Original Article

The impact of musical intervention on pain and anxiety levels during percutaneous nephrostomy tube replacement: a randomized controlled trial

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Abstract

Objective: Percutaneous nephrostomy tube replacement (PNTR) is a significant and frequently performed outpatient urological procedure. Patients undergoing this procedure often experience pain and anxiety. Various non-pharmacological methods are currently utilized to alleviate pain and anxiety. The objective of this study is to investigate the effects of music on pain and anxiety during PNTR .

Materials and Methods: A prospective randomized controlled trial was conducted in patients undergoing PNTR at Loei Hospital from May 1, 2023, to September 30, 2023. A total of 104 patients were randomly assigned to two groups: group 1, where patients did not listen to music during the procedure, and group 2, where patients listened to their preferred choice of music. Demographic data, vital signs, Visual Analog Scale (VAS) pain levels, State-Trait Anxiety Inventory-State Anxiety (STAI-SA), and willingness to repeat procedures were compared.

Results: The VAS pain scores in the music group were significantly lower than in the non-music group during and after PNTR (2.5 vs 5, $p < 0.005$ and 0 vs 3, $p < 0.001$, respectively). Moreover, the STAI-SA levels in the music group were significantly lower post-procedure (32.98±5.61 vs 39.98±6.18, $p < 0.001$), and the willingness to repeat the procedure was significantly higher (41 vs 22, $p < 0.001$).

Conclusion: The results of this study indicate that listening to a preferred choice of music during PNTR has the potential to reduce pain, and anxiety, and increase the willingness of patients to repeat procedure. The intervention of music serves as a cost-effective, safe, and side effect-free non-pharmacological approach to facilitate patient outcome in PNTR.

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Introduction

Percutaneous nephrostomy tube placement (PNTP) is a critical medical intervention in the management of relieving upper urinary tract obstruction associated with urosepsis, acute renal failure, and intractable pain[1], facilitating the diversion of urine from the kidney to an external collection bag.

In cases where a PNTP is employed during the wait for surgical intervention for the resolution of obstructive causes, or as a lifelong measure due to a patient not being a suitable candidate for surgery to collect the obstructive cause or when a cure for the obstructive cause cannot be achieved for the patient, regular percutaneous nephrostomy tube replacement (PNTR) every 6-8 weeks can be performed. Patients undergoing PNTR, approximately 35-64 individuals per month, often experience anxiety and discomfort during the process

There is currently a growing interest in using music to reduce anxiety and pain during outpatient urological procedures[2], for example during extracorporeal shockwave lithotripsy[3,4], transrectal ultrasound-guided prostate biopsy[5,6], cystoscopy[7,8], and urodynamic studies.[9] Music therapy has demonstrated efficacy in reducing pain and anxiety, resulting in an increased willingness to undergo the procedures again.

Despite the potential benefits of music therapy in urological surgeries, there is limited information on its application to reduce pain and anxiety during PNTR. The aim of this research is to investigate the impact of music on pain and anxiety levels throughout the PNTR procedure.

Materials and Methods

Patients

This study was conducted at Loei Hospital, focusing on patients who underwent PNTR between May 1, 2023, and September 30, 2023. Inclusion criteria included patients aged 18 years and older undergoing PNTR, proficiency in the Thai language, and who demonstrated understanding of the procedures and objectives, as evidenced by providing informed consent through signing the consent form. Patients excluded from the study included those with a history of hearing impairment, individuals with neurological conditions that impact sensory perception, and those who were unable to undergo PNTR. Approval for the study was obtained from the Ethics Committee of Loei Hospital (approval number: EC017/2566).

Study design

This study, a single-center randomized controlled trial, used a random allocation method based on a computer-generated random sequence with blocks of 4. Concealment was achieved through identical sequential opaque sealed envelopes, and the envelope draw carried out by staff before the procedure. Patients were then assigned to either group 1, not listening to music but wearing headphones for blinding purposes or group 2, listening to a preferred choice of music (e.g., traditional Thai music, country, international) with headphones during the procedure. While participants could not be blinded to their group, the medical personnel performing the PNTR and the research assistants collecting data were able to be blinded.

