

# A prospective, randomized comparison of a 1940 nm and a 2013 nm thulium: yttrium–aluminum–garnet laser device for Thulium VapoEnucleation of the prostate (ThuVEP): First results

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## ABSTRACT

**Introduction:** We report the early postoperative results of the first prospective, randomized comparison of two commercially available thulium lasers with different wavelengths for the treatment of benign prostatic obstruction (BPO).

**Materials and Methods:** From January to June 2013, 80 consecutive patients were randomized for Thulium VapoEnucleation of the prostate (ThuVEP) with a 2013 nm (RevoLix®) ( $n = 39$ ) or a 1940 nm (Vela® XL) ( $n = 41$ ) thulium laser. Preoperative status, surgical details and the immediate outcome were recorded for each patient. The perioperative complications were assessed and classified according to the modified Clavien classification system.

**Results:** Median operation time, resected tissue, percentage of resected tissue, catheter time, overall operation efficiency and Hb loss differed nonsignificantly between both devices ( $P > 0.05$ ). At discharge, the median maximum urinary flow rate and postvoiding residual (PVR) urine improved significantly in both groups ( $P < 0.001$ ). The PVR was lower in the 1940 nm ThuVEP group ( $P \leq 0.034$ ). Perioperative complications occurred in 18 (22.5%) patients (Clavien 1: 12.5%; Clavien 2: 5%, Clavien 3b: 2.5%, Clavien 4a: 2.5%), with no differences between the groups ( $P = 0.5$ ).

**Conclusions:** The 1940 nm and the 2013 nm thulium lasers are both safe and effective for the treatment of BPO with ThuVEP. Both lasers give equivalent and satisfactory immediate micturition improvement with low perioperative morbidity.

**Key words:** Benign prostatic obstruction, VapoEnucleation, ThuVEP, Tm: YAG,

## INTRODUCTION

Transurethral resection of the prostate (TURP) and open prostatectomy (OP) have been the standard surgical therapy in men with symptomatic benign prostatic obstruction (BPO) for many decades, although both procedures are associated with considerable morbidity.<sup>[1,2]</sup> Minimally invasive laser treatments like holmium laser

enucleation of the prostate (HoLEP) and photoselective vaporization of the prostate (PVP) have been developed as alternatives to TURP and OP with comparable surgical efficacy and decreased morbidity.<sup>[3]</sup> Based on the retrograde HoLEP technique, bipolar enucleation of the prostate (bipolEP)<sup>[4-6]</sup> and Thulium VapoEnucleation of the prostate (ThuVEP)<sup>[7]</sup> have been established as other size-independent, safe and effective modalities for the treatment of BPO. There are thulium laser devices with wavelengths of 2013 nm, 1940 nm and 2010 nm available for the ThuVEP procedure. Khoder *et al.*<sup>[8]</sup> recently found a slight nonsignificant reduction in ablation depth and a significant reduction in axial coagulation for the 2010 nm thulium laser in porcine kidneys compared with the 1940 nm thulium laser. However, there has been no study published so far comparing these thulium lasers of different wavelengths with regard to their clinical efficacy and perioperative morbidity for the ThuVEP procedure. We report the first results of a prospective, randomized comparison of a 1940 nm and a 2013 nm thulium laser for ThuVEP in men with symptomatic BPO.

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## MATERIALS AND METHODS

Eighty consecutive patients with symptomatic BPO were randomized between January and June 2013 for the ThuVEP procedure either with a 2013 or a 1940 nm thulium laser at our department. Randomization was performed by computer generated numbers and the patients were blinded to the procedure. The assessors of the study were blinded as well and not involved into the surgical procedures. Patients with a maximum urinary flow rate (Q<sub>max</sub>) >15 mL/s, international prostate symptom score (IPSS) <7 points, urodynamically diagnosed neurogenic bladder, prostate cancer and previous prostatic or urethral surgery were excluded from the study. Preoperative evaluation included a physical examination with digital rectal examination, transrectal ultrasound measurement of prostate size (TRUS), Q<sub>max</sub>, postvoiding residual urine (PVR), IPSS, quality of life (QoL), prostate specific antigen PSA assay, urine analysis and blood examination.

