



Adjunctive self-hypnotic relaxation for outpatient medical procedures: A prospective randomized trial with women undergoing large core breast biopsy

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Abstract

Medical procedures in outpatient settings have limited options of managing pain and anxiety pharmacologically. We therefore assessed whether this can be achieved by adjunct self-hypnotic relaxation in a common and particularly anxiety provoking procedure. Two hundred and thirty-six women referred for large core needle breast biopsy to an urban tertiary university-affiliated medical center were prospectively randomized to receive standard care ($n = 76$), structured empathic attention ($n = 82$), or self-hypnotic relaxation ($n = 78$) during their procedures. Patients' self-ratings at 10 min-intervals of pain and anxiety on 0–10 verbal analog scales with 0 = no pain/anxiety at all, 10 = worst pain/anxiety possible, were compared in an ordinal logistic regression model. Women's anxiety increased significantly in the standard group (logit slope = 0.18, $p < 0.001$), did not change in the empathy group (slope = -0.04 , $p = 0.45$), and decreased significantly in the hypnosis group (slope = -0.27 , $p < 0.001$). Pain increased significantly in all three groups (logit slopes: standard care = 0.53, empathy = 0.37, hypnosis = 0.34; all $p < 0.001$) though less steeply with hypnosis and empathy than standard care ($p = 0.024$ and $p = 0.018$, respectively). Room time and cost were not significantly different in an univariate ANOVA despite hypnosis and empathy requiring an additional professional: 46 min/\$161 for standard care, 43 min/\$163 for empathy, and 39 min/\$152 for hypnosis. We conclude that, while both structured empathy and hypnosis decrease procedural pain and anxiety, hypnosis provides more powerful anxiety relief without undue cost and thus appears attractive for outpatient pain management.

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1. Introduction

Medical procedures in outpatient settings have limited options of managing pain and anxiety pharmacologically. Nonpharmacologic adjuncts in these busy settings are largely under-investigated. This leaves patients with little

help. The situation is aggravated when the procedure involves pain and is highly anxiety provoking. We therefore chose large core breast biopsy as a model in which to assess the efficacy of biobehavioral interventions.

Breast cancer is one of the most common and feared cancers among women, affecting as many as one in eight (American Cancer Society, 2005). Screening mammography enables early detection and can improve chances of successful treatment and survival (Tabar et al.,

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2003). In the US, more than 60% of women aged 40 or older undergo mammography each year (Centers of Disease Control and Prevention (CDC), 2002). Five to ten percent of mammograms yield abnormal or inconclusive results that require further work-up (American Cancer Society, 2005). For these patients and also those with lumps found by palpation, image-guided large core needle biopsy (LCNB) has evolved as a reliable diagnostic tool (Meyer et al., 1999).

LCNB is typically performed in outpatient settings with local anesthetic (American College of Radiology, 2000) which reduces cost (Groenewoud et al., 2004) but limits the use of intravenous drugs to reduce pain and anxiety. Some advocate the use of oral anxiolytics (van Vlymen et al., 1999; Bugbee et al., 2005) but these restrict patients from driving and working after the procedure. In a mammography study, psychological intervention was found to reduce distress in select patients (Caruso et al., 2001). In a study of breast biopsies, relaxation treatment yielded no demonstrable effects (Bugbee et al., 2005). Encouraged by a prior report which showed less pain, anxiety, and need for intravenous medication in patients having self-hypnotic relaxation during more invasive medical procedures (Lang et al., 2000), we hypothesized that such an intervention could reduce pain and anxiety in patients undergoing LCNB. Thus we designed the following prospective randomized trial.

2. Methods

2.1. Patients

Review Boards of the institution and the funding agency approved this study. Outpatients referred for LCNB in the Radiology Department of an urban, tertiary, University-affiliated Medical Center who were willing and able to give written informed consent and were able to hear and understand English were eligible for this study. Consecutive eligible patients were asked to participate in this study to assess the effect of a self-hypnotic relaxation exercise applied in addition to local anesthetic. Patients who passed screening for mental impairment with the Mini Mental-State Exam (Folstein et al., 1975) and for psychosis with the Schedule for Affective Disorders and Schizophrenia (Spitzer and Endicott, 1979) were randomly assigned to receive standard care treatment, empathy, or self-hypnotic relaxation treatment on the procedure table.

2.2. Large core needle biopsy

Breast biopsy was performed according to standard clinic practice using povidone scrub, local anesthetic, a 5-mm wide blade incision for insertion of an 8 or 14 gauge biopsy gun (Bard, Covington, GA), ultrasonographic or radiographic guidance, and steri strips for closing wound margins. For local anesthesia 5 mL of 1% lidocaine was used superficially and 10 mL 1% lidocaine with epinephrine for the depth. Patients had neither before nor during the procedure oral or peroral anxiolytics or analgesics.

Adverse events were recorded according to the Standards of the Society of Interventional Radiology (Sachs et al., 2003). Room time was defined as the time the patient occupied the procedure room. Total procedure costs were based on calculations suggested for mammography teams (Raza et al., 2001) using the following local cost per minute: \$2.135 for staff radiologists, \$0.692 for fellows/ residents, \$0.726 for technologists, \$0.730 for room and equipment, and \$0.373 for the research assistants providing empathy and hypnosis.

2.3. Test and control treatments

The experiment included three conditions: Standard care, Empathy, and Hypnosis. The behaviors that define the Empathy condition were also included in the Hypnosis condition. The empathy behaviors were designed to develop rapid rapport and set the stage for inducing hypnosis in even hypnosis-naïve patients. Since these behaviors alone might affect reported pain and anxiety, they were included in a separate empathic attention control condition.

As standard care, the biopsy team attempted to comfort patients in their usual way: they warned of upcoming stimuli, asked patients about their experience, commiserated with them about discomfort, and generally expressed sympathy.

The Empathy condition was defined by a set of structured attentive behaviors engaged in by a research assistant. These behaviors were standardized according to a manual and proven suitable for invasive procedures in radiology (Lang and Berbaum, 1997; Lang et al., 1999). The behaviors included matching the patient's verbal and nonverbal communication pattern, listening attentively, providing the perception of control ("Let us know at any time what we can do for you"), swiftly responding to patient's requests, encouraging the patient, avoiding negatively valued language (e.g. "You will feel a burn and a sting"), and use of emotionally neutral descriptors instead ("This is the local anesthetic").

In the Hypnosis condition, patients received all of the attentive behaviors used in the Empathy condition. In addition, the research assistant read a standardized hypnotic induction script (Lang et al., 1999), and, as needed, addressed the patient's anxiety, pain, or worries according to the prescriptions of the script. The script invited patients to roll their eyes upwards, close their eyes, breathe deeply, focus on a sensation of floating, and experience a pleasant setting of their choice with all their senses. The text suggested transforming potential discomfort into a sensation of warmth, coolness, or tingling. If needed, a provision in the script guided patients to project their worries and fears onto the left side of an imaginary split screen and find solutions on the right side of the screen. The research assistants coached the patients according to the script in developing their own imagery and solutions to further the self-hypnotic process. The script is included in Appendix A.

The research assistants included one male and one female physician, two female medical students, and one female pre-medical student with a background in mental health sciences. They had received standardized training in empathic structured attention and hypnosis under supervision of physicians and psychologists. The training included workshops, teaching videos, reading material, a web-based course, and supervised practice with patients (Lang and Berbaum, 1997; Lang et al.,

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