Pain and Anxiety during Interventional Radiologic Procedures: Effect of Patients’ State Anxiety at Baseline and Modulation by Nonpharmacologic Analgesia Adjuncts

Christine J. Schupp, BS, Kevin Berbaum, PhD, Michael Berbaum, PhD, and Elvira V. Lang, MD

PURPOSE: To assess how patients’ underlying anxiety affects their experience of distress, use of resources, and responsiveness toward nonpharmacologic analgesia adjunct therapies during invasive procedures.

MATERIALS AND METHODS: Two hundred thirty-six patients undergoing vascular and renal interventions, who had been randomized to receive during standard care treatment, structured empathic attention, or self-hypnotic relaxation, were divided into two groups: those with low state anxiety scores on the State–Trait Anxiety Inventory (STAI, scores < 43; n = 116) and those with high state anxiety scores (≥ 43; n = 120). All had access to patient-controlled analgesia with fentanyl and midazolam. Every 15 minutes during the procedure, patients rated their anxiety and pain on a scale of 0–10 (0, no pain/anxiety at all; 10, worst possible pain/anxiety). Effects were assessed by analysis of variance and repeated-measures analysis.

RESULTS: Patients with high state anxiety levels required significantly greater procedure time and medication. Empathic attention as well as hypnosis treatment reduced procedure time and medication use for all patients. These nonpharmacologic analgesia adjunct treatments also provided significantly better pain control than standard care for patients with low anxiety levels. Anxiety decreased over the time of the procedure; patients with high state anxiety levels experienced the most significant decreases in anxiety with nonpharmacologic adjuncts whereas patients with low state anxiety levels coped relatively well under all conditions.

CONCLUSION: Patients’ state anxiety level is a predictor of trends in procedural pain and anxiety, need for medication, and procedure duration. Low and high state anxiety groups profit from the use of nonpharmacologic analgesia adjuncts but those with high state anxiety levels have the most to gain.


Abbreviations: PCA = patient-controlled analgesia, STAI = State–Trait Anxiety Inventory

MINIMALLY invasive procedures increasingly replace open surgery and reduce the need for general anesthesia. Despite technical advantages, patients often experience anxiety and pain that may exceed their coping mechanisms (1) and may require a patient-oriented intervention. To better identify patients at risk, it would be desirable to have a simple method for assessing the pertinent individual’s characteristics as a predictor of the patient’s experience during the procedure and the possible effectiveness of various methods of distress management.

Spielberger and colleagues’ (2) State–Trait Anxiety Inventory (STAI) is a well-established measure of anxiety that patients can complete on their own within a few minutes. The state anxiety form of this self-report questionnaire refers to the intensity of anxiety experienced in reaction to a specific event at a given time, assessing “feelings of apprehension, tension, nervousness, and worry” (2). Procedural anxiety and pain are most commonly treated by moderate sedation with narcotics and sedatives.
This study did not evaluate the influence of state anxiety level on performance during the procedure, procedure duration, and effectiveness of the nonpharmacologic intervention. Two hundred thirty-six patients in this institutional review board–approved study filled out STAI state anxiety forms before their procedures and form the basis of this current study (Table 1).

Procedures generally performed under intravenous conscious sedation were eligible for the study. These included all percutaneous transcatheter diagnostic and therapeutic peripheral vascular and renal interventions except simple tube changes and injections. Only patients who were able and willing to give written consent were included. Inclusion in this analysis was limited to patients undergoing vascular procedures (n = 205) and/or percutaneous kidney tube placement (n = 31) to reduce procedure-induced variability. The low state anxiety group consisted of 116 patients, of whom 103 underwent a vascular procedure and 13 underwent a renal procedure. Of the 120 patients with high state anxiety levels, 102 underwent a vascular procedure and 18 underwent a renal procedure. Exclusion criteria were severe chronic obstructive pulmonary disease, psychosis, intolerance of midazolam or fentanyl, pregnancy, and the inability to hear or understand English. An analysis of patient characteristics, other than state anxiety, in the original study demonstrated that randomization had succeeded in providing relatively homogenous treatment groups with regard to their key features such as age, sex, procedure type, anesthesia status, number of previous procedures, and presence or absence of malignancies (Table 1). (8)

On the day of the procedure, a research assistant offered the patients the opportunity to participate in a study to assess whether a relaxation exercise would enhance comfort during a medical procedure. After consenting, subjects completed the STAI state anxiety questionnaire and the Mini Mental State Exam (13). If the latter was passed (with a cutoff of 24 of 30 possible points), patients were randomly assigned to one of the three treatment groups by opening a sealed envelope containing the treatment modality.

