

## Original Article

# Single-blind and Double-blind Randomized Controlled Trials of Palmtherapy<sup>®</sup>, an Alternative Medical Approach, for Anxiety before Cardiac Catheterization

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Alternative medicine is widely used, but lacks consensus regarding its amenability to scientific investigation. Anxiety increases morbidity and mortality in ischemic heart disease. We performed two studies of Palmtherapy<sup>®</sup>, an alternative treatment, for anxiety before cardiac catheterization. In the first study, patients were randomized to receive pressure at particular points on the palm, or at incorrect locations, for about 50 min, while the therapist conversed with them. In the second study, the conversation was conducted by a second, 'blind' investigator. In both studies, patients and nurses, all blind to treatment assignment, completed visual analog scale and National Institute of Mental Health measures of anxiety, respectively. Twenty-three subjects completed study 1, and 17 completed study 2. In study 1, palm therapy was superior to sham therapy for both outcome measures. In study 2, palm therapy was superior for self-reported anxiety, but not for nurses' assessments of anxiety. Future studies should attempt to separate possible mechanistic effects of Palmtherapy<sup>®</sup> from therapist-related variables. Whether alternative medicine deserves to be studied at all remains controversial. Palmtherapy<sup>®</sup> may offer anxiolytic benefit without the harm attributable to drugs.

**Keywords:** complementary medicine – stress – psychiatry – heart disease

## Introduction

There is an increasing interest in the use of alternative medicine (1–3) and Australia and USA have established research institutes to study it (4). Nevertheless, the very idea of studying alternative medicine arouses intense controversy (5–8). Proponents maintain that widespread use by populations cannot be ignored, and is best served by serious study. Opponents maintain that in the absence of accepted scientific theory supporting alternative practice (by definition; otherwise it is not alternative), studies, including outcome studies, can never be more than meaningless statistical exercises, conferrers of pseudo-respectability.

One of the methods in alternative medicine is called 'Palmtherapy<sup>®</sup>' (9). It has been proposed as a treatment for emotional distress, in particular anxiety (10). It is based on the theory that the palm of the hand represents the whole body in miniature, so that certain points on the palm correspond to particular brain areas. It is proposed that continuous moderate pressure on certain points can safely, quickly and effectively reduce anxiety.

There is good evidence that anxiety can contribute to and affect the outcome of myocardial ischemic disease (11). Catheterization of the coronary arteries can provoke anxiety, and pharmacological treatment is only partly effective (11).

The first author has studied Palmtherapy<sup>®</sup> with its originator. We conducted two randomized controlled trials, one single-blind and one double-blind, of palm therapy versus pseudo-palm therapy in anxious patients awaiting cardiac catheterization.

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## Methods

### Subjects

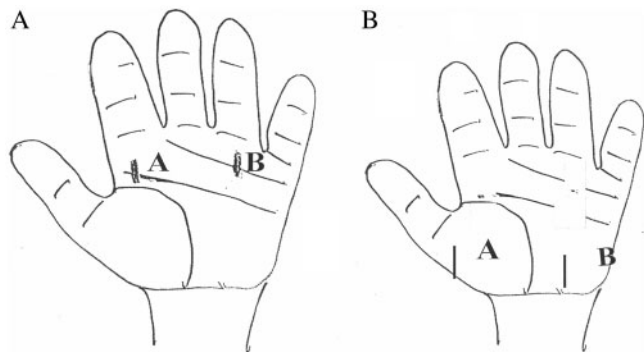
We screened all patients awaiting catheterization in the invasive cardiology unit. Any who mentioned or implied the existence of anxiety were invited to take part. Exclusion criteria were local problems such as inflammation or scarring on the palm, catheterization so urgent that there was no time for Palmtherapy®, and inability to understand and consent to the procedure.

### Procedures

Potential subjects were told that palm therapy is an alternative treatment method that claims effectiveness against anxiety. The study had been approved by the hospital Helsinki Ethics Committee. The response rate was 100%. Subjects signed informed consent, and then were assigned, on the basis of pre-ordained random numbers, to one of the two treatment groups. One group received steady pressure just below the threshold of discomfort at the point designated by the originator of palm therapy (Fig. 1A) for 45 min. During this time, in study 1 the palm therapist conducted 'small talk' to distract the subject's attention, according to the treatment manual (10). Subjects assigned to the other group received the identical treatment, except that the pressure was exerted in the wrong (sham) location (Fig. 1B). After results from the first twenty-three patients had been analyzed, and the treatment appeared to have large effects, we conducted study 2, in which we included a second therapist, blind to treatment condition, to conduct the conversation, and the therapist exerting the pressure remained silent during the procedure.

### Assessments

Before and after the treatment subjects completed seven visual analog scales of measures of anxiety (12). At the same time points nurses' blind to treatment condition



**Figure 1.** (A) Pressure points designated by the originator of Palmtherapy®. (B) Pressure points during sham therapy.

completed the four items from the anxiety subscale from the NIMH self-rating scale (13), but about the patients.

### Analysis

We analyzed the results with Kruskal–Wallis analysis of variance (ANOVA), comparing subjects before and after the intervention (dependent variables), with treatment condition as a grouping (independent) variable.

