Music and pain during endorectal ultrasonography examination: A prospective questionnaire study and literature review.

Introduction
Music interventions have been recognized as a method to reduce pain during medical procedures, but within medical imaging the subject has received little attention. Endorectal ultrasonography examination is in some patients associated with anxiety and pain, and since in Denmark pain relief is usually not administered by the Department of Radiology, it is important to find effective alternative methods to help patients manage their pain during imaging procedures. The primary aim of this study was to evaluate the effect of music on self-reported pain during endorectal examination of rectal cancer patients.

Methods
A prospective questionnaire study of patients undergoing endorectal ultrasonography was conducted. Patients were randomized into two groups to a music group (n=66), and non-music group (n=60). Standard endorectal ultrasonography was performed in all patients. Pain was self-assessed using a Visual Analogue Scale ranging from 0 to 10, with 0 representing “no pain” and 10 maximum pain.

Results
A total of 126 patients were included in the study, 81 (64.3%) men and 45 (35.7%) women. The demographics were similar in the two groups. The mean pain score during endorectal ultrasonography in the music and non-music group was 1.95 and 2.30, (p = 0.404).

Conclusion
In this randomized study music did not significantly affect the pain level experienced by the patients. Endorectal ultrasound was not entirely painless but less painful than colonoscopy (Visual Analogue Scale 2.1 and 3.8, respectively).

Implications for practice
Health care professionals may consider using music during painful procedures.
Introduction

Endorectal ultrasound (ERUS) and colonoscopy are recommended standard procedures for staging of rectal cancer (1,2). The procedures, however, may be experienced as uncomfortable and painful by the patients (3–5). An examination by ERUS may be a stressful situation for the patient, especially if the tumor is large or situated low in the rectum, and if the patient fears pain or discomfort, it may lead to an incomplete procedure. Sonographers and radiologists have the responsibility to establish a stress-reducing and comfortable environment to reduce the patients stress level. Music may be a method to overcome this, and positively affect the patient’s satisfaction (6,7). Using music as pain relief is a growing field of interest within medicine but is far from being a routine procedure.

A music intervention is an easy, safe, and inexpensive method to help reduce patients’ pain and stress. The use of music and its ability to reduce anxiety and pain involve several biomedical and hospital settings, e.g. lowering of heart rate and blood pressure, reduced use of sedation, and as an instrument in palliative care (8–12). However, not all studies have found music to be effective (13,14) and pain might be tolerated better in the healthy population. A study investigating pain in relation to flexible sigmoidoscopy found the procedure to be well tolerated with 87% of the respondents reporting no or mild pain (15). The level of pain during ERUS varies depending on tumor size and movement of the ultrasound probe placed inside the rectum. Anxiety and anal tension will also influence pain tolerance in patients. To our knowledge, there are no studies investigating pain related to ERUS in rectal cancer. The limited number of ERUS studies all focus on pain during ERUS guided prostate biopsy (14,16–19), four of which showed no effect of music on pain (14,16,18,19). On the other hand Chiu et al found a significantly lower VAS score in the music group of patients undergoing pre- and post-biopsy (p=0.03) (17).

Study aim

This study aimed over a period of two years to evaluate the effect of music on pain during ERUS examination in patients newly diagnosed with rectal cancer.
Literature review

Music used as pain and stress relief dates back to the mid-1800s, where Florence Nightingale acknowledged the power of music in hospital wards with effect on the healing process in soldiers. Nightingale pointed out that continuous sound by wind instruments pieces had beneficial effect whereas wind instruments without continuity in sound had the reverse effect (20). Isa Maud Ilsen back in 1926 wrote that music “now is recognized to be adjunct to medicine in the treatment of disease, not only by patients…but by physicians” (21). Modern research in music and analgesia started with Gardner et al in the 1960s, who examined 5000 dental patients and found music and noise intervention reduced pain in the majority of patients (22).

A literature search in the autumn of 2019 of original articles on music applied in medicine was performed using the MEDLINE/PubMed database including the following keywords; music, pain, radiology, and radiography. Article titles identifying other relevant studies were read using the snowball method. Only English language papers were included.

During the last two decades studies on music and pain within radiology have involved a broad range of image modalities. They have focused on interventional radiology (23–33), CT (34–36), ultrasound-guided breast biopsy (37,38), mammography screening (39,40), and endorectal prostate ultrasound (14,16–19).

