

Original Article

Music Therapy for Preoperative Anxiety Reduction in Women Undergoing Total Laparoscopic Hysterectomy: A Randomized Controlled Trial

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ABSTRACT **Study Objective:** To assess the superiority of a music therapy intervention (Music) vs usual care (Control) in reducing the preoperative anxiety of patients undergoing total laparoscopic hysterectomy (TLH) with nononcologic indications.

Design: This was a 1:2 (Music vs Control) randomized controlled study.

Setting: A teaching hospital.

Patients: One hundred patients were available for the analysis: 30 and 70 in the Music and Control arms, respectively.

Interventions: Perioperative music therapy pathway in patients undergoing TLH for benign disease.

Measurements and Main Results: Anxiety was evaluated with the State-Trait Anxiety Inventory Y Form (STAI-Y) at different time points: at baseline and during preoperative, early postoperative, and late postoperative periods. Pathologic anxiety was defined as STAI-Y state >45. Postoperative pain was registered using the visual analog scale.

Women in the Music arm experienced lower anxiety levels (median STAI-Y scores 38.0 vs 41.0; $p = .002$) during the preoperative period. STAI-Y scores did not vary significantly by intervention at each subsequent time point. A significant difference between the groups (Music vs Control) was found in the proportion of women with pathologic anxiety during the preoperative (16.7% vs 37.2%; $p = .04$) and early postoperative periods (0% vs 12.9%; $p = .04$), whereas no significant difference between the groups was registered during the late postoperative period (6.6% vs 7.1%; $p = .93$). Postoperative pain intensity did not significantly differ between the groups at 1, 3, and 6 hours after surgery.

Conclusions: Music therapy might be a viable complementary modality to usual surgical care in the gynecologic setting for its ability to significantly decrease preoperative anxiety in women undergoing TLH for benign conditions. *Journal of Minimally Invasive Gynecology* (2021) 28, 1618–1624. © 2021 AAGL. All rights reserved.

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Hysterectomy is the most common nonobstetric gynecologic procedure performed all over the world. Research suggests that a non-negligible proportion of women undergoing hysterectomy experience preoperative anxiety [1,2]. As with any major surgery, an unfamiliar environment, loss of control, perceived or actual physical risk, and fear of

postoperative pain are all factors that can contribute to the development of such a feeling [3]. However, when dealing with the reproductive sphere, further concerns arise in relation to the definite loss of reproductive potential, loss of a major source of female identity, potential impact on sexual function, and perception of body image [4,5]. Therefore, hysterectomy may be associated with a specific type of anxiety that is not common in other surgical populations.

Collected findings from published studies suggest that higher levels of preoperative anxiety are associated with an increased risk of adverse postoperative outcomes, postoperative pain, increased analgesia use, and anxiety-related negative behavior changes [6–8]. A perioperative multimodal analgesia approach, including nonpharmacologic methods such as a music intervention, has been suggested as an effective strategy for reducing preprocedural waiting anxiety [9].

The authors declare that they have no conflict of interest.

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In a recent meta-analysis that aimed to evaluate anxiety and pain after perioperative music interventions in adult patients, it was found that music significantly reduced preprocedural anxiety and postoperative pain compared with diverse control conditions [10,11]. More recently, a prospective study indicated that music also had a beneficial effect on anxiety in women undergoing minor gynecologic procedures such as office hysteroscopy and oocyte retrieval [12]. In obstetrics, the anxiolytic potential of music listening has been demonstrated both during childbirth [13] and cesarean section [14].

Despite growing interest in the use of music as a therapeutic intervention in the obstetric and gynecologic settings, thus far no investigation has been conducted to specifically evaluate the impact of music therapy on women who are about to undergo a hysterectomy. Moreover, little is known about the potential effects of using passive listening of prerecorded music (i.e., music relayed through a headphone) as opposed to formalized music therapy (i.e., a structured pathway with a defined intervention of a music therapist).

