

THE EFFICIENCY OF MULTIPLE IMPULSE THERAPY FOR MUSCULOSKELETAL COMPLAINTS

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ABSTRACT

Objective: The aim of the study was to document the response of patients to multiple impulse therapy for a variety of musculoskeletal complaints encountered in clinical practice.

Methods: A single practitioner in a private clinic setting provided the therapy to 249 patients. Survival analysis was used to plot probability of pain vs the days required for symptom resolution for each of 8 patient complaints. Analysis of variance was used to examine the influence of covariates such as age, sex, body mass index, and chronicity.

Results: The average number of visits required to achieve a pain-free state for each of 8 patient symptoms, the half-life for response to multiple impulse therapy, and comparison of the results of published studies of low back and neck pain are presented.

Conclusion: Response of patients in the study sample to multiple impulse therapy for symptoms of low back and neck pain appeared to be considerably faster than that obtained in 3 recent studies (J Manipulative Physiol Ther 2006;29:162.e1-162.e9)

Key Indexing Terms: *Manipulation; Musculoskeletal; Survival Analysis*

In a previous pilot study of the effectiveness of multiple impulse therapy for musculoskeletal complaints,¹ it was found that multiple impulse therapy compared favorably with published studies of other therapeutic regimens for the relief of pain. The study presented here uses the methodology developed in the pilot study to examine 249 patient files to report symptomatic responses to multiple impulse therapy. The results of this study are intended to serve as a sample for the comparison of future studies of this mode of musculoskeletal therapy.

METHODS

Setting

This study was performed in a privately owned chiropractic clinic in Dearborn, Mich. The clinical investigator

was experienced in the use of multiple impulse therapy having 9 years of experience in the development and use of the methods and instrumentation used for administration of the therapy.

Selection of Patients for Inclusion in the Study

Following guidelines established by 45 CFR.110 #7, this study was reviewed and approved by a local institutional review board. Two hundred forty-nine consecutive patients were selected for the study in the sequence that the patients sought care. Personal injury and workers' compensation cases were excluded from the study.

Instrumentation

Instrumentation has been used to provide mechanical percussive therapy to the spine since the invention of chiropractic.² Early percussive techniques included single impulses delivered with a stick and mallet and cam or pneumatically operated single and multiple percussive devices. The PulStarFRAS (Sense Technology Inc) was used to provide multiple impulse therapy to all of the patients in the study. This instrumentation was reviewed by the Food and Drug Administration of the United States Government and approved for marketing as a medical device in 1994 (510 K940085) and in its present form in 1998 (510 K973914).

The PulStarFRAS consists of 3 components that function in concert to provide the clinician an analysis of musculoskeletal stiffness at each vertebral level and a multiple impulse treatment. For analysis, the first component, a hand-held impulse head, is pressed against the patient and

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provides a single low-energy impulse to the vertebral level of interest. A force sensor in the impulse head measures the resistance to the impulse.

The second component, the impulse head control system, monitors the impulse head and provides the electrical impulses to the head to create the impulse, interpret the output of the head, and communicate the results of the analysis to the third component, a digital computer. The digital computer displays the results of the analysis, which may be thought of as a computer-assisted palpation of the spine, in a series of bar graphs. The analysis has been found to possess "good to excellent" repeatability.³

During the treatment phase, these components supply multiple impulses to the areas selected by the clinician while measuring the musculoskeletal stiffness at each impulse. The changes in musculoskeletal stiffness that occur during treatment are displayed for the clinician and used to monitor the treatment.

A complete description of the theory and operation of the PulStarFRAS is beyond the scope of this work but may be found in the US patents for the device, the PulStarFRAS User's Manual,⁴ in a publication by Evans.⁵

Protocol

The treatment of musculoskeletal symptoms with multiple impulse percussive therapy can be separated into 6 related steps. These are the following:

1. Collection and evaluation of preliminary general information, that is, completion of patient history, evaluation of patient symptoms, review of radiographs, and ancillary tests;
2. A preanalysis to determine the relative compliance or stiffness of the area of the musculoskeletal system of interest;
3. Analysis of stiffness readings in combination with other tests and observations resulting from patient history to determine site or sites of intervention;
4. Application of multiple impulse therapy to those sites chosen for intervention;
5. Postanalysis of the relative compliance of the same area of the musculoskeletal system;
6. Review of the results of the intervention by the clinician (often in concert with the patient) to confirm that the desired results have been achieved.