## Results

### Study 1

Twenty-three subjects completed this study. Sixteen were male, the mean (SD) age was 58.3 years (11); four were urgent cases. Nine patients were randomly assigned to sham therapy. Sex and age did not affect the results (data available on request).

Patients had similar levels of anxiety before the intervention, but after it levels were lower in those who received Palmtherapy® than in those who received sham therapy, both by self-report and by nurses' observations (Table 1).

### Study 2

Seventeen subjects completed this study. Six were male, the mean (SD) age was 57.6 years (13); 10 patients received sham therapy. Sex and age did not affect the results (data available on request).

**Table 1.** Means (SDs) of anxiety before and after palm or sham therapy

Study 1		
Self-report	Before	After
Palmtherapy®	46.5 (14)	7.1 (4)
Sham therapy	46.6 (16)	40.1 (13) <sup>a</sup>
Nurses report		
Palmtherapy®	16.9 (3)	4.6 (3)
Sham therapy	14.7 (5)	12.6 (3) <sup>b</sup>
Study 2		
Self-report	Before	After
Palmtherapy®	56.3 (11)	11.8 (7)
Sham therapy	47.7 (15)	30.0 (14) <sup>c</sup>
Nurses report		
Palmtherapy®	17.4 (2)	5.5 (4)
Sham therapy	16.6 (4)	7.6 (4) <sup>d</sup>

<sup>a</sup>Kruskal–Wallis ANOVA before treatment  $H(1, n=23)=0.0$ , NS; after treatment  $H(1, n=23)=15.6$ ,  $P=0.0001$ .

<sup>b</sup>Kruskal–Wallis ANOVA before treatment  $H(1, n=23)=1.1$ , NS; after treatment  $H(1, n=23)=14.7$ ,  $P=0.0001$ .

<sup>c</sup>Kruskal–Wallis ANOVA before treatment  $H(1, n=17)=1.5$ , NS; after treatment  $H(1, n=17)=7.8$ ,  $P=0.005$ .

<sup>d</sup>Kruskal–Wallis ANOVA before treatment  $H(1, n=17)=0.0$ , NS after treatment  $H(1, n=17)=0.9$ , NS.

Patients had similar levels of anxiety before the intervention, but after it levels were lower in those who received Palmtherapy<sup>®</sup> than in those who received sham therapy, when the outcome was self-reported anxiety (Table 1). However, there was no difference after treatment when the outcome variable was the nurses' observations.

## Discussion

The results of these studies suggest that Palmtherapy<sup>®</sup> may help against anxiety before cardiac catheterization. This conclusion, however, must be tempered by the fact that the more rigorous study, i.e. in which the unblinded therapist was limited to exerting pressure on the palm, with virtually no verbal contact with the subjects, found fewer effects than the less rigorous study. In addition, both studies were small.

The importance of anxiety in ischemic cardiac disease is well documented (11). Stress-induced hemodynamic changes, particularly increases in systemic vascular resistance, coronary artery vasoconstriction, and microvascular changes may all contribute to the pattern of ischemia. There is, nonetheless, considerable variability in responses to mental stress that is not understood.

'No pharmacological interventions have yet consistently blocked mental stress-induced ischemia' (11). Palm therapy represents a potential non-pharmacological intervention for relaxation and stress reduction. Since the hand, although relatively only a small section of the body, has a large area of representation in the brain, both in the motor and sensory sections of the cerebral cortex, and there is a bidirectional flow of information through the nervous system, the theory hypothesizes that one can affect the mind through a stimulation on specific lines and areas on the hands which are related to specific brain areas, which in turn serve as the physical substrate of certain mental states (9). It also predicts that any anxiolytic effect created by stimulation of a specific area on the palm should be more specific than the general soothing effect that may follow a stimulation of the skin surface in general: 'The hand is like a keyboard of a computer. If you know where to stimulate, you can produce anticipated results' (9). Our results appear to lend some support to these predictions.

The present results make it difficult to offer specific recommendations for future study or practice. Anxiety is unpleasant for anyone, and sometimes dangerous for cardiac patients. Any therapy offering benefits instead of or beyond those of drugs deserves consideration. However, in the absence of a detailed anatomical rationale for palm therapy, it is unclear exactly which specific refinements of the hypothesis might be usefully examined in future mechanistic studies. The same lack of mechanistic understanding, which underlies most

studies of alternative medicine (but compare a recent review of brain imaging studies of acupuncture (14)), was bemoaned by the authors of a recent large study of prayer and music and relaxation before percutaneous cardiac intervention (15). The Lancet editorialized that it would be 'premature...to rule out...[alternative] therapies in modern medicine...hope and belief...are proper subjects for science, even while transcending its known bounds' (16).

The difference between the two studies we conducted leaves room to believe that at least some of the effects were due to the personality and enthusiasm of the first author. It would be instructive to conduct another controlled study, with the pressure on the palm applied by a machine, with the location determined by an investigator familiar with the precepts of palm therapy, and all verbal contact during the procedure conducted by an investigator blind to treatment assignment.

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