In a systematic review including 42 randomized controlled trials in perioperative settings, the music interventions lasted between five minutes and four hours with the majority between 15 and 30 minutes (41). Chen et al showed that 15 minutes of music reduces anxiety in oncology patients (42), which indicate that music can be used in examinations of short duration, including radiology. It is recommended that music as an intervention in clinical practice is slow, flowing non-lyrical, with 60-80 beats per minute, a maximum volume of 60 dB, and possible patient selected (41).

The unanimity theory explaining the biological response to e.g. reduction of pain, anxiety, and blood pressure is that music is a distraction, and the patient will focus away from the unpleasant situation. Nilsson et al write that “music occupies the patients mind…which
allows the patients to escape into his or her own world” (41). When music is used as a
distraction, the regional cerebral flow associated with processing a painful event is reduced.
Distraction reduces the active areas of the brain where the pain is related, such as thalamus,
insula, and cortex (43). Music is emotional and induces an arousal effect and affects the
cardiovascular and respiratory system (44). However, it may be difficult to clarify if music
has a real impact on pain, or if it is the Hawthorne effect that influences the results. The
Hawthorne effect refers to a tendency of some people performing better when participating in
an experiment. The Hawthorne is also referred to as the observer effect.

The UK Society and College of Radiographers (SCoR) have recently focused on the benefits
of music and in 2018 suggested offering music to patients visiting radiology departments.
They also lobbied for the possibility of patients to bring their favorite playlist during stressful
procedures. Music can be used for patients waiting in general, before and during an
interventional procedure (45).

**Methods**

**Design**

This was a randomized, blinded single-center study performed at the Department of
Radiology, Vejle Hospital, University Hospital of Southern Denmark. The hospital is a public
tertiary hospital holding status as Center of Clinical Excellence in colorectal cancer. Patients
were randomized to a music group or a non-music group. Randomization was carried out
with a random number generator. An odd and even number would allocate patients to the
non-music and music groups, respectively. The research group preselected the music.
Relaxing instrumental tunes were playing already when the patients in the music group
entered the examination room, i.e. non-lyrical music with 60-80 beats per minute. The same
music CD was used for all patients and played five minutes before, and also during the ERUS
examination. The volume was preset to allow for undisturbed verbal communication between
patient and radiologist.

**Questionnaire**
The questionnaire was completed by patients attending an ERUS examination for the first time and who had a colonoscopy performed within the last 72 hours. The patients were informed that the questionnaire aimed to explore discomfort during the ERUS examination. They were not told that the investigation also focused on the possible beneficial effect of music during ERUS. The questionnaire contained questions on patient demographics and health characteristics (Tables 1 and 2).

**Inclusion and exclusion criteria**
The inclusion criteria were; above 18 years of age, newly diagnosed with rectal cancer, not started any treatment, colonoscopy (Olympus Video Colonoscops, Japan) performed within the last three days (Fig 1). Hearing disorder and unwillingness to listen to music were exclusion criteria (Fig 2). The patients and radiologists were blinded to the study hypothesis as to the effect of music.

**Pain score**
Visual Analogue Scales (VAS), ranging from 0 (no pain) to 10 (maximum pain) were used for subjective self-assessment of pain ERUS and colonoscopy. The VAS scale has shown good validity and reliability in measuring pain (46).

**Imaging**
The ERUS examinations were performed using a high-frequency endorectal (EC9-4) probe with a frequency bandwidth of 3.45–9 MHz on Siemens S2000 ultrasound machine (Acuson corporation, Siemens Mountain View, CA, USA). The probe had a length of 14 cm and a diameter of 1.1 cm. The probe was covered with an Ultracover® 44/300 (Microtek Medical B.V., Zutphen, Netherlands). Plain ultrasound gel was used as a lubricant. All procedures were carried out with the patient placed in the left lateral position. No sedation was necessary. All procedures followed the EFSUMB recommendation for gastrointestinal ultrasound (1). Experienced senior radiologists (five to 15 years of experience) performed the ERUS examinations with no trainees involved. The ERUS scan time was approximately five minutes. No complications occurred during the procedure.

**Statistics**
Data were analyzed using STATA statistical software (version 15.0, STATA Corporation, College Station, TX, USA). The 95% confidence intervals (CI) for odds ratios (OR) were calculated by logistic regression (Table 1 and Table 2). Mean VAS scores were statistically tested using a Chi-square test. A p-value <0.05 was considered statistically significant.

