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The effect of music with and without binaural beat audio on operative anxiety in patients undergoing cataract surgery: a randomized controlled trial

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Learning Objectives

Upon completion of this activity, participants will be able to:

1. Describe the effects of music with and without embedded binaural beat on subjective measures of anxiety in patients undergoing cataract surgery under local anesthesia, based on a prospective, randomized clinical trial.
2. Describe the effects of music with and without embedded binaural beat on physiologic measures of anxiety in patients undergoing cataract surgery under local anesthesia.
3. Determine the clinical implications of the effects of music with and without embedded binaural beat on subjective and physiologic measures of anxiety in patients undergoing cataract surgery under local anesthesia.

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CLINICAL STUDY

The effect of music with and without binaural beat audio on operative anxiety in patients undergoing cataract surgery: a randomized controlled trial

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Abstract

Purpose **To investigate the anxiolytic effects of binaural beat embedded audio in patients undergoing cataract surgery under local anesthesia.**

Methods **This prospective RCT included 141 patients undergoing cataract surgery under local anesthesia. The patients were randomized into three groups; the Binaural beat music group (BB), the plain music intervention group (MI), and a control group (ear phones with no music). Blood pressure (BP) and heart rate were measured on admission, at the beginning of and 20 min after the start of the operation. Peri-operative anxiety level was assessed using the State-Trait Anxiety Inventory questionnaire (STAI).**

Results **The BB and MI groups comprised 44 patients each and the control group 47. Patients in the MI group and BB group showed significant reduction of STAI state scores after music intervention compared with the control group ($P<0.001$) but the difference was not significant between the MI and BB group (STAI-S score MI group −7.0, BB group −9.0, $P=0.085$). Systolic BP was significantly lower in both MI ($P=0.043$) and BB (0.040) groups although there was no difference between the two groups ($P=1.000$). A significant reduction in heart rate was seen only in the BB group (BB *vs* control $P=0.004$, BB *vs* MI $P=0.050$, MI *vs* control $P=0.303$).**

Conclusion **Music, both with and without binaural beat, was proven to decrease anxiety level and lower systolic BP. Patients who received binaural beat audio showed additional decrease in heart rate. Binaural beat embedded musical intervention may have benefit over musical intervention alone in decreasing operative anxiety.**

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Introduction

Anxiety is a common cause of psychological stress for patients undergoing eye surgery, as most of the operations are performed while the patient is awake. Worries about loss of control, being in an unfamiliar environment and expectation for good surgical results can produce high levels of peri-operative anxiety for patients.

Music, among various interventions, has been proposed to reduce operative anxiety. Musical interventions affect not only the physiologic domains of the patient such as blood pressure and heart rate, but also emotional domains, such as perioperative anxiety levels. Exposure to auditory stimuli in the operation room such as the sound of the phaco machine and the professional conversations of surgeons may also cause emotional stress to the patient. Use of musical interventions, such as having the patient listen to prerecorded music through earphones, can relieve anxiety and reduce exposure to fearsome noises in the environment.[1–4] Bellan *et al*[5] reported a large-scale study of 144 patients undergoing cataract surgery and found that listening to music before surgery was associated with decreased anxiety. Cruise *et al*[6] found similar results in a cohort of 121 patients undergoing cataract surgery under retrobulbar block who were more satisfied with their

experience if they listened to relaxing music rather than operating room noise alone during the surgical procedure.

Binaural beats are special sounds perceived when two auditory stimuli of different frequency are presented to each ear. The use of these beats as a therapeutic tool has recently gained interest among neurophysiologists and clinicians. Binaural beats reportedly influence the brain through the entrainment of brainwaves and can be used to reduce anxiety and increase pain threshold.[7]

Binaural beats are auditory processing artifacts, the perception of which arises in the brain for specific physical stimuli. This effect was discovered in 1839 by Heinrich Wilhelm Dove. When two tones that are close in pitch but not identical are sent to a different ear, the brain creates an interference which is called the binaural beat without any physical interaction between the waves.[7,8] Therefore, to generate binaural beats, pure tones must be presented to each ear through earphones. The frequency of the tones must be below about 1000 to 1500 hertz (Hz) for the beating to be heard. The binaural beat frequency is equal to the difference between the frequencies applied to each ear. The difference between the two frequencies must be small (below about 30 Hz) for the effect to occur. For example, if a 400 Hz sine wave is played into the right ear and a 410 Hz into the left ear, the brain is entrained towards the beat frequency of 10 Hz, in the alpha range which is associated with relaxation.

