

## Prospective Study

**Modern advances in reducing anxiety and pain associated with cystoscopy: Systematic review**

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**Informed consent:** All study participants, or their legal guardian, provided informed written consent prior to study enrollment.

**Conflict-of-interest:** The authors have no conflicts of interest.

**Data sharing:** Technical appendix, statistical code, and dataset available from the corresponding author at email address: kyoko.sakamoto@va.gov. All participants gave informed consent for data sharing.

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**Abstract**

**AIM:** To investigate if music reduces anxiety and pain in the Veterans Affairs population undergoing flexible cystoscopy.

**METHODS:** This study was reviewed and approved by the University of California, San Diego Human Research Protections Program Institutional Review Board. Patients were prospectively randomized to undergo flexible cystoscopy with or without music. Thirty-eight patients were randomized into either the No Music group ( $n = 24$ ) or the Music group ( $n = 14$ ). We used the state-trait anxiety inventory and the visual analog pain scale, respectively. Statistics were generated and compared using an independent  $t$ -test and chi-squared tests.  $P$  values  $< 0.05$  were considered statistically significant. Outpatient cystoscopy is a safe and useful procedure employed frequently in Urology for diagnosis and evaluation of genitourinary pathologies. However, cystoscopy-related distress cannot be ignored. Three components of outpatient cystoscopy have been evaluated to improve the cystoscopic experience: local anesthetic control, cystoscopic equipment redesign and environmental modification. We reviewed the literature pertaining to these modifications.

**RESULTS:** The mean age was 65.3 and 67.1 years for men in the No Music and Music groups, respectively.

Although, the majority of patients in each group self-identified as Caucasians (66%), African American, Hispanic and other ethnicities represented 13%, 8% and 13% respectively. The majority of patients (68%) reported experiencing hematuria. Thirty-four percent had a history of bladder cancer, and eighteen percent had a history of prostate cancer. Ten patients (26%) admitted to taking antidepressants. Physiologic parameters that correlated to pain and anxiety (systolic blood pressure, diastolic blood pressure, and heart rate) were statistically similar in both groups prior to and after flexible cystoscopy. The median delta anxiety between the No Music and Music groups were not significantly different (0.78 *vs* -1.46), and the pain scores between the No Music and Music groups (1.5 *vs* 1.6) were not statistically different ( $P = 0.28$  and  $P = 0.92$ , respectively).

**CONCLUSION:** Preliminary results demonstrate that music does not reduce anxiety or pain associated with flexible cystoscopy.

**Key words:** Flexible cystoscopy; Veterans; Anxiety; Music

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**Core tip:** Flexible cystoscopy is a very common in-office procedure performed in urology. There have been several technological advances made in the instrumentation of flexible cystoscopies, however, there have also been advances made in reducing patient pain and anxiety associated with this procedure such as viscous lidocaine jelly and music. We reviewed the literature on effects of modifiable factors on patient pain and anxiety associated with flexible cystoscopy, and also includes preliminary data on a Veterans Affairs randomized prospective trial evaluating the effect of classical music on pain and anxiety associated with flexible cystoscopy.

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## INTRODUCTION

Cystoscopy is a common urologic examination indicated for a wide variety of genitourinary conditions<sup>[1-4]</sup>. Cystoscopy was first conceptualized over two centuries ago<sup>[5]</sup> and underwent multiple advancements in technology to allow patients to undergo the procedure with relative comfort. Regardless of the reason for the inspection, however, cystoscopy is invasive and can be

a distressing experience for patients.

Since patient distress negatively impacts adherence to cystoscopy guidelines, many studies have investigated techniques to reduce cystoscopy-associated anxiety and pain<sup>[1]</sup>. Three general methods to alleviate pain and anxiety are local anesthetic control, cystoscopic equipment redesign, and environmental modification. Lidocaine lubricants, inhaled nitrous oxide, and anxiolytic medication have been proposed to ameliorate flexible cystoscopy-associated distress, though none sufficiently relieves patient fear, pain, and anxiety<sup>[6-14]</sup>. The cystoscopic instrument has evolved from the rigid cystoscope to the flexible cystoscope, changing from analog visualization to digital and more recently digital high definition visualization.

