Immediately before they underwent femoral angiography, 45 patients were given one of three types of audiotapes: a relaxation response tape recorded for this study, a tape of contemporary instrumental music, or a blank tape. All patients were instructed to listen to their audiotape during the entire angiographic procedure. Each audiotape was played through earphones. Radiologists were not told the group assignment or tape contents. The patients given the audiotape with instructions to elicit the relaxation response \( (n = 15) \) experienced significantly less anxiety \( (P < .05) \) and pain \( (P < .001) \) during the procedure, were observed by radiology nurses to exhibit significantly less pain \( (P < .001) \) and anxiety \( (P < .001) \), and requested significantly less fentanyl citrate \( (P < .01) \) and diazepam \( (P < .01) \) than patients given either the music \( (n = 14) \) or the blank \( (n = 16) \) control audiotapes. Elicitation of the relaxation response is a simple, inexpensive, efficacious, and practical method to reduce pain, anxiety, and medication during femoral angiography and may be useful in other invasive procedures.

Index terms: Anesthesia • Angiography • Ear, 21.1299 • Nervous system, effects of drugs on, 10.1299

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Immediately before they underwent femoral angiography, 45 patients were given one of three types of audiotapes: a relaxation response tape recorded for this study, a tape of contemporary instrumental music, or a blank tape. All patients were instructed to listen to their audiotape during the entire angiographic procedure. Each audiotape was played through earphones. Radiologists were not told the group assignment or tape contents. The patients given the audiotape with instructions to elicit the relaxation response \( (n = 15) \) experienced significantly less anxiety \( (P < .05) \) and pain \( (P < .001) \) during the procedure, were observed by radiology nurses to exhibit significantly less pain \( (P < .001) \) and anxiety \( (P < .001) \), and requested significantly less fentanyl citrate \( (P < .01) \) and diazepam \( (P < .01) \) than patients given either the music \( (n = 14) \) or the blank \( (n = 16) \) control audiotapes. Elicitation of the relaxation response is a simple, inexpensive, efficacious, and practical method to reduce pain, anxiety, and medication during femoral angiography and may be useful in other invasive procedures.

The majority of patients facing medical, dental, or surgical procedures experience moderate to high degrees of fear and anxiety \( (1,2) \), which can be problematic in at least two ways. If the anxiety or fear is of sufficient magnitude, patients may forgo or postpone procedures, thereby adversely affecting prognosis. Fear and anxiety may also complicate the procedures and prolong recovery \( (2) \). Even when patients undergoing invasive procedures are premedicated with analgesics and tranquilizers, a majority still experience moderate to severe anxiety and pain \( (3–5) \).

The lack of symptom relief, coupled with side effects of pharmacologic interventions, led to the examination of the utility of psychologic or behavioral interventions. An assessment of the efficacy of reported behavioral approaches is problematic because of variations in the techniques employed and a lack of consensus about relevant dependent variables. Despite these difficulties of assessment, behavioral techniques seem to alleviate anxiety and fear \( (6–9) \) and reduce physiologic reactivity \( (10–13) \).

Most behavioral techniques that are used to prepare patients for invasive procedures require a substantial commitment for training and practice prior to the actual procedure, and some patients do not want to devote the necessary time and effort. A more promising approach is the acute elicitation of the relaxation response \( (14) \). The relaxation response is characterized by a set of coordinated physiologic changes that include decreased oxygen consumption, heart rate, respiratory rate, and levels of arterial blood lactate; increased production of alpha, theta, and delta waves on the electroencephalogram; and psychologic changes of decreased anxiety and hostility. A decided advantage of the use of the relaxation response in invasive settings could be the ease with which it can be taught. Furthermore, patients can use techniques that elicit the relaxation response during the procedure itself. A simple instructional set that elicits the relaxation response is easily learned by most patients and requires minimal exposure prior to its use during invasive procedures.

PATIENTS AND METHODS

Forty-five patients with peripheral vascular disease who were to undergo femoral angiography were randomly divided into three groups. Informed consent was obtained from each patient. Patients were told that the purpose of this study was to investigate their perceptions during femoral angiography. In the relaxation response tape group \( (n = 15) \), patients were given an audiotape and player just prior to the procedure. The tape was recorded in the Department of Medicine, New England Deaconess Hospital specifically for this study and included directions in progressive muscular relaxation \( (15) \) and cognitive relaxation involving mental focusing and adoption of a passive attitude toward distracting thoughts \( (16–20) \). The patients in the music tape group \( (n = 14) \) were also given a tape and player just prior to the procedure. In this case, the tape consisted of contemporary instrumental music ("Music for Airports," by Brian Eno; EG Music, New York, 1978). The patients in the blank tape group \( (n = 16) \) were given a blank tape and player. In all cases, the patients were instructed to listen to the tape during the entire angiographic procedure. The tape was played through earphones, and Department of Radiology clinicians were not told the group assignment or tape contents. Pa-

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tients were requested not to divulge group assignments to staff members. No patient complained about the assigned audiotape. All instruments were administered by the same staff member (C.L.M.), who did not participate in patient care.

The femoral angiography was identical for all patients. The common femoral artery was the entry artery. Hynpaque-76 (Winthrop Pharmaceuticals, New York) was the radiopaque medium, and standard radiographic filming, in addition to digital imaging, was used.

