STUDY PROTOCOL

Bipolar Plasmakinetic TURP Versus Monopolar TURP in the Treatment of Lower Urinary Tract Symptoms (LUTS) Due to Benign Prostatic Hyperplasia (BPH)

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Patients

Men clinically diagnosed with LUTS in a tertiary-care public institution and who required surgical treatment were invited to participate in the study from December 2014 to August 2016. Inclusion criteria were prostate volume (PV) <80g on transrectal ultrasound (TRUS) with LUTS due to drug-refractory BPH or complications derived from BPH (acute urinary retention (AUR), recurrent hematuria, recurrent urinary tract infection (UTI) or bladder calculi) or both. Patients with a previous history of pelvic surgery or radiotherapy, neurogenic bladder dysfunction, or prostate carcinoma were excluded.

Randomized group assignment was ensured by using a table of aleatory numbers. Only patients who were willing to continue participating in the trial after surgery, filled all the questionnaires during the follow-up and did not present any malignancy requiring additional treatment, were eligible for inclusion in the analyses. An intention to treat analysis was conducted and, as usual for surgical trials, only patients were blinded to the procedure. Ethical approval of the institutional review board (IRB) (APR-14-72) was granted, and informed consent was obtained from all subjects.

Study variables

Baseline characteristics included age, comorbidities, American society of anesthesiologists classification (ASA), laboratory values including prostate-specific antigen (PSA), international prostate symptom score (IPSS), maximum urinary flow rate (Qmax), post voiding residual urine (PVRU) volume, PV by TRUS, QoL score, sexual activity and international index of erectile function (IIEF-5). Direct questions were included to evaluate stress urinary incontinence (SUI), urge urinary incontinence with or without the need for drug use (UUIND and UUIWND), retrograde ejaculation, and dysuria. Drugs for LUTS and hemostasis used before surgery were recorded.

Operative outcomes included irrigation volume, operation time (from the first cut to catheter placement), changes in serum sodium and hemoglobin, amount of resected tissue, speed of resection (dividing resected tissue by operative time), length of stay and length of the indwelling catheter.

Intraoperative, perioperative, and postoperative complications and sequelae at 1, 3, 6, and 12 months were recorded; when applied, complications were classified according to the Clavien-Dindo system (CDS). To measure bleeding, the variable hemorrhagic complications (HC) was created by grouping hematuria and clot retention. Efficacy outcomes (IPSS, QoL score, Qmax, PVRU volume, and PV by TRUS) and sexual function (sexual activity and IIEF-5 questionnaire) were recorded for the same periods.

Treatment failure was characterized by the need for a re-TURP (residual adenoma), readmission or reoperation, or by recurrent UTI.

Surgical technique

Patients were operated by residents and senior urologists, as per the usual daily practice at our teaching institution. M-TURP was conducted with a 26-Ch Olympus/Storz resectoscope under continuous glycine irrigation (1.5% glycine, Baxter), using a monopolar stainless-steel loop connected to a ForceTriad™ generator (Medtronic) (cutting and coagulation, 120W and 80W). PK-TURP was performed with a 26-Ch Storz resectoscope under continuous irrigation with saline solution (0.9% NaCl, Baxter), using a bipolar Superloop platinum-iridium (Gyrus ACMI) resection loop connected to a Plasma Kinetic™ Superpulse generator (Gyrus-ACMI) (180W and 100W). The irrigation liquid was placed 2 meters above the ground in all cases, with the surgical table at 80cm from the floor. A Neptune 2® (Stryker) continuous aspiration system was used during surgery at 80mmHg. Nesbit technique was performed in both groups. All procedures were performed under spinal anesthesia. Recovered tissue was collected and submitted for pathological exam. At the end of both procedures, a 22-Ch three-way Foley catheter was placed into the bladder with a closed drainage system. Continuous irrigation with saline solution was initiated at the end of the procedure and interrupted 24 hours after surgery; the irrigation was definitively withdrawn after 4 hours of clear urine (defined as being able to read the newspaper headline through the urine collection tube). Patients were discharged on the first postoperative day, and the catheter was removed

ambulatory 72 hours after surgery (if clear urine). Blood tests were performed before discharge.

Statistical analysis

The sample size was calculated to detect differences ≥3 points in the IPSS questionnaire. An α-error of 5% and a power of 80% were established. The sample size was calculated using the STATA® program, and 20% patient loss was assumed during follow-up. Comparisons were conducted using the chi-square/Fisher test and T-Student/Mann-Whitney test as needed. Statistical significance was established at $p<0.05$ for all analyses. Statistical analysis was performed using the IBM-SPSS v23.0 statistics.