All ThuVEP procedures were performed by two surgeons (AJG, CN). A 2013 nm Tm: YAG laser (RevoLix<sup>®</sup>, LISA Laser Products, Katlenburg, Germany) and a 1940 nm Tm: fiber laser (Vela<sup>®</sup> XL, Starnedtec, Starnberg, Germany) were used for the ThuVEP procedure in combination with a mechanical tissue morcellator (Piranha<sup>®</sup> TUR-Set Richard Wolf, Knittlingen, Germany) at 90 Watt power output. All ThuVEP procedures were performed using normal saline as irrigation fluid with the patient under spinal or general anesthesia. A 22 French 3-way catheter was inserted into the bladder at the end of surgery and continuous bladder irrigation with 0.9% NaCl was initiated immediately for at least 24 h. All

patients received a perioperative antibiotic treatment with a second-generation cephalosporine routinely until either the indwelling catheter was removed or an antibiotic treatment according to an antibiogram was available. Blood loss was investigated by comparing the preoperative hemoglobin value with the hemoglobin value of the first postoperative day. The catheter was routinely removed at the second postoperative day and patients were discharged after being able to void adequately at the same day or 1 day later.

All complications (except dysuria, transient urge/stress incontinence and retrograde ejaculation) that occurred during the perioperative period (up to the end of the first month after surgery) were noted and classified according to the modified Clavien classification system (CCS)<sup>[7]</sup>. Statistical analysis was performed with SPSS for Windows v11.5.1. Pre- and postoperative patient data were expressed as median (interquartile range). Differences between the 2013 nm and the 1940 nm thulium laser device were assessed by the Mann–Whitney *U* test. Improvements in the assessed parameters (Q<sub>max</sub>, PVR) in each group were calculated by the paired *t*-test. Categorical variables were compared using the Chi square test. A two-sided *P* < 0.05 was considered statistically significant. All patients gave their informed consent prior to their inclusion in the study.

## RESULTS

There were no significant differences between patients in the two thulium laser groups at baseline in terms of median age, PSA, prostate volume, IPSS, QoL score, Q<sub>max</sub>, PVR and ASA-score [Table 1]. At discharge, Q<sub>max</sub> and PVR improved

**Table 1: Baseline characteristics**

	2013 nm ThuVEP	1940 nm ThuVEP	Total	<i>P</i> value
No. of patients ( <i>n</i> )	39	41	80	
Age (years)	70 (64-74)	73 (69-75.5)	72 (65.25-75)	0.107
PSA (ng/mL)	5.21 (2.61-7.91)	4.12 (2.59-11.2)	4.27 (2.6-9.79)	0.689
Prostate volume (mL)	50 (38-65)	60 (40-83)	55 (40-75.75)	0.096
IPSS	20 (15.75-22.25)	21 (15-25)	20 (16-25)	0.727
QoL	4 (3-5)	4 (4-5)	4 (4-5)	0.930
Q <sub>max</sub> (mL/s)				
Preop**	11 (7.7-12.3)	7.65 (4.78-12.3)	8.5 (6-12.3)	0.118
At discharge	25.3 (16.8-28)	21.7 (14.78-24.83)		0.554
<i>P</i> value (preop vs. discharge)	0.001	<0.001		
PVR (mL) **				
Preop**	150 (100-250)	115 (52.5-275)	130 (60-250)	0.732
At discharge	50 (0-80)	0 (0-30)		0.034
<i>P</i> value (preop vs. discharge)	<0.001	<0.001		
ASA score	3 (2-3)	3 (2-3)	3 (2-3)	0.938
Patients with preoperative urinary retention (%)	20 (51.3)	18 (43.9)	38 (47.5)	0.386

Data indicated as median (IQR). PSA = Prostate-specific antigen, IPSS = International prostate symptom score, QoL = Quality of life, Q<sub>max</sub> = Maximum urinary flow rate, PVR = Postvoiding residual urine, ASA = American society of anaesthesiologists, ThuVEP = Thulium Vapoenucleation of the prostate \*\*except those in urinary retention

significantly in both subgroups ( $P < 0.001$ ). However, PVR was significantly lower at discharge in the 1940 nm group compared with the 2013 nm ThuVEP group (0 vs. 50 mL,  $P \leq 0.034$ ).