Inducing brainwave states with binaural beats has been used to decrease anxiety in patients. The purpose of our study was to determine the anxiolytic effect of binaural beat embedded music compared with plain music without binaural beats and no musical intervention in patients undergoing cataract surgery under local anesthesia.

Materials and Methods

The study was approved by the Institutional Review Board of the Faculty of Medicine, Chiang Mai University, Thailand (Research ID 34/ Study Code No. OPT-10-01-28-11-X).

This prospective, randomized, controlled study recruited 141 patients who were diagnosed with senile cataract and scheduled for phacoemulsification with intraocular lens implantation under local anesthesia at the Department of Ophthalmology, Faculty of Medicine, Chiang Mai University, Thailand, from January to April 2011 (Figure 1).

Exclusion criteria included previous cataract surgery, blood pressure >160/100 mmHg, hearing problems, infections in the ears and history of epilepsy.

Patients were randomized in three groups, by using Random Allocation Software (Isfahan, Iran); the binaural beat group (BB), the plain musical intervention group (MI) and the control group (earphones with no music). Patients and researchers were blinded to allocation until administration of interventions.

Subjective assessment of anxiety

The subjects were asked to complete the State-Trait Anxiety Inventory questionnaires (STAI). The STAI measures anxiety with the state subscale and the trait subscale. The state subscale measures temporary anxiety. The value has variations for individuals for subjective feelings of tension, concern, and worries depending on the situation. The trait subscale is relatively stable in showing personal differences in how individuals differently experience anxiety.[9] The State-Trait Anxiety Inventory is a validated 40-item self-report measure that contains 20 items measuring state anxiety (STAI-S) and 20 items measuring trait anxiety (STAI-T).[9–11] Scores for state and trait components each range from 20 to 80 with a higher score corresponding to higher anxiety levels. Blood pressure and heart rate was recorded on admission (baseline), at the start of the operation, and 20-min after the initiation of the operation.

Physiologic assessment of anxiety

Blood pressure and heart rate were used as object measurements of anxiety. Blood pressure and heart rate of each patient was recorded on admission (baseline), at the beginning of the operation, and 20 min after intervention was administered.

Interventions

Binaural beats were synthesized with a Self Hypnosis and Relaxation Machine (S.H.A.R.M., CyberTeam, Ltd., Informer Technologies Inc., Madrid, Spain) version 2.4. The carrier tones at 109 and 209 Hz were utilized to create binaural beats with a frequency of 20 Hz in the first 5 min. The binaural beat frequency was set to decline gradually to the therapeutic frequency of 10 Hz within the following 5 min and sustained for another 50 min. Musical arrangements with relaxing components of melodies, tones and rhythms of 60-minute duration were embedded with the binaural beats. Natural sounds such as waterfall, bird chirping, ocean, river and forest sounds were also inserted. The binaural beat embedded audio was exported in MP3 format with high quality for use in the BB group. A plain music audio without binaural beats was produced for use in the MI group. The presence of binaural beats was very difficult to detect by experimental listeners.

Before the operation, the eyes were dilated with tropicamide 1% (Mydriacyl, Alcon, Fort Worth, TX, USA)

