RESEARCH PROTOCOL

Date	7/20/20
Title	The influence of postoperative environment on patient satisfaction and perception of care following pelvic reconstructive surgery
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Purpose of Study

- To determine the influence of homeopathic therapies such as music therapy and images of calming nature scenes in their hospital suite following vaginal reconstructive surgery for pelvic organ prolapse on parameters of recovery such as pain, satisfaction and perception of care.
    - ***Primary Aim:*** To determine if patients following prolapse repair including vaginal vault suspension have decreased pain measured via a visual analog scale (VAS) on postoperative day one and just prior to discharge when exposed to the diad of music, and positive images compared to patients receiving standard care.
    - ***Secondary Aims:*** To determine if patients following prolapse repair including vaginal vault suspension have improved satisfaction scores and perception of care when exposed to the diad of music, and positive images compared to patients receiving standard care.

Hypothesis or Research Question

- We hypothesize that patients exposed to alternative therapies such as music, and calming nature scenes will have decreased VAS scores for pain following vaginal reconstructive surgery when compared to controls.
- We further hypothesize that patients who experience the modified post-operative environment will report an improvement in overall satisfaction when providing their

overall hospital rating and will be more likely to refer their friends to the hospital for care in the future, as measured by the HCAHPS and VAS satisfaction scores.

Background

Establishing an ideal environment to optimize healing is not a new concept. In the late 1800's, Florence Nightingale wrote about the importance of supportive spaces for patient care and recovery[1]. Over the past decade, interest has grown in improving the patient experience. As part of this movement, studies have sought to evaluate the mechanisms by which the postoperative environment affects a patient's outcome and perception of healing. A report written to the Center for Health Design found over 600 studies linked to hospital environment and its affect on patient satisfaction, stress, outcomes and perception of quality[2]. Critical to the patient experience is reducing their pain, which in turn leads to improved satisfaction. Patient satisfaction has been shown to improve adherence to care plans, reduce 30-day readmission rates and decrease overall mortality[3,4].

Literature review reveals efforts by both medical and design teams towards improving the experience of the patient and developing an environment that promotes healing. Changes to the physical environment have been shown to have an impact on satisfaction. These parameters have included music and art.

Considering alternative therapies, much energy has been devoted to the affect that music can have on satisfaction and pain control in the post-operative period. A recent review in the Lancet, found 73 randomized controlled trials looking at how music can aid in postoperative recovery in adults. They found that the choice of music, timing of delivery and duration of exposure varied. But the studies included, showed that music can consistently reduce pain measured by VAS scores, anxiety, analgesic utilization, and can help improve patient satisfaction with their care[11]. Music has specifically been shown to improve VAS scores for patients following open heart surgery when subjects listened for 30 minutes on post operative day one compared to control. Furthermore, patients recovering from spine surgery who had 30 minutes of music therapy while in the hospital showed significant improvements in their VAS scores over controls[15].

Building on the patient surroundings, art has been shown to improve patient's vital signs, clinical outcomes and diminished cortisol levels[5]. Having a landscape on the wall of inpatient rooms in the critical care unit has been shown to decrease opiate utilization and lead to earlier discharges[6-8]. Landscapes displayed during bronchoscopy at John's Hopkins showed significant decreases in patient VAS scores[9]. Finally, patients are more likely to refer others to seek care at facilities that display art[10].

Considering the effort that is now going into improving the patient experience and developing this theory of healing spaces, there has yet to be a randomized controlled trial evaluating these alternative therapies in the urogynecologic patient population. Although each of these modalities appears beneficial, we believe that a combination of these would be even more useful. Indeed, these treatments are also relatively easy to implement without undue cost or burden to the hospital. Thus, this study seeks to apply music, and art to the post operative environment for patients recovering from major urogynecologic surgery, in an effort to determine if there is an affect on their VAS scores and satisfaction when compared to controls. We also intend to document patient perceptions of their experience.

