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To cite this article: Alison Snow LCSW-R , David Dorfman PhD , Rachel Warbet LCSW , Meredith Cammarata LCSW , Stephanie Eisenman LCSW , Felice Zilberfein PhD , Luis Isola MD & Shyamala Navada MD (2012) A Randomized Trial of Hypnosis for Relief of Pain and Anxiety in Adult Cancer Patients Undergoing Bone Marrow Procedures, Journal of Psychosocial Oncology, 30:3, 281-293, DOI: [10.1080/07347332.2012.664261](https://doi.org/10.1080/07347332.2012.664261)

To link to this article: <http://dx.doi.org/10.1080/07347332.2012.664261>



Accepted author version posted online: 05 Mar 2012.
Published online: 05 Mar 2012.



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A Randomized Trial of Hypnosis for Relief of Pain and Anxiety in Adult Cancer Patients Undergoing Bone Marrow Procedures

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Pain and anxiety are closely associated with bone marrow aspirates and biopsies. To determine whether hypnosis administered concurrently with the procedure can ameliorate these morbidities, the authors randomly assigned 80 cancer patients undergoing bone marrow aspirates and biopsies to either hypnosis or standard of care. The hypnosis intervention reduced the anxiety associated with procedure, but the difference in pain scores between the two groups was not statistically significant. The authors conclude that brief hypnosis concurrently administered reduces patient anxiety during bone marrow aspirates and biopsies but may not adequately control pain. The authors explain this latter finding as indicating that the sensory component of a patient's pain experience may be of lesser importance than the affective component. The authors describe future studies to clarify their results and address the limitations of this study.

Support for this research was provided by grants from the American Cancer Society (119621-DSW-10-096-01-SW) to the first author, and the Jacob and Valeria Langeloth Foundation (Project 614) to the second author. The authors thank Jay Horton, NP, Jacqueline Wu, and Drs. George Davidson, Valentina Dilda, and Lewis Silverman for their help in carrying out this research.

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KEYWORDS *bone marrow biopsies, hypnosis, pain, anxiety, hematological malignancies*

INTRODUCTION

Bone marrow aspiration and biopsy play a central role in the diagnosis and follow-up of many hematological disorders. More than 300,000 patients undergo bone marrow aspirates and biopsies annually for diagnosis and disease monitoring of blood and bone marrow cancers in the United States (American Cancer Society, 2010). Cancer patients frequently find medical procedures sources of psychological and physiological stress. As a result, they are likely to experience high levels of anxiety and distress prior to and during them (Pinnell & Covino, 1999). In particular, needle-related procedures are a common source of pain and distress for oncology patients (Deng & Cassileth, 2005; Uman, Chambers, McGrath, & Kisely, 2006). Bone marrow aspirations and biopsies are typically regarded as painful and traumatic procedures (Vanhalleputte, Nijs, Delforge, Evers, & Vanderschueren, 2003). Although local anesthesia is routinely applied to the skin, subcutaneous tissue, and periosteum, it does not prevent the transient pain experienced during the suction and penetration of the needle into the bone, nor does it prevent the anxiety associated with the procedure. Although patients sometimes receive pain and anxiolytic medications, they are not routinely given prior to procedures. For example, Puntillo et al. (2001) found that less than 20% of patients undergoing potentially painful procedures received preprocedure opiates. Moreover, patients who receive pain and/or anxiety medication often still report pain and discomfort from the procedure, due to the penetration of the needle into the bone and the aspiration. Furthermore, analgesic and anxiolytic medications are often associated with unpleasant side effects. For example, lorazepam was associated with prolonged sedation and amnesia (Milligan, Howard, & Judd, 1987).

