Title:

Impact of verbal compared to structured information on patient's anxiety and satisfaction undergoing uroflowmetry

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STATEMENT OF COMPLIANCE:
This study complies with the Good Clinical Practice (GCP) Guidelines.

Introduction:

Lower urinary tract symptoms (LUTS) significantly impact approximately half of men and women aged >40 years. (1) This entity includes storage/overactive bladder symptoms, voiding, and post-micturition symptoms. (2) Burden of this condition is increased from 18.4 to 45.8% in a few decades. (2) This condition has multifactorial etiologies and has a significant impact on quality of life, public health costs, and economic burden. (2, 3)

Uroflowmetry (UFM) is a non-invasive initial, simple, and widely performed first-line investigation for the evaluation of this condition. (4) This investigation is an objective assessment of the patient's symptoms and can also be used to follow the response of treatment on lower urinary tract symptoms. (4) Literature has shown that to obtain true representative results patients should be comfortable. (1) Few studies have identified factors having an impact on the satisfaction of patients undergoing uroflowmetry. Khavari et al.,2016 in his study found that trained and dedicated staff improves patient satisfaction. (5)

Even though non-invasive nature, this investigation can lead to emotional disturbance and anxiety with a reported prevalence of up to 41.3%. (4) Limited literature is reported regarding the relationship between anxiety and patient satisfaction undergoing uroflowmetry with a lack of validated questionnaires in assessing the impact of non-invasive urological tests on these aspects. In our study, to assess anxiety in patients undergoing uroflowmetry modified Amsterdam Preoperative Anxiety and Information Scale (APAIS-M) will be used as according to Rubilotta et al.,2020 this tool can provide reliable results. (4) To assess satisfaction Dogun et al., 2022 developed and used a patient satisfaction form. This patient satisfaction form will be used in our study. (1)

This study is an initial step in highlighting the significance of different methods of counseling and will help in the future to provide effective means of education which will help in obtaining representative pattern of patient.

Rationale:
With the rising burden of LUTS and the utilization of UFM in its evaluation, improvement in its utilization is critical. The result of UFM is influenced by psychological discomfort. Therefore, psychological discomfort has to be minimized during performance of uroflowmetry to obtain a routine pattern of UFM. In our study psychological discomfort includes anxiety and satisfaction.

This study aims to identify the impact on psychological discomfort after giving structured education and compare it with a group of patients routinely counseled verbally by health care providers which will help in future to improvise counseling method.

Primary Objective

1. To compare the level of anxiety by modified APAIS score in patients undergoing UFM who receive structured versus verbal education.
2. To compare patient satisfaction by patient satisfaction form after UFM in the two groups.

Secondary Objective:

1. To determine length of stay in both samples

Hypothesis:

Alternate hypothesis:
There is a difference in anxiety and satisfaction in patients receiving structured versus verbal education.

Null hypothesis:
There is no difference in anxiety and satisfaction in patients receiving structured versus verbal education.

Operational definitions:
Anxiety:
In the ICD-10 code anxiety is defined as anxious feelings or fear. In our study, modified Amsterdam Preoperative Anxiety and Information Scale (APAIS-M) will be used to assess the level of anxiety as to date there is no validated tool available to assess anxiety in patients undergoing uroflowmetry. This modified version of APAIS was obtained from a previous study conducted in patients undergoing uroflowmetry. This part of the questionnaire will be filled just after providing education and before performing uroflowmetry.
The score for this tool will minimum be 3 and a maximum be 15 and results will be categorized into three groups; (4)
3-6 no anxiety, 7-10 moderate anxiety, 11-15 severe anxiety (4)

Patient satisfaction:
It is an objective assessment of patient satisfaction with provided knowledge by the health care provider. (6) This tool is taken from a study published in 2022 as there is no validated questionnaire available to date to assess satisfaction in patients undergoing uroflowmetry. (1)

Verbal education:
It will include verbal counseling given by a healthcare provider.

Structured education:
It will include a printed brochure having procedural details of uroflowmetry designed by our institute after assessment through the Patient Educational Material Assessment Tool (PEMAT). This will be provided to patients along with video briefing procedural details.

Length of stay:
This duration will be calculated from the time of registration till the printed report of a graph.

Adequate uroflowmetry: It includes the minimum voided volume of 150 ml.

Methodology:

Study Design: Parallel arm study design-Single blind study

Setting: Section of urology at the Aga Khan University Hospital, Karachi, Pakistan.

Study Duration: Data will be collected after DRC and ERC approval from July 10th June 2025 or till sample size achieved.

Study population: Patients visiting the urology suite at Aga Khan University Hospital Karachi.
Sampling technique: Simple random technique/ Non probability purposive sampling

Sample: All those patients who require a UFM test and fulfilling the inclusion criteria will be invited to participate in this study.

After approval from DRC and ERC Questionnaire will be sent to 5 experts (both English and Urdu version) and based on their responses content validity index will be recorded. The score of more than and equal to 0.8 is considered acceptable and then the study will be started.
Patients will be assigned to a group using sealed envelope system. In this system, once patient has consented to enter a trial an envelope is opened and the patient will then inducted in the allocated group. Patient inducted in control group will be called from Thursday till Saturday for uroflowmetry and those inducted in intervention group will be called from Monday till Wednesday for uroflowmetry to prevent contamination.