Each step in this process is conducted according to a basic clinical protocol developed by Collins.⁴ This protocol was supplemented with manual High Velocity Low Amplitude and drop table adjustments at the discretion of the treating physician. Manual adjustments were used for no more than 5% of the total number of patients.

Research Design

Kaplan-Meier survival analysis⁶⁻⁸ was used to estimate the course of recovery of patients with 8 major complaints

when treated with multiple impulse therapy. The output measure used in this study was the number of days from initiation of therapy until the patient was pain-free. A pain relief scale (PRS) was used to record the subjective rating of each patient's current level of pain compared with their pain on their first visit.⁹⁻¹¹ For the purpose of this study, a binary pain scale consisting pain or pain-free states could have served as well.

On the first visit, the clinician informed each patient whose current level of pain should be considered to be a 10 on an 11-point scale from 10 to 0, 10 being their current level and 0 being a pain-free condition. Each patient was asked to rate his/her current pain level compared with his/her initial pain level at the beginning of each subsequent visit. The pain ratings obtained at each patient visit were used to determine the number of days and/or visits required for each individual patient to reach the pain-free state. For the purpose of the Kaplan-Meier analysis used in this study, the visit-to-visit changes were ignored, and only the rating on the pain-free visit (0 PRS score) was used. That is, for the analysis, the pain-free state determined the final visit unless the patient was referred out or voluntarily left the treatment. Each patient reported his or her PRS score at the beginning of each subsequent visit. Therefore, if a patient reported that he/she had reached a pain free state at the beginning of a visit (visit *n*), it was assumed that the attainment of the pain-free state was achieved sometime between visit *n* and the previous visit (*n*-1).

Therefore, two estimates of patient response were generated from the data, one representing days to visit *n* and the other days to visit *n*-1. The larger of these estimates (days to visit *n*) is referred to as the upper bound and the smaller (days to visit *n*-1), the lower bound. Patient progress was followed up only until (1) patient symptoms were resolved, that is, the patient had reached the pain-free state; (2) the patient was referred out, or (3) the patient voluntarily quit the program. Many patients continued treatment after their symptoms were resolved. This study, however, addresses pain relief, not the ongoing preventive stage of patient care.

The days from the initial visit to the final visit on which the patient declared that he or she was symptom free (pain-free, PRS = 0) was used as input to a Kaplan-Meier survival analysis to determine the probability of pain during the course of therapy. If the patient was pain-free on the final visit, the patient was considered to have completed the course of therapy successfully, and the day of the last visit was entered into the Kaplan-Meier analysis as "uncensored." If the patient was not pain-free on the last visit, the patient was considered not to have completed the course of therapy successfully, and the day of the last visit was entered into the Kaplan-Meier analysis as "censored." The Kaplan-Meier survival analysis is designed to account for subjects who exit the trial before achieving the desired outcome (in this case, a "pain-free" state), and subjects who stay during the

Table 1. Patient age and sex by major complaint

| Sex | Number | Age (mean/SD) |
|-----------------|--------|---------------|
| Headache | | |
| F | 7 | 23/9 |
| M | 4 | 24/12 |
| Neck pain | | |
| F | 36 | 44/17 |
| M | 28 | 43/14 |
| Shoulder pain | | |
| F | 9 | 49/17 |
| M | 9 | 44/22 |
| Arm pain | | |
| F | 1 | 17 /- |
| M | 5 | 49/19 |
| Upper back pain | | |
| F | 10 | 34/10 |
| M | 12 | 40/20 |
| Lower Back Pain | | |
| F | 54 | 50/21 |
| M | 42 | 46/18 |
| Leg to knee | | |
| F | 15 | 17/4 |
| M | 4 | 10/5 |
| Leg below knee | | |
| F | 9 | 53/19 |
| M | 1 | 47/- |

F, Female; M, male.

course of the trial but also do not achieve the desired outcome. The terms *censored* and *uncensored* are specific to the Kaplan-Meier analysis procedure and are simply used to classify the outcome of each patient.

Statistical Analysis

Both parametric and nonparametric forms of statistical analysis were used in the analysis of the study data. Analysis of variance was used to examine possible interactions between patient characteristics such as age, sex, height, weight, body mass index, and the interaction between patient symptoms (major complaint and classification of chronic, subacute, and acute) and rate of recovery. The statistical program used for the analysis of variance was StatGraphics (Manugistics Inc, Rockville, Md). Because the distribution of the days to final visit was highly skewed, as what is typical of patient response data, this variable was transformed by a log transformation before analysis to meet the requirement of normally distributed data assumed for parametric statistical analysis. Patients who left the course of treatment before achieving the pain-free state were excluded from the parametric statistical analysis.

