Study Protocol with Statistical Analysis Plan

Official Title: Evaluation of the Effect of Catheter Duration on Prostate Laser Enucleation Surgery Outcomes in Patients With Indwelling Catheters Due to Urinary Retention: A Multicenter Study of the Minimally Invasive Urology Society

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1. Background and Rationale

Benign prostatic obstruction (BPO) is a prevalent condition in aging men, often leading to urinary retention that requires the management of an indwelling urinary catheter. Laser enucleation of the prostate, including Holmium (HoLEP), Thulium (ThuLEP), and Thulium Fiber (ThuFLEP), has emerged as the gold standard for surgical treatment. However, it remains unclear how the duration of preoperative catheterization affects the final functional recovery. This study aims to investigate whether a specific threshold of catheterization duration impacts surgical success and patient-reported outcomes.

2. Objectives

Primary Objective

To compare the 3 month functional outcomes (IPSS, Qmax, and PVR) between patients with short-term and long-term preoperative catheterization following laser enucleation.

Seconder Objective

- To evaluate perioperative complication rates according to the Clavien-Dindo classification.
- To assess the length of hospital stay and postoperative catheterization duration.
- To monitor hemoglobin changes and transfusion requirements.

3. Study Design

Type: Prospective, multi-center, observational cohort study.

Setting: Multiple tertiary urology centers affiliated with the Minimal Invasive Urology Society (MIUS).

Study Groups:

- **Group 1 (Short-term):** Preoperative catheterization less than the average of groups
- **Group 2 (Long-term):** Preoperative catheterization for more than the average of groups

4. Eligibility Criteria

Inclusion Criteria

- Diagnosis of BPO with urinary retention requiring an indwelling catheter.
- Scheduled for laser enucleation of the prostate (HoLEP, ThuLEP, or ThuFLEP).
- Ability to provide informed consent.

Exclusion Criteria:

- Known or suspected prostate cancer (malignancy).
- Diagnosis of neurogenic bladder dysfunction.

5. Study Procedures

Eligible patients will be divided into two cohorts based on their catheterization duration prior to surgery. Standard surgical protocols for laser enucleation will be followed. Demographic data, preoperative parameters, and intraoperative details will be recorded. Patients will be followed for 3 months postoperatively.

6. Outcome Measures

Primary Outcome Measure:

Functional Recovery at 3 Months: Change from baseline in International Prostate Symptom Score (IPSS), Peak Urinary Flow Rate (Qmax), and Post-Void Residual (PVR) volume.

Secondary Outcome Measures:

Postoperative Complication Rate: Graded by Clavien-Dindo classification

Hospital Stay: Number of days from surgery to discharge.

Hemoglobin Drop: Difference between preoperative and 24-hour postoperative hemoglobin levels.

7. Statistical Analysis Plan

General Principles:

Data will be analyzed using standard statistical software. Continuous variables will be presented as means (SD) or medians (IQR), and categorical variables as frequencies (%).

Comparative Analysis:

- The primary analysis will compare the change in functional parameters (IPSS, Qmax, PVR) between the two cohorts using independent samples t-test or Mann-Whitney U test, as appropriate.
- Chi-square or Fisher's exact test will be used for categorical complications data.
- A p-value of <0.05 will be considered statistically significant.

8. Ethical Considerations

- The study will be conducted in accordance with the Declaration of Helsinki. Approval has been obtained from the local Ethics Committee. All patient data will be anonymized before central analysis.