ABSTRACT
Acute and chronic pain are elusive for the clinician not only in defining treatment but also in measurement. Few treatments have been rigorously tested. Faced with rising health costs and poor clinical therapeutic outcomes, the author designed a medically-supervised program of Shiatsu, Swedish muscle massage, and trigger point suppression (SSMMTPS) as a cost-effective alternative to conventional pain management.

Sixty-three patients with traumatically-induced spinal pain were enrolled, and 52 subjects completed a minimum of 6 SSMMTPS treatments. The neuropathologic findings of a herniated disc and/or spinal stenosis with denervation was present in 89% of acute cases and 68% of chronic cases. An 8-session treatment protocol was created with monitoring by a self-administered questionnaire. Current and maximal pain severity were assessed as well as mobility. Patients and massage therapists were blinded to prior responses. Statistical analysis revealed significant improvement in acute and chronic pain.

SSMMTPS is a cost-effective alternative therapy that should be considered in both acute and chronic pain secondary to trauma. Future studies should determine the implications of these preliminary findings and more fully delineate the specific indications for SSMMTPS in multidisciplinary pain management.

INTRODUCTION
A number of conventional and unconventional treatments are widely prescribed for the management of acute and chronic spinal pain, but few have been rigorously tested in controlled trials. The lack of clinical justification for prolonged and sometimes indiscriminate use of physical therapy and chiropractic treatments, as well as increasing health care costs, give sufficient cause to warrant a more thorough evaluation of the problem. Additionally, recent clinical trials have challenged the efficacy and cost of prolonged bed rest, traction, transcutaneous electrical nerve stimulation (TENS) (1), and facet joint injections (2). Similarly, investigators have reported improvement in only one-third of patients in multidisciplinary pain management programs (3). Perhaps in acknowledgment of the limits of conventional pain treatment, some pain patients have turned to an array of alternative therapies. In a recent Time/CNN poll, 30% of the patient population reported use of some form of unconventional therapy (4). In general, American physicians have taken a skeptical view of alternative medical care, insisting that there is no scientific basis, despite some types being rooted in ancient Eastern healing traditions. Deyo, in a recent editorial (5) has challenged and condemned nonconventional/nontraditional treatments as "fads."
The concerned physician is frequently faced with therapeutic dilemmas that often result secondary to the limits of traditional modalities. Mindful of these dilemmas, the author, a community-based neurologist, designed a medically-supervised program of Shiatsu, Swedish muscle massage, and trigger point suppression (SSMMTPS) in a hands-on attempt to interrupt the pain cycle and abnormal impulses generated from soft tissue injury.

Massage with stroking, kneading, and other friction techniques prepares the superficial and deep tissues by local involvement of circulation and energy (6,7). Shiatsu (Japanese acupressure) makes use of charted points which, when stimulated, lead to reflex relaxation (8,9). Trigger point suppression, by direct ischemic pressure, alters the reflex aspects of the pain cycle (10). In addition to the direct response, it is also presumed that these modalities stimulate enkephalin release (11).

The initial objective of this study was to identify a homogeneous population of pain patients with known underlying pathophysiology and measure pain intensity levels. With this as a baseline, an alternative treatment regimen with SSMMTPS would be utilized to determine if clinical progress could be quantified.

**METHODOLOGY**

**Criteria for enrollment.** Between April 1990 and November 1990, 63 patients with traumatically-induced cervical and/or lumbar pain, with and without a radicular component, were enrolled in the 8-session protocol. Entry criteria included subjects that were referred to the author for evaluation of traumatically-induced spinal pain. Vehicular trauma was causative in all but 2 cases. There was no recruitment of subjects. Criteria for exclusion included lack of trauma, presence of a worker's compensation claim, or a patient receiving disability payments. Candidates were also excluded because of factors that would impair follow-up (eg, inability to keep bi-weekly appointments in the physician's office). Eligible patients were provided information regarding the program prior to their enrollement, and informed consent was secured in each case. Each subject received a neurologic examination confirming their presenting complaints. In order to determine diagnostic and pathologic accuracy, a magnetic resonance imaging study (MRI) of the appropriate area(s) and electromyography (EMG) were also performed. The neuropathologic findings of a herniated disc and/or spinal stenosis with denervation was present in 89% of acute and 68% of chronic cases. Pain was defined as *acute* if symptoms were present less than 6 months, whereas *chronic* reflected symptoms persisting greater than 6 months

