A Multi-Center Study for Validating the Complaint of Chronic Back, Neck, and Limb Pain Using "THE MENSANA CLINIC PAIN VALIDITY TEST"

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Key Words: psychological tests for pain, back pain, neck pain, measuring pain, validating pain, predicting organic pathology, misdiagnosis of chronic pain

Abstract

A retrospective chart review was conducted in seven private practice offices in order to evaluate the ability of the Mensana Clinic Pain Validity Test (PVT) to predict the presence or absence of physical abnormalities in patients with chronic back, neck, or limb pain. In this study, 251 patients with complaints of chronic back and/or limb pain were evaluated. A study seeking correlation between the scores on the Mensana Clinic PVT and objective measures of organic pathology was conducted. Results of X-rays, magnetic resonance imaging (MRI), computed tomography (CT), electromyograms (EMGs), nerve conduction studies, bone scans, nerve blocks, and other medical tests were graded in terms of severity of physical abnormality. Patients who scored 17 points or less on the Mensana Clinic PVT had moderate or severe physical abnormalities 94% of the time. Patients scoring 21 points or more had mild or no physical abnormalities 85% of the time. The PVT significantly correlates with the presence or absence of organic pathology (r = 0.554; p < .0001).
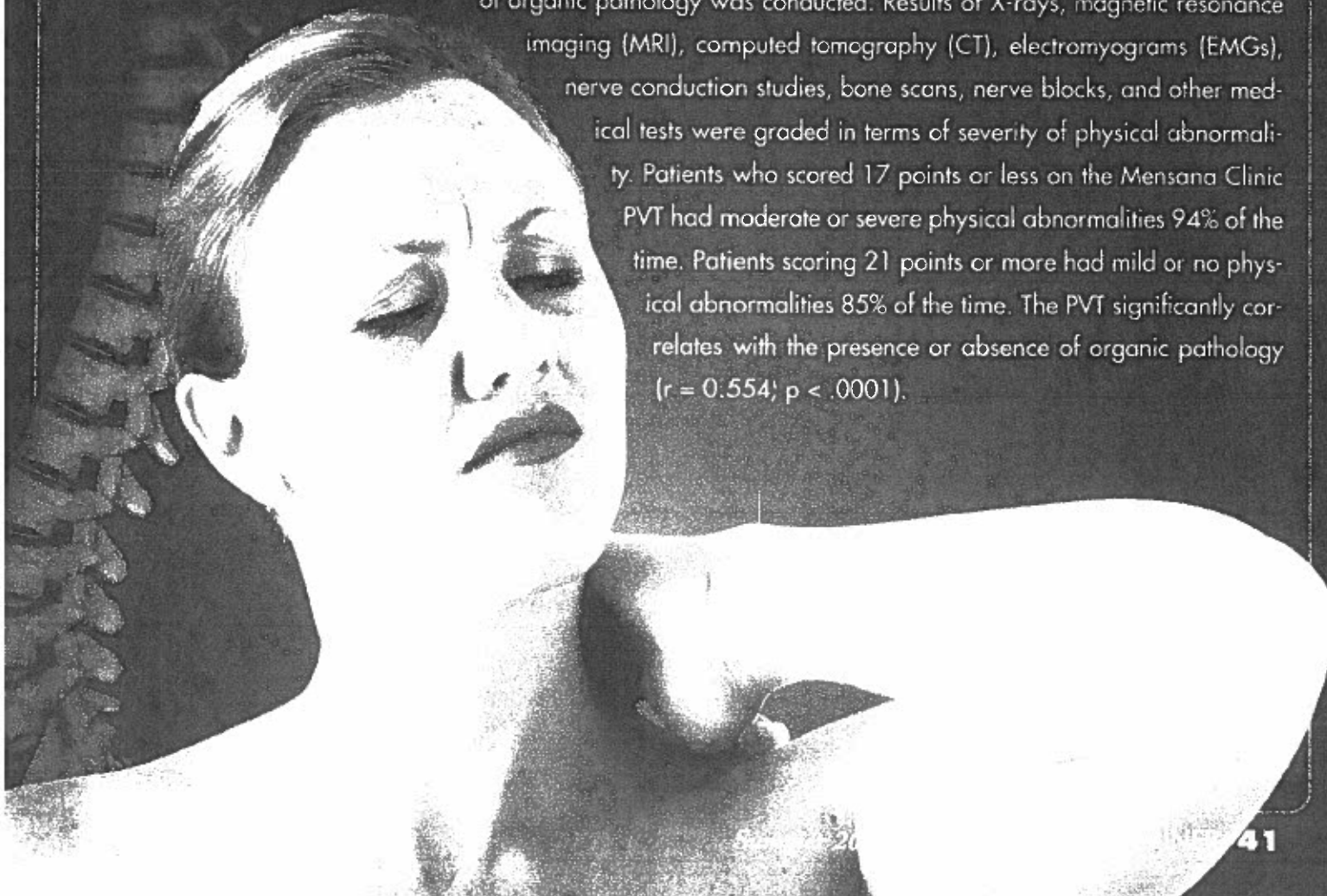
Introduction

