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Title of study: Music distraction and its influence on anesthetic requirements during elective knee surgery

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Hypothesis: music distraction can be used to reduce or eliminate anesthetic requirements when total knee replacement is performed under spinal anesthesia.

Specific aims of the study:

- To use music in a way that distracts participants without distracting other health care workers in the operating room
- To use music in a way that does not disrupt the workflow of the anesthesia team or affect their ability to monitor the participant and administer medications safely
- To determine if the music can be used to reduce anesthetic requirements when total knee replacement is performed under spinal anesthesia

Background:

Music during surgical procedures has been shown to have a number of desirable effects. A review of the literature reveals the following:

- Patients have decreased anxiety, heart rate and blood pressure when music is played for them before and during awake craniotomy(1).
- Patients have decreased pain scores and increased satisfaction when they listen to music under general anesthesia(2).
- Burn patients who listen to music during treatment procedures have decreased anxiety and heart rate(3).
- Surgeons have decreased anxiety when music is played in the procedural suite during cutaneous dermatologic procedures(4).
- Patients have decreased sufentanil opioid requirement when music is played before and after lung resection surgery(5).

To date, there are no studies that assess music and its effect on anesthetic requirements during major elective orthopedic surgery. Spinal anesthesia allows knee and hip surgery to be performed without putting a patient completely to sleep. However, some anesthesia medications are often required as a standard of care to provide patient comfort and reduce patient anxiety. Risks are associated with the use of anesthetic medications, even if the medications are used only for sedation and comfort. These risks include respiratory depression or aspiration of gastric content into the lungs. Occasionally, the aforementioned outcomes result in hospital admission to the intensive care unit. This study has significance because it seeks to explore a non-pharmacologic modality that could ultimately decrease the incidence of complications associated with anesthesia.

Methods:

This prospective study will assess music and its ability to influence anesthetic requirements in patients receiving primary elective knee replacement surgery. All research participants will undergo the same surgical procedure by the same surgeon, who is one of the research investigators (Dr. Gregory Golladay).

Potential participants will be recruited during any of three pre-operative encounters that are considered standard to our institution: 1) the surgery clinic visit, 2) the pre-operative anesthesia clinic visit, or 3) the pre-operative surgical unit on the day of surgery. Formal consent will be obtained in the pre-operative surgical unit on the day of surgery.

Prior to surgery, patient participants will receive a combined spinal-epidural per VCU total joint protocol; the following steps are considered standard of care and not considered study procedures. The combined spinal-epidural procedure creates complete numbness below the abdomen down to the feet, which negates the need for general anesthesia. For patient comfort during the combined-spinal epidural procedure, a one-time dose of 2 milligrams of intravenous midazolam will be given; this dose is adequate for reducing anxiety while allowing the patient to maintain conversation with health care providers if necessary. The standard intrathecal dose for total knee replacement at our institution is 15 mg bupivacaine and 0.2 mg preservative-free morphine; this dose will provide complete numbness to the lower extremities for approximately 3-6 hours. After this dose is administered, the patient will then be positioned appropriately in the operating room and vital signs will monitored per standard protocol.

Each patient participant will be randomized to one of two groups. Participants in the control group will receive noise-cancelling wireless headphones that will not play any noise throughout the procedure. Participants in the experimental group will receive the same noise-cancelling wireless headphones but will be permitted to listen to the music of their choice while in the operating room. Music will be provided via Spotify, which is an Internet streaming music service, and will be played through headphones; this way, no other individual in the operating room will be distracted or influenced by the patient's music selection. Participants will not be able to change the Spotify channel. We will be using the paid Spotify service with no commercials. If participants opt to have the music stopped, we will withdraw them from the study and continue standard of care. The participants will have the music playing for about two hours. If the participant has no music preference, the music will be chosen for them and it will be the same for all participants that have no preference. The volume will be adjusted in the operating room until the participant approves of the volume by saying "yes, the volume is good" or giving another verbal cue of approval. The music will continue playing until the surgical procedure is complete and the patient has reached the post-anesthesia recovery unit.

