

Beneficial Effects of Noetic Therapies on Mood Before Percutaneous Intervention for Unstable Coronary Syndromes

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- ▶ **Background:** Many common medical, surgical, and diagnostic procedures performed for conscious patients can be accompanied by significant anxiety. Mind-body-spirit interventions could serve as useful adjunctive treatments for the reduction of stress.
- ▶ **Objective:** To evaluate the effects of stress management, imagery, touch therapy, remote intercessory prayer, and standard therapy on mood in patients awaiting percutaneous interventions for unstable coronary syndromes as part of the Monitoring and Actualization of Noetic Training (MANTRA) trial, which explored the feasibility and efficacy of noetic interventions on clinical outcomes in a randomized clinical trial.
- ▶ **Methods:** A total of 150 patients were randomized to one of the five treatment conditions. Stress management, imagery, and touch therapy were administered in 30-minute treatment sessions immediately before the cardiac intervention. Intercessory prayer was not necessarily contemporaneous with these treatments. Mood was assessed by a set of visual analog scales before and after treatment for a similar length of time for the standard therapy and prayer groups.
- ▶ **Results:** Analysis of complete data from 108 patients showed that stress management, imagery, and touch therapy all produced reductions in reported worry, as compared with standard therapy, whereas remote intercessory prayer had no effect on mood. The ratings of other similar moods were not affected, perhaps because of the relatively positive emotional state observed in the participants before treatment.
- ▶ **Conclusions:** The results suggest that at least some noetic therapies may have beneficial effects on mood in the course of medical and surgical interventions. Administration of these interventions was feasible even in the hectic environment of the coronary intensive care unit. Given their relatively low cost and limited potential for adverse effects, these interventions merit further study as therapeutic adjuncts.
- ▶ **Key Words:** preoperative care · psychological · relaxation techniques · stress

Many common medical, diagnostic, and surgical procedures performed on the conscious patient can be accompanied by substantial levels of worry. The threat of pain and the risks and discomforts associated with invasive procedures, especially when conducted in the context of life-threatening medical conditions, can elicit strong emotional reactions with negative psychological and physiologic consequences (Linn, Linn, & Klimas, 1988; McCleane & Cooper, 1990). Sedation is used widely in these circumstances, although the sedative-narcotic regimens can have adverse effects and compromise critical homeostatic mechanisms. Many mind-body-spirit techniques known to elicit relaxation and reduce stress could have application in these circumstances. Techniques such as stress management and relaxation, imagery, touch-therapy, and intercessory prayer could reduce patient worry without the risk of adverse effects.

Clinical applications of mind-body-spirit therapies have been reported for cardiovascular diseases (Byrd, 1988; Harris et al., 1999; Mandl et al., 1990; Tusek, Cwynar, & Cosgrove, 1999). The cited studies examined a variety of interventions that relieve stress associated with a broad range of clinical procedures. Results to date have been mixed. Although some of the trials have involved cardiac patients, none has investigated the feasibility and efficacy of these treatments for patients undergoing the com-

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mon invasive procedures associated with the treatment of acute coronary disease.

The Monitoring and Actualization of Noetic Trainings (MANTRA) Study Project is an ongoing investigation of the clinical benefits resulting from the integration of "noetic" treatments into conventional interventional care for acute coronary disease. In this project, a *noetic* treatment is defined as "a treatment discipline whose influence purports to enable, release, channel, or connect an intellectual, intuitive, or spiritual healing influence without the use of a drug, device, or surgical procedure" (Institute of Noetic Sciences, 1999, p. 1). Noetic therapies fit under the rubric of complementary methods or complementary alternative methods, but are specific in that unlike herbal medicine or acupuncture, no external implement for their mechanism of action is required.

The primary aim of the project is to determine the effects of noetic interventions including stress reduction, imagery teaching and practice, conscious application of human touch, and therapeutic prayer on the immediate and long-term clinical outcomes for patients undergoing percutaneous coronary intervention (PCI) for acute coronary syndrome. The MANTRA Phase 1 project (Krucoff et al., 2001) was a prospective, randomized study investigating the feasibility, safety, and efficacy of these four noetic treatment interventions for these particular patients. Although the major goals of the project concerned the evaluation of hard clinical end points, a secondary question concerned the effects of these noetic interventions on the patient's subjective experience during the intervention. It was thought that patients would benefit both psychologically and physiologically from a reduction in the amount of stress they experienced while anticipating or undergoing the invasive procedure.

