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Music for patients with hematological malignancies undergoing bone marrow biopsy: a randomized controlled study of anxiety, perceived pain, and patient satisfaction

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Abstract

Objective—To examine the impact of random assignment to music versus usual care on anxiety, perceived pain level and patient satisfaction in patients undergoing bone marrow biopsies.

Method—Patients were randomized to music or usual care after completing a baseline questionnaire. All patients completed a post-procedure questionnaire.

Results—Study participants (N=59) had a mean age of 50.9 years (SD = 13.9; range 22–78). Post-procedure state anxiety (STAI) and pain rating (VAS) were not significantly different between groups (STAI p=0.766; VAS p=0.771). However, patient satisfaction with music was high; 66% of these patients said they very much preferred to listen to music at a future biopsy.

Conclusions—While there were no significant group differences for the music intervention compared to standard of care for anxiety or perceived pain, additional feedback indicated that patients found the music intervention beneficial and requested use of music during future procedures.

Keywords

Bone Marrow Biopsy; Hematological Malignancy; Anxiety; Pain; Mind-Body Intervention; Music

Introduction

Playing background music is a low-cost technique that has been used effectively in medical procedures such as colonoscopy, colposcopy, and bronchoscopy to reduce physical and psychological discomfort.[1–7] Some studies have shown that providing recorded music can be as or more effective in reducing anxiety than preoperative teaching, counseling, or relaxation training. [8,9] Music has also been used successfully to reduce pain and anxiety in a

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variety of situations including labor, presurgical preparation, post surgical recovery, and hospice care.[10–29] Yet despite the multiple well-accepted applications of music, no study has examined the use of music to reduce distress and discomfort during bone marrow biopsy (BMB).

BMB is often a painful and anxiety-provoking procedure that is necessary for the diagnosis of certain hematological disorders and in evaluating the extent (stage) of other malignancies. [30, 31] In addition to local anesthetic, intravenous sedation is often administered prior to the procedure to reduce patient pain and anxiety levels during the biopsy.[30] However, there is evidence to suggest that individuals experience pain despite the administration of strong pharmacologic agents.[32] While clinicians have begun to explore complementary, non-pharmacologic approaches to reduce pain and anxiety during BMB, the majority of research has focused on pediatric oncology patients. Several studies have shown that mind-body interventions such as music[33], relaxation and visualization[34], art therapy[35], distraction and relaxation[36], and hypnosis and cognitive behavioral training[37] were able to reduce distress, pain, and anxiety in pediatric cancer patients undergoing BMB. Yet within the adult oncology literature, complementary therapies to reduce pain and distress during BMB have not been examined.

The aims of this study were: (1) To determine the feasibility of an intervention to decrease distress and discomfort in patients undergoing BMB; and (2) To measure differences between groups on state anxiety, perceived pain level, and patient satisfaction following BMB. It was hypothesized that the music intervention would result in lower anxiety and perceived pain and greater satisfaction in patients undergoing BMB.

Method

Study Design

This was a randomized controlled study with pre- and post-biopsy measures completed by study participants.

Study Participants

Study participants were identified by a physician or nurse practitioner from the Section on Hematology and Oncology at the Wake Forest University Comprehensive Cancer Center. The following study eligibility criteria were used for patients: (1) adults ≥18 years of age; (2) had been diagnosed with a hematological malignancy; (3) scheduled to receive a BMB; and (4) could understand written and spoken English. There was no exclusion from the study for previous BMBs.

Setting

BMBs and the administration of all study measures took place at the Wake Forest University Comprehensive Cancer Center.

Study Measures

Demographic and Health Information—The following information was collected at baseline on all study participants: age, race/ethnicity, marital/partner status, educational history, household income, employment status, and history of previous BMB (yes/no). For patients who had previous BMBs, they also reported their total number of previous BMB procedures and where they were conducted (Wake Forest University Baptist Medical Center, outside medical center, or both).

Clinical Information—The following clinical information was obtained from the clinical record: cancer diagnosis, date of diagnosis, status of diagnosis (initial diagnosis versus recurrence), current medications, and whether pre-procedure medications were administered.

State-Trait Anxiety Inventory (STAI).[38]—The STAI is a 40-item self-report measure of state and trait anxiety. State anxiety is represented by an immediate sense of how one is feeling, whereas trait anxiety is thought to be dispositional and stable. To measure state anxiety, participants report the intensity of their feelings “right now, at this moment” to 20 items using a 4 point scale (1 = not at all to 4 = very much so). For the 20 trait anxiety items, respondents are instructed to indicate how they “generally” feel by reporting how often they experience anxiety-related feelings and cognitions using the 4-point scale (1 = almost never to 4 = almost always). Higher scores indicate greater state and trait anxiety. Both state and trait anxiety were completed prior to BMB. Since trait anxiety is presumed to remain stable over time, only state anxiety was assessed after the procedure.