The ThuVEP procedure could be completed successfully in all patients. There were no statistically significant differences regarding the operation time, operation efficiency (weight/total operation time), resected weight, percentage resected tissue and hemoglobin decrease between the two groups [Table 2]. The median catheterization time was 2 days in both groups ( $P = 0.397$ ).

Table 3 shows the complications according to the modified CCS. Minor complications requiring no or conservative treatment appeared in 14 (17.5%) of 80 patients (Clavien 1: 12.5%; Clavien 2: 5%). Major complications requiring reoperation were necessary in two (2.5%) of 80 patients (hemorrhage due

to blood clot retention [Clavien 3b]). However, two Clavien 4a complications (2.5%) occurred: ICU treatment due to allergic shock caused by analgetics ( $n = 1$ ) and postoperative cardiac arrhythmia ( $n = 1$ ). Regarding the occurrence of complications, there were no differences between both thulium lasers ( $P = 0.5$ ).

## DISCUSSION

The 1940 nm and 2013 nm thulium lasers were comparable in terms of immediate voiding improvement and the occurrence of perioperative complications after the ThuVEP procedure. They were both safe and effective for the treatment of symptomatic BPO.

TURP and open prostatectomy have been progressively replaced by alternative procedures like HoLEP, PVP, bipolarEP and ThuVEP for the surgical treatment of BPO during the

**Table 2: Operative data**

	2013 nm ThuVEP	1940 nm ThuVEP	Total	P value
No. of patients (n)	39	41	80	
Total operation time (min)	62.5 (40-88.5)	50.5 (35-72.5)	55 (35.75-77)	0.113
Operation efficiency (weight/total operation time) (g/min)	0.53 (0.35-0.75)	0.67 (0.44-0.86)	0.56 (0.41-0.8)	0.154
Resected weight (g)	31 (17.5-48.5)	40.5 (24-56)	35 (20-50)	0.078
Percentage resected tissue (%)	56.67 (37.63-87.27)	60 (44.44-79.57)	60 (41.25-82.8)	0.819
Hemoglobin decrease (g/dL)	1.45 (0.48-2.6)	1.2 (0.5-1.8)	1.3 (0.5-2.05)	0.346
Catheter time (days)	2 (2-2)	2 (2-2)	2 (2-2)	0.397

Data indicated as median (interquartile range). ThuVEP = Thulium vapoenucleation of the prostate

**Table 3: Early complications according to the modified clavien classification system<sup>[7,9]</sup>**

Complication	Treatment	2013 nm ThuVEP (n=39)	1940 nm ThuVEP (n=41)	Overall (n=80) (%)
Clavien grade 1 complications (n=10 of 80; 12.5%)				
Extraperitoneal fluid collection	Oral diuretics, prolonged catheterization	0 (0)	0 (0)	0 (0)
Superficial bladder injury due to morcellation	No special therapy	0 (0)	0 (0)	0 (0)
Capsular perforation	No special therapy	0 (0)	1 (2.4)	1 (1.3)
Bladder neck false passage	Prolonged catheterization	1 (2.6)	0 (0)	1 (1.3)
Urinary retention after catheter removal	Bedside recatheterization	2 (5.1)	2 (4.9)	4 (5)
Clot retention without surgical revision	Bladder irrigation (prolonged) and tamponade evacuation through catheter	2 (5.1)	2 (4.9)	4 (5)
Clavien grade 2 complications (n=4 of 80; 5%)				
Postoperative hematuria	Blood transfusions	1 (2.6)	1 (2.4)	2 (2.5)
Urinary tract infection	Antibiotics	0 (0)	2 (4.9)	2 (2.5)
Clavien grade 3b complications (n=2 of 80; 2.5%)				
Hemorrhage/clot retention	Cystoscopy with clot evacuation, coagulation of prostate fossa	1 (2.6)	1 (2.4)	2 (2.5)
Clavien grade 4a complications (n=2 of 80; 2.5%)				
Cardiac arrhythmia postoperatively	Medical treatment in ICU	1 (2.6)	0 (0)	1 (1.3)
Allergic shock caused by analgesics	Treatment in ICU	1 (2.6)	0 (0)	1 (1.3)
Total		9 (23.1)	9 (22)	18 (22.5)

