The evaluation of phonophoresis and friction massage as treatments for extensor carpi radialis tendinitis: a randomized controlled trial

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The purposes of this study were to determine whether ultrasound and a 10% hydrocortisone ointment (phonophoresis) was superior to ultrasound and a placebo ointment, and to determine whether friction massage was superior to no friction, in patients with the clinical diagnosis of extensor carpi radialis tendinitis (proximal tendon). Forty consecutive lateral epicondylitis patients fulfilling the eligibility criteria were entered into the study. Using a 2 by 2 factorial design, the patients were stratified on the basis of pain-free grip strength. They were then randomly assigned to 1 of the 4 treatment groups. The patients' outcomes were assessed following 9 treatments within 5 weeks of the initial visit. No one therapy was demonstrated to be superior to another; however, site of lesion and history of a prior occurrence were found to be predictors of outcome, independent of therapy. The results suggest that the most cost-effective method of treating the lateral epicondylitis patient is by ultrasound alone.

KEY WORDS: Tennis elbow, lateral epicondylitis, ultrasound

Les objectifs de cette étude étaient de déterminer si les ultrasons additionnés d'onguent d'hydrocortisone à 10% (phonophorèse) étaient supérieurs aux ultrasons additionnés d'un onguent au placebo et de déterminer si le massage par friction était supérieur à l'application d'aucune friction chez les patients présentant un diagnostic clinique de tendinite de l'extenseur du carpe (tendon proximal). Quarante malades consécutifs souffrant d'épicondylite latérale répondant aux critères d'admissibilité ont été inscrits à l'étude. En utilisant une expérience factorielle de 2 par 2, on a placé les malades suivant leur pronostic en se basant sur leur force de prise sans douleur et on les affectant au hasard à 1 des 4 groupes de traitement. On a évalué les résultats chez les patients après 9 traitements (dans les 5 semaines de la visite initiale). On a démontré qu'aucune méthode n'était supérieure à une autre; toutefois, on a constaté que l'endroit de la lésion et l'existence d'une lésion précédente permettaient de prédire le résultat, indépendamment de la thérapie. Les résultats semblent indiquer que les ultrasons seuls constituent la méthode la plus rentable de traitement de l'épicondylite latérale.

Tendinitis of the extensor carpi radialis longus and brevis tendons at or near their proximal attachments—also known as tennis elbow or lateral epicondylitis—appears in sufficient quantities clinically to be of interest to the physical therapist. Allander, in a community survey of 15,000 subjects between the ages of 34 and 74 years, demonstrated age- and sex-specific prevalences of between 1 and 10%.[1] This survey also demonstrated a declining prevalence of epicondylitis after the age of 42, suggesting that it is not a degenerative condition.[1]

Traditionally, a myriad of conservative therapies have been employed by the physical therapist to treat extensor carpi radialis tendinitis. Of the many therapies advocated for the treatment of this condition, only ultrasound alone has been tested in a randomized clinical trial and reported to be effective.[2] Several of the many other therapies used to treat this form of tendinitis—two of which have been phonophoresis and friction massage—have received ongoing attention.

Evidence supporting the clinical use of ultrasound to disseminate subcutaneous infiltrations of hydrocortisone (phonophoresis) appeared in the literature as early as 1954. At that time, Fellinger and Schmid described the apparently successful treatment of polyarthritis of the hand using ultrasound, and a hydrocortisone ointment as the coupling agent.[3] Following this report, results of a variety of descriptive studies supported the use of phonophoresis.[4-8] The first studies to examine the biologic rationale for this mode of therapy were reported on by Griffin and Touchstone.[9,10] These investigators, reporting on histochemical studies performed on swine,

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demonstrated that the entire molecule of hydrocortisone is driven into the tissue. Further, they reported that the depth of penetration is proportional to the intensity of the ultrasound, and that a depth of 6 cm can be achieved. Griffin, in a prospective study, reported on a variety of orthopaedic cases that were treated by phonophoresis and ultrasound alone.[11] The results suggest that the success rate was significantly greater in the phonophoresis group. Kleinkort and Wood reported differences in the success rate for a 1% hydrocortisone ointment compared to a 10% hydrocortisone ointment, when used as a coupling agent for ultrasound.[12]