Kaplan-Meier survival analysis was used to illustrate patient response to multiple impulse therapy for all patients in the study, independent of complaint and for each group of patients sharing the same complaint. Kaplan-Meier survival analysis was developed to account for missing data, and therefore, patients who left the study before achieving the

Table 2. Distribution of patients exiting program before attaining no pain state by major complaint

| Symptom | Early exit | Achieved no-pain state |
|----------------|------------|------------------------|
| Headache | 3 | 8 |
| Neck | 3 | 61 |
| Shoulder | 0 | 18 |
| Arm | 0 | 6 |
| Upper back | 2 | 20 |
| Lower back | 5 | 91 |
| Leg to knee | 2 | 17 |
| Leg Below knee | 2 | 8 |

Table 3. Visits to resolve symptoms by major complaint

| Location of pain | Mean | SD | Median |
|------------------|------|-----|--------|
| Head | 4.5 | 3.5 | 3 |
| Neck | 3.6 | 1.7 | 3 |
| Shoulder | 3.4 | 1.4 | 3 |
| Arm | 3.8 | 2.4 | 2.5 |
| Upper back | 3.2 | 2.9 | 2 |
| Lower back | 3.8 | 2.0 | 4 |
| Leg to knee | 4.8 | 2.4 | 4 |
| Leg below knee | 5.2 | 4.2 | 3.5 |

pain-free state were included in the analysis. The Kaplan-Meier survival analysis was performed with the JMP statistical package (SAS Institute Inc, Cary, NC).

RESULTS

Summary Statistics

Of the 249 patient files reviewed, 107 were men (mean age, 46.7 years; SD, 19.6); 142 were women (mean age 45.7 years; SD, 18.7). Fifty-four patients identified the date of onset of symptoms as being less than 1 month before their first visit; these patients were considered to suffer from acute conditions. Fifty-two patients identified the date of onset of symptoms as being greater than 1 month and less than 3 months; these patients were classified as subacute. One hundred forty-three patients identified the date of onset of symptoms as being equal to or greater than 3 months and were classified as chronic. Table 1 shows the distribution of sex and age by major complaint.

Of the 249 patients, 232 (93%) stayed the course of therapy until they reached a pain-free state. The average number of visits for these patients before attaining that pain-free state was 3.9. Seventeen patients (7%) elected to exit the treatment program before attaining a pain-free state. The average number of visits for this group before leaving the program was 3.6. Table 2 shows the distribution of patients exiting the treatment program before attaining a pain-free state by major complaint. Table 3 shows the average, SD, and median visits for each patient complaint. Three patients'

Table 4. Results of analysis of variance using log of upper bound as the response variable

| Condition | All | | Neck pain | | Low back pain | |
|---------------------------------------|---------|-----|-----------|-----|---------------|-------|
| | F ratio | P | F ratio | P | F ratio | P |
| Factor or covariate | | | | | | |
| Age | 3.27 | .07 | 0.56 | .46 | 4.23 | .0435 |
| Body mass index | 0.69 | .41 | 0.09 | .76 | 0.89 | .35 |
| Acuteness | 2.56 | .08 | 0.11 | .90 | 1.26 | .29 |
| Sex | 0.06 | .87 | 0.60 | .44 | 0.24 | .62 |
| R ² (% variance explained) | 5.7% | | 3.1% | | 11.8% | |

Censored data are not included, and age is selected greater than 12 in an attempt to remove correlation with body mass index (n = 7 for all complaints, n = 2 for neck pain, and n = 1 for low back pain). Type III analysis is used.

Table 5. Results of analysis of variance using log of lower bound as the response variable

| Condition | All | | Neck pain | | Low back pain | |
|---------------------------------------|------|------|-----------|-----|---------------|-------|
| | F | P | F ratio | P | F Ratio | P |
| Factor or covariate | | | | | | |
| Age | 4.40 | .038 | 1.04 | .31 | 10.2 | .0021 |
| Body mass index | 0.08 | .78 | 0.91 | .35 | 0.05 | .82 |
| Acuteness | 0.52 | .59 | 0.24 | .79 | 2.45 | .0975 |
| Sex | 0.10 | .76 | 0.82 | .37 | 6.42 | .015 |
| R ² (% variance explained) | 4.2% | | 6.5% | | 3.6% | |

Censored data are not included and age is selected greater than 12 in an attempt to remove correlation with Body Mass Index (n = 7 for all complaints, n = 2 for neck pain, n = 1 for low back pain). Type III analysis is used.

major complaint of dizziness fell outside the pain categories used and were not included in the survival analysis.

