

Preliminary Findings

LONG-TERM EFFECT ANALYSIS OF IDD THERAPY IN LOW BACK PAIN: A RETROSPECTIVE CLINICAL PILOT STUDY

C. Norman Shealy, MD, PhD, Nirman Koladia, MD, and Merrill M. Wesemann, MD

Abstract. *An analysis of the duration effect of intervertebral differential dynamics therapy (IDD Therapy®), to ascertain the benefits of rehabilitation treatment is presented. Patients from a private practice clinic were administered IDD Therapy®. The treatment was evaluated on 33 patients (17 females), using a numeric pain scale at the first session, last session, and at one year. The mean age of the patients and duration of treatment were 73.49 years (SD = 6.87) and 362.00 days (SD = 148.48), respectively. The mean pain level for the first session (FS), last session (LS), and at one year (1yr) were 6.88 (SD = 2.47), 2.42 (SD = 2.18) and 1.65 (SD = 2.47), respectively. Improvement in pain scores of 4.46 (FS - LS) were noted and corresponded with a previous study. Improvements of 5.23 (FS - 1Yr) and 0.77 (LS - 1 Yr) established that benefits continue after the treatment completion. This correlates to a reported 76% decrease in pain one year after the last therapy session. Of the patients enrolled, 54% (18/33) improved by 5.23 points on the scale (mean improvement) after previous unsatisfactory treatments for low back pain; these previous treatments included vertebral axial decompression (VAX-D), traction, and other modalities.*

Descriptors. *IDD, intervertebral differential dynamics, low back pain, traction, vertebral axial decompression*

AJPM 2005; 15:93-97. Received: 03-23-05; Accepted: 05-04-05

INTRODUCTION

Low back pain is one of the most common problems treated by orthopedic surgeons. Eighty percent of adults will experience significant low back pain sometime during their life. Second to the common cold, problems caused by the lower back are the

most frequent cause of lost workdays in adults under the age of 45 (1).

INTERVERTEBRAL DIFFERENTIAL DYNAMICS THERAPY

Intervertebral differential dynamics (IDD) therapy is a physical modality, which is capable of isolating a lumbar vertebra (L1, L2, L3, L4, or L5) and mobilizing the vertebrae. The treatment can be utilized to alleviate the pain emanating from an injured disc by distracting and re-positioning of the surrounding vertebra. The distraction, on

C. Norman Shealy, MD, PhD, is President of Holos University Graduate Seminary and was Founding President of the American Holistic Medical Association. Nirman Koladia, MD, is Director of Research and Development of North American Medical Corporation in Marietta, Georgia. Merrill M. Wesemann, MD, practices family medicine and acupuncture in Franklin, Indiana. Reprints: www.AJPMOnline.com

average, is between 5 and 7 millimeters. The 25 to 30-minute treatment utilizes variable therapeutic forces on structures that may be causing low back pain. The protocol is termed IDD Therapy®. The treatment objectives of IDD Therapy® are comparable to a conventional physical therapy regimen, whereby the pathology may benefit from a rehabilitative approach. One of the primary differences with this approach is this technology enables the physical modality to be computer directed, and is, therefore, highly duplicable.

The treatment regimen is selected by the therapist according to the diagnosis presented. The treatment objective for facet syndrome is to mobilize the facet thereby relieving dysfunction. In cases where a disc is compressed, a treatment protocol may be utilized specifically targeted to the relief of intradiscal pressure. Protocols intended for this application emphasize a spinal pumping effect to promote retraction of a herniated nucleus pulposus (2). In some cases, intradiscal pressure levels may be diminished from positive 25 millimeters of mercury to negative 150 millimeters of mercury. This negative pressure promotes the diffusion of water, oxygen, and nutrients into the vertebral disc. Degenerative disc pathologies may also be treated more effectively than with conventional physical therapy by utilizing a protocol targeted at disc rehydration and re-positioning of the vertebra at the affected disc level.

OBJECTIVES

The objectives of this study were (i) to produce a follow-up to the Shealy and Borgmeyer Study (3), (ii) to evaluate long-term benefits of IDD Therapy® treatment, and (iii) to determine any benefits of IDD Therapy® in comparison to other treatment options. In 1997, Shealy and Borgmeyer presented a significant new approach to the management of back pain (3). Their preliminary results suggested that

decompressive mobilization of the lumbar spine was beneficial in 86% of patients with ruptured intervertebral disc and 75% of those with facet arthrosis (3). The present study served as a follow-up to the previous study.

