(PD61-10) GreenLight (532nm) laser (XPS) Photoselective Vapo-Enucleation of the Prostate (PVEP) vs. Trans-Urethral Resection of the prostate in saline (TURis) vs. Holmium Laser Enucleation of the Prostate (HOLEP) for Treatment of Moderate To Large Sized Benign Prostatic Hyperplasia: A Randomized Controlled Trial.

Authors

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- Over the past decade, multiple new treatment modalities for BPH have been introduced.
- New minimally invasive surgical therapies (MIST), new medications, and novel combinations of medical therapies have expanded the number of treatment options ranging from watchful waiting to open surgery.



TURP remained the gold standard treatment of mild to moderate sized BPH, however the rate of complications significantly increased when tackling large sized BPH.

Reich, Gratzke et al. 2008



A Prospective Multicenter Evaluation of 10,654				
TURP Patients from Germany				

Resected wt, (gm)	Transfusion	TUR syndrome	Surgical revision	UTI	Mortality	
≤30	2	1.2	5.2	3.7	0.09	
30-60	3.4	1.4	6.2	3.5	0.06	
≥60	9.5	3	9.8	4.5	0.71	
Overall	2.9	1.4	5.6	3.6	0.1	
			<u>Reich et al 2008</u>			



- The morbidity of open simple prostatectomy is even higher than monopolar TURP.
- Serretta et al. reported on a series of simple prostatectomies performed between 1997 and 1998. Of 31,558 patients treated for symptomatic BPH, 5636 underwent open surgery. Severe bleeding occurred in 11.6%, blood transfusions in 8.2% of cases, *sepsis* was reported in 8.6% of the patients and *re-intervention* within 2 years was reported in 3.6% of cases. rology and Nephrology Center Serretta, Morgia et al. 2002

In an effort to limit surgical morbidity, variety of minimally invasive surgical techniques to treat BPH have expanded greatly over the past 2 decades.

Although a growing body of knowledge exists investigating the overall safety and efficacy of such procedures, little of evidence remains regarding the safety and efficacy of these procedures in the management of large prostates ≥ 80 gm in size.

Gratzke, Schlenker et al. 2007



The treatment options include prostate vaporization, resection and enucleation using various energy sources and using physiological saline as an irrigant nullifying the risk of TUR syndrome

Yoon, Kim et al. 2006



Current guidelines state that for large sized prostate open prostatectomy is the standard procedure unless HoLEP is available

AUA 2012 & EAU2015 guidelines



Evolution of bipolar technology revives the concept of transurethral resection for treatment of large sized BPH particularly that it nullifies the risk of TUR syndrome

# Namely, TURiS

Mamoulakis et al 2009



# **Introduction:**

- As well, the recent evolution in the technology of greenlight laser (532nm laser) :
- 1. XPS<sup>™</sup> system "180W"
- Durable and
   efficient MoXy<sup>™</sup>
   fiber





 Furthermore, with adoption of enucleation principles, advocates of Greenlight laser technology suggest greenlight prostate vaporization as an effective alternative Namely, *Greenlight PVEP*

Elshal, Shoma et al. 2015



# Aim of the work



To assess the noninferiority of transurethral resection in saline (TURiS) and Greenlight laser Vapo-Enucleation of the prostate (GL.PVEP) to Holmium laser enucleation of the prostate (HOLEP) for controlling lower urinary tract symptoms (LUTs) secondary to large sized benign prostate hyperplasia (BPH) with comparable 3 yearsretreatment rate.

# **Materials and Methods:**

- Trial ID: ClinicalTrials.gov, NCT02332538
- After IRB approval, consented patients with BPH more than 80ml were randomly assigned to one of the intervention groups.
- HoLEP and GL.PVEP (XPS) were performed as we previously described. TURis was performed classically according to Mauermayer's technique.
- Non-inferiority of retreatment rate was evaluated using a 1-sided test at 5% level of significance.



- At time of analysis, 60 GL.PVEP, 60 HoLEP and 62 TURis procedures were included.
- Baseline patients` demographics, prostate size and indications of intervention were comparable.



 All perioperative parameters were comparable between groups (table 1) however; longer operative time (92 + 32, 73 +30 and 83 +28 min, P=0.005) and less operative efficiency (1.2 +0.4, 1.7 +0.7 and 1.4 +0.6gm/min, P=0.000) have been reported in GL.PVEP vs. HoLEP and TURis respectively.



 All perioperative complications and need for conversion were similar in the three groups however significantly higher rate of capsular violation 5, 8% was reported in TURis group compared to 1, 1.6% in GL.PVEP and none in HoLEP, p=0.01.



 Significantly longer hospital stay and time to catheter removal was reported following TURis. Furthermore, significantly more drop in post-operative Hemoglobin and haematocrit value was reported following TURis with subsequent higher rate of blood transfusion was depicted in TURis group table 1.



• There was significant comparable improvement in IPSS in 3 groups at different follow up points. Among patients without need for retreatment, median IPSS and Q.max at 3-years was 5 (1:12) vs. 4 (1:13) vs. 5.2 (2:14) and 25 (15:35) vs. 28.8 (19:34) vs. 22 (17:29) ml/sec, P=0.4 and 0.3 following GL.PVEP vs. HoLEP and TURis respectively.