The aim of the current study (a component of the larger study) was to determine whether the noetic interventions of the MANTRA pilot study, administered in the anticipatory interval immediately before the invasive procedure, produced acute positive changes in mood. Moreover, the study sought to identify and characterize the nature of any differences among the treatments in their effects on mood.

Methods

Study Design

This study investigating the acute effects of noetic interventions on mood and subjective stress in patients undergoing PCI was conducted as part of the MANTRA project pilot study (Krucoff et al., 2001), which was a randomized controlled clinical trial. The MANTRA participants were assigned at random to one of four noetic interventions or to standard treatment before PCI. Mood assessments were made before and immediately after these noetic interventions. The effects of treatment on posttreatment mood

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scores were tested by analysis of covariance (ANCOVA), with corresponding pretreatment mood scores used as the covariate. The study and its procedures were approved by the appropriate institutional review board.

Patient Population

Patients were considered eligible for the MANTRA project pilot study if they had chest pain at rest, with or without electrocardiographic changes, and were scheduled for invasive diagnostic angiography or PCI procedures. This included patients who already had undergone diagnostic angiography and had been referred for PCI, and those who had been taken *de novo* to the

cardiac catheterization laboratory with chest pain and had electrocardiographic findings highly suggestive or diagnostic of acute myocardial ischemia or myocardial infarction.

Patients were included in the study only if they could be enrolled at least 1 hour before the PCI procedure without interference with their clinical care. Each patient was informed of the study goals and procedures and gave written informed consent before enrollment. All the patients were managed in the coronary care unit of a Veterans Administration (VA) Medical Center before and after the PCI procedure.

The MANTRA Volunteer Practitioners Group

The three hands-on noetic interventions were administered by 19 volunteer practitioners. The professional backgrounds of the volunteers were varied and included full-time professional experience in healthcare, the clergy, carpentry, and noetic practice. All the practitioners had previous experience with at least one of the selected noetic techniques.

The participating practitioners completed 1 day of formal training in the specific noetic interventions, the standard scripts used for each, and the proper administration of mood assessments. Volunteer practitioners completed at least one MANTRA intervention under supervision before working independently. Training and supervision were conducted by healthcare professionals with extensive experience in the hands-on noetic methods used in the study. For the duration of the study, one of the healthcare professionals was available in the critical care unit to provide guidance and support for the noetic practitioners. Regular meetings with the volunteers provided follow-up training and quality control supervision. Volunteer practitioners agreed to be on call 2 days each month for the entire 15-month duration of the study. On these assigned days, the practitioners agreed to remain within 30 minutes of the hospital to ensure availability.

Noetic Therapies and Standard Treatment

Three of the four therapies (stress management, imagery, and touch therapy) were conducted at the bedside before PCI by volunteers trained to conduct the standardized treatments. These interventions followed a standardized

written script or protocol to maintain consistency across sessions and practitioners (protocols are available upon request). Intercessory prayer was conducted off-site as a double-blind component of the study.

Stress Management Stress management emphasized supportive listening, an individualized educational dialog about stress, a brief assessment of the patient's perception of the importance of spirituality in his or her life, and instruction in a meditation technique. The educational component included a characterization of stress in terms of changes in life and the body's physical responses to these changes. The stress management meditation technique included slow abdominal breathing and concentration on a personally selected phrase of meaning such as "easy does it" or "the Lord is my Shepherd." The patient was encouraged to return kindly and gently to the phrase whenever he or she noticed his or her mind wandering to other thoughts. Instruction and practice was presented in the patient's room.

Imagery The first step of the imagery training protocol was to establish rapport and facilitate a therapeutic alliance. Next, the patient was taught a slow, mindful relaxation breath. The practitioner guided the patient in the selection of a preferred place and directed the patient to focus attention and imagination on this place where he or she would rather be (e.g., communing with nature, relaxing in a comfortable chair at home, attending church, or playing golf). The patient then completed a brief practice trial of the intervention, using the relaxation breath and the preferred place imagery.

Touch Therapy The standardized touch therapy in this protocol was a modification of the "chakra connection" technique popularized among nurses nationwide through the Healing Touch International program (Hover-Kramer, 1995). A standard script was used to introduce the technique, teach the relaxation breath technique, and facilitate rapport. Practitioners were encouraged to center and focus a healing intention before touching the patient. The technique comprised gentle touching of the patient with both hands in a prespecified sequence of positions, beginning at the foot and progressing to the top of the head. Each of the 22 hand positions was held for approximately 45 seconds.

