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Impact of Running Water Sound on Anxiety and Urodynamic Parameters: A Multi-Center Randomized Controlled Trial

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Introduction

Urodynamic study is a critical diagnostic tool for assessing lower urinary tract dysfunction but is often associated with patient discomfort and anxiety due to its invasive nature [1]. Anxiety during urodynamics can hinder micturition, affecting the reliability of pressure-flow study results [2]. Previous studies have suggested that auditory interventions, such as the sound of running water, may reduce anxiety and enhance detrusor muscle activity, thereby improving urodynamic parameters [3]. This study seeks to validate the findings of Culha et al. (2023), which demonstrated that listening to running water during urodynamics significantly reduced anxiety and improved micturition parameters [4]. The primary aim is to determine whether this intervention can be effectively implemented in our centers to enhance patient experience and diagnostic accuracy using a robust randomized controlled trial design.

Objectives

The primary objective is to assess the effect of running water sound during urodynamic study on maximum flow rate (Qmax). The secondary objectives are to evaluate the effect of running water sound on patients' anxiety levels, as measured by the Visual Analogue Scale (VAS), other urodynamic parameters and to compare the proportion of patients able to micturate during the pressure-flow study between the experimental and control groups.

Material and methods

This is a multi-center randomized controlled trial conducted at Princess Margaret Hospital and Caritas Medical Centre involving 240 patients undergoing urodynamic

study. CMS system will be used for screening eligible subjects. Eligible patients will be approached during their scheduled urodynamic appointment, provided with the consent form and questionnaire. Written informed consent is obtained from all participants before study group allocation. Patients will be randomly assigned to either experimental group or control group. The experimental group will listen to a standardized recording of running water in relaxed melody played via a smartphone during the pressure-flow study phase of urodynamics. The control group will undergo standard urodynamic testing without any auditory intervention. Urodynamic study will be performed by trained gynaecologists. The urodynamic procedure will be consistent across both groups and centers, involving uroflowmetry, cystometry, and pressure-flow study, with catheters placed as per standard protocol.

Inclusion Criteria

- Chinese women aged 18–90 years scheduled for urodynamic study.
- Understand written traditional Chinese.
- Willing to participate and provide a written informed consent.

Exclusion Criteria

- Patients who refuse to participate or provide written consent.
- Patients who do not understand or comprehend written traditional Chinese.
- Patients with severe cognitive impairment or inability to complete the VAS.
- Patients with known psychiatric conditions that may confound anxiety measurements.
- Patients with hearing impairments that would prevent perception of the running water sound.

Randomization

Participants are recruited and assigned randomly in 1:1 ratio to control group or experimental group. Randomization will be performed using a computer-generated random number sequence with a 1:1 allocation ratio. A block randomization method with random blocks of two, four and six will be used to maintain allocation concealment. The randomization sequence will be generated by an independent statistician and stored in sealed, opaque, sequentially numbered envelopes. Upon enrollment, a nurse will open the next envelope to assign the patient to either the control or experimental group.

This process ensures blinding of the allocation sequence to the research team until assignment.

Data Collection

All participants will provide written informed consent using a standardized consent form approved by the ethics committee. The form will detail the study purpose, procedures, potential risks, benefits and the right to withdraw at any time without affecting their care. A structured questionnaire will collect sociodemographic data, medical history and urinary symptoms. The questionnaire will be distributed to participants by a trained nurse before the urodynamic procedure. Anxiety will be measured using VAS before, during, and after the urodynamic procedure. Urodynamic Parameters will be measured as standard protocol during urodynamic study.

Outcome measures

Primary outcome: Maximum flow rate (Qmax).

Secondary outcome: Difference in mean anxiety levels as measured by VAS between experimental and control groups, proportion of patients able to micturate during pressure-flow study, detrusor pressure at maximum flow rate (PdetQmax), bladder outlet obstruction index (BOOI) and bladder contractility index (BCI).

Sample Size Calculation

The sample size is calculated based on the maximum flow rate (Qmax) of the experimental and control groups, as reported by Culha et al. (2023) [4]. In their study, the maximum flow rate was 5.20 ± 7.13 ml/s in the control group and 8.27 ± 7.76 ml/s in the intervention group, yielding a mean difference of 3.07 ml/s and an approximate pooled standard deviation of 7.45 ml/s (calculated as √((7.13^2 + 7.76^2)/2). The required sample size for comparing two independent means was calculated using a two-sided two-sample t test with a significance level of 0.05 and power of 80%. Using a mean difference of 3.07 ml/s and a common standard deviation of 7.45 ml/s, the formula gives approximately 93 participants per group. Assuming a 20% dropout or non-evaluable rate, the adjusted sample size is approximately 116 participants per group. To ensure adequate power to detect the expected difference in Qmax between groups and account for the multi-center design, we therefore plan to recruit 120 participants per group.

Statistical Analysis

Data will be analyzed using IBM SPSS Statistics (version 27.0.1). Descriptive statistics (mean, standard deviation, frequency) will summarize patient characteristics and outcomes. Comparisons between groups will use Student's t-test for normally distributed continuous variables, Mann-Whitney U-test for non-normally distributed variables, Chi-square or Fisher's exact test for categorical variables. An intention-to-treat analysis will be performed to account for dropouts. Statistical significance will be set at $p<0.05$.

Data Management and Protection

All patient data will be handled in compliance with the Personal Data (Privacy) Ordinance of Hong Kong and the Declaration of Helsinki. Data will be collected via paper-based consent forms and questionnaires, and electronic urodynamic measurements. Each participant will be assigned a unique study ID to anonymize data. Paper forms will be stored in a locked cabinet in a secure office accessible only to the research team. Electronic data will be stored on a password-protected, encrypted server hosted by Princess Margaret Hospital, with access restricted to authorized personnel. All identifiable information will be removed, and only study IDs will be used in analysis and reporting. Only IRB/REC, principal investigator and designated research team members will have access to the data. Data will be retained for 5 years post-study completion, as per institutional guidelines, after which paper records will be securely shredded, and electronic data will be deleted.

Ethical Considerations

The study will be conducted in accordance with the Declaration of Helsinki and the ICH guideline for good clinical practice. Ethical approval will be sought from the Ethics Committees of Princess Margaret Hospital and Caritas Medical Centre. Any participation in the research study is completely voluntary. Any person is free to decline to participate for any reason. Study details will be provided and written informed consent will be obtained. Participants will receive a copy of the consent form. Data confidentiality will be maintained as described in the Data Management section. No financial incentives will be offered, but participants will not incur additional costs.

Conflict of Interest

The principal investigator and the research team declare no conflict of interest related to this study. No funding or sponsorship has been received from entities that could influence the study outcomes.

Timetable

Proposed study period: 1/12/2025 to 30/11/2027

Direct Access to Source Data/Documents

The investigator(s)/institution(s) will permit trial-related monitoring, audits, IRB/REC review, and regulatory inspection(s), providing direct access to source data/documents.

Publication Policy

N/A

References

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2. Suskind AM, Clemens JQ, Kaufman SR, et al. Patient perceptions of physical and emotional discomfort related to urodynamic testing: a questionnaire-based study in men and women with and without neurologic conditions. *Urology*. 2015;85(3):547-551.
3. Kwon WA, Kim SH, Kim S, et al. Changes in urination according to the sound of running water using a mobile phone application. *PLoS One*. 2015;10(5):e0126798. Published 2015 May 15.
4. Çulha Y, Ak ES, Çulha MG. The Effect of Running Water Sound Listened to Patients During Urodynamics on Anxiety and Urodynamic Parameters. *Int Neurourol J*. 2023;27(3):217-223.