Immediately prior to and immediately following angiography, each patient completed the Spielberger State Trait Anxiety Inventory (21). Immediately after angiography, each patient was asked to assess the pain experienced during the procedure by completing the pain rating index and the pain intensity scale of the McGill Pain Questionnaire (22). Anxiety and pain were assessed by a qualified radiology nurse immediately after the procedure. The nurse was asked to rate the degree of anxiety and pain exhibited by each patient during the procedure on a seven-point scale previously used by our group (23).

Antianxiety medication (only diazepam was used) and pain medication (only fentanyl citrate was used) were carefully monitored. No other medications were administered. The specific procedure involved in the requests and administration of medication was the routine protocol of the Department of Radiology: All patients initially were given a loading dose of both diazepam (2.5 mg) and fentanyl citrate (0.93 μg/kg). Patients were told that additional medications could be requested during the procedure in order to minimize discomfort. Depending on the patients' requests or behavior, additional diazepam was administered during the procedure at a dose of 2.5 mg every 20–30 minutes. The maximum total dose of diazepam was kept below 10 mg/h. Requests for pain relief resulted in the additional administration of fentanyl citrate at a dose of 0.93 μg/kg. The maximum prescribed maintenance dose of fentanyl citrate was 2 μg/kg/h. Vital signs consisting of blood pressure and heart rate were monitored throughout the procedure.

An analysis of variance was conducted to examine the main effect of group on each dependent variable. Post hoc individual comparisons were conducted with the Newman Keuls procedure.

RESULTS

Demographic and Psychologic Variables

There were no significant differences among the three groups regarding demographic variables of age, gender, physiologic factors, hospitalization status, and previous experience with femoral angiography prior to this procedure. There were no differences in preprocedure anxiety among the three groups. During the procedure, however, the relaxation response patients had significantly lower scores than the groups exposed to either the music or the blank tapes (\( P < .05 \) and \( P < .01 \), respectively) (Table 1). Furthermore, an intragroup comparison indicated that only the relaxation response tape group reduced their anxiety during the procedure \( (P < .01) \).

The Pain Questionnaire

The mean pain rating index of the patients in the relaxation response tape group was significantly lower than that of patients exposed to either control tape \( (P < .001) \) (Table 2). The mean ratings of the music and blank tape groups did not significantly differ from each other. Additionally, the group exposed to the relaxation response tape had significantly lower pain intensity scores than either control group \( (P < .001) \).

Again, the two control groups did not differ.

Nurse Ratings of Anxiety and Pain

At the conclusion of each femoral angiographic examination, an experienced radiology nurse rated the anxiety and pain exhibited by each patient on a scale of one to seven (Table 2). The nurse ratings of anxiety in the patients exposed to the relaxation response tape were significantly lower than those of patients exposed to the music tape or the blank tape \( (P < .001) \). The assessment of anxiety in the two control conditions did not differ statistically. Similarly, the nurses' pain ratings of patients exposed to the relaxation response tape were significantly lower than the pain ratings for the music tape group or the blank tape group \( (P < .001) \). In this case, the nurses' pain ratings were significantly lower for the music group than for the blank tape group \( (P < .05) \).

Medications

Fentanyl citrate was used significantly less in the relaxation response group than in either the music tape group or blank tape group \( (P < .01) \) (Table 3). Similarly, the amount of diazepam requested was significantly less in the patients exposed to the relaxation response tape than in those using either the music tape or the blank tape \( (P < .01) \). In fact, the relaxation response group required less than one-third the amount of both medications needed by the other two groups. There was no significant difference in the medication usage between the music tape and blank tape groups.

Vital Signs

Prior to, during, and after femoral angiography, blood pressure and heart rate were recorded several times. The relaxation response tape group, the music tape group, and the blank tape group did not differ significantly on any measure of these two variables at any time during the study.

DISCUSSION

Patients undergoing femoral angiography who listened to a tape that instructed them to elicit the relaxation response had a marked reduction in self-reported anxiety and pain, less observed anxiety and pain, and a marked reduction in use of pain-relieving and antianxiety medications. It is noteworthy that there were no significant differences in blood pressure levels despite the decreased medication usage by the relaxation response group. Previous studies have reported the medical and psychological benefits associated with consistent elicitation of the relaxation response (24–26). Our results indicate that acute elicitation of the relaxation response is feasible and useful in an invasive procedure. Because the intervention required minimal patient involvement and therapist interaction prior to femoral angiography, it has a decided advantage over many of the more cumbersome and laborious behavioral procedures previously used.

The efficacy of the relaxation response tape in reducing the distress of patients was not simply a result of distraction, because the music tape would be expected to divert attention with equal efficacy. Rather, some aspect of the instructional set per se was the relevant variable in reducing distress caused by the procedure. Instructing patients to mentally focus on a single repetitive word or phrase and to adopt a passive attitude toward distracting thoughts results in the physiologic alterations of the relaxation response and in psychological reactions that are "calming" (27). We hypothesize that exposure to this instructional set is sufficient to allow patients to adopt a relatively benign
reaction to the discomfort and pain associated with femoral angiography and perhaps other similar procedures. Instructing patients to close their eyes and concentrate on music or on instructions that simply ask patients to relax will not be an effective intervention, because explicit instructions to focus attention and to adopt a passive attitude are necessary to elicit the relaxation response. Minimal costs are associated with this extremely simple intervention, and there are virtually no adverse side effects. In fact, patients feel better. The adverse side effects of medication should also be reduced because of decreased drug usage. We suggest that the behavioral intervention of elicitation of the relaxation response be studied in other invasive procedures. Furthermore, its use should also be considered in combating the fear and anxiety sometimes associated with noninvasive procedures such as magnetic resonance imaging.

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