State–Trait Anxiety Inventory

The STAI is a self-rating 40-item Likert scale discriminating between state (20 items) and trait (20 items) anxiety. Whereas trait anxiety is assumed not to change over time and refers to “relatively stable individual differences in anxiety-proneness” (2), state anxiety refers to the intensity of anxiety experienced in reaction to a specific event at a given time, assessing “feelings of apprehension, tension, nervousness, and worry” (2). Scores

### Table 1

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Total (n = 116)</th>
<th>Standard (n = 43)</th>
<th>Attention (n = 37)</th>
<th>Hypnosis (n = 36)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average STAI-S</td>
<td>32.9 ± 6.1</td>
<td>34.0 ± 5.5</td>
<td>31.1 ± 6.9</td>
<td>33.5 ± 5.7</td>
</tr>
<tr>
<td>Age (y)</td>
<td>55.3 ± 17.7</td>
<td>55.7 ± 19.0</td>
<td>56.1 ± 18.3</td>
<td>54.1 ± 15.8</td>
</tr>
<tr>
<td>Male</td>
<td>62 (53)</td>
<td>21 (49)</td>
<td>21 (57)</td>
<td>20 (56)</td>
</tr>
<tr>
<td>Female</td>
<td>54 (47)</td>
<td>22 (51)</td>
<td>16 (43)</td>
<td>16 (44)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>107 (92)</td>
<td>39 (91)</td>
<td>33 (89)</td>
<td>35 (97)</td>
</tr>
<tr>
<td>Black</td>
<td>8 (7)</td>
<td>4 (9)</td>
<td>4 (11)</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>1 (1)</td>
<td>0</td>
<td>1 (3)</td>
<td></td>
</tr>
<tr>
<td>Weight (lbs)</td>
<td>173.1 ± 36.6</td>
<td>170.6 ± 36.9</td>
<td>176.4 ± 42.7</td>
<td>172.7 ± 29.6</td>
</tr>
<tr>
<td>Mean ASA score</td>
<td>2.2 ± 0.6</td>
<td>2.2 ± 0.5</td>
<td>2.3 ± 0.7</td>
<td>1.9 ± 0.7</td>
</tr>
</tbody>
</table>

Note.—Values presented as means ± SD where applicable. Values in parentheses are percentages. ASA = American Society of Anesthesiologists.

### MATERIALS AND METHODS

#### Patients and Procedure

Patients were recruited from an original study of 241 patients that was designed to assess the effect of nonpharmacologic analgesia adjuncts on patients’ comfort during interventional radiologic procedures (8). This
increase in response to physical danger or psychologic stress and decrease after relaxation exercises (14).

The STAI has been used in more than 300 studies in more than 30 different languages and has been validated on several populations, including college students, neuropsychiatric patients, general patients, and surgical patients. Validity coefficients ranged from $r = 0.52$ to $r = 0.82$ when the STAI was correlated with three other accepted measures of anxiety (2,15–17). After a major revision, the new form of the STAI was also found to differentiate well between anxiety and depression (2). For assessment of preoperative anxiety, we chose the state anxiety questionnaire of the new STAI, consisting of 20 questions. Patients were instructed to circle the number that describes the intensity of their feelings concerning each question best: 1, “not at all;” 2, “somewhat;” 3, “moderately so;” 4, “very much so.” Eleven of these questions express presence of anxiety, (eg, “I am tense,” “I feel strained,” “I am jittery,” “I am presently worrying about possible misfortunes,” “I feel frightened,” “I feel confused”), and nine describe absence of anxiety (eg, “I feel calm,” “I feel self-confident,” “I feel at ease,” “I feel content,” “I feel pleasant”). The latter statements were reverse-scored, so the highest possible anxiety score was 80.

Patients were divided into high and low state anxiety groups around the median: those with a score lower than 43 were designated to have low state anxiety levels and those with a score of 43 or greater were assigned to the high state anxiety group. The composition of the treatment groups is shown in Table 1.