Chronic pain (constant pain lasting 6 months or longer) is a subjective experience that is influenced by many pre-morbid (before the onset of pain) psychological problems. However, chronic pain often causes depression, anxiety, and marital difficulties.[1] Although physical examination and other studies, including X-ray studies, 3D-CT, electromyograms (EMGs), nerve conduction velocity studies, and thermography,[2-4] in many cases may document an organic basis of chronic back pain, some organic syndromes defy definition by objective tests.[5] This may be a greater problem for women, for whom physician prejudice can result in a significantly less-extensive evaluation of their complaints of back pain.[6] Also, any litigation may influence symptoms[7] and the type of litigation may influence outcomes.[8] Therefore, there is a need to differentiate between organic and functional (negative physical and laboratory examination) back pain.[9]

In an effort to provide a consistent method of assessing patients with chronic pain, one must bear in mind that patients with severe personality disorders may also have organic disease. In fact, it would be prudent to think of these two types of disorders as existing on two separate and independent intersecting axes.[10,11] Complicating this is the psychological response to chronic pain, which changes over time. Hendler has termed this "The Four Stages of Pain."[1,12,13] Therefore, one must not only consider the pre-morbid psychological adjustment of the chronic pain patients, but also the chronological stages of their chronic pain in order to determine the appropriateness of their psychological response to pain.

Many psychological tests have been used to evaluate the validity of the complaint of pain.[9] One frequently employed test is the Minnesota Multiphasic Personality Inventory (MMPI), a 566-question self-administered test consisting of true-false answers. By using this test, researchers have identified several clusters of personality traits that occur commonly in chronic pain patients.[14-17] However, the only criterion for inclusion of patients in these reports was the complaint of pain. With the exception of one study from the Mayo Clinic, there have been no MMPI studies that observe patients with chronic pain on a longitudinal basis.[18] Other researchers have used the MMPI to differentiate between organic and functional groups of chronic back pain patients with varying degrees of success.[19-21] In these articles, functional pain is defined as a pain for which there is no organic pathology, while organic pain is defined as pain that does have a medical explanation. This lack of reliability of the MMPI led to the development of other subtests of the MMPI, which were also unreliable.[21-23]

In counter-distinction to the MMPI, The Mensana Clinic PVT (previously called the Hendler 10-Minute Screening Test and the Mensana Clinic Back Pain Test) was developed by the recording of a patient's normal physical and psychological response to documented chronic back, neck, and limb pain regardless of any pre-existing personality disorder.[24] Specifically, it was not validated on facial, abdominal, or genital pain. This 15-question test, which is essentially a structured psychiatric and medical interview, established a psychological and medical profile that retrospectively correlated with objective physical findings 83% of the time and predicted a positive outcome to surgery or pain-related procedures 77% of the time in a group of 315 men and women.[24] Prospective studies found that the test could predict the presence of organic pathological conditions 77% of the time for women, 91% of the time for men, and 85% of the time overall.[25-27]

No attempt has been made to correlate MMPI findings with the presence or absence of objective physical findings other than work by Hendler and his colleagues. They found scale 2 (depression) had a weak correlation with physical findings in men and, in a combined study, found that the F scale (faking) correlated with physical findings.[25-27] However, despite the fact that a relationship could be established between these two scales of the MMPI, the correlation was barely statistically significant.

The MMPI was designed to measure personality traits and the SCL-90 to measure psychological states. However, the PVT was designed to measure the validity of the complaint of pain, regardless of the personality traits or psychological states of patients. The PVT is not designed to measure pain, but rather the impact of pain on a patient's lifestyle.

Hendler categorized chronic pain patients into four broad categories, as described below.

Objective pain patients: Good pre-morbid adjustment, changes in lifestyle over time because of pain, and a definable organic syndrome, with positive objective tests.

Exaggerating pain patients: Poor pre-morbid adjustment, no change in lifestyle, avoidance of unpleasant tasks, and definable medical syndrome, without positive objective tests.

Undetermined pain patients: Good pre-morbid adjustment, changes in lifestyle over time because of pain—similar to the objective pain patients—and a difficult-to-diagnose clinical syndrome, without positive objective tests.

Affective pain patients: Poor pre-morbid adjustment, no change in lifestyle, no recognizable organic syndrome, without positive objective tests.[13,24]

By using these categories, both organic and psychological factors can be considered concurrently.[10,11]

This study was designed to investigate the validity of the PVT for predicting the presence or absence of documented organic pathological conditions in patients with chronic back, neck, and limb pain. This research differs from earlier articles on a similar topic since additional objective measures of organic

pathology, which were not available when the earlier studies were published, were included in this research (MRI, MRI with gadolinium, provocative discograms, 3D-CT, and quantitative flow-meter studies, as well as the use of iohexol myelograms, Indium III studies, and gallium studies).

