

Chapter 2

Chiropractic Research

Introduction

Healthcare services are provided by a practitioner in response to each patient's expressed health concerns. Critical in this process are: the knowledge and experience of the practitioner, the preferences and values of the patient, and the empirical evidence concerning the appropriate care for the patient's health condition (Sackett, Strauss, Richardson, Rosenberg, & Haynes, 2000). This chapter focuses on the current state of scientific evidence regarding chiropractic care. The use of empirical evidence to guide practice is frequently called "evidence-based practice," or "evidence-informed care." Evidence-based practice was defined by one of the leading pioneers of the evidence-based movement, David Sackett, as "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients" (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996).

Because the types of chiropractic research investigations have expanded, this chapter addresses not only clinical and basic science research, but also cost analysis, patient safety, and patient satisfaction. To effectively organize this research evidence, this chapter is primarily focused on findings from systematic reviews and meta-analyses, which combine results from many investigations to provide summaries of evidence in a specific area of healthcare.

Through the application of evidence-based practice principles, chiropractors rely, in part, upon research when making decisions about the care of their individual patients. Likewise, policymakers require evidence on which they can base decisions regarding policies to facilitate improved health outcomes. Additionally, patients depend on their doctors to have knowledge of the best available evidence within their discipline. Therefore, it is important to understand the depth and breadth of the chiropractic evidence base, while also noting the limitations and challenges of the state of evidence. Thus, this chapter is designed to provide evidence which may enhance decision-making by doctors of chiropractic and other health professionals, patients, educators, policymakers, and payors.

Evidence that informs chiropractic practice ranges from systematic reviews/meta-analyses and randomized clinical trials to observational and case-control studies, as well as mechanical force investigations and animal studies. This chapter provides an overview of the most recent and highest quality research evidence, but is not an exhaustive listing of all studies. Additional

information and discussions of other research efforts are available in Chapter 2 of the *Practice Analysis of Chiropractic 2010*, as well as the *Job Analysis of Chiropractic 2005, 2000, and 1993*. (Christensen et al. 1993, 2000, 2005, 2010).

Clinical Effectiveness

Back Pain

The number and methodological quality of studies investigating spinal manipulation for the treatment of low back pain have steadily increased over the past decade. Numerous systematic reviews have summarized the evidence pertaining to the effectiveness of spinal manipulation for low back pain. The majority of these reviews have demonstrated that spinal manipulation has a consistent treatment effect equivalent to, and sometimes better than, other commonly used therapies for chronic and acute low back pain. Several recent systematic reviews evaluating the effectiveness of spinal manipulation techniques for low back pain are summarized below. It is important to note that not all of these studies included treatment by a doctor of chiropractic. However, they all focus on spinal manipulation, the cornerstone of chiropractic care.

Efficacy of Manipulation versus Sham or No Treatment

The Agency for Healthcare Research and Quality (AHRQ) has concluded that spinal manipulation confers significant clinical benefit in reducing pain and improving function for those with chronic nonspecific low back pain. In fact, spinal manipulative therapy was significantly more effective at reducing pain in the short-term when compared to placebo or no treatment (Furlan et al., 2010).

Efficacy of Manipulation versus Usual Care or Other Interventions

A recent Cochrane review examined the effects of spinal manipulative therapy in adults with acute low back pain (Rubinstein, van Middelkoop, Assendelft, de Boer, & van Tulder, 2011). This review identified 20 randomized controlled trials, comprising 2,674 participants, with sample sizes ranging from 36 to 323. The results provide substantial evidence that spinal manipulative therapy offers similar clinical benefits to that of other commonly recommended therapies such as exercise, physiotherapy, and non-steroidal anti-inflammatory pain medications. In another systematic review concerning spinal manipulation for the treatment of acute low back pain, the authors concluded that 5 to 10 sessions of spinal manipulative therapy administered over 2 to 4 weeks achieve a clinically significant reduction in pain and disability similar to that of therapies such as education, exercise, medication, and physical modalities in the short, intermediate, and long-term time frames (Dagenais, Gay, Tricco, Freeman, & Mayer, 2010).

Another review identified 38 randomized controlled trials that focused on patient-centered outcomes of high-velocity, low-amplitude (HVLA) spinal manipulation for the treatment of low back pain (Goertz, Pohlman, Vining, Brantingham, & Long, 2012). The authors concluded that HVLA spinal manipulation conveys a small, but consistent therapeutic benefit (reduced pain and improved function) similar to that of other conservative therapies for low back pain. In this review, doctors of chiropractic delivered the spinal manipulation in only about a third of the studies. The other two thirds evaluated spinal manipulation performed by either physical therapists or medical doctors and osteopaths. The authors were not able to identify differences in treatment outcomes among provider types.