Both of these studies included a variety of conditions (bursitis, tendinitis, osteoarthritis) at an assortment of sites. In order to minimize the impact that the unequal distribution of conditions may have had on the previous two studies, we performed a sub-analysis on the condition, epicondylitis at the elbow. This analysis revealed similar success rates for the 1% phonophoresis group and the ultrasound alone group (31% and 28% respectively), as well as similar success rates for the 10% phonophoresis groups (Kleinkort 66%, Griffin 62%). These differences were determined to be statistically significant. The similarity in success rates is interesting given the difference in treatment regimens.

The regimen reported on by Griffin consisted of an ultrasound intensity that never exceeded 1.5 w/cm² and a treatment duration of 5 minutes for each 25 sq ins of skin. The patients were treated once a week for 3 weeks. The authors further reported that, if at the end of this time the patient was not experiencing lasting pain relief, an additional 6 treatments were performed on alternate days. The regimen reported on by Kleinkort and Wood consisted of a maximum ultrasound intensity of 2.0 w/cm² and a treatment duration of 6 minutes. Treatments were performed daily and usually consisted of 5 to 7 treatments.

Treatment of tendinitis by deep transverse friction massage has been advocated by Cyriax[13] and is currently being applied extensively in clinical practice; however, no clinical trials either supporting or refuting the benefits of this approach have appeared in the literature. The reported effects of deep friction massage are (1) traumatic hyperemia to the involved area, and (2) movement of the involved tissues resulting in a breaking down of adhesions.[11]

The purposes of this study, in the treatment of patients with the clinical diagnosis of extensor carpi radialis tendinitis (proximal tendon), were (1) to determine whether ultrasound and a 10% hydrocortisone ointment (phonophoresis) was superior to ultrasound and a placebo ointment (coupling gel only), and (2) to determine whether friction massage was superior to no friction massage.

METHODS

Patient sample

The study setting was a community sports injuries clinic. Forty consecutive patients who provided informed consent and fulfilled the eligibility criteria were entered into the study. A review of the sample characteristics are provided in Table 1.

Selection criteria

Patients were eligible for this study if they had complained of discomfort at or about the lateral epicondyle and had tenderness on palpation over one of the following areas: (1) the origin of the extensor carpi radialis longus tendon (ECRL); (2) the origin of extensor carpi radialis brevis tendon (ECRB-O); (3) the extensor carpi radialis brevis at the tendon body (ECRB-TB); or (4) the extensor carpi radialis brevis tendon, with tenderness extending from the origin to the tendon body (ECRB-O+TB), pain at the lateral aspect of the elbow during resisted wrist extension, and radial deviation during complete elbow extension. Subjects were excluded from the study if they had (1) combined lesions (e.g., cervical and elbow problems or multiple lesions about the elbow), (2) bilateral elbow problems at initial assessment, (3) history of prior elbow surgery, or (4) history of an injection to the elbow within the past 6 months.

TABLE 1 Pre-intervention characteristics by treatment group

Variable	*Ultrasound plus Placebo Ointment*	*Ultrasound plus Frictions*	*Phonophoresis*	*Phonophoresis plus Frictions*
Sample size	9	11	10	10
Age (yr)	43.8 (9.8)*	44.6 (9.8)	40.1 (8.3)	44.7 (8.7)
Sex (male)	2	5	5	8
Duration (mo)	4.3 (3.2)	2.1 (1.2)	5.2 (7.2)	5.4 (4.1)
First occurrence	6	8	7	4
Dominant involved	8	7	10	8
Site				
ECRL	0	0	1	0
ECRB (O)	1	3	1	4
ECRB (TB)	4	6	4	3
ECRB (O&TB)	4	2	4	3