### Treatment Conditions

In the original study, patients were prospectively randomized to receive standard care, empathic attention, or self-hypnotic relaxation treatment. Patients in the standard care group received the care typical for the institution; nurses were advised to behave naturally and to do their best to comfort the patients. In the attention group, an additional provider displayed structured empathic attention according to a treatment manual (18), including eight components: matching patients’ (i) verbal and (ii) nonverbal communication patterns, (iii) attentive listening, (iv) provision of perception of control (eg, “let us know at any time what we can do for you”), (v) response to patients’ requests, (vi) encouragement, (vii) emotionally neutral descriptions (eg, “what are you experiencing?”), (viii) and avoidance of negative suggestions (eg, “you will feel a pinch or burning”). For the hypnotic treatment group, an additional three key components were added: (i) starting and completing a standardized relaxation script read to the patient and addressing (ii) anxiety and (iii) pain if necessary with separate instructions in the script.

Providers sat close to the head end of the patient table behind a lead glass shield. They included two male and two female staff members (a nurse, a psychology graduate student, and two medical students) who underwent special training of 24 hours of classroom instruction and role play, study of the treatment manual and video, supervised clinical practice, and a second 8-hour workshop held by a psychologist.

The nonpharmacologic adjuncts (empathic attention and guidance to self-hypnotic relaxation) were applied in the procedure room with the patient on the procedure table. No earlier patient teaching took place outside the interventional suite, and the application of nonpharmacologic adjuncts was included in the procedure time. Patients were not screened for their hypnotizability because the goal was to provide assessment of an intervention for all patients on an intent-to-treat basis.

### Procedure Duration

Procedure duration was defined as total time from the moment the patient entered the room to the moment of departure from the angiographic suite.

### Medication Use for Intravenous Conscious Sedation

Sedatives and analgesic agents were administered in a patient-controlled analgesia (PCA)/sedation model that would reflect patients’ needs and drug-seeking behavior. PCA is well-suited for acute pain management during and after medical procedures and is thought to enhance comfort while providing patients with a means of control (19,20). Patients were given a button that signaled the attending nurse to deliver 0.5 mg of midazolam and 25 μg of fentanyl through an in-dwelling intravenous access per request a maximum of four times, with a lockout time of 5 minutes, and with a subsequent lockout time of 15 minutes. Medication was withheld during the lockout times if systolic blood pressure was lower than 89 mm Hg, oxygen saturation decreased to less than 90%, or the patient developed slurred speech or became poorly re-
Assessment of Anxiety and Pain during the Procedure

Immediately before, every 15 minutes during, and immediately after the procedure, patients were asked to rate their anxiety and pain levels on a linear numeric scale ranging from 0 to 10. Because dimmed lights and immobilization of patients in the radiographic equipment made the use of visual scales cumbersome, verbal scales were used with 0 indicating no anxiety at all and 10 indicating the worst pain imaginable. Reliability and validity of the verbally administered anxiety rating have been shown previously (21).

Statistical Analysis

Effects of treatment on total procedure duration and units of medication requested and administered were studied among the 236 patients with use of univariate analyses of variance with a between-patient factor for treatment group (standard, attention, hypnosis) and another between-patient factor for the standard care group versus the combined attention and hypnosis groups. Another supplemental analysis of variance was performed with one between-subject factor for low versus high state anxiety groups and another between-subject factor for the attention group versus the hypnosis group.

The repeated-measures analysis of pain response was designed to characterize and compare trends in patient pain ratings for the three treatment conditions crossed with the two state anxiety groups (low and high) over procedure time (23,24). The analysis employed reports from as many as 13 successive 15-minute intervals. The dependent variable for these analyses was ln(pain score + 1) to correct skewness; residuals appeared normally distributed and no outliers were identified. For descriptive flexibility, the statistical models included separate parameters for intercepts and linear trends. The intercepts are parameters estimated at a time equivalent to the time zero. These parameters adjust the overall level or height of the curves. Correlations among residuals differed according to the time between observations, decreasing with increasing separation (termed a banded or Toeplitz covariance structure) and reaching negligible levels after six intervals; there was a slight decrease in error variability in later intervals, but not enough to model. These linear mixed models were estimated with use of restricted maximum likelihood in BMDP program 5V (25), which provides unbiased estimates of the intercepts and slopes; comparisons among slopes employed two-tailed Wald statistics. Similar analyses were conducted for anxiety as measured on the 0–10 self-reporting scale.

