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Letter from the Editor-in-Chief, Dr. B. Gundersen

This concludes our 8th year of publication and we have attracted some great sponsors, writers, editors and friends; as well as a host of new readers. We have had a very good collaborative effort and have been able to improve the lives of our patients and the awareness of the public. This is the primary part of our mission as a journal.

As always at this time of year, I like to express appreciation to all those who work with us here from the editorial boards to our technical support staff. I extend to each of them my most profound thanks. Especially this year, I thank my editor, Jim Demetrious, who will be retiring as editor at this time. He has done a terrific job for us and made our product a thing of beauty and something of which we can all be proud. He has agreed to stay on as a special editor for the coming years. Companion to that is the anticipation and excitement I feel with this first issue of our new Editor, Stan Bacso. As you will see, he can carry on the traditions Jim set and has unique insight and commitment to taking giant steps for us. I am pleased to have him with us.

You will also notice that I have asked several of our board members to take on a new role as members of the Editorial Advisory Board. These are all friends whose efforts and dedication have helped us identify others to serve with us. I have asked them to continue in an advisory capacity now to help expand our editorial ranks. We can expect to see our editorial board take on a variety of specialties. This will ultimately help us to become more in-line with trends in the health care delivery systems throughout the world.

In this regard, I hope to expand the concept feature called “Ask the Doctor” wherein we offer to receive email questions regarding particular concerns, issues, or patient conditions. Each question will be assigned to a member of the advisory board depending upon his or her particular expertise and the question and answer will be published in the next issue. We will begin to develop this in the next few months.

As our participation increases from the standpoint of readership, sponsors, editors and advisors, we have an obligation to increase the quality of our work. We consider that a responsibility for the privilege of working in the effort. More contribution is necessary from every level. As you read this issue, I invite you to ponder ways you can contribute. Think about what is needed and what you can offer personally. When you have a good idea, email me and let’s play it out. It will enrich your life when you give of yourself in ways you may not have thought of before. As you read the work of others in this issue, remember that each has been down this similar road of offering some time to help. Collectively, it becomes a thing of beauty and it belongs to each of us as individuals and to all of us as a group. As with all things, giving of yourself makes life better.

I appreciate your reading this and welcome your input. I wish the very best for you and your family and hope the seeds born from this information may help provide you prosperity and joy.

Bruce

Lake Superior

(Courtesy of Dr. J. Brandt)



Facts:

- The surface area of Lake Superior is 31,700 square miles. That is greater than the combined areas of Vermont, Massachusetts, Rhode Island, Connecticut and New Hampshire.
- Lake Superior contains 3,000,000,000,000,000 (3 quadrillion) gallons of water – enough to flood all of North America and South America with a foot of water.
- The underwater visibility of Lake Superior is 27 feet, making it easily the cleanest and clearest of the Great Lakes. In some places, underwater visibility reaches 100 feet
- Lake Superior contains 10% of all the Earth's fresh surface water.

Independent Research

Heart Rate Variability and Spinal Manipulation: A Review of the Literature

David M. Swensen, DC, FACO, MAppSc.

Acknowledgements: I would especially like to thank Dr. Phillip Ebrall for his help and guidance, in his role as my Master's of Applied Science thesis advisor. I would like to thank Carla Skorin and for her support throughout the academic program and through this project. I would like to thank the library staffs of RMIT and SCUHS for aiding me in locating and obtaining my research materials. Very special thanks to my wife, Dr. Deanna O'Dwyer-Swensen, and our children, for their loving support and understanding during this project.

Abstract

Background: The notion that spinal manipulation has an effect upon visceral function has existed since the early history of the chiropractic profession. Patients have reported incidental changes such as improved function of the respiratory and digestive systems. Over the past two decades the use of Heart Rate Variability to assess sympathovagal balance has expanded from the fields of cardiology and obstetrics to a broad array of disciplines, including, but not limited to, acupuncture, psychology, exercise physiology, and manual therapy. The effect on the autonomic nervous system may be a factor in the therapeutic effects of these varied interventions.

Objective: The purpose of this paper is to systematically review all peer-reviewed, published studies regarding the use of Heart Rate Variability to assess changes in the autonomic nervous system resulting from spinal manipulative therapy.

Data Sources: Several online databases, including Medline, MANTIS, OVID, ICL, CINHAL, and Cochrane were searched using keywords spinal manipulation and/or chiropractic manipulation, combined with heart rate, heart rate variability, autonomic nervous system. Articles from 1996 forward were included.

Study Selection: English and non-English articles were included in this review. Randomized clinical trials and prospective observational trials on heart rate variability and spinal manipulation were included. No unpublished material or non-peer reviewed literature were included in this research.

Data Extraction: Each of the studies was critically reviewed. The following were extracted from each paper and entered into a Microsoft Excel spreadsheet: author; study design; sample size, intervention, outcomes.

Data Synthesis: A critical evaluation list of 20 methodological items and their operational definitions was used to assess each paper. This evaluation list is based on work done by Bronfort and colleagues, as well as by Owen. A validity score resulting from the 20-point critical evaluation was calculated for each paper.

Results: Nine papers met criteria for inclusion. One of the studies was a randomized clinical trial, and eight of the nine studies were prospective observational studies. The validity scores ranged from 27% to 83%.

Conclusion: There is evidence demonstrating an effect of spinal manipulation on sympathovagal balance. There is also evidence supporting a regional effect of manipulation of the thoracic and lumbar spine. This review also revealed the need for a rigorous protocol to be followed in order to obtain valid recordings.

Introduction

Shortly after Harvey Lillard's hearing was reported to be restored after a spinal adjustment, D.D. Palmer wrote of a patient who presented with heart trouble, 'I examined the spine and found a displaced vertebra pressing against the nerves which innervate the heart. I adjusted the vertebra and gave immediate relief...' (Palmer, 1910). This observation by Dr. Palmer leads to the proposal of spinal manipulation having a causal effect of change in cardiac control through autonomic system regulation. The suggestion of a neurological mechanism for this cause and effect relation was presented several decades later (Korr, 1978).

In the treatment of musculoskeletal conditions, the utilization of outcomes assessments has become necessary to demonstrate the clinical necessity and efficacy of care. This is especially true in the case of managed care and other third party payers. Many of the outcome assessment tools are subjective in nature because they are patient oriented (i.e., questionnaires completed by the patient). With the extensive research into these subjective questionnaires, Their (as cited in Yeomans, 2000, p. 23) has noted that they have gained more respect as outcome assessment tools. One such questionnaire is the Short Form 36 SF-36, which was found to be the most widely evaluated generic patient assessed health outcome measure in a study of the development of "quality of life" measures (Garratt, Schmidt, Mackintosh, & Fitzpatrick, 2002).

One of the basic tenets of chiropractic wellness care is the improvement of neurological and visceral function through regular spinal manipulation. Although functional and quality of life questionnaires are acceptable outcome measures, a more concrete, objective method of evaluating treatment outcome may be desirable in some circumstances. However, as stated by Yeomans, "the introduction of new or novel measurements in the clinical setting should be preceded by formal investigation into the 'meaningfulness' of the test or measure" (Yeomans, 2000, p. 9).

The purpose of this review is to investigate whether the current literature supports the use of heart rate variability (HRV) as a useful tool to assess the changes occurring in the autonomic nervous system related to spinal manipulation. With several companies marketing HRV equipment to chiropractic physicians, this review hopes to shed light on the utilization of HRV in the chiropractic field. This may be important in the medicolegal arena in either supporting or negating the utility of HRV analysis for musculoskeletal complaints or injuries, or to support the concept of wellness oriented chiropractic care. This review also hopes to summarize the existing body of knowledge regarding the use of HRV to assess the effect of spinal manipulation on the autonomic nervous system. In other words, is it a valid tool to use to support the idea of wellness care? And, is there evidence for use in the evaluation of efficacy of care for musculoskeletal complaints?

Background

The use of heart rate variability (HRV) as a measure of change in autonomic function in non-musculoskeletal conditions has increased over the past three decades. HRV offers a method of detecting early signs of pathological processes, or functional disorders (Riftine, 2000). The European Society of Cardiology and the North American Society of Pacing and Electrophysiology formed a task force in order to standardize nomenclature and define terms, specify standards of measurement, define physiological and pathophysiological

correlates, review appropriate applications, and identify possible areas of future research. The review presented by the task force reported observable changes in HRV in patients with myocardial infarction, cardiac transplantation, cardiac ventricular dysfunction, and tetraplegia, (Malik, 1996). HRV has also been used to detect changes in autonomic function in essential hypertension, diabetic neuropathy, and sudden infant death syndrome (M. D. Driscoll & Hall, 2000). In a large community based study, decreased heart rate variability was found to be a predictor of mortality in elderly subjects (Tsuji et al., 1994).