PNTR technique

In this study, all PNTR procedures were carried out in the operating room and a single urologist carried out all cases. The procedure followed a standardized protocol for PNTR, including informed consent, cleaning with antiseptic solution, sterile draping, and, for some participants, listening to music via headphones. During the procedure 7 ml of 1% Xylocaine without adrenaline is administered, old ties are cut, and the tube is shortened before inserting a guide wire. The old tube is then removed, replaced with a new one, and tested for proper positioning by irrigating with water. Suturing is performed, and a final test ensures the secure placement of the new urinary drainage tube.

Data collection, definitions, and primary outcomes

In this research, demographic data collection included gender, age, body mass index (BMI), underlying medical conditions, and causes of obstruction. Procedure-related data included details about the location of the PNT, pain and anxiety scores, vital signs and willingness to repeat the procedure.

The primary outcomes for this study were pain and anxiety scores. Secondary outcomes included vital signs and willingness to repeat the procedure.

Pain scores: pain was be assessed using the Visual Analog Scale (VAS) with scores ranging

from 0 to 10. The assessments were conducted three times: baseline pain evaluation before changing the PNT, procedural pain assessment immediately upon completion of suturing of the new PNT to the skin, and post-procedural pain.

Anxiety scores: anxiety was assessed using The State-Trait Anxiety Inventory-State Anxiety (STAI-SA), developed in 1970 by Spielberger and colleagues. The validity of the Thai version, established in 1983 by Nonthasak T[10], demonstrated a Cronbach's alpha internal consistency level of 0.78. The STAI-SA measures a person's feelings in a specific situation at a certain time. The STAI-SA consists of 20 statements, with total scores ranging from 20 to 80. Anxiety levels are categorized as no or low anxiety (20-37), moderate anxiety (38-44), and high anxiety (45-80).[11] The STAI-SA assessment was conducted twice: before commencing the procedure, and 10 minutes after the procedure was completed.

Vital signs: vital signs, including systolic blood pressure, diastolic blood pressure, mean arterial pressure, and heart rate, were measured using appropriate medical instruments. The vital signs were measured at three distinct times along with the VAS pain assessment

Willingness to repeat the procedure was evaluated after completion of the procedure. Patients were asked whether they are satisfied or dissatisfied with the idea of coming back for the next PNTR.

Statistical analysis

The statistical analysis involved descriptive statistics for the sample group undergoing PNTR, sex, age, BMI, underlying disease, side of PNT, procedural indicators, and cause of hydronephrosis. Data are presented as frequency and percentage distributions, with mean and standard deviation for normally distributed continuous variables and median with interquartile range (IQR) for non-normally distributed data.

Differences in general characteristics between the music-listening and non-music-listening groups were assessed using the Chi-square test or Fisher's exact test if expected values are less than 5 in more than 20% of cells.

STAI-SA scores, VAS pain scores, vital signs and willingness to repeat the procedure were compared between the music-listening and non-music-listening groups. The choice between an independent t-test or Mann-Whitney test was dependent on whether the data was normally or non-normally distributed.

The researchers based the statistical analysis on 4 protocols; protocol A, patients undergoing their first PNTR only, protocol B, patients undergoing 2-4 PNTR changes, protocol C, patients undergoing 5-17 PNTR and finally, protocol D, patients undergoing more than 17 PNTR. All of the above were used for comparing the differences in VAS between music and non-music therapy by two-way analysis of variance. The correlation between VAS and frequency PNTR was analyzed using Spearman correlation coefficient.

Results

A total of 108 patients were initially enrolled for the PNTR procedure, with 4 individuals (3.7%) excluded from the study. Among these exclusions, 3 did not meet the inclusion criteria, and 1 did not cooperate in completing the questionnaire. Subsequently, 104 participants were randomized and divided into two groups, each consisting of 52 individuals (Figure 1).

