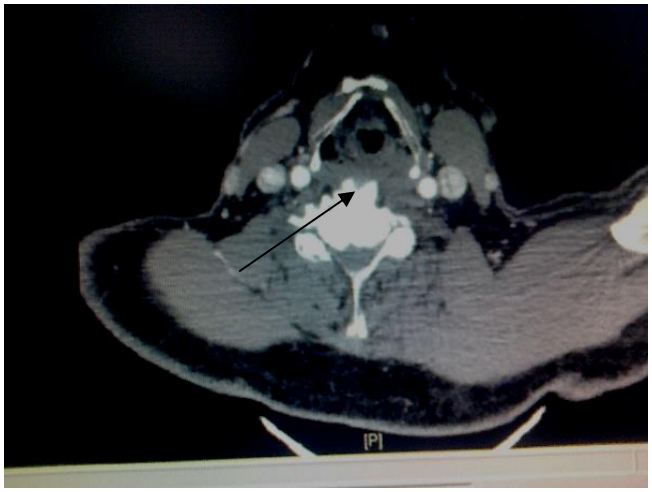

Figure 2
Large C3-4 anterior osteophytes (arrow)

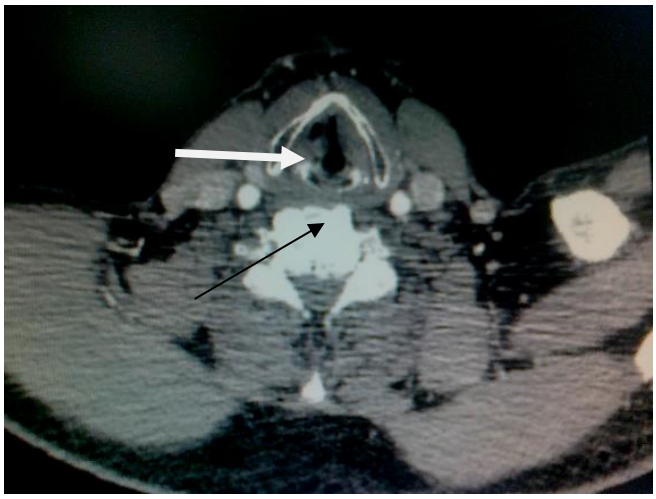

Figure 3
Right vocal cord palsy (white arrow) and large osteophytes (black arrow)

DISCUSSION

Cranial nerves IX, X, and XI exit their respective nuclei at the brain stem below the pons, where they bend medially to exit the skull via the jugular foramen along with the jugular vein. CN XII exits the brain stem and bends medially into the hypoglossal canal where it exits the skull.[2] The canal is located 5 millimeters antero-lateral to the brim of the foramen magnum and the jugular foramen is located 10 millimeters lateral to it.

They descend in front of the C1 and C2 transverse processes and bundled with the internal carotid as the vagal bundle. This bundle is further protected between the internal carotid artery and the jugular vein. The vagal bundle is also protected by musculature from the front by the anterior and medial scalene, longus capitus, longus coli, sternothyroid, and sternohyoid muscles. From the front and sides, it is protected by the sternocleidomastoid, omohyoid, and the platysma. From the back, it is protected by the thickest layers of the posterior scalene, levator scapulae, upper trapezius, and splenius capitis and cervicis muscles. In addition, the bundle is protected by lymph node chains that travel along the large blood vessels of the neck.

CN XII crosses over the vagal bundle and travels under the mandible at the level of C2 to innervate the tongue. It gives off branches to the C1and C2 anterior roots to form the ansa cervicalis (branches from C1,2,3) that innervate the inner cervical spinal musculature.

CN XI leaves the bundle at the level of C2 and travels posterior along the inner layer of the upper trapezius to innervate, along with the posterior efferent of the C1-C5 spinal nerves, the posterior neck musculature, and the serratus anterior. CN IX and X innervate the soft palate, esophagus, trachea, and the complex musculature of the epiglottis and vocal cords.[15-17]

The bilateral recurrent laryngeal nerves (RLNs) branch off the bilateral descending vagal bundles and enter the larynx just behind the cricoarytenoid joints. They supply the intrinsic laryngeal muscles and function to abduct the vocal cords, which affects the space for air passage while a person is attempting to speak or initiate vocalization.

The cricothyroid muscle is the only intrinsic laryngeal muscle not supplied by the RLN, with its motor neuronal supply coming directly from the superior laryngeal branch of the vagus nerve. Juxta to the intrinsic muscles are the posterior cricoarytenoid muscles, the main vocal cord abductors, innervated by the ipsilateral RLN.[17]

A literature search related to injuries of the vocal cord and/or soft palate and tongue revealed dozens of case reports and several studies.[18-22] Unilateral temporary vocal cord paralysis due to an iatrogenic compressive force, also known as Tapia Syndrome, has been reported several times in the literature.[18] This occurs while modifying the patient's airway when performing intubation or bending and laterally flexing the neck, resulting in mechanical compression of the RLN, entrapment of the anterior branch of the inferior laryngeal nerve (ILN) by the cuff of an endotracheal tube against the postero-medial part of the thyroid cartilage. Hypoglossal nerve damage could also be caused by stretching/compressing the nerve against the greater horn of the hyoid bone by a laryngeal mask or endotracheal tube or compression of the posterior part of the laryngoscope or oro-tracheal tube. Most reports pertain to iatrogenic injuries to the RLN due to surgical procedures. Vocal cord paralysis is the most common otolaryngologic complication after anterior cervical spine surgery with plating.[22]

