

Laser Vaporization of the Prostate Using Local Anesthesia in an Office Setting

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PURPOSE: Although transurethral resection of the prostate remains the gold standard surgical treatment for alleviating obstruction from benign prostatic hyperplasia (BPH), the procedure is typically performed in an operating room setting. Office based minimally invasive treatment modalities are increasingly being utilized under local anesthesia. This study assessed the feasibility of laser vaporization of the prostate performed in the office under local anesthesia as an alternative treatment option for patients with obstructive symptoms secondary to BPH.

METHODS: Thirty patients underwent laser vaporization of the prostate with a 100 Watt Ceralas Diode 980 laser (Evolve, Biolitec Inc.) through a continuous flow cystoscope. Patients were administered local anesthesia using a transrectal ultrasound guided prostate block as well as intraurethral lidocaine jelly and intraprostatic injection of 1% lidocaine HCL through the cystoscope. Patients went home with catheter drainage for four days and then were evaluated one-month post procedure with a bladder scan for post void residual, uroflow test, questionnaire, and American Urological Association (AUA) symptom score.

RESULTS: Patients experienced minimal discomfort during the procedure and the average laser vaporization required 57,143 joules of energy over 16 minutes. There were no immediate complications related to the procedure. All patients were able to void postoperatively. Average reduction of AUA symptom score was from 27 to 11 points at one month. Preoperatively the average flow rate (Q ave) was 3.4 ml/sec (0.5-10.1) and the peak flow rate (Q max) was 7.2 ml/sec (0.5-11.9). Postoperatively, Q ave was 18.6 ml/sec (11.4-24) and average Q max was 21.8 ml/sec (14.4-29.2). All patients reported being satisfied with the procedure. Post void residuals decreased from an average of 255 to 43 milliliters. Four patients in refractory urinary retention were successfully able to void postoperatively.

CONCLUSIONS: Laser vaporization of the prostate using local anesthesia in an office setting can be considered an option for select patients who have obstructive symptoms due to BPH. Patients appear to be satisfied with a subjective improvement of symptoms and a decrease in post void residual. By utilizing local anesthesia, this procedure offers a novel method of treating prostate obstruction and may provide a means to treat patients who previously were not candidates for intervention.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a significant cause of urinary tract dysfunction in men. The treatment has included both medical and surgical measures. As symptoms progress, many patients will seek relief.¹

Transurethral resection of the prostate has been a standard of care for many decades, but requires monitored anesthesia in an operative setting. Many forms of prostatic ablation have been described, but the trend has been to reduce the complications and perform more minimally invasive surgeries under local anesthesia. Guidelines by the American Urological Association (AUA) have included minimally invasive therapies such as transurethral microwave therapy, transurethral needle ablation, and laser therapies. Laser therapy of the prostate has been shown to be an effective and durable therapy for men with symptomatic BPH.^{2,3}

Although transurethral resection of the prostate remains the gold standard, it has traditionally carried 1% mortality and 15% morbidity. Some of the risk is related to the procedure itself while there is also an inherent risk with general and spinal anesthesia.²

Many of the office based therapies were welcomed by urologists as a means to treat BPH symptoms with minimal risk. However, the procedures have also been at times associated with minimal improvement in the relief of symptoms.⁴ Interstitial laser coagulation of the prostate has been performed in an office setting under local anesthesia.^{5,6} Laser vaporization of the prostate has recently been embraced as a clinically effective and cost effective treatment for symptomatic BPH, and though the procedure has been performed in an office setting, there are no known studies to date demonstrating results under local anesthesia.⁵

As an alternative to current means of minimally invasive procedures, patients who met selected criteria were given an option of undergoing laser vaporization of the prostate under local anesthesia.

MATERIALS AND METHODS

All patients who had failed medical management or were dissatisfied with the medical management of their BPH symptoms were initially evaluated with a bladder scan to measure post-void residual. Patients who desired a minimally invasive procedure of the prostate were then scheduled for further evaluation with transrectal ultrasonography, uroflow, and office cystoscopy. Available minimally invasive treatment options offered to patients included microwave thermotherapy, interstitial laser coagulation of the prostate, and laser vaporization of the prostate. Beginning in June 2006, thirty consecutive patients, over a 6 month period, opted to undergo laser vaporization of the prostate using a 100 watt Ceralas diode laser (Evolve, Biolitec Inc.).