**Procedure.** Each subject completed a questionnaire which was designed to determine prior responses to treatment (eg, physical therapy, chiropractic, drugs), presence of litigation, attitude towards the protocol, and current and maximal pain intensities. A Likert scale was superimposed on a 100 mm visual analog scale (VAS) with subjects delineating the intensity of their pain, (ie, 0=no pain, 4=worse pain). Additionally, the patients rated areas of pain on a diagram of the human body (0 - 4). To minimize inconsistencies and bias, the same questionnaire was readministered before and after each treatment session. Subjects were blinded to their prior responses. The patients found the
questionnaire easy to complete and, with repeated use, appeared to reflect their status accurately. The scoring was on the 4-item VAS served as the primary measure. This technique has been previously validated (12, 13, 14,).

**Treatment.** Treatment sessions were bi-weekly for a total of 8 sessions. Each session began with the patients scoring their pain status. A licensed massage therapist then examined each patient and, using a similar VAS, independently quantified the presence of spasms, rigidity of movement, and trigger-point sensitivity to touch. Computerized muscle testing was not performed. The therapist then treated the subject with SSMMTPS and, upon completion, scored the three areas again. Scores from prior sessions were not made available. Prior to the end of each session, the patient completed another form, scoring the level of current pain and localizing it on a diagram. Each patient also assessed the treatment as helpful, not helpful, or no opinion. Each treatment session was 1 hour with 1-2 therapists assigned to the same patient for the duration of the protocol. There were no new co-interventions allowed during this protocol nor was there any attempt at randomization or controls. Mobility scores were also handled subjectively both by patients and therapists rather than by computerized muscle testing.

**Assessment.** The criteria for current and maximal pain relief were based upon the VAS scores reported on all visits. Additionally, a comparison was made of the first and last treatment scores.

The author arbitrarily created a mobility scale consisting of three aspects of dysfunction including spasm, rigidity of motion, and trigger point sensitivity to touch. Each was graded 0-4, and the highest number was considered to represent the current status, prior to treatment. Similarly, after treatment, numbers were again assigned to each category of mobility. A pre-treatment to post-treatment category-specific decrease in grading suggests progress and improvement (eg, 4->3). However, a category-specific increase in grading indicates deterioration (eg, 3->4). This subjective mobility scale is useful in rapidly characterizing the complexity of pain and dysfunction. It should be noted that the numeric relationships are arbitrary. There was no attempt to utilize computerized muscle testing to objectify this scale.

Patient attitude toward this program were also assessed with subjects describing their feelings regarding SSMMTPS as negative, no opinion, or positive. Assessment of each treatment was also noted as helpful, worse, or no change or no opinion. All measures of outcome were provided by the patients and therapists in a blinded manner.

**Compliance.** Compliance with the mandates of the program was validated by a minimum completion of at least 6 treatments. This number was determined in pilot data that indicated that patients could make a definitive statement regarding response by the sixth visit, whereas the therapist could detect some specific changes by the fourth or fifth treatment. In view of these findings, it was felt that a valid statement could be assessed after the completion of at least 6 treatments. Eleven (11) patients of the original 63 could not complete this requirement for a variety of reasons. The most common reasons given
for dropping-out were inconvenience and difficulty with transportation. The 11 patients represented a 17% drop-out rate.

**Analysis.** Group data were expressed in means and standard deviation. Differences in outcome measures were analyzed with t-tests. All p-values were 2-tailed, and levels less than 0.05 were considered statistically significant. For categorical data, chi square analysis for association was utilized.

**Results.** Eighty-three percent (83%) of the patients completed this study. In the acute group, the gender composition was 6 females (average age 36.2) and 4 males (average age 44.5 years). The time interval from onset of symptoms to first treatment was 2.3 months. The MRI was positive for disc herniation or spinal stenosis in 89%, and the EMG demonstrated denervation in 86%. Litigation was present in 60%; a positive attitude towards this program was present in 70%

In the chronic group, the gender composition was 27 females (average age 41.7 years) and 15 males (average age 46.1 years). The time interval from onset of symptoms to first treatment was 33.3 months. Litigation was present in 76%; a positive attitude was present in 70%. The MRI was positive in 68% and the EMG in 58% of cases.