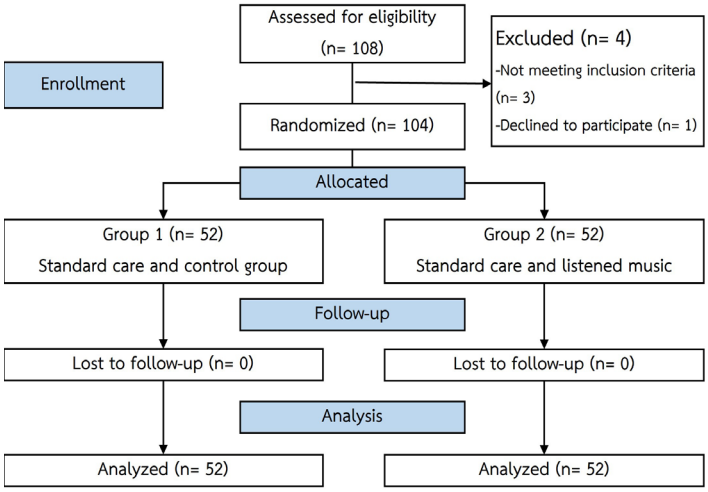

Figure 1. Flowchart of this study

Table 1. Demographic data

Variables	Control group (n=52)		Music group (n=52)		P-value
	n	%	n	%	
Sex					0.694[a]
Male	23	44.23	25	48.08	
Female	29	55.77	27	51.92	
Age (years) mean±SD	66.48	±13.66	62.71	±12.60	0.147[b]
BMI (kg/m^2) mean±SD	22.21	±4.41	22.85	±4.91	0.487[b]
Side					0.691[a]
Right	29	55.77	31	59.62	
Left	23	44.23	21	40.38	
Underlying disease					0.169[a]
No	1	1.92	4	7.69	
Yes	51	98.08	48	92.31	
Diabetes mellitus	13	25.00	13	25.00	1.000[a]
Hypertension	21	40.38	25	48.08	0.430[a]
Dyslipidemia	7	13.46	10	19.23	0.426[a]
Chronic kidney disease*	38	73.08	32	61.54	0.210[a]
Gout	7	13.46	4	7.69	0.339[a]
Bladder cancer	5	9.62	3	5.77	0.462[a]
Cervix cancer	7	13.46	7	13.46	1.000[a]
Prostate cancer	1	1.92	2	3.85	0.558[a]
Colon cancer	0	0.00	1	1.92	0.315[a]
Rectal cancer	0	0.00	1	1.92	0.315[a]
Cause of obstruction					
Ureteric calculi	16	30.77	14	26.92	0.510[a]
Renal calculi	17	32.69	13	25.00	0.530[a]
Ureteral stricture	5	9.62	4	7.69	1.000[a]
Ureteropelvic junction obstruction	0	0.00	3	5.77	0.133[a]
Benign disease**	3	5.77	4	7.69	0.689[a]
Malignant disease	11	21.15	14	26.92	0.368[a]

SD = standard deviation, BMI = body mass index
Statistical analysis was conducted using tests as indicated: aFisher'sexact, bIndependent t-test
*Chronic kidney disease is defined as a condition where the glomerular filtration rate is less than 60 ml/min/1.73 m^2 for a minimum duration of 3 months.[12]
**Benign diseases in this research include ovarian tumor, benign prostatic hyperplasia with bilateral hydronephrosis, and neurogenic bladder.

The demographic data included gender, age, BMI, the side of PNT, underlying medical conditions, and the cause of hydronephrosis. Statistical analysis reveals no statistically significant differences between the two groups when these variables are compared (Table 1).

In this study, it was observed that the systolic blood pressure of the music-listening group was lower than the non-music-listening group during and after PNTR, but the difference was not statistically significant (Table 2).

VAS pain score of the music-listening group was significantly lower than that of the non-music-listening group during and after PNTR (2.5 vs 5, $p < 0.005$ and 0 vs 3, $p < 0.001$, respectively). Additionally, statistically significant differences were observed in STAI-SA levels post- PNTR and the willingness to repeat procedure, with the music-listening group exhibiting lower anxiety (32.98±5.61 vs 39.98±6.18, $p < 0.001$) and higher willingness in comparison to the non-music-listening group (41 vs 22, $p < 0.001$) (Table 3).

Table 2. Operation time and hemodynamic parameters.

