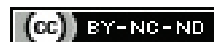


Comparative Evaluation of Two Audio-analgesic Tracks on Reduction of Anxiety Level in Patients undergoing Root Canal Treatment: A Randomised Clinical Study

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ABSTRACT

Introduction: Patients often experience dental anxiety, which can range from mild apprehension to severe phobia. In addition to pharmacological treatments, methods like sedation, aromatherapy, behavioural techniques, and music therapy have proven effective in reducing anxiety. Music, in particular, has been well-studied in clinical settings.

Aim: To compare the reduction in anxiety levels of patients undergoing endodontic therapy with two different audio-analgesic tracks.

Materials and Methods: This randomised clinical study was carried out in the Department of Conservative Dentistry and Endodontics at KM Shah Dental College and Hospital, Vadodara, Gujarat, India, from May 2019 to November 2019. A total of 120 patients were enrolled in the study. Before initiating endodontic therapy, patients were assessed for baseline anxiety using the Visual Analogue Scale (VAS), along with measurements of Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), and Pulse Rate (PR). Participants were randomly divided into three groups: Group A: Om chanting music; Group B: weightless music; and Group C: control (no music). Vitals (SBP, DBP, PR) were recorded at three intervals: before treatment, at 30 minutes, and at one hour. The results were then statistically analysed

using Statistical Packages of Social Sciences (SPSS) software version 22.0, employing the Analysis of Variance (ANOVA) test and Tukey's Post-hoc analysis.

Results: Out of the 120 patients, 82 (68.33%) were male and 38 (31.66%) were female, with a mean age of 35 years. The results indicated that SBP was significant during ($p=0.004$) and after treatment ($p=0.002$). Additionally, DBP was significant after treatment ($p=0.037$). PR was highly significant before, during, and after treatment ($p<0.001$ for all). The differences in SBP between groups B and C during treatment ($p=0.003$), as well as between groups A and C ($p=0.004$) and groups B and C ($p=0.008$) after treatment, were statistically significant. Additionally, a significant difference in DBP was observed between groups A and C after treatment ($p=0.043$). However, no significant differences in Heart Rate (HR) were found before, during, or after treatment among the groups ($p>0.05$).

Conclusion: In the present study, both music tracks demonstrated clinically and statistically acceptable performance compared to the control group, with the Om chanting track having a more substantial influence on anxiety levels, SBP, and DBP than the weightless track. Additionally, there was a significant difference in HR, indicating the efficiency of music in reducing anxiety during dental treatment.

Keywords: Audio-analgesia, Dental anxiety, Music therapy, Om chanting track, Weightless track

INTRODUCTION

Root canal therapy is a well-accepted treatment for diseases of the dental pulp and their sequelae in the periapical tissues [1]. However, patient management is an important and sometimes challenging component of endodontic therapy, and it can be perceived by some patients as painful, leading to fear. Patients generally view dental care as invasive. Dental anxiety encompasses a wide range of emotions, from mild apprehension to extreme anxiety or dental phobia. Patients receiving endodontic treatment frequently experience significant preoperative and intraoperative anxiety, which can heighten their perception of pain and cause instability in vital signs during the procedure [2].

During endodontic treatment, patients are exposed to various fear-inducing factors, such as the metallic sounds of instruments, drill noises, the sight of sharp instruments, injection needles (anaesthesia), the often frustrating rubber dam application procedure, and professional conversations among staff members. These perceptions are further accentuated if patients have had previous negative experiences at a dental clinic.

Adjunctive methods practised to reduce dental anxiety include meditation and hypnosis [3], inhalational anaesthetic (nitrous oxide)

[4], aromatherapy (the use of essential oils and scented volatile liquid substances for therapeutic purposes) [5], various behavioural techniques (such as yoga or meditation practice) [6], verbal relaxation therapy [7], virtual reality distraction [8], and music therapy (audio-analgesia) [2].

Out of all the above-mentioned methods, the relationship between music and medicine has been extensively studied, particularly in clinical practice [2]. It has been suggested that listening to music has a psychophysiological effect that helps to calm the sympathetic nervous system, stabilising blood pressure, heart rate, and respiration rate, and inducing relaxation [9].