IDD Therapy®, as previously explained, is a modality that utilizes a technology designed to conjoin the successful protocols originally set forth by Shealy, with an expanded physical therapy component to address the pathogenesis of low back pain conditions. We expected therefore, the treatment benefits should continue after the sessions are over, this study aimed to find out the level of such long term benefits obtained. There is anecdotal observation amongst IDD Therapy® clinicians that IDD Therapy® treatment benefits many patients who have failed with other treatment modalities, including traction, vertebral axial decompression, conventional physical therapy, NSAIDs and corticosteroids. This study also aimed to serve as a pilot to evaluate this observation.

Methodology

Patient selection. The investigation presented was a pilot study to establish the maintenance of the therapeutic effect of IDD Therapy® at one-year follow-up. The authors expected that the private practice sample chosen would not be very different from a randomized sample. The ideal random sample for IDD Therapy® treatment would be patients suffering from low back pain. The patients were selected from a private practice clinic from a group of patients who may otherwise have been referred for conventional physical therapy rehabilitation and who, instead, were prescribed a computer directed regimen with IDD Therapy® technology best suited to their specific pathologies. This sample should closely represent the ideal sample because IDD Treatment is prescribed to patient suffering from low back pain, with or without previous treatments. A bias would

be potentially manifested if the patients presenting to this clinic were significantly different from the general population of such patients, which in the authors' opinion, is but a slight possibility considering the setup and location of the medical practice.

Inclusion/exclusion criteria. Patients with low back pain, with/without previous failed attempts with other treatments, were included in the study. The study included patients of all ages, gender, and ethnicity. Patients with severe osteoporosis, vertebral fractures, spondylolisthesis (grade 2 or higher), unstable post-surgical conditions, any kind of surgical hardware, vertebral fusion (within 6 months), and spinal instability were excluded. Patients who could not provide a legal consent were also excluded.

Protocol. The included patients were administered the appropriate IDD Therapy® treatment protocol; administered via the IDD Therapy® approved equipment. The parameters of the protocol involve treatment time, treatment intensity, and positioning angle (4). These parameters are set on the basis of pathology, vertebral level indicated, and patient characteristics (4). Twenty treatment sessions are recommended within a 4-6 week range, provided that early evaluation is showing a positive patient response. Patients with protocol deviations were dropped-out of the study (see also, Results).

Pain scale and endpoints. The pain scale selected for this study was the numeric pain scale (NPS) (5). Each patient was asked to delineate her/his pain intensity from 0-10 (0-no pain, 10-most unpleasant pain imaginable) on the administered NPS. The first NPS evaluation was administered before the first session of IDD Therapy® treatment. After completion of the full regiment, the second NPS was administered and designated *last session*. After an average of one year subsequent to the last treatment, the

patients were again administered the NPS for the third time.

RESULTS

The study was initiated with 35 patients. Two (2) patients were dropped from the study because they could not complete the treatment. Therefore, the total number of patients completing this treatment was 33. Nine (9) patients could not be contacted for the 1-year follow-up. This left 24 patients that could be assessed for the 1-year duration effect analysis.

Of the 24 patients (17 female and 18 males), the mean age was 73.49 years (SD = 6.87). The last treatment sessions were completed between November 8, 2002 and March 5, 2004. The date of the first session was 4-6 weeks before the last session for each patient. The date for 1-year duration effect analysis was May 18, 2004. The mean duration for the study group was 362.00 days, or approximately 1 year (SD = 148.48). The average number of sessions per patient was 19.24 (SD = 5.44).

The mean pain level (Figure 1) for the first session was 6.88 (0-10 NPS, SD = 2.47). The mean pain level for the last session and 1-year duration effect analysis were 2.42 (SD = 2.18) and 1.65 (SD = 2.47), respectively. Therefore, the mean improvement for the first session to last session was 4.46 ($p < 0.01$), and the mean improvement from the first session to 1-year duration effect analysis was 5.23 ($p < 0.01$), a 0.77 improvement over the last session. This correlates to a reported 76% decrease in pain one year after the last therapy session.

