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Platinum Priority – Benign Prostatic Hyperplasia

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GreenLight HPS 120-W Laser Vaporization Versus Transurethral Resection of the Prostate for Treatment of Benign Prostatic Hyperplasia: A Randomized Clinical Trial with Midterm Follow-up

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Abstract

Background: Photoselective vaporization (PVP) with the GreenLight HPS 120-W laser (GLL) was recently introduced for treatment of benign prostatic hyperplasia (BPH).

Objective: To compare results of GLL PVP and transurethral resection of the prostate (TURP) for treatment of BPH.

Design, setting, and participants: A total of 120 patients with BPH were randomly assigned to two equal groups: TURP or PVP.

Measurements: Both groups were compared regarding all relevant preoperative, operative, and postoperative parameters. Functional results in terms of improvement of International Prostate Symptom Score (IPSS), maximum flow rate (Q_{max}), and post-void residual (PVR) urine were assessed at 1, 3, 6, 12, 24, and 36 mo. A total of 55 and 54 patients completed 36 mo of follow-up in the TURP and PVP groups, respectively.

Results and limitations: Baseline characteristics were comparable. Mean operative time was significantly shorter for TURP. Compared to preoperative values, there was significant reduction in hemoglobin and serum sodium levels at the end of TURP only. A significant difference in favor of PVP was achieved regarding the duration of catheterization and hospital stay. In the PVP, no major intraoperative complications were recorded and none of the patients required blood transfusion. Among TURP patients, 12 (20%) required transfusion, 3 (5%) developed TUR syndrome, and capsule perforation was observed in 10 patients. There was dramatic improvement in Q_{max} , IPSS, and PVP compared with preoperative values and the degree of improvement was comparable in both groups at all time points of follow-up. Storage bladder symptoms were significantly higher in PVP. By the end of 36 mo, five patients in TURP and six in PVP were lost to follow-up. A redo procedure was required in one TURP patient and six PVP patients ($p < 0.05$). Two TURP patients and four PVP patients developed bladder neck contracture ($p > 0.05$) treated by bladder neck incision; none in either group experienced urethral stricture or urinary incontinence.

Conclusions: Compared with TURP, 120-W GLL PVP is safe and effective in treatment of BPH.

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1. Introduction

Laser therapy has gained increasing acceptance as a relatively less invasive treatment for lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). From the early procedure of interstitial laser coagulation through to the use of holmium laser enucleation of the prostate, there has been an expanding body of evidence on the efficacy of such procedures [1]. One of the newer lasers is the potassium-titanyl-phosphate (KTP) laser. Early studies with this GreenLight laser (GLL) (American Medical Systems, Inc, Minnetonka, MN, USA) involved 60-W power and showed effective photoselective vaporization of the prostate (PVP) in both canine [2] and human [3]. The laser was further developed to operate at 80 W with several clinical studies showing results as good as those of transurethral resection of the prostate (TURP) [3–6].

The most recent advance in GLL PVP is the introduction of a high-performance system (HPS) 120-W laser. In a recent porcine study, Heinrich and associates [7] showed that the 120-W laser offers a significantly higher tissue ablation capacity compared with the conventional 80-W laser. The International GreenLight User database was originally set up to pool outcome from eight centers on patients treated with the 80-W laser, and this has been extended to collect outcome on patients treated with this new 120-W laser [1]. A total of 305 consecutive patients who were treated with the GLL HPS laser at eight international centers since July 2006 were included. The study showed that the 120-W GLL HPS can be used effectively and safely in patients in retention or anticoagulant therapy, and in those with a large prostate. Cleynenbreugel et al. [8] reviewed the literature regarding the use of 120-W GLL HPS and concluded that this technology needs to be further studied in a prospective randomized manner to see whether it will provide better results while maintaining the same degree of patient safety.