* Mean and standard deviation

Study design

The study design was a two by two factorial design (Appendix 1). On the basis of their pain-free grip strength expressed in ratio format (RPFG), patients were prognostically stratified as (1) greater than 0.50, or (2) less than or equal to 0.50. This index was determined by dividing the pain-free grip strength by the maximum grip strength of the uninvolved limb. Following stratification, the subjects were randomly assigned, using a balanced blocked randomization table (within stratum), to receive either (1) ultrasound and placebo ointment without frictions, (2) ultrasound and placebo ointment with frictions, (3) phonophoresis without frictions, or (4) phonophoresis with frictions (Table 1). The study ended following 9 treatments. Usually, 3 treatments were performed each week. All follow-up assessments were performed within 5 weeks of the initial visit.

Interventions

At the time of this study, no therapeutic ultrasound dose-response curves for patients with tendinitis of the extensor carpi radialis tendons, or for humans with chronic tendonitis at any site, were available. (This study was initiated prior to publication of the article by Binder et al[2].) The dose determination was therefore based on current principles employed in clinical practice. In determining the dose for an individual patient, consideration was given to patient comfort, proximity to bony prominences, and the apparent amount of adipose tissue present. The dosage varied from 1.5 w/cm² continuous output to 0.5 w/cm² pulsed (1:4) output. The output of the soundhead was verified weekly using a water-balance arrangement. The application technique consisted of moving the soundhead in slow concentric circles, while at the same time maintaining soundhead contact with the patient. Treatment was applied for 6 minutes. The coupling mediums were prepared by a pharmacist in such a way that neither the therapists nor the patients knew which mixture contained the hydrocortisone. The base consisted of ultrasonic transmission gel.

The friction massage technique used in this study was the one advocated by Cyriax.[13] Briefly, the technique consisted of a vigorous 10-minute friction massage applied perpendicular to the structure of interest. When the lesion lay at the origin of the extensor carpi radialis longus tendon or the origin of the extensor carpi radialis brevis tendon, the patient's elbow was flexed to 90 degrees and the forearm was fully supinated. When the lesion was at, or included, the tendon body of the extensor carpi radialis brevis tendon, the patient's elbow was flexed to 45 degrees, and the forearm was fully pronated.

In addition to the interventions described above, all patients were asked to avoid activities that irritate the elbow, and to refrain from taking anti-inflammatory medication during the course of the study. Prior to each treatment session, patients reported the extent to which they complied with these instructions, and this information was recorded on data sheets.

Prior to initiating the study, the 3 therapists involved conducted practice sessions aimed at standardizing administration of the specific treatment techniques to be provided. No stratification by therapist was performed.

Outcome assessment

Five outcome measures were used to evaluate the patients. The principal outcome measure was the dichotomous rating of success or failure. Success was defined as a major positive step in patient management. At the initial visit, all patients experienced moderate discomfort with resisted wrist extension (performed with the elbow extended). The initial management program therefore avoided stressing the wrist extensors. A major positive step in patient management was

TABLE 2 Pre-intervention group score means and standard deviations

	Ultrasound plus Placebo Ointment	*Phonophoresis*	*Combined*
No massage			
PFF	2.1 (1.8)	3.3 (1.9)	2.7 (1.9)
PVAS	32.9 (22.4)	20.8 (18.1)	26.5 (20.6)
FVAS	66.0 (25.0)	80.0 (21.0)	73.1 (23.9)
RPFG	0.6 (0.3)	0.6 (0.3)	0.6 (0.3)
Friction massage			
PFF	2.3 (1.4)	3.5 (2.2)	2.9 (1.9)
PVAS	56.0 (27.0)	24.8 (17.1)	41.1 (27.4)
FVAS	65.3 (24.9)	79.6 (21.6)	72.1 (23.9)
RPFG	0.5 (0.2)	0.5 (0.3)	0.5 (0.2)
Combined			
PFF	2.2 (1.5)	3.4 (2.0)	2.8 (1.9)
PVAS*	45.6 (27.1)*	22.8 (17.3)*	34.2 (25.2)
FVAS	65.6 (24.3)	79.8 (20.7)	72.7 (23.4)
RPFG	0.6 (0.23)	0.6 (0.3)	0.6 (0.3)