Patients who had a prostate measuring greater than 70 cubic centimeters on transrectal ultrasound were advised to have either a transurethral resection or laser vaporization of the prostate under general anesthesia. One patient with a prostate volume of 71 cubic centimeters did undergo laser vaporization in the office since he was

considered high risk for general anesthesia, due to his severe chronic obstructive pulmonary disease.

All patients underwent flexible cystoscopy to confirm obstruction from benign prostatic hypertrophy. Also noted was any trabeculation or thickening of the bladder musculature that would help confirm long term obstruction. Alternative therapies for the prostate were discussed including but not limited to observation, herbals, alpha blockers, 5 alpha reductase inhibitors, microwave thermotherapy, interstitial laser coagulation, vaporization of the prostate in the operative suite, and transurethral resection of the prostate. No patients were recommended for open prostatectomy.

Patient's who were offered laser vaporization in the office had one of three criteria: a prostate under 70 cubic centimeters, re-growth of prostate tissue after prior resection, or patients who were felt to be at increased risk for undergoing general anesthesia. Patients were not offered laser vaporization if they had a large median lobe, concomitant urologic problems such as bladder neck contracture or bladder tumor, or if the patient experienced considerable pain during flexible cystoscopy.

A total of 70 patients were evaluated for surgical management of their obstructive uropathy over the six month period. Twenty eight underwent surgical intervention in the operative suite under general anesthesia because of not meeting inclusion criteria. Of the 70 patients, 10 patients (14%) had general anesthesia because of experiencing pain during flexible cystoscopy under local anesthesia. A total of 42 patients were given an option of laser vaporization of the prostate in the office under local anesthesia.

Patients underwent informed consent including but not limited to risks of pain, hematuria, failure of procedure, need for hospitalization, need for further surgery, bladder neck contractures, urgency, dysuria and possible chronic discomfort. After explanation of the procedure, 12 patients opted to either undergo surgical intervention in the operative suite or remain on medications.

Patients were informed of possible need to abort the procedure since it would be performed under local anesthesia. During the procedure, all were assessed for pain using a verbally administered 0-10 numeric rating scale⁷. Patients were also informed that if they would experience significant pain during the procedure (above 4 on a scale of zero to ten), it would be terminated.

Two tablets of acetaminophen with propoxyphene (Darvocet N-100) and one 5 mg tablet of diazepam were administered upon arrival to the waiting room thirty minutes prior to procedure and all patients were instructed to have a family member present preoperatively and postoperatively. Headphones were used to listen to biorhythmic music with intra-operative suggestions as a means of creating a relaxed and comfortable environment.⁸

Triple anesthetic blockade of the prostate was utilized. First, patients had 20 ml of 2% lidocaine jelly instilled into the urethra and bladder. Lidocaine jelly was stored in a freezer and injected intraurethrally while still chilled. A penile clamp was applied and the lidocaine jelly was allowed to set for 20 minutes. Patients were then instructed to roll on their side and a transrectal ultrasound probe was inserted into the rectum. Transrectal ultrasonography was performed and under direct guidance 5 ml of 1% lidocaine HCl was injected, using a spinal needle, at the juncture of the seminal vesicle and prostate bilaterally. The third component of anesthetic blockade consisted of direct injection of anesthetic into the prostate. After placing the patient in a dorsal lithotomy position, rigid

cystoscopy was performed and using a flexible needle, lidocaine HCL anesthetic was injected into the lateral lobes of the prostate. Each lobe was slowly infiltrated with 5 ml of lidocaine HCL.

Laser vaporization of the prostate was performed with a Ceralas D 100 laser (Evolve 980 nanometer, Biolitec, inc.). The majority of the prostate tissue was removed from the lateral lobes, with very little tissue removed from the base to prevent undermining of the bladder neck. Prostate ablation continued until an open channel, as determined by the surgeon, was obtained. Patients were asked to rate their pain during the procedure every 2 minutes. If pain was greater than a level 2 of 10 then the patient was asked whether he would like to proceed. If he chose to proceed, an additional 2 ml of xylocaine HCl was injected transurethrally into the prostate via the flexible needle at the location on the prostate where the patient was experiencing pain. If the patient was to experience pain greater than a level 2 then the procedure would be terminated. Blood pressure was monitored during the procedure.