Variables	Control group (n=52)		Music group (n=52)		P-value
	mean±SD		mean±SD		
Duration of PNTR (minutes)	5.51	0.89	5.46	0.81	0.591[b]
Pre-PNTR SBP (mmHg)	139.15	22.59	141.78	21.11	0.54
Pre-PNTR DBP (mmHg)	77.53	11.78	79.76	14.06	0.382
Pre-PNTR MAP (mmHg)	101.38	16.45	104.17	17.07	0.398
Pre-PNTR HR (mmHg)	88.54	16.32	88.42	14.81	0.97
Procedural-PNTR SBP (mmHg)	140.84	22.62	138.57	19.54	0.585
Procedural-PNTR DBP (mmHg)	77.75	14.31	78.11	14.65	0.97
Procedural-PNTR MAP (mm Hg)	103.09	17.91	103.59	16.31	0.882
Procedural-PNTR HR (mmHg)	88.04	15.63	89.59	13.28	0.585
Post-PNTR SBP (mmHg)	139.53	21.92	137.25	18.98	0.571
Post-PNTR DBP (mmHg)	75.92	12.28	75.82	13.8	0.97
Post-PNTR MAP (mmHg)	101.21	17.32	100.51	15.55	0.831
Post-PNTR HR (mmHg)	88.28	15.38	87.69	14.32	0.838

SBP = systolic blood pressure, DBP = diastolic blood pressure, MAP = mean arterial pressure, HR = heart rate, SD = standard deviation, PNTR = percutaneous nephrostomy tube replacement
[b]Statistical analysis was conducted using an Independent t-test

Table 3. Pain scores, anxiety scores, and willingness to repeat the procedure.

Variables	Control group (n=52)		Music group (n=52)		P-value
Pre-PNTR VAS; Median (IQR)	0	4	0	4	0.849[c]
Pre-PNTR STAI-S; mean ± SD	41.9	6.54	41.21	6.52	0.590[b]
Procedural-PNTR VAS; Median (IQR)	5	3.5	2.5	4	<0.005[c*]
Post-PNTR VAS; Median (IQR)	3	5	0	1	<0.001c*
Post-PNTR STAI-S; mean ± SD	39.98	6.18	32.98	5.61	<0.001[b*]
Willing to repeat procedure n (%)	22	42.31	41	78.85	<0.001[a*]

Statistical analysis was conducted using: [a]Fisher's exact, [b]Independent t-test, [c]Mann-Whitney U test, [*]Statistically significant
STAI-SA = State-Trait Anxiety Inventory-State Anxiety, VAS = visual analog scale, PNTR = percutaneous nephrostomy tube replacement

In this study, we investigated whether patients experience a decrease in pain during PNTR procedures. We conducted a per-protocol analysis to assess the relationship between the number of PNTR and the pre-PNTR VAS scores for pain.

Pre-PNTR process

We considered the differences between the two groups using comparisons between the 4 protocols. Two-way analysis of covariance revealed that VAS differed in the Music and Non-music therapy groups, but the results did not reach statistical significance ($p = 0.064$). The grand mean for this analysis was calculated to be 2.019231. Tukey multiple comparisons of means, also showed no statistically significant differences ($p > 0.05$) between all 4 protocols, even though the mean VAS for pain were 2.8432 for the control group and 1.0991 for the music group.

Furthermore, when analyzing the linear correlation of VAS between the control group and the music group, we found that in this population, VAS in pre-PNTR and frequency of PNTR are not linearly correlated ($p = 0.1491$)

Overall, our per-protocol analysis revealed no statistically significant differences ($p > 0.05$) in the relationship between pre-PNTR VAS in patients across different protocols and between

the control and music groups. A summary of the results are shown in Table 4.

Procedural-PNTR process

The overall mean for the number of PNTR is 4. The mean number of PNTR for each protocol (A, B, C, D) ranges from 3.308 to 4.654. The means of the two groups are 4.902 in the control group and 3.098 in the music group. The interaction in terms of the comparisons of the two groups have shown results consistent with pre-PNTR. Comparison of the VAS in Music and Non-music therapy showed also non-significant outcomes (p = 0.731)

The comparison between protocols in the Procedural-PNTR as regards VAS using Tukey multiple comparisons of means resulted in no statistically significant differences in the relationship between Procedural -PNTR VAS scores and pain among patients across different protocols and between the control and music groups. These results were similar to the linearity test that showed that VAS in Procedural-PNTR and frequency of PNTR were not linearly correlated (p = 0.4226) (Table 5).