Other reports describe ipsilateral RLN effects following posterior cervical spine laminoplasty due to spinal stenosis and prone placement of the patient. In that surgical position, patients were anesthetized and endotracheally intubated with the patient's head and neck flexed, leading to RLN compression against the endotracheal tube (ET).[19] Additional reports center around other interventions such as open-heart surgery, thyroiditis either from inflammation, neck trauma, or thyroid cancer, rhinoplasty operation, or radiation-induced cranial nerve paralysis in head and neck cancer.[18-22] A 2007 cohort study found that over a 20 year longitudinal study, a unilateral RLN palsy occurred 2/3 of the time due to unilateral neck surgeries (66%), such as anterior cervical spine, external carotid aneurism, or carotid endarterectomy. Unilateral thyroid surgeries were found as the most common (33%) iatrogenic causes. Bilateral iatrogenic vocal fold palsy occurred most often after bilateral thyroidectomies.[21,23]

Patient positioning during surgeries of the rotator cuff often use the upright beach chair position, which has resulted in neurapraxia of the RLN due to mechanical head and mandible flexion compression of the endotracheal tube (ET) and the laryngeal wall over the RLN, followed by an immediate temporary vocal cord palsy.[24-26] In iatrogenic cases due to neck and shoulder surgeries, about 50% of patients were found to have a favorable prognosis of full recovery in about 6 months.[30] Yamada et al., reported recovery of vocal fold mobility in 13 of 19 patients.[28] In contrast, recurrent laryngeal nerve temporary paralysis (RLNTP) of unknown causes were found to have a less favorable prognosis with recovery rates of 29.5% unless they were actively engaged with ear, nose, and throat (ENT) follow-ups and speech rehab post-surgery.[29]

Kawamura et al. reported that 33.3% (37 of 111 patients) followed over 6 months after onset, showed a certain degree of improvement in vocal fold movement within 3 months.[29] The rest of the patients with unilateral RLNTP required an appropriate treatment for hoarseness.

Additional literature review for different extra-spinal related nerve injuries indicated several cases resulting from spinal manipulation, motor vehicle accident, or other trauma.[31] There were 4 cases of phrenic nerve injuries from 1985 to 2007 that occurred after or closely after cervical spine manipulation.[32-36] Additional cases of nerve stretching injuries such as Neck-tongue Syndrome occur due to a traumatic stretch of the ansa cervicalis neural loop that encompasses portions of CN XII below the angle of the mandible. This syndrome has been reported to respond well to chiropractic care.[36-37]

The aforementioned 20-year study which examined reported cases of RLN palsy did not report even one case due to spinal manipulation.[21] There was however, a relatively recent case study describing chiropractic rehabilitation of a patient suffering transient vocal cord palsy post rotator cuff surgery. This surgical patient's position allowed the persistent compressive load of the head and mandible over the hyoid bone and trachea, anterior neural bundles, and musculature while under anesthesia. The chiropractic rehab protocol consisted of soft tissue therapy such as light stretching and instrument-assisted soft tissue mobilization aimed at entrapment of the LGN bundle, as well as gentle passive spinal mobilization and gentle spinal manipulation. This study postulated a therapeutic effect resulting in complete symptom relief and functional resolution of the vocal cord palsy.[30]

Considering the close proximity of the RLN to the large spinal osteophytes presented in this patient's cervical spine CT, it would be reasonable to consider the possibility of daily friction to nerve and muscle tissues resulting from his active lifestyle. Additionally, contributing factors such as past physical traumas, cigarette smoking, drinking habits, borderline diabetes, and hypertension in addition to stress may all have a possible contribution to weakening neural tissues and making them more susceptible to shearing/stretching injuries such as neuropraxia, even before and without the chiropractic manipulations. The rarity of such vocal cord injury under the realm of chiropractic care due to spondylotic changes in the cervical spine and myofascial syndromes can be attributed to other causative factors aside from shearing/stretching due to spondylotic osteophytes. Anatomically protective soft tissues and the lack of advanced imaging findings suggestive of soft tissue edema, or identifiable neural stretching injury sites, or clots, or thrombus, or tumors in this patient, may suggest a plausible conclusion of a shearing accident at the sites of osteophytic friction at C1 and C2, and/or C3 and C4 affecting the nerve bundles.

Moreover, the proximity of the paralytic event effecting the vocal cord, soft palate, and tongue shortly after the manipulation do raise a suspicion for a correlative relationship between treatment and the evolving tongue, soft palate, and right sided vocal cord paralysis.