Anxiety can also amplify pain perception in procedural settings (Deng & Cassileth, 2005). When a patient experiences a painful procedure, the memory can cause anxiety about subsequent procedures. Moreover, anxiety can increase the pain severity patients experience during later procedures (Kellerman, Zeltzer, Ellenberg, & Dash, 1983; Weisman, Bernstein, & Shechter, 1998). Hypnosis has been frequently studied as an intervention for children and adolescents undergoing bone marrow aspirates and biopsies and has been shown to have a good response to the acute pain associated with this procedure (Patterson & Jensen, 2003). There are at least five studies that involved children undergoing bone marrow aspirates and biopsies that resulted in decreased pain and anxiety compared to control groups (Katz, Kellerman, & Ellenberg, 1987; Kuttner, Bowman, & Teasdale, 1988; Lioffi & Haitra, 1999; Wall & Womack, 1989; Zeltzer & Lebaron, 1982). However,

these studies have some methodological limitations including underpowered sample sizes and lack of reporting of the method of randomization (Richardson, Smith, McCall, & Pilkington, 2006). Of the five published works, Kuttner et al. (1988) had the largest sample size of 48 patients with an unknown method of randomization, whereas another (Wall & Womack, 1989) had only had 20 pediatric patients in their nonrandomized sample. Despite positive findings in the literature involving children, support for the effectiveness of hypnotic interventions is limited by heterogeneity, small sample size, and absence of treatment manuals (Neron & Stephenson, 2007; Pinnell & Covino, 1999). Furthermore, the field of child hypnosis is in an early stage of development regarding “gold standard” validation (Alladin, Sabatini, & Amundson, 2007).

Although providers may find premedication with pharmacologic agents inexpensive and easy to employ, they also have substantial disadvantages. For example, Lang et al. (2006) pointed out that patients who are premedicated cannot drive or engage in work involving machinery. Such limitations burden patients and their care providers as well as adding costs to the health care system following the procedure (Lang & Rosen, 2002). As previously noted, nonpharmacological alternatives have been proposed and tested in pediatric patients, including art therapy, hypnosis, and cognitive-behavioral therapy (Liossi & Hatira, 1999). However, there has been relatively little research on alternative therapies in adult hematologic patients. Behavioral methods have been broadly accepted because of their positive impact on patient distress and suffering, the ease of their application, and the sense of control their use provides to a vulnerable patient population (Redd, Montgomery, & DuHamel, 2001). Montgomery, DuHamel, and Redd (2000) conducted a meta-analytic review of 18 articles and 27 effect sizes to determine the effectiveness of hypnotic suggestions for pain relief relative to other psychological interventions. They recommended broadening the use of hypnosis for pain control as a result of their positive findings. Additionally, Schnur et al. (2008) conducted a meta-analytic review of hypnosis on emotional distress associated with medical procedures and reported a large effect size, supporting hypnosis as an intervention that reduces emotional distress.

Although a variety of behavioral methods have been shown to reduce treatment related pain, increasing evidence demonstrates that hypnotic methods have the greatest potential for benefit to the patient. These methods involve relaxation and suggestions for reduced pain and anxiety (Redd et al., 2001). Behavioral interventions, either alone or together with standard pharmacological approaches, have shown effectiveness in the management of acute pain syndromes (Portenoy & Kanner, 1996). They also have the advantage of cost effectiveness and lack of side effects. Hypnotherapy in particular has several advantages in making it a possible treatment for pain and anxiety associated with adult bone marrow aspirates and biopsies. Hypnosis has

the advantage of cost effectiveness in comparison to patients who choose to get bone marrow biopsies under monitored airway control (MAC) anesthesia in an operating room. Although bone marrow aspirates and biopsies are routinely performed in the outpatient setting, when patients chose to get MAC, the costs are considerable (Christensen & Fatchett, 2002). Additionally, hypnosis used in other procedural settings was shown to reduce institutional costs (Montgomery et al., 2007). Hypnosis offers patients a drug-free choice for reducing pain and anxiety without adding procedure time, cost, or side effects. In this context it would be advantageous to use psychobehavioral interventions to manage pain and distress in bone marrow biopsy patients. Either alone or in conjunction with medication, such approaches are effective in treating side effects associated with cancer treatment, especially in procedural settings (Flory & Lang, 2008; Neron & Stephenson, 2007).