The relation between vertebral segmental motion and the autonomic nervous system was initially identified in rats when it was demonstrated that movement of spinal segments may affect the autonomic nervous system. Mechanical stimulation of the lower thoracic and lower lumbar regions induced a decrease in blood pressure, an increase in heart rate, as well as changes in adrenal nerve activity (Sato & Swenson, 1984). Further study then led to the suggestion that these somatovisceral responses may occur in humans with spinal manipulation (Sato, 1992).

Nansel and Szlczak (1995) performed a review of 350 articles to examine the scientific basis of theories which propose that internal diseases are found to respond in a rapid fashion to therapies directed to somatic structures. They noted most articles to be anecdotal in nature and did not find any controlled studies that convincingly demonstrate spinal manipulation to be a curative strategy for any visceral condition. They concluded that all portal of entry providers need to have an appreciation of afferent convergence mechanisms which can create signs and symptoms of which the etiology may not be distinguishable (Nansel & Szlczak, 1995).

With the increased utilization of HRV in the management of cardiac patients the European Society of cardiology and the North American Society of Pacing and Electrophysiology developed a task force to investigate HRV, with specific goals to, “(1) standardize nomenclature and develop definition of terms, (2) specify standard methods of measurement, (3) define physiological and pathophysiological correlates, (4) describe currently appropriate clinical applications, and (5) identify areas of future research” (Malik, 1996, p. 1044). The task force’s publication described two methods of evaluating HRV - time domain method, and frequency domain method. Standardized recording durations are short term 5-minute recordings, and nominal 24 hour recordings.

The time domain method evaluates the intervals between the adjacent QRS complexes to detect the normal to normal (NN) intervals, or the instantaneous heart rate, in a continuous ECG recording. The R to R interval has been the standard portion of the ECG from which the measurement is derived. Using a long duration recording, which is usually 24 hours, two classes of statistical measures can be calculated: those from direct measurements of the NN intervals or instantaneous heart rate; or those from the differences between NN intervals. The simplest statistical variable calculation is the standard deviation of the NN intervals (SDNN), the square root of variance which is equal to total power of spectral analysis, and reflects all of the cyclic components responsible for the variability which occurs during the time period of the recording. SDNN is dependent upon the length of the recording, and it is inappropriate to compare measures of SDNN taken from different length recordings. Other measures recommended by the task force include the HRV triangular index as an estimate of overall HRV, the standard deviation of the average NN interval (SDANN) as an estimate of long term components of

HRV, and the square root of the mean squared differences of successive NN intervals (RMSSD) as an estimate of short term components of HRV (Malik, 1996).

In frequency domain methods of HRV analysis, spectral methods are used to analyze the tachogram derived from the ECG. Power spectral density (PSD) analysis is one method, and it offers information on “how power variance-distributes as a function of frequency” (Malik, 1996, p. 1048). The main components of spectral analysis are very low frequency (VLF), low frequency (LF) and high frequency (HF). In long term recordings, ultra low frequency (ULF) is also utilized.

The task force recommended the use of frequency domain methods over time domain methods when short term recordings are investigated. They indicate the duration of the recording should be dictated by the needs of the study. In order to standardize studies using the analysis of short term recordings, 5-minute recordings are preferred, and it is recommended that the subject is stationary in order to avoid the effects of movement on the HRV (Malik, 1996).

In interpretation of the HRV, it is important to understand that the HF component is an indicator of vagal activity to the heart. The LF component is considered either an indicator of sympathetic activity, or both parasympathetic and sympathetic activity. The LF/HF ratio is an indicator of sympathovagal balance. A ratio of 1 indicates that the sympathetic and parasympathetic nervous systems are balanced. A value greater than 1 indicates a sympathetic nervous system predominance, and a value less than one indicates a parasympathetic predominance (D. Driscoll & DiCicco, 2000). The physiological interpretation of VLF and ULF is not fully understood, and thus these components are not typically utilized in HRV analysis. HRV measures the fluctuations in autonomic input to the heart, not the mean level of autonomic input and “thus both autonomic withdrawal and saturatingly high level of sympathetic input lead to diminished HRV” (Malik, 1996, p. 1050). As previously noted, diminished HRV has been associated with increased mortality in elderly subjects (Tsuji et al., 1994).

Methods

Data Sources and Study Selection

Six databases were searched according to the strategy presented in Table 1. Studies were further identified by means of a manual search of obtained article references. Two of the authors were located and contacted, with no reply obtained.

Several online databases, including Medline, MANTIS, OVID, ICL, CINHALL and Cochrane were searched using keywords spinal manipulation and/or chiropractic manipulation, combined with heart rate, heart rate variability, autonomic nervous system. Articles from 1996 forward were included. The articles were reviewed to be sure the subject included the topic of the effect of spinal manipulation, or chiropractic manipulation on HRV. Articles from peer-reviewed journals were included. It was determined that it was necessary to include previous articles for background knowledge regarding HRV. The terms ‘spinal manipulative therapy’ (SMT) and ‘chiropractic manipulative therapy’ (CMT) are used throughout the literature reviewed, and in order to avoid confusion for the reader, the term SMT will be used henceforth to refer to both SMT and CMT.

The initial search process resulted in 22 studies. Two studies were excluded because they were investigations of the effect of massage (Toro-Velasco, 2009) and cranial manipulation (Milnes & Moran, 2007) on HRV, and one was excluded because it was a reference to a poster presentation (Stiles & McCoy, 2008). Two studies were reviews of HRV (A. M. Eingorn & G. J. Muhs, 1999; Kent, 2006) and one was a review of the autonomic effects of SMT (Lynch, 2009) which did mention HRV. One study was cross sectional in an effort to establish norms for age and gender (Zhang, 2007). Two studies did not assess HRV changes associated with SMT, but looked at the effect upon HRV recordings of variables during the recording procedure, specifically body position (R. J. Watanabe N, Polus B, 2007) and paced breathing (D. Driscoll & DiCicco, 2000). One study looked at the effect of acute musculoskeletal pain upon HRV (Grimm, Cunningham, & Burke, 2005). Of the remaining eight articles, three were case studies, two of which discussed changes of cardiac arrhythmia resulting from spinal manipulation (B. S. Budgell & Igarashi, 2001; Igarashii & Budgell, 2000) and one which looked at the effect of spinal manipulation on autonomic activity through electrocardiogram and arterial tonometry (M. D. Driscoll & Hall, 2000). The remaining nine studies assessed the changes in HRV associated with spinal manipulation by quasi-experimental design (B. Budgell & Hirano, 2001b; B. Budgell & Polus, 2006; Roy R, 2009; Shell, Jarmel, & Charuvastra, 1996; P. B. Watanabe N, 2007; Welch A, 2008; Zhang, 2000b; Zhang, Dean, Nosco, Strathopulos, & Floros, 2006; Zhang & Snyder, 2005) and were included for data extraction and assessment.

Data Extraction

The following were extracted from each paper and entered into a Microsoft Excel spreadsheet: Author; study design; sample size; description of intervention; recording; and conclusion.

Assessment of Methodological Quality of Studies

The quality of the studies was assessed using a critical evaluation instrument consisting of an initial list of twenty methodological items and their descriptions. The list is a adaptation by Bronfort of a qualitative assessment instrument used in a meta-analytic review of treatment for recurrent tension headache (Bogaards, 1994), Bronfort first utilized the assessment instrument in a review of clinical trials of spinal manipulation for the treatment of headache (Bronfort, Assendelft, Evans, Haas, & Bouter, 2001), and it was subsequently used in a review of homeopathic treatment of headache (Owen, 2003). The number of criteria was decreased to 18 because two criteria, “intention to treat analysis” and “comparison to other treatment options” were not applicable to the studies reviewed. Thirteen of the items addressed validity issues, yielding a validity score, and five of the criteria items concerned descriptive information. This instrument by Bronfort was selected over another instrument which was particularly designed for use with quasi-experimental studies in the field of education (Gersten R, 2005) because of its previous use in the area of manual therapy. It is noted that the criteria presented in both instruments was similar.

One criterion was modified because it was not applicable to the objectives of the studies reviewed. The criteria assessed whether a main outcome measure was used. The objectives for the various studies reviewed were not to look for a treatment effect on a certain condition. They were observational in nature, looking at the effect of treatment on the ANS. HRV has been demonstrated to be a valid assessment of sympathovagal (SV) balance (Malik, 1996), therefore, the studies currently reviewed did not need to seek to further validate the use of

HRV. The objective, for the most part, was to look for an affect of SMT upon the sympathovagal balance. There is no gold standard of sympathovagal measurement, and, based on the literature, treatments may affect various autonomic functions differently. For example, one intervention may result in mixed effects on heart rate and systolic and diastolic blood pressures (Fujimoto, Budgell, Uchida, Suzuki, & Meguro, 1999).

The outcome measure must be explicitly established by investigation, appropriately referenced, or generally accepted (e.g., VAS scales, Oswestry, or Roland Morris disability scales). If all of the above conditions are not met, a NO score is given,” to “A yes score is given if at least one comparative physiological objective measure/data was collected which has been demonstrated to be relevant to the condition under study (e.g. vital signs, strength, range of motion, algometry).”