CONCLUSION

Transient vocal cord palsy (TVCP) or in similar acronym as recurrent laryngeal nerve temporary paralysis (RLNTP) following spinal manipulation or physical treatment to the cervical spine is rare, and to the author's knowledge the case reported here is the first reported event.[38,39] It mostly occurs in frontal-approach neck surgeries or in rotator cuff surgeries where anesthetized patients are positioned by the surgeon in an upright seated-beach position with their head and neck being flexed, with an occurrence rate of up to 50%.[24,25,30] It may occur when the vagal and the recurrent laryngeal nerve bundles are compressed or sheared over a rigid element such as vertebrae or when the inserted endotracheal tube (ET) presses against the laryngeal wall, or when there is an extended physical stretch time period by utilization of a surgical retraction system during a frontal approach surgery.[22] These nerve injuries scale in severity classification from neuropraxia to axonotmesis with relatively good prognoses.[24,30]

In cases of known severe osteophytosis, consideration of utilization of a low force therapeutic approach can limit neck rotation and may reduce the likelihood of fast stretching and shearing effects of the neural bundle, soft tissues, and the cervical spine.[2,30]

Many different management strategies exist for neck pain and no single modality can address all issues. Instead, a multimodal patient-centered approach is recommended where modalities such as exercise and manual therapy can be used in addition to a thorough patient-specific explanation including possible underlying reasons for the condition and potential work practice and self-management strategies.[1-4,30] Due to the rarity of this condition and the presumed relationship to spinal manipulation, conclusions should be drawn cautiously.

Further studies of cervical manual multimodal therapies to patients with advanced spondylosis are needed to evaluate and examine the above-mentioned etiologies and therapeutic protocols. Amendment of the list of red flags when considering chiropractic manipulation in the accepted professional guidelines should be considered.

LIMITATIONS

There are several limitations of this case study. It is impossible to scientifically conclude causation between the manipulation of the cervical spine directly with this patient's symptoms. Further, the imaging findings from the radiologists' reports did not reveal evidence of anatomical injury to any nerve or vascular tissue, and as a result it is impossible to ascertain exactly what transient injuries such as neuropraxia may have occurred to the CN IX-XII neural tracts.

CONSENT

Written informed consent was obtained from the chiropractor and the patient for the publication of this case report and any accompanying images. Copies of the written consents are available for review by the Editor-in-Chief of this journal.

COMPTETING INTERESTS

The author declares no competing interests.

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Feasibility of Three-Speed Isokinetic Knee Testing Protocol

April L. McPherson, PhD[1-5]
Corey M. Kunzer, DPT, ATC[6]
Nathaniel A. Bates, PhD[4,5,6]
Nathan D. Schilaty, DC, PhD[5-8]

[1] Emory Sport Performance and Research Center (SPARC), Flowery Branch, GA
[2] Emory Sports Medicine Center, Atlanta, GA
[3] Department of Orthopaedics, Emory University School of Medicine, Atlanta, GA
[4] Department of Orthopaedics, The Ohio State University Wexner Medical Center, Columbus, OH
[5] Department of Physiology & Biomedical Engineering, Mayo Clinic, Rochester, MN
[6] Sports Medicine Center, Mayo Clinic, Rochester, MN
[7] Department of Neurosurgery & Brain Repair, University of South Florida, Tampa, FL
[8] Department of Medical Engineering, University of South Florida, Tampa, FL

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ABSTRACT

Objectives: Develop a protocol to assess isokinetic concentric knee flexion and extension testing at three different velocities.

Methods: Ten subjects were each assessed on two test days by two clinicians. Clinicians followed a protocol developed to ensure consistency in subject set-up on the isokinetic dynamometer. Knee flexion and extension were assessed at three different velocities. Average peak torque, angle of peak torque, and total work for both the quadriceps and hamstrings muscles were assessed for reliability, via intra-class correlation coefficients (ICC), between testers and between days. Limb symmetry indices (LSIs) were also calculated and compared between testers and between days.

Results: Intra-rater reliability varied; peak torque, for both muscles, had moderate reliability for both clinicians [ICC(3,1) ≥ 0.669 (95% CI: 0.546-0.773)], total work was good to excellent for both clinicians and had the highest reliability values for all variables of interest [ICC(3,1) = 0.813 (95% CI: 0.731-0.877)]. Inter-rater reliability ranged from poor to moderate depending on the variable; total work had the highest reliability for both the

quadriceps and the hamstrings, whereas the angle of peak torque had the lowest inter-rater reliability for both muscle groups. Limb symmetry indices for peak torque and total work were not significantly different between clinicians (p=0.72 and p=0.94, respectively).

Conclusion: The findings of this study demonstrated that testers who are trained and familiar with isokinetic dynamometer testing set-up and protocols prior to performing assessments on patients may help to minimize the effect set-up may have on output measurements.

Key terms: lower extremity, dynamometer, flexors, extensors

INTRODUCTION

Isokinetic dynamometry is considered the gold standard for clinical assessment of muscle strength and is used to monitor rehabilitation progress.[1] In particular, clinicians frequently use isokinetic dynamometry testing to assist in return-to-sport after anterior cruciate ligament (ACL) injury decision making.[2–4] Absolute limb strength of both the involved and uninvolved limbs are typically assessed, and is used to determine bilateral deficits. A bilateral strength deficit of 10-15%, or 85-90% limb-symmetry, is one of several requisite criterions a clinician uses to determine if a patient can safely return to sport.[5–7] However, some patients may require several dates of isokinetic testing throughout their rehabilitation to reach a 90% strength limb-symmetry. With such a small observable difference in muscle strength necessary for return-to-sport clearance, isokinetic dynamometry tests must be consistent between testing sessions. Therefore, it is critical to establish a repeatable and reliable isokinetic testing protocol to ensure that differences observed between limbs and between test dates are reflective of a patient's true rehabilitation progress, not due to error (tester, machine, joint alignment, measurement, etc.).