For environmental modification, music is gaining increasing recognition as an effective tool to alleviate perceived pain and has been shown to be beneficial in a variety of clinical settings<sup>[15-23]</sup>. Herein, we report the result of a prospective randomized trial of the effect of music on pain and anxiety in the Veterans Affairs patient population during flexible cystoscopy. Furthermore, we reviewed the above-mentioned three factors (local pain control, equipment redesign and environmental modification) incorporated to lessen the anxiety and pain levels during cystoscopy.

## MATERIALS AND METHODS

This study was reviewed and approved by the University of California, San Diego Human Research Protections Program Institutional Review Board (IRB). Patient privacy and confidentiality are protected according to HIPAA guidelines. Following IRB approval, male patients at the Veterans Affairs San Diego Medical Center were prospectively randomized to undergo flexible cystoscopy with or without music. Thirty-eight patients were randomly assigned into one of two groups using an adaptive biased-coin randomization method: (1) the No Music group (patients did not hear music during preparation and draping of patient and anesthetization of urethra); or (2) the Music group (patients listened to the same excerpt of classical music). Inclusion criteria were age > 18 years old. There were no women in this study, although that was not an exclusion criterion. Exclusion criteria were current urinary tract infection, anatomic urethral abnormalities, and inability to complete the surveys. Patients' past medical history, including history of bladder cancer, prostate cancer, hematuria, and current or past use of anti-depressants and anti-anxiety medication, was recorded. All patients with a prior history of bladder cancer were confirmed to have had prior cystoscopy and were currently undergoing cystoscopy for surveillance, while those without bladder cancer were undergoing cystoscopy for diagnostic purposes (*e.g.*, microhematuria). Each patient was consented for the study on the day of the procedure.

	← Least anxious			→ Most anxious
I feel pleasant	[1]	[2]	[3]	[4]
I feel nervous and restless	[1]	[2]	[3]	[4]
I feel satisfied with myself	[1]	[2]	[3]	[4]
I feel I could be as happy as others seen to be	[1]	[2]	[3]	[4]
I feel like a failure	[1]	[2]	[3]	[4]
I feel rested	[1]	[2]	[3]	[4]
I am calm cool and collected	[1]	[2]	[3]	[4]
I feel that difficulties are piling up so that I cannot overcome them	[1]	[2]	[3]	[4]
I worry too much over something that really doesn't matter	[1]	[2]	[3]	[4]
I am happy	[1]	[2]	[3]	[4]
I have disturbing thoughts	[1]	[2]	[3]	[4]
I lack self-confidence	[1]	[2]	[3]	[4]
I feel secure	[1]	[2]	[3]	[4]
I make decisions easily	[1]	[2]	[3]	[4]
I feel inadequate	[1]	[2]	[3]	[4]
I am content	[1]	[2]	[3]	[4]
Some unimportant thought runs through my mind and bothers me	[1]	[2]	[3]	[4]
I take disappointments so keenly that I cannot put them out of my mind	[1]	[2]	[3]	[4]
I am a steady person	[1]	[2]	[3]	[4]
I get in a state of tension or turmoil over my recent concerns and interests	[1]	[2]	[3]	[4]

Figure 1 State-trait anxiety inventory.