In this paper, the efficacy of the new GLL 120-W versus the gold standard TURP in patients with LUTS due to BPH was tested in a prospective randomized clinical trial (RCT). To the best of our knowledge, the present study is the first RCT comparing 120-W laser versus TURP in treatment of patients with BPH with a midterm follow-up (<36 mo).

2. Materials and methods

2.1. Study population

Between March 2007 and September 2007, a total of 140 patients with LUTS due to BPH were assessed for eligibility to enter the study. All patients requested surgical treatments and provided an informed written consent; the study was approved by our ethical committee. Twenty patients were excluded for different reasons; 120 were included in the study (Fig. 1). Inclusion criteria were patients with moderate or severe LUTS (International Prostate Symptom Score [IPSS] >16), failure of previous medical treatment with a washout period of at least 2 wk, maximum flow rate (Q_{max}) <15 ml/s, PVR urine <100 ml, prostate volume <100 ml on transrectal ultrasonography (TRUS), and ability to give a fully informed consent. Exclusion criteria were patients on permanent anticoagulants, those with urethral strictures, bladder stone, or neurogenic bladder.

Patients diagnosed or suspected of having prostate cancer were also excluded.

All patients were subjected to the standard urologic preoperative evaluation, including history taking, clinical examination including digital rectal examination (DRE), urine analysis (with or without urine culture), routine blood chemistry including prostate-specific antigen (PSA). TRUS was needed to estimate the size of the prostate and transabdominal ultrasound was needed to measure PVR urine excluding those with an indwelling catheter. Urine flowmetry was carried out to measure Q_{max} . IPSS was completed by self assessment after translation and validation to the patient's language. TRUS-guided biopsy was carried out in patients with PSA >4 ng/ml, abnormal DRE, and/or suspicious echogenicity on TRUS.

2.2. Study design

Patients were randomly assigned to one of two groups according to the method of surgical treatment: TURP or GreenLight 120-W HPS PVP. Randomization was carried out using computer-generated simple random tables in a 1:1 ratio. Sample size was determined after consideration of three factors: (1) an expected difference in the overall outcome of about 25% between TURP and PVP, based upon previous studies comparing TURP and 80-W Laser PVP [9]; (2) type 1 statistical error <5%; and (3) type 2 statistical error <20%. Considering the previous factors, a sample size of 60 patients in each group was estimated. This sample size provided a statistical power of 80% and allowed a dropout rate of 10%. A summary of the study design and follow-up is given in Fig. 1. Follow-up continued until March 2010 and a total of 55 and 54 patients completed a 36-mo follow-up in the TURP and PVP groups, respectively. For all patients, the follow-up period had a mean \pm standard deviation (SD) of 31.3 ± 6.3 mo and a median of 33 mo.

2.3. Surgical technique

TURP was carried out by two urologists and PVP was performed by two other urologists. All procedures were carried out under epidural anesthesia. TURP was performed in the standard manner with a 26-F continuous irrigation resectoscope using a diathermy machine (Valleylab, Boulder, CO, USA) and the passage of a three-way 22-F Foley catheter after the surgery followed by continuous irrigation with saline.

PVP was carried out using the 120-W GLL HPS. The 120-W HPS laser uses a lithium triborate (LBO) crystal, which replaces the KTP crystal used in the former 80-W system, to produce a 532-nm laser beam that is more collimated and powerful than the 80-W laser [10]. This should translate into faster vaporization and a greater ability to penetrate prostate tissue from longer fiber distances [11]. Flexible 600- μ m side fiber was used in a rear mode to vaporize the tissue.

2.4. Outcome assessment

In both groups, preoperative parameters were recorded together with intraoperative data, including operative time (time that the resectoscope remained in the urethra), changes in hemoglobin and serum sodium, and transfusion rate. Postoperative data were also recorded, including catheterization time, hospital stay, and peri- and postoperative complications. Functional results in terms of improvement of IPSS, Q_{max} , and PVR urine were assessed at 1, 3, 6, 12, 24, and 36 mo. Patients suspected of developing complications such as bladder neck contracture, residual prostate, or urethral stricture were investigated accordingly and treated. Observers were not blinded to the group assignment.