Although the importance of isokinetic strength assessment has been noted in return-to-sport readiness after ACLR, a standardized and reliable protocol has yet to be established.[4] To the authors' knowledge, no previous study has investigated three clinically relevant isokinetic velocities, between testers, between sessions, and between sites as part of a single study. Therefore, the purpose of this feasibility study was to develop a reliable protocol to assess isokinetic concentric knee flexion and extension testing at three different velocities for future methods to be utilized with larger clinical studies. It was hypothesized that the protocol would yield excellent reliability for all variables of interest (e.g., peak torque, total work, and angle of peak torque) and no difference in limb symmetry indices between clinicians.

METHODS

The study was approved by the Mayo Clinic Institutional Review Board (IRB 17-001833, Rochester, MN, USA). Informed consents were obtained from each participant. Ten subjects were recruited from a sample of convenience. Subjects were included if they were recreationally active a minimum three times per week for sixty minutes. Subjects were excluded (1) if they had a history of lower extremity musculoskeletal injury within two years, (2) if they were taking any medication or supplements known to affect performance,

or (3) if they had a reported medical condition that could affect strength (e.g., acute infection, neurological, or cardiovascular disease). Anthropometric data were measured for each subject (height, weight) prior to testing. Subjects were asked their preferred leg to kick a soccer ball to determine the dominant leg.

Two testers (NDS, CMK) were trained on how to properly execute the protocol prior to the first test date. All tests were performed on two HumacNORM isokinetic dynamometers (CSMi, Stoughton, MA, USA) at two sports medicine clinics.[8] On the two days of testing, one clinician completed the entire protocol with each subject at Mayo Clinic Sports Medicine Center (Rochester, MN). The subject returned in the afternoon and the second clinician repeated the protocol with each subject. Subjects returned to the testing center seven days later and both clinicians re-tested each subject a second time. A subset of subjects (n=5) completed a third day of testing at Mayo Clinic Square Sports Medicine Center (Minneapolis, MN, USA) by one clinician (NDS). The dynamometer was calibrated prior to the start of each test day according to the manufacturer's recommendations.

Subjects were instructed to warm up on a bicycle for five minutes. The first leg tested was randomized for each subject. Subjects were seated in the HumacNORM chair with the posterior of the subject's knee joint two finger widths from the edge of the seat and the chair position set to manufacturer's recommendations. The chair seatback was brought forward to meet the subject's lumbar region. To limit extraneous movement, restraining straps were secured across the subject's trunk, hips, and thigh (**Figure 1A**). The dynamometer height was raised to align with the lateral femoral epicondyle. A custom wooden block, the size of an iPhone 6, was used to ensure constant distance between the knee and dynamometer head for all subjects (**Figure 1B**). The force pad was secured two inches proximal to the medial malleolus, with the ankle aligned in neutral position (**Figure 1C**). Once all components were fastened, the chair and dynamometer rotation were unlocked, and the subject was asked to slowly extend their leg. With leg in full extension, the chair and dynamometer rotations were locked.

Range of motion during testing was set using voluntary maximal full extension (0°) to 100° of knee flexion. Before testing began, the subjects' limb was locked by the machine in a position of minimal knee flexion and subjects were asked to fully relax their leg to determine the passive effects of gravity on the limb. A fixed test sequence was established. Concentric strength of the knee flexors and extensors was tested at three velocities, first 60° per second, then 180° per second, and finally 300° per second. For familiarization with the test protocol, subjects completed four repetitions at each isokinetic velocity prior to the actual test. They were instructed to increase their perceived effort with each repetition (25%, 50%, 75%, 100% effort). The practice set was followed by a ten second rest period before the isokinetic test began. Subjects completed five continuous knee flexion and extension repetitions with maximum effort at 60° per second. Next, subjects completed ten continuous knee flexion and extension repetitions at 180° per second. The final test consisted of fifteen continuous knee flexion and extension repetitions at 300° per second. During all tests, the clinician verbally encouraged the subject to give their maximal effort and subjects were permitted to see the computer monitor for feedback during the test. The setup and testing protocol was repeated on the contralateral leg.

