RESEARCH ARTICLE

Limited Impact of Music Therapy on Patient Anxiety with the Large Loop Excision of Transformation Zone Procedure - a Randomized Controlled Trial

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Abstract

Background: Many studies have pointed to strategies to cope with patient anxiety in colposcopy. Evidence shows that patients experienced considerable distress with the large loop excision of transformation zone (LLETZ) procedure and suitable interventions should be introduced to reduce anxiety. This study aimed to investigate the effects of music therapy in patients undergoing LLETZ. Materials and Methods: A randomized controlled trial was conducted with patients undergoing LLETZ performed under local anesthesia in an out patient setting at Ramathibodi Hospital, Bangkok, Thailand, from February 2015 to January 2016. After informed consent and demographic data were obtained, we assessed the anxiety level using State Anxiety Inventory pre and post procedures. Music group patients listened to classical songs through headphones, while the control group received the standard care. Pain score was evaluated with a visual analog scale (VAS). Statistical analysis was conducted using Pearson Chi-square, Fisher's Exact test and T-Test and p-values less than 0.05 were considered statistically significant. Results: A total of 73 patients were enrolled and randomized, resulting in 36 women in the music group and 37 women in the non-music control group. The preoperative mean anxiety score was higher in the music group (46.8 VS 45.8 points). The postoperative mean anxiety scores in the music and the non-music groups were 38.7 and 41.3 points, respectively. VAS was lower in music group (2.55 VS 3.33). The percent change of anxiety was greater in the music group, although there was no significant difference between two groups. Conclusions: Music therapy did not significantly reduce anxiety in patients undergoing the LLETZ procedure. However, different interventions should be developed to ease the patients' apprehension during this procedure.

Keywords: Thai female patients - colposcopy - LLETZ - anxiety - music therapy

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Introduction

The pathway before the diagnosis of cervical cancer includes colposcopy, punch biopsy or large loop excision of transformation zone (LLETZ). Knowing an abnormal Pap smear result was associated with higher level of anxiety (McDonald et al., 1989; Idestrom et al., 2003). Significant level of distress was reported among women undergoing colposcopy (Heinonen et al., 2013; Jerachotechueantaveechai et al., 2015; O'Connor et al., 2015). The concern of having cancer and being investigated by invasive procedure might lead to a difficult procedure and also poor adherence to the treatment (Mao, 2002).

Many studies purposed strategies to cope with anxiety in colposcopy including nurse reassurance, giving more information, video screen, gentle language and music (Chan et al., 2003; Kola and Walsh, 2009; Carwile et al., 2014; Dalton et al., 2014). Interestingly, music has been a great modality to significantly decrease anxiety in colposcopy and many procedures (Galaal et al., 2011; Wang et al., 2014). Although, evidences revealed that patients experienced greater distress and pain in LLETZ procedure than colposcopy (Kola and Walsh, 2009; Kola-Palmer et al., 2016). To our knowledge, there has been no published study to determine whether music could be helpful to reduce anxiety in LLETZ procedure.

This research was conducted in order to study the impact of music on the level of anxiety in patients undergoing LLETZ procedure.

Materials and Methods

In February 2015, the research was approved by

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the Committee on Human Rights Related to Research Involving Human Subjects of the Faculty of Medicine, Ramathibodi Hospital, Mahidol University. Patients scheduling for LLETZ procedure at out patient clinic in Ramathibodi Hospital between February 2015 and January 2016 were enrolled in this randomized controlled trial. Inclusion criteria were women who had indication for LLETZ procedure and willing to join the research. Women who could not comprehend Thai or sustained hearing problems were excluded from the study.

Based on pilot study, the mean (SD) of anxiety score difference in control group was 9.67 (5.77). If the music is efficacious, it should be able to decrease anxiety score at least 4 compare with control group. The ratio between music and control groups was set at 1:1. Type I and II errors were set at 5% and 20%, respectively. Using sample size calculation of two independent means, 33 patients in each arm were required. After including a 10 percent loss, a total sample size of 74 patients was acquired.

