Trauma: An Interim Analysis of Trial Efficacy in a Pilot Study Investigating the Effects of Music Therapy in Ventilated ICU Patients

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Abstract
Music Therapy (MT) is quickly becoming a standard of care to reduce patient distress and promote emotional, psychological, and psycho-social well-being in the medical field. The available alternatives to achieving these patient results often have serious side effects. MT is frequently used bedside on hospital floors, but its effects on critically ill patients requiring sedation in an ICU has not been previously studied. The recovery of patients suffering from traumatic injuries in an ICU setting is often complicated or lengthened by adverse effects of the ventilators and other noxious stimuli. MT holds the potential to reduce ventilator time, reduce hospital stay, and decrease the possibility of potential mortality. In this study, we set out to investigate differences in pharmacological sedation requirements for patients exposed to MT as compared to when they are at rest with no MT. We collected data, including total sedation medication required as well as changes in sedatives and pain medications, for 27 patients over a 2.5-year period (March 2013 to May 2015). A regression model analysis showed that sedation requirement rose by an average of 62.34% across the total patient population on non-MT days. A chi-square test demonstrated a statistically significant reduction of pharmacological sedation requirements for trauma patients in a hospital ICU setting.

Background
According to the American Music Therapy Association, Music Therapy (MT) is the clinical and evidence-based use of music interventions by a licensed individual to accomplish customized goals within a therapeutic relationship. MT has been seen to promote emotional, psychological, and psycho-social well-being in humans, accomplished by diverting patients' attention from the disconcerting environment surrounding them in most critical care settings, such as the ICU. MT has been shown to reduce anxiety, fear, and the effects of noxious stimuli while promoting relaxation, rest, and sleep without pharmacological use (Chlan, 2000).
Many patients in the ICU experience feelings of exhaustion, fear, anxiety, and pain due to the invasive nature of the procedures/conditions (Ho, et al., 2012; Henry, 1995; Cardozo, 2004; Pattison, 2005; Friese, 2008). They often become combative or lose necessary sleep, which prevents the health care providers from adequately caring for the patient. Sedation is often initiated in such cases, and then maintained throughout the patient's length of stay. Although this allows the patient to calm down and relax, pharmacologic intervention to this degree has shown potentially serious side effects, some of which include respiratory depression, unwanted gastrointestinal effects (e.g., decreased gastric motility), muscle atrophy, hypotension, venous stasis, pressure damage to soft tissue, respiratory muscle weakness, increased infection risk, mental status changes (e.g., psychosis, delirium), and extended days on the ventilator, as well

as consequently increased ICU and hospital length of stay, and even potentially increased mortality (Chlan, 2000; Hogarth & Hall, 2004; Cardozo, 2004; Tracy & Chlan, 2011).
Since the 1990s, numerous studies have investigated music therapy in the critical care setting (Almerud & Petersson, 2003; Chlan, 1998; Ho et al., 2012; Lee, Chung, Chan, & Chan, 2005). In 1998, Chlan investigated MT's relaxation and anxiety reduction effects in intubated patients. In the study, 54 non-sedated ICU patients received 30 minutes of MT or 30 minutes of rest each day. The analysis of the data looked at longitudinal changes in the patients' heart rates, respiratory rates, and other significant vital signs (Chlan, 1998). Wong, Lopez-Nahas, and Molassiotis (2001) also conducted a similar study with ventilated ICU patients, again looking at their vital signs for improvements when receiving MT.
Although considerable research has investigated the effects of music therapy on patients in a critical care setting, most of the studies had limitations, including homogenous study population, solely looking at physiological changes, short MT/RP lengths, and limited music selection. In this study, we aimed to revise the limitations of previous studies through strict procedural outlining and participant selection criteria. We hypothesized that music therapy would lessen the pharmacological sedation requirements in trauma ICU patients.

Methods

Setting and Participants

The study's primary objective was to show a change in pharmacological sedation requirements when patients are exposed to MT as compared to when they are not exposed to MT. The study was conducted at the Lehigh Valley Health Network Cedar Crest, Allentown, PA, USA. The study was directed at patients admitted to the Trauma/Neuro ICU (TNICU) due to the homogeneous nature of the population. For example, those admitted are usually younger, accustomed to listening to music, and often require sedatives due to injury. A total of 27 participants were enrolled in a 2.5 year period. All participants received standard care, regardless of which therapy was being administered.
Inclusion criteria included that the patient was 18 years of age or older, admitted to the TNICU, sustained trauma-related injuries, required the assistance of mechanical ventilation including full-vent support, tracheotomy, C-Pap, and Bi-Pap. Criteria also included that the patient fell at a Glasgow Come Scale (GCS) of 9 or above for 24 hours prior to enrollment, required intermittent sedation, was able to understand and sign the informed consent form (ICF) or have a legally authorized representative (LAR) who can provide the ICF, and the music preference was known by family at the time of consent.