Research Plan

- **Study Design**
  - Randomized Controlled Trial

- **Setting for the study**
  - Patients of Cincinnati Urogynecology Associates, TriHealth Inc, undergoing inpatient vaginal reconstructive surgery for pelvic organ prolapse at Good Samaritan Hospital or Bethesda North Hospital will be eligible for enrollment.
  - Subjects will be enrolled during their preoperative consent or in the preoperative holding area
  - Patients who enroll in the study will provide written informed consent
  - Following enrollment, a SNOSE will dictate to which group the patient has been randomized.

- Intervention group:
    - Those patients randomized to experience a modified post-operative environment will be provided with a standard private hospital room with two portable modifications.
    - They will have access to a Bluetooth capable speaker with selections of music allowing them to play music or relaxation sounds of their choosing. They will be asked to listen to a minimum of 30 minutes of music three times during their stay. Music will be played at a low enough volume to allow concurrent conversation.
    - Additionally, the room will be decorated with a wall hanging image of a soothing nature landscape. The landscape will be hung on the wall near the foot of the bed throughout the participant's length of stay.

- Control group:
    - Those patients randomized to experience an un-modified post-operative environment will experience a private hospital room at Good Samaritan or Bethesda North hospitals without alteration.

- On POD 1, following breakfast, patients will be asked to rate their pain using a VAS scale from 0-100 mm.
- Prior to discharge they will complete a second VAS regarding their current pain. They will also complete VAS questions regarding satisfaction and overall pain during their hospital stay.
- They will be asked two modified questions similar to the Hospital Consumer Assessment of Healthcare Providers and Systems survey (HCAHPS) to determine perception of care. A modification is necessary because these questions cannot be utilized while patients remain admitted to the hospital per federal regulation.
- They will be asked two questions regarding overall perception of care (VAS 0-100mm)

- The intervention group will also be asked regarding their appreciation of music, and the landscape as a part of their healing experience.
- At their 2 weeks postoperative follow-up appointment, they will be provided similar VAS questions for satisfaction and pain, followed by the unmodified HCAHPS questions. They will also be asked to report their overall satisfaction with the results their surgery and their decision to have surgery.
- The intervention group will be asked similar questions regarding their experience with music and landscape during their recovery.
- Demographics, medical and surgical information, complications, postoperative narcotic use, voiding trial results, CBC, etc will be recorded from their chart.
- Post-operative orders will be completed through a standardized order set which provide the standard of care for the post-operative management of patients having vaginal reconstructive surgery. There will be no differences in these orders between intervention and control group with exception of the music and landscape.

- **Participants**
  - Study population: All women 18 years of age or older, who undergo vaginal vault suspension in conjunction with pelvic organ prolapse reconstruction, with or without additional concomitant procedures by a physician at Cincinnati Urogynecology Associates, TriHealth for treatment of pelvic organ prolapse (POP) will be approached for recruitment at their office visit when they sign surgical consent or at the pre-operative holding area.
  - Inclusion/Exclusion criteria:
    - Inclusion
      - Adults 18-85 years of age
      - English speaking

- Undergoing surgery for pelvic organ prolapse to include an apical vaginal vault suspension by a physician at Cincinnati Urogynecology Associates, TriHealth
- Concomitant procedures such as hysterectomy, suburethral sling, anterior or posterior colporrhaphy, bilateral salpingectomy or salpingooophorectomy will be included
- Ability to complete the questionnaires and provide consent
- Willingness to listen to music at the minimum recommended time intervals

▪ Exclusion

- Unwillingness to participate in the study
- Physical or mental impairment that would affect the subject's ability to utilize the modified environment such as deafness, blindness or dementia.
- Patients who take daily narcotics or NSAIDS
- Patients with history of Drug or Alcohol Abuse
- Patients with chronic pain syndromes.
- Non English speaking
- Patients that do not undergo a vaginal apical suspension procedure

o Sample Size

▪ In the literature there does not exist a trial that has addressed these components in isolation or conjunction for patients undergoing pelvic reconstructive surgery.

▪ Our sample size calculation took into account several factors, as well as our divisions' prior experience with studies evaluating pain following this surgical approach.