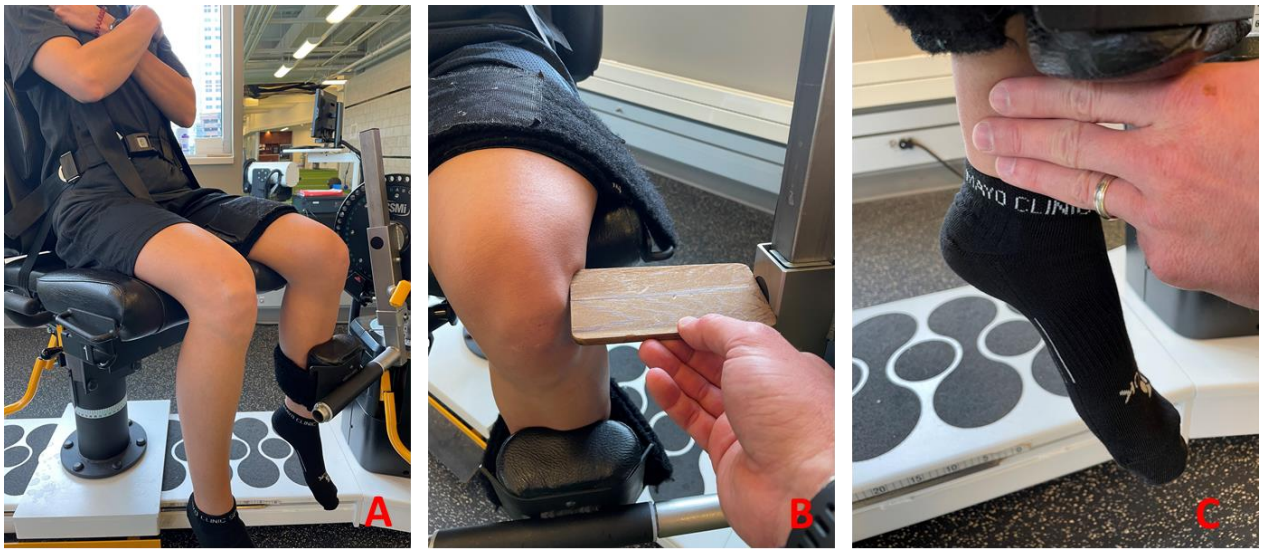

Figure 1: Subject alignment seated on the dynamometer. A) Restraining straps secured across subject's truck, hips, and thigh, B) distance measured between knee joint center and dynamometer head, and C) force pad secured two inches superior to medial malleolus.

Data were processed with a custom LabVIEW graphical user interface to extract variables of interest from the raw data (National Instruments, Austin, TX, USA). Variables of interest included average peak torque, angle of peak torque, and total work for both the quadriceps and hamstrings muscles. Limb symmetry indices were calculated for each peak torque and total work (Dominant / Non-dominant x 100). Statistical analyses were performed in BlueSky Statistics (BlueSky Statistics LLC, Chicago, IL, USA) and JMP 14 Pro (SAS Institute, Cary, NC, USA). Intra-rater, inter-rater (k=2), and inter-site reliability were determined using interclass correlation coefficients (ICC). Intra-rater [ICC(3,1)] and inter-rater [ICC(3,k)] correlations were examined separately for each of the independent variables (peak torque, angle of peak torque, and total work) for each of three velocities.[9–12] Intra-rater reliability was calculated from all repetitions for each velocity for each subject. There were no significant differences between limbs or velocities, therefore, they were combined in each ICC assessment. The average of all repetitions for each subject was used to calculate inter-rater reliability. Values less than 0.5, between 0.5 and 0.75, between 0.75 and 0.9, and greater than 0.90 are indicative of poor, moderate, good, and excellent reliability, respectively.[13] Limb symmetry indices were compared using paired t-tests (p<0.05).

RESULTS

Ten participants (5M/5F) were recruited for the study (average age 27.4 ± 2.0 years, average height 173.9 ± 11.6 cm, and average weight 73.0 ± 14.5 kg). One subject (F) did not return for the second day of testing, resulting in nine subjects included in analysis for inter-rater and intra-rater reliability.

Intra-rater

Intra-rater reliability varied from poor to moderate and poor to excellent for Clinician 1 and

2, respectively (**Table 1**). Peak torque, for both the quadriceps and the hamstrings, had moderate reliability for both clinicians. Total work for both muscle groups was good to excellent for both clinicians and had the highest reliability values for all variables of interest. Angle of peak torque had poor reliability for both muscle groups and both clinicians, with the exception of moderate reliability for quadriceps as set-up by Clinician 1.

Inter-rater

Inter-rater reliability ranged from poor to moderate for both the quadriceps and hamstrings muscle groups (**Table 2**). Total work had the highest reliability for both the quadriceps [ICC(3,k) = 0.881 (95% CI: 0.836-0.914)] and the hamstrings [ICC(3,k) = 0.872 (95% CI: 0.823-0.907)], whereas the angle of peak torque had the lowest inter-rater reliability for both muscle groups [ICC(3,k) < 0.447 (95% CI: 0.237-0.600)].

Inter-site

For the subset of subjects who completed testing at both sites, reliability for all three variables of interest ranged from moderate to excellent (**Table 3**). Similar to intra-rater and inter-rater reliability, total work had the highest reliability of all three variables and was considered excellent for both the quadriceps and the hamstrings [ICC(3,k) ≥ 0.980 (95% CI: 0.971-0.986)]. Peak torque for both muscle groups was good [ICC(3,k) ≥ 0.852 (95% CI: 0.788-0.897)] and angle of peak torque only had moderate reliability between test sites [ICC(3,k) ≤ 0.713 (95% CI: 0.588-0.800)].

Limb Symmetry Indices

Limb symmetry indices for peak torque and total work were not significantly different between clinicians (p=0.72 and p=0.94, respectively). Moreover, peak torque LSIs both favored the dominant leg (104% and 105% for Clinician 1 and Clinician 2, respectively). Similarly, total work LSIs also both favored the dominant leg (102% for both clinicians).