We designed a randomized clinical trial to determine the effect of music therapy on perioperative anxiety in patients scheduled for elective hysterectomy with nononcologic indications.

Materials and Methods

This was a randomized trial designed to assess the superiority of a music therapy pathway (Music) over standard perioperative management without music therapy (Control) to reduce preoperative anxiety (i.e., anxiety while waiting to undergo surgery) in patients undergoing total laparoscopic hysterectomy for benign conditions. As a secondary outcome, we evaluated the effect of Music on early postoperative pain at 1, 3, and 6 hours postoperatively. Women scheduled for total laparoscopic hysterectomy for presumed benign disease at Del Ponte Women's and Children's Hospital in Varese (Italy) between March 15, 2020, and September 30, 2020, represented the intended population. Patients scheduled for any other associated nongynecologic procedure and/or history of previous malignancies were excluded from the study. We also excluded individuals with hearing impairment (total or partial hearing difficulties), patients with neuropathic pain or chronic pain needing regular anti-inflammatory drugs, non-Italian-speaking women, and those enrolled in any other research study involving drugs or devices. Perioperative settings such as ward and room facilities and postoperative management were consistent over the study period.

During the preadmission clinic, approximately 2 to 4 weeks before the planned admission date, the patients were approached while they were waiting for the preoperative surgical consultation and were invited to participate in the study. If patients expressed an interest in taking part, they were given an information sheet to read through before

giving their consent. Women enrolled in the study had a joint psychological–music therapy interview before leaving the preadmission clinic at which the following evaluations were made: (1) the level of anxiety was evaluated by the State-Trait Anxiety Inventory Y Form (STAI-Y) [15]. This is a 40-item self-administered questionnaire with an intensity scale ranging from 1 to 4 for each item. The items are grouped into 2 clusters on the basis of the features of 2 different types of anxiety: state, or static anxiety (anxiety level at that specific instant), and trait, or dynamic anxiety (patient's predisposition to become anxious in stressful situations). A preoperative STAI-Y score >60 (either state or trait) was indicative of moderate to severe baseline anxiety, and the patients were considered ineligible for the present study; (2) a psychotherapist interview focusing on the patient's history of psychopathologic symptoms, emotional and behavioral responses to previous surgical or medical interventions, the patient's emotional experience (e.g., mental representation and fear of the scheduled surgery), and coping strategies; and (3) evaluation by a music therapist to define the patient's musical identity through the assessment of their musical tastes and preferences.

Randomization took place the same day as the surgery and was performed in real time on the basis of the Sequentially Numbered, Opaque, Sealed Envelopes allocation system [16]. Before their admission to the study, the women were informed by dedicated trained physicians about the aims, methods, reasonably anticipated benefits, and potential hazards of the study. After counseling, written signed consent was obtained from the participants. After the psychotherapist interview, the women allocated to the Control arm received usual care as supplied in everyday practice and completed all outcome measures in the same time frame as the intervention arm.

Music Arm

On the day of surgery, the patients enrolled in the Music arm were accompanied by the music therapist all the way from the ward to the operating room to monitor and adapt the music therapy intervention. One hour before anesthesia, the patient settled in a preoperative room and underwent a 1-hour music therapy intervention made up of 3 phases. The first phase was an active music therapy intervention and consisted of a session of music improvisation. The second phase was a receptive music therapy intervention where the therapist played live music to relax the patient with autogenic training, breath control techniques, and diaphragm exercises [17]. In the last phase, the patient listened to a personal music therapy playlist with a dedicated MP3 player with earphones inserted into the ear canal at a maximum volume of 60 dB (previously set with a sound level meter) [18,19]. After anesthesia, the music therapy continued with the earphones for the entire duration of the surgery until the patient came awake and for another hour afterward.