In the last decade, hypnosis has gained recognition as a useful and beneficial clinical pain tool (Pavlek, 2008). Although there is a growing body of knowledge demonstrating the effectiveness of hypnosis to control anxiety and pain with children undergoing bone marrow biopsies, the issue of whether hypnosis is also beneficial to adult cancer patients undergoing the same procedures has not been adequately addressed. In this article we present the results of a randomized controlled trial of a brief hypnosis intervention for the pain and anxiety experienced by cancer patients undergoing bone marrow aspirates and biopsies.

METHOD

Participants

The study was approved by the Mount Sinai Medical Center Institutional Review Board, and participants provided informed consent. Participants were adult male and female English speaking patients undergoing bone marrow aspirations and/or biopsies at Mount Sinai Medical Center's outpatient cancer treatment center receiving standard of care procedures as defined below. All were volunteers serving without pay.

Measurement Tools

As in previous similar studies (e.g., Lang et al., 2006; Montgomery et al., 2007), pain and anxiety were assessed using visual analog scales (VAS) (Price, McGrath, Rafii, & Buckingham, 1983). Typically, the scale consists of a 100-millimeter horizontal line anchored by verbal descriptors at each end of the line. Patients are instructed to place a vertical line at a point between anchors equivalent to the psychological magnitude being assessed. For the pain VAS, the anchors were *no pain at the biopsy site* versus *very severe pain*

at the biopsy site. For the anxiety VAS, the anchors were *no anxiety* versus *very severe anxiety*.

In addition to the outcome measures described above, we administered the “Trait” section of the State Trait Anxiety Inventory (STAI; Spielberger, 1981). The purpose of this measure was to assess whether the two groups were equivalent in terms of chronic levels of anxiety. Blood pressure and heart rate were also recorded before and after the procedure. Patient overall satisfaction with the visit was assessed using a 7-step scale of verbal descriptors: *very satisfied*, *pretty satisfied*, *somewhat satisfied*, *neutral*, *somewhat dissatisfied*, *pretty dissatisfied*, *very dissatisfied*.

Procedure

Patients were informed of the availability of the study by a member of their cancer care health team. Those who expressed an interest in participating were referred to a member of the research team, who explained the study and obtained informed consent. Patients signed informed consent either in the days leading up to the procedure or on the same day. Patients were randomized to either standard of care or to hypnosis just prior to the procedure. Patients were notified of their treatment group and then the prebiopsy scales (VAS, STAI, etc.) were collected immediately prior to the procedure, for the hypnosis and standard of care groups.

In the hypnosis arm, patients received the standard of care along with the hypnosis intervention during the procedure. That is, following the injection of the local anesthetic by the physician hypnosis was performed by an oncology social worker (AS, RW, MC, SE). Each oncology social worker had undergone 40 hours of advanced training in hypnosis administration. After 15 minutes, the physician and oncology nurse returned to the room and began the aspiration/biopsy procedure. The oncology social worker continued to deliver the hypnosis until the procedure was completed. In the standard of care arm, the oncology social worker was not present in the room during the biopsy, and the patient received the standard bone marrow aspiration/biopsy procedure as outlined below. Procedure time was recorded for each study participant.

An oncology social worker provided instruction to patients regarding completion of the measures taken before the biopsy, and a different oncology social worker provided instruction with regard to completion of the measures taken immediately following the procedure. The oncology social worker administering the postprocedure measures were blinded with respect to which arm of the study the participant had been assigned. One of the medical personnel (typically the medical assistant) took each participant's blood pressure and heart rate just prior to, and immediately following, the procedure.