PFF = pain-free function (average number of items), PVAS = pain visual analog scale (average score in mm), FVAS = function visual analog scale (average score in mm), RPFG = ratio index of pain-free grip strength ÷ grip strength of the uninvolved limb
* $p < 0.05$

TABLE 3 Post-intervention group score means and standard deviations

	Ultrasound plus Placebo Ointment	*Phonophoresis*	*Combined*
No massage			
PFF	2.7 (2.1)	3.6 (2.6)	3.2 (2.3)
PVAS	28.3 (17.0)	21.8 (30.4)	24.9 (24.5)
FVAS	78.1 (16.5)	78.8 (23.7)	78.5 (20.0)
RPFG	0.6 (0.3)	0.7 (0.3)	0.6 (0.3)
Friction massage			
PFF	3.8 (2.7)	3.7 (2.8)	3.8 (2.7)
PVAS	44.8 (33.4)	24.6 (20.6)	35.2 (29.3)
FVAS	76.3 (21.9)	82.5 (16.3)	79.2 (19.2)
RPFG	0.7 (0.3)	0.5 (0.3)	0.6 (0.3)
Combined			
PFF	3.3 (2.4)	3.7 (2.6)	3.5 (2.5)
PVAS	37.4 (27.9)	23.2 (25.3)	30.4 (27.3)
FVAS	77.1 (19.2)	80.7 (19.8)	78.9 (19.4)
RPFG	0.6 (0.3)	0.6 (0.3)	0.6 (0.3)

PFF = pain-free function (average number of items), PVAS = pain visual analog scale (average score in mm), FVAS = function visual analog scale (average score in mm), RPFG = ratio index of pain-free grip strength ÷ grip strength of the uninvolved limb
$p > 0.05$ for all values in this table

defined as the ability to progress the patient to a pain-free strengthening program for the wrist extensor muscles, performed with the elbow extended, with no subsequent regression within 4 weeks of follow-up. This decision was made by the physician assessor who was blind to both interventions.

Further, this judgment was made independent of the 4 remaining outcome measures which consisted of a vertical 100 mm visual analog pain scale (PVAS measured in mm), a vertical 100 mm visual analog function scale (FVAS measured in mm), an 8-item pain-free function index (PFF measured as the number of pain-free items), and a measure of pain-free grip strength of the involved limb (PFG measured in kg of force), expressed as a ratio of the maximum grip strength of the uninvolved limb (i.e., pain-free grip divided by the maximum grip of the uninvolved limb). The extent to which these outcome measures have been demonstrated to be reliable, valid and sensitive to change has been reported previously.[14] Briefly, for outcome measures used in the current study, the validation study demonstrated intraclass correlation coefficients (Shrout and Fleiss type [1,1][15]) in the order of 0.85 to 0.93 and sensitivity coefficients that were a minimum of 5 times greater than the random error.

Analysis

In keeping with a factorial design, the data analysis for the dichotomous outcome measure success or failure was based on chi-square tests of proportions and focused on the two main effects questions: (1) Was phonophoresis superior to ultrasound alone? and (2) Was friction massage superior to no massage? Due to an initial imbalance in some of the pre-intervention scores, an analysis of covariance was performed on the remaining outcome measures. The covariate used in each case was the pre-intervention score (i.e., post-intervention score = constant + pre-intervention score + ointment group + friction group + interaction).[16] An analysis of covariance was also performed to examine the effect of therapy after adjusting for the effect of different ultrasound dosages (i.e., ultrasound intensity and mode of application were added to the above equation).

In addition to the primary analysis mentioned above, secondary analyses were performed in order to identify potential predictors of patient outcome, independent of therapy. This approach consisted of a forward stepwise multiple regression analysis for the following variables: age, compliance with rest, duration of symptoms and pre-intervention scores. At the same time, contingency table analyses were performed on the variables: sex, site of lesion, dominance and history of prior occurrence.