Also, expansion upon earlier research to include primary and secondary care centers as well as a tertiary referred center was needed to test the efficacy of the Mensana Clinic PVT on a general pain population.

Methods

Patients. Patient charts were derived from various sources. Mensana Clinic, a tertiary referral center, provided 122 charts, of which 120 were used. Of these 120 patients, 76% were from 25 states, while the remainder were from the state of Maryland. Chris Brigham, MD, from Occupational Health Excellence provided 50 charts representing patients from Maine, of which 35 were used. Philip Osborne, MD, from the Willis Knighton Medical Center in Shreveport, Louisiana, provided 49 charts of patients from Louisiana, of which 33 were suitable for inclusion. Pierre LeRoy, MD, from the Delaware Pain Clinic provided 25 charts, of which 24 were used. These patients were referred by Delaware doctors to the Delaware Pain Clinic for evaluation and treatment. B. Todd Graybill, PhD, from Muskogee, Oklahoma, provided 25 charts of patients from Oklahoma, of which 24 were suitable for inclusion. L. Catlett, MD, from Lewiston, Maine, provided 10 charts of patients from Maine, of which 8 were suitable for inclusion. Mats Gronblad, MD, PhD, from the University Central Hospital in Helsinki, Finland, supplied a synopsis of 7 patients, and all were suitable for inclusion. All of these patients were from Finland.

A total of 251 charts were selected for inclusion in the study. Since PVT was designed only to assess the impact of the complaint of chronic back and limb pain, all the patients with the chief complaint of consistent pain in the back, back and legs(s), neck, neck and arm(s), or all the combinations thereof of 6 months' duration or longer were included in the study. In addition, all of those who had received the appropriate objective physical tests (see below) were included. Excluded from the study were patients with too few tests, pain of less than 6 months' duration, and inappropriate location of the pain (headache, gastrointestinal pain, facial pain, etc.).

For the 251 patients, demographic data was derived from chart review, if the information was available. The average age of all patients was 40.3 (n = 251, range 17-70). There were 133 males and 118 females in the study. Racial data was available on 195 patients, of which 178 were Caucasian, 16 were African American, and 1 was Asian. Socioeconomic data was available for 199 patients, which included employment information as well as educational level. Using the methodology described by Hollingshead, patients were (a) assigned a numerical scale to various categories of jobs, then this score was multiplied by a weighting factor of 7, and (b) cataloged by educational achievement into cells with a numerical value, and this was multiplied by 4. The sum of educational and employment scores results in a total score, which is then grouped into socioeconomic classes ranging from I, the highest level of education and professional attainment, to V, the lowest level.[28,29] Of the 199 patients, 3 were class I, 11 were class II, 76 were class III, 104 were class IV, and 5 were class V.