Off-Site Intercessory Prayer For this intervention, messages were sent by phone, e-mail, or Internet connection to eight participating prayer groups. The messages contained the patient's name as well as the nature of the illness and the procedure. The eight groups were the Unity School of Christianity in Missouri, the Moravian church in North Carolina, a Baptist congregation in North Carolina, the "Send a Prayer" link Virtual Jerusalem Web site in Jerusalem (Jewish), the Abundant Life Christian Center in North Carolina, the Nalanda Monastery in France (Buddhist), the Kopan Monastery in Nepal (Buddhist), and the Carmelite Monastery in Towson, Maryland (Catholic). Each site followed its standard routines with respect to the number of individuals praying, the prayer recited, and the timing, frequency, and duration of the prayer. All eight par-

ticipating groups prayed for every patient randomized to the off-site prayer treatment.

Standard Therapy Standard therapy was defined as the absence of any systematic interaction with a MANTRA volunteer practitioner or off-site prayer group. No attempt was made to alter, restrict, or prohibit bedside compassion, physical contact with the patient, prayers, or the use of any noetic or stress management technique by the patients, families, staff, or chaplains. The presence of family, clergy, or chaplain before PCI was systematically recorded, as well as whether the patient was aware of specific prayers for his health.

The patients who received any of the in-person noetic interventions were not blinded to the treatment received. The patient knew that he or she was not in the control group or in the prayer group when the practitioner arrived and began working with him or her in stress management, imagery, or touch therapy. However when no noetic practitioner arrived, the subject and the staff were both blinded as to whether the patient was in the standard therapy group or in the prayer group.

Measurement of Mood

Mood was assessed with a series of eight visual analog scales printed on a single page. The visual analog scale (VAS) has a long history of use for the assessment of subjective mood, strain, and pain, and the validity and reliability of this method is generally accepted (Ahearn, 1997; Kindler, Harms, Amsler, Ihde-Scholl, & Scheidegger, 2000; Scott & Huskisson, 1976; Wewers & Lowe, 1990). Each VAS was a horizontal line 10 cm in length, and the ends of each scale were labeled "not at all" and "very much" to anchor the lower and upper limits of the patient's ratings. The patient was instructed to make a vertical mark across the VAS at a point that represented his or her current experience of mood relative to the two verbal anchors. The eight scales included four positive mood descriptors (happy, hopeful, calm, and satisfied) and three negative mood descriptors as well as one unpleasant physical sensation (worried, sad, upset, and short of breath).

Intervention Protocol

A researcher or cardiologist on the interventional team approached the hospitalized patient at least 2 hours before the cardiac intervention. The study was described, and informed consent was obtained. After consent, the assigned treatment was determined from a computer-generated random sequence of 150 assignments sealed in individual envelopes. If the patient received one of the three hands-on interventions, the on-call noetic practitioner was notified of the patient and assigned treatment.

The practitioner approached the patient approximately 1 hour before the PCI. The VAS was explained to the patient, and the initial pretreatment assessment of mood was conducted. The noetic intervention then was provided. The second VAS was administered immediately after completion of the intervention. The patients assigned to intercessory prayer or standard treatment received the two VAS administrations from one of the interventional cardiology staff, separated by a comparable 30-minute interval. All

training and assessment procedures were completed before the administration of any sedation or movement to the cardiac catheterization laboratory.

Medical and Invasive Therapy

All the patients were treated medically and underwent invasive procedures according to the routine standard to the medical center at the discretion of the attending cardiologist. Routine treatment included the use of aspirin, heparin, nitrates, beta blockers, intraaortic balloon pumps, balloon angioplasty, rotational atherectomy, and stenting. Clinical end points were evaluated as part of the larger MANTRA project (Krucoff et al., 2001).

Data Reduction and Statistical Analysis

An individual blind to the treatment received by the patient scored the VAS ratings. The distance in millimeters from the left end of the scale to the subject's mark was measured, and the score was entered into a database for analysis at the completion of the study.

The VAS scores were analyzed using ANCOVA to test for treatment group differences in the posttreatment VAS scores, with covariate adjustment for pretreatment scores. Specific group contrasts were evaluated when the omnibus test for a mood descriptor was significant, including comparisons of all four noetic treatments with standard treatment and comparisons of each treatment with this standard treatment control. In addition, the three treatments that involved the bedside presence of a volunteer practitioner were contrasted with the two conditions in which no person was present (intercessory prayer and standard treatment). Because independent tests were conducted for each of the eight VAS scales, a Bonferroni correction was applied to control for overall type 1 error. The criterion p value for significance in each of the ANCOVAs was adjusted downward to a p value less than .0064. Adjust-

ments were not made in follow-up planned comparisons of treatments, which were protected by the significant omnibus test.