End point for the procedure was pain or adequate vaporization to open the prostatic channel. After completion of the procedure, a 20 french foley catheter was inserted. Patients were discharged home with a prescription for acetaminophen with propoxyphene tablets and were instructed to contact the office with any bleeding, pain, or any other abnormal reactions. Patients returned four days later for catheter removal.

Patients were reassessed one month postoperatively with an AUA symptom score, scheduled for a uroflow test, and all were asked to rate their experience with office based laser vaporization. Patients were asked to complete a brief questionnaire consisting of two questions. The first question asked patients, "Please recall the laser procedure you had in the office. On a scale of one to ten, with zero being no pain and ten being the worst pain you ever experienced, what level of pain did you experience during the procedure." The second asked patients to circle one of five statements: 1) would definitely not recommend procedure to a friend, 2) would probably not recommend procedure to a friend, 3) neutral, 4) would probably recommend procedure to a friend, 5) would definitely recommend procedure to a friend.

RESULTS

A total of thirty patients underwent laser vaporization of the prostate using local anesthesia in the office. Average age was 76 years old (55-95). Average AUA symptom score was 27.

Patients had a preoperative prostate volume averaging 48.9 cubic centimeters (12-71). All underwent preoperative cystoscopy which confirmed outlet obstruction from prostatic tissue. In one patient, cystoscopy was performed one year prior to being scheduled. It was noted during vaporization that the patient had developed bladder stones in the interim period and he was scheduled for a litholopaxy at a later date.

Two patients had re-growth of prostate tissue from a prior transurethral resection of the prostate. One had undergone transurethral resection of the prostate 5 years previously and another underwent resection over 10 years ago. Four patients were in refractory acute urinary retention and failed a trial of void on three separate attempts, despite taking oral alpha-blocker and a 5-alpha reductase inhibitor.

A total of 22 patients had a uroflow test preoperatively, and 19 of these 22 patients had a uroflow test one month postoperatively. The average preoperative peak flow rate (Q max) was 7.2 ml/sec (0.5-11.9) and average flow rate (Q ave) was 3.4 ml/sec (0.5-10.1). Postoperative average Q max was 21.8 ml/sec (14.4-29.2) and Q ave was 18.6 ml/sec (11.4-24).

Patients experienced minimal pain and the highest pain reported was a level 4 out of a possible 10. No patient requested that the procedure be aborted due to discomfort. Two patients required additional peri-urethral injection of 5 ml of 2% xylocaine and they did not require any additional analgesia subsequently.

Two patients had prostate cancer with bladder neck obstruction due to prostate growth. One prostate cancer patient had received external beam radiation in the past. The other patient was started on hormonal therapy with a LHRH- agonist approximately 5 years earlier.

Prostate vaporization was successfully performed in all patients. The average prostate received 57,143 joules of energy (25,000-94,000 joules) during vaporization. The amount of prostate vaporized was based upon the author's subjective interpretation of what would be needed for a successful outcome.

Laser time averaged 16 minutes. The shortest laser time was 8 minutes in a patient with regrowth of prostatic tissue causing obstructive uropathy. The longest laser time was 26 minutes in a patient with a 70 gram prostate.

All patients were sent home with a catheter, which was removed 4 days post operatively. No patients required continuous irrigation in the immediate postoperative period. A total of six patients required reinsertion of the catheter after failing the initial trial of void and all six patients had the catheter removed one week later and voided without difficulty.

There were no significant changes in preoperative to postoperative blood pressure. No patient had a postoperative systolic or diastolic blood pressure reading of greater or less than 10 points from their preoperative systolic or diastolic blood pressure reading.

Post void residuals of urine were reduced from 255 ml to 43 ml on average at one month follow-up. Of those with less than 500 ml residuals preoperatively, the average reduction was from 197 ml to 17 ml. The four patients in urinary retention had post void residuals of 23 ml, 44 ml, 65 ml and 261 ml at one month follow-up.

Twenty nine patients (97%) experienced no complications in the initial 30 day postoperative period. One patient developed gross hematuria, with clot retention, on the fourth postoperative day. He was voiding well with clear urine until resuming aspirin and clopidogrel bisulfate (Plavix) on the third postoperative day. The patient required three-way irrigation and clot evacuation.