A separate Cochrane review evaluated the effectiveness of combined chiropractic interventions (manipulation plus ice, massage, and/or exercise, etc.) relative to other commonly used therapies (educational booklet, back school, McKenzie therapy, etc.) for the treatment of nonspecific low back pain in adults age 18 or older (Walker, French, Grant, & Green, 2010). The review included 12 clinical trials, comprising 2,887 participants, evaluating combined chiropractic therapies in patients with acute, subacute, or chronic low back pain. Of these, four trials were on acute/subacute low back pain, three were on chronic low back pain, and five were on mixed duration of low back pain. Only three of the twelve studies were identified as having a low risk of bias. However, study findings were consistent with the results found in other reviews. Specifically, the authors concluded that short-term and medium-term improvement in pain was greater in the combined chiropractic intervention group relative to other interventions; furthermore, disability ratings in the combined chiropractic group showed significantly more improvement in the short-term when compared with other interventions for low back pain.

The AHRQ report referenced earlier in this chapter concluded that spinal manipulative therapy effectively and significantly reduced pain and improved function for patients with chronic nonspecific low back pain (Furlan et al., 2010). The analysis demonstrated that spinal manipulation was as effective as medication in the treatment of low back pain. In addition, spinal manipulation was superior to acupuncture for improving pain and function in chronic nonspecific low back pain. The authors noted that the most significant clinical benefits of manipulation occurred either immediately following treatment or within 2 to 6 weeks.

Efficacy of Adding Chiropractic Treatment to Standard Medical Care

A randomized controlled trial pilot study that enrolled 91 active-duty military personnel between the ages of 18 and 35 with acute low back pain investigated the comparative effects of standard medical care versus standard medical care with the addition of chiropractic manipulative therapy (Goertz et al., 2013). This study differed from other randomized controlled trial designs in that it examined the effectiveness of spinal manipulation for acute low back pain in a real-world setting rather than within the confines of a controlled clinical research environment. When compared with standard medical care alone, patients receiving the addition of spinal

manipulation experienced clinically and statistically significant reductions in back pain intensity and improvements in physical function; additionally, 73% of participants in the combined treatment group versus 17% in the group receiving only standard medical care perceived their pain as “completely gone,” “much better,” or “moderately better” following four weeks of care. A large scale, multisite, Department of Defense funded follow-up trial of 750 active-duty military personnel is currently underway to further investigate these preliminary findings.

Efficacy of Numbers of Sessions

A recent study investigated the number of spinal manipulation sessions administered by a doctor of chiropractic that were required to achieve maximal clinical benefit (Haas, Vavrek, Peterson, Polissar, & Neradilek, 2014). In the first randomized controlled trial of its kind, 400 chronic low back pain participants were randomized to receive one of four dose levels of spinal manipulative care. One hundred participants were assigned to each of the four dose groups and visits were scheduled three times per week over a six-week period regardless of group assignment. During these visits participants received either spinal manipulation (0, 6, 12, or 18 manipulation sessions) or light massage, which served as an active control. Based on this study, it appears that 12 sessions of spinal manipulation may yield the most favorable response for a reduction in pain intensity and functional disability in patients with chronic low back pain. Furthermore, there was no deterioration of clinical benefit at the 52-week follow-up, which indicated a sustained response to treatment.

Recommendations from Guidelines

Multiple guidelines for the treatment of patients with low back pain recommend spinal manipulation. Recent examples include the guidelines issued by the Department of Defense (Office of the Army Surgeon General, Pain Management Task Force, 2010) and the American College of Physicians/American Pain Society (Chou et al., 2007). The latter, based on an extensive literature search of randomized controlled studies published between 1966 and 2006, listed spinal manipulation as one of seven recommendations, and was reported in the *Annals of Internal Medicine* (Chou et al., 2007).

Summary of Evidence

A significant amount of research is now available regarding chiropractic treatment of patients with low back pain and disability. These data show a consistent treatment effect for spinal manipulation that is essentially equivalent to other commonly used therapies for acute and chronic low back pain. Several guidelines for treatment of low back pain now recommend the inclusion of spinal manipulation. In contrast to the substantial amount of research addressing the efficacy of spinal manipulation for low back pain, little evidence is currently available concerning the number of treatment sessions required to achieve optimal clinical outcomes. Specifically, a single study indicated that twelve sessions of spinal manipulation may yield the most favorable response for a reduction in pain intensity and functional disability in patients with chronic low back pain. Thus, more research is needed in this area.

Neck Pain

Research regarding spinal manipulation for the treatment of neck pain is ongoing, although there are some data currently available. A 2008 systematic review and report from the Bone and Joint Decade Task Force recommended spinal manipulation and other conservative therapies for the treatment of patients with this condition. The authors concluded that “therapies involving manual therapy and exercise are more effective than alternative strategies for patients with neck pain” (Hurwitz et al., 2008).

