

GreenLight™ Laser (XPS) Photoselective Vapo-Enucleation versus Holmium Laser Enucleation of the Prostate for the Treatment of Symptomatic Benign Prostatic Hyperplasia: A Randomized Controlled Study

Ahmed M. Elshal, Mohamed A. Elkoushy, Ahmed R. El-Nahas, Ahmed M. Shoma, Adel Nabeeh, Serge Carrier and Mostafa M. Elhilali*,†

From the Urology Division, McGill University, Montreal, Canada (AME, MAE, SC, MME); Mansoura Urology and Nephrology Center, Mansoura (AME, ARE, AMS, AN), and Department of Urology, Suez Canal University, Ismailia (MAE), Egypt

Purpose: After the advent of the GreenLight XPS™ (180 W) 532 nm laser, photoselective vapo-enucleation of the prostate could compete with holmium laser enucleation of the prostate as a size independent procedure. We assessed whether photoselective vapo-enucleation of the prostate-XPS is not less effective than holmium laser enucleation of prostate for improvement of lower urinary tract symptoms secondary to benign prostatic hyperplasia.

Materials and Methods: A randomized controlled noninferiority trial comparing holmium laser enucleation of the prostate to photoselective vapo-enucleation of the prostate-XPS 180 W was conducted. I-PSS, flow rate, residual urine, prostate specific antigen and prostate volume changes as well as perioperative and late adverse events were compared. Noninferiority of I-PSS at 1 year was evaluated using a 1-sided test at 5% level of significance. The statistical significance of other comparators was assessed at the (2-sided) 5% level.

Results: Overall 50 and 53 patients were included in the holmium laser enucleation and photoselective vapo-enucleation of the prostate groups, respectively. Operative time, hospital stay and time to catheter removal were comparable between the groups. There was significant, comparable improvement in I-PSS and post-void residual urine volume at 1, 4 and 12 months. After 4 months prostate size reduction was significantly higher in the holmium laser enucleation of prostate group (74.3% vs 43.1%, $p=0.001$). At 12 months maximum urine flow rate was significantly higher in the holmium laser enucleation of prostate group (26.4 ± 11.5 vs 18.4 ± 7.5 ml per second, $p=0.03$). Re-intervention was needed in 2 and 3 cases in the holmium laser enucleation and photoselective vapo-enucleation of the prostate groups, respectively ($p=1.0$). Mean estimated cost per holmium laser enucleation of prostate procedure was significantly lower than per photoselective vapo-enucleation of the prostate procedure.

Conclusions: Compared to holmium laser enucleation of prostate, GreenLight XPS laser photoselective vapo-enucleation of the prostate is safe, noninferior and effective in treatment of benign prostatic hyperplasia.

Abbreviations and Acronyms

5ARI = 5 α -reductase inhibitor

BPH = benign prostatic hyperplasia

CAD = Canadian dollars

HoLEP = holmium laser enucleation of prostate

IIEF-15 = International Index of Erectile Function

I-PSS = International Prostate Symptom Score

LUTS = lower urinary tract symptoms

PSA = prostate specific antigen

PVEP = photoselective vapo-enucleation of the prostate

PVP = photoselective vaporization of the prostate

PVR = post-void residual urine volume

Qmax = maximum urine flow rate

QOL = quality of life

TRUS = transrectal ultrasound

TURP = transurethral resection of prostate

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* Correspondence: Division of Urology, McGill University, Royal Victoria Hospital, 687 Pine Ave. West., Room S6.95, Montreal, Quebec H3A

1A1 Canada (telephone: 514-843-1516; FAX: 514-843-1552; e-mail: mostafa.elhilali@muhc.mcgill.ca).

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TRANSURETHRAL resection of the prostate was almost always referred to as the gold standard treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. However, the perioperative morbidity increased with resection of prostates larger than 60 gm.¹ These complications might even be higher with open prostatectomy, for which a blood transfusion rate of 24.7% and perioperative morbidity of 42.6% have been reported.² In 1998 holmium laser enucleation of the prostate was introduced,³ and was found to be equivalent to open prostatectomy⁴ and TURP with superior urodynamic relief of obstruction in HoLEP.^{5,6} Furthermore, HoLEP has no size limits,⁷ is safe in patients on anticoagulation⁷ and is durable.⁸ However, the remaining concern with HoLEP is the relatively long learning curve.