Table 1. *Intraclass Correlation Coefficients and 95% Confidence Intervals for Each Variable of Interest for Clinician 1 and Clinician 2.*

		Intra-rater ICC(3,1) Clinician 1	Interpretation	F	*P*	Intra-rater ICC(3,1) Clinician 2	Interpretation	F	*P*
Quads	Peak Torque	0.669 (0.546, 0.773)	Moderate	7.064	<0.001	0.717 (0.606, 0.808)	Moderate	8.605	<0.001
	Total Work	0.833 (0.757, 0.890)	Good	15.916	<0.001	0.919 (0.879, 0.948)	Excellent	35.102	<0.001
	Angle of Peak Torque	0.580 (0.439, 0.705)	Moderate	5.136	<0.001	0.392 (0.232, 0.549)	Poor	2.930	<0.001
Hams	Peak Torque	0.725 (0.616, 0.814)	Moderate	8.922	<0.001	0.659 (0.533, 0.765)	Moderate	6.785	<0.001
	Total Work	0.813 (0.731, 0.877)	Good	14.072	<0.001	0.886 (0.831, 0.926)	Good	24.245	<0.001
	Angle of Peak Torque	0.342 (0.181, 0.505)	Poor	2.556	<0.001	0.470 (0.316, 0.616)	Poor	3.660	<0.001

Table 2. *Intraclass Correlation Coefficients and 95% Confidence Intervals for Each Variable of Interest between raters.*

	Inter-rater ICC (3,k)	Interpretation	F	*P*
Peak Torque	0.737 (0.637, 0.810)	Moderate	3.805	<0.001
Total Work	0.881 (0.836, 0.914)	Good	8.425	<0.001
Angle of Peak Torque	0.447 (0.237, 0.600)	Poor	1.809	<0.001
Peak Torque	0.774 (0.688, 0.836)	Good	4.425	<0.001
Total Work	0.872 (0.823, 0.907)	Moderate	7.783	<0.001
Angle of Peak Torque	0.221 (-0.076, 0.435)	Poor	1.283	0.065

Table 3. *Intraclass Correlation Coefficients and 95% Confidence Intervals for Each Variable of Interest for inter-site testing.*

		Inter-Site ICC (3,k)	Interpretation	F	*P*
Quads	Peak Torque	0.852 (0.788, 0.897)	Good	6.776	<0.001
	Total Work	0.983 (0.976, 0.988)	Excellent	60.714	<0.001
	Angle of Peak Torque	0.713 (0.588, 0.800)	Moderate	3.484	<0.001
Hams	Peak Torque	0.857 (0.795, 0.901)	Good	7.005	<0.001
	Total Work	0.980 (0.971, 0.986)	Excellent	49.543	<0.001
	Angle of Peak Torque	0.648 (0.495, 0.755)	Moderate	2.840	<0.001

DISCUSSION

The purpose of this feasibility study was to determine the reliability of an isokinetic knee flexion and extension testing battery in healthy participants. The results of the study partially support the hypothesis. Total work, for both quadriceps and hamstrings muscle groups, had overall the best reliability (intra-rater, inter-rater, and inter-site) of all variables, ranging from moderate to excellent. In addition, LSI values for both peak torque and total work were not significantly different between clinicians. The results of this study suggest that total work is a more reliable measurement of isokinetic dynamometry performance than peak torque and angle of peak torque when a standardized patient set-up and testing battery is used.

Previous studies have investigated the reliability of isokinetic concentric knee flexion and extension at a range of velocities, from 60° per second to 300° per second.[14–16] Despite the same gross motor task, different isokinetic testing velocities elicit different neural recruitment and co-coordination of musculature.[17] Thus, multiple velocities have been used to assess muscle strength in variable testing conditions. Previously reported reliability has ranged from acceptable to excellent, depending on variables reported and study designs.

Similar to the current study, high relative reliability of peak torque and average work was observed for knee flexors and extensors for all velocities when assessed by one tester between three sessions.[15] Intra-machine reliability of the knee flexors and extensors peak torque has been reported from good to excellent.[14] Faster velocity (180°/second vs. 60°/second) was shown to have poorer within-day and between-day reproducibility.[16] In addition, significant bias was observed for peak torque between testing sessions for knee flexors at 180° per second.[16]

The specific testing battery of isokinetic speeds and repetitions utilized in the current study aligns with previously described methodologies. For example, in a study that utilized knee flexion and extension isokinetic dynamometry to assess the likelihood of anterior cruciate ligament (ACL) graft rupture, 60°, 180°, and 300° per second testing velocities were used when testing 150 athletes after ACL reconstruction.[5] In addition, the protocol developed and utilized in the current study aligned with previous investigations that assessed concentric knee flexion and extension at 60° per second in a restricted range of motion from 0° to 100° with a gravity correction applied.[4]

In addition, we have developed a clinician-friendly protocol that reduced set-up time by using standardized distances for alignment (e.g., distance of posterior knee from chair, knee joint center to dynamometer, and force pad from ankle joint center) rather than requiring documentation of chair and dynamometer position settings to replicate for future testing. Exact chair and dynamometer settings and position numbers may not actually be the most important for repeatable and reliable testing, as this study found knee joint alignment resulted in reliable total work measurements. It is important to note that each step in the protocol presented here may be critical; it is unknown how skipping or altering a step would affect the overall set up and subsequent reliability of total work performed during the testing battery. The protocol presented in the current study presents a clinician-friendly strategy to assess knee flexion and extension capabilities at three different velocities to reliably assess total work performed during the test. Utilization of this protocol in future studies of pathological conditions or longitudinal rehabilitation subjects would help to ensure confidence that observed changes may be associated with clinical changes rather than noise associated with altered set-up or position in the dynamometer itself during isokinetic testing.