Outcome Measures

Anxiety levels were evaluated using the STAI-Y state form [15] at 4 time points during the study period: baseline, at the preadmission clinic; preoperative period, in the operating room (holding area before administration of the anesthesia); early postoperative period, 6 hours after the end of surgery; and late postoperative period, 1 month after surgery. The pathologic anxiety status cutoff was placed at STAI-Y state >45 [20]. Postoperative pain was evaluated by using the visual analog scale 1, 3 and 6 hours after surgery [21]. Nausea was evaluated with a dedicated scale (0–10) within the first 24 hours after surgery by reporting the highest value referred; the occurrence of vomiting during the first postoperative day was also registered. The bladder catheter was always removed the same day as the surgery, and the time to mobilization was recorded and reported in hours. During the study period, there was consistency in perioperative management and patient care (reported elsewhere [22]); anesthetic management was carefully controlled and standardized over the study period. Any occurrence of major perioperative surgical complications (Clavien-Dindo score ≥ 2 [23]) within 30 days from surgery was also recorded.

Statistics

Before the main trial, a pilot study was conducted to gather information on the mean preoperative anxiety level experienced by the women about to undergo elective hysterectomy in our operating room. The aim was to estimate statistical parameters for later analyses. Selection criteria and the mode of STAI-Y questionnaire [15] administration were the same as in the main study. The pilot study consisted of 20 consecutive patients and was conducted over a period of 2 months. The mean (standard deviation) preprocedural anxiety STAI-Y state score was 43.0 (standard deviation 5.1) points. A previous study reported a 5-point reduction in preoperative anxiety (STAI-Y) by using music therapy in patients undergoing large loop cervical excision [24]. Accordingly, the sample size of the present study was calculated with the ratio between the Music and Control groups set at 1:2. Type I and type II errors were set at 5% and 20%, respectively. Using sample size calculation of 2 independent means, with allocation following the 1:2 ratio (Music vs Control), 29 patients in the Music arm were required. After taking into account a 10% loss, a total sample size of 100 patients was estimated to be required. Baseline demographic characteristics, medical and surgical histories, and details of healthcare received from admission to discharge were recorded and collected in a dedicated electronic database.

The Pearson chi-square test (or Fisher exact test) was used to compare categorical data between the groups, whereas the *t* test (or quantile regression) was applied for comparing continuous data. The study received University

of Insubria institutional review board approval (approval number 2147); the full protocol is available on clinicaltrials.gov (NCT04243967; date of trial registration: January 28, 2020; the protocol is available on clinicaltrials.gov, <https://clinicaltrials.gov/ct2/show/NCT04243967>; data repository: 10.6084/m9.figshare.13521908).

Results

After excluding data of the women lost to follow-up, 100 patients were included in the analysis, 30 and 70 in the Music and Control arms, respectively (flow chart: see Supplemental Fig. 1). Baseline characteristics did not significantly differ between the groups in terms of body mass index and menopausal status at the time of surgery. The patients in the Music arm were on average 2.3 years younger than those in the Control group (median age: 48.2 vs 50.5 years; $p = .02$). No difference in terms of the indications for surgery was found ($p = .6$), with fibromatosis being the most common reason for hysterectomy in both groups. Surgery was uneventful for all the enrolled patients, and no major surgical complications within 30 days from surgery occurred. No conversion to open surgery was registered. Similarly, no differences were found in regard to uterus weight, operative time, and postoperative hemoglobin drop. The median hospital stay was 2 days in both groups (Table 1).

The baseline level of anxiety (Music vs Control) assessed with the STAI-Y score was similar between the groups, both in terms of static anxiety (38.5 vs 38.5; $p = .98$) and dynamic anxiety (38.0 vs 39.0; $p = .95$); in addition, the proportion of women with pathologic anxiety at baseline did not significantly differ between the groups (30.0% vs 31.4%; $p = .89$).