A total of 7 patients (23%) were given tolterodine tartrate (Detrol LA) for irritative bladder symptoms. The length of time on the medication did not exceed four weeks and there are no study patients currently on the medication.

AUA symptom scores improved significantly. The average postoperative AUA symptom score at one month was 11 (5-20), which was an average drop of 16 points on the symptom score.

To date, ten patients have been seen at 6 month follow up. All were asked to complete another AUA symptom score and the average preoperative symptom score was

28 (26-33) and 9 (6-13) at six months post procedure. All ten patients responded that they were voiding well without difficulty. None of these ten patients were taking prostate medications at 6 months post procedure.

All patients were asked on their initial follow-up visit whether they were satisfied with the procedure and results and twenty nine patients (97%) responded affirmatively. They were also asked if they regretted undergoing the procedure and one patient did state that he would have had the procedure in the operative suite due to the anxiety felt preoperatively anticipating the procedure under local anesthesia. This patient did state that his anxiety was lessened during the procedure once he realized there was minimal pain.

On the one-month postoperative follow-up survey, on average, patients recalled their pain as a level 2 (1-4) out of 10. Twenty patients (67%) responded that they would definitely recommend the procedure to a friend and seven patients (23%) responded that they would probably recommend the procedure to a friend. Two patients (7%) remained neutral, and one patient (3%) responded that he would probably not recommend the procedure to a friend.

DISCUSSION

Although general anesthesia may be commonly used during laser vaporization, recent trends towards minimally invasive surgeries encourage use of local anesthesia and minimizing risk for patients. The prostate block was initially developed for outpatient prostate surgery and biopsies. The perineal prostate block has been utilized for office based interstitial laser coagulation under local anesthesia.⁹ Additional techniques were developed and utilized for interstitial laser coagulation procedures.¹⁰

It is known that minimally invasive therapies confer treatment benefits in a single treatment under local anesthesia, but the challenge has been for urologists to identify the treatment that provides both short and long-term benefits with minimal adverse events. The long-term durability of minimally invasive therapies remains uncertain.¹¹ There are currently several lasers that have been developed for use on the prostate, however, transurethral resection of the prostate remains the gold standard treatment for surgical management of symptomatic BPH.¹²

A common ambulatory laser treatment is interstitial laser coagulation (ILC), which involves use of an Indigo laser (Johnson & Johnson). The Indigo laser is a diode laser with a wavelength of 808 nm. This laser is used in our office as an office-based treatment under local anesthesia. The Indigo laser allows heating of a small amount of prostate tissue, which then undergoes sloughing, and involution over a period of several weeks.¹³ Another popular ambulatory procedure is transurethral microwave thermotherapy. Microwave therapy involves heating of prostate tissue, which undergoes apoptosis and sloughing over several weeks. Unlike laser vaporization, this form of therapy does not result in immediate removal of prostate tissue.¹⁴

Photoselective vaporization of the prostate has become a popular laser treatment in ambulatory settings. Photoselective vaporization is performed with Greenlight laser (American Medical Systems) which is a KTP laser with a wavelength of 532 nm. This allows for the immediate vaporization of prostate tissue under direct visualization. The

vaporization of tissue has been used to open the prostatic urethra and alleviate obstruction from the prostate. This laser has been used in a similar capacity to transurethral resection of the prostate.¹⁵ The 100-watt Ceralas diode 980 laser performs laser vaporization of the prostate in a similar fashion utilizing the advantages of a longer wavelength.¹⁶ This procedure has been reported in an office setting but there are no studies to date reporting patient outcomes.¹⁷

Initial studies with the Cerelas D 50 laser showed that a laser at 980 nm can produce effective vaporization with minimal tissue edema, minimal residual effect of carbonization and a sharp bloodless cut. This technology was applied to the Cerelas D100 laser which uses 100-Watt power to allow enhanced vaporization of tissue.¹⁶

Office-based surgery has advantages in scheduling, convenience, and compensation and there may be advantages for convenience for both the patient and the surgeon. Urologists throughout the country are increasingly utilizing office-based surgery.¹⁸ It is believed that laser vaporization will be an increasing trend outside of the hospital setting.¹⁷

Laser vaporization has been used to create a surgical defect equivalent of transurethral resection of the prostate, but what remains unknown is how much tissue vaporization is necessary to create adequate short term and durable long term results. In transurethral resection of the prostate, the goal is to remove as much tissue as possible without perforating the prostate capsule. However, with office based minimally invasive procedures a much smaller amount of tissue is removed or allowed to undergo involution in order to provide symptomatic improvement. The current study suggests that the answer may lie somewhere in between utilizing direct vision to open the prostatic urethra. Indeed it is not clear if it has ever been determined as to how much tissue should be removed in order to demonstrate improved urinary flow.