Two orthogonal contrasts were formulated to study differences in trend among the treatments. Because there are only two degrees of freedom available, we needed to structure our analysis around two tests. The first tested whether there was any difference in trend in attention and hypnosis treatments. These contrasts were performed separately for patients with low and high state anxiety levels.

RESULTS

Analysis of Variance of Procedure Duration

There were significant main effects among the state anxiety groups and treatment groups. Patients with high state anxiety levels requested significantly longer procedure times than those with low state anxiety levels (71 minutes vs 63 minutes), and procedures in the standard group lasted significantly longer than those in the attention and hypnosis groups (77 minutes vs 63 minutes; Table 2). There was no significant interaction between treatment condition and attribution to anxiety group.

Analysis of Variance of Medication Use

There were significant main effects among the state anxiety groups and treatment groups. Patients with high state anxiety levels requested and received significantly more medication than those with low state anxiety levels, and patients in the standard group requested and received significantly more medication than those in the attention and hypnosis groups (Table 2). There was no significant interaction between treatment condition and attribution to anxiety group.

Time-course Analysis of Pain Perception

The time course of pain perception is depicted in Figure 1. The intercepts for all six combinations of treatment by state anxiety group were significantly different from zero. This indicates that patients in all groups felt some pain from the beginning of the procedure. There were no statistically significant differences between low and high state anxiety groups in any treatment group. Because there was no effect of state anxiety on intercept in any of the groups, we conclude that patients with high state anxiety levels started the procedure experiencing no more pain than those with low state anxiety.
anxiety levels in any of the treatment groups.

Table 3 shows the pain course over time as slope of $\ln(pain\ score + 1)$ for the groups tested. Patients in the low and high state anxiety groups experienced a significant increase of pain over time under standard care, but not under attention and hypnosis conditions. The slope of pain trend was significantly greater for standard care than attention and hypnosis conditions for patients with low state anxiety levels and came close to but missed significance for patients with high state anxiety levels ($P = .061$).

That attention and hypnosis treatment provided better control of pain than standard care can be seen in Figure 1 as a widening gap between the curves for standard care and attention and a widening gap between the curves for standard care and hypnosis as the procedures continue over time.
Please note that this phenomenon is observed for patients in the high and low state anxiety groups.

**Time-course Analysis of Anxiety Ratings**

The time course of patients’ anxiety self-rating is shown in Figure 2. The intercepts for all six combinations of treatment by state anxiety were significantly different from zero, which means that all patients in all conditions reported anxiety at the beginning of the procedure. Within each of the three treatment groups, the intercept for the high state anxiety group was significantly greater than the low state anxiety group receiving attention treatment, as evidenced by a widening gap between the curves in Figure 2. This was not the case for patients with low state anxiety levels who started at a lower anxiety level, as described earlier.

**DISCUSSION**

Patients with high state anxiety levels required more procedure time and requested and received more medication than patients with low state anxiety levels. These findings are consistent with previous studies that described a relationship between anxiety and analgesia consumption in PCA models (19,26). One explanation for greater requests for drugs in anxious patients could be the greater fear of pain or the wish for sedation to overcome anxiety, as another investigator suggests (27).

Although patients with high state anxiety levels rated their anxiety significantly higher at the beginning of the procedure than did patients with low state anxiety levels, as one might expect, anxiety decreased over time for all groups (with the exception of the low state anxiety group receiving attention treatment). As Figure 2 and the analyses suggest, patients with low state anxiety levels fared relatively well and were able to cope with their anxiety regardless of whether they were supported by nonpharmacologic adjunct treatments. Starting the procedure at higher anxiety levels, patients with high state anxiety levels experienced significantly greater anxiety at all procedure intervals than patients with low state anxiety levels when left to their own coping mechanisms. Although this may be one of the causes of greater medication use in this PCA model, as pointed out earlier, there may also be practical implications in models of intravenous conscious sedation in which nurses and physicians determine the amounts of drugs patients receive. Fear of patients possibly becoming anxious and patients demonstrating anxiety represent two of the strongest triggers for provider-directed medication (28), and therefore risk of oversedation for patients with high state anxiety levels may increase.

Hypnotic interventions have been shown to decrease anxiety during invasive medical procedures in various patient populations (7–9,29). The findings of this study suggest that patients with high state anxiety levels are expected to benefit to a greater extent and contribute substantially to the main positive outcome effects observed in the literature.