Visual Analogue Scale (VAS) for Pain—Participants were asked to rate anticipated pain level (prior to the procedure) and perceived pain experienced (following the procedure) by marking a point on a 100mm line with “no pain” on one end and “worst pain” on the other end as anchors. Possible scores ranged from 0 to 100.

Patient Satisfaction Questions—After completion of the procedure, participants responded to 10 items about their level of satisfaction with the health care provider and the medical encounter. They rated health care providers on several items (showing concern, experience with the procedure, confidence in the provider) on a scale from 0 (no, not at all) to 3 (yes, as much as I wanted). Patients were asked to provide an overall rating of the care they received on a scale from 0 (poor) to 4 (excellent). For those who had previous BMBs, they were also asked to compare this BMB to previous procedures (overall pain, pain/burning from local anesthesia, pain/pressure from aspiration, pain/pressure from twisting sensation) on a scale from 0 (much worse) to 4 (much better). They indicated how long the procedure seemed to last in comparison to previous biopsies on a scale from 0 (much shorter) to 4 (much longer) and approximately how long they felt the procedure lasted. (The practitioners provided the actual length of procedure for comparison purposes.) Study participants in the music intervention group also responded to three items about the intervention (rating how much they liked the music, helpfulness of the music, desire to use music during future procedures), rated on a scale from 0 (not at all) to 4 (very much so).

Procedure

This study had approval from the Institutional Review Board at Wake Forest University Health Sciences. Informed consent was obtained by a research assistant when the patient arrived to clinic for the BMB procedure. Once informed consent was obtained, study participants were asked to complete baseline questionnaires (STAI, VAS for anticipated pain). Study participants were randomly assigned to one of the two groups (music, usual care), stratified by practitioner (3 practitioners/strata).

The BMB procedure was performed using sterile technique and infiltration of 2% lidocaine for local anesthesia. A unilateral aspirate, using a 13 gauge Illinois aspiration needle, and a unilateral biopsy, using an 11-gauge Jamshidi biopsy needle, were obtained from either the right or left posterior iliac crest. During the BMB procedure, participants in the music group were instructed to listen to the compact disc (CD). Immediately following the procedure, study participants completed post-procedure questionnaires (STAI, VAS for perceived pain during the procedure, patient satisfaction questions) before leaving the clinic. A research assistant was responsible for assembling study forms/materials and data entry.

Intervention

Study participants were randomized into one of two groups: (1) music; and (2) usual care (control). Participants in the music group were given a choice from 8 music CDs with various types of music (e.g., classical, harp, general instrumental, nature sounds, country, gospel, and jazz). Patients in the intervention group listened to the audio recording through headphones from the time the procedure started until the procedure was completed. Patients were also encouraged to listen while waiting for the procedure to begin, but this time was not required or recorded. The usual care group underwent the procedure as typically conducted, with no audio recording. Patients typically were in the clinic room for BMB for 20–60 minutes; the procedure lasted 5–40 minutes.

Statistical Methods

The goals of the statistical analyses were to explore if participation in a music intervention group during BMB versus usual care would result in less anxiety and perceived pain as well as greater patient satisfaction. The study was designed to detect a pre-specified difference of 0.74 standard deviation (SD) difference in state anxiety scores between groups at the 5% two-sided significance level with 80% Power assuming the SD of change was 10. Descriptive statistics such as mean +/− SD or frequencies and percentages were calculated to explore sample characteristics and assess balance after randomization. Demographic and pre-biopsy medical and psychosocial characteristics were compared between groups using a two-group t-test or Wilcoxon rank-sum test for continuous variables and a Chi-square or Fisher's exact test for categorical variables. State anxiety score (STAI) and VAS pain rating post-biopsy were analyzed using analysis of covariance (ANCOVA) adjusted for the baseline score. These models were performed both unadjusted for other covariates (but adjusted for baseline measure) as well as adjusted for the following covariates: baseline pre-biopsy value of the outcome variable, baseline pre-biopsy value of trait anxiety, age at biopsy, sex, marital status, race, education history, annual family income, employment status, time since diagnosis, preprocedure medication use, previous number of bone marrow biopsies, location of previous biopsies, and block randomization by practitioner (random effect for practitioner). A secondary analysis was performed on patients that were in the upper 50^{th} percentiles on baseline state anxiety or anticipated pain scores to examine if the effects of the intervention were different for those with higher baseline anxiety or anticipated pain. Comparisons between groups on patient satisfaction measures were performed using Wilcoxon rank-sum tests. A two-sided p-value <0.05 was considered to be statistically significant. All analyses were performed using SAS v9.1.3 (SAS Inc., Cary, NC).