Analysis of the Influence of Patient and Symptom Characteristics on Rates of Recovery

Analysis of variance revealed a statistically significant effect between age and the upper and lower bound of days to resolution of symptoms for low back pain. Sex was statistically significant for the lower bound for low back pain (Tables 4 and 5). No other statistically significant effects were found between the main outcome measures and patient or symptom characteristics.

Kaplan-Meier Analysis of Response Rates

The results were plotted using a Kaplan-Meier procedure for all patients independent of symptom as well as for each symptom subgroup (Figs 1-9). Two estimates of response rate were used because the pain evaluations were obtained

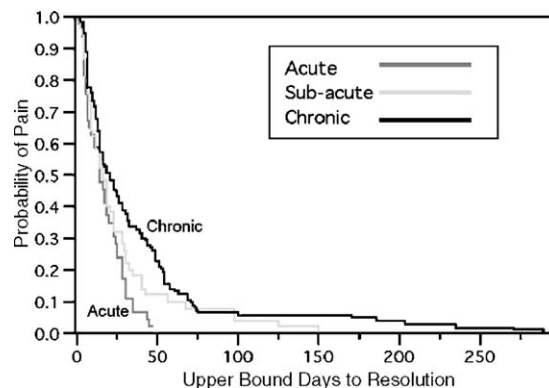


Fig 1. Comparison of response of patients classified as acute subacute and chronic for all complaints. Patients classified as acute had fewer members resistant to treatment than the subacute and chronic groups, although initial response rates were similar. These results were significant at the .001 level for the log-rank and the .014 level of the Wilcoxon formulations of χ^2 .

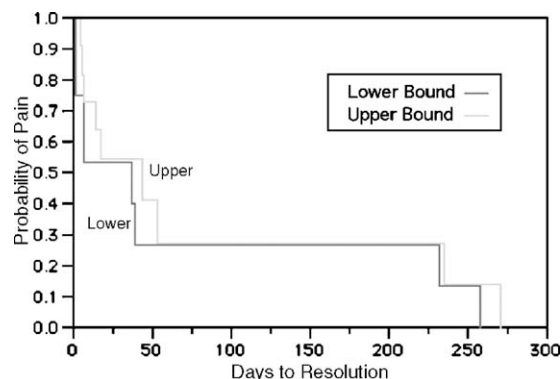


Fig 2. Kaplan-Meier results for headache.

before each visit. Each patient's pain status was reached sometime immediately after the last visit and before the current visit. Therefore, one Kaplan-Meier curve was generated using the last visit, and a second Kaplan-Meier curve was generated using the next to last visit. These 2 estimates of the rate of patient response form an upper and lower bound on the response rates. The experimentally determined days to 50% response for each patient symptom is shown in Table 6.

The Kaplan-Meier method was then extended in the following manner: the results of the Kaplan-Meier plot for low back pain were fitted to a logarithmic function using nonlinear regression. The Kaplan-Meier results and the fitted curves for low back pain are shown in Fig 10, along with the results for low back pain for general medical treatment (no manipulative treatment) from van den Hoogen et al.¹² The fitted curves are of the form:

$$P = Ce^{kt} + b$$

where P equals the probability of pain; C is a constant (in our case, $C = 1$ because the value of the function P equals

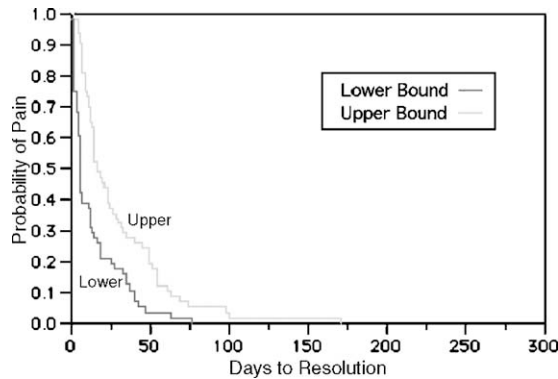


Fig 3. Kaplan-Meier results for neck pain.

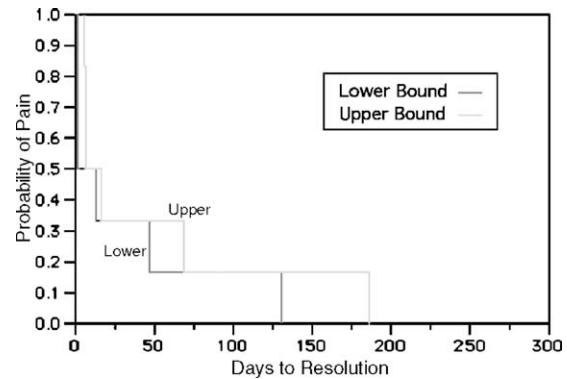


Fig 5. Kaplan-Meier results for arm pain.