Bone marrow aspiration/biopsy procedure. The site of the procedure was either the right or left posterior iliac crest of the hip bone. Standard of care for pain control is lidocaine injected to the skin, subcutaneous tissue, and periosteum for local anesthesia. Fifteen minutes later, an aspirate needle is inserted through the skin and advanced through the bony cortex into the marrow cavity. A syringe is attached to the needle and used to obtain liquid bone marrow. The aspirate needle is removed and a Jamshidi needle is inserted and anchored into the bony cortex. It is used to obtain a trephine biopsy for pathological analysis. Subsequently, this needle is removed and pressure is applied to the site to prevent bleeding.

Hypnosis induction. The hypnosis induction followed a script devised by two of the authors (AS, RW) using procedures similar to those utilized by Dorfman and colleagues (2008). The script focused on relaxation and reduction of sensation in the area of needle insertion. The script begins with an induction focusing on progressive muscle relaxation and suggestion designed to generate feelings of calm and ease followed by a visualization of a beach scene to further enhance feelings of relaxation and bring patients into a deeper state of trance. Patients were encouraged to “let go of as much tension as they were ready to; allowing themselves to go deeper and deeper in a state of relaxation; letting go of any cares and concern,” For pain management participants were encouraged to distract themselves, that is, “in a movie you can become absorbed and distracted so that you do not even notice a headache.” There were also suggestions that patients could control the sensations by “dialing down the pain” and “placing their breath in the area that needed it the most.” The script also provided suggestions for “cool, comfortable numbness,” and imagery suggestions associated with those feelings were provided. Toward the end, posthypnotic suggestions assured for patients that they “had the ability within them to return to this special place in the future whenever they needed to.”

Statistical Analysis

The statistical analyses addressed three questions: (1) whether the two groups (hypnosis vs. standard of care) were comparable in terms of demographic, medical, and psychological variables; (2) whether the two groups differed in VAS pain scores; and (3) whether the two groups differed in the extent to which their anxiety was reduced. To address the first question we used either χ^2 or independent samples t tests. To address the second question we compared the pain scores with an independent samples t test. To address the third question we computed change scores (VAS anxiety prior to procedure minus VAS anxiety following procedure) for each patient. The resulting changes scores for the two groups were compared using a nonparametric test.

TABLE 1 Characteristics of Study Population ($N = 80$)

	Hypnosis ($n = 41$) n (%)	Standard of Care ($n = 39$) n (%)
Ethnic composition		
Non-Hispanic White	21 (51%)	30 (77%)
Hispanic	5 (12%)	3 (8%)
African American	8 (20%)	6 (15%)
Asian	5 (12%)	0
Other	2 (5%)	0
Sex		
Female/male	20/21	18/21
Highest level of education		
Secondary school	14 (34%)	5 (13%)
College	10 (24%)	18 (46%)
Postbaccalaureate	16 (39%)	16 (41%)
Unknown	1 (2%)	0
Diagnosis		
Leukemia	5 (12%)	9 (23%)
Lymphoma	10 (24%)	2 (5%)
Plasma cell dyscrasias	6 (15%)	5 (13%)
Myelodysplastic syndrome	7 (17%)	10 (26%)
Myeloproliferative disorder	9 (22%)	9 (23%)
Aplastic anemia	2 (5%)	0
Multiple or other disorders	2 (5%)	4 (10%)
Analgesic or anxiolytic medications		
Analgesics	7 (17%)	8 (21%)
Anxiolytics	4 (10%)	3 (8%)
None	29 (71%)	27 (69%)
Unknown	1 (2%)	1 (2%)
Other characteristics	M (SD)	M (SD)
Age in years	58 (\pm 14)	61 (\pm 14)
Body mass index	25 (\pm 5)	27 (\pm 7)
Trait anxiety score	38 (\pm 11)	34 (\pm 10)
Baseline anxiety level	48 (\pm 28)	36 (\pm 27)

RESULTS

A total of 80 patients signed informed consent and were randomized to either the hypnosis ($n = 41$) or standard of care only ($n = 39$). Data were also gathered from two additional participants, but their data were discarded because they had been premedicated with anxiolytics and thus had not received standard of treatment as defined earlier.