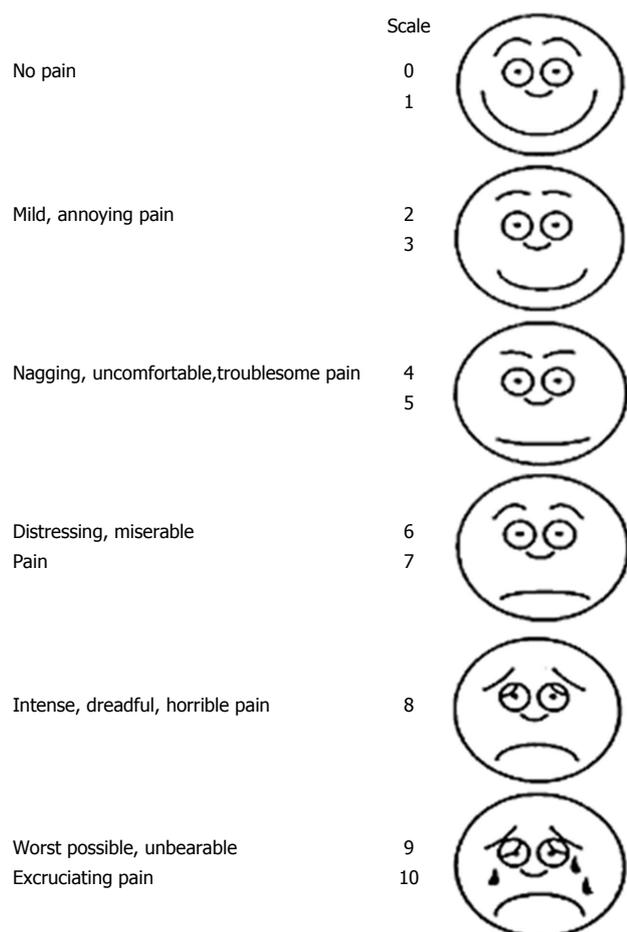


Figure 2 Visual analog pain scale.

Pre-operative and post-operative systolic and diastolic blood pressure, heart rate, and respiratory rate were measured for each patient. The pre-procedure vital signs, including blood pressure, heart rate,

and respiratory rate, were all obtained prior to the cystoscopy and prior to playing music. Post-procedure vital signs were obtained after the cystoscopy was completed. During the 10-min dwell time of the 2% intraurethral lidocaine jelly, the patient either listened to classical music for 10 min or did not hear any music at all. A 15 French Olympus® digital flexible cystoscope was connected to a digital video monitor that was used for all procedures. The music was played prior to the cystoscopy.

To measure anxiety level and pain level, we used the State-Trait Anxiety Inventory (STAI) and the Visual Analog Pain Scale, respectively (Figures 1 and 2)<sup>[24,25]</sup>. Both are validated surveys. The State-Trait Anxiety Inventory (range 20-80) measures the transitional emotional status evoked by a stressful situation, such as a medical procedure or surgery. The Visual Analog Pain Scale (range 0-10) quantifies pain level using verbal and visual descriptors. Higher scores indicate higher anxiety and pain for both tests. The patients were asked to complete two anxiety surveys, one pre-procedure and one post-procedure. Patients were also asked to complete a visual analog pain scale survey post-procedure.

Statistics were generated and compared using an independent *t*-test and chi-squared tests. *P* values < 0.05 were considered statistically significant. Delta anxiety score is defined as pre-cystoscopy anxiety score - post-cystoscopy anxiety score.

## RESULTS

Thirty-eight patients were randomized into either the No Music group (*n* = 24) or the Music group (*n* = 14). The subjects were all male as noted above. Table 1 outlines the demographics and clinical characteristics of these subjects. The mean age was 65.3 and 67.1

**Table 1 Summary of patients' demographics and clinical characteristics of the music and number of music groups *n* (%)**

Variables	Groups		P value
	Music group ( <i>n</i> = 14)	No music group ( <i>n</i> = 24)	
Age, mean + SD	67.1 + 9.9	65.3 + 10.4	0.9541
Race			0.698
Caucasian	10 (71)	15 (63)	
African American	1 (7)	4 (17)	
Hispanics	1 (7)	2 (8)	
Others	2 (15)	3 (12)	
History of bladder carcinoma	10 (71)	3 (1)	0.1488
History of prostate carcinoma	2 (14)	5 (21)	0.3039
History of hematuria	12 (87)	14 (58)	0.2049
Antidepressant or antianxiety medications	4 (29)	6 (25)	0.7092