It is interesting to note that we anecdotally noticed both testers become more efficient in their subject alignment as testing progressed, which indicates there was a learning effect of the protocol even though they were both trained clinicians who had previously used the HumacNORM. This suggests that for future testing, testers should practice subject set-up prior to data collection to gain confidence and experience in properly setting up a patient to collect the most accurate data. This is particularly interesting since both testers were clinicians who were previously familiar with HumacNORM testing. It is unknown how new users of the HumacNORM would affect reliability of the total work measurement.

As a feasibility study to assess the developed protocol, no *a priori* power analysis was performed. Therefore, analysis and interpretation of the ICC values presented herein is limited due to the small sample size that was used to explore if a larger reliability study is warranted with a larger, properly powered sample size. Finally, the sample in this feasibility study consisted of healthy participants, whereas the target population of isokinetic

measurement is typically a clinical population. Therefore, determining reliability in larger future studies that include symptomatic or clinical subjects is warranted to further understand the reliability of the testing protocol.

CONCLUSION

In conclusion, we recommend that testers are trained and familiar with isokinetic dynamometer testing set-up and protocols prior to performing assessments on patients and athletes to minimize the effect the set-up may have on output measurements. We have demonstrated a reliable knee flexion and extension isokinetic testing protocol that warrants larger studies and that may one day be used in return-to-sport isokinetic testing, which is a particularly important component of the multifactorial assessment of function and recovery after ACLR for return to sport decision making. In addition, this protocol could be used to help monitor progress throughout rehabilitation at time points of interest (e.g. 6-month post-ACLR, 9-month, 12-month).

LIMITATIONS

A small sample of convenience was used (n=9 for analysis) and said analysis should be viewed with caution if applied for a clinical purpose. Furthermore, it is possible that highly-trained athletes or injured athletes in recovery may have more advanced strategies and repeatable muscle power output, and thus could result in additional variables having improved reliability.

COMPETING INTERESTS

The authors declare they have no competing interests.

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Pain Management of a Career Veteran Diagnosed with Fibromyalgia: A Case Report

Jason Nicholas Belcher, DC[1]
Jesse Slinger[1]

[1] Palmer College of Chiropractic, Port Orange, FL

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ABSTRACT

Background
Fibromyalgia is a chronic condition that affects an estimated 10 million people in the United States, and veterans may be at higher risk of developing this condition due to their exposure to physical and psychological trauma during their military service. The diagnosis of fibromyalgia can be challenging, and treatment often involves a combination of medications, physical therapy, and lifestyle changes.

Case Presentation
A 58-year-old female veteran presented to a chiropractic clinic with a chief complaint of low back pain. The patient had previously been diagnosed with fibromyalgia and wished to pursue chiropractic treatment. The patient completed outcome assessment tools that revealed chronic pain and psychological components. Activities of daily living were also noted to be affected. Examination pointed to fibromyalgia as the cause of low back pain. Conservative chiropractic treatment was administered 2 times a week for 12 weeks. Treatment included chiropractic manipulative therapy (CMT), Jeanie Rub (mechanical massage) to the surrounding tissues, and recommendation of at home exercise.

Results
There was a decrease in tender point sensitivity both subjectively and upon palpation. After 12 weeks of treatment, the patient was given the same outcome assessment tools as at the initial examination. Scores were decreased compared to the start of treatment and activities of daily living were less affected. Results demonstrated relief of pain when mechanical

massage was paired with CMT.

Conclusion
A career veteran diagnosed with fibromyalgia experienced pain relief with conservative treatment. This veteran's response to conservative manual therapies and exercise was promising but cannot be generalized to larger populations. Larger studies would be required to assess the efficacy of chiropractic manual therapies for those with fibromyalgia in the veteran and civilian populations.

Key words: veteran, pain management, fibromyalgia, chiropractic

INTRODUCTION

Fibromyalgia is defined as "chronic widespread pain and reduced pain threshold to palpation".[1] The diffuse symptoms are commonly attributed to central sensitization with enhanced responsiveness to stimuli.[2,3] Patients with fibromyalgia perceive pain from noxious stimuli at lower thresholds than healthy patients.[3-5] The specific pathophysiology for this hyperexcitability is not well defined.[6] Various speculations implicate the central nervous system, autonomic nervous system, peripheral nervous system, neurotransmitters, endocrine system, and immune system, as well as mitochondrial dysfunction, adrenal fatigue, and psychological origins.[6-16] Cumulative mental or physical trauma is believed to be an etiological trigger and exacerbating factor for the disturbed pain modulation seen in fibromyalgia patients.[4,5,16] Veterans may be at a higher risk of developing this condition due to their exposure to physical and psychological trauma during their military service.