The characteristics of the study population are shown in Table 1. The two groups do not differ in ethnicity ($\chi^2 = 5.87$, $df = 4$, ns), sex ($\chi^2 = .105$, $df = 1$, ns), highest level of education ($\chi^2 = 3.26$, $df = 4$, ns), cancer diagnosis ($\chi^2 = 9.59$, $df = 6$, ns), or use of analgesic or anxiolytics ($\chi^2 = .281$, $df = 4$, ns). The two groups are also comparable in age, $t(78) = .920$,

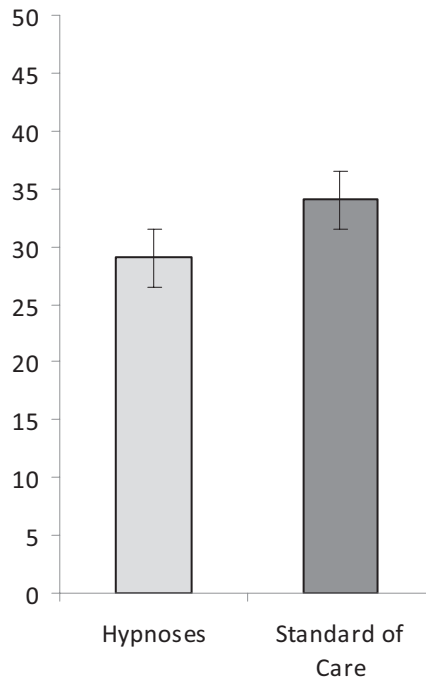


FIGURE 1 Visual analog scales pain scores in millimeters: Means and Standard Error.

ns, body mass index, $t(78) = 1.25$, ns, chronic levels of anxiety, $t(78) = 1.78$, ns, and baseline VAS prior to the procedure, $t(78) = 1.84$, ns. There were 12 hematologists who participated and the analysis showed that no hematologist was over represented in one group versus another group, $\chi^2 = 6.79$, $df = 11$, ns.

VAS pain scores are presented in Figure 1. As can be seen in Figure 1, the scores are slightly lower in for the hypnosis group; however the difference is not statistically significant, $t(78) = .916$, ns. To determine any reductions in anxiety, a change score was calculated for each patient by subtracting the VAS anxiety measure taken after the procedure, from the VAS anxiety measure taken before the procedure. These data are presented in Figure 2. As can be seen, the reduction in anxiety was substantially greater in the hypnosis group than in the standard of care group. Nonparametric tests show that the difference is statistically significant (median test, $p = .026$). There were no discernable differences between the two groups in terms of the physiological measures (blood pressure and heart rate). The time that the procedure took was comparable for both groups (28 minutes 18 seconds in the hypnosis group vs. 24 minutes and 23 seconds in the control group). Patients in both groups expressed high levels of satisfaction with their experience; specifically 72 patients (36 in each group) rated themselves as either “very satisfied or “pretty satisfied” with their experience.

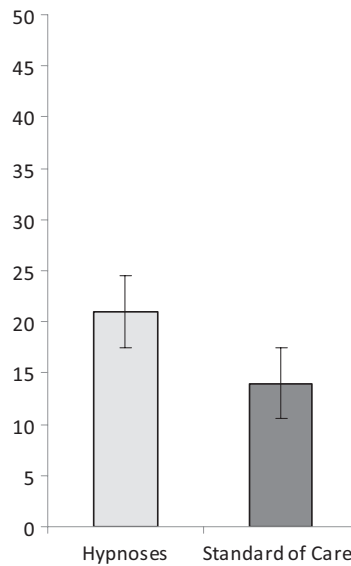


FIGURE 2 Reduction in visual analog scales anxiety scores in millimeters: Means and Standard Errors.

