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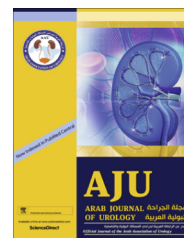


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ORIGINAL ARTICLE

Diode laser vaporisation of the prostate vs. diode laser under cold irrigation: A randomised control trial[☆]



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KEYWORDS

Benign prostate hyperplasia;
Diode laser vaporisation;
Cold irrigation

ABBREVIATIONS

LVP, diode laser vaporisation of the prostate;
LUCI, (diode) laser under cold irrigation;
 Q_{max} , maximum urinary flow rate;
PVR, postvoid residual urine volume;
PS, pain scale;

Abstract Objective: To compare the perioperative morbidity and early follow-up after diode laser vaporisation of the prostate (LVP) and its modification, diode laser under cold irrigation (LUCI) in patients with symptomatic benign prostatic hyperplasia, as the main disadvantages of LVP are the postoperative pain, dysuria and storage urinary symptoms.

Patients and methods: This was a single-centre prospective randomised control trial in which 100 patients were randomised to receive LVP (50) or LUCI (50) from June 2011 until July 2012. LUCI is similar to LVP except that it is done under normal irrigation with saline at 4 °C instead of saline at room temperature. The primary outcome measures were the International Prostate Symptom Score (IPSS), IPSS-Dysuria, a pain scale (PS), maximum flow rate (Q_{max}), a quality-of-life (QoL) score and the postvoid residual urine volume (PVR) after 1 month, then the IPSS, Q_{max} , QoL, and PVR at 3 and 12 months. Secondary outcomes included intraoperative surgical variables, e.g., the decline in core temperature, bleeding, peri- and postoperative morbidity.

Results: The baseline characteristics of both groups were similar. For the primary outcome measures, there was a statistically significant difference between the groups in all variables except Q_{max} after 1 month, in favour of LUCI. The mean (SD) IPSS at 1 month in the LVP group was 8.97 (1.68), statistically significantly different from

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PVP, photoselective vaporisation of the prostate;
QoL, quality-of-life (score);
KTP, potassium titanium phosphate;
HOLEP, holmium laser enucleation of the prostate

that after LUCI, of 6.89 (1.5) ($P < 0.05$). The mean IPSS-Dysuria at 1 month was also significantly, at -2.32 (0.91) for LVP and 3.54 (1.07) for LUCI ($P < 0.05$). The respective mean PS at 1 month was 7.84 (2.92) and 5.7 (2.1) ($P < 0.05$). The QoL and PVR at 1 month were also significantly different. Within the first month 17% of patients in the LVP group and 4% in the LUCI group complained of transient urgency or stress incontinence, and this difference was statistically significant ($P < 0.05$). There was no significant bleeding in either group. The mean operative time or applied energy of LVP was not statistically significant from that of LUCI, and there was no significant difference in the decline in core temperature between the groups ($P > 0.05$).

Conclusion: LUCI is a good modification for reducing the pain, dysuria and storage symptoms associated with LVP. The procedure appears to be safe, with no significant decrease in core temperature in either group.

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Introduction

BPH is a major cause of LUTS in elderly men, and surgical treatment remains the most effective option for men with symptomatic BPH who are refractory to medical treatment. TURP is considered to be the standard surgical treatment for BPH [1], but the perioperative morbidity, e.g., bleeding requiring blood transfusion (25%), TUR syndrome (2%), stress incontinence (2.2%), urethral stricture (3.8%), bladder neck contracture (4%), retrograde ejaculation (65–70%) and prolonged catheterisation time has encouraged the search for alternatives that can reduce these complications and offer at least similar clinical results [1–4].

Laser vaporisation of prostate (LVP) is one such method for symptomatic BPH. Different types of laser are available for this method, e.g., potassium-titanium phosphate (KTP), holmium, diode and thulium. Of these, the photoselective vaporisation of the prostate (PVP) using the KTP laser, and holmium laser enucleation of the prostate (HOLEP) are gaining popularity [5,6].

The diode laser is considered to be the best in terms of haemostatic properties, but is less acceptable due to postoperative dysuria, pain and storage urinary symptoms [7]. Here we introduce a new concept, using cold irrigation to reduce the wound oedema and modify the coagulation zone, and thus improve the postoperative urinary symptoms. The rationale behind this idea is from previous dichromatic absorptiometry studies to quantify oedema, which showed that the immediate application of cold irrigation might reduce the massive wound oedema associated with burning [8]. Thus we compared the perioperative morbidity and early follow-up after diode LVP and its modification, diode laser under cold irrigation (LUCI) in patients with symptomatic BPH.