Results

Recruitment & Study Sample Description

Over a 9-month period, 78 potential participants scheduled for a bone marrow biopsy in our outpatient clinic were identified. Of these patients, 1 did not meet study criteria (did not speak English), 12 patients refused study participation (10 patients were not interested, 1 patient was already using distraction techniques during the procedure, 1 patient could not wear earphones due to a recent ear surgery), and 2 patients were not approached to participate (1 patient was in extreme emotional distress, 1 patient was scheduled for the BMB when no Research Assistant was available for recruitment). A total of 63 of the 76 patients approached provided informed consent to participate in the study (recruitment rate = 83%); however data from 4 participants were not analyzed due to missing data. See Table 1 for a description of the resultant study sample by group (N=59). Prior to BMB, mean state anxiety score was 38.2 (SD = 12.0; range 20–77) (≥42 indicates significant anxiety in medical patients)[38].

Table 1 gives the demographics and clinical characteristics of the sample. The only significant difference between the groups was annual family income (p=0.042; 50% ≥ $50,000 annual family income in usual care group vs. 31% in music group). The number of previous biopsies was marginally significant (3.9 +/− 4.7 for music group versus 5.6 +/− 5.9 in usual care group, p=0.058).

Anxiety, Perceived Pain, and Patient Satisfaction Outcomes

Means and standard deviations for the two outcome measures (state anxiety and perceived pain) are presented in Table 2. There were no significant between-group differences in post-procedure state anxiety or pain in unadjusted modeling (state anxiety t=−0.41, df=55, p=0.67; pain t=−1.27, df=56, p=0.21). In addition, models adjusted for demographic, medical and psychosocial characteristics of the participants did not yield any significant between-group differences (Table 2; state anxiety t=−0.300, df=31, p=0.766; pain t=−0.293, df=31, p=0.771). When restricting each of these analyses to just the subgroups in the upper 50^{th} percentiles on baseline state anxiety or anticipated pain scores, again there were no significant differences between groups in outcomes.

Finally, we examined distributions of patient satisfaction responses (Table 3). There were no significant between-group differences in post-procedure patient satisfaction for questions asked of both groups. However, 66% of the participants in the music arm responded that they very much would prefer listening to music again during a future BMB.

Discussion

To our knowledge, this manuscript presents the first randomized study investigating the effects of music on anxiety, perceived pain, and patient satisfaction for patients undergoing a BMB procedure. Recruitment of an adequate sample of BMB patients was quite feasible. However, contrary to expectations, no between-group differences were observed for anxiety, perceived pain, or patient satisfaction. Even when we adjusted for a variety of demographic variables, including number of previous BMBs, there were no significant differences in trait anxiety or anticipated pain level. Further, the interventions had no demonstrable impact even on those participants who started out with the highest anxiety and anticipated pain levels. With regard to patient satisfaction, it must be noted that the ratings for both music and usual care groups were too high and had too little variability to demonstrate any between-group differences. This ceiling effect for provider and care ratings precluded our ability to detect any significant group differences. As stated in the statistical methods section, the study was designed to detect a 0.74 SD difference in STAI between-group scores assuming a SD of change of 10. What was actually observed in the trial was a change less extreme than that and a SD of change larger than that. Adjusting for other covariates in an ANCOVA analysis did not account for enough variation to overcome this. So while the actual number of study patients (N=59) was close to the pre-specified accrual target of N=60 patients and with higher than anticipated recruitment rates (observed 83% vs. hypothesized 50%), the lack of significant findings in this study was not unexpected given the observed differences. Future studies with larger sample size could be warranted.

There are several limitations in this study that should be noted. First, the choice of music selections may not have been the most preferred or appropriate for our group of participants. Previous studies have found that a significant reduction in anxiety level depended on whether study participants were able to choose their music.[39, 40] While we attempted to give participants a choice, it was limited to 8 selections that may not have included the types of music some patients would have preferred most. A second limitation is that listening time for the intervention groups was not monitored or tracked in this study, limiting our ability to verify that patients, in fact, listened to the CDs. Finally, it is not clear whether our choice of

an anxiety measure may have been inappropriate for measuring distress related to the bone marrow biopsy procedure. We do not necessarily think this is the case given that the STAI is a “gold standard” measure of anxiety, frequently used in studies with medical patients. However, in our study, we may have seen different results by using a brief measure of general distress or mood. The greater issue may have been that post-procedure anxiety was measured after the stress of the procedure had ended so that anxiety levels were naturally lower for both groups. A better potential question may have been to ask patients to recall their anxiety during the procedure rather than after it. Clearly, the ideal approach would be to obtain these ratings during the procedure rather than after it. However, asking patients to provide these ratings while undergoing a BMB would likely be quite difficult and would detract from the goal of the study intervention to distract patients.