Physical Tests. Objective physical tests were divided into two groups based on the ability of these tests to assist in the diagnosis of chronic back and/or back and limb pain. The first group consisted of electromyography, nerve conduction studies, quantitative flow-meter studies (Doppler), provocative discometry, and thermography. The second group consisted of myelogram and/or iohexol-enhanced CT of the back or a combination of the two tests. Also in this group were MRI, with or without gadolinium
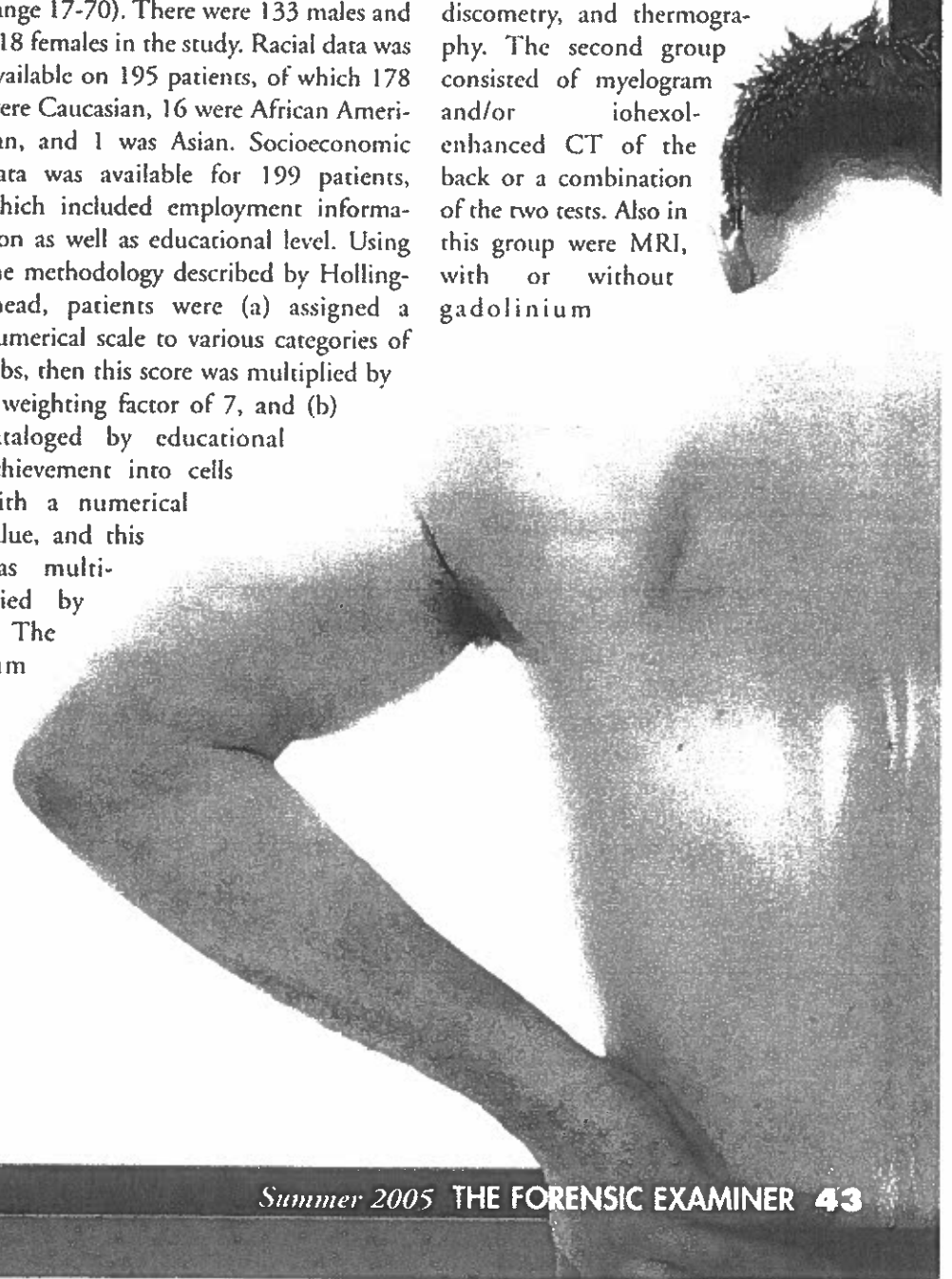
enhancement; 3D-CT; CT; flexion-extension X-rays with obliques; bone scan; gallium scan; or Indium III scan. A patient had to receive at least two tests in the first group or two more tests in the second group to be included in the study.

Results

Analysis of Physical Test Results. Dr. Nelson Hendler (NH), Ann M. Cashen (AMC), and Sam Hendler (SH) reviewed the patients' medical charts. Two of the researchers (AMC and SH) had never seen the patients clinically. The third researcher (NH) had treated 120 of the patients. These three researchers, analyzing the medical charts, graded the severity of physical findings based on a simplified ranking system. Their scores were confirmed by an outside consultant (Donlin Long, MD, PhD, professor and chairman, Department of Neurosurgery, Johns Hopkins University School of Medicine). Physical tests in which there were no abnormal findings were assigned a score of 0; those with equivocal and minimal findings were scored as a 1. Tests interpreted as moderate or severe were given scores of 2 or 3 respectively. The ratings were based on the reported results from the various laboratories in which the objective tests were performed. Assessment of the physical values for the objective tests was standardized. Thermography was considered either a 0 or 1 if interpretations of thermography showed mild or no abnormalities. However, if there was a significant temperature difference of 1 degree centigrade from one side to the other of the same anatomical distribution, this was given a score of 2. If the difference exceeded 1.5 degrees centigrade, it was given a score of 3. Gradients from the upper arm to the lower hand that exceeded 2 degrees centigrade from the shoulder to the hand were considered abnormal. They were scored as 2 if they exceeded 2 degrees and 3 if they exceeded 3 degrees. On EMG nerve conduc-

tion velocity studies, any mild abnormalities were considered a 2 and moderate and severe abnormalities were considered a 3. No findings were given a 0. On MRIs, a bulging disc was considered a 1, a bulging disc with nerve root displacement and/or impingement on the spinal cord was considered a 2, and any mention of a herniated disc was considered a 3. On CT scans, the same criteria applied. On MRI and CT scans, as well as X-rays, minimal facet hypertrophy was considered a 1, while moderate and severe facet hypertrophy was considered a 2 or 3 respectively. Foraminal stenosis, if mild, was considered a 1; if moderate, considered a 2; and if severe, considered a 3. Likewise, all spinal stenosis considered mild, moderate, and severe were scored 1, 2, or 3 respectively. It should be noted that spinal stenosis (abnormal narrowing of the spinal canal) could be caused by a triad of hypertrophy of the ligamentum flavum, facet hypertrophy, and a bulging disc. Likewise, facet hypertrophy and a bulging disc could cause foraminal stenosis.

