Interstitial Laser Photocoagulation for Treatment of Benign Prostatic Hypertrophy: Outcomes and Cost Effectiveness

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- **Background:** We examined the efficiency and cost effectiveness of a temperature feedback diode-laser system in the treatment of benign prostatic hypertrophy (BPH).
- **Methods:** One hundred twenty patients with symptomatic BPH were included in this study between October 1997 and January 1998. Sixty of them were treated by transurethral resection of the prostate (TUR-P), and 60 patients were treated by temperature feedback interstitial laser coagulation (ILC). Direct and indirect cost parameters, such as operative time, operation-related consumables, duration of hospitalization, and amount of medication used were compared between the 2 groups.
- **Results:** All subjective and objective urinary parameters exhibited significant improvement 12 months after ILC. A reduction of 26.8% (46.6 to 34.1 ml) of the pretreatment prostate volume was observed at 12 months following ILC. The duration of hospital stay, operative time, and postoperative medications were significantly lower for those receiving ILC (5.9 to 2.5 days, p < 0.001) than for those who underwent TUR-P. The variety of laboratory tests needed for preoperative evaluation was no less when ILC was chosen for treating BPH (p = 0.849). Indirect costs, such as investment in laser equipment and laser accessories were higher in the ILC group (p < 0.001).
- **Conclusion:** The low morbidity profile, particularly the absence of retrograde ejaculation, makes ILC a valuable and attractive option for treatment of BPH patients who wish to retain their ejaculation ability, who have serious underlying diseases, or who have surgical risks for TUR-P or other invasive modalities. (*Chang Gung Med J 2003;26:799-806*)

Key words: benign prostatic hypertrophy, laser, temperature control, obstruction.

Benign prostatic hypertrophy (BPH) is a common condition among elderly men, with an estimated prevalence of up to 85%.⁽¹⁾ BPH can cause urinary dysfunction and urinary tract infections. Most patients receive surgical or pharmacological treatment. Although recent research has presented new

therapeutic choices for BPH therapy, transurethral resection of the prostate (TUR-P) seems to be the gold standard of treatment.^(2,3) The morbidity associated with this technique has remained in the range of between 15% and 18%.⁽⁴⁾ However, new surgical techniques and pharmacological therapies have

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recently been introduced. An effective treatment for BPH and bladder outlet obstruction that can safely be used in clinics would free the patient from a daily medication regimen, be cost effective, and be welcomed by urologists.⁽⁵⁾ A laser technique, which can be performed under local or regional anesthesia in clinics and has high cost effectiveness, is interstitial laser coagulation (ILC) of the prostate. Transurethral ILC allows efficient delivery of heat to prostatic tissue through a laser fiber manipulated under cystoscopic vision. This technique has the theoretical advantage of preserving the urothelium overlying the prostatic urethra and causes less post-treatment voiding irritation, which is common to other laser devices.^(6,7) Differences in cost effectiveness between TUR-P and ILC have been little discussed. This study addresses the use of ILC as a treatment for BPH; we found decreased duration of hospital stay and fewer side-effects compared to TUR-P.

METHODS

Between October 1997 and January 1998, 60 patients with symptomatic BPH between the ages of 55 and 86 (average, 73.3) years were enrolled in this study from 3 medical centers. The costs and durations of stay for these patients were compared with those of 60 patients treated by the same physician using TUR-P at our institution. All patients were treated under spinal anesthesia. Those patients with symptoms and signs of BPH and obstruction who met the following criteria were recruited: (1) American Urologic Association Symptom Index (AUA-SI) of 15 or higher; (2) a prostate size of greater than 30 g on transrectal ultrasonography (TRUS) study; (3) a peak flow rate of less than 12 ml/s; and (4) a post-voiding residual volume of less than 100 ml. Those patients whose prostate-specific antigen (PSA) levels were initially above 4.0 ng/ml received a thorough TRUS evaluation of the prostate with sextant biopsy to rule out the possibility of malignancy. Patients with evidence of prostate cancer or neuropathic voiding dysfunction were excluded.