Inclusion criteria:

1) Age 18 years and above
2) Undergoing uroflowmetry for the first time
3) Patients, who can hear, read and comprehend the education in either Urdu or English language.

Exclusion criteria:

1) Language barrier
2) Known psychiatric illness
3) Unable to comprehend instructions due to any neurological issue
4) Unable to void adequate volume even after 3 attempts

Randomization:

In this study, patients will be assigned to a group using sealed envelope system. In this system, once patient has consented to enter a trial an envelope is opened and the patient will then be inducted in the allocated group. Patient inducted in control group will be called from Thursday till Saturday for verbal counselling and uroflowmetry and those inducted in intervention group will be called from Monday till Wednesday for structured counselling and uroflowmetry to prevent contamination. This randomization method is done by principal investigator or co-investigators.
All registered patients will be counselled verbally (in the control group) or through brochures and video (in the intervention group). After counseling first and second part of the proforma (basic demographics and anxiety score) will be filled before performing uroflowmetry and then once uroflowmetry is performed, the third part (satisfaction score) will be filled. All this assessment will take approx. 20-25 minutes.

The interim analysis will be done and if results are going towards any extreme or if patients are getting any unexpected harm, following the stopping rule the study will be stopped and will conclude results.
To minimize bias, single blinding will be done and data analysts will be kept blind and data will be stored in coded form.

Data collection strategy:

Control Group (Verbally counseled):

As per hospital routine, all patients undergoing UFM procedures will be educated verbally about the procedure. There will be no difference in care level.
After counselling first and second part of the proforma (Appendix 3 and 4) (basic demographics and anxiety score) will be filled and then once uroflowmetry is performed, the third part (satisfaction score) will be filled All this assessment will take approx. 20-25 minutes.

Intervention Group (Counselled with structured education):

As per new practice, all patients undergoing UFM will be educated through structured educational material provided in the brochure (Appendix 5) along with a video tutorial briefing details of uroflowmetry. There will be no difference in care level.
After counseling first and second part of the proforma (basic demographics and anxiety score) will be filled and then once uroflowmetry is performed, the third part (satisfaction score) (Appendix 3 and 4)will be filled. All this assessment will take approx 20-25 minutes.

Measures to minimize bias:

To minimize bias baseline characters of both groups will be kept similar. Groups will be divided into two equal numbers of participants on basis of morning and afternoon shifts to minimize contamination. Single blinding will be done and data analysts will be kept blind and data will be stored in coded form.

Sample size:

The sample size was calculated on open epi software version 3.01. A sample size of 132 is calculated in total with 66+/-7 in each group; with an anticipated mean and SD of 19.1+/-3.4 in group 1, 22.4+/-2.7 in group 2, and considering the difference of 1.5 (1); and with a level of significance of 5%, power of 80% and ratio of sample size 1:1. This is calculated by using available literature of second objective as no values are available for first objective.
The strength of our study would be that both groups will be equal.

Statistical methods:
To minimize bias, single blinding will be done and data analysts will be kept blind and data will be stored in coded form.
Data will be analyzed on SPSS window 22.0 (SPSS Inc. Chicago). Descriptive statistics for quantitative variables such as age, patient satisfaction, and length of stay will be reported as mean and standard deviation/ median (IQR). Frequencies and percentages will be reported for anxiety. The normality of continuous data will be determined by applying the Shapiro-Wilk test. The independent t-test/ Man Whitney test will be used to determine statistically significant differences for the mean and standard deviation of two groups (verbally counseled and counseled with structured education) for quantitative variables including age, patient satisfaction and length of stay and the Chi-square/Fisher test will be used for categorical variables calculated in percentages and frequencies including anxiety. The association between counseling done by verbal and structured education with anxiety and patient satisfaction will be checked by multivariable analysis and crude and adjusted odds ratio with a 95% confidence interval will be reported. A p-value of <0.05 will be considered significant.

Limitations:
In our study, limitations will be its single-center study and lack of a validated questionnaire to assess patient satisfaction as this score is obtained from the previous study.

ETHICAL CONSIDERATIONS:
This trial will be conducted in compliance with the principles of the Declaration of Helsinki, the principles of Good Clinical Practice (GCP), and all of the applicable regulatory requirements.
In this study, after taking approval from DRC and ERC data collection will be started. After getting informed consent in provided English/Urdu language as per patient preference, we will be collecting data including demographics, anxiety assessment, and patient satisfaction in both groups (receiving verbal or structured education) from patients visiting the urology clinic and undergoing uroflowmetry. Data will be collected in a separate room for privacy. Data will be kept in lockers and will be secured by the investigators and it will only be accessible to primary investigator and co-investigator. Patient confidentiality will be maintained using a specific code for each patient.

Reporting and recording procedures of adverse events:

There will be no adverse events anticipated. Though during our assessment if the patient is found to be anxious, a referral letter for an appropriate psychologist/psychiatrist will be provided for support and further evaluation.

References:

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