Efficacy of Manipulation versus Sham or No Treatment

A more recent Cochrane review assessed the effects of manipulation/mobilization alone on multiple outcomes in adults with neck pain (Gross et al., 2010). The review included 27 trials, comprising 1,522 participants and compared manipulation/mobilization with no treatment, sham treatment, other therapies, and manipulation versus mobilization. The authors concluded that cervical spinal manipulation results in pain relief superior to that of a sham control in the immediate and short-term for acute or chronic neck pain conditions. However, the studies were of mixed quality, and there was insufficient evidence to suggest a long-term effect.

Efficacy of Manipulation versus Usual Care or Other Interventions

Another systematic review of the literature investigated the effectiveness of manual therapy (spinal manipulation and/or mobilization) combined with exercise on multiple outcomes in adults with neck pain (Miller et al., 2010). This review included 17 randomized controlled trials described in 31 research journals. The authors reported high quality evidence that manipulation/mobilization combined with exercise demonstrated greater improvements in short-term pain reduction relative to exercise alone in subacute/chronic neck pain patients. Likewise, long-term improvements in pain, physical function, global perceived effect, patient satisfaction, and quality of life were observed. For chronic neck pain, moderate evidence suggested that manipulation/mobilization combined with exercise produced greater reductions in pain and improved quality of life than manipulation/mobilization alone. For acute whiplash associated disorders, moderate quality evidence favored manipulation/mobilization combined with exercise relative to traditional care options (collar, medication, advice) for short-term reductions in pain. The previously discussed 2010 Cochrane review concluded that manipulation alone for subacute and chronic neck pain is as effective in the short-term as certain medications, acupuncture, soft-tissue treatments, and some combined therapies. Additional high quality evidence is required to support these findings.

Efficacy of Combined Manipulation Therapies versus Manipulation Alone

A recently published randomized controlled trial evaluated the effectiveness of spinal manipulative therapy relative to combined spinal manipulative therapy with home exercise and home exercise alone in participants 65 or older with neck pain (Maiers et al., 2014). Two

hundred forty-one participants were divided into three groups: spinal manipulative therapy with home exercise (n=80), supervised exercise plus home exercise (n=82), and home exercise alone (n=79). Participants in each group received 12 weeks of care and follow-up outcomes were assessed at weeks 4, 12, 26, and 52. The primary outcome was self-reported pain in the week prior to the assessment date. The cervical spinal manipulation therapy was described as “diversified thrust technique and mobilization.” The number and frequency of spinal manipulative therapy treatments was determined by each chiropractic physician, but not to exceed 20 visits per patient within the 12-week study period. Overall, the combined spinal manipulative therapy with home exercise group exhibited a statistically significant reduction in participant self-reported pain levels at 12 weeks.

Recommendations from Guidelines

A recent evidence-based guideline for chiropractic management of adults with neck pain recommended several commonly used chiropractic treatment modalities including spinal manipulation (Bryans et al., 2014). Recommendations were based on evidence from randomized controlled trials reported in the literature. Overall, 11 treatment recommendations were derived based on the evidence generated from 41 randomized controlled trials. These 2014 guidelines support a moderate recommendation for spinal manipulation for the treatment of acute neck pain when used in conjunction with other commonly used chiropractic adjunctive therapies such as advice, exercise, and mobilization. A strong recommendation for the use of spinal manipulative therapy combined with commonly used chiropractic modalities (advice, upper thoracic manipulation, diathermy, exercise, massage, and stretching) was made for the management of chronic neck pain.

Summary of Evidence

Further research in the area of chiropractic care for patients with neck pain is required to address gaps in our understanding. To date, a consistent treatment effect for spinal manipulation has been found that appears to be equivalent to that of other commonly used therapies for acute and chronic neck pain.

Headache

Spinal manipulation for the treatment of headaches has been studied in clinical trials and analyzed in several systematic reviews of the literature. Results from previous systematic reviews have been mixed, but generally favorable for spinal manipulation alone as a treatment for cervicogenic-type headaches (originating from disorders in the neck region), with reduction in the intensity, frequency, and duration of symptoms (Jull et al., 2002; Nilsson, Christensen, & Hartvigsen, 1997). Studies regarding tension-type headaches have also been generally favorable, but less conclusive (Bove & Nilsson, 1998; Castien, van der Windt, Grooten, & Dekker, 2011). A 2011 systematic review examined the efficacy of manual therapies, including chiropractic spinal manipulative therapy, on migraine headaches (Chaibi, Tuchin, & Russell, 2011). The authors identified four randomized controlled trials of chiropractic spinal

manipulative therapy for migraine, and concluded that spinal manipulative therapy may be as effective as propranolol and topiramate medication for the treatment and also for the prevention of migraine headaches.

