Official Title:

Evaluation the Effects of Dynamic Video Education Compared to Static Images and Verbal Information on Pain Perception and Anxiety in Patients Undergoing Transrectal Ultrasound-guided Prostate Biopsy (TRUS-Bx)

National Ethics Committee Number: AEŞH-EK1-2023-100

Date: 10/12/2023

RESEARCH PROTOCOL

CLINICAL RESEARCH (Studies excluding medications, test kits, or medical devices)

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1. Full Title of the Study:

"A Prospective Comparative Study of the Effect of Video Education on Pain and Anxiety in Patients Undergoing TRUS-Guided Prostate Biopsy"

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2. Purpose and Significance of the Study:

The widespread use of PSA (Prostate-Specific Antigen) has facilitated the early detection of prostate cancer. Biopsies are performed on patients who are suspected to have prostate cancer based on elevated PSA and digital rectal examination. Transrectal ultrasound-guided prostate biopsy is the standard diagnostic procedure. The increasing use of PSA has led to a rise in the number of biopsies.

It has been reported that prostate biopsies and the diagnosis of prostate cancer cause anxiety in men. These procedures may lead to pain, anxiety, and stress.

Today, patients frequently use the internet to gather information. Watching videos of procedures before surgery via digital platforms is common. This study aims to measure the effect of watching TRUS-BX videos before and after the procedure on patients' anxiety and stress levels.

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3. Expected Benefits and Risks:

If an increase in patients' anxiety and stress scores is observed, it may highlight the need for additional measures to inform patients prior to procedures. Videos could be adjusted to reduce stress, potentially making the biopsy experience more comfortable. However, patients who become overly anxious after watching such videos might delay or avoid diagnosis and treatment, as seen in psychiatric consultations. This study may also guide how digital content should be curated.

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4. Study Design:

This is a comparative study of anxiety scores and visual analog scale (VAS) pain scores before and after the procedure. All patients are informed in the outpatient clinic about the TRUS-BX procedure after elevated PSA is detected.

The study was reviewed and finalized with the contributions of Dr. Ayşe Gökçen Gündoğmuş from the Psychiatry Department of Ankara Etlik City Hospital.

Control Group:

Patients are given verbal information about the procedure. Then:

- VAS test is applied.
- STAI-II (Trait Anxiety) and STAI-I (State Anxiety) scales are administered pre-procedure.
- After biopsy: VAS and STAI-I are re-administered.
- No visual material is shown.

Video Group:

Patients are given verbal information. Then:

- VAS test is applied.
- Videos about the procedure are found and watched with the patients via digital video platforms.
- STAI-II and STAI-I are administered pre-procedure.
- After biopsy: VAS and STAI-I are re-administered.

Image Group:

Patients are given verbal information. Then:

- VAS test is applied.
- Illustrated drawings (from books) about the procedure are shown to the patients.
- STAI-II and STAI-I are administered pre-procedure.
- After biopsy: VAS and STAI-I are re-administered.

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5. Target Volunteer Group:

Adult males with elevated PSA levels and planned biopsy.

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6. Age Range:

Men aged 50–80 (PSA screening typically begins at age 50 and is not routinely done after 75 unless clinically indicated).

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7. Sample Size:

No similar study was found in the literature. There are three independent groups:

- Video group,
- No visual group,
- Image group.
- Assuming an alpha (α) level of 0.05 and a beta (β) level of 0.20 (power of 80%), and an effect size (Cohen's f) of 0.40, it was calculated that approximately 26 participants per group (78 in total) would be required to detect meaningful differences between the three groups.

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8. Inclusion Criteria:

- Male patients aged 50–80
- Biopsy planned due to elevated PSA
- Voluntary participation

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9. Exclusion Criteria:

- Organic mental disorders, dementia, depressive and anxiety disorders, PTSD, acute psychotic or bipolar disorders
- Patients with cognitive or physical impairments that prevent informed consent (e.g., blindness, moderate to severe mental retardation)
- Panic disorder diagnosis
- Patients with pre-procedure VAS ≥ 5, suggestive of significant anxiety-stress disorders

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10. Withdrawal Criteria:

- Participants may withdraw at any time.
- Patients who become excessively anxious or restless during biopsy will have the procedure rescheduled under general anesthesia and be excluded from the study.

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11. Parameters to be Measured:

- Age
- PSA levels
- Subjective findings of rectal examination
- Post-procedure complications
- Anxiety and stress scores (STAI-I and II, pre-op and post-op)
- Pain scores (VAS)

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12. Where and by Whom Parameters Will Be Collected:

All patients will be recruited from the Urology outpatient clinics of Etlik City Hospital. Assessments will be carried out by Clinical Urology Physicians.

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13. Routine vs. Study-Specific Parameters:

All parameters are part of routine clinical evaluations for patients with high PSA. No study-specific laboratory or additional tests will be requested.

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14. Estimated Study Duration:

- Start: 10.12.2023
- End of patient recruitment: 30.12.2024
- 12 months of data collection, 5 months for manuscript preparation and submission
- Total: 17 months

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15. Study Endpoint:

- The study will conclude on 20.05.2025

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16. Criteria for Termination:

- Data collection will end once sufficient data is collected.

17. Outcome Evaluation:

The primary endpoint is the tabulation and statistical analysis of STAI responses before and after the procedure among different groups. The secondary endpoint is the writing and publication of the study results.

Previous literature has shown that prostate biopsy induces anxiety and depression. Zisman et al., in a prospective study of 211 men, found that 64% experienced decreased well-being and anxiety from the pre-biopsy period up to 30 days after. Fowler et al. showed that anxiety may persist for up to 12 months, even in patients with negative biopsy results. Our study seeks to answer whether pre-procedural videos intensify the anxiety already known to be associated with the biopsy.

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18. Statistical Analysis:

Both parametric tests (t-test, ANOVA, Pearson correlation, linear regression) and non-parametric tests (Wilcoxon, Mann-Whitney U, Kruskal-Wallis, Friedman, Spearman correlation) will be used.

Descriptive statistical analyses will be performed using SPSS software (version 20, SPSS Inc., Chicago, USA).

Name / Signature

Principal Investigator:
Fatih SANDIKÇI

Statistical Analysis

All statistical analyses were performed using SPSS software [insert version]. Continuous variables were expressed as mean ± standard deviation, and categorical data as frequencies and percentages. Group comparisons were made using the Kruskal-Wallis test for non-parametric data and ANOVA for normally distributed data. Post-hoc pairwise comparisons were conducted using the Mann-Whitney U test with Bonferroni correction. A p-value <0.05 was considered statistically significant. A priori power analysis was conducted using G*Power

software version 3.1.9.7 to determine the adequate sample size. Assuming an alpha (α) level of 0.05 and a beta (β) level of 0.20 (power of 80%), and an effect size (Cohen's f) of 0.40, it was calculated that approximately 26 participants per group (78 in total) would be required to detect meaningful differences between the three groups.