The use of music in reducing pain during outpatient hysteroscopy: prospective randomised trial

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Background and literature search

Outpatient hysteroscopy is nowadays a commonly used procedure in Gynaecology in order to evaluate the uterine cavity and to diagnose different intrauterine diseases. It is a safe, convenient and cost-effective procedure in aiding the management of abnormal uterine bleeding [1]. However, outpatient hysteroscopy can be associated with significant pain [2] which would have impact on the woman's satisfaction and pain is one of the most common reasons for failure of the procedure [3].

Listening to music could be an easy and non-invasive way to reduce pain. A meta-analysis conducted on the effects of music on pain revealed that music interventions had statistically significant effects in decreasing pain on 0-10 pain scales [4]. Researches on this topic in gynaecological office procedures, however, showed variation in the results. The randomized controlled trial of Mak et al. showed no positive effect of music on patient's level of pain, anxiety or satisfaction of patient or doctor for office hysteroscopy and colposcopy [5]. On the other hand, Angioli et al. showed a positive effect of the use of music with a reduction of pain and anxiety during office hysteroscopy [6]. A local randomized controlled trial of Chan et al. also showed that music can significantly reduce pain during colposcopy examination [7].

Thus, the aim of this study is to demonstrate the value of music in outpatient hysteroscopy on patients' level of pain and satisfaction. This may have a role in our daily practice in providing a better patient care in outpatient hysteroscopy.

Hypothesis/research question

Is music an effective measure to reduce pain during outpatient hysteroscopy?

Objectives of the study

This study aims to investigate the effect of music in reducing pain during outpatient hysteroscopy.

Methods

Design

This will be a prospective randomized trial to be conducted in the Department of Obstetrics and Gynaecology, Pamela Youde Nethersole Eastern Hospital from June 2019 to December 2019.

Participants

All patient referred for outpatient hysteroscopy from June 2019 to December 2019 will be invited to join the study. Inclusion criteria were indication for hysteroscopy (abnormal uterine bleeding, abnormal findings on ultrasound, and infertility), signed informed consent, and ability to read Chinese or English. Exclusion criteria were hearing impairment, known anatomical abnormalities which would make performing the procedure more difficult and use of premedication for cervical ripening. Withdrawal criteria was procedure cannot be completed.

Outcomes

The primary outcome is the experience of pain during hysteroscopy, measured with the visual analog scale (VAS) on a 0-10 scale, with 0 indicating “no pain” and 10 indicating “worst pain possible”. Each participant will assess the anticipated pain before the procedure and also the real pain after the procedure using VAS. Secondary outcomes are vitals parameters including blood pressure and heart rate. They will be recorded before the procedure and during the hysteroscopy after traversing the cervix. Satisfaction of the patient and doctor will be described using a scale of 1 to 5 after the procedure.

Procedure

Written informed consent will be obtained from each participant before data collection and the procedure. Background characteristics including age, body mass index, occupation, religion, education, marital status, parity, number of vaginal deliveries and history of hysteroscopic surgery will be collected. Participants will be randomized to the music group or control group. Sealed numbered opaque envelops will be used for randomization. Participants in the music group will be asked to choose among pop, classical, jazz or spa music playlists which are prepared by the study team. The music that chosen by the participant will be played through a speaker by the nursing staff. Music will be played through a speaker instead of headphone in order to maintain a good communication and interaction between the participant and the doctor. The volume of the music can also be adjusted according to individual preference. On the other hand, participants in the control group will be examined in the same setting without music.

Hysteroscopy will be performed in a dedicated room in the day ward by resident trainees without any type of anaesthesia. No premedication will be given. The procedures of hysteroscopy will be standardized. Participant will be put in lithotomy position. A Bivalve speculum or Sims speculum will be used to visualized the cervix. Tenaculum might be used depending on surgeon’s preference. Normal saline was used as the distending medium. A CAMPO TROPHYSCOPE of outer diameter 2.9mm will be used. An operating sheath of outer diameter 4.4mm might be applied to the hysteroscope if necessary.