Efficacy of Numbers of Sessions

A pilot randomized controlled trial compared 8 versus 16 treatment sessions of high-velocity, low-amplitude spinal manipulation to the cervical and upper thoracic regions for treatment of chronic cervicogenic headaches (Haas, Spegman, Peterson, Aickin, & Vavrek, 2010). This study was also designed to explore differences in treatment effect relative to a light massage control. The trial included 80 participants, 20 in each of four study groups. The primary outcome was self-reported pain intensity via the Modified Von Korff scale. There were no clinically important changes in treatment effect relative to dosage. However, statistically significant and clinically important differences were observed between groups with respect to intervention type. Participants receiving the spinal manipulation intervention consistently outperformed those assigned to the light massage control group with a reduction in headache pain intensity and disability. During eight weeks of care, headache frequency decreased by more than 50% for the average participant. This effect was sustained throughout the 24-week follow-up assessment period.

Recommendations from Guidelines

The UK evidence report on the effectiveness of manual therapies concludes that spinal manipulation is effective for both migraine and cervicogenic headaches, but evidence is inconclusive for the effectiveness of spinal manipulation for tension-type or myogenic headaches (originating from hypertonic facial or neck muscles) (Bronfort, Haas, Evans, Leininger, & Triano, 2010).

Evidence-based treatment guidelines were developed for chiropractic treatment of adults with headache based on a review of 21 articles, including 16 clinical trials and 5 systematic reviews. Recommendations were as follows: “Spinal manipulation is recommended for the management of patients with episodic or chronic migraine with or without aura (evidence level, moderate),” “Spinal manipulation is recommended for the management of patients with cervicogenic headache (evidence level, moderate),” and “Spinal manipulation cannot be recommended for the management of patients with episodic tension-type headache (evidence level, moderate)” (Bryans et al., 2011).

Summary of Evidence

There is now good evidence supporting the effectiveness of spinal manipulative therapy for treatment of cervicogenic and migraine headaches and some evidence for the prevention of migraines. In contrast, treatment of tension-type headaches with manipulation has not shown a consistent beneficial effect. Additional research is needed to investigate chiropractic treatment for headaches.

Extremity Conditions

Doctors of chiropractic have employed the use of spinal manipulative therapy and adjunctive procedures for the treatment of extremity conditions for decades. The *Practice Analysis of Chiropractic 2010* reported that approximately 16% of new patients sought chiropractic care for an upper and/or lower extremity chief complaint within the previous year (Christensen et al., 2010). The use of manipulative therapy for conditions of the upper and lower extremities is the subject of a growing body of research. Recent contributions to the literature on the subject are discussed within this section.

Upper Extremity

Recently, a review of the scientific literature regarding the use of manual and manipulative therapy for upper extremity conditions has been performed (Brantingham et al., 2013). The authors concluded that there is a fair level of evidence for the use of manipulative therapies alone or in combination with multimodal treatments for upper extremity conditions such as lateral epicondylopathy and carpal tunnel syndrome for short-term (≤ 3 -6 months) outcomes. Regarding the short-term effectiveness of manipulative therapy for wrist, hand or finger conditions, the evidence is insufficient to draw conclusions.

A similar review was conducted focusing on the effectiveness of chiropractic care for shoulder pain and disorders (Brantingham et al., 2011). Following a review of 35 published studies, the authors concluded that a fair level of evidence exists to support the use of manual and manipulative therapies alone or in combination with multimodal therapies for the treatment of rotator cuff disorders, shoulder disorders, adhesive capsulitis, and soft tissue disorders. In contrast, only a limited level of evidence exists for use of manual and manipulative therapies for shoulder pain.

Lower Extremity

Forty-eight clinical trials were included in a systematic review of manipulative therapy for the treatment of lower extremity conditions (Brantingham et al., 2012). Results showed limited evidence in support of manipulative treatment for long-term treatment of hip osteoarthritis. However, manipulative therapy for common lower extremity conditions such as knee osteoarthritis, patellofemoral pain syndrome, and ankle inversion sprains is supported by a fair level of evidence for short-term effectiveness and limited evidence for long-term effectiveness. The authors noted the need for additional high quality clinical trials in this area.

Non-musculoskeletal Conditions

While the majority of chiropractic research efforts have focused on spinal conditions, several small studies of non-musculoskeletal conditions have been conducted, without conclusive results. Conditions studied include: cardiovascular function, attention deficit/hyperactivity disorder, asthma, cervicogenic vertigo, dysmenorrhea and premenstrual syndrome, hypertension, infantile colic, otitis media, respiratory disease, temporomandibular disorder, etc.