 After 3 years, retreatment for recurrent BOO was significantly higher following TURIS and GL.PVEP in contrast to HoLEP. table 2.



# **Results: (Table 1; perioperative data)**

Table 1; perioperative data	GL.PVEP	HoLEP	TURIS	Р		
Number of patients	60	60	62			
Preoperative data						
Mean age at time of surgery ( <u>+</u> SD) years	64.5 <u>+</u> 6	66.2 <u>+</u> 7	66.1 <u>+</u> 7	0.3		
Mean TRUS-estimated prostate volume ( <u>+</u> SD) ml	103 <u>+</u> 25	107 <u>+</u> 21	106 <u>+</u> 23	0.6		
Number of catheterized patients (%)	25 (42)	32 (53)	21 (39)	0.09		
Operative data						
Mean operative time ( <u>+</u> SD) min)	92 <u>+</u> 32	73 <u>+</u> 30	83 <u>+</u> 28	0.005		
Mean operative efficiency (preoperative prostate weight divided by operative time) ( <u>+</u> SD) gm/min)	1.2 <u>+</u> 0.4	1.7 <u>+</u> 0.7	1.4 <u>+</u> 0.6	0.000		
Mean volume of intraoperative irrigation ( <u>+</u> SD) Liters	38 <u>+</u> 11	37 <u>+</u> 13	33 <u>+</u> 14	0.17		
Auxiliary measures (Monopolar TUR)						
For hemostasis	1	1		0.3		
Machine failure			2			
Perioperative outcome						
Median hospital stay in days (range)	1 (1:8)	1 (1:5)	2 (2:10)	0.000		
Median time to catheter removal in days (range)	1 (1:5)	1 (1:4)	2 (2:7)	0.01		
Median dysuria analogue scale (range) at 2 weeks	4 (0:10)	2 (0:10)	2 (0:10)	0.1		
Median HB-Deficit gm/dl (range)	0.5 (0.1:2.7)	0.65 (0.1:5)	1.2 (1:4)	0.002		
Median HCV-Deficit % (range)	5.7 (-12:57)	5.4 (-8:90)	9.1 (-14:90)	0.047		

#### **Results:** (Table 2: Perioperative and delayed postoperative complications)

Table 2: Perioperative and delayed postoperative complications	Clavien- Dindo grade	Management	GL.PVEP	HoLEP	TURIS	Р		
Perioperative (intraoperative and 1 <sup>st</sup> 30 days) No (%)								
Capsular violation	I	Prolonged catheter drainage	1 (1.6)		5 (8)	0.01		
Bladder wall injury	I	Prolonged catheter drainage	1 (1.6)			1		
Retention/ re-catheter	I	Catheterization & repeat voiding trial	2 (3.3)		1 (1.6)	1		
Epididymo-orchitis	II	Antibiotics & lead-subacetate foments	1 (1.6)			1		
Uro-sepsis	II	Systemic antibiotics & ICU measures	1 (1.6)			1		
Anemia necessitating blood transfusion	II	Blood transfusion			4 (6.5)	0.03		
Postoperative hematuria			5 (8.3)	4 (6.6)	3 (4.8)	0.1		
Conservative	II	Continuous bladder irrigation	5 (8.3)	3 (5)	3 (4.8)			
Hemostasis	Illa	Cystoscopic haemostasis		1 (1.6)				
	Delayed	postoperative (after 30 days) No (%)						
Recurrent BOO No (%)			16 (26.7)	3 (5)	17 (27.4)	0.03		
Residual/ recurrent obstructive LUTs	Ш	Resume Alpha blockers; control LUTs	12 (20)	2 (3.3)	11 (17.7)	0.01		
• LUTs with residual prostate adenoma	Illa	Redo for adenoma (TURP)	4 (6.7)		6 (9.7)	0.04		
Bladder neck contracture	Illa	Bladder neck incision		1 (1.6)		0.3		
Persistent urge urine incontinence	II	anticholinergic medicines	7 (11.7)	6 (10)	6 (9.7)	0.3		
Persistent Stress urine incontinence; patient subjective reporting			4 (6.7)	9 (15)	2 (3.2)	0.2		
<ul> <li>1-hour pad test*, Grade Zero (dry pad)</li> </ul>	I	Pelvic floor exercise	2 (3.3)	7 (11.7)	1 (1.6)			
• 1-hour pad test*, Grade I (< 10gm)	I	Pelvic floor exercise	1 (1.6)	1 (1.6)				
• 1-hour pad test*, Grade II (11-50gm)	Illa	Anti-incontinence surgery	1 (1.6)	1 (1.6)				
<ul> <li>1-hour pad test*, Grade III (51- 100gm)</li> <li>BOO: bladder outlet obstruction, LUTs: low/</li> </ul>	Illa	Anti-incontinence surgery			1 (1.6)			

BOO: bladder outlet obstruction, LUTs: lower urinary tract symptoms, \* Abrams P et al 2003

## **Conclusion:**

- The perioperative outcome of GL.PVEP and HoLEP surpasses that of TURIS for treatment of large sized prostate with significantly more operative time with GL.PVEP.
- The three techniques achieve good functional outcome however 3-years retreatment rate following TURIS and GL.PVEP was inferior to HoLEP.