2.5. Statistical analysis

Results were given as mean plus or minus SD. Statistical analysis was performed using the SPSS 8.0 statistical software package (SPSS Inc,

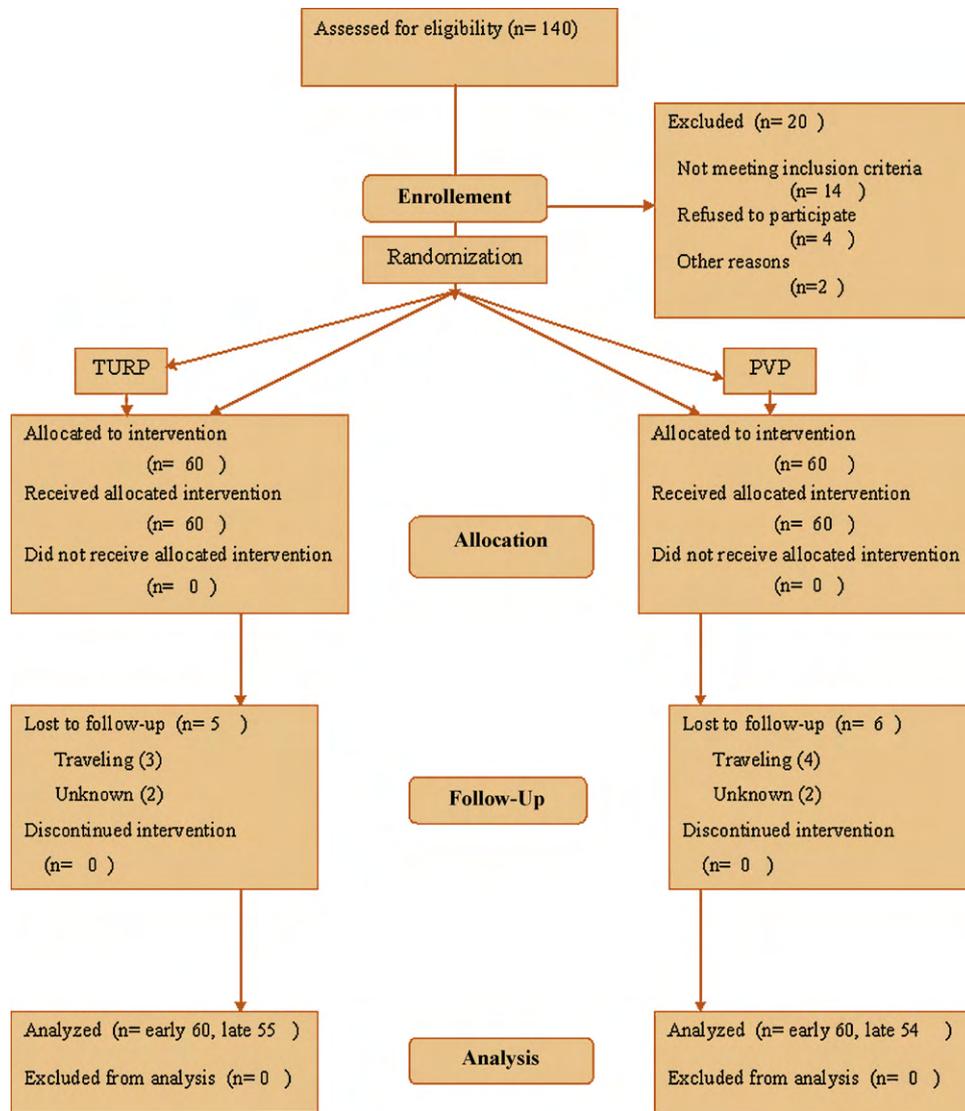


Fig. 1 – Cohort flowchart.

Chicago, IL, USA). Student *t* test, χ^2 , and Fisher exact tests were used when appropriate. A *p* value <0.05 was considered significant.