The most definitive systematic review on the subject to date, a recent update to the 2010 UK Evidence Report found that substantial gaps in the research evidence resulted in an inability to draw definitive conclusions regarding efficacy or effectiveness of manual therapy treatments for these conditions (Clar et al., 2014).

Although many patients and their chiropractors have reported health benefits extending beyond the musculoskeletal system, the limited research and sometimes conflicting results require additional research in this area. One example is hypertension. A randomized clinical trial compared the effects of chiropractic spinal manipulation and diet intervention with diet intervention alone in 140 individuals with high normal or stage 1 hypertension. Results of this study indicated that there was no *additive* benefit of spinal manipulation in lowering either diastolic or systolic blood pressure, since both groups had similar drops in blood pressure (Goertz et al., 2002). In contrast, more recent studies have identified a hypertension treatment effect attributed to spinal manipulation. For example, McMasters et al. (2013) recruited a sample of 24 African Americans with a diagnosis of pre-hypertension and stage 1 hypertension. Patients received a course of chiropractic care consisting of an average of 22.5 treatments. Results of this study showed a reduction in blood pressure in the stage 1 hypertension group, but not the pre-hypertensive group. Another study randomized a group of 50 stage 1 hypertensive patients into active upper cervical treatment or a sham manipulation (Bakris et al., 2007). Results of this study showed a statistically significant drop in blood pressure in the upper cervical treatment group compared to the sham procedure group. However, these smaller stage 1 hypertensive studies may have limited generalizability. Further research is required to evaluate the potential role of chiropractic treatment as part of the management of patients with hypertension.

Another example where the evidence is insufficient to make definitive conclusions regarding the effectiveness of manipulation is for infantile colic. A recent Cochrane review and meta-analysis found a significant reduction in crying time with manipulation treatment; however, the studies reviewed were described as small and prone to bias (Dobson et al., 2012).

Cost Analysis Research

Cost Assessment

A recent study of 12,036 records in the Medical Expenditure Panel Survey (MEPS) investigated the costs of treating patients with low back and neck pain (Martin et al., 2012). The study estimated the expenditures for care among complementary and alternative medicine (chiropractic, homeopathy, herbalism, acupuncture, and massage) users relative to non-users. This study included a chiropractic-specific analysis of expenditures for chiropractic users versus non-users, as approximately 75% of all complementary and alternative medicine services were rendered by doctors of chiropractic. Survey data were analyzed for the years 2002-2008. The analysis demonstrated that seeing a CAM/chiropractic provider did not add to overall medical

spending. In fact, adjusted annual healthcare costs among chiropractic users were \$424 lower for spine-related costs when compared to non-CAM users. Additionally, those who used complementary and alternative providers, including doctors of chiropractic, had significantly lower hospitalization expenditures.

Liliedahl, Finch, Axene, & Goertz (2010) investigated the differences in paid costs of episodes of care associated with management of low back pain across two provider types, medical doctors and doctors of chiropractic. This study was a retrospective analysis of Blue Cross Blue Shield of Tennessee's general health plan claims data from October 1, 2004 to September 30, 2006. Health plan members were provided equal access to both provider types with unlimited services (exception: 20 visits per year cap on physical therapy) and equal co-pays and deductibles between providers. Low back pain claims were identified on the basis of six commonly-used diagnostic codes from the *International Classification of Diseases, Ninth Revision*. Overall episode costs of care were lower when low back pain treatment was initiated with a doctor of chiropractic as compared to care initiated with a medical doctor. Paid claims were 40% lower when care was initiated with a doctor of chiropractic versus a medical doctor while risk-adjusted costs were 20% lower.

A systematic review that examined the cost-effectiveness of guideline-endorsed treatments for low back pain found that spinal manipulative therapy was a cost-effective treatment modality for both sub-acute and chronic low back pain (Lin, Haas, Maher, Machado, & van Tulder, 2011). In contrast, the evidence regarding the use of spinal manipulative therapy for acute low back pain was insufficient to infer cost-effectiveness.

Another systematic review investigated the relative cost-effectiveness of spinal manipulative therapy for the treatment of neck pain and back pain compared to general practitioner care, exercise, and physiotherapy (Michaleff, Lin, Maher, & van Tulder, 2012). The authors concluded that spinal manipulation, either alone or in combination with general practitioner care or advice/exercise, was cost-effective relative to general practitioner care, exercise, or any combination of general practitioner care, exercise, and physiotherapy. Consistently noted, however, was the need for further research in this area.