For patients in the **acute pain category** assessment scores for **current pain** decreased significantly (p<0.05) between the first (mean=2.90±0.74) and last visit (mean=210±0.99). Assessment scores for **maximal pain** decreased significantly (p<0.05) between the first (mean=3.67±0.50) and last visit (mean=2.53±0.67). Similar comparison for patients in the **chronic category** were not statistically significant. However, there was a statistically significant (p<0.01) increase in reported treatment benefits from the first visit (56.1%) to the last visit (87.8%).

Therapists evaluated patients mobility at the beginning and end of each visit. Evaluation scores decreased (improved mobility) significantly (p<0.001) across all visits from the beginning (mean=3.10±1.90) to the end of a visit (mean=1.90±0.62) for **acute patients**, and from the beginning (mean=3.09±0.60) to the end of a visit (mean=1.91±0.64) for **chronic patients** (p<0.001).

There was no deterioration in the status of any patient with this treatment. A pretreatment negative attitude was reversed in over 50% of cases.

**Cost Analysis.** At present, there are limited data on the use and cost effectiveness of physical therapy and chiropractic treatment. To determine means and ranges and practice norms for the period of time from intervention to stabilization, the author surveyed two hospital-based physical therapy programs and one private therapist. While each program is tailored to individual patients and their subsequent responses, the general pattern in this community for treating acute spine pain is 2-3 treatments/week for a 3-month period. Chronic spinal pain patients usually receive 2 treatment/week for 3-6 months depending upon response. Three community chiropractors were also surveyed to determine their current treatment patterns. It was again emphasized that each program is tailored to the
patients' symptoms and their responses to treatment. As a generalization, in acute spinal pain, the treatment frequency is 3-5 times per week for 3 months, whereas chronic spinal pain requires 3 treatments per week for 3-6 months.

Currently, New York State no-fault reimbursement is fixed at $41.50 for a 45-minute session. This rate is standardized for both physical therapists and chiropractors, irrespective of the varying modalities utilized. Costs were calculated by multiplying the current 1990 no-fault reimbursement rate by the average number of visits. For physical therapy, the cost for treatment of acute pain was calculated to be $1245.00, whereas cost for chronic pain was calculated to be $984.00. The cost for acute chiropractic treatment was calculated to be $1743.00, and chronic treatment was calculated to be $1494.00 (3 months). The relevance of these projections recognizes that treatment patterns differ and are based on the individual symptoms and responses. Likewise, reimbursement rates may vary from state to state. Consequently these projections reflect averages in the community setting of this study.

The charges for a one-hour treatment session for SSMMTPS were based on pooled data for therapist treatment, physician supervision and analysis, linens, equipment, and supplies. A $100.00 per session charge was determined utilizing code #T97799/97799. A current procedural terminology (CPT) code is currently not available. Thus, a one-month treatment program consisting of 8 sessions would cost $800.00.

The author decided to subsidize the total cost of this study in an attempt to dispel any concerns by the patients as to who would pay for this treatment and, more importantly, to obtain statistical data to affirm or deny the value of this modality. It is acknowledged that the cost-free nature of the treatments may have affected the patients' perception of benefits and their attitudes toward the treatment.

**DISCUSSION.**

Far beyond simply feeling good, SSMMTPS leads to impressive therapeutic effects in pain reduction as well as greater muscle flexibility and tone. Despite the presence of herniated disc, spinal stenosis, denervation, litigation, and prior treatment failure, this program achieved improvement in 86% of chronic cases and improvement in 100% of acute cases. Although these preliminary observations need to be extended over longer periods to determine functional outcomes, they provide the first clinical study of the safety and efficacy of a medically-supervised program utilizing SSMMTPS on a homogeneous population of traumatically-injured individuals. In addition, there was no diagnostic ambiguity as to the causation of pain with the demonstration of structural pathology in 89% of the acute cases and 68% of the chronic cases.

**Limitations of study.** Several limitation of this study deserve comment. First, the sample population consisted almost exclusively of vehicular trauma and no-fault cases which may not be a representative sample; it is well recognized that pain is a heterogenous problem. The size of the cohort may be considered too small, and the short follow-up of 8 sessions may not be adequate. Deyo and co-workers observed that one month of intervention may be insufficient to expect the full effect and benefits (1). It should be
noted that 13 patients requested and received additional treatment. This represented 25% of the sample. The problem of patient drop-out (compliance) is inherent in all studies despite good intentions. The drop-out rate of 17% in the present study was deemed to be acceptable based upon prior studies (15).