▪ In order to represent a clinically significant change in pain when using the VAS score, studies completed in emergency medicine looking at acute pain reported that a difference in the VAS score of 9-13 mm represents a

true change[12,13]. Other studies in gynecology has also confirmed that a difference between 10-20 mm may be clinically relevant following an intervention[17,20-23]

- Previous studies looking at the effect of music on post-operative pain in other specialties have shown an average decrease in the VAS score of 7-26mm[11,14-16]. These studies do however display a variety in effect and differing standard deviations.
- Review of referenced studies in a large meta-analysis published by Hole et al[11] produced a heterogeneous population and varied results and sample sizes.
- The most reliable statistics appear to be in a paper by Cutshall[16] et al, which reported results of an intervention of music for cardiac surgery patients in the ICU. The data demonstrates a narrow standard deviation and results in agreement with overall conclusion of the meta-analysis
    - Decrease in mean pain score was 1.4cm for their music group and 0.4cm for the control group, with a difference of 10mm between the groups (SD was 1.4).
- This study was therefore selected for calculation of our sample size.
- We powered our study to detect a difference of 10mm in the postoperative VAS score between intervention and control groups. We deem this reasonable considering the review article by Hole[11] reporting on 73 randomized trials, found a mean overall difference in pain scores of 23mm between intervention and control groups.
- Power Analysis
    - Our calculation demonstrated need to enroll 43 patients in each arm based on the following:
        - A difference of 1cm on subjects' VAS scores for pain
        - Power at 90%
        - Standard deviation at 1.4
        - Effect size at 0.714

    - Assuming an estimated loss rate of 15%, the number of patient enrollment per arm was set to 51, for a total of 102 patients. [Attrition calculation: (43/0.85)]
    - This study met challenges with personnel shifts within Hatton Institute that impacted data collection. Following review, hiring of new staff and re-training, we determined to perform an interim analysis. Of the 52 subjects enrolled since restructuring, 42 have completed follow-up. This interim analysis reveals a true attrition rate of 20%; five percent higher than the original 15% used in the power calculation. Assuming this loss rate remains constant through the close of the study, in order to reach significance, we will need to enroll an additional 27 subjects above the planned 102. For sake of randomization, we have set new total enrollment to 132.
  - Subjects will be randomized by using a random numbers table and sealed sequential envelopes prepared by an independent statistician.

- **Data Collection**
  - Primary outcome:
    - VAS scores for pain "right now" and "most intense pain" [0-100mm], administered following breakfast on post-operative day one, comparing intervention and control groups
  - Secondary Outcomes*:*
    - VAS pain scores prior to discharge based on the validated SPS pain questions[25].
    - VAS for satisfaction with their hospital stay prior to discharge
    - Nursing recording pain scores prior to delivery of pain medications (recorded in Epic)
    - Total morphine equivalents during hospital stay

- Patient reported impression of the music and art using Likert scales, at discharge and 2 weeks post operatively for the intervention group
- Patient impression of the hospital based on responses from modified HCAHPS questions prior to discharge on post-operative day one:
    - First Question in VAS format: "Compared to other hospitals, how would you rate this hospital"?
    - Second Question in VAS format: "How likely are you to recommend this hospital to family and friends?"
- Patient VAS scores concerning their perception of the healing environment of the hospital and whether they would choose the hospital again
- Responses at the 2 week postoperative appointment to another identical series of VAS for satisfaction and pain, questions 21 and 22 from the HCAHPS survey, a question on pelvic symptoms after surgery, and the validated Decision Regret Scale for pelvic floor disorders[24]

- General Demographic Data
    - Age, BMI, race, history of depression, home medications, sexual activity, alcohol use, prolapse stage, procedures performed, voiding trial results, length of stay, surgical and postoperative complications, and estimated blood loss

- *VAS Score Validity:*
    - The VAS score is a well-established tool for measuring a patient's pain level that has been in clinical practice for decades. This tool has been applied throughout the medical field as a standardized measure of pain and remains a common method of characterizing pain levels by researchers. It has been shown to be reliable in the assessment of acute pain[18].