Patients and methods

From June 2011 until July 2012, 100 patients with symptomatic BPH were recruited into a prospective, randomised, single-centre study to compare the peri- and postoperative variables between two techniques. The study plan was approved by the appropriate ethics committee. After giving informed consent, 50 patients had diode LVP and 50 patients had LUCI. Patients were randomised using a computer program, on a 1:1 basis, to receive LVP or LUCI. Patients were included if they had a maximum urinary flow rate (Q_{max}) of ≤ 15 mL/s, transvesically measured postvoid residual urine volume (PVR) of > 50 mL, an IPSS of > 10 and a prostate volume of < 80 mL. All patients underwent a treatment trial with at least one of the given α -blockers (tamsulosin or alfuzosin) for ≥ 6 weeks before surgery. Patients with definite indications for surgery who already had trial of α -blocker therapy were directly included. All patients underwent a general and urological standard evaluation before, including a DRE, urine analysis and culture, transvesical ultrasonographic measurement of the prostate, an ultrasonographic evaluation of the kidney, blood sample analysis, including a measurement of the PSA level, IPSS, Q_{max} , a quality of life score (QoL), and estimate of PVR. In three patients with a PSA level of > 4 ng/mL with a normal DRE, TRUS-guided biopsies were taken before inclusion into the study.

Patients were excluded if they had a neurogenic bladder disorder, urethral strictures, a PVR of > 400 mL and previous lower urinary tract surgery. A urodynamic study was done before inclusion in any patients with a suspected overactive bladder. Two patients showing detrusor overactivity in the urodynamic study were excluded from the study.

All LVP and LUCI procedures were performed by one surgeon who had formal training in LVP. The primary outcome measures after surgery were the IPSS, the IPSS-Dysuria, a pain scale (PS), Q_{\max} , QoL score and PVR at 1 month, then the IPSS, Q_{\max} , QoL and PVR at 3 and 12 months. The IPSS-Dysuria was adopted from a previous study on dysuria after brachytherapy [9], and was assessed by a questionnaire which asks 'During the last month or so how often have you had a burning sensation while passing urine', and the score is given similar to the standard IPSS (0–5). The PS was a standard 11-point numeric rating scale to represent pain, asking 'If you have had a burning sensation, rate the severity of the pain on a 0–10 scale'. The secondary outcomes included intraoperative surgical variables, e.g., the decline in core temperature (the core rectal temperature was measured at the beginning and end of the procedure), bleeding, and peri- and postoperative morbidity.

Parametric numeric data were compared using Student's *t*-test and nonparametric data using the Wilcoxon signed-rank test. The categorical data were analysed using Fisher's exact test.

LVP and LUCI (Fig. 1a–d) was performed with a semiconductor diode laser at a wavelength of 980 ± 10 nm (HPLAS I, 150 W laser, Wuhan Gigaa Optonics Technology Ltd, China) using a 600- μ m side-firing fibre or 'hook-shot' fibre, or those combined. The diode laser machine used was a Sino-German technology having both continuous and pulsed-wave mode. For aiming, a red pilot beam of 635 nm was used, with a maximum power of 4 mW. Both groups had diode LVP under normal saline irrigation (0.9%) at room temperature for the LVP group and at 4 °C for the LUCI group. Both procedures used the same standard techniques. The working space was made by vaporising the lateral lobes. The middle lobe was vaporised using a side-firing fibre (600 μ m) or hook-shot fibre, or combined, depending on the anatomy. The laser power setting was 80–120 W. The vaporisation was done through a 24 F Karl Storz continuous-flow laser resectoscope. A temperature regulation mechanism was used to maintain the temperature of cold irrigation at 4 °C. The procedure was done under general or spinal anaesthesia, depending on the indications and patient preference. A 20–22 F three-way Foley catheter was inserted over a 'road runner' guidewire, avoiding any trauma and no further irrigation in most patients. Throughout the procedure the core temperature was closely monitored.

After surgery all patients were placed on antibiotic prophylaxis for 72 h and anti-inflammatory medication for 1 week, except in those for whom this was contraindicated.