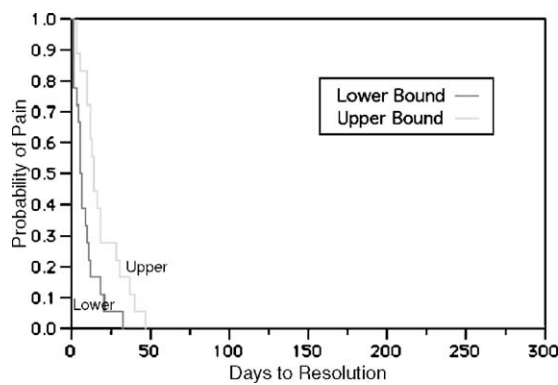


Fig 4. Kaplan-Meier results for shoulder pain.

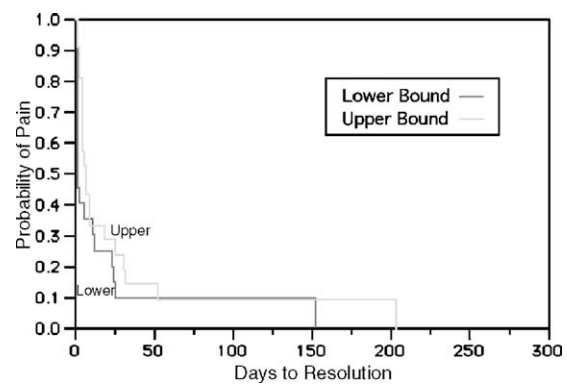


Fig 6. Kaplan-Meier results for upper back pain.

1 at time 0); e equals the base of natural logarithms (approximately 2.71828); k is a constant ($1/k$ is referred to as the time constant); t is time (in our case, expressed as days); b is a constant (in our case, $b = 0$ because the exponential function is asymptotic to the x-axis).

Knowledge of the constants C and k allows the time to 50% response (or half-life) to be calculated.

The half-life for the lower bound for low back pain is 9 days. This means that 50% of the patients have had their symptoms completely resolved in that 9-day period. The half-life for the upper bound for low back pain is 16 days. This extension of the Kaplan-Meier methodology enables a comparison of the results using only one figure of merit, the half-life of the patient response to therapy.¹³

DISCUSSION

Because the visual analogue scale (VAS) is more commonly used as an output measure in musculoskeletal research, the reader may be unfamiliar with the PRS and its use as a measure of pain relief rather than pain severity as measured by the VAS. The PRS is designed to measure the patient's current level of pain compared with initial pain on entering therapy. One end of the PRS scale represents the initial pain level (denoted by a value of 10) and the other

represents the pain-free state (denoted by a value of 0). Huskinson⁹ recommended the use of the PRS over the VAS when pain relief was the subject of the investigation. A recent study by Gridley and van den Dolder¹⁰ found that the PRS showed good correlations with all components of the Short Form McGill Pain Questionnaire except the affective component and also showed "very high" interrater reliability, concluding that the PRS was a valid and reliable alternative to the Short Form McGill Pain Questionnaire. A second study by Oshiro¹¹ comparing the VAS to the PRS over a period of 2 years concluded that the use of the PRS was preferable to the VAS because the PRS showed better correlation with an independent measure of patient satisfaction with treatment. In addition, Brauer et al¹⁴ studied the ability of subjects to recall previous pain states and concluded that patients are able to accurately recall and rate the severity of their pain for a period of 3 months.

The response of patients to multiple impulse therapy as reflected in the results of this study are similar to the results of the preceding pilot study¹ and appear to be more rapid than that reported in some studies of other methods of therapy for the case of low back and neck pain. For example, two recent studies of chronic neck pain^{15,16} indicate that after 12 to 20 sessions of treatment within 6 to 11 weeks (42-77 days), participants experienced approximately a 50% reduction in

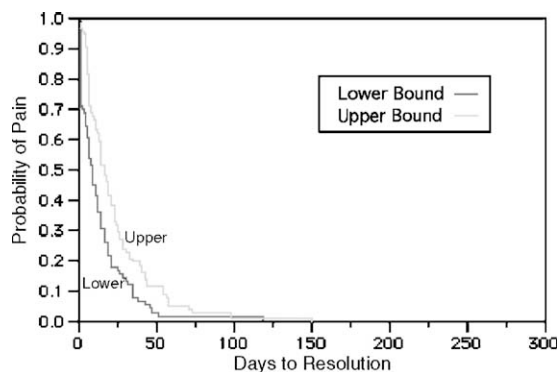


Fig 7. Kaplan-Meier results for low back pain.