Quantitative flow-meter studies were considered mildly abnormal if there was a 10% or greater reduction of blood flow when the arm was elevated compared with the neutral position; moderate if there was a 20% reduction in blood flow; and severe if blood flow was reduced 30% or more. These were scored 1, 2, or 3 respectively. Any chiropractic X-rays were discounted. Myelograms were considered abnormal using the same criteria as a CT scan, MRI, and X-ray. In addition, nerve root filling was considered on myelogram with mild blunting of the nerve root filing being considered a 1, and moderate and severe amputation of the nerve root considered a 2 or 3 respectively. It is important to note that a patient might have a herniated disc that showed on MRI, CT, or a myelogram and was scored in the above-mentioned manner, but the level of herniation was not compatible with the patient's symptoms. Therefore, in this fashion, test results were biased against

the researchers since an asymptomatic herniated disc could occur in an exaggerated pain patient, resulting in a high physical score in a patient who was not having symptoms.

After all physical tests were scored, the number value for the test with the most severe physical abnormality was used to represent the degree of objective physical findings in a particular patient. For example, if a patient had no abnormalities on X-ray (a score of 0), but had mild abnormalities on CT (a score of 1), mild findings on EMG nerve conduction velocity studies (a score of 2), and a herniated disc on MRI (a score of 3), based on the combination of findings, the patient would be given a physical finding score of 3, the highest (most severe) physical abnormality.

Test Interpretation. Each scale score on the PVT, when available, was recorded for analysis, as well as the total score on the PVT. In the past, the PVT was administered by five persons at a single center, previously reported as having a 91% rate of interrater reliability.[24] However, in this study, interrater reliability between centers was not tested. Several errors occurred in scoring the PVT. The most common error consisted of scoring the question dealing with the patient's response to sleep. In this question, the patient was asked to rank his or her difficulty with falling asleep at night or waking during the night as a result of chronic pain. The lower of the two scores should have been used, not the combined total of the two scores. Other errors consisted of applying the test to headaches and other types of pain for which the test was not designed, which invalidated several sets of data. The other complication occasionally found was the utilization of the test for patients who had pain less than 6 months. Tests administered by non-clinicians without medical expertise, such as secretaries or assistants, were found to have errors on evaluating medication or correct anatomical location of pain. In one set of data, 9 out of 24 tests had to be cor-

rected because the question pertaining to sleep was scored incorrectly. Several of the researchers did not include the actual test results, but only total scores on the test. Therefore, there are several potential sources of error. For patients scoring 21 points or greater and having a score of 2 or 3 on objective physical findings: (1) the questions pertaining to sleep medication or location of pain might have been inaccurately scored, resulting in a false elevation of their score on the PVT, or (2) these patients might have had a herniated disc or some other physical abnormality that was asymptomatic but resulted in a high physical score.

On the other hand, the patients scoring 17 points or less with 1 or 0 points rating their physical abnormalities could have had errors that were the result of incomplete medical evaluations and an absence of exhaustive physical testing. In fact, 6 of 7 patients who fell within the category of 17 points or less and had scores of 0 or 1 on physical testing had the minimum number of tests performed as defined above. A set of 25 tests had to be completely discarded because the physician who submitted this group of tests had used only X-ray and/or thermography in evaluating his patients. Another physician submitted 50 tests, 15 of which had to be discarded since there were no physical tests or only X-rays were obtained.

Data Analysis. A correlation coefficient using the Pearson Product Moment Correlation Test (R Test) was computed between the most severe objective physical test rating of each patient and the total of the Mensana Clinic PVT score. Scattergrams were plotted for the Mensana Clinic PVT versus the most severe physical finding. A chi-square test was used to analyze the significance of the frequency distribution of the scattergram, despite its limitations.[31]

Results

The scattergram for PVT scores compared with the severity of physical findings is shown in Figure 1. PVT scores for each patient were compared with scores for the most severe objective physical finding. A correlation of $r = 0.554$ was obtained, which is significant at the level of $p < 0.0001$.