Before surgery, the patients in the Music arm experienced significantly lower anxiety levels (median STAI-Y score 38.0 vs 41.0; $p = .002$) and had a lower prevalence of pathologic anxiety cases (5, 16.7% vs 26, 37.1%; $p = .04$). The STAI-Y scores did not vary significantly by intervention at each subsequent time point (31.0 vs 32.0; $p = .19$ during the early postoperative period and 34.5 vs 31.0; $p = .68$ during the late postoperative period) (Table 2). However, a significant difference between the Music and Control arms was found in the proportion of women with pathologic anxiety during the early postoperative period (0% vs 12.9%; $p = .04$), whereas no significant difference between the groups was registered during the late postoperative period (6.6% vs 7.1%; $p = .93$) (Fig. 1). Postoperative pain intensity as assessed by the visual analog scale did not differ between the groups at 1, 3, and 6 hours after surgery (Table 3). Three patients (10.0%) and 16 patients (22.2%) required additional postoperative intravenous analgesic in the Music and Control arms, respectively ($p = .13$). All patients were fully mobilized within 24 hours after surgery. Median postoperative nausea did not significantly differ between the groups ($p = .33$), whereas vomiting occurred in

Table 1

Baseline and surgery-related characteristics of the study population

Study cohort	Music (N = 30)		Control (N = 70)		p-value
Age, yrs	48.2 (46.6–49.8)		50.5 (49.4–51.7)		.02
BMI, kg/m ²	26.7 (24.7–28.7)		24.6 (22.9–26.2)		.09
Menopause	2 (6–7)		7 (10–0)		.59
Surgical indication	n	%	n	%	.6
Fibromatosis (no heavy bleeding)	8	26.7	20	28.6	
Fibromatosis (with heavy bleeding)	20	66.7	46	65.7	
Endometrial hyperplasia	2	6.6	1	1.4	
Pelvic organ prolapse	0	0	2	2.9	
Endometriosis	0	0	1	1.4	
Uterus weight, g	274.5 (100–2000)		335 (50–1500)		.4
Operative time, min	103.5 (37–220)		92 (34–560)		.51
Hospital stay, d	2 (1–5)		2 (1–4)		.04
Δ-hemoglobin levels*	1.3 (0–3)		1.3 (0–3.8)		.79

BMI = body mass index.

Values are given in absolute number and percentage (%) for dichotomous variables and median and range (minimum-maximum) for continuous variables.

* Defined as the difference between the preoperative hemoglobin level and the nadir hemoglobin level during a patient's hospitalization.

Table 2

State and trait anxiety scores at the study time points

STAI-Y score	Music (N = 30)	Control (N = 70)	p-value
Baseline			
Median STAI-Y state	38.5 (21–60)	38.5 (21–60)	.98
Median STAI-Y trait	38.0 (25–57)	39.0 (24–60)	.95
Preoperative			
Median STAI-Y state	38.0 (23–50)	41.0 (24–64)	.002
Early postoperative			
Median STAI-Y state	31.0 (20–43)	32.0 (20–58)	.68
Late postoperative			
Median STAI-Y state	34.5 (25–55)	31.0 (21–58)	.17

STAI-Y = State-Trait Anxiety Inventory Y Form.

Values are given in median and range (minimum-maximum).

2 (6.7%) and 7 (10.0%) women in the Music and Control arms, respectively ($p = .59$) (Table 4).

Discussion

The results of the present study suggest that a music intervention, provided by a board-certified music therapist, is effective in reducing the preoperative anxiety of women undergoing laparoscopic hysterectomy for benign conditions. This result is consistent with that of previous randomized trials providing evidence for the implementation of music therapy in other surgical populations [10,11]. Alleviating preoperative anxiety in the surgical arena is a clinically relevant issue because this state has been recognized as a potential and preventable risk factor for poor

perioperative experience, higher intensity of postoperative pain, higher anesthesia and analgesia requirements, and impaired postoperative recovery. Women, in particular, experience higher levels of anxiety during surgery than men [25,26]. Although studies on the prevalence of anxiety in women undergoing gynecologic surgery are scarce, Carr et al [20] found that the rate of high-anxiety cases, defined as patients who scored >45 on the STAI, reached 67% just before the administration of anesthetic agents for gynecologic procedures. Similarly, in our Control group more than half of the patients experienced “pathologic” anxiety in the immediate preprocedural period.