GreenLight 532 nm laser PVP is an appealing treatment modality with hemoglobin as tissue target chromophore and relatively short learning curve.⁹ However, with earlier generations of GreenLight laser, the improvement in the symptoms score and flow rate was disproportionate between small and large glands, with a higher re-treatment rate noted when treating large glands.¹⁰

Introduction of the XPS-180 W with adoption of the enucleation principle in accomplishing the ablation process make it a real contender to HoLEP in treating BPH and control of LUTS. Recently data from the GOLIATH trial showed that PVP is not inferior to TURP with reduced side effects, catheterization time and hospital stay.¹¹ Moreover the literature is striving for trials comparing 180 W XPS 532 nm laser with other competitors.¹² Therefore, in this study we prospectively assessed the noninferiority of the GreenLight XPS vapo-enucleation of the prostate vs HoLEP in reduction of LUTS secondary to BPH in a randomized controlled trial.

PATIENTS AND METHODS

Study Design and Enrollment

After receiving institutional review board approval patients were recruited in the study between January 2012 and March 2013. Inclusion criteria were patient age greater than 50 years, refractory LUTS secondary to BPH, I-PSS greater than 15, QOL score 3 or greater, Qmax less than 15 ml per second or patients with acute urinary retention secondary to BPH in whom trial of voiding failed, and prostate size on preoperative TRUS of 40 to 150 ml. Patients with neurological disorder, active urinary tract infection, active bladder or prostate cancer were excluded.

Randomization

Computer generated random tables in a 1:1 ratio were used. Patients were randomly assigned to one of the treatment groups by stratified-blocked randomization across 2 strata derived from predetermined size grouping (40 to 80 ml and more than 80 ml) and 2 strata derived from preoperative indication (catheterized and non-catheterized). Preoperative evaluation included serum PSA, urinalysis and urine culture, I-PSS, QOL, IIEF-15, TRUS and biopsy whenever indicated, and measurement of PVR and Qmax.

Intervention

Procedures were performed by a single surgeon (MME) who has performed more than 1,200 HoLEP and 400 GreenLight procedures. A similar size, 26Fr resectoscope was used for both procedures. In case of coexisting urinary bladder stone, holmium laser cystolithotripsy was done first. For HoLEP, enucleation of the adenoma followed by intravesical morcellation was performed as previously described.¹³ For PVEP the GreenLight 532 nm XPS-180 W with MoXy™ fiber was used. Our technique is similar to thulium laser vapo-enucleation of the prostate¹⁴ with early identification of the capsule by blunt dissection of the adenoma.¹¹ Starting with 80 W at the bladder neck, a side-to-side sweeping movement of the side firing fiber was done from the area of the bladder neck to just lateral to the verumontanum, creating a working channel up to the capsule. The adenoma was partially enucleated bluntly but remained attached anteriorly followed by introducing the scope using the same sweeping movement of the fiber through the space created underneath 1 lateral lobe (vapo-enucleation principle). As more space was created the landmarks became clearer and the energy was increased up to 180 W. Dissection of the left and right lobes stopped at 3 and 9 o'clock, respectively, and restarted at 12 o'clock. The same maneuvers were performed to dissect the adenoma downward toward the 3 and 9 o'clock position. In the presence of a prominent median lobe, the deepest groove at the bladder neck (5 or 7 o'clock) was chosen to start creating the working channel. One lateral lobe was ablated followed by vapo-enucleation of the median lobe starting at the bottom of the working channel in front of the verumontanum underneath the median lobe sweeping the tissue off the capsule. Vaporization of the apical tissue was done at the conclusion of the procedure. The created TURP-like cavity was inspected after emptying the bladder for further hemostasis.

The patient would have the catheter removed in the recovery room or sent home with the catheter if the urine was sufficiently clear and the surgeon was comfortable about early catheter removal. Otherwise, patients were kept overnight with bladder irrigation and a voiding trial attempted the next morning once the urine was clear.

Outcome Measures

The primary outcome was I-PSS at 12 months. Our hypothesis was that PVEP-XPS and HoLEP might be comparable in improving LUTS. The outcome variables

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