Results

The baseline variables were similar between the groups (Table 1). At 1 month after surgery there was a statistically significant difference between the groups in all variables except Q_{\max} , in favour of LUCI. The mean IPSS at 1 month in the LVP group was statistically significantly different from that in the LUCI group ($P < 0.05$), as was the mean IPSS-Dysuria, the mean PS, the mean Q_{\max} , QoL and PVR (all $P < 0.05$). Within the first month 17% of patients in the LVP group and 4% in the LUCI group complained of transient urgency or stress incontinence (also statistically significant, $P < 0.05$). All these symptoms resolved before the next follow-up visit. Only one patient, who was 80 years old, in the LUCI group complained of occasional urgency incontinence even after 3 months. At 3 months, three more patients were lost to follow-up in the LVP group and two in the LUCI group. At 1 year, 35 patients in the LVP group and 40 in the LUCI group were available for follow-up. There was no statistically significant difference in any variables at the 3- and 12-month follow-up (Table 1).

For the secondary outcomes, the perioperative variables of both groups also showed no significant differences (Table 1). Even on anticoagulant therapy, intraoperative bleeding was not a problem in both groups, as assessed by the clear irrigation fluid at the end of the procedure. The mean operative time of LVP (59.8) was not statistically significantly different from that of LUCI (62.4; $P > 0.05$). The mean applied energy was also similar in both groups (Table 1, $P > 0.05$). There was no significant difference in the decline in core temperature between the groups ($P > 0.05$; Table 1). All patients had a standard trial without catheter, the catheter being removed after 2 days. Six patients in the LVP group required re-insertion of the Foley catheter on the second day, mainly due to severe storage symptoms. Of these six men, three had the catheter removed successfully after 5 days and another three after 7 days. Three patients in the LUCI group also needed re-insertion of the Foley catheter at 2 days, two of whom had a successful removal at 5 days and one 7 days.

Discussion

LVP is one of the latest methods being used to replace standard TURP in the developed world [5,6]. PVP and HoLEP are considered as good alternatives to TURP for treating BPH because of increasing evidence from various studies [5,6]. However, the main disadvantages of laser surgery for BPH are the lack of long-term data on its benefits and the severe pain, dysuria and storage

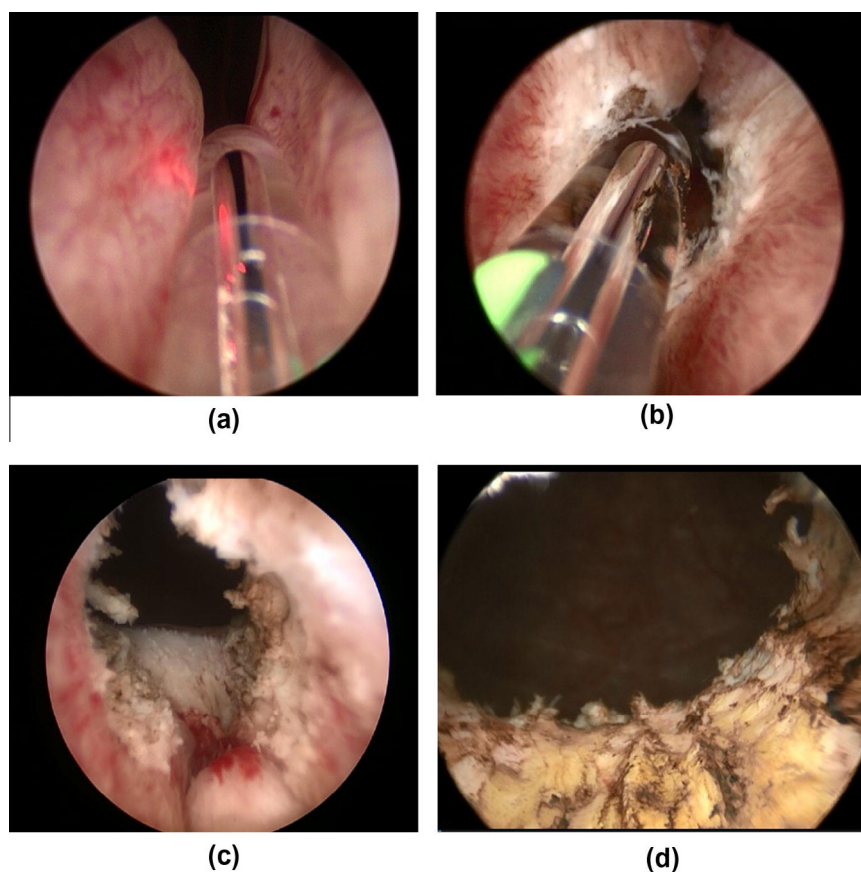


Figure 1 (a) Starting LVP; (b) Vaporisation of the lateral lobes; (c) A view at the level of the verumontanum; (d) A good prostate cavity after vaporisation.