In yoga philosophy, 'OM' is regarded as the driving force behind all thoughts, and focusing on or chanting Om is said to induce a calm mental state [10]. Studies have shown that chanting 'OM' can help lower elevated HR and blood pressure by enhancing blood circulation [11,12]. When chanted, the sound Om resonates at a frequency of 432 Hz, which aligns with the natural vibrational frequency present throughout all of nature [12].

Many musicians and musicologists believe that the frequency most closely resembling natural human frequencies is 432 Hz. Pythagoras, a Greek philosopher, mathematician, and scientist, is credited with

creating the 432 Hz frequency, also known as Pythagorean tuning, based on a mathematical formula [13].

On the other hand, a song titled 'Weightless' by the band Marconi Union has been shown to alleviate anxiety symptoms most effectively when utilised as audio-analgesia on participants, according to a recent study by neuroscientists in the United Kingdom. According to Curious Mind magazine, the results of that study demonstrated that the 'Weightless' track could reduce anxiety by 65% and lower the listener's typical psychological resting states by 35% [14].

The present study is unique as it involves a comparison of music tracks that have never been previously evaluated concerning individuals' anxiety levels before and after music therapy. Hence, the purpose of present study was to compare the audio-analgesic efficiency of the Om chanting track with that of the Weightless track in reducing the anxiety levels of patients undergoing root canal treatment, in terms of SBP, DBP and PR.

A null hypothesis was established, stating that there would be no difference in the audio-analgesic efficiency of both tracks—the Om chanting track and the Weightless track—on the anxiety levels of patients undergoing root canal treatment. Additionally, an alternative hypothesis posited that there would be a difference in the outcomes between the two music tracks.

MATERIALS AND METHODS

The present randomised clinical study was carried out in the Department of Conservative Dentistry and Endodontics at KM Shah Dental College and Hospital in Vadodara, Gujarat, India, over six months, from May 2019 to November 2019. The study commenced after obtaining Institutional Ethical approval (SVIEC/ON/DENT/SRP/19113). Informed consent was obtained from all patients included in the study.

Inclusion criteria: Healthy patients aged between 18 and 60 years, with the ability to hear radio or Television (TV) easily without a hearing aid, and the ability to speak and understand the language well enough to communicate, were included in the study, provided they were indicated for primary endodontic treatment.

Before starting the endodontic treatment, patients were sensitised to the VAS and the pre-treatment VAS score was recorded by Co-investigator 2. The patients were subsequently classified into four anxiety levels based on the VAS scale: no anxiety (score <0), mild anxiety (score 1-2), moderate anxiety (score 3-4, 5-6), and severe anxiety (score 7-8, 9-10). Only patients with moderate and severe anxiety were included in the study [15].

Exclusion criteria: Patients who had significantly impaired hearing or used hearing aids; those who were pregnant; had abnormal cognitive function; were receiving known anxiolytic or sedative medications; had a medical diagnosis of seizures or hypertension (as baseline values should be within the normal range for the study); or had any systemic disease were excluded. Additionally, patients who did not give consent due to religious constraints regarding the particular music track were also excluded from the study.

Sample size calculation: Total 120 patients were recruited using the formula $(\text{Sample size} = 2 * (Z_{\alpha/2} + Z_{1-\beta})^2 / (m_1 - m_2 / \sigma)^2)$ Where, $\alpha/2 = 1.96$, $Z_{1-\beta} = 0.84$ with 92% Confidence Interval [2]. Total sample size was 120, where each group had n=60.

Study Procedure

As there was no patient follow-up in the present study no dropouts were considered.