Exclusion criteria included a presentation of a neurological deficit with a GCS less than or equal to eight, radiologic evidence of severe head injury with a GCS less than or equal to eight, and continuous sedation that required propofol, pentabarbital, or paralysis. Criteria also included a diagnosis of dementia, known hearing impairment or use of a hearing aid, unknown music preference, and required support of mechanical ventilation indefinitely.

Procedures

Prior to Day 1 of therapy, informed consent, music selection, and coordination of bedside healthcare activities were completed. MT and undisturbed rest periods (RPs) were given on alternating days until the end of therapy. Each session of MT and RP lasted one hour and was administered twice per day at a minimum of five hours apart. On Day 1, two sessions of MT were delivered. On Day 2, two sessions of RP were delivered. From Day 3 forward, the study intervention alternated daily between MT and RP until the end of therapy. To ensure that the patient was undisturbed, health care providers with direct access to the patient were educated and a do-not-disturb sign was posted outside the patient's door. However, quiet visitation during research sessions was allowed.

Music was delivered by the bedside nursing staff via Mp3 player devices with headphones. Music selection was determined by patient preference or the LAR from a researcher-provided music library. Approximately 10-15 songs were downloaded and placed onto the Mp3 player. The songs were played in a random order during the therapy sessions through headphones. Headphones were also worn during the rest sessions. Bedside nurses recorded any interruptions during treatment sessions. Participants were permitted to keep the music devices at the end of the study.

Data Collection

Data were collected from enrollment through the end of therapy for each participant on a 24-hour basis. The start and end time of each therapy session was recorded. Changes in pain and sedative medications and/or their dosages were recorded. The total amount of sedation medication given in a 24-hour period was collected. Additional data collected during the study were: gender, date of intubation and extubation, indication for intubation, ICU length of stay, hospital length of stay, type of injury, injury severity score, number of MT sessions provided, number of RP sessions provided, and any interruptions during research intervention periods. All collected data were de-identified and kept in a secure office. Subjects were identified by a unique number, consisting of initials and age. Data were analyzed to compare sedation requirement differences between MT days and non-MT days; P-value of >0.05 was considered significant.

Results

From 27 total patients with collected data, 23 patients were included in the analysis. The four participants not included were not enrolled long enough to collect a satisfactory amount of data. Of the 23 patients in the analysis, 75% of the participants were male and 25% were female. The summation of sedation for all patients (in mcg/ml) was divided by the total number of days of MT, resulting in an average amount of sedation per day of 223 886.5 mcg/ml. Using the same formula for all patients on RP, the average amount of sedation per day was determined to be 359 157.1 mcg/ml. Therefore, 62.34% more sedation was used during the rest period than during the MT period. Table 1 lists the distribution of days enrolled in the study, and total pharmacological sedation administered on MT days versus RP days per subject. Table 2 shows changes in sedation requirement from the first day of study enrollment to the last day of study enrollment. The chi-square test for independence generated P <0.001, demonstrating a significant difference in sedation requirements for MT days compared to non-MT days.

Discussion

Previous studies on the effects of MT noted considerable improvements in patient heart rate, respiratory rate, and other physiologic responses (Almerud et al., 2003; Chlan, Engeland, Anthony & Guttormson, 2007; Lee, et al., 2005; Tracy et al., 2011; Wong et al., 2001). Therefore, we hypothesized that the amount of sedation required by the patients would decrease on the days that they received the MT treatment, and would increase on days when they were receiving the RP. The results showed that, across the study population, patients required 62.34% more sedation on RP days than on MT days.

