Music as an Anxiolytic Before Upper Gastrointestinal endoscopy

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A. Statement of study and purpose rationale

The purpose of the study is to evaluate the use of music as an anxiolytic before upper gastro-intestinal endoscopy. Upper GI endoscopy is a common procedure which is routinely performed, but can be stressful to many people. A high level of anxiety can result in fear and hostility leading to decreased cooperation and decreased pain tolerance during the procedure. This can lead to longer procedure time, more sedation and longer recovery room monitoring afterwards. [1] Music has been shown to be an effective way to reduce patients' anxiety before invasive procedures.[2] Studies have shown that patients rate their anxiety as lower if they listen to music before procedures such as surgery or cardiac catheterization or during flexible sigmoidoscopy.[3] However, none of these studies have been blinded. Furthermore, although calmer patients require less sedation, there has not been a comparison of the amount of time spent in the recovery room after the procedure. In addition, previous studies have included the STAI (State Trait Anxiety Inventory) questionnaire, which is time consuming. A Visual Analogue Scale has been shown to be as reliable as the STAI in anxiety evaluation, but faster and simpler. We hypothesize that listening to music before upper endoscopy will decrease patients' anxiety as rated in a Visual Analogue Scale and reduce the amount of sedation necessary and thus the amount of time spent in the recovery room. This study will be hopefully used for further research that will enable faster procedures with less sedation and better utilization of the endoscopy suite.

B. Study design

This will be a randomized, double blind, placebo-controlled trial of listening to music tape vs. placebo (recent news tape), prior to upper endoscopy. Patients who will be selected will be out-patients who are undergoing non-emergent upper endoscopies, at the CPMC Endoscopy Suite. Patients will be randomly assigned to either group after registering for their endoscopy at the Endoscopy Suite and informed consent is obtained. Each patient will be given a Walkman with headphones and a tape labeled A or B. The tapes will have been prelabeled by an unblinded person. A randomization table will determine which tape is assigned to which patient, so that each patient has an equal likelihood of receiving either tape. The tape letter (A or B) assigned to the patient will be recorded.

a. We will measure the effect of music listening vs. placebo primarily on the patient's anxiety. The patients will rate their anxiety on a Visual Analogue Scale by writing an 'Y' on a 100 mm horizontal line at the point where they feel their anxiety level is. We will measure the distance from the left border of the line to the 'Y'. The patients will do this two times; before listening to the music and then during the endoscopy when the scope is at the duodenal bulb (by pointing to the visual analogue).
b. 2) We will measure the amount of time the patient spends in the recovery room until s/he is allowed to go home. The average amount of time spent in the recovery room is 20 minutes. Less anxiety should lead to less sedation and less time in the recovery room. The decision to allow the patient to go home indicates that the sedation has worn off to the point of return to physical and mental baseline function. We will also record the amounts of sedation used during the endoscopy. All patients are routinely given 50 mg of IV Demerol and 1 mg of IV Versed at the start of an upper GI endoscopy. More medication is usually administered during the procedure based on the patient's anxiety and discomfort.

C. Methods of statistical analysis

1) Patient anxiety: We will compare, between the two groups, the independent change in the patient's anxiety from baseline to mid- endoscopy. In other words, we will evaluate the change in the anxiety level, or the slope of the anxiety, from baseline to mid-procedure. We will compare the mean slope of the treated vs. the untreated groups. We will then do a secondary analysis to make sure that the slopes are not different based only on different initial baseline anxiety levels.
2) Recovery room time: The patients will be ranked according to the amount of time spent in the recovery room, from shortest time to longest time (the Assigned Ranks Test). We will analyze whether the patients in the music group were more likely to be ranked lower. This method will compare the median amount of time and minimize any distortion that would occur from looking at a mean value (since there may be a few patients who remain in the recovery room for an unusually long time).

There are potentially confounding factors that will be controlled for, which include: -variation in endoscopists (some may be more reassuring or more liberal with sedation medications) -variation in the endoscopy procedure (some patients may require a biopsy and they may or may not know that beforehand)

D. Study Procedures

Each patient will be given a Walkman with headphones. The placebo group will receive a tape of recent news of 20 minutes duration. The experimental group will have a 20 minute tape with classical music, such as Pachabell's Canon in D. The patients will start to listen to the tapes 20 minutes before their endoscopy is scheduled to begin, so that the tape should end right before the start of the endoscopy. However, certain patients may have to wait longer if there is a delay (such as a complication in the preceding endoscopy). Twenty minutes is the average amount of time that patients wait in the waiting room. The measurements with the Visual Analogue Scale would occur before and during the procedure; standard clinical care would not routinely require these measurements. The duration of each subject's participation is until s/he leaves the Endoscopy Suite. The Endoscopy Suite handles approximately 100 upper gastrointestinal endoscopies per week, five days a week, Monday through Friday. We will be at the Endoscopy Suite on two mornings a week, Tuesday and Thursday. This should allow us to be present for 20 endoscopies per week. We expect a one out of ten refusal rate. We will ask the patients who refuse to rate their anxiety on a Visual Analogue Scale to rule out any selection bias between those who refuse and consent. The duration of the study will be the amount of time needed to accumulate 50 patients, or around one month.

E. Study Drugs

none

F. Medical Devices

none

G. Study Questionnaires

Visual Analogue Scale:

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x "the calmest you have ever felt" — x "the most anxious you have ever felt"

"Please place an "x" where you feel your anxiety is now".

H. Study Subjects

The subjects will be recruited from all out-patients coming to the CPMC Endoscopy Suite on the twelfth floor of Presbyterian Hospital for non-emergent upper endoscopies. Exclusion criteria will be: patients who are currently on anti-anxiety medications, who are psychotic, who have a history of a previous endoscopy, who are non- English speaking. Twenty five subjects will be needed in each group to see a 50% decrease of anxiety on the Visual Analogue Scale. This will give us 80% power to achieve a one standard deviation difference at an alpha level of .01.

Potential subjects will be approached after they have registered for the endoscopy by the investigator. Their primary physician will be contacted to ascertain their eligibility. The subjects will be told that they can participate in a study which seeks to ascertain the effects of listening to a tape before endoscopy. Risks and benefits will be discussed. If the subject agrees, s/he will be screened for the exclusion criteria above.

I. Confidentiality

All data will be kept confidential.

J. Location of study

To be conducted in the CPMC Endoscopy Suite

K. Risks and Benefits

Risks: none Benefits: patients may find the endoscopy experience less stressful, require less sedation, wait less time in the recovery room.

L. Alternative Therapies

None

M. Compensation and cost

Patients will be compensated with $20.00 each. The only cost incurred will be the use of the Walkmans and tapes.

N. Minors

none (study in adult Endoscopy Suite)

O. Radiation

none

[1] Warner 1992, Murphy 1993.
[2] palakanis 1993. 3 Evans 1994,
[3] Palakanis 1993.