Women undergoing hysterectomy may be particularly vulnerable to psychologic distress because of the sensitive and emotive nature of their treatment, which results in altered body image with associated implications for the patients' normal personal identity. Therefore, gynecology patients would most benefit from management strategies aimed at reducing the adverse effects of preoperative anxiety. Although surgical anxiety can undoubtedly be managed with sedative drugs, increased medication can produce adverse effects, making nonpharmacologic alternatives a point of interest. Music is a safe, noninvasive adjuvant to reduce anxiety in the immediate preprocedural period.

In the current study, lower preprocedural state anxiety in the intervention arm did not translate into a significant reduction in postoperative pain or analgesic requirement. Kain et al [27], using a path analysis, demonstrated that there were both direct and indirect effects of preoperative state anxiety on postoperative pain in women who underwent elective abdominal hysterectomy. One possible explanation for the discrepant results is a type II error owing to the small sample size.

Fig. 1

Proportion of patients with pathologic anxiety by treatment arm at the study time points. Pathologic anxiety was considered when STAI-Y state >45. STAI-Y = State-Trait Anxiety Inventory Y Form.

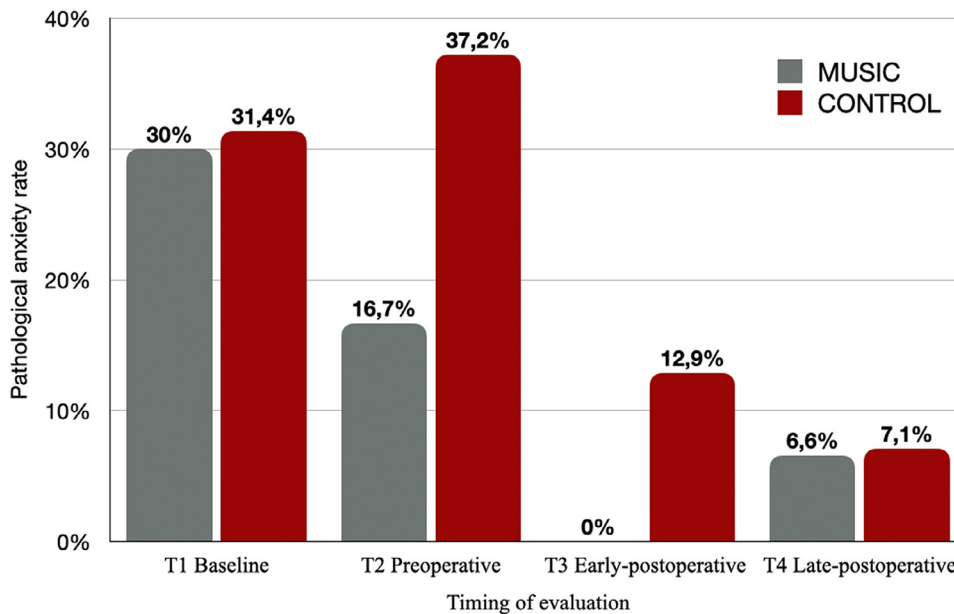


Table 3

Postoperative pain appraisal of the study population

Study population	Music	Control	p-value
Median VAS, 1 h postoperative	1 (0–4)	2 (0–7)	.87
VAS, 1-h stratification	n	%	n
Score = 0	5	16.7	7
Score = 1	10	33.3	26
Score = 2	5	16.7	11
Score = 3	6	20.0	16
Score = 4	4	13.3	7
Score = 5	0	—	2
Score = 7	0	—	1
Median VAS, 3 h postoperative	1 (0–4)	1 (0–6)	.43
VAS, 3 h stratification	n	%	n
Score = 0	10	33.3	25
Score = 1	9	30.0	23
Score = 2	9	30.0	10
Score = 3	1	3.3	8
Score = 4	1	3.3	3
Score = 6	0	—	1
Median VAS, 6 h postoperative	0 (0–3)	0 (0–2)	.17
VAS, 6 h stratification	n	%	n
Score = 0	22	73.4	53
Score = 1	7	23.3	12
Score = 2	0	0	5
Score = 3	1	3.3	0
Rescue analgesic medication	6 (0–24)	6 (3–24)	.13

VAS = visual analog scale.