past 20 years.<sup>[3-7,9-11]</sup> The outcome and complications of HoLEP and the PVP procedure have been evaluated in numerous studies.<sup>[3]</sup> Transurethral prostate enucleation procedures are typically performed by bipolar energy<sup>[4-6]</sup> or by thulium<sup>[7,12-15]</sup> and holmium lasers.<sup>[3,12]</sup> The thulium and holmium lasers both use water as the tissue target but differ with regard to wavelength, penetration depth and the way of applying laser energy.<sup>[12]</sup> The continuous wave thulium laser is available in wavelengths of 1940, 2010 and 2013 nm with a penetration depth (i.e. the coagulation zone) of 0.2 mm.<sup>[12]</sup> Since the thulium laser has its maximum absorption in water at a wavelength of 1940 nm, the maximum ablation capacity should be theoretically achieved at this wavelength.<sup>[16]</sup> Khoder *et al.*<sup>[8]</sup> recently found a slight nonsignificant reduction in ablation depth and a significant reduction in axial coagulation for the 2010 nm thulium laser in porcine kidneys compared with the 1940 nm thulium laser. These slight differences in coagulation depths may have consequences for the ThuVEP procedure as the ThuVEP literature was primarily based on the use of the 2013 nm thulium laser.<sup>[7,13-15]</sup> We therefore report the early results of the first prospective, randomized comparison of a 1940 nm and a 2013 nm thulium laser for the ThuVEP procedure.

In the current study, an immediate improvement of PVR and Qmax was found with both lasers. At discharge, there were no differences in Qmax between the two lasers, while PVR was significantly lower in the 1940 nm laser group (0 vs. 50 mL,  $P \leq 0.034$ ). These results for PVR and Qmax in both groups were in line with previous ThuVEP series<sup>[7,13-15]</sup> and well comparable with TURP<sup>[2,3]</sup> and open prostatectomy<sup>[1,3,17-19]</sup> as well as with minimally invasive procedures like HoLEP,<sup>[3,20-22]</sup> PVP<sup>[3,23]</sup> or bipolarEP.<sup>[4-6]</sup> Longer follow-up is however needed to assess differences in PVR and Qmax between the two thulium lasers.

There were no differences in the preoperative prostate volume (median 55 mL) and total operation time (median 55 min) between the thulium lasers. The total operative time in relation to the prostate size in this series is well comparable with other enucleation procedures like HoLEP,<sup>[24,25]</sup> with nearly the same preoperative prostate weight, and lower than in PVP.<sup>[23]</sup> In addition, the overall operation efficiency (weight/total operation time) (0.56 g/min) and percentage of resected tissue (60%) were not different between both thulium lasers. Again, both variables were well comparable with the HoLEP series.<sup>[23]</sup> There were no differences in postoperative catheterization times between both thulium lasers (median 2 days), although the catheterization times in this ThuVEP series were longer than in HoLEP,<sup>[3,20-22,24,25]</sup> bipolarEP<sup>[4-6]</sup> or PVP.<sup>[3,23]</sup> This difference in catheterization time could however be expected as the Foley catheter has been routinely removed at the second postoperative day in this series.

The total complication rate was 22.5% using the modified CCS (Clavien 1,2: 17.5%; Clavien 3,4: 5%) with mainly minor complications. There were differences in the total complication rate and the complication rates at each Clavien grade between the lasers. The most relevant complications were acute urinary retention (5%), clot retention without surgical intervention (5%), urinary tract infections (2.5%), and blood transfusions (2.5%). These complication rates are comparable with other minimally invasive transurethral procedures for the treatment of BPO, like bipolarEP,<sup>[4-6]</sup> HoLEP,<sup>[3,20-22,24,25]</sup> PVP<sup>[3,23]</sup> and former ThuVEP series.<sup>[7,13-15]</sup>

Finally, we conclude that the 1940 nm and 2013 nm Tm: YAG laser devices are both safe and effective for the treatment of BPO with the ThuVEP procedure. Both laser devices give equivalent and satisfactory immediate voiding improvement with low perioperative morbidity. However, it must be emphasized that these data represent a single centre 30-day short-term data.

## CONCLUSIONS

The 1940 nm and 2013 nm Tm: YAG laser devices are both safe and effective for the treatment of BPO with the ThuVEP procedure. Both laser devices give equivalent and satisfactory immediate voiding improvement with low perioperative morbidity.

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