**Table 2 Summary of patients' peri-procedural vital signs between the music and number of music groups**

Variables	Groups		P value
	Music group ( <i>n</i> = 14)	No music group ( <i>n</i> = 24)	
Pre Cystoscopy			
Systolic blood pressure (mmHg), mean + SD	135.5 + 17.7	135.5 + 17.9	0.9834
Diastolic blood pressure (mmHg), mean + SD	79.4 + 12.9	80.0 + 11.5	0.7908
Hear rate (beat/min), mean + SD	73.5 + 13.3	75.3 + 14.3	0.4405
Post Cystoscopy			
Systolic blood pressure (mmHg), mean + SD	139.1 + 22.8	137.2 + 17.3	0.5837
Diastolic blood pressure (mmHg), mean + SD	81.8 + 13.0	83.0 + 11.6	0.5717
Hear rate (beat/min), mean + SD	71.3 + 15.6	74.9 + 14.2	0.16

years for men in the No Music and Music groups, respectively. The majority of patients in each group self-identified as Caucasians. A majority of patients (68%) reported experiencing hematuria. Thirty-four percent had a history of bladder cancer, and 26% admitted to taking antidepressants. Physiologic parameters that correlated to pain and anxiety (systolic blood pressure, diastolic blood pressure, and heart rate) were statistically similar in both groups pre- and post-flexible cystoscopy. Patients' peri-procedural vital signs between the Music and No Music groups are summarized in Table 2. The median delta anxiety between the No Music and Music groups were not significantly different (0.78 vs -1.46), and the pain scores between the No Music and Music groups (1.5 vs 1.6) were not statistically different ( $P = 0.28$  and  $P = 0.92$ , respectively).

## DISCUSSION

Outpatient cystoscopy is a safe and useful procedure

employed frequently in Urology for diagnosis and evaluation of genitourinary pathologies. However, cystoscopy-related distress cannot be ignored<sup>[1]</sup>. Three components of outpatient cystoscopy have been evaluated to improve the cystoscopic experience: local anesthetic control, cystoscopic equipment redesign and environmental modification. We reviewed the literature pertaining to these modifications. In addition, since flexible cystoscopy is a more tolerable procedure more commonly utilized in the United States, we performed this study to investigate if music reduces anxiety and pain in American veterans undergoing flexible cystoscopy.

A recent study suggests that listening to classical music during rigid cystoscopy enhances patient comfort and decreases post-procedure pain and anxiety<sup>[23]</sup>. In addition to this report, prior studies have demonstrated music's ameliorating effect on pain and anxiety in patients undergoing a variety of procedures, including rigid cystoscopy<sup>[16-18,20]</sup>.

Contrary to these studies, our study did not show reduction of cystoscopy-related anxiety by listening to classical music during flexible cystoscopy, regardless of its indication. The lack of the effect of music in our group may be due to the small number of subjects. In addition, due to the patient demographics of the Veterans Affairs hospitals, the majority of our patients have been Caucasian males. Subsets of patients treated at the Veterans Affairs Hospitals respond to painful stimuli differently than their civilian counterparts, possibly due to the increased prevalence of PTSD and generalized anxiety disorder<sup>[24,25]</sup>. A subset of patients with history of bladder carcinoma that required repeated surveillance using office-based flexible cystoscopies were also included in this cohort. We observed that listening to music at time of respective cystoscopy did not influence their peri-procedural STAI anxiety scores when adjusting for other variables. We included blood pressure, heart rate, and respiratory rate as objective representations of the emotional state of the patient in addition to validated questionnaires. These parameters are directly influenced by sympathetic nervous system activation due to emotional distress or anxiety through the release of catecholamines, specifically norepinephrine and epinephrine<sup>[26,27]</sup>. Higher catecholamine levels from anxiety and fear result in elevated blood pressure, heart rate, and respiratory rate. Thus, the combination of these objective physiologic indicators with the subjective patient-provided information on anxiety and fear provided a more holistic assessment of the impact of music on how a patient experiences flexible cystoscopy.