Results

Characteristics of Papers Reviewed

The results of the literature search, with inclusion/exclusion criteria, included nine studies summarized in Table 1:

Author	Sample size	Study design	Variables recorded	Description of Intervention	Findings/conclusion
Shell (1996)	23		HRV analysis from 5 minute interval taken from 24 hour recording in which the lowest HR attained during sleep	SMT 3x/week 4 weeks	Upper T/S dysfunction may be an unrecognized source of cardiac sympathetic activation
Zhang (2000)	27	observational	HRV, HR	SMT associated with being Chiro student	Decreased HR and increased parasympathetic stimulation was noted with chiropractic care over the first year of chiropractic college
Budgell (2001)	24	controlled cross over trial	HRV, HR, VAS (pre-intervention only)	Supine cervical rotary adjustment and sham adjustment	Autonomic changes associated with authentic manipulation but not with sham
Zhang (2005)	control-17 experimental - 28	controlled-cross over	EMF, HRV (weekly)	Low Force toftness adjustment (6 visits over 4 weeks)	Decreased EMF, no change in HRV
Budgell (2006)	28	controlled cross over trial	HRV	2 sessions one week apart, SMT to upper T/S or sham	No effect with sham. Increased sympathetic output to heart with SMT
Zhang (2006)	539	observational	HRV, VAS, HR (one group one Tx with pre-post recording, another group once per week for 4 weeks)	SMT multiple techniques	VAS decreased with each Tx, but then returned to pre-treatment level. HRV increased with each visit, and over 4 weeks. HR decreased
Watanabe (2007)	11	pre and post controlled trial	HRV, HR, BP, VAS (pre-intervention,	SMT (Activator) or sham, in supine and seated positions	Both authentic and sham manipulation can acutely influence cardiovascular function.
Welch (2008)	40 (7 undergoing HRV analysis)	pre-post	pre-post HRV (seated), BP, HR, PP	SMT to cervical or thoracic region, 2 visits, diversified	LF/HF decreased in cervical region and increased in thoracic region. Decreased diastolic and increased PP in C/S/group. Non-sig. decrease in PP in thoracic group.
Roy (2009)	50 (11 Control, 10 each for sham, activator, sham lumbar roll, authentic activator, authentic lumbar roll)	RCT	HRV pre and post	single lumbar adjustment vs. sham for activator and lumbar roll in pain free and acute LBP	Shift of SV balance toward parasympathetic predominance with SMT independent of adjusting technique

Table 1 - Characteristics of papers reviewed

Eight of the studies were observational (B. Budgell & Hirano, 2001b; B. Budgell & Polus, 2006; Gersten R, 2005; Shell, Jarmel, & Charuvastra, 1996; P. B. Watanabe N, 2007; Welch A, 2008; Zhang, 2000a; Zhang et al., 2006; Zhang & Snyder, 2005), and the remaining study was a randomized clinical trial (Roy R, 2009).

All studies obtained pre- and post-treatment electrocardiogram recordings from which HRV analysis was performed. Seven of the studies assessed other variables in addition to HRV. Six studies evaluated heart rate (HR) (B. Budgell & Hirano, 2001b; B. Budgell & Polus, 2006; P. B. Watanabe N, 2007; Welch A, 2008; Zhang, 2000b; Zhang et al., 2006); two assessed changes in blood pressure (P. B. Watanabe N, 2007; Welch A, 2008); one measured electromagnetic frequency (EMF) (Zhang & Snyder, 2005); one measured pulse pressure (Welch A, 2008); and of the three studies that collected visual analogue scores (VAS), two collected only pre-intervention VAS in order to determine the presence or absence of pain (B. Budgell & Hirano, 2001b; P. B. Watanabe N, 2007), and one collected pre- and post-intervention VAS in order to investigate a relation of HRV changes to VAS changes (Zhang et al., 2006).

Four of the studies compared manipulation to a sham procedure (B. Budgell & Hirano, 2001b; B. Budgell & Polus, 2006; Roy R, 2009; P. B. Watanabe N, 2007). Two studies evaluated response to cervical manipulation only (B. Budgell & Hirano, 2001b; P. B. Watanabe N, 2007); two studies looked at thoracic manipulation (B. Budgell & Polus, 2006; Shell, Jarmel, & Charuvastra, 1996); one compared responses of cervical vs. thoracic manipulation (Welch A, 2008); one investigated the response to lumbar manipulation (Roy R, 2009); and three studied the effects of general chiropractic care (Zhang, 2000a; Zhang, Dean, Nosco, Strathopoulos, & Floros, 2006; Zhang & Snyder, 2005). The longest treatment duration was 4 weeks (Shell et al., 1996; Zhang et al., 2006; Zhang & Snyder, 2005). All, except one study, noted changes in HRV with SMT (Zhang & Snyder, 2005), and of the studies utilizing a sham procedure, two noted a change in cardiovascular function with the sham (Roy R, 2009; P. B. Watanabe N, 2007).

Quality Assessment

The critical evaluation list contains 20 items (A-T) of which 14 (B-G, J, L-N, P-S) have been classified as (internal) validity items and six (A, H, I, K, O and T) as information items. The Appendix contains a description of each item as worded in the list. The results are shown in Table 2:

Author	B	C	D	E	F	G	J	K	L	M	O	P	Q	S	Validity score	A	H	I	N	R	T
Shell, 1996	N	-	-	-	-	p	-	+	p	+	p	+	-	-	37.5%	+	n	p	p	-	-
Zhang, 2000	N	-	+	-	-	-	-	-	+	-	+	n	-	-	27%	+	+	p	+	+	+
Budgell, 2001	N	-	+	-	-	-	-	-	+	-	n	n	+	+	30%	+	n	+	-	+	+
Zhang, 2005	+	p	-	-	-	-	-	p	+	+	n	n	-	-	36%	+	p	+	+	p	P
Budgell, 2006	N	p	-	p	-	-	-	p	+	+	n	n	n	n	39%	+	n	+	+	+	+
Zhang, 2006	-	-	+	-	-	-	p	+	+	p	p	p	-	-	38%	+	+	+	+	+	+
Watanabe, 2007	N	-	+	-	-	-	-	p	+	n	+	n	+	+	45%	+	n	+	+	+	+
Welch, 2008	-	-	+	-	-	-	-	+	+	-	-	n	n	N	27%	p	n	p	+	+	+

Roy, 2009	+	+	-	+	-	+	+	+	+	+	+	n	+	+	83%	+	n	+	+	p	p
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Table 2 - Assessment of Study Quality; (+) yes. (-) no. (p) partly or unclear. (n) not applicable.

Validity score is the percentage of the applicable validity items. (+) = 1, (p) = 0.5, (-) = 0.

Eight of the nine studies clearly defined the inclusion/exclusion criteria for the study subjects, with one study describing only inclusion criteria, but no exclusion criteria (Welch A, 2008). Baseline assessment of groups was comparable in the studies which did utilize different groups (Roy R, 2009; Zhang & Snyder, 2005). Four studies described randomization procedures for either placement of subjects in groups, or order of intervention (i.e., sham or authentic) (B. Budgell & Hirano, 2001b; B. Budgell & Polus, 2006; Roy R, 2009; Zhang & Snyder, 2005). Two studies utilized serial outcome measures (VAS) along with HRV recordings (Zhang, 2000b; Zhang et al., 2006).

Other studies measured additional parameters associated with autonomic function, and these were mentioned in the data distraction section of this paper. Blinding of the subject to sham or authentic manipulation was performed to the degree possible in three studies (B. Budgell & Hirano, 2001b; B. Budgell & Polus, 2006; Roy R, 2009). Blinding of the treatment provider was not possible in any of the studies reviewed because of the nature of the application of spinal manipulative therapy. Two study authors discussed the effectiveness, and difficulty, of blinding (Roy R, 2009; Shell et al., 1996). Several of the studies were four weeks or longer in duration, however, none of the studies had adequate post-intervention follow-up to determine prolonged effects of SMT on HRV.

The interventions of the studies were all, at least, partially described, if not fully detailed, and all are replicable in a clinical setting. Attention bias was not specifically discussed in the studies, but one study offered detailed descriptions of the intervention protocol and the absence of deviation from that protocol (Roy R, 2009). The primary study objective, or hypothesis, was not clearly defined in terms of group contrasts, if applicable, or with regard to comparative outcomes using additional measures of autonomic function, in two of the studies (B. Budgell & Hirano, 2001b; Zhang, 2000b), and only partially presented in three studies (B. Budgell & Polus, 2006; P. B. Watanabe N, 2007; Zhang & Snyder, 2005).

The choice of statistical tests for the main result was appropriate in all of the studies. Adequate statistical power was determined in one study (Roy R, 2009), however confidence intervals were calculated in all of the studies. Dropouts were accounted for in three studies (Roy R, 2009; Shell et al., 1996; P. B. Watanabe N, 2007; Zhang, 2000b) and missing data was addressed in two (Shell et al., 1996; Zhang et al., 2006). Intention to treat analysis was not applicable in these studies, whereas per protocol analysis was utilized. Adjustments were made for the number of statistical tests in four of the studies (B. Budgell & Hirano, 2001b; B. Budgell & Polus, 2006; Roy R, 2009; P. B. Watanabe N, 2007), and valid conclusions, based upon the findings and related to the primary objectives of the study, were stated in all of the studies.