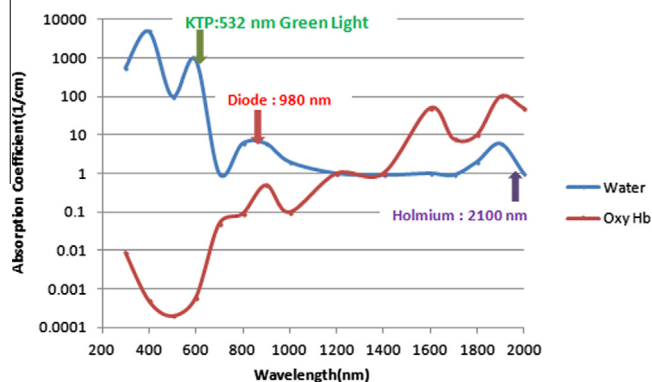
symptoms associated with it [5,6]. Some retrospective studies showed that diode LVP provides excellent intra-operative safety, instant tissue removal, and immediate relief from obstructive voiding symptoms, similar to the results of TURP, and with minimal bleeding and no TUR syndrome [7]. As the absorption of fluid is minimal, the chance of cold irrigation-induced core-temperature change is minimal.

Diode LVP and PVP are comparable in terms of the improvement in subjective and objective variables for assessing BPH [10]. One of the most common side-effects of diode laser surgery was dysuria (18%) and storage symptoms (34%) after the surgery, which can last for 4–6 weeks [10]. There are many short-term follow-up studies of up to 12 months which show the efficacy of diode LVP. Few studies showed a significant improvement in urodynamic variables (Q_{\max} and PVR). The reduction in PSA was used as a surrogate marker for the reduction of prostate volume in some studies [11–15]. The diode laser at a wavelength of 980 nm offers the highest simultaneous absorption of water and haemoglobin (Fig. 2), which is why it has the best tissue-ablative capacity. The peculiar absorption pattern of this wavelength also gives a better haemostatic property. The bleeding increases with decreasing frequency, while the ablation and coagulation zones are unaltered. The diode

laser can be applied continuously or in pulsed mode. We use the continuous wave mode for LVP. From ex-vivo studies, the tissue ablative property of the diode laser is double that of the KTP laser [16]. The tissue ablative capacity of the diode laser is 7.24 (1.48) g/10 min [16], which is much less than standard TURP, with a resection capacity of 8.28 (0.38) g/30 s, but far better than the KTP laser, which has an ablative rate of 3.99 (0.48) g/10 min. The coagulation zone of the KTP laser is more than twice as dense as that of the diode laser, due to its affinity for haemoglobin. From experimental studies the coagulation zone depth of a 100-W diode laser is 255.1 (28.2) μm . With the diode laser, a large amount of energy is absorbed at the surface, resulting in vaporisation of the tissue [16]. From dichromatic absorptiometry studies to quantify oedema, we know that the immediate application of cold irrigation can reduce the massive wound oedema associated with burning [8]. The same studies showed that cold treatment beginning 2 min after the burning did not decrease oedema formation and impaired resorption. Based on this information we introduced the concept of cold irrigation during laser surgery. This might reduce the wound oedema and modify the coagulation zone, which in effect can reduce the postoperative pain, dysuria and urinary storage symptoms.

Table 1 Baseline, peri- and postoperative variables.