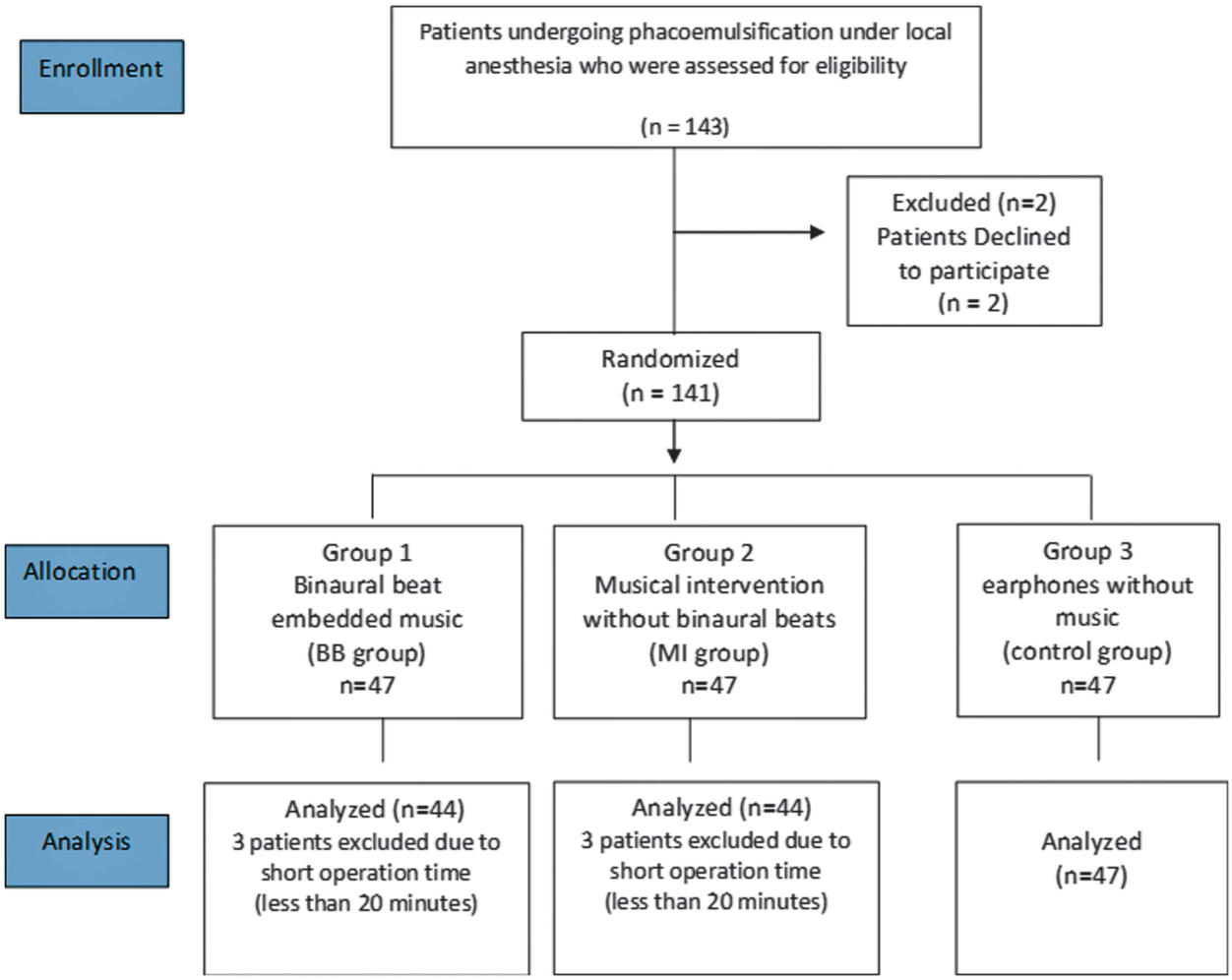

Figure 1 CONSORT flow diagram of the progress through phases of the study.

& phenylephrine hydrochloride 10% (Silom Medical, Bangkok, Thailand) and anesthetized with topical tetracaine hydrochloride 0.5% (Alcon). Lidocaine hydrochloride 2% (Xylocaine jelly, AstraZeneca, London, UK) was applied on call. A retrobulbar block was performed for all patients. Patients were assigned to one of the three groups: the BB group, the MI group or the control group. An iPod shuffle (Apple, Inc., Cupertino, CA, USA) MP3 player and canal-type stereo earphones (Elecom, Shanghai, China) were used to play music for both the BB and MI groups. Earphones were placed in both ears of the patients 10 min before the start of the operation. Patients in the control group wore earphones connected to an iPod without music. An appropriate volume level was chosen by the patient, which would still allow them to hear the surgeon's communication regarding the procedure or requesting their cooperation.

Blood pressure and heart rate were recorded at the beginning of the operation and 20 min after the start of the operation time. Duration of the operation and intra-operative complications were recorded. All surgeries were performed by third year ophthalmology residents. Surgeons were not aware of the patients' intervention group. After completion of the operation, patients were transferred to the ward and asked to complete only the STAI-S questionnaire post-operatively.