Results

The results of randomization (pre-intervention data) are provided in Tables 1 and 2. A significant difference ($p < 0.05$) in the pre-pain visual analog (PVAS) scores is evident in Table 2. No other significant differences in the pre-intervention data were noted (i.e., $p > 0.05$).

Five of the 20 patients (25%) assigned to the placebo ointment group and 5 of the 20 patients (25%) assigned to the phonophoresis group were deemed to be successes. Clearly, this difference is not statistically significant (see Figure 1).

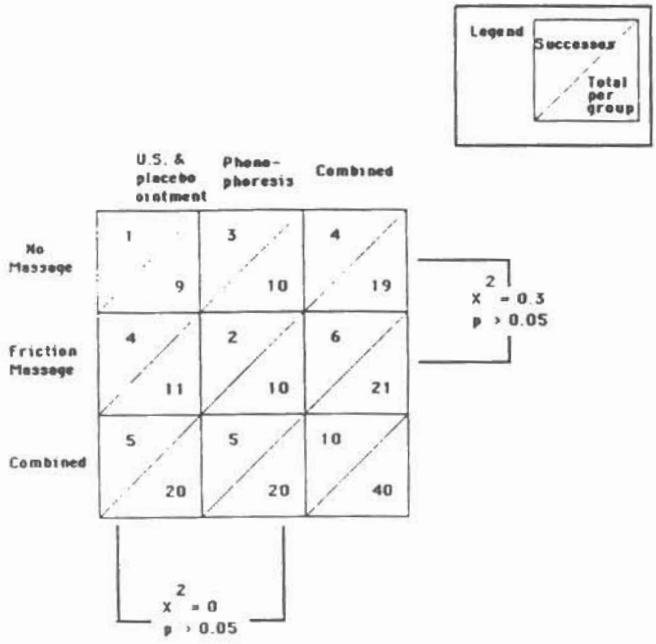

Figure 1 This figure illustrates the number of successes for each treatment combination and also includes the chi-square and probability values for the main effects questions.

Four of the 19 patients (21%) not receiving frictions and 6 of the 21 patients (29%) receiving frictions were also successes. This difference is neither statistically significant ($p > 0.05$) nor does it fulfill our criteria for a clinically significant difference.

Analysis of both the adjusted and unadjusted postintervention scores failed to detect statistically significant differences or interaction* between the two main effects questions (i.e., placebo ointment versus phonophoresis and no massage versus friction massage). (See Tables 4 to 7 for the analysis of covariance.) A second analysis of covariance, adjusting for ultrasound dosage—both intensity and mode (i.e., continuous or pulsed), also failed to highlight any significant difference ($p > 0.05$) among the treatment groups. Further, this analysis did not demonstrate an association between ultrasound dosage and patient outcome, regardless of treatment group.

The results in Table 8 suggest that patients with tenderness over the origin of extensor carpi radialis brevis and patients with a recurrent episode of epicondylitis have a poorer response to conservative therapy.

Discussion

The finding that phonophoresis does not appear to be superior to ultrasound and placebo ointment is in disagreement with works by Griffin[9] and Kleinkort[10]. A review of the methods section of these papers suggests that neither study

* *The analysis of covariance also included interaction terms relating to the pre-score with treatments. As these terms were not statistically significant, they were removed from the ANOVA tables. While the treatment interaction term (ointment × friction) was not significant, it was left in the ANOVA tables to demonstrate a uniform treatment effect.*

TABLE 4 Analysis of covariance for pain-free function

Source	DF	SS	MS	F	p
Pre-score	1	95.12	95.12	23.61	0.00
Phonophoresis	1	0.06	0.06	0.02	0.90
Friction	1	5.03	5.03	1.25	0.27
Interaction	1	2.93	2.93	0.73	0.40
Error	35	141.02	4.03		

TABLE 5 Analysis of covariance for pain VAS score

Source	DF	SS	MS	F	p
Pre-score	1	6764.47	6764.47	12.59	0.00
Phonophoresis	1	5.76	5.76	0.01	0.92
Friction	1	14.55	14.55	0.03	0.87
Interaction	1	5.88	5.88	0.01	0.92
Error	35	18,807.17	537.35		