As stated previously, spinal anesthesia provides numbness that negates the need for general anesthesia, but patients often times need additional sedation, which will be defined as anesthesia medication that is

used to treat patient anxiety and discomfort in the operating room. Patient participants in both groups will receive sedation via the same protocol, which is outlined below.

It is important to note that the standard of care for this procedure involves the administration of sedation that is given at the anesthesiologist's discretion; sedation is generally given when the patient exhibits signs of discomfort or anxiety. The protocol described below is designed specifically for this study in order to provide standardization within the study participants; the protocol instructions fall within the standard of care for the administration of sedation by an anesthesia provider.

Sedation will only be given as needed per patient request; the patient will be given a noise-making device (such as a rubber duckie that makes sound when squeezed) that will inform the anesthesia provider that the patient is uncomfortable and needs some sedation. A weight based dose of 0.3 micrograms per kilogram of intravenous propofol will be given for each patient request. This dose is expected to provide amnesia or light sleep for a few minutes. For patient safety, if the patient requests sedation more than once within a two minute window, the anesthesia provider will not administer any more medication during this two minute period. Additionally, the anesthesia provider may withhold sedation if he or she determines with physical exam and hemodynamic monitors that the patient is already over-sedated.

After five propofol boluses have been given to a patient, a propofol continuous infusion will be initiated at 25mcg/kg/min. The patient may still request additional sedation with the request instrument if he or she is still conscious enough to do so. If the anesthesia provider has given more than five boluses even with the baseline propofol infusion, the infusion will be increased to 50mcg/kg/min. In the highly unlikely scenario that five additional boluses are required with a propofol infusion rate of 50 mcg/kg/min, the anesthesia providers and investigators will make a clinical decision as to what is the safest next step.

There may be scenarios that warrant conversion to general anesthesia. These scenarios include, but are not limited to, hemodynamic instability, regurgitation of gastric content, obtundation, excessive agitation, and inadequate spinal anesthesia. The decision to convert to the general anesthesia will be made by the anesthesiologist and anesthesia provider in the operating room; implementation of this study should not prevent or delay this decision if it is necessary.

Documentation will be completed by the anesthesia provider per standard protocol for electronic anesthesia charting at VCU. This will allow for data acquisition by the investigators through the anesthesiology printed record in Cerner. The primary outcome for this study will be the amount of sedation required during the surgical procedure; this will be calculated into micrograms of propofol per kilogram per minute. For this study, propofol will be used during the surgical procedure and intravenous midazolam and intrathecal morphine will be used for the spinal procedure; no other sedating

medications will be used. The secondary outcomes for this study will include pain scores and patient satisfaction at determined time intervals before and after the surgery.

Primary data elements that will be obtained are as follows: 1) the total amount of propofol given, 2) the duration of operating room time, which will be defined as "in the operating room" time to "out of the operating room" time. Data will be entered into a spreadsheet; the amount of propofol per unit of time will be calculated by dividing #2 from #1; if there is a difference and it is statistically significant, then our hypothesis is true.

Secondary data elements will include numerical pain scores, which are taken via standard of care nursing assessment immediately after surgery and every four hours afterwards; the study will collect the numerical pain scores that describe each four hour interval for a 24 hour time period. The numerical pain scores will be collected through the patient's medical record after the 24 hour time period has passed. Data will placed into a spreadsheet and a statistical analysis will be performed for each time interval. This will answer the question of whether or not post-operative pain scores are affected the music intervention.

Another secondary data element will include patient satisfaction, which will be determined through a hospital survey that is completed by the patient and is standard of care. The data points will focus on two patient satisfaction questions on the survey, which ask "did you feel like your pain was controlled" and "did you feel like the doctors did everything that could to control your pain." These are yes/no questions, and data can be collected and presented as the percentage of participants that answered "yes" to these questions. As standard of care, the surveys are completed when the patient is discharged from the hospital, the survey data is scanned into the electronic medical record; therefore, this data will need to be collected in the medical record after the participant has completed their hospital stay. This will answer the question of whether or not the music intervention affects patient satisfaction with respect to pain management, which is the area of interest for the study team.

References

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