Figure 2 shows a tabulation of the chi-square test for the Mensana Clinic PVT. The chi-square test result was 113, which was significant at $p < 0.00001$. On PVTs, the cut-off score considered to be an objective pain patient is 17 points or less. If a patient had 17 points or less, 94.2% of the time he or she had a physical abnormality that could be documented using objective testing
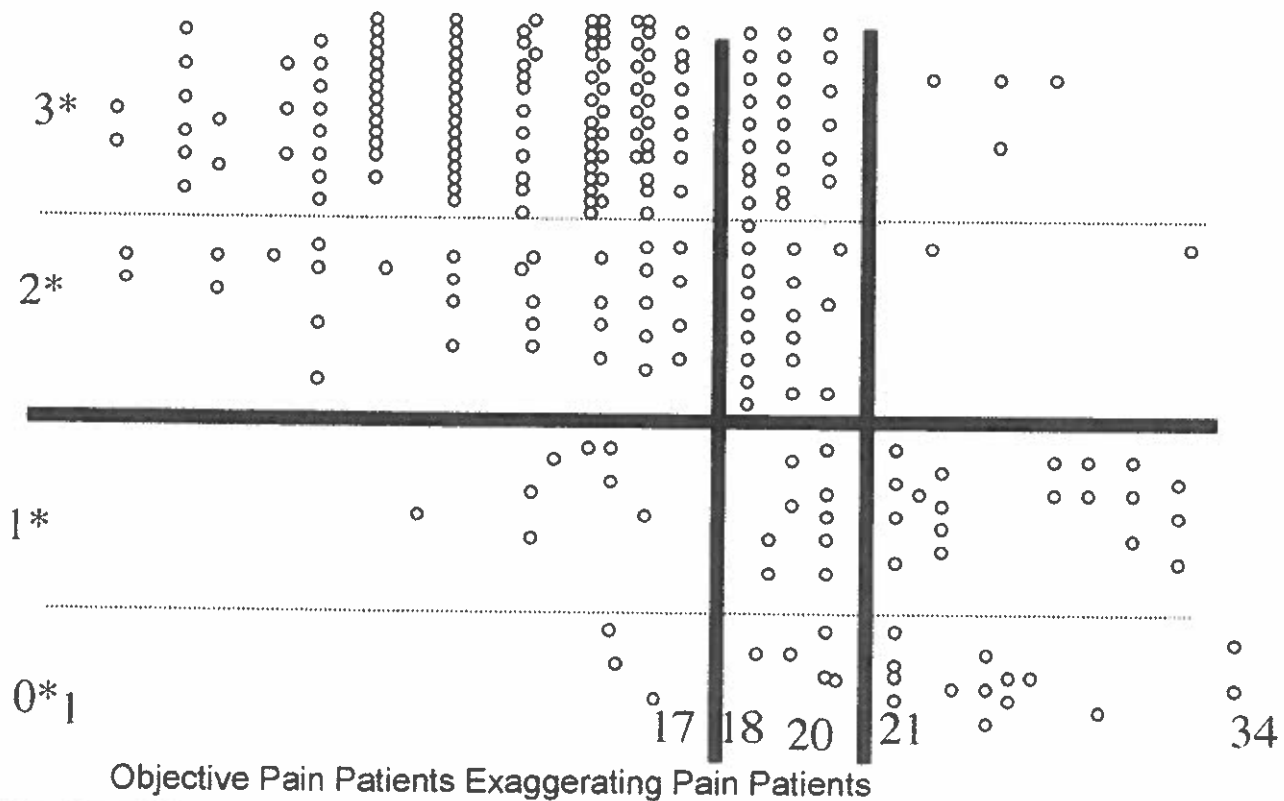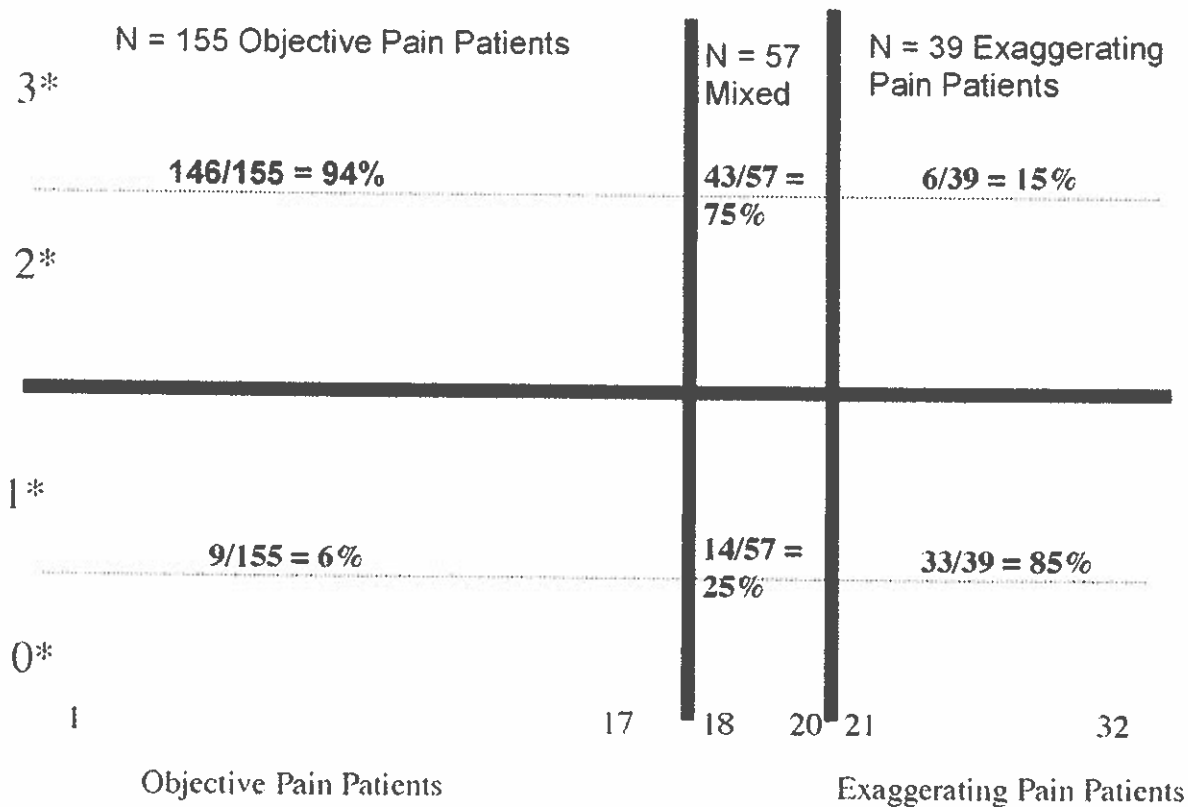