**Ethics**

The study was approved by the Danish Data Protection Agency and conducted in accordance with the Helsinki II Declaration. In general, questionnaire studies need no further approval according to Danish National legislation. All patients received oral and written information on the study and signed the consent form before entering the study and undergoing ERUS examination.

**Results**

A total of 126 patients were included, 81 (64.3 %) of which were men and 45 (35.7 %) women. The patients were randomized into a music group (66 patients) or a non-music group (60 patients) (Figure 2).

The median age was 68.5 years (range 34–91). Figure 3 shows the age distribution. The mean age of women was 65.2 years (range 34–91) and men 68.3 years (range 39–87). Table 1 shows the patient characteristic. A total of 10 (7.9%) men and four women (3.2%) used a hearing aid. Overall, the characteristics were all similar, and there were no statistically significant differences between patients in the music group and non-music group. Table 2 shows the number of patients experiencing pain in the two groups.

The primary endpoint was the severity of pain as measured by VAS. Figure 4 presents the scores. The ERUS pain score assessed in the two groups did not differ significantly (1.95 and 2.30 for the music and non-music group, respectively, p=0.404). Statistical significance was found for pain before ERUS examination compared to pain during ERUS, 16 versus 42 out of 126 patients (p<0.001).
There was no statistically significant difference between men and women in pain during ERUS (p=0.637) or during colonoscopy (p = 0.133).

Borderline significance was found between ERUS and colonoscopy. The mean VAS score in ERUS and colonoscopy was 2.1 and 3.8, respectively. The VAS was higher during colonoscopy compared to the ERUS examination (p=0.07).

**Discussion**

ERUS is important in the staging of rectal tumors, as the ultrasound images clearly visualize the depth of the tumor (47,48) and the examination is frequently performed in radiology departments worldwide. Also, ERUS seems to be well tolerated by the majority of patients even if the procedure may be painful.

A small number of studies have investigated music’s ability to reduce pain during ERUS, and all studies so far have focused on prostate biopsy. Hou et al investigated variables associated with pain during ERUS of the prostate and found that previous ERUS experience, external hemorrhoids, and stool accumulation in the rectum influenced the sensation of pain with moderate and severe pain reported by 21.5% and 12.1% of the patients, respectively (5). Chang et al investigated music and pain in 76 patients undergoing ERUS and prostate biopsy and found music to lower heart rate and systolic blood pressure (18). In the present study, 126 patients were randomized into a music group and a non-music group. This is one of the largest studies investigating music during ERUS examination, and to our knowledge only exceeded in population size by Packiam et al with enrolling 182 prostate patients (14).

VAS is a simple tool consisting of a 10 horizontal line numbered from zero to 10 and is very easy to comprehend and complete. The patients rate their pain by placing a mark on the line reflecting their level of pain. In this study the VAS score for the ERUS examination tended to be lower than of the colonoscopy (p=0.07). The patient-reported VAS score was not significantly influenced by music, and a mean VAS of 1.95 and 2.30 in the music and non-music group (p=0.404). Statistical significance was found in relation to the difference in pain before ERUS and during ERUS in both groups (p<0.001). Hou et al investigated ERUS pain
variables in 498 prostate patients and found a mean VAS score of 2.87 (5). This slightly higher VAS score could be explained by the ultrasound probe being placed higher in the rectum of prostate patients compared to rectal cancer patients, since some tumors are situated just above or at the level of the anal sphincter.

Music is known to have a wide range of physiological effects on the body and mind, including biochemical responses. Acute emotional anxiety activates the sympathetic nervous system, which causes activation of physiologic indications of stress such as elevated blood pressure (49). The application of music has also led to lower pain levels during various stressful procedures, e.g. sigmoidoscopy, colonoscopy, and urological procedures (4,50,51), but not all studies have found music to reduce pain during sigmoidoscopy or colonoscopy (7,52). We found five studies investigating the effect of music on the pain VAS score during ERUS biopsy. The outcome of two of the studies was insignificant (14,16) and three had statistically significant results (17–19). More invasive procedures may lessen the effectiveness of the music intervention, which may be an explanation of the difference in significance. Age probably also plays a role, since taste and preferences within music differ between age groups.