The Indigo[®] 830e ILC module used in this study was a gallium-aluminum-arsenide diode laser emitting a marking beam of 625-680 nm and a low-power therapeutic infrared wavelength at 830 ± 20 nm. The specifications and procedural details of the

Indigo[®] 830e ILC module are described elsewhere.⁽⁸⁾

All patients completed AUA-SI questionnaires prior to treatment, and 3, 6, and 12 months after treatment. They were also questioned about their sexual function (erection and ejaculation). Uroflow and post-voiding residual volumes were obtained before treatment, and at 3, 6, and 12 months after treatment. A complete history of patients admitted to the hospital was recorded, a physical examination including a digital rectal examination was performed, and results of laboratory investigations of PSA level, urine analysis, complete blood count, chest X-ray, and electrocardiography were recorded. Symptoms were evaluated through the AUA symptom score, including a quality-of-life questionnaire and sexual function questionnaire. Patients also underwent TRUS of the prostate to determine any abnormalities. TRUS of the prostate was performed with a Bruel & Kjaer ultrasonic scanner (model 1846, B & J Electronics, Copenhagen, Denmark) and a biplaner transrectal probe (model 8551). The prostate volume was calculated by multiplying the measurement of 3 dimensions at the largest crosssectional area by a factor of 0.52. The volume measurements were performed before and 3, 6, and 12 months after ILC by the same urologist at each institution. Uroflowmetry studies, including the measurement of post-voiding residual volume allowed changes in voiding variables after the laser prostatectomy to be documented. All patients were evaluated through specific laboratory tests; X-ray examinations and other tests were ordered by attending physicians as deemed necessary. Table 1 details the clinical pathway. Indigo Medical Inc. made the Indigo[®] 830e BPH treatment system (Indigo Johnson & Johnson, Cincinnati, OH, USA). The system is composed of a treatment duration-programmable as well as wattageadjustable portable diode laser unit operating at 830 nm and 15 W (variable); a specialized fiberoptic delivery system contains an optical temperature monitoring system and a laser fiber. Transurethral application of ILC to the prostate was achieved through standard cystoscopic techniques (Fig. 1).

The results of treatment after ILC were compared with the results of 60 patients who had received TUR-P from the same group of physicians between October and November 1997. A mean duration of stay of greater than 5 days was defined as an increase in the duration of stay. Details of the

Category	Admission (pre-op)	Day 1 (OP day)	Day 2 (discharge)
Laboratory tests	CBC, urine analysis, BUN		
	creatinine, sugar, PSA, EKG		
	bilirubin, Na, K, Cl, albumin		
Radiology	Chest X-ray		
Pharmacology	Intravenous fluids	С	
	Antibiotics sent to operating room	Intramuscular analgesics	
		Laxative (oral)	С
		Analgesics (oral)	С
		Antibiotics	С
Operation &	Operating permit	ILC	
Anaesthesia	Anesthesia preparation		
	Nursing preparation		
Specific tests	TRUS		
	Urodynamics		
Others	Vital signs	С	
	Fleet enem	Diet as tolerated	
	Nothing by month from midnight	Suprapubic cystostomy	С
		or 2 way Foley	Removal of Foley

 Table 1. Categories of Information Evaluated for Assessing the Results of Implementing ILC

Abbreviations: ILC: interstitial laser coagulation; C: continued; CBC: complete blood count; BUN: blood urea nitrogen; PSA: prostate-specific antigen; TRUS: transrectal ultrasonography.

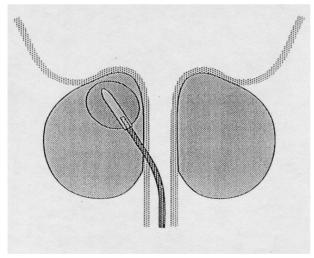


Fig. 1 Illustration of ILC of the prostate.

ILC and TUR-P manipulations as to duration of stay were determined by 4 factors, including clinical complications, change in clinical regimen, patientrelated psychological/social delay (patient anxiety or inadequate social assistance), and hospital-related problems. Accordingly, a primary outcome measure was the number of patients with an increased length of stay after the surgery. Total admission charges were divided into 6 categories: laboratory tests (e.g., routine tests, serum chemistry, and PSA), radiological studies (e.g., plain abdominal X-ray, intravenous urography), pharmacological agents (all agents used during admission except those during anesthesia), operation and anesthesia (the operation fee and the agents used during anesthesia), specific tests (e.g., ultrasonography, cystoscopy, and urodynamic studies), others ward fees, and other charges related to treatment, (e.g., bladder irrigation with normal saline, fleet enema, and perineal care).

Differences in admission charges of these 6 categories after ILC and TUR-P treatment were determined, and the results were compared between these 2 groups. Student's *t*-test was used to assess the statistical significance of differences between the ILC and TUR-P procedures.