The validity scores ranged from 27% (Welch A, 2008; Zhang, 2000b) to 83% (Roy R, 2009).

Discussion

In reviewing the literature on the topic of SMT and HRV, three case studies were revealed. Although these studies were not utilized in the data extraction or study assessments, the case study is an important step in the

hierarchy of research to the development of further research, and this author thought it important to include these studies in this discussion. Being that the use of HRV in evaluating autonomic response to SMT is relatively recent, these cases may be essential to setting the course for further research on this topic.

Two of these case studies demonstrated changes of arrhythmia associated with SMT (B. S. Budgell & Igarashi, 2001; Igarashii & Budgell, 2000). One study (Igarashii & Budgell, 2000) discussed the case of a 22-year-old male with a history of fatigability, dizziness associated with prolonged standing, and palpitations with normal activities. He reported breathlessness and tightness across his chest with mild exercise, and a history of tachycardia, which was confirmed by ECG. He underwent a course of treatment consisting of diversified spinal manipulation to the upper cervical and upper thoracic regions. No other modalities were utilized. Five-minute pre- and post-treatment ECG recordings were taken. He underwent two treatments in one week after which he stopped treatment because of improved symptoms. The symptoms shortly returned, and he underwent another course of treatment which consisted of six treatments over a four week period. He noted cessation of dizzy spells and increased tolerance to exercise. No significant difference was noted on the pre- and post-treatment recordings on the individual treatments for HRV analysis or the number of ectopic beats. However, there was decreasing trend noted in the sympathetic activity and an increasing trend noted in the parasympathetic activity over the four week course of treatment. The number of ectopic beats also decreased (Igarashii & Budgell, 2000).

A second study presented the case of a 23-year-old male with bradycardia and a trigeminal rhythm who underwent a single cervical manipulation to the C2 vertebra. An ECG was continuously monitored before, during, and after the treatment. Respiration was paced with a metronome, although the rate of respiration is not mentioned by the authors. A 5-minute pre-treatment and a 5-minute post-treatment portion of the recording underwent HRV analysis. The ECG analysis revealed that the trigeminal rhythm stopped with the administration of a single adjustment. The power spectrum analysis of the HRV was not valid because of the pre-treatment trigeminal rhythm and the reduced RR intervals due to the bradycardia; however, the authors noted that there appeared to be a noticeable change in the sympathetic and parasympathetic output to the heart after the manipulation. ECG recordings 4 and 7 days post-treatment showed that the trigeminal rhythm had not returned, but the bradycardia was still present. (B. S. Budgell & Igarashi, 2001)

Another case study which included a subject without arrhythmia utilized ECG and arterial tonometry to evaluate changes in the autonomic nervous system activity after SMT (M. D. Driscoll & Hall, 2000). The subject in this case was a 25 year old female who presented with bilateral elbow and mid-forearm numbness of 3 to 4 week duration, chronic lower back pain, intermittent headaches with increasing persistence over the prior two years, and neck and shoulder pain of 3 to 4 month duration. The pain levels of each of her complaints were rated using a Visual Analogue Scale (VAS). A Revised Oswestry Low Back Disability Scale questionnaire was also filled out by the subject. Her lab work (UA, CBC, Thyroid panel) and her ECG were unremarkable. Two baseline measurements of arterial tonometry and HRV analysis were performed over the first week, and then two treatment measurements were taken each week for five weeks. Pre- and post-treatment recordings were taken. The treatments consisted of SMT, and were scheduled the same time each day in order to avoid diurnal variations. The spinal levels which were adjusted varied slightly each visit, but included one segment in the cervical, thoracic, and lumbar levels on all but the 5th, 8th and 10th visits. On these visits manipulation was

applied to the cervical and SI, cervical and lumbar, and the cervical, thoracic, and SI levels, respectively. HRV and arterial tonometry changes were observed, with a relative increase in the sympathovagal ratio compared to baseline after most of the treatments. The changes in LF were not consistent. HF generally decreased after the treatment compared to the baseline, indicating decreased parasympathetic activity. These changes were noted to be non-significant. They attributed some of the change between baseline and treatment measurements to the subject's anxiety level, and suggested the level of anxiety be assessed pre and post treatment in future studies (M. D. Driscoll & Hall, 2000). The authors did not mention whether additional VAS or Revised Oswestry Low Back Pain Disability Questionnaires were completed by the patients.

The effect of SMT on cardiac dysrhythmic abnormalities was evaluated earlier in a study of 23 subjects who received SMT (diversified technique) three times per week for four weeks. Twenty-three of these subjects demonstrated symptoms of tachycardia and palpitations and spinal joint dysfunction in the upper thoracic region. On ECG recordings, 14 were found to have cardiac dysrhythmia. HRV analysis was performed on 24-hour ECG recordings before and after the treatment period. The low frequency power to high frequency power ratio was measured during a five-minute period during sleep with the lowest heart rate was measured. The results suggested that upper thoracic joint dysfunction may be a source of cardiac sympathetic activation, and that SMT significantly enhances autonomic balance (Shell et al., 1996).

Eingorn and Muhs (1999) reviewed the use of heart rate variability analysis to calculate a quantitative index of autonomic function, in order to assess the sympathetic and parasympathetic tone and the sympathovagal balance. They noted that autonomic tone had previously been assessed "on the basis of subjective data such as pupil dilatation, distal skin temperature, heart rate, and sympathoadrenergic biochemical criteria such as blood levels of adrenaline, noradrenaline, and corticosteroids" (Eingorn & Muhs, 1999, p. 161). They concluded that, because the previous literature demonstrated that HRV analysis is a reliable and accurate method of ANS assessment, and because there is evidence suggesting SMT may have an effect on the autonomic tone of a patient's nervous system, that further study may contribute to the understanding of the effects of SMT on an individual's general health, on an individual's susceptibility to lowered immunity and their recuperative capacity, and the effect of autonomic changes, induced by SMT, on non-musculoskeletal conditions (Eingorn & Muhs, 1999).

The suggestion that HRV could become a useful assessment of treatment outcomes in clinical chiropractic practice (Eingorn & Muhs, 1999) has appeared to motivate researchers to further investigate the effects of spinal manipulative therapy (SMT) on HRV in order to demonstrate the effect SMT has upon the autonomic nervous system. Several of these studies measured initial pain levels by having patients fill out a visual analogue scale (VAS) (M. D. Driscoll & Hall, 2000; Grimm et al., 2005; J. Zhang, Dean, Nosco, Strathopoulos, & Floros, 2006), but only Zhang et al (2006) reported subsequent pain scores. A significant decrease in pain rating by visual analogue scale (VAS) was noted, concurrent with noted HRV changes with one adjustment, and with each adjustment over 4 weeks of chiropractic treatment. The findings demonstrated that the improvement in VAS pain rating was not maintained throughout the four weeks of the study.

HRV data has been collected in order to investigate normal values with regard to age and gender (Zhang, 2007). Decreased HRV was found to be associated with age, with a lesser effect based on gender.

In a study performed to promote the development of a reliable method of collecting data to demonstrate the effect of CMT on the ANS (D. Driscoll & DiCicco, 2000), blood pressure, arterial tonometry, and ECG measurements were taken from 8 subjects while a strain gage was applied to the chest in order to measure respiratory rate. Data was collected while the subjects breathed normally, and while they breathed to a rate of 12 breathes per minute, paced by a metronome. An increase in HF values was associated with metronome breathing, indicating increased parasympathetic activity. Also noted were significantly decreased variability of LF, HF, and LF/HF measurements. No other significant changes with paced breathing were noted in the other autonomic nervous system measurements taken. The authors draw attention to the possibility of the increased parasympathetic activity associated with metronome breathing overriding the effect of spinal manipulation, and suggest further study before paced breathing is instilled in the protocol of HRV data collection.

Another study investigated the effect of the chiropractic care, associated with being a chiropractic student, has on the autonomic nervous system (Zhang, 2000b). HRV analysis was performed on 27 chiropractic students once a month for three months and then again at the end of the 12 month period. Sympathetic nervous system activity was predominant in all four measurements, but parasympathetic activity did increase over the 12 month period. The third measurement did show a slight decrease in the parasympathetic activity compared to the initial two measurements.(Zhang, 2000a) The assumed treatment effect was not able to be truly identified because it was assumed the students were undergoing a level of chiropractic care over the time period. It is reasonable to suppose that there may have been some effect from the stress level associated with the students beginning a new academic program.