These limitations notwithstanding, this study had a number of strengths that increase its valuable contribution to the literature. First, it was a randomized, controlled study examining potential benefits of a simple music intervention to reduce procedural distress in patients undergoing BMBs, a painful and stressful procedure for most patients. While our quantitative findings were nonsignificant, patient feedback from those in the intervention group suggested a strong preference for use of music during future procedures. In fact, the majority of those in the intervention group reportedly found the music very helpful and desired to use it again during future procedures. Further, while group differences for perceived pain and anxiety were not significant in the music arm, ratings of perceived pain were 11.8 points lower than anticipated pain levels and post-procedure anxiety ratings decreased by 7.5 points (as opposed to 4.5 and 7 points, respectively, in the usual care arm). Thus, while findings were nonsignificant, the effect was still in the anticipated direction.

This study also has important clinical implications. Providing patients with music during BMB is a relatively simple, cost effective strategy for improving patient care and potentially reducing distress. While additional research is necessary, qualitative data from this study, as well as findings from previous research, suggest that patients may find this intervention helpful and desirable. In future studies, it may be advantageous to have options available from different genres of music, radio stations or even an opportunity to bring personal materials (although this final option may introduce research challenges). Despite its difficulties, this approach could increase the meaningfulness of the musical selection and its potential for aiding in relaxation for patients. However, such an approach would introduce challenges in terms of both feasibility and empirical validation. Another consideration is creating a protocol that is given to the patient in conjunction with the music intervention, which provides step-by-step instructions for how to use the intervention. Previous research in music therapy has suggested that creating such guidelines would enable the patient to maximize the benefit of music and more effectively shift focus away from pain.[41] It would also be useful in future research to examine the impact of music interventions and how these compare to positive interactions between the health care provider and patient during the procedure. It is likely that speaking to the patient in a calm soothing voice and explaining the procedure would decrease patient distress as well. Our practitioners were quite experienced at doing this before the intervention was introduced, possibly negating any potential effects of the intervention. Another future direction is comparing the use of music to other cost-effective interventions, such as guided imagery or relaxation. While there is some preliminary support for using such interventions with children undergoing BMB, this area of research has virtually been unexplored in adults.

In conclusion, music is a useful and cost-effective instrument shown in previous studies to have therapeutic effects, both physical and psychological. In light of the discrepancy between previous research and our findings on the benefits of music interventions to

decrease anxiety and perceived pain for patients undergoing BMBs, further research in this area is warranted, especially on interventions tailored to individual preferences.

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Table 1

Demographic, Medical, and Psychosocial Characteristics of Sample (N=59)

Characteristic	Usual Care N=30	Music N=29	p-value*
Age at Biopsy, years			0.70
Mean ± SD, [Range]	51.6 ± 13.8 [23–78]	50.2 ± 14.1 [22–78]	
Sex			0.34
Female	16 (53)	19 (66)	
Male	14 (47)	10 (34)	
Marital/Partner status			0.36
Never married	2 (7)	5 (17)	
Divorced/Separated/Widowed	6 (20)	7 (24)	
Married/Partnered	22 (73)	17 (59)	
Race			0.70
White	24 (80)	22 (76)	
Black	6 (20)	7 (24)	
Educational history			0.93
High school/GED or less	9 (30)	9 (31)	
More than high school	21 (70)	20 (69)	
Annual Family Income ($)			0.04
<$20,000	1 (3)	7 (24)	
$20,000–<$50,000	9 (30)	7 (24)	
$50,000 or more	15 (50)	9 (31)	
Do not know	1 (3)	4 (14)	
Employment Status			0.19
Employed full or part time	12 (40)	7 (24)	
Other	18 (60)	22 (76)	
Time from Diagnosis to Biopsy (yrs.)			0.43
Mean ± SD, [Range]	3.4 ± 3.4 [0.04–13.4]	3.0 ± 3.3 [0–11.2]	
Perceived length of biopsy (minutes)			0.83
Mean ± SD, [Range]	18.1 ± 10.5 [6–60]	17.5 ± 9.47 [8–50]	
Pre-procedure Medications			0.69
Yes	15 (50)	13 (45)	
No	15 (50)	16 (55)	
Previous No. bone marrow biopsies			0.06
Mean ± SD, [Range]	5.6 ± 5.9 [0–30]	3.9 ± 4.7 [0–16]	
Location of previous biopsies			0.47