RESULTS

Forty-five of the 60 patients in this study provided complete data over 16 months for analysis. The reasons for patients not complying with the fol-

	Initial	1 month	3 months	6 months	12 months
AUA-SI	25.7± 5.7	13.2 ± 6.6	9.7± 6.5	6.8± 5.0	7.2± 4.7
Peak flow (ml/s)	5.6 ± 4.7	14.2 ± 5.5	$13.7\pm$ 7.1	14.4 ± 5.2	14.8 ± 6.1
Prostate volume (ml)	46.6 ± 34.7		45.4 ± 25.8	34.8 ± 20.6	34.1 ± 19.5
QOL	4.4± 1.1	2.15 ± 0.83	1.94 ± 0.65	1.77 ± 0.65	1.64 ± 0.92

Table 2. Results of ILC in 45 Patients

Abbreviations: ILC: interstitial laser coagulation; AUA-SI: American Urologic Association symptom index; QOL: quality of life.

low-up schedule were: death unrelated to ILC in 4 (6%); dissatisfaction with ILC treatment effects in 3 (5%) and TUR-P performed by other urologists; and living or traveling abroad and no-show after a telephone appointment at 12 months in 8 (13.3%). Table 2 displays the treatment outcomes. The mean operative duration of ILC was 45 (range, 20-75) min, and blood loss was negligible. In the first 10 patients, the safety and accuracy of laser fiber placement via the urethra was monitored with TRUS in real-time while the surgeon was puncturing the prostate under 30° cystoscopic vision.

All subjective and objective urinary parameters showed significant improvement after ILC. The AUA-SI fell from 25.7 to 9.7, 6.8, and 7.2 at 3, 6, and more than 12 months post-ILC, respectively. Forty (89%) of the ILC patients improved not only in terms of the AUA symptom score but also in the maximum peak flow rate. Figure 2 displays the change in AUA-SI, with standard deviation (SD), in the 45 patients at various stages after ILC. The quality of life index also fell from 4 to 2, representing an improvement in voiding satisfaction from mostly dissatisfied to mostly satisfied. Figure 3 displays the comparison of peak flow rate with SD at various times after ILC. The peak flow rate steadily improved over time, reaching a plateau of 14-15 ml/s 3 months after ILC, where it remained for 12 months or more. The peak flow rate increased by over 160% of the pre-ILC rate in the year following ILC. The change in prostate volume after ILC was also significant, showing a reduction of 26.8% (46.6 to 34.1 ml) over 12 months. The mean catheterization time for ILC was 10 days. Among ILC patients, 10%, 20%, and 80% were catheter free by days 1, 7, and 14; while 20%, 50%, and 80% of TUR-P patients were catheter free by days 1, 2, and 3, respectively. Prolonged voiding irritation manifested as dysuria, frequency, and perineal discomfort. Although mild

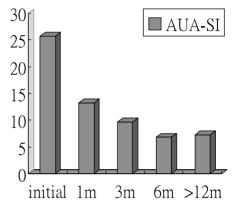


Fig. 2 Improvements in AUA symptom index after ILC.

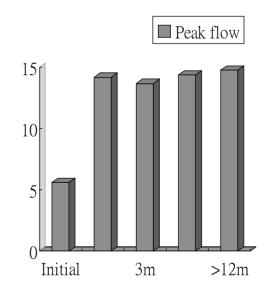


Fig. 3 Change of average peak flow rate after ILC.

and tolerable, prolonged voiding was observed in 63.3% (38/60) of patients who underwent ILC treatment. This symptom was most prominent right after

Table 3. Morbidity Profile (the Number of Cases Evaluated with-in 12 Months of ILC was 60)

Item	Number	Incidence (%)	
Post-ILC bleeding	8	13.3	
Irritative voiding symptoms	38	63.3	
UTI by urinalysis	17	28.3	
Prolonged hematuria	8	13.3	
Chronic UTI with stone formation	1	1.7	
Retrograde ejaculation	3	5	

Abbreviations: ILC: interstitial laser coagulation; UTI: urinary tract infection.