Mean (SD or range)	LVP	LUCI	P
Age (years)	58.21 (45–74)	59.9 (42–82)	
Body mass index (kg/m ²)	27.64 (3.37)	27.78 (4.58)	> 0.05
Prostate volume (mL)	48.4 (12.5)	48.29 (16.47)	> 0.05
PSA level (ng/mL)	2.27 (1.62)	2.24 (1.94)	> 0.05
PVR (mL)	158.0 (69.5)	154.8 (83.1)	> 0.05
Q _{max} (mL/s)	8.22 (2.35)	7.87 (2.88)	> 0.05
IPSS	20.75 (4.45)	21.4 (4.8)	> 0.05
QoL score	3.4 (1.9)	3.9 (1.7)	> 0.05
<i>Anticoagulant (n patients)</i>			
Aspirin	11	15	
Warfarin	2	1	
Clopidogrel	5	3	
<i>Perioperative</i>			
Operative time (min)	59.8 (15.0)	62.4 (22.5)	> 0.05
Applied energy (kJ)	287.0 (148.8)	299.3 (107.8)	> 0.05
Irrigation during surgery (L)	2.64 (0.79)	2.55 (0.69)	> 0.05
Catheterisation time (days)	2.53 (1.36)	2.23 (0.93)	> 0.05
Core temperature decrease (°C)	3.08 (0.77)	3.38 (0.89)	> 0.05
<i>1-month follow-up</i>			
No. of patients	46	49	
Occasional haematuria (%)	96	92	
Bleeding requiring intervention	0	0	
IPSS	8.97 (1.68)	6.89 (1.50)	< 0.05
IPSS-Dysuria	2.32 (0.91)	3.54 (1.07)	< 0.05
PS	7.84 (2.92)	5.70 (2.10)	< 0.05
Q _{max} (mL/s)	20.82 (5.37)	21.4 (5.12)	> 0.05
QoL score	2.5 (1.18)	1.9 (0.95)	< 0.05
PVR (mL)	37.1 (22.40)	23.7 (20.4)	< 0.05
Urgency/stress incontinence, n (%)	8 (17)	2 (4)	< 0.05
<i>3-month follow-up</i>			
n patients	43	47	
IPSS	5.9 (1.9)	5.6 (1.8)	> 0.05
Q _{max} (mL/s)	20.34 (3.40)	20.73 (4.28)	> 0.05
QoL score	1.4 (0.9)	1.2 (0.9)	> 0.05
PVR (mL)	14.1 (18.2)	13.5 (22.2)	> 0.05
Bladder neck stenosis, n	2	1	
<i>12-month follow-up</i>			
No. of patients	35	40	
IPSS	4.9 (1.6)	4.52 (1.8)	> 0.05
Q _{max} (mL/s)	19.37 (2.11)	19.58 (2.40)	> 0.05
QoL score	1.1 (0.9)	1.1 (0.8)	> 0.05
PVR (mL)	13.9 (20.2)	13.1 (18.3)	> 0.05

**Figure 2** Absorption coefficients of various lasers.

In the present study the computer-based task of randomisation of patients was done by the theatre staff, but the surgeon was aware of the temperature of the irrigation solution, so this is considered to be a limitation of the study. A major concern was the possibility of hypothermia in such surgery, but there was no significant difference in the decrease in core body temperature between the groups. This agrees with the results of the various studies showing no significant fluid absorption in laser prostate surgery [11]. There was a statistically significant difference between the groups in variables such as the IPSS, QoL, IPSS-Dysuria, PS, PVR and transient incontinence at 1-month follow-up, in favour of LUCI, which suggests that cold irrigation can modify the side-effects of

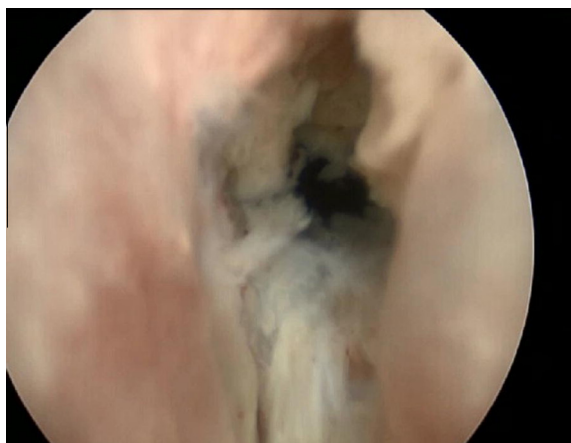


Figure 3 Bladder neck stenosis after LVP.

LVP. However, the major limitation of the study is that a postoperative biopsy and further dichromatic absorptiometry studies are needed to confirm the effects. The irrigation was clear at the end of the procedure in most patients in either group. Thus intraoperative bleeding was never a problem in both groups, even in patients on anticoagulant treatment. Another concern was whether the cold irrigation would slow the vaporisation and increase the lasing time, but there was no significant difference in lasing time or energy used in either group.

All patients had a standard trial without catheter after 2 days. Urgency or stress incontinence is a common complaint after transurethral laser surgery and during the first month more patients in the LVP than in the LUCI group complained of such problems, with a statistically significant difference between them. However, all these symptoms resolved before the next follow-up visits. Two patients in the LVP group and one in the LUCI group developed stenosis of the bladder neck or prostate region, probably due to adhesion from ‘hanging’ tissues (Fig. 3). All these patients were easily managed by one dilatation. Considering the overall pattern, there was a statistically significant improvement from baseline in all variables in both groups, which is consistent with previous studies.

In conclusion, diode LVP provides instant tissue removal and immediate relief from obstructive voiding symptoms, but it is associated with postoperative pain, dysuria and storage symptoms that can last for a month. LUCI is a good modification for reducing such symptoms. The procedure appears to be safe, causing no significant decrease in core temperature associated with the use of cold irrigant. We need further randomised controlled trials with various lasers to assess the effects of this modification on a larger scale and over the longer term.

Conflict of interest

None.

Source of funding

None declared.

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