Summary of Evidence

There is now good evidence that chiropractic care costs no more, and perhaps a little less, than other conservative treatments for back and neck pain. Because patients of chiropractors are less likely to undergo surgery and hospitalization, when these costs are included in global calculations, the overall cost of chiropractic care can be significantly less than medical care. However, direct comparisons are difficult to make using existing databases as, typically, there are important demographic and health status differences in patients that go to a doctor of chiropractic versus those who do not. As stated above, this is clearly an area where more research is needed.

Adverse Events & Safety

Several reports in the literature have suggested that cervical spine manipulation increased the risk of vertebrasilar artery injury, leading to cerebrovascular accidents (i.e., stroke) (Gouveia et al., 2001). Furthermore, some legal proceedings suggest the possibility of potential serious neurological consequences arising from spinal manipulation, such as cauda equina syndrome (Boucher & Robidoux, 2014). However, no evidence has demonstrated a causal effect; moreover, current findings reveal that serious adverse events associated with spinal manipulation are extremely rare. Short-term adverse events such as temporary soreness and increased pain are fairly common following spinal manipulation (Hurwitz, Morgenstern, Vassilaki, & Chiang, 2005). Research within the past 5 years has expanded and added to the growing level of evidence surrounding the safety of spinal manipulation.

Mild and Moderate Adverse Events

Mild adverse events associated with spinal manipulation appear to be common, but are generally self-limiting (Walker et al., 2013). Reported symptoms are increased pain, muscle stiffness, headache, radiating symptoms, and fatigue. Other, less commonly reported symptoms include impaired vision, tinnitus, dizziness, and nausea. A study by Eriksen, Rochester, and Hurwitz (2011) prospectively examined the incidence of adverse events associated with manipulation of the upper cervical spine. In this practice-based study, 1,090 participants received 2,653 upper cervical manipulations over a period of 17 days. Thirty-one percent of participants reported “symptomatic reactions” (defined as a new symptom not present at baseline or worsening of a presenting complaint by >30% occurring ≤ 24 hours) following upper cervical manipulation while just over 5% of participants experienced an “intense symptomatic reaction” (also scoring ≥ 8 on the 11-point NRS). Irrespective of these reported reactions, patients’ clinical outcomes improved significantly for all measures.

Rare but Serious Adverse Events

In a large Canadian population-based, case-control and case-crossover study, Cassidy et al., (2008) concluded that there is no evidence that patients receiving chiropractic care are at higher risk of suffering vertebrasilar artery (VBA) stroke than patients visiting a primary care provider. The 818 hospitalized patients identified in this study who had suffered a VBA stroke were just as likely to have recently visited a medical doctor as a doctor of chiropractic. Because the symptoms of vertebrasilar arterial dissection (VAD) include headaches and/or neck pain, the results of this study are consistent with the hypothesis that these stroke patients were experiencing a dissection prior to initiation of health care.

Research using cadaveric specimens has demonstrated that vertebral and carotid artery strains during spinal manipulative procedures are less than those encountered during normal movement (Herzog, Leonard, Symons, Tang, & Wuest, 2012; and Herzog, Tang, & Leonard,

2012). These findings suggest that cervical spine manipulation is not likely to cause micro injury due to excess tension placed on the vertebral or carotid arteries during the procedure.

Estimates based on case studies and case series suggest that serious adverse events associated with spinal manipulation, including: stroke, cauda equina syndrome and disc herniation, occur approximately 5-10 times per 10 million manipulations (Bronfort et al., 2010).

Summary of Evidence

Consistent with initiating an exercise regimen or undergoing any physical treatment of an injured and/or painful body part, spinal manipulation sometimes results in transitory soreness or a short-term increase in pain. Serious adverse events associated with spinal manipulation are quite rare; with the likelihood of developing a stroke following chiropractic care the same as that following medical care.

Patient Satisfaction

As reported in the *Practice Analysis of Chiropractic 2010* (Christensen et al., 2010), satisfaction among patients of chiropractic physicians has been historically very high. High levels of patient satisfaction are likely due in part to manually delivered therapies and personalized, team-based treatment methods (Butler & Johnson, 2008; Gaumer, 2006). Patient satisfaction is included as a secondary outcome of some clinical trials. Such is the case in a 2011 prospective, multicenter, cohort study of upper cervical chiropractic care for neck pain, headache, mid-back, and low back pain. Results of the study found a mean score of 9.1 out of 10, indicating a very high level of patient satisfaction (Eriksen et al., 2011). Recently, a secondary analysis was performed of a study involving acute/sub-acute neck pain patients being randomized to groups receiving spinal manipulation delivered by doctors of chiropractic, home exercise and advice delivered by exercise therapists, or medication prescribed by medical doctors. Researchers found higher levels of patient satisfaction with general aspects of care in both the spinal manipulative therapy group and the home exercise group compared to participants receiving medical care (Leininger, Evans, & Bronfort, 2014).