When initiating the study, there was concern as to whether the patients would not be able to tolerate bladder distension from a continuous flow cystoscope. In those who underwent office based laser vaporization, this did not seem to be an issue. Some reported a feeling of pressure in the bladder, but there was not a point in which a patient experienced excessive water distension of the bladder and none requested that the procedure be terminated due to bladder distension.

Patients did not experience a significant amount of urgency or irritative symptoms. Seven required use of an anticholinergic medication but this was limited. This may be a result of surgical technique, although it is not possible to establish this conclusion with certainty. Laser vaporization was performed to remove only the obstructive tissue and vaporization of the bladder neck and floor of the prostate was kept to a minimum. In the author's experience, postoperative urgency appeared less than with other laser vaporization procedures, however, no objective comparisons can be made. Postoperative urgency appears to be a common side effect of laser vaporization, and this appears to resolve with healing of the vaporized tissue.¹⁹

Patients were informed of the possibility of discomfort or pain from use of the laser and they were instructed to state if they had any discomfort during the procedure. In addition, they were asked approximately every two minutes if they were experiencing any pain and to assign a level from 1-10. No patient requested that the procedure be aborted.

This study reveals that short term results are achievable using an office based laser procedure under local anesthesia. Long term results and durability remain unknown. It is unclear if the removal of the urethral mucosa will lead to increased bladder neck contractures. Previous office based procedures have left the mucosa intact and it is possible that bladder neck contractures will develop, however all patients had a wide-open bladder neck due to adequate tissue vaporization intra-operatively.

One of the limitations of this study is the lack of long-term follow-up. A clear benefit, however, is seen at one month and the ten patients at 6-month follow-up continue to do well without complications. It is assumed that since laser vaporization of prostate involves tissue removal and establishes an open channel, these patients should continue to do well.

The quantity of tissue vaporized appeared to be significantly more than expected. Patients tolerated the procedure well with minimal pain, thus allowing a longer vaporization time. No procedure was aborted due to patient discomfort, thus, patients could have potentially had additional prostate tissue removed.

The ideal candidate for this procedure may be the patient who has had a previous transurethral resection of the prostate. Some who have prior transurethral resection and focal growth of the prostate with only a small portion of the obstructing prostate tissue causing the obstruction. Vaporization was performed on this focal obstruction with minimal need to vaporize other areas of the prostate. This may reduce the risk of opening an additional venous sinus and may potentially reduce the risk of inducing a bladder neck contracture.

It has been shown that transurethral needle ablation of the prostate (TUNA) can result in up to 83% of patients requiring an additional procedure, mostly TURP. Many patients who underwent TUNA were restarted on alpha blockers.²⁰ Of patients undergoing laser vaporization of the prostate in an office setting, no patients required additional resection or use of alpha-blockers. Unlike TUNA, laser vaporization involves tissue removal and based on these short term results, this may result in durable improvement of voiding symptoms.

It is the author's opinion that laser vaporization in the office, under local anesthesia, is applicable for a select group of patients. Those who may be at higher risk of undergoing general anesthesia may be appropriate candidates. The same procedure can be performed in an operative suite under local anesthesia with monitoring of the patient's vital signs. It may be better to perform a minimally invasive procedure, rather than commit the patient to long-term catheter drainage. This may be particularly relevant for nursing home patients or those who are at increased risk for general anesthesia.

CONCLUSIONS

Laser vaporization of the prostate, under local anesthesia, in an office setting, appears to be a feasible option for select patients. Patients appear to tolerate the procedure well and there appears to be short term benefits of improved urinary symptoms

and reduction in post void volumes. Further studies and increased experience by others is necessary to assess objective parameters in both short term and long term outcomes.

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