A noticeable difference was apparent in a study comparing the effect of thoracic SMT on HRV to the effects of a sham manipulation on HRV (B. Budgell & Polus, 2006). In this study, 28 healthy, normotensive adults recruited on the basis that they did not have neck or upper back pain, completed VAS for cervicothoracic spinal discomfort with full active right and left rotation. Subjects were examined for contraindications to cervical manipulation. The subjects received either a sham manipulation or spinal manipulation to the upper thoracic region, determined by a coin toss immediately before the first trial. Automated HRV analysis of ECG recordings for 5-minute pre- and post-treatment recordings was performed. There was no significant change in the LF or HF components for the subjects receiving sham manipulation, however there was a decrease in the HF component, an increase in the LF component, and an increase in the LF/HF ratio, indicating increased parasympathetic output to the heart. Similar changes had been noted in a previous study with manipulation to the cervical spine (B. Budgell & Hirano, 2001a) using a cohort of healthy young adults.

Based on the work of Gandevia & Mahutte, and Bogduk & Twomey (as cited in B. Budgell & Polus, 2006, p. 608), suggesting that the muscle spindle fibers in the deep paraspinal muscles act as sensory receptors, and may be stimulated by postural changes, it is proposed that high velocity low amplitude manipulation stimulates the muscle spindle fibers, triggering reflex regulation of cardiac function. This may explain why no change was found with the sham manipulation. Also contributing to the explanation for this suggestion is the finding by Pomeranz, et al (as cited in B. Budgell & Polus, 2006, p. 607) that cardiac sympathetic output is increased in the standing position vs. the supine position. However, afferent stimulation from baroreceptors in response to

decreased blood pressure when changing from sitting to standing is a well known source of sympathetic input to the heart and must be considered to play a role in the autonomic changes that occur with changes in posture.

The largest study to investigate HRV changes in response to SMT involved 96 study sites and 133 subjects in a 4-week treatment group, 479 subjects in a single treatment group, and 157 subjects in a control group (Zhang et al., 2006). Doctors of chiropractic were recruited from the United States. These practitioners were asked to then recruit 10 subjects from their practice. Patients were recruited into the study, and were to be randomly selected from different age, sex, and racial groups. Pre- and post-treatment HRV data was collected from 8 of the 10 subjects for one visit only. HRV data was collected from the other 2 subjects while undergoing treatment over a 4 week period. The ECG data was analyzed using both time domain and frequency domain methods. On the days in which measurements were taken, patients sat for 5 minutes in the room where recordings took place, had a 5-minute ECG recording, received spinal manipulation, and then sat for 5 minutes again, and then had a post-treatment ECG recording taken. The subject filled out a pre and post treatment questionnaire during the respective 5-minute sitting period. These forms included a VAS as well as questions regarding adverse effects of the treatment. The treating doctor also filled out a questionnaire regarding the levels adjusted and the adjustive technique applied after the treatment was rendered. In this study, HRV data was collected with the subject in a seated posture.

Results of this multicenter study showed no change in HRV in the control group; however, significant improvement in HRV was seen in both the single visit and the 4-week groups when the post-treatment analysis was compared to the pre-treatment analysis. The VAS was found to decrease significantly from the pre-treatment form to the post treatment form for each visit, but the decrease in VAS was not maintained between visits. The authors conclude that the HRV measurements appear to be a useful outcome assessment tool for monitoring autonomic nervous system activity. (Zhang et al., 2006)

Two inconsistencies were found in this article. The first exists where it is stated in the subjects description of the methods section that the recordings from the 4-week group were taken once per week (Zhang et al., 2006, p. 268), yet in the “heart rate variability” description in the methods section the authors stated the recordings were taken twice per week (Zhang et al., 2006, p. 269). Another inconsistency was noted where the authors state in the methods section that the subjects with bodily pain were recruited into the study (Zhang et al., 2006, p. 268), yet in the discussion section it stated that “subjects were not recruited because of pain” (Zhang et al., 2006, p. 271). Whether the noted discrepancies have any bearing on the conclusions drawn from the study is questionable.

In an investigation of the effect of a brief mechanical impulse applied to the upper cervical region on autonomic and cardiovascular function, comparison of an authentic manipulation and a sham manipulation was performed (P. B. Watanabe N, 2007). A mechanical impulse was delivered by the investigator placing their fingertip on the lateral aspect of the transverse process, and then applying the mechanical stimulus from an Activator instrument through the investigators fingertip. The sham procedure was performed by the investigator directing the impulse to the dorsum of their hand rather than the fingertip. The sham and “authentic” procedures were performed in both supine and seated postures, with paced breathing at a rate of 15 breaths per minute. When this procedure was performed in a supine position, the subject was lying comfortably, face up, on a chiropractic adjusting

table. The subject was asked to remain quiet, still, and awake. When performed in a seated posture, subjects sat in a custom designed chair designed to minimize movement of the body and head. They were fitted with a helmet/helmet frame apparatus which was attached to the chair frame, in order to restrict head movement. According to the article, all efforts to assure subject comfort were taken, including pillows, foot rests, back supports, and avoidance of sudden disturbing sounds from the outside environment. All of these measures were taken in order to minimize the influence of these factors upon the autonomic and cardiovascular systems.

An interesting procedure that was performed in this study was the cold pressor test, which was not used in the other studies reviewed. The cold pressor test was performed on subjects after one of the seated recording sessions in order to determine whether the subject had normal autonomic function. In this test, one of the subjects' hands was placed in a bucket of icy water, and they were asked to keep their hand submerged as long as they could tolerate, but no longer than a minute. HR and BP were monitored during the cold pressor test. The mean HR and BP during the paced breathing in a seated posture, and the minimum/maximum points of HR and BP change during the cold pressor test were compared. Normal autonomic function was determined by a minimum/maximum point exceeding 2 standard deviations of the mean HR and BP recorder during synchronized breathing. All 11 subjects were determined to have normal autonomic function base on the findings of the cold pressor test (P. B. Watanabe N, 2007). The authors did not state whether or not the data would have been excluded had an abnormal cold pressor test occurred.

The results of this study included a shift toward sympathetic dominance of the low frequency and high frequency bands of the frequency spectrum after the sham procedure in the seated posture. No significant HRV changes were found in the supine sham or authentic, or the seated authentic manipulation. Acute changes were noted in HR and BP immediately following both the authentic and sham manipulations. These changes returned to baseline within 60 seconds. The authors concluded that innocuous mechanical stimulation to the upper cervical region may result in an acute cardiovascular change in the conscious human. They also suggested that there may have been an equipment malfunction during the procedure, or the sham may have been contaminated (P. B. Watanabe N, 2007).

Welch and Boone (2008) performed an investigation of the results on the autonomic nervous system of manipulation in different regions of the spine. They hypothesized that cervical manipulation would result in increased parasympathetic influence and thoracic manipulation would result in greater sympathetic influence. The reasoning behind this hypothesis was based on the anatomical location of the cell bodies of the pre-ganglionic fibers of the parasympathetic and sympathetic nervous system, with the sympathetic fibers arising from the lateral horn of T1 through L2 spinal segments, and the parasympathetic arising from the motor nuclei of cranial nerves III, VII, IX, X, XI, and the S2 through S4 sacral segments.

HR and BP were measured in all 40 of the subjects in this study, and HRV was evaluated in only 7. The inclusion criteria were described as "being between the ages of 21 and 55, non-hypertensive and no history of heart disease." The first two visits were to establish a baseline, followed by the application of spinal manipulation on the third and fourth visits, and the fifth visit post-adjustment recordings were taken. During the baseline visits, chiropractic assessment was performed in order to determine the level/region of adjustment. This analysis included static and motion palpation, leg length measurements, and thermography. With regard to the

subjects from which HRV data was recorder, four were placed in the cervical group and three in the thoracic group. Diurnal variations were considered when scheduling subsequent visits.

No changes were noted in HR, systolic pressure, or diastolic pressure in the thoracic group. However, there a decrease in the diastolic blood pressure was noted in the group receiving cervical manipulation, resulting in an increased pulse pressure in the cervical group. With regard to the seven subjects from which HRV data was gathered, the standard deviation of the average normal to normal R-R interval (SDNN) was found to be lower at baseline in the group determined to have cervical dysfunction, and it remained lower, relative to the thoracic group, post-treatment. The LF/HF ratio, which is the measure most indicative of the sympathovagal balance of the autonomic input to the heart, showed an increase in parasympathetic dominance after treatment in the cervical group. This was due to either a larger increase or a smaller decrease of the HF component, which is indicative of parasympathetic tone. The opposite was evident in the group receiving thoracic adjustments. The LF/HF ratio increased post adjustment, demonstrating increased sympathetic dominance, either from a greater increase or a lesser decrease in the LF component (Boone, 2008). The shortcoming of this particular study was the low number of subjects.