The patients were used as their own controls to determine differences in sedation requirements. Historical controls were not used for comparison because of difficulties in accounting for all the variables, even if we performed a 1:1 match—by age, gender, ISS, GCS score—of each study participant with a patient in the LVHN Trauma Registry. The summation of sedation, in mcg/ml, for the days a patient received MT was divided by the number of days on the study. Consequently, the summation of sedation, in mcg/ml, for the days a patient received RP was divided by the number of days on the study. This process was conducted for 23 of the 27

patients enrolled in the study. The four patients remaining could not be analyzed because they were not enrolled long enough to obtain a suitable amount of data.
Previously published studies limited the amount of time that patients received MT to 30 minutes per day (Almerud et al., 2003; Chlan, 1998; Lee et al., 2005; Wong et al., 2005). The patients enrolled in this study received two 60-minute sessions of MT on each alternate day, which is more therapy than previous studies, which is something that aided in determining the efficacy of MT.

Sample size was a noticeable limitation in this study. Originally, the study team planned to enroll 100 patients; however, this projected number was realized by less than half of the expected number of participants. The lack of participants can be attributed to the fact that the study was limited to the TNICU. The data collection was also fraught with complications and subsequent missing data. Speculations as to the cause led researchers to informally survey nurses on the TNICU floor. Anecdotal responses among the nursing staff were similar. They felt that one-hour sessions were too lengthy for patients and often interrupted by either familial distractions (e.g., family pulling out the headphones to listen to the music at MT times, or family trying to talk loudly to patients and startling them awake during RP days) or medical interventions (e.g., suctioning the ventilator tube, or patient coughing and dislodging the headphones). However, when the data were able to be collected, the one-hour sessions allowed for a more definitive correlation between the sedation requirements and the MT.

Although a goal of the study was to achieve more heterogeneity in the sample population when compared with previous studies, limiting the patient pool to TNICU patients was a possible cause for difficulties with patient accrual. In future studies, all patients in critical care settings—TNICU, medical ICU (MICU), and surgical ICU (SICU)—should be included in MT studies. This would create an ideal population, as the majority of TNICU patients are of a younger age, and MICU/SICU patients trend toward more advanced ages, on average.

Conclusion

Although limitations affected the data collection stage of this study, the results clearly showed that MT plays a key role in reducing sedation requirements for patients on days when they received the MT sessions. Reduction of sedation has the potential to lessen ventilator time and expedite discharge from the TNICU/ICU. Until this study, no one had looked at the effects of MT on patient sedation requirements. Further research with a larger sample size should be conducted to confirm the results of this study. Additionally, the study could be expanded to investigate the effect of music characteristics (e.g., with or without lyrics, slow vs. fast tempo) on patients' sedation requirements.

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Table 1. Pharmacological sedation administered on MT days versus RP days

Subject ID	Total Days on MT	Total Sedation in mcg/mL	Total Days on Non MT	Total Sedation in mcg/mL
DSP18	1	50	1	0
M-M19	5	14,000,200	9	30,002,000
EWB33	6	500	11	200
M-R25	4	1300	11	12,002,000

DAS69	8	1000	9	1200
LMK69	1	300	2	800
A-Z28	4	2000	4	2000
CLS48	6	1700	12	2400
T-H64	1	700	2	700
RAM23	4	1000	5	1200
G-K51	1	800	2	400
GTM75	7	3,001,100	6	1400
V-S27	3	1700	3	1950
D-B51	2	400	2	300
RHD51	2	0	3	0
ASF46	2	100	6	1700
E-G33	3	500	3	750
SLM19	2	1500	8	1500
J-L40	5	0	11	50
B-W45	3	125	3	0
CPM40	2	0	3	0
BDS61	3	0	6	0
R-C65	1	400	4	325
Total	**76**	**17,015,375**	**117**	**42,021,375**

MT, music therapy; RP, rest period

Average amount of sedation per day on MT = 223886.5132 mcg/mL

Average amount of sedation per day on RP = 359157.0513 mcg/mL

Table 2. Change in sedation requirements from first to last days of study enrollment

Identification	Sedation initial (mcg)	Sedation final (mcg)	Sedation change (mcg)
DSP18	50	200	150
BDS61	0	0	0
M-M19	3,000,325	0	-3,000,325
EWB33	500	0	-500
M-R25	600	0	-600
DAS69	0	0	0
R-C65	300	25	-275
D-B51	0	200	200
RHD51	0	0	0
ASF46	100	100	0
LMK78	0	0	0
A-Z28	400	100	-300
CLS48	700	0	-700
T-H64	0	200	200
RAM23	200	0	-200
E-G33	100	450	350
SLM19	1500	0	-1,500
G-K51	2450	500	-1,950

J-L40	0	0	0
GTM75	0	0	0
CPM40	0	0	0
B-W45	100	0	-100
V-S27	600	600	0