Results

The sample included 149 men and 1 woman with a mean age of 64 years. A total of 150 patients scheduled for invasive cardiac catheterization were randomized to the five conditions of the MANTRA study. Of the 150 patients, 114 (76%) underwent PCI, whereas 30 (20%) had only diagnostic catheterization and 6 (4%) did not undergo an invasive procedure. Of the 120 patients assigned to receive a noetic intervention, 118 (98%) completed the assigned treatment. Patients who did not complete both VAS assessments were excluded from the analysis. The excluded patients were 31 patients who did not complete either VAS and 11 patients who failed to complete the posttreatment VAS. Complete VAS data were available from 108 of the 150 subjects. Data collection was more complete for the three hands-on therapies (involving 24 subjects for imagery and touch therapy and 23 subjects for stress management) than for in the intercessory prayer group (involving 19 subjects) and the standard treatment group (involving 18 subjects).

There were no significant differences among the five groups for any of the eight mood scales on pretherapy mood ratings. The treatment groups were equivalent in the ratings of mood before the start of the intervention.

The results of the ANCOVAs comparing adjusted posttreatment VAS scores for the five groups are summarized in Table 1. The VAS for worry was the only one that yielded significant treatment effects in the omnibus comparison of all five treatments. The main effect of treatment group in the ANCOVA was significant ($F[4,102] = 4.28$; $p = .003$). The planned follow-up test contrasting the four

TABLE 1. Posttreatment Visual Analog Scale Mood and Symptom Scores (Mean \pm SE) by Treatment Group

Mood or Symptom	Treatment Condition					
	Baseline All Groups ($N = 108$)	Guided Imagery ($n = 24$)	Healing Touch ($n = 24$)	Intercessory Prayer ($n = 19$)	Stress Management ($n = 23$)	Standard Care Control ($n = 18$)
Worry*	32.7 \pm 2.9	19.8 \pm 3.8**	23.2 \pm 3.8**	31.0 \pm 4.3	16.9 \pm 3.9**	37.8 \pm 4.4
Upset	23.8 \pm 2.4	14.3 \pm 3.5	16.1 \pm 3.5	26.8 \pm 3.9	18.7 \pm 3.5	19.7 \pm 4.0
Sad	24.2 \pm 2.6	5.4 \pm 3.7	17.0 \pm 3.7	23.0 \pm 4.2	16.5 \pm 3.8	19.2 \pm 4.3
Calm	56.7 \pm 3.1	74.9 \pm 4.9	77.9 \pm 4.8	69.7 \pm 5.5	65.8 \pm 4.9	71.1 \pm 5.6
Hope	78.3 \pm 2.6	78.5 \pm 3.8	86.6 \pm 3.8	79.3 \pm 4.3	76.4 \pm 3.9	79.6 \pm 4.4
Happy	63.1 \pm 2.9	71.8 \pm 3.5	75.9 \pm 3.5	64.7 \pm 3.9	68.4 \pm 3.6	67.2 \pm 4.0
Satisfied	64.5 \pm 2.8	74.8 \pm 4.4	80.5 \pm 4.5**	69.9 \pm 5.1	69.9 \pm 4.5	66.5 \pm 5.1
Short of Breath	28.5 \pm 2.6	21.8 \pm 4.0	17.1 \pm 4.0	31.1 \pm 4.5	28.6 \pm 4.1	24.0 \pm 4.6

Note. Means and tests of treatment effects are adjusted for baseline levels (also shown) using analysis of covariance.

*Denotes significant difference among groups by analysis of covariance, $p < .00625$.

**Denotes difference between that treatment group and control group, $p < .05$.

noetic treatments with standard treatment also was significant ($F[1,105] = 10.14; p = .002$). Contrasts of the individual noetic treatments with standard treatment showed significant differences for guided imagery ($F[1,105] = 9.68; p = .002$), stress management ($F[1,105] = 12.92; p = .0005$), and healing touch ($F[1,105] = 6.41; p = .01$), but not for intercessory prayer ($F[1,105] = 1.26; p = .27$). This pattern of effects was confirmed by the planned contrast of the three treatments that included the presence of a practitioner (guided imagery, stress management, and healing touch) and the two treatments that did not (intercessory prayer and standard care). The test of this contrast also was significant ($F[1,105] = 14.5; p = .0002$). No effects of treatment were found for any of the other items rated by VAS (calm, happy, hopeful, sad, satisfied, short of breath, upset). All the ANCOVAs for these yielded p values greater than .15 in the omnibus test of all the treatments.