Because the satisfaction of patients is an important concern of all healthcare practitioners, chiropractic researchers have worked to refine the instruments used to measure patient satisfaction with chiropractic care. Rowell and Polipnick (2008) examined the use of mixed-methods designs for measuring patient satisfaction associated with chiropractic care in low back pain patients. Their study offers promising results, but acknowledges the limitations inherent in the small sample. Beattie, Nelson, and Murphy (2011) have developed a patient satisfaction instrument unique for use in chiropractic settings. The instrument, called MedRisk, was assessed to have preliminary validity, but requires further research to confirm these results.

Summary of Evidence

There is a long history of patient satisfaction with chiropractic care. Recent studies and reanalysis of previous data have concluded that patient satisfaction with chiropractic care remains high.

Basic Science Research

The relationship between spinal joint mobility and changes to physiology is of particular interest to the chiropractic profession. Although the biological mechanisms underlying the effectiveness of spinal manipulation remain unknown, impaired spinal biomechanics are thought to have adverse physiological consequences. The therapeutic benefits of spinal manipulation have been ascribed to increased joint mobility following the mechanical elimination of adhesions in hypomobile spinal facet joints (Cramer et al., 2000, 2002, 2010, 2013; Henderson, 2012) and/or to the subsequent neurophysiological consequences following the improvement of aberrant spinal joint motion (Henderson, 2012; Pickar, 2002). The use of animal models is necessary to investigate the complex biological interactions associated with spinal manipulation that would otherwise be difficult, impossible, or unethical to perform with human subjects. Several examples of recent advances in knowledge pertinent to the mechanisms and physiological effects of chiropractic spinal manipulation using animal models are discussed in this section.

Anatomy and Biomechanics

By its very nature, spinal manipulation introduces mechanical forces into the spine and adjacent soft tissues. This makes quantification of the associated forces and delivery times critical to the study of the efficacy and optimization of chiropractic manipulation.

Recent studies using human participants and a custom-made mannequin investigated the biomechanical characteristics of high-velocity low-amplitude (HVLA) spinal manipulation and provided useful information for clinical instruction (Gudavalli, 2014). In an additional study, Gudavalli et al. (2013) have measured the pressure changes in the lower cervical intervertebral discs of human cadavers during manual cervical distraction. Decreases in intradiscal pressure, which may be important for the relief of pain, were most significant during combined cervical traction and moving flexion procedures. These findings may help researchers determine optimal biomechanical clinical delivery parameters for spinal manipulation.

Recently, a cat model was used to investigate the biomechanical characteristics that influence chiropractic treatment efficacy such as dosage, frequency, thrust duration, thrust amplitude, and anatomical site of treatment (Edgecombe, Kawchuk, Long, & Pickar, 2013; Vaillant, Edgecombe, Long, Pickar, & Kawchuk, 2012). Changes in spinal stiffness before and after

simulated spinal manipulation were determined by the researchers. Relative to a no-manipulation control, significant decreases in spinal stiffness followed spinal manipulation and terminal instantaneous stiffness was significantly decreased. These stiffness changes in the cat spine were similar in magnitude and direction to those observed in symptomatic human subjects who report benefits after spinal manipulation (Edgecombe et al., 2013).

Other animal models have been developed by chiropractic researchers to study the effects of spinal joint fixation/hypomobility and spinal joint misalignment in the rat (Bigland, Budgell, & Bolton, 2013; Budgell & Bolton, 2010; Cramer, Fournier, Henderson, & Wolcott, 2004; Cramer et al., 2010; Henderson, Cramer, Zhang, DeVocht, & Fournier, 2007; Henderson et al., 2009; Homb & Henderson, 2012). One of these novel rat models allows the L4, L5, and L6 rat vertebrae to be externally fixated/misaligned for various durations of time by placing removable noninvasive links between yokes attached to the rat spinous processes. Changes in spinal stiffness, the formation of adhesions, and spinal joint degenerative changes due to chronic hypomobility as a result of external linkage have all been reported using this particular animal model (Henderson et al., 2007). These rat models permit investigation of the progressive nature of the degenerative changes that often result from spinal joint fixation/subluxation. Preventing the deleterious effects of joint fixations is a primary objective of spinal manipulation.

Neurophysiology

Several animal models have been developed to investigate the neurophysiological effects of aberrant vertebral motion and/or spinal manipulation. The effects of spinal nerve encroachment and inflammation have been evaluated in a rat model by inserting a small steel rod into a lumbar intervertebral foramen (IVF) (Song, Gan, Cao, Wang, & Rupert, 2006) or injecting inflammatory substances into an IVF (Song, Hu, Greenquist, Zhang, & LaMotte, 1999). These researchers reported increased heat and mechanical sensitivity in the hindpaws, as well as increased spontaneous neural discharge in the nerve cells on the side of spinal nerve encroachment/IVF inflammation. When instrument-assisted HVLA spinal manipulation was applied at the rat L5-L6 spinous processes, a reduction in the severity and duration of thermal, mechanical, and nerve sensitivity was reported (Song et al., 2006). The implications of this research were that mechanically applied spinal manipulation can significantly reduce the severity and duration of pain and related neural hyperexcitability caused by inflammation at the lumbar IVF.