Characteristic	Usual Care N=30	Music N=29	p-value*
Wake Forest	11 (38)	12 (44)	
Other	5 (17)	7 (26)	
Both	13 (45)	8 (30)	
Practitioner			0.98
1	10 (33)	10 (34)	
2	10 (33)	10 (34)	
3	10 (33)	9 (31)	
Anticipated pain (VAS) (0–100)			0.92
Mean ± SD, [Range]	51.1 ± 23.8 [0–100]	51.7 ± 23.7 [5–90]	
Baseline STAI state score (20–80)			0.84
Mean ± SD, [Range]	38.5 ± 12.5 [20–77]	37.9 ± 11.6 [20–68]	

* p-value from t-test or Wilcoxon rank-sum for continuous variables or Chi-square or Fisher's exact test for categorical variables

Table 2

Anxiety and Pain, Pre- and Post-Biopsy (Adjusted Model)

Outcome Variable [Mean (SE)]*	Usual Care (N=30)		Music (N=29)		Estimate (SE)	t value (df)	*p-value***
	PRE	POST	PRE	POST			
Anxiety (STAI state anxiety score)	38.5 (2.3)	31.5 (2.1)	37.9 (2.2)	30.4 (1.4)	−0.758 (2.53)	−0.300 (df=31)	0.766
Pain rating (VAS)****	51.1 (4.3)	46.6 (4.9)	51.7 (4.4)	39.9 (4.3)	−1.73 (5.91)	−0.293 (df=31)	0.771

* Mean (SE) are descriptive based (non-model based) unadjusted for other covariates.

** Estimate (SE), t value (df), p-value from ANCOVA model for change score adjusting for: PRE score, trait anxiety score (PRE), age, sex, marital status, race, education, annual family income, employment status, time since diagnosis, pre-procedure medication use, previous # of BMBs, location of previous biopsies and block randomization by practitioner; estimate is adjusted group difference in change scores.

*** For the VAS, “pre” pain ratings refer to anticipated pain ratings and “post” ratings refer to perceived pain ratings after the completion of the BMB.

Table 3

Patient Satisfaction Ratings

Item	Usual Care (N=30) Mean (SD)	Music (N=29) Mean (SD)	p-value*
Did your health care provider show genuine concern for you? (range=0–3)	3.0 (0.0)	3.0 (0.0)	1.00
Did you feel your health care provider had experience conducting the procedure you came in for? (range=0–3)	2.9 (0.3)	3.0 (0.0)	0.16
Did you have confidence in the health care provider who did your bone marrow biopsy? (range=0–3)	2.9 (0.3)	3.0 (0.0)	0.16
How would you rate the care you received today? (range=0–4)	3.8 (0.5)	3.9 (0.3)	0.14
Please estimate about how long you believe the bone marrow biopsy procedure took today. (range=6–60 min)	18.1 (10.5)	17.5 (9.5)	0.74
How would you rate your overall pain from today's bone marrow biopsy in comparison to your previous bone marrow biopsies? (range=0–4)	3.0 (1.1)	2.6 (1.3)	0.17
How would you rate your pain and burning sensation from the numbing (local anesthesia) during today's bone marrow biopsy in comparison to your previous bone marrow biopsies? (range=0–4)	3.0 (0.9)	2.6 (1.1)	0.24
How would you rate your pain and pressure from the aspiration during today's bone marrow biopsy in comparison to your previous bone marrow biopsies (range=0–4)	2.9 (1.1)	2.6 (1.1)	0.29
How would you rate your pain and pressure from the twisting sensation during today's bone marrow biopsy in comparison to your previous bone marrow biopsies? (range=0–4)	3.00 (1.1)	2.7 (1.1)	0.34
How long did today's procedure seem to last in comparison to previous procedures? (range=0–4)	1.5 (1.1)	1.5 (1.1)	0.96
M How well did you like the CD? (range=0–4)	-	3.3 (1.1)	-
M How helpful was the CD to you? (range=0–4)	-	2.9 (1.3)	-
M If you were to have another bone marrow biopsy, would you prefer listening to music again? (range=0–4)	-	3.3 (1.1)	-

* p-value from Wilcoxon rank-sum test for between group differences.

M = Music group only.