TABLE 6 Analysis of covariance for function VAS score

Source	DF	SS	MS	F	p
Pre-score	1	2689.86	2689.56	8.05	0.01
Phonophoresis	1	92.63	92.36	0.28	0.60
Friction	1	12.16	12.16	0.04	0.85
Interaction	1	72.98	72.98	0.22	0.64
Error	35	11,695.31	334.15		

TABLE 7 Analysis of covariance for ratio pain-free grip*

Source	DF	SS	MS	F	p
Pre-score	1	1.42	1.42	29.64	0.00
Phonophoresis	1	0.05	0.05	0.88	0.35
Friction	1	0.08	0.08	1.62	0.21
Interaction	1	0.11	0.11	2.27	0.14
Error	35	1.68	0.05		

* Pain-free grip divided by maximum uninvolved grip

TABLE 8 Probability of success by site and prior occurrence

Item	Probability of Success	95% Confidence Interval
ECRL (n = 1)	0	Undefined
ECRB–O (n = 9)	0	Undefined
ECRB–TB (n = 17)	0.47	0.23–0.71
ECRB–O&TB (n = 13)	0.15	0–0.34
Prior occurrence (n = 15)	0.07	0–0.20
First occurrence (n = 25)	0.36	0.17–0.55

represents a randomized clinical trial. Further, the extent to which the outcome measures used by these authors were reliable, valid and sensitive to a clinically important change was not reported. Our findings are in agreement with the work of Halle and colleagues. In a randomized clinical trial, they evaluated 4 therapies (ultrasound, phonophoresis–10% hydrocortisone, transcutaneous electrical nerve stimulation, and injection with lidocaine and hydrocortisone) in patients with lateral epicondylitis at the elbow, and reported no one therapy to be more effective than the others.[17] These authors did not recognize potential confounding variables nor did they report the power of their statistical test. Similar findings were also reported by Antich and colleagues, who, in a randomized controlled trial of 4 treatment modalities (2 of the 4 modalities included ultrasound and ice and phonophoresis) advocated for knee extensor disorders, concluded that phonophoresis was not superior to ultrasound and ice.[18]

No clinical trials, either controlled or uncontrolled, reporting the effectiveness of friction massage could be found. In a study performed on rabbits to examine the effect of deep transverse friction massage on the healing of minor medial collateral ligament sprains, Walker concluded that her histologic study did "not support the hypothesis that deep transverse frictions prevent random binding of newly formed collagen fibers."[19]

The overall success proportion in our study was 0.25 and this proportion is comparable to the ultrasound alone groups for both the Griffin[11] (0.28) and Kleinkort[12] (0.31) studies. In a more recent study, Binder and colleagues reported a success proportion of 0.63 for those patients treated with ultrasound.[2] Many factors, could account for the differences in success proportions among these studies. These include failure to standardize diagnostic criteria, failure to acknowledge that all patients with the diagnostic label of lateral epicondylitis do not have the same short-term prognosis when treated with conservative therapy, failure to standardize treatment and treatment progression, failure to use outcome measures of known validity, failure to express the data in a meaningful fashion, and failure to define and adhere to a common end-point.

For example, neither Griffin[11], Kleinkort[12] or Binder[2] identified their diagnostic criteria. No prospective studies attempting to identify predictors of outcome have appeared in the English-language literature, and therefore, all 4 studies were deficient with regard to this feature. Standardization, including duration of each treatment episode, of ultrasound dosage was also deficient in all 4 studies, and perhaps the principal reason for this is that no dose-response curves for humans with chronic inflammation have appeared in the English-language literature. Griffin[11] and Kleinkort[12] did not address the issue of outcome measures, and of the outcome measures used by Binder, sensitivity to change has only been reported for grip strength.[14] Further, it is important to note that, based on the literature, grip strength will tend to overestimate success.[14] Also, with respect to data analysis, improvement scores are difficult to interpret in the absence of baseline scores. This factor makes it difficult to appraise much of the data presented by Binder and colleagues, particularly in the absence of a defined end-point.[2]