Fibromyalgia is diagnosed in patients complaining of widespread chronic pain and fatigue. The criteria for this diagnosis include: (1) Generalized pain, defined as pain in at least 4 of 5 regions, is present, (2) Symptoms have been present at a similar level for at least 3 months, (3) Widespread Pain Index (WPI) score ≥ 7 and Symptom Severity Scale (SSS) score ≥ 5 OR WPI of 4-6 and SSS score ≥ 9, (4) A diagnosis of fibromyalgia is valid irrespective of other diagnoses. A diagnosis of fibromyalgia does not exclude the presence of other clinically important illnesses.[17]

Fibromyalgia patients account for almost 20% of rheumatologic visits.[18,19] The condition is at least twice as common in females and there seems to be a strong genetic correlation.[20,21] Many pharmaceutical drugs have been tested to treat fibromyalgia with only slight improvements to the condition of the patient specifically with drugs that target molecular mechanisms. There has been no single drug that has been found capable of treating all the symptoms of fibromyalgia with sufficient efficacy.[22] The preferred treatment plan for fibromyalgia at this point is a multimodal approach in order to address all symptoms.[23]

CASE PRESENTATION

The patient was a 58-year-old female who served in the Air Force for 20 years. She was a non-smoker, was of normal weight, and had an unremarkable past medical history except for a diagnosis of fibromyalgia received after retiring from the Air Force. The patient reported that while in the Air Force she could be touched by another service man or woman and

instantly fall to the floor in agonizing pain. The patient realized that something was wrong but went undiagnosed for quite some time. She could not remember any single incident or injury that contributed to her symptoms. She had previously been treated with medication to aid the symptoms and was curious as to whether chiropractic care could help her condition.

The patient presented with low back pain and bilateral sacroiliac (SI) joint pain. She described the pain as extreme tenderness to touch. The patient exercised throughout the week by walking around the neighborhood and reported a healthy diet and adequate water intake throughout the day. The patient reported emotional distress due to her years in the military and previous experiences within the Veterans Affairs Healthcare system.

The patient had already been diagnosed with fibromyalgia by a medical doctor. Upon examination the patient had multiple tender points widespread throughout her body, exceeding the accepted limit of 11/18. When applying light pressure to the tender points the patient was in extreme pain, rating the pain at a 9/10. When at rest the patient rated the pain at 5/10. Movement and range of motion in all directions did not elicit pain for the patient. When applying pressure to the muscles of the back, they were extremely tender to touch. Orthopedic tests including Valsalva's, Iliac Compression and Distraction, Straight Leg Raise, Thigh Thrust, Patrick/Fabre, Nachlas, Ely's, Yeoman's, Hibb's, and Sacral Thrust were all negative for reproduction of the low back pain. Initial differential diagnosis included SI joint dysfunction, muscle strain, facet syndrome, and/or muscle spasms. After a negative result for all the above orthopedic tests, a diagnosis of low back and SI joint pain caused by fibromyalgia was suspected. The patient completed outcome assessment tools (OATs), including the Back Bournemouth Questionnaire and Pain Disability Questionnaire, and the results were high regarding chronic pain and psychosocial components. The Patient Specific Functional Scale was used to identify activities of daily living (ADLs) that were difficult to perform because of the condition. The ADLs affected included sitting, cleaning the house, bending over, and crouching.

DISCUSSION

Many veterans may face barriers to accessing adequate care, including limited access to specialized providers and a lack of insurance coverage. Therefore, it is important to increase the awareness of fibromyalgia in the veteran population and provide support and resources to those who are affected.

Many different therapies were utilized to reduce the patient's pain and symptoms. These therapies included chiropractic manipulative therapy (CMT), Jeanie Rub (mechanical massage), massage therapy, and regular exercise to include walking, swimming, water aerobics, and resistance training. When coupled, Jeanie Rub and CMT provided the best reduction of pain symptoms. There could be a correlation between manipulation and release of dopamine in the treatment of fibromyalgia. Starting the appointment with eight minutes of Jeanie Rub applied to the SI joints, lower back, midback, and upper back bilaterally immediately diminished the extremely tender points on the patient's back. The patient would then receive CMT to the SI joints utilizing Thompson Drop technique, and to the thoracic and cervical regions utilizing diversified technique.

Twelve weeks of conservative care yielded positive results for the patient's symptoms. OATs scores were decreased, ADLs improved, and the patient was noticeably in a happier mood after treatments. The patient would describe her pain level as "negative a million", and noted her symptoms had dramatically decreased throughout the treatment plan.

CONCLUSION

There is minimal evidence for the utility of chiropractic spinal manipulation in the treatment of fibromyalgia. Many authors suggest being cautious when using hands-on techniques as they might be poorly tolerated. This case demonstrates a potential pathway of treatment for patients with fibromyalgia and shows that CMT coupled with mechanical massage may have a notable impact on patients living with the condition.

LIMITATIONS

This is a single-patient case report and the results may not be generalizable to other individuals presenting with similar conditions.

CONSENT

Written informed consent was obtained from the patient for publication of this case report. A copy of the written consent is available for review by the Editor-in-Chief of this journal.

COMPETING INTERESTS

The authors declare no competing interests.

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