removal of the Foley or suprapubic catheter and usually declined within 2 weeks. Voiding discomfort lasted for up to 4 weeks in a few cases. Less than 5% of patients developed sexual dysfunction, persistent urinary incontinence, or retrograde ejaculation (Table 3). Table 4 displays the age, duration of stay, and mean admission charges categorized according to the experience of the attending physician and the therapy (TUR-P or ILC). Patients treated with TUR-P were not significantly older (p=0.85) than those treated with ILC. The mean duration of stay was significantly lower (5.9 to 2.5 days, (p < 0.001) following ILC treatment but the cost savings to patients treated by ILC group appeared to be slightly greater than in the TUR-P group. Significantly different (p < 0.001) numbers of patients showed psychological/social delays after ILC than after TUR-P. No significantly different laboratory tests were ordered by attending physicians after ILC treatment (Table 4), and the operating fees and the costs of specific tests showed no significant differences. Operation times and anesthesia fees were lower for ILC. Significantly fewer (p < 0.001) pharmacological agents were used after ILC of the prostate. Table 4 displays the separate procedural effects of TUR-P and ILC. The physician ordered significantly fewer laboratory tests or pharmacological agents after ILC. Total admission charges for the ILC group exceeded those for the TUR-P group because of the cost of the laser equipment and accessories (laser fiber). The use of radiological studies, duration of stay, operation times, and anesthetic fees for ILC significantly differed (p < 0.001) from those for TUR-P. Readmission rates to the hospital after discharge did not significantly differ between the ILC and TUR-P groups.

Table 4. Details of Age, LOS, and Admission Charges in

 Patients Categorized According to Experience of Attending

 Physician between Implementation of the ILC and TUR-P

	ILC	p
60	45	
68	67	0.849
5.9	2.5	< 0.001
45,106	50,705	> 0.05
6,264	5,285	
359	187	
4,453	1,607	
26,741	25,260	
306	197	
3,983	3,169	
3,000	15,000	< 0.001
:		< 0.001
3	0	
2	0	
6	2	
0	0	
11	2	
	68 5.9 45,106 6,264 359 4,453 26,741 306 3,983 3,000 : : 3 2 6 0 11	68 67 5.9 2.5 45,106 50,705 6,264 5,285 359 187 4,453 1,607 26,741 25,260 306 197 3,983 3,169 3,000 15,000 : 3 0 2 0 6 2 0 0 6 2 0 0 0 0

NT\$: New Taiwan dollar; rate for 1997-1998 NT\$30.5 = US\$1. *Differences were considered statistically significant at p < 0.05. **Abbreviations:** TUR: transurethral resection of the prostate; DOS: duration of stay.

DISCUSSION

Laser prostatectomy was first introduced by Costello and associates who used side-fire laser technology to establish a worthwhile outcome for BPH treatment.⁽⁹⁾ Following their initial success, other laser methods, including transurethral ultrasoundguided laser-induced prostatectomy, visual laser ablation of the prostate, transurethral evaporation of the prostate, and the modality used in this study have attracted urologists.⁽¹⁰⁻¹³⁾ Among the various laser options, the procedures of transurethral and transperineal ILC have demonstrated the lowest morbidity profiles and consistent therapeutic outcomes similar to that of TUR-*P*.^(II-17) This paper further verifies the therapeutic value and safety of ILC, and shows that ILC is an attractive option for BPH treatment. Urologists have always been eager to adopt the new therapeutic modalities in clinical practice.

Over the last few years, laser prostatectomy has become a popular treatment option for lower urinary tract symptoms caused by BPH. Side-fire laser devices destroy the prostate urethra along with the underlying prostate, leading to tissue sloughing and significant voiding irritation for several weeks.⁽¹⁸⁾ Contact laser ablation and electrovaporization mimic TUR-*P* and result in immediate tissue removal with minimal bleeding. These techniques are suitable only for prostates smaller than 50g.^(19,20) Transurethral needle ablation is a new anesthesiafree, outpatient modality for BPH treatment, which is suitable for small prostates.⁽²¹⁾ The long-term efficacy of this method remains to be confirmed.