In order to determine the extent to which our "no difference" findings could be attributed to sample size, a power analysis was performed. This was based on our stated a priori estimates for the two main effect questions. Powers of 0.99 and 0.94 were calculated for the ultrasound–phonophoresis comparison, and the ultrasound–ultrasound and friction comparisons, respectively. (For an elaboration of these calcula-

tions, see Appendix 2.) Power calculations were also performed based on the adjusted scores for the following outcome measures: pain-free function, pain, function, and pain-free grip expressed in ratio format. These calculations also produced powers in excess of 0.95, based on an anticipated difference equal to one standard deviation. Thus, when one considers lateral epicondylitis as a whole, it is unlikely that the findings of "no difference" are a reflection of this study's sample size.

With respect to potential confounding variables, no association could be detected between patient outcome and age, compliance with rest, duration of symptoms, pre-intervention scores, sex or dominance.

At this point, we could find no direct evidence in the literature either to support or refute the apparent finding that site of lesion and frequency of occurrence are potential predictors of patient outcome. However, indirect descriptive information is available that may support the finding that patients with tenderness over the origin of extensor carpi radialis brevis may have a poorer immediate prognosis to conservative therapy. (This phenomenon is consistent with Cyriax's[13] diagnostic scheme for tendinitis at the origin of extensor carpi radialis brevis.) Cyriax noted that 9 out of 10 cases of lateral epicondylitis occurred at the origin of extensor carpi radialis brevis.[20] This is in sharp contrast to our figures of 9 of 40 (23%). It is our hypothesis that Cyriax's estimate was based on his own practice as a consultant. In contrast, the estimate in this study was based on a primary care practice. Accordingly, patients referred to a consultant usually represent either diagnostic or treatment challenges. We propose that the diagnosis of lateral epicondylitis is straightforward, and therefore, patients referred to a consultant would likely represent the subset of those patients who were resistant to initial therapy. Our results suggest that patients with tenderness over the origin of extensor carpi radialis brevis are resistant to conservative therapy, and Cyriax's seemingly high estimate of the clinical prevalence of tendinitis at the origin of extensor carpi radialis brevis may, in part, support this theory.

Conclusion

This study does not support the notion that either deep friction massage or phonophoresis are superior to ultrasound in the treatment of lateral epicondylitis at the elbow. The significance of this finding is that lateral epicondylitis patients can be treated at a reduced cost, both in terms of dollars and therapist time, with ultrasound alone rather than ultrasound in combination with a hydrocortisone ointment or friction massage. Further, the data suggest that all patients with the diagnosis of lateral epicondylitis do not have the same prognosis. Specifically, patients with tenderness over the extensor carpi radialis brevis tendon at its origin, and recurrent cases, appear to have a poorer short-term prognosis following conservative therapy. In order to validate the potential predictors identified in our study, a prospective clinical history study with a priori hypothesis specifically identifying these variables would be required. It was not the initial intent of our study to evaluate the therapies on specific lateral epicondylitis sub-populations, and we therefore leave any conclusions on this topic to future studies. Finally, the high powers presented in this paper refer only to the main effects and do not apply to between-cell comparisons (e.g., ultrasound alone versus ultrasound combined with both friction massage and phonophoresis).

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Appendix 1

The factorial experiment* allows for the examination of two or more independent variables in one study. This is achieved by crossing all levels of each factor with all levels of the remaining factors. In this study, the factors are phonophoresis and friction massage. The levels of phonophoresis are phonophoresis not applied and phonophoresis applied, while the levels of friction massage are friction massage not applied and friction massage applied. This concept is represented pictorially in the figure below.