Values are given in absolute number and percentage (%) for dichotomous variables and median and range (minimum–maximum) for continuous variables.

Second, in our study, hysterectomies were performed with a minimally invasive approach, which is recognized as being associated with reduced postoperative pain compared with open surgery. For this reason, it can be difficult to find a pain-relieving effect of music therapy when baseline levels of postoperative pain are already low.

We conducted database searches for randomized trials published within the last 20 years (March 2000 to March 2020) using PubMed/MEDLINE, Scopus, and Web of Science, using the following search terms: (1) music therapy/music intervention/music-based intervention combined with (2) hysterectomy/gynecology/surgery. We could not find any results matching these selected criteria, suggesting a lack of evidence-based knowledge of the role of music therapy to enhance a patient’s perioperative experience in the gynecologic setting. A previous study by Labrague and McEnroe-Petitte, using a pre- and post-test experimental design with a nonrandom assignment, found that women undergoing mixed gynecologic surgery who listened to pre-recorded music experienced significantly lower anxiety levels, heart rates, and blood pressure levels than patients who did not listen to music [28]. However, passive listening of recorded music relayed through a headphone should be contrasted with music interventions provided by credentialed music therapists because offering live, therapist-directed interventions tailored to the unique circumstances of the patients allows them to meet their emotional needs within the context of their treatment experience.

Table 4

Postoperative outcomes of the study population by treatment arm

Study cohort	Overall (N = 100)	Music (N = 30)		Control (N = 70)		p-value
Postoperative vomiting	9 (9%–0%)	2 (6%–7%)		7 (10%–0%)		.59
Median postoperative nausea	0 (0–8)	0 (0–5)		0 (0–8)		.33
Postoperative nausea (0–10)	N	n	%	n	%	
Score = 0	71	20	66.6	51	72.9	
Score = 1	19	6	20.0	13	18.5	
Score = 2	2	0	0	2	2.9	
Score = 3	3	2	6.7	1	1.4	
Score = 5	3	2	6.7	1	1.4	
Score = 8	2	0	0.0	2	2.9	
Mobilization (hours after surgery)	6 (0–24)	6 (0–24)		6 (3–24)		.24

Values are given in absolute number and percentage (%) for dichotomous variables and median and range (minimum-maximum) for continuous variables.

Several limitations of the current study should be noted. First, the design of a trial with a usual care control arm is a controversial issue [29]. The care received by this control group is supposed to reflect the care usually received by patients in daily practice. However, various actions by the researchers, including the invitation to participate, the informed consent process, and the request to patients to complete questionnaires to measure the outcome may influence the behavior of caregivers and patients. This, in turn, may affect the interpretation of the results. Second, because no studies have specifically examined preoperative anxiety in the population of patients undergoing hysterectomy using the STAI score, no clear minimal clinically significant differences have been defined. Therefore, a statistically significant difference does not necessarily represent a difference that is perceived as meaningful by music therapy recipients. Third, it was not possible to define any interaction between the variable altered state of mind of general anesthesia and the early postoperative data collection. Finally, music therapy is associated with increased operational costs, but we did not address economic impacts during this research. Nevertheless, a benefit-cost analysis is mandatory before implementation to ensure efficient allocation of scarce public health resources.

Conclusions

Music therapy seems a viable complementary modality to usual surgical care in the gynecologic setting for its ability to significantly decrease preoperative anxiety. Women undergoing hysterectomy are a distinct patient group at higher risk of preprocedural anxiety and its detrimental effects and would most benefit from anxiety-reduction interventions. We hope our findings may inspire further research projects to look into the role of a music therapist-facilitated process for anxiety management in this patient population.

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Supplemental Fig. 1

Flow chart and randomization of the study population.