- *HCAHPS survey questions:*
    - Survey is the first national, standardized, publicly reported survey of patients' perspectives of hospital care. HCAHPS (pronounced "H-caps"),

also known as the CAHPS® Hospital Survey, is a 32- item survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience. Beginning in 2002, CMS partnered with the Agency for Healthcare Research and Quality (AHRQ), another agency in the federal Department of Health and Human Services, to develop and test the HCAHPS Survey. AHRQ and its CAHPS Consortium carried out a rigorous and multi-faceted scientific process, including a public call for measures; literature review; cognitive interviews; consumer focus groups; stakeholder input; a three-state pilot test; extensive psychometric analyses; consumer testing; and numerous small-scale field tests. CMS provided three opportunities for the public to comment on HCAHPS and responded to over a thousand comments. The survey, its methodology and the results it produces are in the public domain[19].

- HCAHPS question 21: "Using any number from 0-10, where 0 is the worst hospital possible, and 10 is the best hospital possible, what number would you use to rate this hospital during your stay?"
- HCAPS question 22: "Would you recommend this hospital to your friends and family?"
    - Definitely No
    - Probably no
    - Probably yes
    - Definitely yes

- Data Collection tool

- **Intervention or experimental aspect of the study**
    - Music
        - The patients will have access to a blue tooth capable audio device in their hospital rooms that can connect to their own device or one that will be provide for them. Selections of music and relaxation sounds will be

available and they will be shown how to use the device during post-operative rounds.

- Music selections will generally maintain a relaxing tempo of 60-80bpm.
- Subjects will have no limit to the amount of music they can listen to, however they will be asked to spend 30 minutes upon arrival to their room, when getting up to the chair for the first time, and following their voiding trial. At a minimum, the audio device will be turned on for the patient during post-operative rounds, and during morning rounds if they have not yet done so.

- Landscape
  - Patients will have a large print of a soothing nature landscape hung on the wall near the foot of their bed. The size will approximate 24x36 inches. Each subject will have one scene in their room.
  - The scenes will be hung to the wall with a removable hanger.
  - Scenes were selected based on the preferences of individual surveys carried out with 86 volunteers.

- **Statistical Analysis**
  - Descriptive statistics will be calculated for all continuous and categorical data. Continuous variables will be summarized as mean (SD) or median (range). Categorical variables will be presented as frequency (Percentage). The primary outcome is the VAS scores for pain in the morning of post-op Day 1 (POD 1). Student's t-test or Mann-Whitney U test (Wilcoxon Rank Sum test) will be implemented to test for significant difference in pain and satisfaction scores and narcotic use between intervention and control groups. Assumptions will be examined and appropriate parametric or non-parametric tests will be used. For categorical data, Chi-square or Fisher's exact test will be employed to test the association.

Ethical Considerations

- **Informed consent**

- Patients who agree to participate in the study will sign a written informed consent. They will be consented by one of the stated investigators or trained Research Nurse and they will receive a copy of the signed informed consent statements (ICS). A copy will be put in their medical file.

- **Privacy information**
  - Extensive efforts will be made to ensure participant confidentiality and prevent unauthorized release of personal information. Electronic study documents will be stored on a secure drive and hard copy documents stored in a locked area. Thereby, all identifying and protected health information, including name and date of birth, will be maintained in a secure area at all times, accessible by authorized personnel only.
  - All communication between staff members regarding participant data will occur via the Subject ID number only. However, identifying information will be retained in the original/source documents.
  - The participant will be logged in the Excel spreadsheet and assigned a Subject ID number. Each participant will be assigned the next available Subject ID number. Once each Subject ID number has been assigned, it will not be reassigned.
  - Study documentation, both electronic and hard copy will be stored securely for ten years and then destroyed.

- **When and how will results be disseminated?**

- We plan for the results to be disseminated in Spring 2020 at a national meeting in the form of a poster or oral presentation. We also plan for the results to be published.

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