The vertebral levels were L1 through S1. Previous treatments involved acupuncture, back support, back surgery, chiropractic, epidural block, pain medication, conventional physical therapy, and trigger point therapy. Forty-five percent (16/35) of the patients had previous treatments before being enrolled into the present study.

CONCLUSIONS

The study results have revealed an improvement of 4.46 points (on the NPS) from the first session to last session. An overall improvement of 5.23 points occurred from the last treatment session to the 1-year duration effect analysis. Improvement from the last treatment session to the date of the 1-year duration effect analysis was 0.77 points. A direct conclusion that can be drawn from the data is that improvement in pain continues after the treatment sessions are completed.

DISCUSSION

Possible explanations of the conclusions drawn from this study regarding prolonged therapeutic effect phenomenon include (i) an etiological solution to the pathology being

Forty-five percent (16/35) of patients in this study were administered their IDD Therapy® after previous treatments of low back pain. The average improvement of 5.23 points on the NPS suggested that IDD Therapy® benefits patients when other treatment options have failed.

The results of this study beg the questions - could IDD Therapy® computer directed physical therapy protocols lead to prevention of recurrence in patients that have been treated by IDD Therapy® protocol equipment, and could these treatment protocols prevent the pathologies of back pain, before the first occurrence. This study involved only 35 patients; a large study should be devised to confirm further the results and address the explanations proposed.

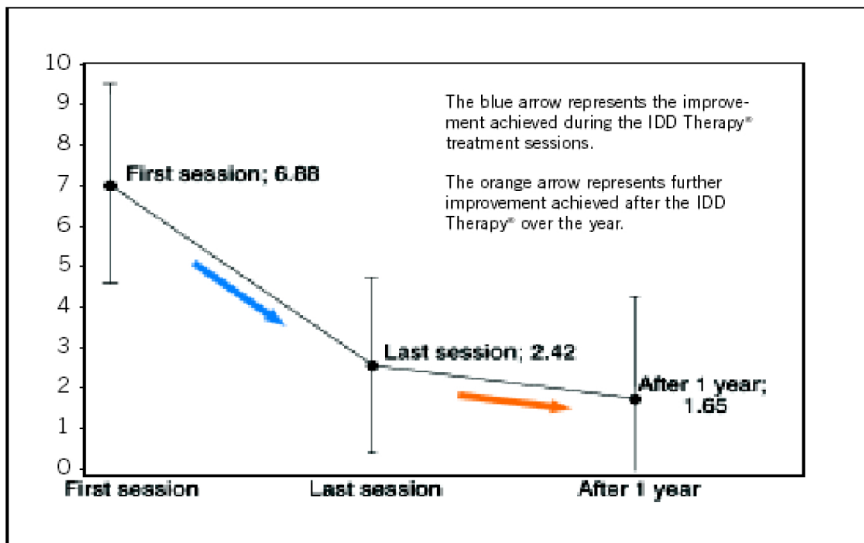


FIGURE 1. The chart shows mean NPS of 6.88 at the beginning of IDD Therapy® treatment after the completion of treatment the mean NPS is reduced to 2.42 (last session). After a duration of one year the patients continue to improve and the mean NPS is 1.65.

achieved during the session which slowly leads to the decrease in pain, (ii) the patient adapting to pain over time, or (iii) the patient undergoing other treatments. Further trails should be designed to address these possible theories.

Disclosure. The authors have a proprietary interest in IDD Therapy®.

REFERENCES

1. American Academy of Orthopedic Surgeons, "Low Back Pain", January 2005,

http://orthoinfo.aaos.org/brochure/thr_report.cfm?Thread_ID=10&topcategory=Spine

2. IDD Therapy® Website, "How IDD Therapy® Works". December 2004: <http://www.iddtherapy.com/whatis/index.html>.
3. Shealy CN, Borgmeyer V. Decompression, reduction, and stabilization of the lumbar spine: a cost-effective treatment for lumbosacral pain. AJPM 1997; 7(2):63-65.

4. North American Medical Staff, The IDD Therapy® Protocols for computer directed physical modalities, North American Medical Corporation, 2003.
5. Bolton JE, Wilkinson RC, Responsiveness of pain scales: a comparison of three pain intensity measures in chiropractic patients, Journal of Manipulative & Physiological Therapeutics 1998; Jan 21(1):1-7