Several randomized studies have shown the benefit of intraurethral lidocaine gel in reducing the pain associated with flexible cystoscopy and others have shown no improvement<sup>[6,8-13]</sup>. However, a recent meta-analysis<sup>[28]</sup> evaluating the effect of lidocaine gel on pain during flexible cystoscopy concluded that intraurethral instillation of lidocaine gel vs plain lubricating gel

reduces the likelihood of moderate to severe pain during flexible cystoscopy. Although fiber optic technology is still utilized for many of the flexible cystoscopes in the country, digital technologies are available. In other endoscopic devices, visualization using digital technology has higher resolution, decreased distortion, improved color representation, and larger image size compared with the standard fiber optic visualization with a narrower field of view<sup>[29]</sup>. More recently, digital technology with distal sensor high definition images has been compared to standard digital visualization<sup>[30]</sup>. These reductions will likely result in improved patient comfort during outpatient flexible cystoscopy.

Modern advances in flexible cystoscopic instrumentation and peri-procedural instillation of intraurethral lidocaine have both decreased pain associated with flexible cystoscopy. Listening to music during rigid cystoscopy has been shown to reduce pain and discomfort. Our prospective, randomized study explored the effect of classical music on pain and anxiety associated with flexible cystoscopy, and preliminarily demonstrates that music does not reduce anxiety or pain associated with flexible cystoscopy in the Veterans Affairs population.

## COMMENTS

### Background

Flexible cystoscopy is a very common in-office procedure performed in Urology. Several technological advances have been made in flexible cystoscopy instrumentation, however, there have also been advances in reducing patient pain and anxiety associated with this procedure, such as viscous lidocaine jelly and music. The authors reviewed the literature on effects of modifiable factors on patient pain and anxiety associated with flexible cystoscopy, and also include preliminary data on a Veterans Affairs randomized prospective trial evaluating the effect of classical music on pain and anxiety associated with flexible cystoscopy. This study explored the effect of classical music on pain and anxiety associated with flexible cystoscopy, and preliminarily demonstrates that music does not reduce anxiety or pain associated with flexible cystoscopy in the Veterans Affairs population.

### Research frontiers

Flexible cystoscopy is a very common in-office procedure performed in Urology. Several technological advances have been made in flexible cystoscopy instrumentation, however, there have also been advances in reducing patient pain and anxiety associated with this procedure, such as the use of viscous lidocaine jelly and music.

### Innovations and breakthroughs

In this systematic review, the authors attempted to evaluate whether listening to music at time of office-based flexible cystoscopy can alleviate pain and anxiety associated with this procedure. Previous studies have highlighted that listening to music during rigid cystoscopy reduces pain and discomfort. In contrast, they study did not show reduction of cystoscopy-related anxiety by listening to classical music during flexible cystoscopy, regardless of its indication. The lack of effect of music in their group may be due to the small number of subjects recruited in this study. Additionally, owing to the patient demographics of Veterans Affairs hospitals, the majority of our patients have been Caucasian males. Subsets of patients treated at Veterans Affairs hospitals respond to painful stimuli differently than their civilian counterparts, possibly due to the increased prevalence of PTSD and generalized anxiety disorder.

### Applications

Although listening to music at time of office-based flexible cystoscopy may play a limited role in reducing pain and anxiety in the Veteran population, these findings cannot be generalized to the general patient population, particularly civilian, as responses to pain and/or anxiety associated with flexible cystoscopy

can manifest differently among heterogeneous patient populations.

### Terminology

Well described medical and technological terminology commonly known to the general audience and the wider medical community was used. State-trait anxiety inventory; visual analog pain scale.

### Peer-review

This study investigated cystoscopy-related distress, reviewing benefits of intraurethral lidocaine use as well as of digital cystoscopes for reducing procedural anxiety and pain. Indeed, the authors performed a study to investigate if listening to classical music reduces anxiety and pain in patients undergoing flexible cystoscopy who were treated at a Veterans Affairs hospital in the United States.

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