* *Armitage P: Statistical Methods in Medical Research. New York, John Wiley and Sons, 1974*

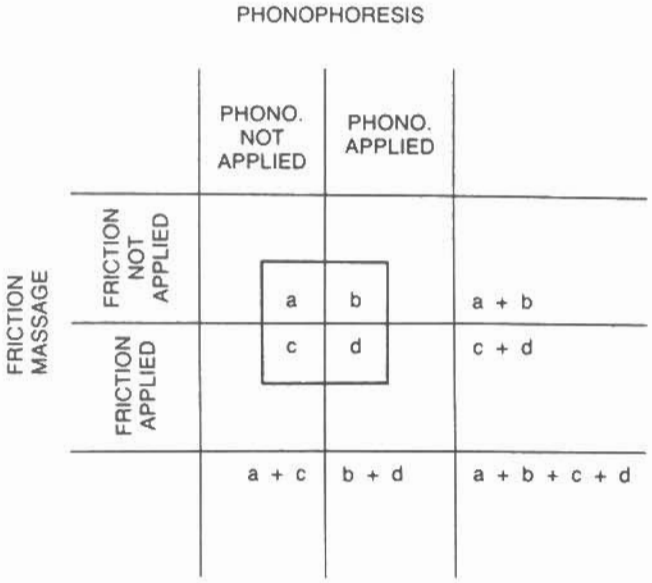

Figure A1 Pictorial representation of the factorial experiment.

The boxes a, b, c, and d are referred to as cells and the remaining boxes (e.g., a+b) are termed marginals. The marginal "a+c" represents all patients not receiving phonophoresis and the marginal "b+d" represents all patients receiving phonophoresis. Similarly, the marginals "a+b" and "c+d" represent all patients not receiving and receiving friction massage.

For those readers unfamiliar with the factorial experiment, the design may appear to disregard a characteristic commonly purported to be essential to a sound clinical study, that of examining only one variable at a time. This is not the case. By crossing all levels of one factor with all levels of the second factor, an investigator is able to answer two research questions for the sample size cost of one. This increased efficiency relates only to the main effects (i.e., phonophoresis vs no phonophoresis and friction massage vs no friction massage) and does not apply to between-cell comparisons (i.e., Does the effectiveness of treatment combination "a" differ from that of combination "d"?)

The format of tables 2 and 3, presented in the main text, is consistent with the figure presented above, and this allows the reader to examine both the cell and marginal values.

Appendix 2

The purpose of this appendix is to illustrate the power calculations for a statistical test assuming the study has taken place. This approach is lucidly described by Feinstein.*

The relationship between power (the ability to detect a statistical difference, assuming a true difference between therapies does exist) and the probability of committing a Type II error (i.e., the probability of falsely accepting the null hypothesis, denoted by the symbol "β") is such that the power statistical test is equal to 1-β.

$$Z_\beta = \frac{\Delta - \delta}{\sqrt{(p_1q_1/n_1) + (p_2q_2/n_2)}}$$

where Z_β is the Z score representing the probability of a Type II error, Δ is equal to the a priori estimate of a clinically significant difference (0.30 for our study), δ is equal to the observed difference between treatments (0.25−0.25 or 0 for the phonophoresis intervention and 0.29−0.21 or 0.08 for the friction intervention), p_1 and q_1 are the success and failure proportions, respectively, in one treatment group while p_2 and q_2 are the success and failure proportions in the other treatment group. The sample sizes for the two groups are represented by n_1 and n_2.

Thus, for the phonophoresis comparison the equation becomes:

$$Z_\beta = \frac{0.30 - 0}{\sqrt{(0.25 \times 0.75/20) + (0.25 \times 0.75/20)}}$$

$Z_\beta = 2.19$ (always 1-tailed)

$\beta = 0.0143$

Power = 0.9857

For the friction analysis, it becomes:

$$Z_\beta = \frac{0.30 - 0.08}{\sqrt{(0.29 \times 0.71/21) + (0.21 \times 0.79/19)}}$$

$Z_\beta = 1.62$ (always 1-tailed)

$\beta = 0.0526$

Power = 0.9474

* Feinstein AR: *Clinical Biostatistics*. St. Louis, MO, CV Mosby, 1977, 327