Statistical analysis

On the basis of the data provided by previous studies,[12] a sample size of 47 patients in each of the three groups was required to provide 90% power at the 5% two-sided level. Statistical analyses was performed using Epi Info for Windows Version 3.5.1 (CDC, Atlanta, GA, USA) and STATA version 11 (Stata Corp, College Station, TX, USA). The frequency distribution of demographic descriptive variables was used to identify the patients' demographic profiles. The demographic factors were controlled for by Random Allocation Software (freeware).

The results are shown as mean ± standard deviation. Comparison of baseline characteristics between groups was performed with Fisher Exact test. Univariate analysis of anxiety-associated factors between the three groups (difference STAI-scores, blood pressure, heart rate) was performed with Sidak analysis. *P*-value ≤ 0.05 was considered statistically significant.

Results

Of the 143 patients recruited, two refused to participate because of personnel reason. Forty-seven patients were randomly allocated to one of the three intervention groups. Six patients (three patients in the BB and three patients in the MI group) were excluded because the duration of the operation was less than 20 min (Figure 1).

There were no statistically significant differences in age, gender, baseline blood pressure, heart rate, operating time, and initial STAI-T and STAI-S scores between groups (Table 1). Post-operatively, STAI-S score was re-assessed at the ward and revealed significantly decreased scores in the MI and BB groups compared with the control group ($P<0.001$) (Table 2). The BB group showed a slightly larger decrease in STAI-S score although this difference was not statistically significant. At 20 min into the operation, patients' heart rate was significantly lower in the BB group compared with the control group ($P<0.001$) and the MI group ($P<0.050$) (Table 3). No adverse events occurred.

Discussion

Previous studies have reported the benefits of music for patients undergoing various types of surgery.[13–16] One such benefit is the relief of anxiety. Recent studies suggest that binaural auditory beats can affect anxiety.[17] Padmanabhan *et al*[12] reported that binaural beat audio can help decrease acute pre-operative anxiety before undergoing general anesthesia. To the best of our knowledge, this is the first study of the effect of binaural beat audio on operative anxiety patients in patients undergoing ophthalmic surgery under local anesthesia. Furthermore, we compared the effect of binaural beat embedded music with plain music and no musical intervention at all in order to document any additional effect of binaural beats on anxiety reduction.

In our study, anxiety level was assessed by the Spielberger's STAI, which is one of the most commonly used subjective self-measuring tests. The STAI is now the standard tool for measuring preoperative anxiety.[10]

Le Scouarnec *et al*[17] studied the use of binaural beat tones for treatment of patients diagnosed with mild anxiety. Their results showed a significant reduction in post-treatment STAI scores after 4 weeks of regularly listening to tapes imbedded with binaural beat music tones, although physiologic measure of anxiety reduction was not performed. Weiland *et al*[18] compared anxiety reduction effects of different original sound compositions (electroacoustic music, audio field recordings obtained from natural and constructed settings and audio field recordings with embedded binaural beat) with reconstructed ambient noise simulating an emergency department environment and headphones only without music in emergency department patients. They reported that musical interventions including binaural beat embedded compositions significantly reduced anxiety (assessed subjectively by STAI scores) compared with headphones only or simulated emergency department noise.

In our study, we assessed the anxiety status of the patients by using both subjective and physiological measurement. We also found a statistically significant decrease in STAI-S score in both the BB group and MI group compared to the control group. The patients in the

Table 1 Baseline characteristics of patients in different intervention groups

Baseline characteristics	*Control* (N = *47*)	*MI* (N = *44*)	*BB* (N = *44*)	P-*value*
Age (years)	69.0 ± 10.0	67.0 ± 7.8	68.4 ± 8.2	0.226
Sex (Female ratio)	1.0 (24:23)	1.4 (18:26)	1.6 (17:27)	0.442
Initial STAI-T score	36.3 ± 6.3	35.4 ± 5.7	37.2 ± 5.5	0.340
Initial STAI-S score	33.8 ± 4.7	33.2 ± 5.1	35.2 ± 4.3	0.123
Blood pressure (mmHg)[a]				
Systolic	131.9 ± 12.2	137.2 ± 13.1	132.9 ± 9.4	0.079
Diastolic	74.9 ± 8.5	76.8 ± 10.5	75.0 ± 11.1	0.593
Heart rate (beats/min)[a]	70.9 ± 8.2	73.7 ± 8.5	73.9 ± 8.8	0.173
Operative time (min)	32.8 ± 11.6	31.5 ± 9.0	33.9 ± 10.8	0.589

