

Chronic Low Back Pain: The Use of Massage and Acupuncture as Treatment Modalities

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A. Introduction: Purpose and Rationale

Chronic low back pain is a major health consideration given its prevalence in our society, some estimates quote figures as high as 70-80% of adults will have low back pain at some point in their lifetime. Low back pain also causes significant morbidity exhibited in time lost from work, and tremendous health care costs. While most low back pain is usually self limited, there is a significant population of chronic back pain sufferers who experience frequent recurrences despite multiple therapies. Standard treatment often consists of analgesics, back exercises, physical therapy and occasionally when warranted psychotherapy and anti-depressive medications. This particular group of patients is often plagued with depression and labeled "difficult patients", presenting a frustrating therapeutic challenge for the physician. Despite many non surgical treatments there is little evidence that any are particularly effective. There are several problems impeding the design of clinical trials that provide useful treatment directives. In many of these studies the outcomes are rarely clear cut as they are usually based on subjective findings such as symptoms and functioning. In addition, the method of measurement may influence the degree of treatment success or failure. To confuse things even more, back pain tends to be a non specific diagnosis and as such the patient population upon which the treatment is tried is rarely homogenous, making the results less than definitive. There are widely disparate findings on the differences between therapies. Cherkin, et al. in the recent NEJM study found the effects of physical therapy and spinal manipulation were only marginally better than the effect of reading an educational booklet. While a recent Finnish study in Spine found marked differences in pain intensity and functional disability in patients who underwent a program of active rehabilitation versus patients in the control group. Because of the chronicity and morbidity experienced by the patient and our lack of clearly efficacious treatment modalities, more and more patients are seeking alternative methods of healing, some including massage and acupuncture.

There is a wealth of literature on the use of acupuncture as a means of remedying pain. Several small studies look at acupuncture and its use in low back pain. Gunn et al. compared acupuncture to standard therapy and saw statistically significant improvement in the group receiving acupuncture compared to the control group, approximately 67% of patients who received acupuncture were able to return to their previous level of functioning versus 15% of the standard therapy group. Despite the mass popularity that massage enjoys, there is a modicum of literature on massage therapy as a remedy for low back pain. The studies available are poor analyses at best with small sample sizes making it difficult to draw any conclusions. In no analysis readily available does there appear to be a comparison of massage therapy with acupuncture for low back pain. Given that physical therapy is the most accepted method of treating patients with low back pain, I propose a study comparing the effects of acupuncture and massage therapy as adjuncts to physical therapy. While I do not presuppose to have happened upon a cure-all for low back pain I do offer that there may be additional treatment modalities that we can add to our bag of tricks to aid these "difficult patients" in their quest for well-ness.

B. Methods: Study Design and Statistical Analysis

Subjects: Patients will be culled from the AIM clinics at Columbia Presbyterian Hospital. Subjects will be identified and referred by their primary care physician. Inclusion criteria will include back pain localized to the lumbosacral region of at least three months duration and using analgesics for at least two weeks consistently. Men and women between the ages of 35 and 50, who score greater than or

equal to 12 on the Roland Disability score will be eligible for enrollment. Patients must be able to undergo a program of active rehabilitation. Exclusion criteria will include patients with sciatica or pain radiating below the knee and positive nerve root tension signs, evidence of neurological deficits or infections, history of spondyloarthropathy, osteoporosis, vertebral fractures or present pregnancy, or evidence of systemic causes of pain will also be excluded. Additionally, patients who are currently undergoing treatment by physical therapists, massage therapists, chiropractors or any other practitioner for their low back pain will be excluded from the study.

Study Design: After selection all patients will be consented for the study and then will undergo a screening process including a history and physical exam by the research physician. The history will be focused on the history of low back pain: length of disability, modalities used, analgesics used, surgical history, inciting injury vs. non specific occurrence, concomitant depression or other illnesses, etc. The Roland Disability Scale will then be administered. Patients fulfilling the inclusion criteria will be randomized to one of three arms comparing the efficacy of physical therapy and acupuncture, physical therapy combined with massage therapy, and physical therapy alone. Patients will be randomized to the various arms in patient blocks of 3 and 6 to maintain comparable study group sizes in each arm. All patients will be supplied with educational information regarding back care and exercises, and will be allowed to continue analgesic therapy. There will be 65 patients in each arm. This was calculated using a standard deviation of 6 which has been demonstrated in previous studies using the Roland Disability as their primary outcome and a projected effect size of 3, to give the study a power of 80%.