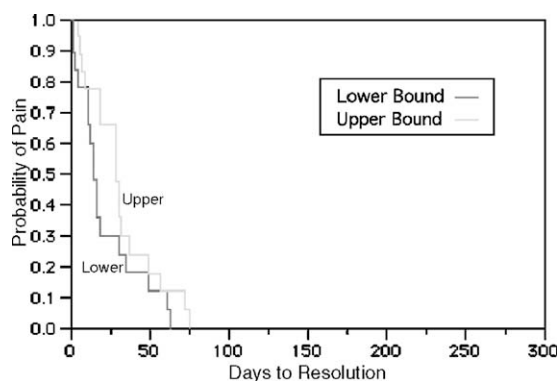


Fig 8. Kaplan-Meier results for leg-to-knee pain.

pain.^{17,18} Giles and Muller¹⁹ reported a median 42% improvement in VAS scores after 18 treatment sessions of 20 minute duration over a 9-week (63-day) period. The results of the present study indicate that 50% of patients treated with multiple impulse therapy for neck pain independent of chronicity experience a 100% reduction in pain in a mean of 3.6 treatments (median, 3 visits) within a period of 4 to 24 days (−95% confidence limit of lower bound to +95% confidence limit of upper bound). The patients in the current study included acute and subacute as well as chronic neck pain, but no differences in response were found that were attributable to this classification.

Comparing the results of the current study to recently published studies of low back pain, Giles and Muller¹⁹ report a 50% reduction in pain after 18 treatments using high-velocity, low-amplitude manipulation over a 9-week (63-day) period. Giles and Muller also reported that 27% of the patients treated with manipulation achieved asymptomatic status (pain-free) in the 9-week treatment period. The current study indicates that 50% of patients treated with multiple impulse therapy for low back pain independent of chronicity experience a 100% reduction in pain in a mean of 3.8 treatments (median, 4 visits) within a period of 5 to 21 days (−95% confidence limit of lower bound to +95% confidence limit of upper bound). Seventy-five percent of

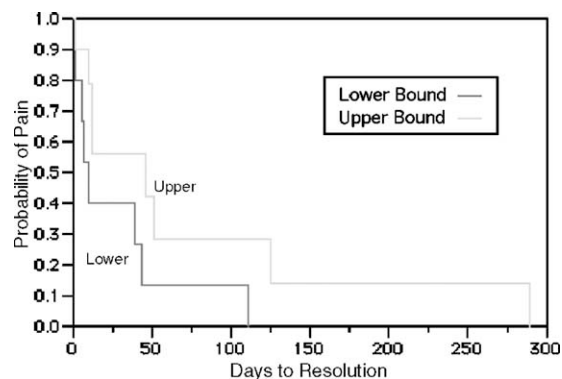


Fig 9. Kaplan-Meier results for leg-below-knee pain.

those patients had achieved the pain-free state within a median of 28 days after initiation of treatment.

It is difficult to construct a test of any therapy designed to treat musculoskeletal symptoms because there appears to be a large and rapid response to most interventions, even interventions that possess no manipulative component.^{20,21} This phenomenon is referred to as “spontaneous recovery” by Mathews et al.²² Unless the natural progress (natural history) of the condition can be explicitly accounted for in the research design, the researcher has no way to determine the effectiveness of the intervention over and above no intervention. This is especially important in the case of musculoskeletal complaints because there exists the possibility that the natural response of the body is predominant and that a specific intervention has no measurable effect in and of itself. This problem is not circumvented by even the most carefully designed randomized controlled trials (RCTs) if a no-treatment group is not included. Comparing the effects of 2 different manipulative techniques with an RCT without explicitly including the effect of the natural response rate leads to the result that all manipulative techniques show a treatment effect and, if the natural healing process is in fact predominant, that all manipulative techniques are equally effective.