Abbreviations: BB, Binaural Beats and Musical Interventions; Control, No music; MI, Musical Interventions; STAI-S, State-Trait Anxiety Inventory-State; STAI-T, State-Trait Anxiety Inventory-Trait.
Values are mean ± SD. [a]Blood pressure and heart rate on admission.

Table 2 Difference in pre and post-intervention STAI-S scores compared between groups by Sidak analysis

	Mean (S.D.)			P-*value*		
	Control (n = *47*)	*MI* (n = *44*)	*BB* (n = *44*)	*Control vs MI*	*Control vs BB*	*MI vs BB*
Difference in pre and post STAI-S scores*	−2.9 (4.4)	−7.0 (4.8)	−9.0 (4.2)	<0.001	<0.001	0.085

Abbreviations: BB, Binaural Beats and Musical Interventions; Control, No music; MI, Musical Interventions; STAI-S, State-Trait Anxiety Inventory-State.
*Differences in STAI-S scores (Initial STAI-S score minus Post STAI-S score). Subjective measurement of decrease in anxiety.

Table 3 Comparison of change in blood pressure and heart rate after intervention between groups (Sidak analysis)

Vital sign	*Mean (S.D.)*			P-*value*		
	Control (n = *47*)	*MI* (n = *44*)	*BB* (n = *44*)	*Control* vs *MI*	*Control* vs *BB*	*MI* vs *BB*
Blood pressure						
Systolic[a]	+5.3 (17.5)	−3.3 (15.5)	−3.2 (16.0)	0.040	0.043	1.000
Diastolic[a]	−0.1 (9.7)	2.5 (9.4)	0.7 (7.6)	0.505	0.988	0.716
Heart rate[a]	+0.4 (11.0)	−1.5 (7.7)	−5.3 (7.8)	0.303	0.004	0.050

Abbreviations: BB, Binaural beat embedded musical intervention; Control, No music; MI, Musical intervention without binaural beat. [a]Difference in vital signs at the beginning of the operation minus vital signs at operative time 20 min.

BB group had lower post-intervention STAI scores compared with the MI group, although the difference was not significant (−9.0 *vs* −7.0; $P = 0.085$). Our physiologic outcome measurement of anxiety included systolic blood pressure and heart rate. Systolic blood pressure in the BB and MI groups were significantly lower than the control group. Patients in the control group who were not exposed to any music had increased systolic blood pressure during surgery. Heart rate in the BB group was significantly lower than the MI ($P = 0.050$) and control groups ($P = 0.004$) while there was no difference in heart rate of patients in the MI group compared with the control group ($P = 0.303$). Therefore, we suggest that binaural beats may have an additional anxiolytic effect to plain musical interventions without binaural beats.

Theoretically, an audio embedded with binaural beats can induce a predictable alteration in brainwave activity. The waxing and waning in amplitude of the resultant tones gives a characteristic binaural beat perception with a frequency equal to the difference between the two pure tones presented, provided that the original impulses are less than 1000 Hz and the difference between the two tones is between 1 and 30 Hz. If sustained binaural beat frequencies resonate throughout the brain, it will stimulate the brain and alter the levels of arousal via activation of the reticular-thalamic activating system. This process is called 'entrainment' and has been reported in previous researches with EEG (electroencephlogram) recording.[19]

A weakness of our study was that the cataract surgery was performed by multiple surgeons in order to obtain a sufficient sample size for the study which may have confounded the results. In addition, deficiency of hearing was self-reported by the patient and not objectively tested in every patient, therefore, patients with mild hearing loss especially unilateral, may have been unaware of their deficit which may have influenced the results of the interventions. Other limitations of our study include lack of EEG recording facilities in the operating room and patients' post-intervention blood pressure was recorded only once. Furthermore, patients in the control group could only be masked until intervention was administered. Awareness of an individual's intervention group may have caused some bias in answering the post-intervention STAI. Keeping this in mind, we also recorded physiologic outcomes of anxiety which included heart rate and systolic blood pressure in order to confirm the decrease or increase in anxiety state of each patient.