An adult sheep model has been used to investigate the effects of disc degeneration on the ability of spinal support muscles to respond to stimuli. The researchers reported that disc degeneration reduced back muscle electromyographic (EMG) responses and was associated with increased L4 nerve root discharge (Colloca, Keller, Moore, Gunzburg, & Harrison, 2008). In animals with disc degeneration there was less vertebral movement and reduced back muscle EMG activity during simulated spinal manipulation (Colloca et al., 2012). These findings illustrate the detrimental effects of intervertebral disc degeneration on the neuromuscular stabilizing system of the spine and its ability to respond appropriately to daily demands.

A series of investigations over the last decade using a cat model have found that clinically relevant manipulative thrust durations significantly increase neural activity in back muscles. This increase in sensory response during the manipulative thrust occurs in the presence or absence of spinal joint dysfunction (Cao, Reed, Long, Kawchuck, & Pickar, 2013; Pickar & Kang, 2006; Pickar, Sung, Kang, & Ge, 2007; Reed, Cao, Long, Kawchuk, & Pickar, 2013; Reed, Long, Kawchuk, & Pickar, 2014; Reed, Long, & Pickar, 2013). These studies have also revealed the inherent variability in neural response to spinal manipulation and the need for standardization in the application of these clinical procedures (Reed et al., 2014). The findings from both sets of studies using sheep and cat models, described previously, suggest that therapeutic outcomes of spinal manipulation can be adversely affected by the chronic, degenerative spinal joint conditions that are commonplace among individuals seeking chiropractic care.

Animal models have also proven beneficial in investigating the effects of spinal manipulation and other forms of manual therapy on visceral function. Somatovisceral reflexes are elicited through stimulation of skin and/or musculoskeletal tissues, and are often mediated by the autonomic nervous system (Budgell, 2000; Sato, Sato, & Schmidt, 1997). It has been shown in anesthetized rats that chemical irritation of the interspinous ligament elicits reflexive effects on cardiac function, adrenal nerve activity, and urinary bladder and gastric motility (Budgell, Holtz, & Sato, 1995; Budgell, Sato, Suzuki, & Uchida, 1997; Budgell & Suzuki, 2000; Budgell, Hotta, & Sato, 1998). Pickar and colleagues reported that injection of a chemical irritant into the lower back muscles of a cat resulted in sustained increases in heart rate, splenic and renal sympathetic nerve activity, and complex responses in blood pressure (Kang, Kenney, Spratt, & Pickar, 2003). These studies provide support for the commonly-reported visceral effects of spinal manipulation.

Conclusions

The increasing quantity and quality of current chiropractic healthcare investigations allow better, evidence-based decisions to be made by doctors, patients, and policymakers. The effects of spinal manipulation, the cornerstone of chiropractic practice, are now supported by substantial research – including randomized controlled trials, practice-based and cost-effectiveness studies, and basic science investigations using cadavers and animals.

As more funding becomes available, future research will aim to fill the gaps in our knowledge previously identified in this chapter, as well as answering questions such as, “Can we better predict which patients are most likely to benefit from chiropractic care?” “How well do doctors of chiropractic deliver prevention and wellness care?” “Why do clinicians in private practice experience more dramatic outcomes than found in clinical trials?” and “In what ways can chiropractic care help pediatric, elderly, and pregnant patients?” Answering these questions through further research will enhance our understanding of contemporary chiropractic practice.

The scientific review published in 2010 titled *Effectiveness of Manual Therapies: The UK Evidence Report* summarized the scientific evidence on the effectiveness of joint manipulation and mobilization for musculoskeletal and non-musculoskeletal conditions. The authors reported that, according to current standards of scientific evidence, spinal manipulation/mobilization is effective in adults for acute, subacute, and chronic low back pain, migraine and cervicogenic headaches, cervicogenic dizziness, acute/subacute neck pain, and several extremity joint conditions. These researchers also supported the safety and appropriateness of spinal manipulation/mobilization for all of the conditions noted (Bronfort et al., 2010). In an accompanying commentary, Scott Haldeman, D.C., M.D., Ph.D., an internationally-recognized spine care specialist and researcher, concluded that the scientific community now recognizes that manipulation is of value for the vast majority of patients who seek chiropractic care (Haldeman & Underwood, 2010).