3. Results

3.1. Baseline characteristics

Table 1 provides a summary of the baseline characteristics of both groups. There was no significant difference between the groups regarding any of the studied parameters.

3.2. Intraoperative and early postoperative outcomes

Intraoperative and early postoperative outcomes are summarized in Table 2. The mean operative time was significantly shorter for TURP (80 ± 13 min vs 89 ± 18 min for TURP and PVP, respectively [*p* < 0.01]). Compared to preoperative values, there was no significant reduction in the hemoglobin and serum sodium levels at the end of PVP procedure. In contrast, there was significant reduction in the hemoglobin and serum sodium

levels in the TURP group compared with preoperative values. The average duration of catheterization was 1.4 ± 0.6 d for PVP group and 2.7 ± 0.9 d for TURP group (*p* < 0.0001). A total of eight patients in the PVP group were treated at the day-care unit

Table 1 – Baseline characteristics of patients of both groups

	TURP	PVP	<i>p</i> value
Patients, No.	60	60	
Median age, yr ± SD	67.1 ± 8	66.3 ± 9.4	0.3
Mean prostate volume, ml ± SD	60.3 ± 20	61.8 ± 22	0.7
Mean PSA, ng/ml ± SD	2.8 ± 1.4	2.6 ± 1.8	0.6
Mean IPSS ± SD	27.9 ± 2.7	27.2 ± 2.3	0.13
Mean Q _{max} , ml/s ± SD	6.4 ± 2	6.9 ± 2.2	0.25
Mean PVR, ml ± SD	57 ± 21	53.2 ± 25	0.39
Patients preoperatively catheterized, No. (%)	5 (8.3)	6 (10)	1.0

TURP = transurethral resection of the prostate; PVP = photoselective vaporization of the prostate; SD = standard deviation; PSA = prostate-specific antigen; IPSS = International Prostate Symptom Score; Q_{max} = maximum flowrate (urine); PVR = postvoid residual.

Table 2 – Intraoperative and early postoperative outcomes in the two study groups

	TURP	PVP	<i>p</i> value
Patients, No.	60	60	–
Mean operative time, min ± SD	80 ± 13	89 ± 18	0.003
Mean serum sodium, mmol/l ± SD			
Preoperative	138 ± 3	138.6 ± 2.9	–
Postoperative	136 ± 5	138.6 ± 3.1	–
<i>p</i> value	0.03	0.54	–
Mean hemoglobin, g/l ± SD			
Preoperative	14.2 ± 1.2	13.8 ± 1.6	–
Intraoperative	11.3 ± 1.9	13.1 ± 1.5	–
<i>p</i> value	<0.0001	0.2	–
Mean catheterization time, d ± SD	2.7 ± 0.9	1.4 ± 0.6	0.0001
Mean hospital stay, d ± SD	4.1 ± 0.6	2.3 ± 1.2	0.0001

TURP = transurethral resection of the prostate; PVP = photoselective vaporization of the prostate; SD = standard deviation.

(patients with prostate volume <40 g, without comorbidities, and requiring no postoperative irrigation). The average time of hospital stay was shorter in the PVP group (4.1 ± 0.6 vs 2.3 ± 1.2 d for the TURP and PVP [treated as inpatient] groups, respectively; $p < 0.0001$).

3.3. Complications

Intraoperative, early (≤ 30 d), and late (≤ 3 yr) postoperative complications are summarized in Table 3. In the PVP group, no major intraoperative complications were recorded and none of the patients required blood transfusion. Among patients of TURP, 12 (20%) required blood transfusion (intraoperative or immediate postoperative) and 3 (5%) developed TUR syndrome during surgery. Capsule perfora-

Table 3 – Intraoperative, early, and late postoperative complications in patients of both groups