Roy, Boucher, and Comtois (2009) compared the effect on HRV of a single sham adjustment to spinal manipulation in subjects with and without acute low back pain, as defined by the North American Spine Society. They assessed HRV in three groups, including a control, a pain-free group, and pain group. All groups had been previous chiropractic patients, but none had received chiropractic treatment in the week prior to the investigation. The pain free group received either a sham Activator adjustment or an Activator adjustment, while the pain group received either a sham lumbar roll or a traditional lumbar roll with a pisiform contact on the ipsilateral L5 mamillary process. Five-minute pre- and post-recordings were taken with the patient in the prone position and used for HRV analysis. These researchers observed the parasympathetic output was affected by spinal manipulation of the lumbar spine, independent of technique. They also noted that the strength of parasympathetic reaction was greater in the pain-free group. This strength of this study was limited because the analysis of HRV changes was of the effect of only one manipulation.

Conclusion

The key findings of this investigation indicate that spinal manipulation has an effect upon the autonomic nervous system, and that the analysis of HRV can be used to evaluate that effect. There is evidence to support a regional effect of spinal manipulation on sympathovagal balance. Although there was only one study which assessed the effect of SMT to the lumbar spine (Roy R, 2009), the quality of this study was very good, with strong internal validity. This study demonstrated an increase in parasympathetic output with manipulation of L5. SMT of the thoracic region has been shown to increase sympathetic contribution to the sympathovagal balance (B. Budgell & Polus, 2006; Welch A, 2008). However, findings are mixed in regard to manipulation of the cervical spine, with evidence suggesting that SMT of this region results in increased sympathetic contribution (B. Budgell & Hirano, 2001b; P. B. Watanabe N, 2007), as well as evidence demonstrating that cervical SMT resulting in increased parasympathetic input (Welch A, 2008). Further research will give greater insight into the phenomenon of regionalization.

This review revealed an incidental finding of HRV research, which is evidence demonstrating a therapeutic effect of SMT on cardiac dysrhythmia (M. D. Driscoll & Hall, 2000; Igarashii & Budgell, 2000; Shell et al., 1996). Further research regarding this effect is warranted, and may contribute to non-pharmacological treatment of certain dysrhythmic conditions.

Another key finding which must be taken into consideration is that the use of HRV in the clinical setting must follow a rigorous protocol in order to obtain valid results. This “tool” cannot be used as a scan. Multiple factors which can affect the results of the HRV analysis must be taken into consideration. These include, but are not limited to, diurnal factors, pre-recording exercise, caffeine intake, medications, auditory stimulus, anxiety, posture, pain, age, respiratory rate, patient comfort level, and movement (D. Driscoll & DiCicco, 2000; Grimm et al., 2005; Malik, 1996; P. B. Watanabe N, 2007; R. J. Watanabe N, Polus B, 2007; Zhang, 2007).

Future research will contribute to better understanding of the usefulness of HRV in assessing ANS changes associated with SMT. Research regarding the effect of posture and respiratory rate has contributed to HRV experimental protocol, and should be considered in future study design. Studies of longer treatment duration and with longer follow-up periods should be performed in order to improve internal validity. The relation between changes of perceived level of pain, evaluated through numerical rating scales, and changes in HRV after SMT, has been attributed to the role of pain in increasing the sympathetic input. (Zhang, 2006; Grimm, 2005; Roy, 2007). SMT has also been shown to affect HRV in patients without pain, and to correlate with improved prognosis in diseased conditions (Malik, 1996). Therefore, future studies should also investigate a possible relation between changes in HRV and quality of life outcome measures (e.g. SF-36). Such studies may be useful in demonstrating benefits of wellness chiropractic care.

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Abstracts & Literature Review

The Effect of a Manual Therapy Knee Protocol on Osteoarthritic Knee Pain: A Randomised Controlled Trial

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Authors' Abstract:

Background

Knee osteoarthritis (OA) as many clinicians realize is a highly prevalent condition with a significant socioeconomic burden to society. Knee OA affects sufferers through pain, loss of function and changes in the patient's related activities of daily living. One method of the management of OA currently involves pharmacologic and/or exercise based therapy approaches to reduce pain. Studies in the past have shown that multiple modal treatments incorporating manual therapy to be an effective method in the treatment of certain joint pain. The purpose of this study was to determine in a randomized control trail if manual therapy technique protocol would alter the patients self reporting of the pain experienced in chronic knee OA conditions. In previous studies multimodal treatment approaches incorporating manual therapy was shown to be effective. The purpose of this study was to determine if a manual therapy technique knee protocol would alter the self-reported pain experienced by a group of chronic knee osteoarthritis patients in a randomized controlled trial setting.

Methods

Forty-three participants were chosen with a chronic, non-progressive history of osteoarthritic knee pain. Participants were randomly chosen with age category between 47-70 years of age. The Participants were matched for present knee pain intensity which was measured on a visual analogue scale. The participants were divided into two treatment groups, one group (Intervention Group) using the (MIMG) Macquarie Injury Management Group- Knee Protocol; the second group (Control Group) protocol was the involvement of non-force manual method in conjugation of interferential therapy with a zero setting.

Results

Results were analyzed using descriptive statistics. Prior to the encounter of treatments protocols there were no significant differences in age or knee pain presentation. Following treatments, the intervention group reported a significant decrease in the presentation of pain severity as compared to the control group.

When the participants were questioned, the intervention group felt that the treatment protocol had helped them by decreasing their symptoms, crepitus, improved their knee mobility and improved their abilities in performing general activities.

Conclusions

After a two week trial treatment period the self-reported evaluation revealed that the manual therapy protocol significantly reduced the pain suffered by the participants with osteoarthritic knee pain and the reporting system also revealed improvements of the patient's knee function.

Clinical Relevance

This study showed the relationship of subjective reporting of patient's signs and symptoms in relationship to two different treatment protocols. One method (Control group) was of a general non-force manual contact to the knee followed by interferential therapy set at zero. The second method (Intervention group) consisted of the Macquarie Injury Management Group (MIMG). The intervention group clearly demonstrated a favorable response as compared to the control group. This randomized control trial review shows the relationship of subjective findings with regards to the patient's responses to two sets of treatment methodology.

JACO Editorial Summary:

- This study was approved by the Macquarie University and the University of Wollongong Human Ethics Committees
- Osteoarthritis is a one of the most common cause for disability and one of the leading causes affecting our socioeconomic status.
- The purpose of the study was to determine by a self reporting methodology if a protocol of a manual therapy technique of the knee would alter the self reporting of pain in a group of patients (randomly selected) who were experiencing chronic knee pain
- Patients received three treatments per week for two consecutive weeks.
- Patients were evaluated immediately after their last treatments.
- Patients completed an eleven questions evaluation
- Patients used a visual analogue scale to evaluate their present pain intensity and their response to treatments.
- It was not determined if patients in the study were currently taking supplementation or participating with concurrent treatment.
- The MIMG manual therapy revealed a significant short term relief of self-reported pain and dysfunction.
- The intervention groups reported no adverse reactions to the treatment afford them.
- Further research is necessary to investigate the long term results by the methods used in this study as it relates to osteoarthritis.

Summary

Typically in traditional medicine the use of pharmaceuticals and/or exercise therapy or the combination of the two is a common approach for joint pain. Physical medicine such as manipulative therapies for the treatment of osteoarthritic conditions as found in the knees is often overlooked as a method of treatment of joint pain and mobility. This assessment of the patient's subjective reporting clearing demonstrated the positive effects of manual therapy benefits for the patient population as a fair and equitable treatment of joint pain and improvement of joint mobility commonly found in osteoarthritis of the knees. The evaluation reviews further

demonstrates that progressive research and literature searches should be implemented to substantiate the validity and legitimacies of manipulative therapy procedures.

Abstracts & Literature Review

Predictive Factors for New Onset or Progression of Knee Osteoarthritis One-Year after Trauma: MRI Follow-Up In General Practice

Ingrid M. Koster, Edwin H. G. Oei, Jan-Hein J. Hensen, Simone S. Boks,
Bart W. Koes, Dammis Vroegindeweij, M. G. Myriam Hunink, Sita M. A. Bierma-Zeinstra

Eur Radiol (2011) 21:1509-1516

JACO Editorial Reviewer: Richard P. Corbett DC, FCCO(C), FCCR(C)

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Author's Abstract:

Background

Osteoarthritis (OA) of the knee is a common cause of functional impairment and pain in the general population. The extent to which traumatic knee abnormalities predict the development of OA within the joint years after trauma has been sparsely documented. The purpose of this study was to prospectively evaluate prognostic factors for new onset or progression of degenerative change on follow-up MRI one year after knee trauma and the association with clinical outcome.

Methods

Within a prospective observational cohort study in general practice, we studied a subgroup of 117 patients with acute knee trauma (mean age 41 years, 43% women). Degenerative change was scored on MRI at baseline and after one year follow-up. Multivariate logistic regression analysis was performed to evaluate prognostic factors for new onset or progressive degenerative change on follow-up MRI. Association between new or progressive degeneration and clinical outcome after one year was assessed.

Results

On follow-up MRI, 15% of patients with pre-existing knee osteoarthritis showed progression and 26% of patients demonstrated new degenerative change. The only statistically significant prognostic variable in the multivariate analysis was bone marrow edema on initial MRI (OR 5.29 (95% CI 1.64-17.1), $p=0.005$). A significant association between new or progressive degenerative change and clinical outcome was found ($p=0.003$).