We explored the potential of the binaural beat frequency of 10 Hz (alpha frequency range) to decrease acute operative anxiety. The initial frequency of 20 Hz (beta frequency range) during the first 5 min of the audio file was set to be tuned with pre-operative anxiety in which the brainwave pattern was likely to be a beta pattern or arousal state. Therefore, through brain entrainment, a 10 Hz binaural beat would encourage the brain to produce a 10 Hz beat corresponding to a relaxed state of consciousness or alpha pattern.

Decreased patient anxiety results in better patient compliance and better surgical outcomes. This is especially important for patients undergoing cataract surgery which is usually performed under local anesthesia.

Conclusion

Our study supports the evidence that music can decrease operative anxiety. We suggest that binaural beat embedded musical intervention may have additional anxiolytic effects over music without binaural beats. Further studies on autonomic nervous system alteration in correlation with EEG recordings during exposure to binaural beats is needed to better understand how and to what extent these special tones can effect anxiety state.

Summary

What was known before

- Peri-operative anxiety can result in poor patient compliance and surgical outcome.
- Music therapy can help decrease anxiety for patients in some circumstances.

What this study adds

- Binaural beat embedded musical intervention has additional anxiolytic effects over music alone when anxiety was assessed both subjectively and objectively.

Conflict of interest

The authors declare no conflict of interest.

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The effect of music with and without binaural beat audio on operative anxiety in patients undergoing cataract surgery: a randomized controlled trial

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1. Your patient is a 72-year-old man undergoing cataract surgery under local anesthesia. According to the randomized clinical trial by Wiwatwongwana and colleagues, which of the following statements about the effects of music with and without embedded binaural beat on subjective measures of anxiety in patients undergoing cataract surgery under local anesthesia is ***correct***?

   A Patients in the music without binaural beat group did not have significant reduction of State-Trait Anxiety Inventory (STAI) scores compared with the control group
   B Patients in the music with binaural beat group had significant reduction of STAI scores compared with the music without binaural beat group
   C Perioperative STAI-S score reduction was −7.0 in the music without binaural beat group and −9.0 in the music with binaural beat group
   D White noise reduced subjective anxiety

2. According to the randomized clinical trial by Wiwatwongwana and colleagues, which of the following statements about the effects of music with and without embedded binaural beat on physiologic measures of anxiety in patients undergoing cataract surgery under local anesthesia is ***correct***?

   A Systolic blood pressure (BP) did not decrease significantly in the music without binaural beat group, compared with the control group
   B Systolic BP was significantly lower in the music with binaural beat group vs the music without binaural beat group
   C Heart rate did not decrease significantly in the music with binaural beat group, compared with the control group
   D Physiologic measures suggest that binaural beat may have an additional anxiolytic effect to plain musical interventions without binaural beat

3. According to the randomized clinical trial by Wiwatwongwana and colleagues, which of the following statements about the clinical implications of the effects of music with and without embedded binaural beat on subjective and physiologic measures of anxiety in patients undergoing cataract surgery under local anesthesia is ***correct***?

   A The study showed that binaural beat music induced electroencephalographic (EEG) changes associated with relaxation
   B Through brain entrainment, a 10-Hz binaural beat may encourage the brain to produce a 10-Hz beat corresponding to a relaxed state of consciousness or alpha pattern
   C Some patients exposed to binaural beat had paradoxically increased anxiety
   D Some patients exposed to binaural beat had reduced hearing after surgery

Activity evaluation

1. The activity supported the learning objectives.

Strongly disagree				Strongly agree
1	2	3	4	5

2. The material was organized clearly for learning to occur.

Strongly disagree				Strongly agree
1	2	3	4	5

3. The content learned from this activity will impact my practice.

Strongly disagree				Strongly agree
1	2	3	4	5

4. The activity was presented objectively and free of commercial bias.

Strongly disagree				Strongly agree
1	2	3	4	5