The precise course of natural healing of the body when suffering a specific musculoskeletal complaint is unknown. However, in the case of nonspecific low back pain, there exists in the literature what might be thought of as a good first-order approximation. Here, we refer to the work of van den Hoogen et al.¹² who compared the response of patients treated with physical therapy and general medicine over the course of one year. The results reported by van den Hoogen et al may be as close an approximation of a “Gold Standard” for comparison of musculoskeletal treatments as exists in the literature. The rate of response of patients treated with an initial short period of care under the direction of a general practitioner represents a conservative estimate of the rate of response that might be obtained with no treatment at all. That is, intervention by the general practitioner would be expected to result in an increase in patient response over no

Table 6. Estimated half-lives of patient response for each major complaint with upper and lower 95% confidence limits and quartile response

| Location of pain | Lower limit | | | | | Upper limit | | | | |
|------------------|-----------------|---------|---------|-----|-----|-----------------|---------|---------|-----|-----|
| | Median response | -95% CL | +95% CL | 25% | 75% | Median response | -95% CL | +95% CL | 25% | 75% |
| Head | 37 | 1 | 231 | 7 | 231 | 44 | 4 | 235 | 14 | 235 |
| Neck | 5 | 4 | 11 | 3 | 18 | 16 | 14 | 24 | 9 | 45 |
| Shoulder | 6 | 3 | 10 | 3 | 11 | 14 | 10 | 19 | 10 | 28 |
| Arm | 13 | 0 | . | 1 | 47 | 16 | 5 | . | 7 | 68 |
| Upper back | 1 | 1 | 12 | 1 | 23 | 6 | 4 | 19 | 4 | 25 |
| Lower back | 9 | 5 | 12 | 1 | 18 | 16 | 13 | 21 | 7 | 28 |
| Leg to knee | 15 | 11 | 30 | 11 | 30 | 28 | 18 | 37 | 18 | 37 |
| Leg below knee | 18 | 0 | 44 | 5 | 44 | 46 | 0 | 125 | 12 | 125 |

CL, Confidence limit.

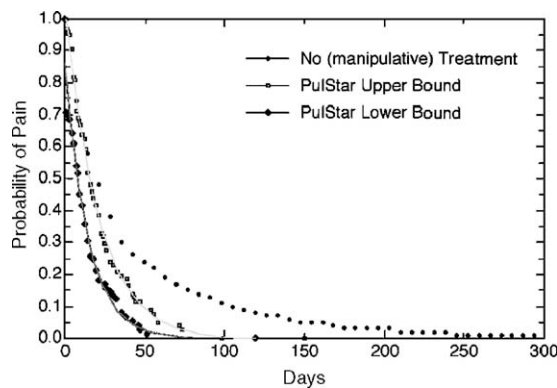


Fig 10. Comparison of response rates for low back pain patients treated with multiple impulse therapy (PulStar upper and lower bound) to results for general medical treatment (no manipulative treatment) from van den Hoogen et al.¹²

treatment. The van den Hoogen et al results represent an independent, external reference or standard for comparison to the results of other studies.

To be considered an effective intervention, the results of the intervention must exceed the rate of recovery observed without intervention. Figure 10 shows the results of the current study for low back pain compared with the results published by van den Hoogen et al¹² for the category of low back pain. Comparison of the graphs of the results of the two studies indicates that the patients treated with multiple impulse therapy evidenced a higher rate of response than patients treated with a medical protocol that included no manipulative therapy. The van den Hoogen et al results indicate that 50% of patients suffering low back pain experienced a 100% reduction in pain within a period of 14 to 28 days (-95% confidence limit to +95% confidence limit), whereas the results of the current study indicate that 50% of patients treated with multiple impulse therapy for low back pain independent of chronicity experience a 100%

Table 7. Results of current study compared with results of van den Hoogen et al¹²—estimated half lives of patient response for low back pain with upper and lower 95% confidence limits and quartile response

| Group | Median response | Lower 95% CL | Upper 95% CL | 25% | 75% |
|------------------------------------|-----------------|--------------|--------------|-----|-----|
| Lower bound | 9 | 5 | 12 | 1 | 18 |
| Upper bound | 16 | 13 | 21 | 7 | 28 |
| van den Hoogen et al ¹² | 21 | 14 | 28 | 7 | 49 |

reduction in pain in a mean of 3.8 treatments (median, 4 visits) within a period of 5 to 21 days (-95% confidence limit of lower bound to +95% confidence limit of upper bound) (Table 7). Thus, multiple impulse therapy would be considered effective by this standard.

It should be noted that the results of van den Hoogen et al¹² were based on data obtained through the use of patient questionnaires and not through a face-to-face encounter. The responses might reflect a better outcome if the data were obtained directly by the clinician because the patient might wish to please the clinician. This may be cited as a shortcoming of the current study. That is, the response of patients in the current study to multiple impulse therapy may have been less rapid if each patient had indicated the pain relief score on a form rather than by reporting verbally to the clinician. On the other hand, if reporting to the clinician may be used as a tool to encourage the patient to respond more quickly, then perhaps this mode of communication has a clinically important role and should be considered a strength rather than a weakness in the clinical setting.