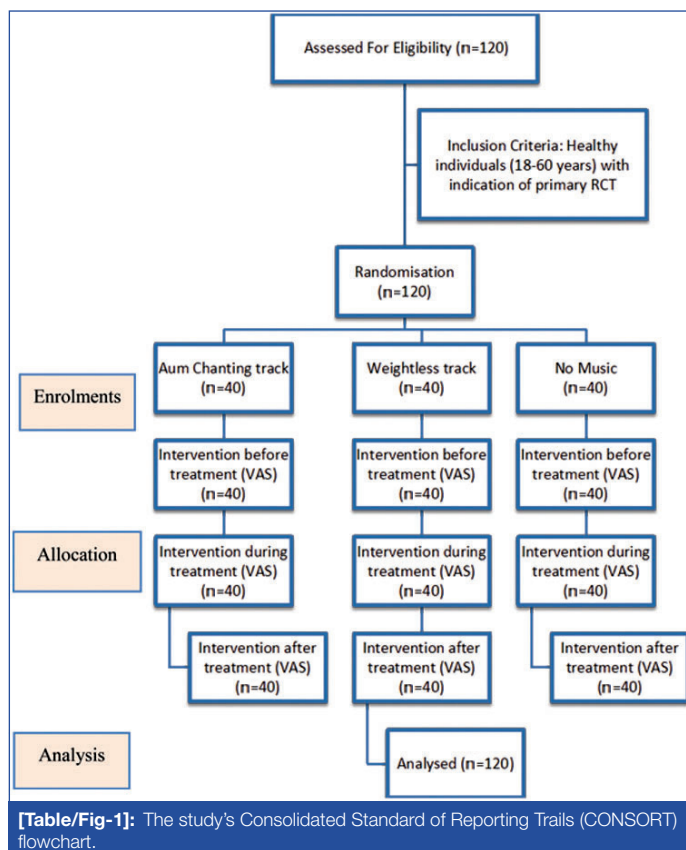
The roles of the investigators involved were as follows:

A. Primary investigator: performed the root canal treatment

B. Co-investigator 1: carried out the randomisation process and the allocation of specified music tracks to the patient.

C. Co-investigator 2: recorded the vital measurements before, during, and after the root canal treatment.

Both the primary investigator and the data analyst were blinded, ensuring it was a double-blinded study [Table/Fig-1].



The patients were randomised using computerised randomisation (www.randomisor.org) into three groups (n=40) as follows:

Group A: Om chanting track;

Group B: Weightless track;

Group C: Control group (no music).

All the patients were provided with noise cancellation headphones (Bose™), and the volume of the tracks was adjusted to a level that was inaudible to the primary investigator. Before initiating the root canal treatment, the patients were seated comfortably, and baseline vital signs SBP, DBP, HR were recorded using a digital sphygmomanometer (OMRON™) by co-investigator 2. The entire root canal treatment was performed by the primary investigator under local anaesthesia (1:200,000 Lignocaine with Adrenaline) and rubber dam isolation in a standardised manner. Vitals were recorded by Co-investigator 2 at 30-minute and 1-hour intervals.

STATISTICAL ANALYSIS

The results obtained were tabulated and sent for statistical analysis, where the p-value and Chi-square value were calculated using SPSS software version 22.0 (p<0.05).

RESULTS

Upon analysing the demographic data of 120 patients, it was found that 82 were males (68.33%) and 38 were females (31.66%), with a mean age of 35 years. No co-morbidities were present in any of the three groups. Of the total, 45 participants (37.5%) were undergoing dental treatment for the first time, while 75 participants (62.5%) had previously received dental treatment [Table/Fig-2].

According to the ANOVA test, the values were as follows: (i) SBP for all three groups during the treatment (p=0.004) and after the

Variables	n (%)	n (%)	Group A	Group B	Group C
Gender					
Male	82	68.33	29	27	26
Female	38	31.66	11	13	14
Age					
≤40 years	54	45.00	12	19	23
Above 40 years	66	55.00	28	21	17
Mean±SD age (years)	35±8.04		20±08	20±01	20±03
Number of dental visits					
First dental visit	37	30.83	11	08	18
More than one dental visit	83	69.16	29	32	22

[Table/Fig-2]: Patients' demographic data.

treatment ($p=0.002$) were <0.05 , indicating significance; (ii) DBP for all three groups after the treatment ($p=0.037$) was <0.05 , indicating significance; (iii) PR for all three groups before the treatment ($p<0.001$), during the treatment ($p<0.001$), and after the treatment ($p<0.001$) were all <0.05 , indicating high significance [Table/Fig-3].