Post-PNTR process

This process has been used to investigate the comparisons between the groups when a combination of the protocols that non-significantly corresponded to the first period before PNTP including procedural PNTR (p = 0.817). Each of protocols analysis was conducted to compare the mean scores of post-PNTR VAS across the different protocols and between groups. The grand mean for all protocols and groups combined was found to be 1.971154 whereas the correlation coefficient based on Spearman's method among VAS in post-PNTR did not show any linearity with frequency PNTR (p = 0.5244)

Table 4. The Tukey multiple comparisons of means pre-PNTR VAS.

Comparison	Difference in mean	Lower CI of mean	Upper CI of mean	Adjusted p-value of mean	Spearman's correlation coefficient (95%CI)	P-value of correlation
A-B	0.7307	1.2374	2.6989	0.7663	-0.142 (-0.326, 0.052)[a]	0.1491[b]
A-C	0.4615	1.5066	2.4297	0.9276		
A-D	0.7307	1.2374	2.6989	0.7663		
B-C	0.2692	1.6989	2.2374	0.9842		
D-B	0.0000	-1.9682	1.9682	1.0000		
C-D	0.2692	1.6989	2.2374	0.9842		

[a]spearman correlation coefficient: linear correlation between VAS before PNTP with frequency of PNTR, [b]p-value Spearman's correlation coefficient
STAI-SA = State-Trait Anxiety Inventory-State Anxiety, VAS = visual analog scale, PTNR = percutaneous nephrostomy tube replacement, CI = confidential interval

Table 5. The Tukey multiple comparisons of means using the mean procedure-PNTR VAS.

Comparison	Difference in mean	Lower CI of mean	Upper CI of mean	Adjusted p-value of mean	Spearman's correlation coefficient (95%CI)	P-value of correlation
B-A	1.1538	-0.8982	3.2059	0.4594	0.0794[b] (-0.268, 0.115)	0.4226[a]
C-A	1.0384	-1.0135	3.0905	0.5505		
A-D	0.1923	1.8597	2.2443	0.9947		
B-C	0.1153	1.9366	2.1674	0.9988		
B-D	1.3461	0.7059	3.3982	0.3215		
B-A	1.1538	-0.8982	3.2059	0.4594		

[a]Spearman's correlation coefficient: linear correlation between VAS procedural-PNTR with frequency of PNTR, [b]p-value Spearman's correlation coefficient, CI = confidential interval

The mean scores between different protocols (A, B, C, D) were compared using Tukey multiple comparisons of means. The results showed that there were no statistically significant differences ($p > 0.05$) between Protocol B and Protocol A, Protocol C and Protocol A, Protocol D and Protocol A, Protocol C and Protocol B, Protocol D and Protocol B, or between Protocol D and Protocol C (Table 6).

However, upon consideration of the comparison of mean VAS for pre-procedural, procedural, and post-procedural phases of PNTR, it is evident that the mean VAS does not decrease with an increasing number of PNTR, as shown in Table 7.

In conclusion, the analysis indicates that there were no statistically significant differences ($p > 0.05$) between the protocols, indicating that the mean pre, procedure, post-PNTR VAS did not vary significantly across different protocols according to spearman correlation coefficient in 3 periods. Moreover, an increased frequency of PNTR does not show any correlation with a reduction in pain.

Discussion

When patients undergo percutaneous nephrostomy tube placement they commonly experience pain and anxiety.[13] The actual procedure of PNTR exacerbates these symptoms. This procedure is frequently performed in a urologist's office, and patients often face increased pain and anxiety due to the alien surroundings.

Currently, there are no standard pain relief recommendations for PNTR. The common practice involves local administration of analgesic agents around the PNT insertion, at the precise location of the suture site where the PNT is attached to skin. However, there are a range of pharmacological and non-pharmacological approaches being used to reduce pain and anxiety. Pharmacological approaches have limitations, including cost, side effects, and the risk of drug dependence.[14,15] Non-pharmacological methods are attracting increasing interest due to their lower side effect profile.[16-18]

Non-pharmacological pain relief methods encompass various techniques including educa-

Table 6. The Tukey multiple comparisons of means in post- PNTR VAS.