An alternative explanation for these results is that the patient population in the current study is composed of subjects who respond more favorably to therapy than those in the van den Hoogen et al¹² study. Although the results obtained in the current study are similar to those obtained in a

prior pilot study using a different patient population, the comparison between the results of the current study and the results of the van den Hoogen et al study is of the first-order meaning that it is not a precise comparison. Comparing the results of one study to another or even comparing the results observed in two groups of patients in the same study may be more dependent upon factors that may influence the response of individual patients to therapy that are unknown. All studies suffer from this problem, as there is no classification system of patients with low back pain who enable the investigator to be assured that two groups are balanced in their response to therapy. Therefore, even in RCTs, the possibility exists that the patients may suffer from fundamentally different complaints simply because the investigators have no method of randomizing or otherwise grouping subjects that will ensure that each patient group is composed of equal proportions of patients with similar severity, responsiveness to therapy, or even basic underlying causes.

Suggestions for classifying patients based on response to the first adjustment²³ may have merit but cannot be implemented a priori. One might propose that patients be classified based on pain severity using the VAS. Although the VAS is considered by many^{24,25} as a validated instrument for the measurement of pain severity, other researchers have reservations.²⁶⁻²⁹ Although apparently widely held among practitioners, the belief that a patient with greater pain intensity will respond more slowly to treatment than a patient with lower pain intensity is not supported in the literature. In fact, the literature is surprisingly silent on this issue. An immediate problem with this approach is that patients exposed to the same painful stimulus report greatly different VAS scores.³⁰ This undermines the assumption that the VAS score may be used to differentiate the true severity of an individual's perception of pain, which is an irreducibly subjective phenomenon.

“In whatever way we try to define pain, it is not clear that we can ever meaningfully contradict a person who says that he or she is in pain—if somebody complains of pain, then by definition what he or she is experiencing must be pain. The definition of what is or is not pain lies firmly within the individual concerned. . .there is a fundamental uniqueness to the pain experience, and this works against the second goal of criterion-related validity. If the fact that somebody is in pain is ultimately to be judged by that person alone, it follows that the degree of pain similarly has no external, criterion measure.” (Sim and Waterfield³¹).

The nascent study of classification systems for the prediction of patient response to manipulation that is ongoing at the University of Pittsburgh School of Medicine^{32,33} may prove to be useful in the effort to identify factors that influence the outcome of manipulative therapy, but as of now, investigators simply do not know what variables to include in manipulative studies as covariates.

This study is original in at least 2 dimensions. First, the study presents patient response rates to therapy for 8 musculoskeletal conditions commonly seen by clinicians. Secondly, the outcome measurement used in the study is the complete relief of pain. This is a departure from the norm because similar studies published in the literature accept partial resolution of pain, such as 50% or 80% reduction, as sufficient to show the effectiveness of a therapy. This study shows that complete pain resolution is a possible outcome measure and a practical measure as well. An important aspect of the study is that the results strongly suggest that even with a higher standard for judging success, it is possible to attain the goal of symptom resolution at a rate considerably faster and with fewer visits than that reported by other studies in the literature, even when those studies used output measures that were considerably less stringent.

The results presented here represent a snapshot in time of the response of musculoskeletal symptoms to multiple impulse therapy. As clinicians gain greater experience with this methodology and as studies such as this increase the knowledge base regarding multiple impulse therapy, we expect that the results obtained in future studies will show improvement over the results obtained in the current study.

Limitations of the study include the following: the clinician supplemented the multiple impulse therapy with manual adjustments; the study was conducted at a single clinic; and only one clinician provided the treatment. The patients reported their pain scores directly to the clinician, which may have biased the study toward a more rapid patient response to therapy. The comparisons of the results of the study with other published studies were of the first order, and although suggestive, are not definitive. Before these results may be extended to the general patient population, additional studies are required that include multiple clinicians and clinics and improved research designs to include blinded data collection and RCTs.

CONCLUSION

Response of patients in the study sample to multiple impulse therapy for symptoms of low back and neck pain appeared to be considerably faster than that obtained in 3 recent studies. The results of this study are in agreement with a previous pilot study and support the continued study of multiple impulse therapy provided by the PulStarFRAS as a means of resolving musculoskeletal symptoms.

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