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Platinum Priority – Benign Prostatic Obstruction

Editorial by Jean-Nicolas Cornu and Stephan Madersbacher on pp. 103–104 of this issue

A Multicenter Randomized Noninferiority Trial Comparing GreenLight-XPS Laser Vaporization of the Prostate and Transurethral Resection of the Prostate for the Treatment of Benign Prostatic Obstruction: Two-yr Outcomes of the GOLIATH Study

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Abstract

Background: The GOLIATH study is a 2-yr trial comparing transurethral resection of prostate (TURP) to photoselective vaporization with the GreenLight XPS Laser System (GL-XPS) for the treatment of benign prostatic obstruction (BPO). Noninferiority of GL-XPS to TURP was demonstrated based on a 6-mo follow-up from the study.
Objective: To determine whether treatment effects observed at 6 mo between GL-XPS and TURP was maintained at the 2-yr follow-up.
Design, setting, and participants: Prospective randomized controlled trial at 29 centers in nine European countries involving 281 patients with BPO.
Intervention: Photoselective vaporization using the 180-W GreenLight GL-XPS or conventional (monopolar or bipolar) TURP.
Outcome measurements and statistical analysis: The primary outcome was the International Prostate Symptom Score for which a margin of three was used to evaluate the noninferiority of GL-XPS. Secondary outcomes included Q_{max}, prostate volume, prostate specific antigen, Overactive Bladder Questionnaire Short Form, International Consultation on Incontinence Questionnaire Short Form, occurrence of surgical retreatment, and freedom from complications.
Results and limitations: One hundred and thirty-six patients were treated using GL-XPS and 133 using TURP. Noninferiority of GL-XPS on International Prostate Symptom Score, Q_{max}, and freedom from complications was demonstrated at 6-mo and was sustained at 2-yr. The proportion of patients complication-free through 24-mo was 83.6% GL-XPS versus 78.9% TURP. Reductions in prostate volume and prostate specific antigen were similar in both arms and sustained over the course of the trial. Compared with the 1st yr of the study, very few adverse events or retreatments were reported in either arm. Treatment differences in the Overactive Bladder Questionnaire Short Form observed at 12-mo were not statistically significant at 24-mo. A limitation was that patients and treating physicians were not blinded to the therapy.
Conclusions: Twenty-four-mo follow-up data demonstrated that GL-XPS provides a durable surgical option for the treatment of BPO that exhibits efficacy and safety outcomes similar to TURP.
Patient summary: The long-term effectiveness and safety of GLP-XLS was similar to conventional TURP for the treatment of prostate enlargement.

1. Introduction

The incidence of benign prostatic hyperplasia (BPH) is 50–60% in the 6th decade of life and increases to 80–90% in the 7th and 8th decades of life [1]. Due to the progressive nature of the disease, many men initially treated with conservative therapies require surgical intervention to relieve their symptoms. Previously, we reported [2,3] the 6-mo and 12-mo results of a clinical trial comparing GreenLight XPS Laser System (GL-XPS) with transurethral resection of prostate (TURP) for efficacy and safety (The GOLIATH study) in the treatment of benign prostatic obstruction (BPO). This large, prospective, randomized study demonstrated that GL-XPS vaporization of the prostate (PVP) was noninferior to TURP with respect to International Prostate Symptom Scores (IPSS), Q_{max}, and proportion of patients free of complications. Time-to-stable health status, catheterization time, length of hospitalization, and immediate surgical reintervention rates (within 30 d postoperation) were statistically significant in favor of GL-XPS.

Herein we report 2-yr study results with an emphasis on the assessment of durability: sustained reduction in BPO signs and symptoms, retreatments, quality of life (QoL), and safety. This analysis is intended to provide practitioners with contemporary high quality long-term data on the outcomes of both techniques.

2. Patients and methods

2.1. Patients

To be randomized, patients had to be candidates for the surgical relief of BPO, with IPSS scores of $\geq$12 and prostate sizes $\leq$100 g. The complete list of inclusion/exclusion criteria was previously published [2] (see Supplementary data). The trial was conducted under the oversight of country specific ethics committees, and all patients underwent an ethics committee approved informed consent process. The enrollment of patients was the responsibility of the principal investigator at each clinical center. The trial was registered at www.clinicaltrials.gov (NCT01218672).

2.2. Study design

The study was an open-label, multicenter, prospective, randomized, and controlled noninferiority trial comparing GL-XPS and TURP with a 24-mo follow-up. The trial was conducted at 29 centers in nine European countries with the primary endpoint being IPSS at 6-mo. Secondary outcomes included assessments of BPH Impact Index (assessed up to Mo 3), Q_{max}, proportion of patients classified as complication-free, post void residual (PVR), prostate-specific antigen (PSA), and prostate volume ascertained with transrectal ultrasonography. Lower urinary tract symptoms, erectile function, and QoL were assessed using validated questionnaires (Overactive Bladder Questionnaire–short form Symptoms [OABq-SF], OABq-SF Health, International Consultation on Incontinence Questionnaire-Urinary