Comparison	Difference in mean	Lower CI of mean	Upper CI of mean	Adjusted p-value of mean	Spearman's correlation coefficient (95%CI)	P-value of correlation
B-A	0.2307	-1.5546	2.0162	0.9866	0.0630 (-0.131, 0.252)[a]	0.5244[b]
C-A	0.4230	-1.3623	2.2085	0.9255		
D-A	0.4615	-1.3239	2.2469	0.9059		
C-B	0.1923	-1.5931	1.9777	0.9921		
D-B	0.2307	-1.5546	2.0162	0.9866		
D-C	0.0384	-1.7469	1.8239	0.9999		

[a]Spearman's correlation coefficient: linear correlation between VAS procedural-PNTR with frequency of PNTR, [b]p-value Spearman's correlation coefficient
CI = confidential interval

Table 7. Mean VAS for pre-procedural, procedural, and post-procedural phases of PNTR for the control group and the music intervention group across different protocols (A, B, C, D).

Protocol	Pre-PNTR VAS		Procedural-PNTR VAS		Post-PNTR VAS	
	Control group	Music group	Control group	Music group	Control group	Music group
A	2.846	2.154	4.308	2.692	2.308	1.077
B	1.250	2.214	5.583	3.857	2.667	1.286
C	1.200	3.182	5.000	3.909	3.000	0.909
D	2.750	0.929	4.833	2.000	3.417	1.071

PTNR = percutaneous nephrostomy tube replacement, VAS = visual analoque scale

tion, music therapy, mind-body techniques, relaxation training, distraction, biofeedback, humor, massage, aromatherapy, reflexology, acupuncture, therapeutic touch, and transcutaneous electrical nerve stimulation.[19]

Several studies have explored the use of music to reduce anxiety and pain during urological procedures.[2-9] Music, as a stimuli-directed intervention, stimulates the part of the brain controlling emotional responses faster than the part responsible for pain perception, increasing pain tolerance and alleviating suffering.[20,21]

This study chose to have patients listen to their preferred music because previous research by Cift A and colleagues found that providing patients undergoing shock wave lithotripsy with their preferred music choice contributed significantly to lower levels of pain and anxiety, as well as higher satisfaction levels, when compared to responses to exposure to Turkish art music and Western classical music.[22]

Despite previous research into the use of music during office-based surgical procedures, no studies have investigated its efficacy during PNTR. This study aimed to assess the impact of music on pain and anxiety during PNTR.

The study found that VAS pain score and STAI-SA scores in the music group were significantly lower than those in the non-music group, with a statistically significant proportion in the music group expressing a willingness to repeat the procedure. This finding is in alignment with other randomized controlled trials in which patients listened to music during minor urological procedures. These trials included nephrostomy tube placement by Hamidi et al.[23], extracorporeal shock wave lithotripsy by Bozkurt M and coworkers[24], and a urodynamic study by Öztürk E and colleagues.[9]

However, in a study by Cakmak et al.[25], listening to music during extracorporeal shockwave lithotripsy, found significantly lower systolic blood pressure, diastolic blood pressure, and heart rate in comparison to the non- music group. These outcomes were in contrast to the findings of this study, where although systolic blood pressure in the music group was lower than in the non-music group during and after PNTR results were not statistically significant. The lack of significant differences in vital signs may be due to the shorter duration of pain stimulation during PNTR compared to shockwave lithotripsy.

There are a few potential limitations to this study. Firstly, the absence of an evaluation regarding the success of the PNTR, a factor which could easily be incorporated into a future investigation. Secondly, an inability to assess the relationship between the type of music and the reduction in VAS pain score and STAI-SA scores, again an aspect which could be included in the future.

Conclusions

The outcomes of this study demonstrate that listening to a preferred choice of music during PNTR has the potential to reduce pain, anxiety, and increase the willingness of the patients to repeat procedure. This music intervention serves as safe and side effect-free non-pharmacological approach.

Conflicts of Interest

The authors declare there are no conflicts of interest.

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