Study Protocol with

Statistical Analysis Plan

Official Title: Minimal Invasive Urology Society Benign Prostatic Obstruction (BPO) Study Group Data Collection Project

NCT Number: Not yet assigned

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1. Background and Rationale

Benign prostatic obstruction (BPO) is a highly prevalent condition among aging men and remains a leading indication for surgical intervention. Various surgical techniques are available worldwide, including transurethral resection of the prostate (TURP), laser enucleation, open or robotic simple prostatectomy, and minimally invasive modalities. Despite widespread use, robust multicenter data comparing real-world outcomes remain limited.

The Multicenter International Urological Surgery Registry for Benign Prostatic Obstruction (MIUS-BPO) is designed as a prospective registry to collect comprehensive clinical, procedural, and outcome data across multiple centers. The registry will facilitate descriptive analyses and provide a foundation for hypothesis-driven research in the future.

2. Objectives

Primary Objective

To establish a prospective, multi-center data registry describing patient demographics, baseline characteristics, perioperative details, and postoperative outcomes of BPO surgeries.

Secondary Objectives

- To identify trends in surgical practice patterns across institutions.
- To monitor short- and long-term perioperative and functional outcomes.
- To provide a platform for future hypothesis-driven comparative studies.

3. Study Design

- **Type:** Prospective, multi-center, observational data registry.
- **Duration:** Ongoing registry with no fixed termination date.
- **Setting:** Academic and community urology centers participating internationally.
- **Population:** Adult male patients undergoing surgery for benign prostatic obstruction.

4. Eligibility Criteria

Inclusion Criteria

- Male patients aged ≥ 40 years.
- Undergoing surgical intervention for BPO (any technique, including TURP, laser-based, open, robotic, or minimally invasive approaches).
- Ability to provide informed consent, where required.

Exclusion Criteria

- Surgery performed primarily for malignant disease (e.g., prostate cancer).
- Incomplete baseline or procedural data.

5. Study Procedures

- Collection of baseline demographic and clinical characteristics.
- Documentation of surgical technique and perioperative details.
- Postoperative outcomes, complications, and follow-up information.
- Data entry into a secure electronic case report form (eCRF).

6. Outcome Measures

Primary Outcome Measure

- Descriptive statistics of baseline characteristics, perioperative parameters, and early postoperative outcomes.

Secondary Outcome Measures

- Complication rates (graded by Clavien–Dindo classification).
- Length of hospital stay.
- Re-intervention rates.
- Patient-reported outcomes where available (e.g., IPSS, QoL indices).

7. Statistical Analysis Plan

General Principles

- Analyses will primarily be descriptive at this stage, reflecting the registry's observational and hypothesis-generating nature.
- Continuous variables will be summarized using means (±SD) or medians (IQR) as appropriate.
- Categorical variables will be presented as frequencies and percentages.

Future Analyses

At the time of registry initiation, no specific hypothesis has been formulated. Analyses will primarily be descriptive. Future inferential and comparative analyses will be defined and pre-

specified based on scientific questions arising from the accumulated dataset and may require separate protocol amendments and/or statistical analysis plans.

Note: Future studies using registry data will be registered separately on ClinicalTrials.gov with their own prespecified hypotheses and SAPs.

8. Ethical Considerations

- Approval obtained from local Ethics Committees/IRBs where required.
- Informed consent will be collected in accordance with local regulations.
- Data will be anonymized before central analysis.

9. Dissemination Plan

- Registry results will be published in peer-reviewed journals.
- Interim descriptive analyses may be presented at international urology meetings.
- Authorship will follow ICMJE criteria.