Conclusion

Bone marrow edema on MRI for acute knee injury is strongly predictive of new onset or progression of degenerative change of the femorotibial joint on follow-up MRI one year after trauma, which is reflected in clinical outcome.

Clinical Relevance

The present study suggests that following knee trauma, a significant prognostic indicator of new onset or progression of OA in the femorotibial joint is bone marrow edema on initial MRI.

JACO Editorial Summary:

- The article was written by authors from: The Department of Radiology, Maastad Ziekenhuis, Rotterdam, and University Medical Center, Rotterdam
- The purpose of the study was to evaluate MRI signs from initial post-trauma study to determine if there is an association with new onset or progression of degenerative change one year after knee trauma.
- The initial and follow-up MRI examinations were evaluated for the presence of degenerative abnormalities of the femorotibial joint. For this purpose, the authors used the items of the Knee Osteoarthritis Scoring System (KOSS).
- To grade the severity of osteoarthritis, the authors used the Kellgren and Lawrence scoring system, which was originally developed for grading osteoarthritic change on conventional radiography (Grade 0 to Grade 4).
- Self-reported questionnaires were completed at baseline and 12 months after trauma. On the questionnaires, the authors recorded a pain score measured on an 11-point numeric rating scale ranging from 0 (no pain) to 10 (unbearable pain), the Lysholm knee function score, recurrence, level of sports activities, referral to a medical specialist, and whether an operation had been performed.
- At 12 months the authors also scored perceived recovery as rated by the patient and measured on a 7-point Likert scale, ranging from 'Complete Recovery', 'Strong Improvement', 'Some Improvement', 'Unchanged', 'Some Deterioration', 'Strong Deterioration', to 'Worse Than Ever'.
- Ninety-seven patients reported complete recovery or strong improvement after 12 months follow-up, whereas three patients experienced some deterioration. Seventeen of the 27 patients with new or progressive osteoarthritic change reported complete recovery or strong improvement in terms of perceived recovery versus 80 of the 90 patients with absent or unchanged OA. There was a statistically significant association between new or progressive osteoarthritic change on follow-up MRI and perceived recovery (Fisher's exact test p value 0.003).

Summary

The results of this study may help clinicians identify the patients that are at higher risk of developing OA at the femorotibial joint post-trauma.

Abstracts & Literature Review

Non-traumatic Knee Pain

American College of Radiology - ACR Appropriateness Criteria

D. Lee Bennett, MD, MA; Richard H. Daffner, MD; Barbara N. Weissman, MD; Judy S. Blebea, MD;
Jon A. Jacobsen, MD; William B. Morrison, MD; Charles S. Resnik, MD; Catherine C. Roberts, MD; David A. Rubin, MD;
Mark E. Schweitzer, MD; Leanne L. Seeger, MD; Mihra S. Taljanovic, MD;
James N. Wise, MD; William K. Payne III, MD, MPH.

JACO Editorial Reviewer: Neil L. Erickson DC, DABCO, CCSP

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Authors' Abstract:

No abstract was provided with this article.

JACO Editorial Summary:

- The article was written by, and frequently refers to, the committee of doctors listed above.
- The authors recommend that for diffuse non-localized knee pain “a *Merchant* or axial view may be useful” in addition to the AP and lateral projections. Field practitioners may know the Merchant view as the “Skyline or Sunrise projection.” The authors do not describe the axial view any further. The AP view includes a 5 degree cephalic tube tilt and is therefore an axial projection.
- The authors recommend that when surgical intervention is recommended for elderly patients with osteoarthritis, a weight-bearing view of the knee while in flexion is indicated. The authors do not describe this seemingly awkward position, nor do they suggest how this type of patient might comply with this procedure.
- The authors reasonably recommend that a CT arthrogram be used when there is some contradiction to an MRI. However, they unreasonably recommend the CT when claustrophobia, large body habitus or any other MRI intolerance is present. These same issues would be problematic with the CT procedure. The authors fail to suggest that placing the claustrophobic or obese patient in the MRI tube feet first as an acceptable alternative.
- The authors appear to be sensitive to the judicious use of ionizing radiation for all age groups of patients by including the “Relative Radiation Level (RRL) Designations” in the article. However, the reporting is questionable as they give the same RRL for a knee x-ray as they do a CT of the knee. The former

requiring at least two views, but the later utilizing upwards of 20 views. The authors also fail to make any recommendations for the use of gonadal shielding.

- The authors recognize the value of certifying the medical necessity for diagnostic services as they discourage advanced imaging when the results will not alter the management of the case.

Abstracts & Literature Review

Anatomy and Physical Examination of the Knee Menisci: A Narrative Review of the Orthopedic Literature.

Dr. Michael D. Chivers, BPhE, D.C., FCCSS(C)

Dr. Scott D. Howitt, B.A., CK, CSCS, D.C., FCCSS(C), FCCRS(C)

J Can Chiropr Assoc 2009; 53(4)

JACO Editorial Reviewer: Donald S. Corenman, D.C., M.D.

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Authors Abstract:

Objective

The objective of this study was to review the physical examination tests available to a practitioner in order to arrive at a clinical diagnosis or suspicion of a meniscal lesion.

Background

The menisci transmit weight-bearing forces and increase stability of the knee. The menisci also facilitate nutrition, provide lubrication and shock absorption for the articular cartilage and promote knee proprioception. The combinations of torsional and axial loading appear to be the cause of most meniscal injuries. Diagnosis of acute knee injuries has long been a topic for discussion throughout the orthopedic literature. Many clinical tests and diagnostic studies have been developed to increase the clinician's ability to accurately diagnose these types of disorders of the knee.

Conclusion

The accuracy of all diagnostic tests is thought to be dependent upon the skill of the examiner, and the severity and location of the injury. The multitude of tests described to assess meniscal lesions suggests that none are consistently reliable. However, recent research has focused on a composite score to accurately predict meniscus lesions. The combination of a comprehensive history, multiple physical tests and diagnostic imaging for confirmation is typical for a clinical meniscal lesion diagnosis while the gold standard remains the arthroscopic procedure itself. (JCCA 2009; 53(4): 319–333)

JACO Editorial Summary:

- This article was written by authors from the Canadian Memorial Chiropractic College, Toronto, Canada.
- The purpose of the study was to review the anatomy of the menisci of the knee, discuss the injury mechanisms and assess the value of current physical examination findings found in the literature.
- The authors provided a detailed review of anatomy of the knee, the physiology and a listing of the biomechanics of injuries that can occur to the menisci. The authors then discuss symptomatology of meniscal injuries and then correlative physical examination findings. The authors then go on to describe the tests as found in the literature and the potential value of each test. This is an excellent review.
- The authors discuss vascular injury, which is the most devastating injury to the knee joint. An unrecognized injury to the popliteal artery can result in loss of the extremity without timely diagnosis and treatment. With discussion of vascular injury, knee dislocation should be revealed as the major cause of this injury with the resultant global disruption to all the restraining ligaments of the knee. The evaluation of distal pulses and comparison from uninjured side to injured side should be completed with any examination of the knee. If differences are noted, quick referral to a vascular surgeon is necessary.
- Many of the traditional tests that are cited are quite valuable for diagnosis. These tests need to be considered in the associated broad range of injuries that occur to the knee including ACL and PCL tears, tendonosis, medial and lateral collateral tears and cartilage injuries including osteochondral defects and chondromalacia patella. The meniscal tests will be affected by ligamentous injury.
- The authors are correct that surgical arthroscopy is the basis for accurate diagnosis of meniscal injuries but MRI should be noted as the gold standard for knee evaluation. MRI can diagnose injuries to the menisci that may not even be apparent to the surgeon on initial visual examination during arthroscopy. Further probing of a visually “normal” meniscus revealed to have intra-substance tears through MRI can reveal these defects.

Summary

This paper is a thorough review of the anatomy and current literature regarding diagnosis of meniscal injuries and the value of available tests that can help with diagnosis.

Abstracts & Literature Review

Acute Trauma to the Knee

The ACR Committee on Appropriateness Criteria on Imaging Examination for
Diagnosis and Treatment of Specific Medical Conditions.

Michael J. Tuite, MD, Richard H. Daffner, MD, Barbra N. Weissman, MD, Laura Bancroft, MD,
D. Lee Bennett, MD, MA, Judy S. Blebea, MD, Michael A. Bruno, MD, Ian Blair Fries, MD,
Curtis W. Hayes, MD, Mark J. Kransdorf, MD, Jonathan S. Luches, MD

JACO Editorial Reviewer: Dr. J.C. Romney, DC

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Authors' Abstract:

Background

The appropriateness of radiographic imaging of acute trauma to the knee in emergency departments. This discussion includes prudence of radiographic imagery on trauma to the knee, and the frequency of use. It looks at parameters in the clinical decision of imaging based on age, palpatory findings, and function. It invites the inclusion of the "OTTAWA knee rule" that give criteria when making a choice to determine the most practical image to evaluate and diagnose the injured knee. The study also analyzes the relative radiation levels that involve some of the imaging procedures.