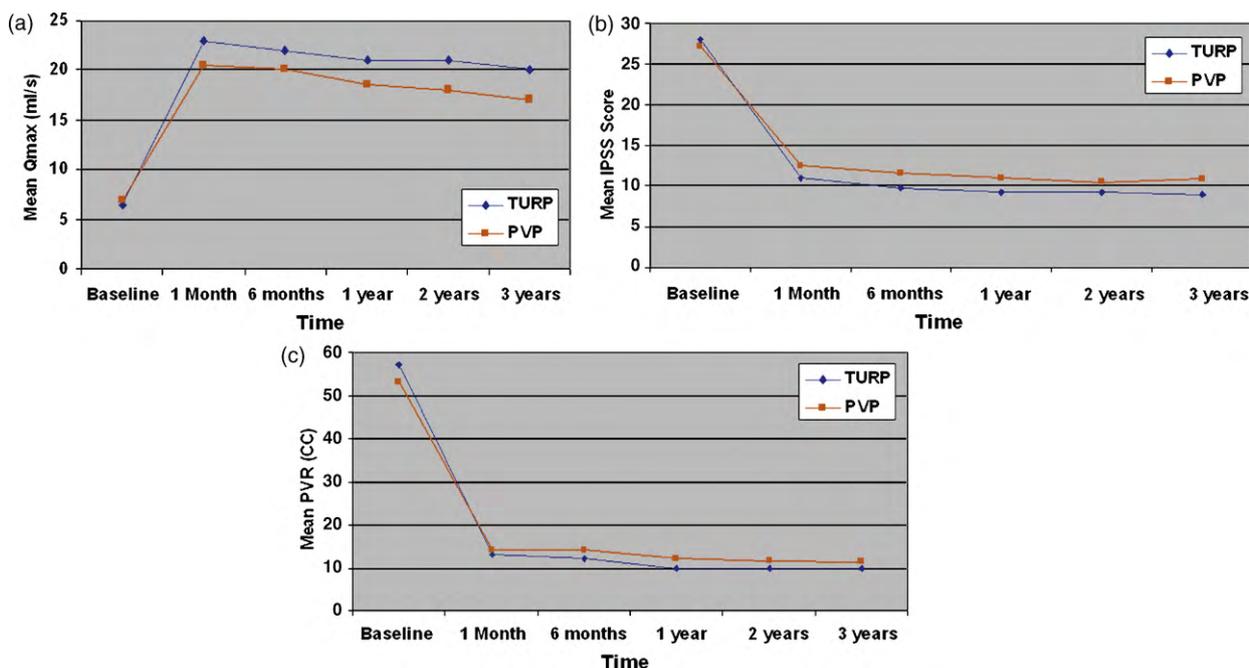
	TURP	PVP	<i>p</i> value
Intraoperative complications			
Patients, No.	60	60	–
Blood transfusion, No. (%)	12 (20)	0	0.0001
Capsule perforation, No. (%)	10 (16.7)	0	0.0001
TUR syndrome, No. (%)	3 (5)	0	0.079
Early (<30 d) postoperative complications			
Patients, No.	60	60	–
Clot retention, No. (%)	6 (10)	0	0.01
Dysuria/urge, No. (%)	19 (31.7)	56 (93.3)	0.001
Late (≤ 3 yr) postoperative complications			
Patients, No.	55	54	–
Redo TURP/PVP, No. (%)	1 (1.8)	6 (11)	0.04
Bladder neck contracture, No. (%)	2 (3.6)	4 (7.4)	0.44

TURP = transurethral resection of the prostate; PVP = photoselective vaporization of the prostate; SD = standard deviation; TUR = transurethral resection.

tion was observed in 10 patients (16.7%) in the TURP group and none in the PVP group ($p < 0.001$).

Clot retention was observed during the early postoperative course in six patients in the TURP group and in none of the patients in the PVP group ($p < 0.01$). The proportions of patients suffering from storage bladder symptoms were significantly higher in the PVP group.