The operative time will be measured from entry of the hysteroscope into external os to exit from the cervix. The type of procedure (diagnostic or operative) performed will be measured again after insertion of the hysteroscope through internal os.

Sample size and statistical methods

The mean decrease in VAS ranged from 4.83 to 2.95, as reported in the literature [6]. Fifty-one participants in each group will be required to detect such a difference, with a power of 90%. Statistical analysis would be performed with Statistical Package for the Social Sciences (SPSS). Student's t test and Chi square test would be used where appropriate. Patients' demographic data would be presented in tables or graphs. Paired t test would also be performed, if appropriate. P value of <0.05 would be considered as statistically significant.

Ethical consideration

The issue of confidentiality is the major ethical issue, and will be solved by recording the data in a manner that does not allow the participants to be identified (ie. using a non-recognizable code for each patient).

The protocol complies with the ICH-GCP.

Data Handling and Record Keeping

Records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.

To protect patient privacy, all research data would be handled in line with HA/Hospital's policy in handling/storage/destruction of patients' medical records. They would be locked in cabinets where the department or ward keeps patients' confidential information. Electronic data should be saved in secured computer of the hospital with restricted access.

Day ward staff and the principal investigator will be responsible for safekeeping of the personal data during and after the study. Only the principal investigator and delegate will have access to the personal data collected during and after the study. The personal data will be kept for 3 years after the study. All the personal data will be discarded and destroyed after the storage period.

Reference

[1] Best Practice in Outpatient Hysteroscopy. RCOG Green-Top Guideline No.59. March 2011.

[2] Morgan M, Dodds W, Wolfe C, Raju S. Women's views and experiences of outpatient hysteroscopy: implications for a patient-centered service. Nurs Health Sci. 2004 Dec.

[3] Amer-Cuenca JJ, Marín-Buck A, Vitale SG, La Rosa VL, Caruso S, Cianci A, Lisón JF. Non-pharmacological pain control in outpatient hysteroscopies. Minim Invasive Ther Allied Technol. 2019 Feb 22.

[4] Lee JH. The Effects of Music on Pain: A Meta-Analysis. J Music Ther. 2016 Winter;53(4):430-477. Epub 2016 Oct 19.

[5] Mak N, Reinders IMA, Slockers SA, Westen EHMN, Maas JWM, Bongers MY. The effect of music in gynaecological office procedures on pain, anxiety and satisfaction: a randomized controlled trial. Gynecol Surg. 2017;14(1):14.

[6] Angioli R, De Cicco Nardone C, Plotti F, Cafà EV, Dugo N, Damiani P, Ricciardi R, Linciano F, Terranova C. Use of music to reduce anxiety during office hysteroscopy: prospective randomized trial. J Minim Invasive Gynecol. 2014 May-Jun;21(3):454-9.

[7] Chan YM1, Lee PW, Ng TY, Ngan HY, Wong LC. The use of music to reduce anxiety for patients undergoing colposcopy: a randomized trial. Gynecol Oncol. 2003 Oct;91(1):213-7.

Consent Form

Research title: The use of music in reducing pain during outpatient hysteroscopy: prospective randomised trial"

I hereby consent to participate in the research study.

I have read and understand this document. The study has been explained to me. I understand all the benefits and risks related to this study. I have opportunities to raise questions to the investigators and they have answered my questions to my satisfaction. I have collected sufficient information regarding this study.

If I have any physical or emotional discomfort as a result of participating in this study, the study investigators will treat me, or will refer me to receive treatment. Signing this informed consent form does not imply that my legal rights would be waived.

I understand that I can freely withdraw my consent on the participation of this study and it would not affect my present and future medical care.

I understand my identity will be kept confidential. I also authorize the research ethics committee and the regulatory authority(ies) to access my data for verification of clinical trial procedures and/or data, without violating the my confidentiality, to the extent permitted by the applicable laws and regulations.

_____	_____	_____
Name of Subject	Signature of Subject	Date
_____	_____	_____
Name of Investigator	Signature of Investigator	Date
_____	_____	_____
Name of Impartial Witness	Signature of Impartial Witness	Date

By signing a written informed consent form, I will be given a signed and dated copy of the consent form and information sheet for storage.