Methods

In 2001, a study of 1.3 million annual emergency departments of acute knee trauma reported that one billion dollars was spent on radiographs of the knee. The study found radiographs of an injured knee offer a low yield for diagnostic findings. Implementation of a clinical decision rule (Ottawa knee rule) was emphasized and discussed for clinical significance. By following the criteria found in the Ottawa knee rule the number of radiographs utilized could be reduced. Radiation levels were presented to the study in the various images and assessing concerns of the overuse of radiation.

Results

Based on clinical decision rules for evaluating knee trauma and the use of radiographs, the study found that the initial evaluation of knee injury can reduce the number of radiographs without missing that unusual fracture. Clinical criteria for non-indicated radiographs include: patients who walk without a limp and patients who had a twisting injury with no effusion, many soft tissue injuries, pregnancy, or skin disorders. Clinical criteria for

ordering radiographs include: joint effusion within 24 hours after a direct blow or fall, palpate tenderness over fibular head or patella, inability to walk or bear weight, inability to flex knee to 90 degrees or impaired mental status. A MRI best evaluates injuries of internal joint tissues of the knee joint.

Conclusions

The pattern of the use of radiographs for the acute knee has been shown to be over utilized. The studies indicated that clinical decision making in the evaluation of the acute knee might be better without radiographic imaging.

Clinical Relevance

Radiographs can be over utilized in the evaluation of knee injury where clinical findings and treatment trials may be all that is required. MRI is utilized when clinical findings and patient function indicates.

JACO Editorial Summary:

- This article is a compilation of several hospitals, principally The University of Wisconsin and the Hospital of Madison Wisconsin. The purpose of the study is to show the evidence of over-utilization of x-rays on knee injuries.
- The OTTAWA knee rule: the applied clinical decision rule using parameters based on age, palpable tenderness and function. The following parameters should have radiographic examination:
 - 55 years of age or older
 - Have palpable tenderness over the head of the fibula
 - Have isolated patellar tenderness
 - Cannot flex knee to 90 degrees
 - Cannot weight bear immediately following the injury
 - Cannot walk in the ED
- 93.5% of patients who present with knee injuries have a soft tissue condition which is better examined diagnostically by MRI.
- MRI is a valuable tool for many common knee conditions: osteochondral defects, transient dislocation of the patella, meniscus injury, ACL tears and acute locked knee.
- Radiation levels are to be considered when selecting the appropriate imaging procedure.

Summary

The results of this review show that hospitals, medical clinics and even chiropractic clinics might consider reducing the number of radiographs when evaluating knee trauma. This can be done by following specific criteria or rules that determine prudent need for x-rays after knee trauma.

Abstracts & Literature Review

A Mechanical Theory for the Effectiveness of Bracing for Medial Compartment Osteoarthritis of the Knee

Dan K. Ramsey, PhD, Kristen Briem, PT, MHSc, Michaels J. Axe, MD
and Lynn Synder-Mackler, ScD, PT, SCS

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JACO Editorial Reviewer: Raymond S Nanko, MD, DC, DAAPM

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Author's Abstract:

Background

Evidence that knee braces used for the treatment of osteoarthritis mediate pain relief and improve function by unloading the joint (increasing the joint separation) remains inconclusive. Alternatively, valgus-producing braces may mediate pain relief by mechanically stabilizing the joint and reducing muscle co-contractions and joint compression. In this study, therefore, we sought to examine the degree to which so-called unloader braces control knee instability and influence muscle co-contractions during gait.

Methods

Sixteen subjects with radiographic evidence of knee malalignment and medial compartment osteoarthritis were recruited and fitted with a custom Generation II Unloader brace. Gait analysis was performed without use of the brace and with the brace in neutral alignment and in 4° of valgus alignment. A two-week washout period separated the brace conditions. Muscle co-contraction indices were derived for agonist and antagonist muscle pairings. Pain, instability, and functional status were obtained with use of self-reported questionnaires, and the results were compared.

Results

The scores for pain, function, and stability were worst when the knee was unsupported (the baseline and washout conditions). At baseline, nine of the sixteen patients reported knee instability and five of the nine complained that it affected their activities of daily living. Poor knee stability was found to be correlated with low ratings for the activities of daily living, quality of life, and global knee function and with increased pain and symptoms. Knee function and stability scored best with the brace in the neutral setting compared with the brace in the valgus setting. The co-contraction of the vastus lateralis-lateral hamstrings was significantly reduced from baseline in both the neutral ($p = 0.014$) and valgus conditions ($p = 0.023$), and the co-contraction of the vastus medialis-medial hamstrings was significantly reduced with the valgus setting ($p = 0.068$), as a result of bracing.

Patients with greater varus alignment had greater decreases in vastus lateralis-lateral hamstring muscle co-contraction.

Conclusions

When knees with medial compartment osteoarthritis are braced, neutral alignment performs as well as or better than valgus alignment in reducing pain, disability, muscle co-contraction, and knee adduction excursions. Pain relief may result from diminished muscle co-contractions rather than from so-called medial compartment unloading.

JACO Editorial Summary

- The article was written by authors from the Department of Physical Therapy, Graduate Program in Biomechanics and Movement Science, and Center of Biomedical Engineering Research, University of Delaware, Newark, Delaware
- Osteoarthritis of the knee is the most common cause of functional disability among Americans, and the medial compartment is most often affected.
- Joint laxity and mediolateral instability necessitate increased muscle activity and co-activation of antagonistic muscles to stabilize the knee. Greater laxity raises the likelihood of episodes of knee instability.
- The purpose of this study was to evaluate the effectiveness of bracing for Medial Compartment Osteoarthritis of the knee. Additionally, the aim of this study was to examine the degree to which valgus-producing unloader knee braces control instability and influence muscle co-contraction during gait.
- Sixteen subjects who had genu varum and medial compartment osteoarthritis of the knee were referred from a local orthopedic practice. They had a mean age (and standard deviation) of 54.9 ± 8.8 years and a mean body mass index of 31.1 ± 4.2 kg/m².
- The patients underwent three-dimensional lower-extremity gait analysis with simultaneous surface electromyographic measurement on three separate occasions (without braces, with the braces in neutral alignment, and with the braces in 4° of valgus correction).
- The individuals wore the brace in neutral alignment throughout the day for two weeks before returning for the second gait analysis. Following Test 2, no brace was worn for two weeks (the washout period). After the washout period, braces were reset to the original setting at 4° of valgus, relative to the varus alignment measured at the time of fitting. Patients then wore the brace for an additional two weeks before the final gait analysis
- At the time of the baseline assessment when the knee was unsupported, the patients demonstrated significantly greater co-contraction of the vastus medialis-medial hamstrings ($p = 0.068$) and vastus lateralis-lateral hamstrings ($p = 0.014$) during weight acceptance, which may be an attempt to stiffen the knee through use of increased joint compression. Both bracing conditions led to a significant overall lowering of antagonist muscle co-contractions on both the medial and lateral sides
- Pain and functional status were assessed during each of the brace conditions and the washout period with use of the Knee Injury and Osteoarthritis Outcome Score (KOOS)
- Knee adduction excursions were significantly reduced as a result of bracing ($p = 0.038$ for the neutral setting and $p = 0.000$ for the valgus setting - Fig. 4), with excursions being lowest at 4° of valgus correction.
- Self-reported knee pain and functional disability in patients with medial compartment osteoarthritis were significantly reduced when the knee was braced in both the neutral condition and with a 4° of valgus correction. Muscle co-contraction and knee adduction excursions were also lower when the knees were braced.

- Functional knee stability improved with the neutral brace setting, with only one patient reporting that instability affected daily activity. Functional knee instability worsened during the washout period, with eight patients who reported that instability affected their activities of daily living.

Summary

This was a small study. The study was limited to 16 participants and there were no randomized controls. There is inherent weakness in the study when patients serve as their own controls.

Musculature co-contraction and ligamentous laxity of the unsupported or braced osteoarthritic knee results in progression of the disease process. Neutrally aligned bracing of the osteoarthritic knee may result in reduced muscle co-contractions, mediated by the brace mechanically stabilizing the knee. The authors report that when a neutrally aligned brace is worn for the treatment of medial compartment osteoarthritis of the knee, positive effects results in reduced pain and improved functional stability. Mechanical Bracing also improved functional scores with the Knee Injury and Osteoarthritis Outcome Score (KOOS) and improved activities of daily living.

Additional large scale randomized controlled studies may be helpful.

Announcements

Academy of Chiropractic Orthopedists - 2012 Diplomat Examination

The Academy of Chiropractic Orthopedists announced the date of the 2012 Diplomat examination. It will be held on September 29, 2012 at Northwestern Health Sciences University.

Please contact Dr. Jerry Wildenauer for details at: aco@dcorthoacademy.com