Contrary to expectations, we observed no statistically significant decrease in the pain level of patients listening to music during ERUS examination compared to the control group. The patients were not offered a choice of music, which may have had an impact on the result. Although, most imaging studies with focus on music intervention and pain used relaxing music (17,23,24,28,29,35,36,38,53), some authors argue that it is important to play music selected by the patients in order not to disturb and aggravate them unnecessarily (16,26,30–33,37,39).

**Limitations and strengths**

To our knowledge, this is the first randomized case-control study assessing the effect of music in rectal cancer patients undergoing ERUS. Its single-blind design, i.e. the patients did not know the role of music in this study, is considered a strength. The radiologists were blinded to the study aim. It is a limiting factor that the study was not double-blind, but it was
important for the radiologist to be able to communicate with the patient during the procedure, and therefore using headphones was impractical. Also, Tsivian et al did not find lower pain in patients using headphones during ERUS biopsy (19). On the other hand, music may not distract the radiologist, as a study found that doctors were only disturbed by the music playing in 3% to 12% of the time (54).

It is possible that the patients VAS score was lower in colonoscopy compared to ERUS due to recall bias since the colonoscopy was performed between one and 72 hours earlier. Sedation during colonoscopy may affect the short-term loss of memory associated with pain during the procedure (55) whereas ERUS examination did not involve sedation and consequently, pain may be remembered more clearly. This could explain our finding of a border significant difference between ERUS and colonoscopy (p=0.07).

We used plain ultrasound gel as a lubricant, and a study comparing lidocaine gel with plain lubricating gel in patients during ERUS found no significant difference in pain score between the two types of ultrasound gel (56).

Conclusion
Although music is being recognized as increasing important within medicine, in this randomized study we found that music did not affect the pain level of ERUS (VAS 1.95 versus 2.30, in the music and non-music group, respectively). We found no statistically significant difference between the pain score of men and women. Endorectal ultrasonography was less painful compared to colonoscopy with a VAS of 2.1 versus 3.8.
We consider offering music to our patients before painful procedures. Music may not lower the pain level but could provide a calm environment for both sonographers and patients. Offering the patients to make their own choice of music will most likely increase satisfaction.
Future randomized music studies on patients undergoing ultrasonography with invasive procedures such as liver and kidney biopsies are warranted.

Words: 2648

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<td>EFSUMB recommendations for Gastrointestinal Ultrasound Part 3: Endorectal,</td>
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pain and patient satisfaction by music therapy in patients with endoscopy/colonoscopy.


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life-value-music-radiology-departments


Figure legends

Figure 1.
ERUS of a T3b rectal adenocarcinoma with an outgrowth of 4.8 mm and a distance to the pelvic wall of 2.9 mm (Arrow). No lymph nodes metastases were encountered.

Figure 2:
Patient flow.

Figure 3.
Age distribution of the 126 included patients.

Figure 4
Distribution of VAS score during ERUS and colonoscopy. Blue represents ERUS and red colonoscopy.
Table 1
Characteristics of patients in the music group and the non-music group

<table>
<thead>
<tr>
<th>Patients characteristics</th>
<th>All patients n= 126</th>
<th>Music n=66</th>
<th>Non-music n=60</th>
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<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
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<tr>
<td>Men</td>
<td>80</td>
<td>63.5</td>
<td>40</td>
<td>60.6</td>
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<td>Women</td>
<td>46</td>
<td>36.5</td>
<td>26</td>
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<td>Mean age (years)</td>
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<tr>
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<td>Mean weight (Kg)</td>
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<td>Mean BMI</td>
<td>26.1</td>
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<td>23.3</td>
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Marital status

|                          | %    |      | %    |      | %    |      | Odds ratio | 95 % CI    | P-value |
| Married or living with partner (%) | 95  | 75.4 | 50  | 75.8 | 45  | 75.0 | ref        |            |         |
| Single (%)                | 10  | 7.9  | 5   | 7.6  | 5   | 8.3  | 0.83       | 0.22 - 3.05| 0.77    |
| Widow(er) (%)             | 16  | 12.7 | 7   | 10.6 | 9   | 15.0 | 0.64       | 0.22 - 1.87| 0.41    |
| Divorced (%)              | 5   | 4.0  | 4   | 6.0  | 1   | 1.7  | 0.55       | 0.09 - 3.45| 0.52    |

Table 2
Shows the number of patients who experienced pain before, and during procedure.

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<th>Pain variables</th>
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<th>Non-music n=60</th>
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<td></td>
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<td>%</td>
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<td>%</td>
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