During the follow-up period, two patients in the TURP and four in the PVP group experienced bladder neck contracture ($p > 0.05$). The six patients were treated by bladder neck incision. None of the patients in either group developed urethral stricture or urinary incontinence. None of the 82 potent patients in both groups experienced erectile

**Fig. 2 – Functional results in both groups with respect to (a) maximum flow rate (Q_{max}); (b) International Prostate Symptom Score (IPSS); and (c) postvoid residual urine.**

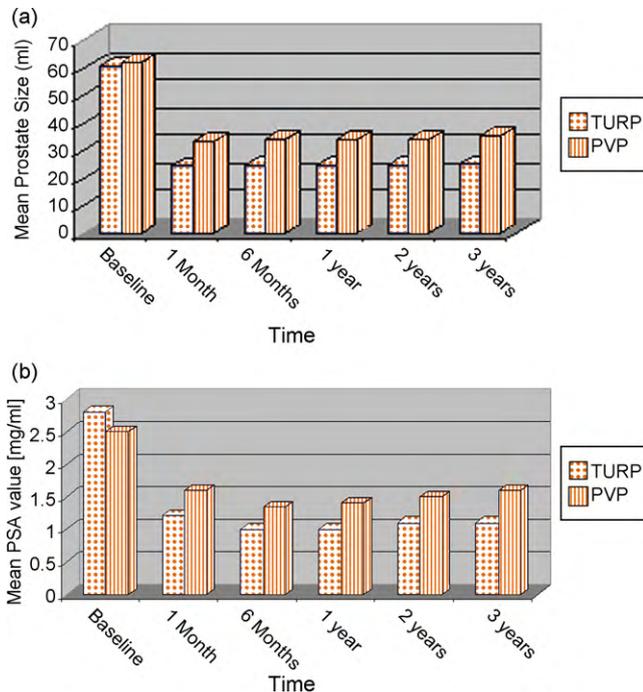


Fig. 3 – (a) Prostate size and (b) prostate-specific antigen (PSA) levels over time in both groups.

dysfunction at follow-up. One patient in the TURP group required a redo TURP, while six patients of the PVP group required redo PVP; all had a volume >80 ml ($p < 0.05$).

3.4. Functional outcome

Outcome in terms of increase in Q_{max} , decrease in IPSS, and decrease in PVR urine are shown graphically in Fig. 2a–c. There was dramatic improvement in the three parameters compared with preoperative values and the degree of improvement was comparable in both groups at all time points of follow-up. Compared with the preoperative values, there were significant reductions in PSA level and prostate volume after TURP and PVP at all time points of follow-up. The percentage reductions in PSA level and prostate volume were significantly higher in the TURP group (Fig. 3a and b).

4. Discussion

In a recent review, Cleynenbreugel et al. [8] looked at four prospective studies [5,6,12,13] comparing GLL PVP with TURP. The outcome parameters of GLL PVP and TURP were significantly improved when compared with preoperative values, with no significant difference between the two groups [5,6,12]. Moreover, patients undergoing TURP experienced more severe adverse effects as compared with GLL PVP patients, thus giving the latter a more favorable perioperative safety profile.

The present study, to the best of our knowledge, is the first RCT comparing 120-W GLL PVP versus TURP with a long-term follow-up of 36 mo. Twelve patients (20%) in the

TURP group developed significant bleeding, confirming the previous observation that bleeding is a major complication after TURP often requiring transfusion. Clot retention may occur as a consequence as well as premature termination of procedure, with consequent inadequate relief of obstruction. The PVP laser causes very little bleeding and has been used successfully in patients on anticoagulant therapy [1,14]. Performing conventional TURP in patients who are on oral anticoagulant therapy has a high complication rate with a transfusion rate of 30% [8]. Usually the patient is commenced on low-molecular-weight heparin preoperatively as bridging therapy. This, however, is associated with longer hospital stay and catheterization time [8].

Three patients in the TURP group also experienced TUR syndrome during surgery, an incidence of 5%, which is higher than the 2% proportion reported by Han [15]. In contrast, none of the patients in the PVP group developed significant change in the hemoglobin or sodium levels compared with the preoperative levels, an advantage of PVP over TURP. This could be explained by the fact that PVP uses saline as an irrigant, thus almost removing the risk of TUR syndrome.