The overall efficacy has been shown by many investigators worldwide to be comparable to and often indistinguishable from that of TUR-P. However, laser prostatectomy also has disadvantages: anesthesia is still required, prolonged catheterization is required, irritative voiding complaints may occur after treatment, and the treatment outcome is variable. ILC therapy is performed with a standard cystoscope, a solid-state diode 830-nm laser, with a special fiberoptic delivery system. Under direct observation, the laser fiber is introduced directly into the prostate through a small puncture in the prostatic urethra. Low-power energy is then delivered to thermally destroy a controlled volume of tissue. The fiberoptic probe can be introduced into any region of the prostate. The number sticking and sites are determined individually for each patient, according to the size and architecture of the gland. The procedure takes between 20 and 30 min each time. Periprostatic block which can be done only during such treatment, and this preserves the urethral mucosa.⁽²²⁾ ILC therapy of the prostate aims to provide better patient care and decrease surgical morbidity. TUR-P is the second most common operation performed by our group. In 1996, 20%-25% of admitted patients suffered from BPH and received TUR-P. An efficacious and cost-effective therapy for BPH is important since patients are frequently admitted. ILC therapy is less expensive than TUR-P if laser equipment and laser accessories are excluded. The duration of stay and mean admission charges excluding laser costs were significantly lower, by 42% and 15%, respectively (Table 4). The main cause of the longer duration of stay after ILC was that patients were delayed for psychological/social reasons (Table 4); such problems can stem from patient anxiety and inadequate social support, or by such causes as postoperative bleeding and pain. Traction of the Foley catheter for several hours is required to prevent postoperative bleeding after TUR-P. Post-traction irritation occurred in 38% of patients, who were then given meperidine. As to minor transient adverse effects, the need for postoperative acute pain management was significantly lower (p < 0.01) in the ILC treatment group, which actually may have been partly due to a reduction in patient anxiety resulting from pre/postoperative teaching. Educating the patient and family members about the nature of the illness and expected outcome of treatment decreases the patient's anxiety and instills a sense of certainty that they will be discharged from the hospital on the expected day. Postoperative normal saline bladder irrigation with normal saline can decrease patient suffering and nurses' workload. Traction of the Foley catheter and normal saline bladder irrigation after ILC have been reported to maintain the efficacy of the procedure while not increasing mortality. The major saving in laboratory tests after ILC arose because fewer serum chemistry tests were performed. The reduced use of pharmacological agents after ILC therapy was wholly the result of differences in management by each physician. Operational fees, specific tests, and other fees after ILC showed no significant reduction. The mean admission charges were significantly higher in the ILC group because of the high cost associated with the laser fiber. However, the average cost will be approximately NT\$6,000 less than that of TUR-P if ILC can be performed only as an outpatient procedure. The mean admission charges of ILC versus TUR-P did not significantly differ (p > 0.01). In summary, use of ILC is highly acceptable in the near future; it can be used for treatment on an anesthesiafree basis or with local anesthesia only and on an outpatient basis; and should reduce total treatment costs.

The Indigo[®] 830e transurethral ILC has the advantage of more-efficient intraprostatic energy delivery and the potential for preserving the prostatic

urethra, which markedly reduces the likelihood of voiding irritation after treatment. The efficiency, short learning curve, and low morbidity profile together with a reliable treatment outcome make ILC a highly acceptable modality for the treatment of BPH. Despite this, there are certain limitations when using the Indigo module. The lack of prostatic tissue for pathological analysis has raised the concern of possibly missing a malignancy in the prostate. The solution to this is to biopsy any patient suspected of having cancer. Moreover, since the laser is a new technology to most urologists, the expense, safety precautions, long-term effectiveness, and general acceptance are all important limiting factors. Future studies should include a large sample and prolonged follow-up of patients undergoing ILC.

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組織間質雷射凝固療法在良性攝護腺肥大症: 治療效果及經濟效益

崔克宏 張慧朗 張世忠'鄭鴻琳2

- **背 景**: 評估組織間質雷射凝固療法在良性攝護腺肥大症之治療效果及經濟效益。
- 方法: 自1997年10月至1998年1月間,有120位攝護腺肥大症之病人接受治療,其中60位病 人是接受經尿道攝護腺切除術 (TUR-P),另外60位的病人接受組織間質雷射凝固療 法(ILC)。我們利用此兩組病人來評估,不同的手術治療方式,它們的臨床治療效果 及經濟效益。
- 結果:在接受組織間質雷射凝固療法的病人,在臨床上、症狀都有顯著的改善。病人的攝護腺體積在手術之後12個月時,有減少26.8百分比(從46.6毫升縮小到34.1毫升)。同時、它與傳統的經尿道攝護腺切除術比較,無論在手術時間上,住院天數和術後止痛藥物的使用,都相對的減少(p<0.001)。但是,組織間質雷射凝固療法的缺點是手術所使用的探頭設備,比一般經尿道攝護腺切除術昂貴。</p>
- 結論:由於組織間質雷射凝固療法的併發症少,特別是逆行性射精的發生率遠低於接受經尿道攝護腺切除術之病人,所以,組織間質雷射凝固療法在攝護腺肥大症的治療上扮演者很重要的角色。特別是病人希望在術後保留正常的射精功能,或者是手術高危險群,且不適合接受經尿道攝護腺切除術者。組織間質雷射凝固療法乃提供另外一種選擇。

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關鍵字:攝護腺肥大症,雷射,溫度調控,阻塞。

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