Although patients with high and low state anxiety levels reported sig-

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**Table 3 Repeated-Measures Analyses**

<table>
<thead>
<tr>
<th>Group</th>
<th>Slope ± SE</th>
<th>Slope of Standard vs Attention and Hypnosis</th>
<th>Slope of Attention vs Hypnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Standard Care ln(score+1)</td>
<td>Attention ln(score+1)</td>
<td>Hypnosis ln(score+1)</td>
</tr>
<tr>
<td>Pain perception</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low state anxiety</td>
<td>0.10 ± 0.03 (P &lt; .001)</td>
<td>0.04 ± 0.04 (NS)</td>
<td>−0.07 ± 0.04 (NS)</td>
</tr>
<tr>
<td>High state anxiety</td>
<td>0.14 ± 0.03 (P &lt; .01)</td>
<td>0.04 ± 0.02 (NS)</td>
<td>−0.01 ± 0.03 (NS)</td>
</tr>
<tr>
<td>Anxiety self-rating</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low state anxiety</td>
<td>−0.06 ± 0.02 (P &lt; .01)</td>
<td>−0.07 ± 0.04 (P = .06)</td>
<td>−0.07 ± 0.03 (NS)</td>
</tr>
<tr>
<td>High state anxiety</td>
<td>−0.30 ± 0.01 (P &lt; .05)</td>
<td>−0.08 ± 0.02 (P &lt; .001)</td>
<td>−0.14 ± 0.03 (P &lt; .0001)</td>
</tr>
</tbody>
</table>

**Note.** NS = not significant at P < .05. The level of significance for the slopes indicates whether a slope is different from zero. Zero equals a statistical “flat line” with no significant increase or decrease over time. For comparison of negative, decreasing slopes note that “>” means a less steep decline per time; ie, less therapeutic effect. Standard errors take the correlation into account: (SE = SD * SQRT[1 – r²]).
nificantly different anxiety levels at the beginning of the procedure, there were no differences in self-reported pain at the onset. The widening gap in pain perception between standard care treatment and nonpharmacologic analgesia treatments over time reached significance in the low state anxiety group, but closely missed significance in the high state anxiety group (Fig 2).

The relationship between anxiety and pain has been a subject of interest in many studies (2,10,30–35). Anxiety is defined as a future-oriented emotional state characterized by negative affect, such as “subjective feelings of tension, apprehension, nervousness, and worry” (2). Anxiety has to be discriminated from fear, an immediate alarm reaction to a present threat characterized by impulses to escape (30). Fear is considered pain-irrelevant whereas anxiety is seen as pain-relevant and can even be caused by pain (10). Pain is a sensory and emotional experience. Pain is influenced by physiologic, cognitive, sensory, affective, sociocultural, and behavioral components that are integrated by limbic and reticular structures of the central nervous system to modulate the pain perception and response (10). Anxiety is part of the affective component (10). Anxiety and pain evoke similar physiologic responses. On this basis, Walding (31) concluded that anxiety likely potentiates pain. Although some laboratory studies were not able to demonstrate an effect of anxiety on pain (32,33), others found that anxiety increases pain (30,34). Nelson et al (10) showed that high postoperative anxiety levels, measured by the STAI state anxiety form, were associated with increased pain, as measured by the McGill Pain Questionnaire, in patients undergoing coronary artery bypass graft procedures. Bodden-Heidrich (35) described a positive relationship between anxiety and pain in young girls undergoing their first gynecologic examination. In our study, anxiety did not seem to affect baseline pain levels, but settings with less procedural anxiety tended to be associated with less pain and less medication use. Therefore, one may construct an interaction between intraoperative anxiety and pain in the interventional radiology setting. It remains unclear whether high anxiety provokes a pain response or higher pain increases anxiety.

Increased procedure times for the high state anxiety group may be in part because of a greater need for sedation, requiring medication delivery and monitoring of side effects. This may already divert attention from progression of the procedure. Also, an anxious patient may elicit matching responses from the personnel, thereby further interfering with workflow.

CONCLUSIONS

We conclude that patients’ baseline anxiety level predicts trends of procedural anxiety, need for medication, and procedure duration. Patients with low and high state anxiety levels profit from the use of nonpharmacologic analgesia adjunct treatments, but those with high state anxiety levels have the most to gain because they require more resources and are at greater risk of having their anxiety and pain suboptimally addressed under standard care conditions.

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References