Anxiety level was evaluated by 20 questions of Thai version self-evaluation questionnaire (State-Trait anxiety inventory, STAI), developed by Spielberger and colleges in 1970 (Spielberger et al., 1970). This questionnaire has been used in studies with Thai participants (Phahuwatanakorn, 2004; Ratanasiripong, 2012). The internal consistency (Cronbach's Alpha) of the State Anxiety Scale for the current sample was 0.91. This questionnaire comprised 40 questions that were divided into two parts, 'State' and 'Trait'. We chose only the state part to measure momentary anxiety. Participants rated their anxiety level on a 4-point scale ranging from 1 (not at all) to 4 (the most). The score ranged from 20-80 points, as the higher score reflected higher level of anxiety.

The widely used pain measurement, visual analog scale (VAS), was used to assess pain. Patients were requested to draw a vertical line on a 10-centimeter horizontal line ranging from "no pain at all" to "worst pain" on the other end. Satisfactory score was scaled from 1(very bad) to 7(most satisfied) by asking 'How do you rate our care today?'

Classical music has been reported to help reduce negative emotional states (Labbe et al., 2007). A slow-rhythm classical song was played with a portable media player and a headphone for the patients in the music group.

Informed consent and patients' demographic data were obtained from women scheduled for LLETZ procedure.

Table 1. Patient Demographic Data

Characteristic	Music group N=36	Non-music group N=37	P
Age (yr), mean (SD)	44.0 (10.9)	41.9 (10.5)	0.39
Occupation, N (%)			0.22*
Government officer	9 (26.5)	8 (21.6)	
Employee	12 (35.3)	15 (40.6)	
Housewife	1 (2.9)	6 (16.2)	
Others	12 (35.3)	8 (21.6)	
Income (Baht), N (%)			0.33
0 - 20,000	10 (32.3)	15 (44.1)	
More than 20,000	21 (67.7)	19 (55.9)	
Education, N (%)			0.38
Primary school	3 (8.6)	5 (13.5)	
High school	9 (25.7)	14 (37.8)	
Bachelor degree	23 (65.7)	18 (48.7)	
Marital status, N (%)			0.18*
Single	6 (16.7)	8 (21.6)	
Married	19 (52.8)	25 (67.6)	
Divorced	8 (22.2)	2 (5.4)	
Widow	3 (8.3)	2 (5.4)	
Parity, N (%)			0.54
0	10 (27.8)	8 (21.6)	
>1	26 (72.2)	29 (78.4)	
Frequency of listening to music, N (%)			0.23*
Once a day	20 (55.6)	21 (56.8)	
3 days per week	13 (36.1)	8 (29.7)	
3 days per month	3 (8.3)	5 (13.5)	
STAI anxiety score before operation; Mean (SD)	46.8 (9.5)	45.8 (8.7)	0.61
STAI anxiety score after operation; Mean (SD)	38.7 (9.62)	41.3 (9.98)	0.25

*Fisher's Exact test

Table 2. Value of Pre- and Post- Procedure Anxiety, Pain and Satisfaction Score

Score	Music group	Non-music group	P
Percent change in anxiety score; median (interquartile range)	15.9 (3.58,26.8)	10.2 (-5.76,20.7)	0.27
Pain score during procedure	2.55 (0.2,5.76)	3.33 (0.75,6.01)	0.64
Satisfaction score	6.38 (0.77)	6.24 (0.82)	0.42

With the use of opaque envelopes containing computerized randomized papers; patients were randomly allocated into the music and the non-music group. In order to assure patients' safety, we checked that the patients were able to hear the doctors' voices even under headphones. Accordingly, the patients were told not to move their legs during the procedure. The patients were asked to answer a pre procedure State Anxiety Scale. In the non-music group, the patients received a standard care. The music group listened to the slow-rhythm song through a headphone. The gynecologic oncology staff and fellows performed LLETZ procedure in the standardized fashion. An operative time was recorded by research nurses. The patients were asked to complete post-procedure State Anxiety Scale, visual analog score (VAS) and satisfaction score at the end of the procedure.

Study data was analyzed by STATA version 14 for Windows (StataCorp LP, College station, Texas, USA). Continuous data were described by mean (SD) or median (range) and categorical data were described by numbers (%). Pearson Chi-square (or Fisher's Exact test) was used to compare categorical data between two groups. T-test (or quantile regression) was applied for comparing continuous data between two groups.