Figure 1. The Mensana Clinic Pain Validity Test

3*

2*

1*

0*1   17 18 20   21   34

Objective Pain Patients Exaggerating Pain Patients

Figure 2. The Mensana Clinic Pain Validity Test

N = 155 Objective Pain Patients   N = 57 Mixed   N = 39 Exaggerating Pain Patients

3*

146/155 = 94%   43/57 = 75%   6/39 = 15%

2*

1*

9/155 = 6%   14/57 = 25%   33/39 = 85%

0*

1   17   18   20 21   32

Objective Pain Patients   Exaggerating Pain Patients

*Severity of objective physical abnormality, 0=none, 1=mild, 2=moderate, 3=severe

described under physical tests (146/155). A score between 18 and 20 points, inclusively, was considered a mixed objective-exaggerating pain patient, and 75% of the time these patients had objective physical findings (43/57). This group may represent patients with a poor pre-morbid physiological adjustment who had documented physical pathological conditions. If a patient scored 21 to 29 points, inclusively on PVT, he or she was considered an exaggerating pain patient, and 83.3% of the time had only mild findings on objective tests of organic pathology or no positive tests (30/36). However, this group consisted of patients with definable organic syndromes, with only mildly abnormal or absent objective findings, such as those found in myofascial syndrome or facet syndrome. Only three of the patients had scores of 30 or more points on the PVT. This is consistent with earlier reported low incidence of functional pain patients, which would have placed them in the affective-pain patient category.[30] When combining exaggerating and affective pain patients, 84.6% (33/39) of these patients either had mild or absent objective measures of organic pathology.

Discussion

Much of the confusion that has arisen in the diagnosis of patients with chronic pain is based on the failure to recognize that organic pathology and psychiatric disorders may exist independently and do not necessarily have a cause and effect relationship.[10] Although much has been written about psychiatric disorders presenting as pain problems,[31,32] the incidence of this occurrence has never been clearly defined. However, the clinician must consider that chronic pain may create anxiety and depression.[9] In a study conducted in the psychiatry department of Johns Hopkins Hospital, Edwin and his co-workers were surprised to find that 80% of the 67 patients admitted to a psychiatry ward because of their complaint of chronic pain had physical abnormalities to explain their complaints.[33] Also, the incidence of psychiatric diagnosis using the American Psychiatric Association's *Diagnostic and Statistical Manual* criteria or the Symptom Checklist 90 Test was nearly the same in these pain patients whether or not they had documented physical disorders. Rosenthal lends credence to the concept that pain complaints and psychiatric disturbance exists on two separate axes and a clinician may not automatically assume that the coexistence of psychiatric disease and the complaint of pain means functional pain.[34] Indeed, chronic pain may create psychiatric problems, such as

depression, in a previously well-adjusted individual.[1,10,13]

The F scales of the MMPI correlated with the severity of objective organic pathologic conditions.[2] However, in two other test populations, it was found that either the depression scale (scale 2) of the MMPI negatively correlated with physical pathology,[26] or that none of the scales of the MMPI correlated with the severity of objective organic pathological conditions.[25] The variability in MMPI results suggests this test is unreliable for determining the validity of physical complaints.