Tukey's post-hoc analysis indicated a significant difference in SBP between Group B and Group C during the treatment ($p=0.003$),

between Group A and Group C after the treatment ($p=0.004$), and also between Group B and Group C after the treatment ($p=0.008$). A significant difference in DBP was observed between Group A and Group C after the treatment ($p=0.043$). Additionally, there were significant differences in PR before the treatment between Group A and Group B ($p<0.001$) and between Group B and Group C ($p=0.004$); during the treatment, there was a difference between Group A and Group B ($p<0.001$) and between Group A and Group C ($p=0.03$); and after the treatment, there were differences between Group A and Group C ($p<0.001$) and between Group B and Group C ($p<0.001$) [Table/Fig-4].

DISCUSSION

Dental treatment can be a source of anxiety for patients, given the invasive nature of certain dental procedures. Chanpong B et al., concluded in their study that there is a significant demand for sedation and anaesthesia in dentistry due to the fear of dental treatment [16].

A study conducted by Ilkkaya NK et al., compared the effects of music, white noise, and ambient (background) noise on patients' anxiety and sedation. The study concluded that 'patient-preferred'

Variables	Group	Time of treatment	n	Mean±SD	F-value	p-value
Systolic Blood Pressure (SBP)	Group A	Before (Baseline)	40	124.05±23.302	1.806	0.169
	Group B		40	122.13±7.904		
	Group C		40	129.43±18.591		
	Group A	During	40	122.43±12.110	5.843	0.004*
	Group B		40	117.88±7.727		
	Group C		40	129.65±22.756		
	Group A	After	40	120.63±1.234	6.648	0.002*
	Group B		40	121.28±4.025		
	Group C		40	132.70±28.547		
Diastolic Blood Pressure (DBP)	Group A	Before (Baseline)	40	80.45±18.394	0.378	0.686
	Group B		40	82.18±12.391		
	Group C		40	83.53±16.164		
	Group A	During	40	79.85±10.536	0.690	0.504
	Group B		40	81.58±7.732		
	Group C		40	82.70±13.702		
	Group A	After	40	80.58±1.083	3.388	0.037*
	Group B		40	81.40±3.303		
	Group C		40	85.45±15.134		
Pulse Rate (PR)	Group A	Before (Baseline)	40	90.38±15.052	9.766	<0.001**
	Group B		40	76.93±14.673		
	Group C		40	87.35±13.036		
	Group A	During	40	87.20±12.484	12.912	<0.001**
	Group B		40	75.20±8.630		
	Group C		40	79.15±10.829		
	Group A	After	40	71.90±1.172	21.666	<0.001**
	Group B		40	73.00±3.789		
	Group C		40	81.20±11.282		

[Table/Fig-3]: ANOVA test for Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and Heart Rate (HR) for all three groups.

Variables	Group	Group A			Group B			Group C		
		Before	During	After	Before	During	After	Before	During	After
SBP	A	-	-	-	0.879	0.393	0.983	0.371	0.098	0.004*
	B	0.879	0.393	0.983	-	-	-	0.879	0.003*	0.008*
	C	0.371	0.098	0.004*	0.163	0.003*	0.008*	-	-	-
DBP	A	-	-	-	0.878	0.761	0.911	0.662	0.476	0.043*
	B	0.878	0.761	0.911	-	-	-	0.923	0.890	0.112
	C	0.662	0.476	0.043*	0.923	0.890	0.112	-	-	-

PR	A	-	-	-	<0.001**	<0.001**	0.757	0.612	0.003*	<0.001**
	B	<0.001**	<0.001**	0.757	-	-	-	0.004*	0.233	<0.001**
	C	0.612	0.003*	<0.001**	0.004*	0.233	<0.001**	-	-	-

[Table/Fig-4]: Tukey's post-hoc analysis between various groups.

music reduced perioperative anxiety and contributed to patient satisfaction during the perioperative period [17]. Other studies by Stegemann T et al., and Bradt J et al., demonstrated the pharmacological benefits of music therapy in medicine [18,19].