Discussion

The results of this study suggest that noetic interventions may contribute to an improved emotional state of mind when administered during the stressful period before invasive medical procedures such as PCI for acute coronary syndrome. Patients with acute ischemia responded favorably to healing touch, stress management, and imagery training, with reductions in ratings of worry.

One limitation of the study was the lack of complete VAS data for all the patients. Only 73% of the 150 patients completed both the pre- and posttreatment VAS. The percentages were lower for the two groups in which a noetic practitioner was not present (intercessory prayer and standard care). Several factors contributed to missing data in all the treatment groups. Visual impairment was a problem for some subjects when an emergency trip to the hospital left them without their glasses. Some elderly patients had difficulty comprehending the use of the VAS to express their moods, and some found it too difficult to complete the scales while supine. These problems have been reported for the VAS in other studies (Wewers & Lowe, 1990). The higher rate of completion failures in the intercessory prayer and standard care groups is likely attributable to the fact that the VAS was administered to patients in these groups by staff of the cardiac catheterization laboratory and not by a noetic practitioner. The pace of clinical activities sometimes prevented cardiac catheterization laboratory personnel from leaving the laboratory for the coronary care unit to administer the scales.

The results of this study show that the noetic interventions had a statistically significant effect on self-reported worry. It is less clear whether the effects were clinically significant, or whether the treatment effects actually made a difference in the patient's experience of the PCI or the clinical outcome. This limitation is common to most studies on the application of noetic or psychological relaxation techniques to reduce pain, stress, or negative emotions associated with cardiac procedures (Blankfield, Zyzanski, Flocke, Alemagno, & Scheurman, 1995; Halpin, Speir, Capobianco, & Barnett, 2002; Hattan, King, & Griffiths, 2002; Miller & Perry, 1990), especially when the investi-

gation focuses on patients' subjective experiences.

As reported in greater detail elsewhere (Krucoff et al., 2001), the MANTRA Phase 1 study provided clear evidence that these noetic interventions are feasible, even in the hectic environment of the coronary care unit. Both patients and staff readily accepted the hands-on interventions. A large number of the eligible patients (88%) agreed to participate. Staff welcomed the interventions with apparent enthusiasm. Volunteer practitioners were able to complete most (97%) of the assigned treatments without interrupting the flow of care for the patients in this study. The experiences of this study suggest that it is feasible to administer noetic interventions such as these, even to patients with coronary disease who need urgent catheterization or PCI.

The three noetic therapies that had significant effects (stress management, guided imagery, and healing touch) reduced patient ratings of worry by 30% to 50%. In contrast, the VAS scores for worry increased by 16% in the standard treatment control condition as the time for the cardiac procedure approached. Although different stress reduction interventions were presented to the three groups, there was no evidence that any one of these three interventions was superior to the others. It may be that all three types of noetic intervention are effective for reducing stress before PCI. However, these three interventions shared an important feature: direct contact with a volunteer practitioner at the patient's bedside. The current study was not designed to differentiate the direct effects of the noetic treatments from the indirect effects of receiving treatment from a practitioner. However, the encouraging results may stimulate further studies with more extensive experimental controls.

Significant effects were limited to ratings for "worry" and not found for the apparently related mood descriptors "calm" and "upset." This may have resulted in part from the quality of the emotional state exhibited by the patients before the intervention. Notably, the patients in this study demonstrated relatively little evidence of stress and dysphoria at the time of pretreatment mood assessment. Despite the fact that each patient was facing an invasive procedure in the very near future, self-reported moods on the VAS ratings were positive for the most part. Average ratings for the positive moods (happy, hopeful, calm, satisfied) were consistently above the midpoint of the 0 to 100 scales, and average ratings for the negative items (sad, short of breath, upset, worried) generally were well below the midpoint (Table 1). The surprisingly high level of initial well-being exhibited by these patients may have left little room for more dramatic improvement with the noetic treatments.

Despite the limitations noted, it is reasonable to conclude that a 30% to 50% reduction in self-reports of worry indicates a nontrivial benefit for the patients in this study. These results suggest that three noetic therapies may be useful additions to the protocols for threatening medical and surgical procedures. ▼

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