Over 300 articles have been published using the MMPI to assess chronic pain patients. However, only one research report ever followed patients prospectively. From a pre-operative sample of 50,000 MMPIs, Hageron and his colleagues at the Mayo Clinic found 59 patients who subsequently had back surgery over a 20-year follow-up.[18] This group concluded that the MMPI abnormalities noted after the onset of back pain were the result of pain rather than a reflection of pre-existing personality traits.[18] In the absence of longitudinal studies, one cannot determine whether or not the MMPI scales are elevated prior to or as a result of the chronic pain syndrome.[35]

In summary, it seems that the MMPI cannot differentiate organic from functional low back pain with any degree of validity or reliability. In addition, it would be imprudent and irresponsible for a clinician to label any patient with chronic pain who happens to have elevations of MMPI scales as functional, since the MMPI cannot predict the presence or absence of an organic pathological condition with any degree of certainty in patients with chronic back pain.[36] Additionally, elevated MMPI scores in pain patients seem to be the result of pain rather than the cause of the complaint.[18,30]

Other psychological tests may correlate with the presence or absence of physical abnormalities, but, with the exception of PVT, no articles report any psychological tests capable of predicting the presence of absence of organic pathology. DSM-IV defines somatization disorder as a disorder that occurs in patients whose "multiple somatic complaints cannot be fully explained by any known general medical condition..."[37] However, this definition suffers from circular logic since many patients with concurrent psychiatric disease and chronic pain receive inadequate physical evaluations and are medically misdiagnosed 40% to 71% of the time.[38,39,40] This high misdiagnosis rate creates a self-fulfilling prophecy, leading to inappropriate psychiatric diagnoses, when in truth, the patient never received a proper medical diagnosis. In counter-distinction to the use of the DSM-IV criteria, the PVT assesses the impact of pain on the patient's life regardless of pre-existing abnormal personality traits or reactive psychological states.

When comparing the results from the research reported in this paper with earlier results, an improvement was noted in the ability of the PVT to predict the presence of abnormal physical findings on objective measures of organic pathology. This improvement is attributable to the increased number of objective tests that were ordered, as well as the addition of several previously unavailable, objective tests.

Specifically, in three previous articles I authored[25-27] only results of EMG, nerve conduction velocity studies, thermography, CAT scans, myelograms, or X-rays were used. In addition to those tests, this current research utilized MRI, both with and without gadolinium enhancement, quantitative flow-meter studies, provocative discometry, 3D CT, bone scans, and Indium scans. This may explain the improvement in the overall predictability of the objective patient component of the test, which increased from 85%[27] to 94% as reported in this article. On the other hand, in three previously reported studies, none of the patients (N = 13) who scored 21 points or greater had abnormal physical findings on objective measures of organic pathology.[25-27] With the increased number of patients who scored above 21 points as reported in this research, as well as the utilization of patients from clinics other than the Mensana Clinic, the predictive component of the exaggerating part of the test dropped from 100% to 86%.[27] This may be attributable to the small numbers, inaccurate scoring of the PVT on several questions that may give spuriously high readings on the overall test score, and/or the possibility that asymptomatic disc herniation and other abnormalities were scored as being positive physical findings but did not relate to the complaints that the patient had, but were included for the sake of completeness.

Additionally, since the interrater reliability seemed to be a variable that introduced a number of erroneous PVT scores, a method to reduce score variability was needed. Several self-scored versions of the PVT were developed, and the final version produced a 97% correlation of tests scores, with tests administered by Hendler, the developer of the PVT (unpublished data). The PVT is now available in a computer-administered version, and computer-scored forms and will soon be available over the Internet.

Only two other tests in the medical literature try to correlate the verbal history with actual findings on medical testing, the Ottawa ankle rules and the Ottawa knee rules. These tests were found to correlate with the presence and absence of organic pathology, and resulted in cost savings of over $50 million a year in preventing unnecessary X-rays for the Ottawa province of Canada.[42,43] The PVT differs from these two verbal tests since it can be used to predict the presence or the absence of abnormal laboratory tests of all types, not just X-rays, in patients with back, neck, and limb pain. This could result in even larger savings for health care systems.

The PVT may offer a viable objective

alternative to the more subjective psychiatric evaluation, independent medical evaluation, or the inappropriate use of the MMPI for differentiating organic from functional disorders. These current methods of evaluating the validity of a patient's complaint have a lesser chance of meeting the Daubert criteria since they do "not meet the applicable 'general acceptance' standard for the admission of expert testimony."[40] Furthermore, "expert opinion based on a scientific technique is inadmissible unless the technique is 'generally accepted' as reliable in the relevant scientific community."[41] With five published articles in peer-reviewed medical journals describing the accuracy of the Mensana Clinic PVT, medical evaluations utilizing this test are more likely to be accepted than just a medical evaluation alone or those that employ the MMPI. Additionally, the PVT may provide cost savings for insurance carriers in the same fashion as the Ottawa ankle and knee rules do while improving the quality of health care. By employing a multidisciplinary model rather than just a medical or psychological model for diagnosing chronic pain patients, a clinician may improve the accuracy of his or her evaluation to the benefit of all parties involved in the health care process.

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