The laser is fully transmitted through the aqueous irrigant but is highly absorbed by oxyhemoglobin in the tissue. This allows the laser energy to be selectively absorbed by tissue with high oxyhemoglobin content, such as prostatic tissue. This results in vaporization that is focused and the short optical penetration at this wavelength confines high-power laser energy to a superficial layer of prostatic tissue with only 1–2 mm of coagulation with optimum technique [9,16]. This explains the fact that perforation of the capsule occurred in none of our patients in the PVP group compared with 10 patients in the TURP group. In a recent update, significantly lower rates of intraoperative bleeding, blood transfusion, capsular perforation, and early postoperative clot retention were reported in the GLL PVP group as compared with the TURP group [13].

The cost issue was not calculated in the present study. Nevertheless, the high initial and maintenance cost of laser therapy may be partially compensated by the shorter hospital stay and the more rapid return to work. Goh and Gonzalez recently studied the cost of laser PVP versus TURP and concluded that the former procedure has a lower cost [17]. Another concern of PVP is the significantly higher incidence of storage bladder symptoms. These symptoms, however, almost disappear 1 mo after surgery.

There is some concern regarding the long-term reoperation rate with PVP. There are few long-term studies available at present, and none is in the setting of a randomized trial. In the multicenter trial from the United States, the reoperation rate at 3 yr was 4.3% [18]. In a recent study, Ruzat et al. [19] reported the long-term results of 500 patients who underwent 80-W PVP. The retreatment rate was 6.8%. Urethral and bladder neck strictures were observed in 4.4% and 3.6%, respectively [19]. In the present series, the reoperation rate in the PVP group was 11% over 36 mo. Notably, the prostate size in all redo cases was >80 g. Therefore, we do not recommend doing PVP for prostate >80 g at the present time. Nevertheless, with increasing experience it would be expected that more tissue would be vaporized.

Long-term functional results showed dramatic improvement in both groups regarding reduction of IPSS and PVR and improvement of Q_{max} , with no significant difference between both groups. Nevertheless, the percentage reductions in prostate size and PSA were significantly higher in the TURP group. This could be explained by greater resection of transitional zone among the TURP group due to different degrees of experience among the surgeons. This difference is expected to disappear with increasing experience and confidence with PVP in the future. In a recent update, Cleynenbreugel et al. [8] compared the long-term functional outcome of GLL PVP and TURP. The improvement in Q_{max} was greater following the TURP. The change in IPSS and PVR volumes postoperatively was similar in both groups. After 12 mo, the overall reduction in prostate size was 60% after TURP and 48% after GLL PVP. The rate of repeat TURP/PVP procedures within a 2-yr follow-up period was higher in the GLL PVP group (11% vs 1.9%). Although this was statistically significant, the incidences of urethral and bladder neck stricture formations were comparable [8].

One of the limitations of the present study is the drop-out rate of 9.2%. Moreover, the surgical procedures were carried out by urologists with differing amounts of experience, which may explain the relatively high transfusion and perforation rates in the TURP group. In addition, sexual function was not properly assessed via sexual health questionnaires before and after the procedures. Furthermore, observers were not blinded to the group assignment. Therefore, the highly significant statistical difference between the two groups should be cautiously interpreted.

5. Conclusions

The present prospective RCT showed that GLL PVP is a safe and effective treatment for patients suffering from LUTS due to BPH in comparison with the gold standard treatment of TURP. It provides better intraoperative and early postoperative outcomes, but induces more storage bladder symptoms.

Author contributions: Ahmed A. Shokeir had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Al-Ansari.

Acquisition of data: Gul.

Analysis and interpretation of data: Younes.

Drafting of the manuscript: Al-Rumaihi.

Critical revision of the manuscript for important intellectual content: Shokeir.

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