Clearly, the study was an open, uncontrolled trial. Perhaps the greatest limitation, inherent in any treatment evaluation, especially in traumatically-induced spinal pain, is the degree of spontaneous improvement which may occur. In addition, the placebo effect is also a potentially significant factor in any hands-on treatment program. However, it must be recognized that patients in the acute category were in moderate to severe pain for a minimum of 2.3 months, and that 89% displayed a structural abnormality. In view of the high degree of organic deficit, as well as the prior treatment failure rate of 50%, it would be most surprising to see a significant spontaneous resolution of complaints. The patients in this study comprised a vastly different cohort when compared with those patients in acute cervical and lumbar distress without evidence of herniated disc, spinal stenosis, or denervation where resolution would be expected. Also, it is acknowledged that the influence of litigation plays a role in treatment outcome and cannot be underestimated (16).

Exclusive dependence upon pain questionnaires for understanding the complex aspects of pain for heterogeneous populations is unacceptable and may be fraught with error due to the subjective influences such as litigation and psychologic factors. Thus, objective aspects are more relevant, and, in this regard, the arbitrary creation of the mobility index score is reasonable since the 3 most important aspects of mobility were addressed. This study could have been strengthened by use of objective computerized muscle testing initially and at end of study. Even though patient satisfaction is an important aspect, return to functional status is the critical measure of a successful therapeutic program.

Another limitation that must be addressed is the use of more than one therapist. This raises questions not only of standardization of technique, but also therapist bias and intertherapist rating reliability. In addition, the issue of a placebo effect is always raised whenever a hands-on approach is utilized by both the patient and the therapist. These limitations notwithstanding, the observed scores were reproducible throughout the study, and each therapist received similar training, all graduating from the Swedish Institute.

**Theoretical basis of treatment.** What does SSMMTPS actually do? In theory, healing (ie, enhanced joint and muscle mobilization) is promoted by a more direct approach to the injured tissue. This effects a greater likelihood of reducing and reversing tissue changes. Joint and muscle mobilization arise as well as release of enkephalins. The identification and supression of the 2-3 focal trigger points within the trapezius, supraspinatus, and infraspinatus muscles in cervical radicular pain were clearly necessary to break the reflex aspect of this pain. Patients with lumbar radicular pain usually had 1-2 tender trigger points within the paraspinal muscles at L4- L5 and L5-S1, and it is clearly necessary to suppress this sensitivity in order to break the reflex aspect of this pain propagation.
The conflicting claims of benefit by physical therapy, utilizing physical agents, must take into account the protective thermal insulation of the subcutaneous fat which allows little penetration. Advocates of physical therapy and chiropractic manipulation have not scientifically demonstrated benefit in many chronic pain patients in controlled trials. Given the relatively high cost associated with prolonged and occasionally unlimited physical therapy and chiropractic treatments as well the large expenses associated with multimodality pain clinics, this 8-session (one month) treatment protocol is, indeed, cost effective.

CONCLUSION
Consideration should be given to non-traditional/non-conventional techniques that attempt to reduce pain and increase function. Based on these preliminary results, SSMMTPS can be used safely and is deserving of increased attention and further study. It must be recognized that this unconventional therapy is not a panacea, but rather appears to be a useful alternative or adjunct to the treatment of the traumatically-injured patient. Deyo's condemnation of "fads" may be a disservice to meaningful progress and clinical research. Few would argue that a critical appraisal of all modalities, traditional and unorthodox, is warranted if this sociologic and economic burden to society is to be resolved (17). It appears that a prospective, randomized trial will be necessary to judge definitively the merits of current modalities of treatment.

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REFERENCES


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ABSTRACT

Acute and chronic pain are elusive for the clinician not only in defining treatment but also in measurement. Few treatments have been rigorously tested. Sixty-three patients with traumatically-induced spinal pain were enrolled, and 52 subjects completed a minimum of 6 SSMMTPS treatments. The neuropathologic findings of a herniated disc and/or spinal stenosis with denervation was present in 89% of acute cases and 68% of chronic cases. An 8-session treatment protocol was created with monitoring by a self-administered questionnaire. Current and maximal pain severity were assessed as well as mobility.