DISCUSSION AND CONCLUSIONS

In this article we present the results of a randomized controlled trial of a brief hypnosis intervention for the pain and anxiety experienced by cancer patients undergoing bone marrow aspirates and biopsies. We found that though hypnosis resulted in a reduction in the affective component of pain, that is, anxiety, there was no statistically significant reduction in the sensory component of pain. The first finding is consistent with many of the previous findings that hypnosis is effective in controlling the affective morbidities associated with medical procedures. The second finding, that there was no measurable reduction in pain, is at first glance unexpected. Not only is this latter result contrary to a large literature pointing to the effectiveness in reducing pain associated with medical procedures, but also the studies on which we closely modeled our protocol (Lang et al., 2006; Montgomery et al., 2007) did find such a reduction.

If we compare this study with those of Montgomery et al. (2007) and Lang et al. (2006), the difference in results is in retrospect less surprising, because the etiological components of the two types of pain are different. Specifically in bone marrow aspirations and biopsies, a large part of the pain experience arises from transient activation of neuropathic pain mechanisms as the needle penetrates the periosteum and the aspirate is withdrawn. The nociceptive component is relatively minor because little tissue mass is involved. Thus the sensory component of the patients' pain experience could

be expected to be brief and not as salient to a patient's overall pain experience as the affective component. By contrast, in excisional breast biopsy, the entire suspicious mass or area, plus a margin of normal appearing tissue, is removed with a scalpel. Thus for patients undergoing excisional breast biopsy, the sensory component of the pain experience would not only be intense, but also more long lasting and more salient. In such circumstances our findings appear less surprising.

This point is reinforced if we compare our VAS pain intensity scores with those reported by Montgomery et al. (2007). They found that the pain intensity was 47.83 millimeters for their attention control group, significantly higher than we found in our standard of care condition, $t(38) = 3.61$, $p = .001$. On the other hand, the scores in their hypnosis condition were 22.43 millimeters, which does not differ from the VAS scores in our hypnosis condition, $t(40) = 1.78$, ns. This pattern suggests a floor effect: that is, though our hypnosis procedure may have resulted in some pain reduction, the reduction was modest at best; because our patient's untreated level of pain was low to begin with.

To conclude, our results show that though hypnosis is effective in reducing the affective component of a patient's pain experience, there was little evidence for a reduction in sensory component. Further, our results suggest that when compared to other medical procedures that oncology patients undergo, the sensory component makes a relatively smaller contribution to patient's pain experience than the affective component.

Future studies of hypnosis in managing pain related morbidities of bone marrow aspirates and biopsies should address three limitations of this study.

1. More extensive measurement of the pain related experience: In this study, there was a single VAS measure of pain intensity and of anxiety. Yet neither the sensory or affective components of a patient's pain experience is unidimensional. Thus a measure designed to capture multiple aspects of patients' pain experiences could be more appropriate than a unidimensional scale. An example of such a scale is the Short Form McGill Pain Scale (Melzack, 1987) that allows measurement of qualitative sensory dimensions such as "hot-burning" and "throbbing" as well as affective dimensions such as "unpleasant" and "sickening."
2. Larger sample size: Although this study was sufficiently powered to detect the main effects on pain and anxiety, there was not sufficient power to determine the possible effects of moderating variables such as cancer type, or remove the effect of nuisance variables, such as differences between hypnotherapists and the differences between physicians performing the biopsies.
3. Procedural difficulties: In this study, the hypnosis induction was administered during the interval between the injection of the local anesthesia and

the time the procedure was done. Although the interval was nominally 15 minutes, in practice the time varied, and in some instances the induction was incomplete when the procedure began. In future studies the procedure should be adjusted such that the procedure does not begin until the induction is completed to the hypnotherapist's satisfaction.

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