According to a study by Dubey P et al., on patients with a history of delayed sleep latency, music played at 432 Hz provided noticeable soothing effects, as evidenced by increased alpha activity, but had no discernible impact on daytime nap sleep latency [20]. In addition to its claimed ability to repair Deoxyribonucleic Acid (DNA) and restore physical and mental wellness, 432 Hz is said to resonate with the heart chakra. There is even a theory which states that music set to 432 Hz stimulates the right brain, which is responsible for many of our most admirable human characteristics. A study on "Cymatics" revealed that 432 Hz produced different shapes that suggest resonance with nature. This experiment, conducted with water, yielded equivalent results. It is claimed that since the human body comprises approximately 70% water, these harmonious ripples can certainly impact our cells [21].

The effects of Om meditation on the brain and other areas of the body have been examined using various techniques, including EEG research, neuroimaging studies, evoked potentials investigations, and other procedural studies, in a review by Harne BP et al., [22]. This research indicates that Om meditation affects the heart rate and respiration rate, as well as the prefrontal cortex, vagus nerve, amygdala, and other areas of the brain. An evaluation of Om chanting's impact on depression, anxiety, stress, and cognition in older women with hypertension was conducted in a study by Amin A et al., [23]. The results indicated that practising Om chanting traditionally could be one of the most effective ways to enhance memory and calm the mind.

In a study conducted by Gurjar A et al., on the acoustic effect of OM, the results aligned with those of our study. The study indicated that not only is chanting Om beneficial, but also listening to Om chants offers advantages. It was claimed that listening to the Om mantra chant at a slow tempo calms the mind. It was observed that if the Om mantra is repeated at a slower pace, both the body and mind begin to relax within minutes, significantly sweeping away negative thoughts. Similar results were observed in the current study. Given the limited number of studies on the acoustic effect of Om chanting, the present study could prove to be a breakthrough in this area [24].

In another instance, a 14-year-old girl in India discovered the benefits of Om chanting by studying its effects on body fatigue, which was found to decrease due to an increase in oxygen levels and a decrease in carbon dioxide and lactic acid levels in the blood [25]. This led to a generous production of alpha, theta, and delta waves, resulting in the secretion of hormones or neurotransmitters that facilitated the dilation of blood vessels.

The frequency of the Om chant used in the present study was around 430 Hz to 432 Hz. This may explain why the audio track exhibited similar effects to the audio chant, as it vibrates at 432 Hz and sends positive signals throughout the body.

In the present study: (i) Om chanting normalised SBP values (whether increased or decreased) by the end of the treatment; DBP (whether increased or decreased) were also normalised by the end of the treatment, and PR (whether increased or decreased) returned to normal during treatment and by the end of the treatment; (ii) the weightless track helped to normalise SBP during treatment and by the end of the treatment, and PR returned to normal after the treatment.

Thus, both clinically (based on visual observations) and statistically, the music tracks demonstrated acceptable performance compared to the control group, with the Om chanting track being more effective than the weightless track in terms of anxiety levels, SBP, and DBP, thus alternative hypothesis was accepted.

These results are consistent with those of the study conducted by Nasso LD et al., [2], which showed that a direct comparison between patients who listened to music and those who did not revealed a significant decrease in all measured vital signs throughout the entire period (during and after canal therapy) in the group exposed to 432 Hz music ($p < 0.05$) [5].

Limitation(s)

Patients had only the choice of two music tracks; therefore, no other music preferences were available.

CONCLUSION(S)

Within the limitations of the present study, both music tracks demonstrated acceptable performance clinically and statistically when compared to the 'No music' group, with the Om chanting track showing an edge over the weightless track in terms of anxiety levels, SBP group and DBP group. The symbiotic effect of music and medicine has led to the emergence of audio analgesia as an adjunct to anxiety management in endodontic treatments.

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