Results

Through an 11-month period, 77 participants were enrolled in LLETZ procedure from February 2015 to January 2016. Three participants were excluded because of unable to understand Thai language. One participant was discontinued the procedure due to having a high blood pressure, inferring a total of 73 patients eligible for final analysis. Thirty-six participants were allocated to the music or study group and 37 participants were in the non-music or control group. The mean age was 44 in the study group and 42 in the control group. All patients were Buddhists. Most of the participants in both groups worked as employees. Monthly incomes were averagely above 20,000 baht. Most participants graduated with a bachelor's degree, were married and had a child. The mean operative time was 5 minutes. Table 1 demonstrated the baseline patient characteristics. Both groups generally appeared to be similar with respect to income, education, religion, marital status, parity, frequency of listening to music and result of cervical cytology.

Table 2 showed that the postoperative mean anxiety scores in the music and the non-music groups were 38.7 and 41.3 points, respectively. The percent change of anxiety was greater in the music group, although there was no statistically significant difference between the two groups. The pain score was lower and the satisfactory score was better in the music group. However, there was no significant difference in anxiety, pain or satisfactory score between both groups.

Discussion

This research was among the first few randomized controlled trials investigating the effects of music on anxiety for patients participating in LLETZ procedure. We also utilized a Thai version of State Anxiety Scale that suited the study population. A number of studies have shown music as a simple and inexpensive strategy to minimize anxiety (Chan et al., 2003; Wang et al., 2014). A research in Turkey on 402 physicians working in medical oncology concluded that music therapy should be regarded as an additional therapy in oncology clinics (Tanriverdi and Aydemir, 2013). In contrast, this research demonstrated that providing music to patients during LLETZ procedure resulted in no significant change in anxiety level.

Some studies in music therapy had similar outcomes to ours. A study in 170 women conducted in North Carolina found no significance of music or guided imagery for stress reducing in women undergoing colposcopy (Danhauer et al., 2007). Furthermore, a meta-analysis reported that music had little effects in colposcopy (Wang et al., 2014), which could represent the great resemblance to LLETZ procedure.

Because of an insignificant outcome, several limitations should be discussed. First, patients undergoing LLETZ procedures in our hospital were thoroughly educated about cervical cancer by nurses and had been through a colposcopic examination. The educational leaflets about the procedure were also provided. According to a recent qualitative study, more detailed and practical information about the cervical smear result and the procedure may reduce stress and anxiety (Bosgraaf et al., 2013). Women receiving leaflets showed lower anxiety level as compared to women who did not receive an information (Wilkinson et al., 1990; Marteau et al., 1996). These pre-procedure experiences could reduce notable levels of distress and anxiety in many patients.

Secondly, previous studies indicated a higher level of anxiety in LLETZ patients than colposcopy patients. They also established that women reported greater pain intensity with more intensive management procedure (Kola and Walsh, 2009; Kola-Palmer et al., 2016). This could be the reason why music had positive effect in colposcopy but did not affect sufficiently in LLETZ procedure. LLETZ was considered more invasive, possibly with more pain and could cause more anxiety than colposcopy.

Another limitation to be considered was the choice of music. There have been studies stating that significant reduction of negative emotional and physiological arousal were obtained after listening to self-selected music or classical music (Burns et al., 2002; Labbe et al., 2007). Increased reduction was proclaimed in the self-selected group. For further study, self-selected song should be a good choice to be compared with classical music.

Regardless of the previous study's preference to choose a relaxing, slow-rhythm song, very limited number of Thais regularly listen to classical music. Some might feel that the song was not truly relaxing and, consequently, brought negative effects to the anxiety level. Future study regarding the genre of music suitable for Thai population could diminish this limitation.

Headphones gave both positive and negative effect. Stressful moments could occur when patients in the music

group were unable to hear what was currently happening. Nonetheless, participants were advised to take off the headphones whenever they felt insecure.

In addition, the State Anxiety Inventory was uncertainly an appropriate measure for this study. Although it was already validated, we found some questions imprecise, insufficiently specifying if the concern was merely about the procedure or other influences. One last limitation was a small sample size. Whilst the tendency towards higher reduction in anxiety and pain in the music group was observed, a larger study populations may possibly verify the significant difference between groups.

Future study should focus on the appropriate choice of music, a different type of measurement and a higher number of participants.

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