C. Study Procedures Treatments

Subjects will undergo therapy for 8 weeks and will be seen by the practitioners between 2 and 3 times per week, with session lengths of 45 minutes to one hour. Patients will be reminded of their visits and the importance of the analgesic diary weekly by a study coordinator to promote compliance and minimize drop out rates.

a. Physical Therapy

The physical therapy will be carried out by 3 certified physical therapists on staff at CPMC and will be a program of active rehabilitation in which patients will engage in physical exercises, stretching and relaxation exercises aimed at training the trunk muscles to increase strength and mobility. Patients will also be instructed in back exercises that can be done at home. In the physical therapy arm alone patients will be seen for 24 one hour sessions, 3 sessions per week for 8 weeks.

b. Massage Therapy and Physical Therapy

A second physical therapist will administer treatments using the same method but will also employ Therapeutic Massage and Trigger-Point Therapy. Therapeutic Massage is often known as Swedish massage and is based on five strokes: effleurage (long, gliding stroke), petrissage (kneading), friction, tapping and vibration. Often as an adjunct heat therapy is added to this technique which will be added as indicated. Trigger-Point Therapy is the application of deep, sustained pressure to tender points in the musculoskeletal system, followed by stretching of the muscles surrounding the trigger points.

c. Acupuncture and Physical Therapy

A third physical therapist will engage the third group of patients in the active rehabilitation program. In addition these patients will receive classical acupuncture performed by a licensed acupuncturist. The treatments will consist of the insertion of needles in classical points along meridians, the pathway through which Qi (energy) flows, in order to reestablish the balance between yin and yang and relieve pain and dysfunction. Traditionally these points are identified by measuring from landmarks using the patient's middle finger as a standard unit. Needle placement is further guided by the sensation of deqi or the teh ch'i phenomenon. This is a sensation of aching, numbness or distention felt around the site of needle insertion thought to be due to the stimulation of type III muscle fibers. Often acupuncture is accompanied by the use of electrical or manual stimulation, or the burning of herbs. For purposes of this study only manual stimulation (turning) of the needles will be allowed.

D. Analysis

a. Outcome Measurements

Patients will have a baseline assessment of their pain and disability before the start of treatment. Our main outcome measurement will be the change in their disability score assessed by the Roland Disability Scale. We also want to do secondary analyses of their pain using the McGill Pain Questionnaire, and use of an analgesic diary, as well as assessment of functional status where we will look at the patient's ability to perform four simple maneuvers: toe touching, straight leg raise, raising from a hard chair and lifting weighted objects. There will be a baseline analysis, a post treatment analysis at the end of 8 weeks, and a long term assessment at week 26 focused on the rate of recurrence of back pain and the level of disability. The person administering the assessments at all three time points will be a medical student blinded to the patients' arm of the study. The Roland Disability Scale is a self administered questionnaire that is specific to back pain. It is a sensitive tool and has been validated, with a test-retest correlation of .91 in the same day and .83 at 3 weeks. Similarly, the McGill Pain Questionnaire is a sensitive tool that has been validated in Spanish speaking patients with chronic pain. The analgesic diary will be reviewed at the 8 week assessment. The maneuvers will be assessed by a single observer. To quantify intra-observer reliability, the observer, the medical student, will undergo a training period followed by reliability testing, in which she will observe 5 patients at 5 different times- performing the four maneuvers. We will attempt to standardize these measurements. For the straight leg raises, 30, 45 and 60 degrees will be marked on the wall next to the examining table, in other studies using this method the test-retest reproducibility was .78. In order to assure the acupuncture, massage and physical therapy are being performed under the best practice methods we will randomly videotape 60% of the sessions which will be reviewed by a master practitioner in that treatment modality to confirm that the treatment sessions adhere to standard practices for that specialty and this patient type.

To analyze the data we plan to use an analysis of covariance with a Bonferroni post hoc test to determine the difference between treatment modalities upon disability in low back pain. We will do secondary analyses to assess the effect of the modalities on pain and physical maneuvers. We will also look at other factors that may skew the results, such as lifestyle changes, overall changes in exercise, weight, waist to hip ratio, etc. In addition, we will do a sub-group analysis with specific attention to unearth markers that would suggest less responsiveness to treatment. Such markers might include: extensive length of pain prior to start of study, multiple modalities used, pain not related to a specific injury, and history of depression.

E. Potential Risks

In acupuncture serious adverse events can be associated with the use of non sterile needles, specifically infections. Complications are also possible, such as tissue trauma from unskilled use of needles. These complications would be extremely unlikely in the hands of competent acupuncturists. A recent NIH consensus report stated that one advantage of acupuncture is that the incidence of adverse effects is substantially lower than that of many other accepted medical interventions. For patients without fractures, nerve root tension signs or spondyloarthropathy (which would exclude them from the study) physical therapy and massage therapy have very little if any risk.

F. Alternative Therapies

Acupuncture and Massage have been discussed above.

G. Compensation and Cost to Subjects

There will be no compensation nor cost to subjects.

H. References

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