LASER TREATMENT OF THE PROSTATE USING THE UROLASE FIBER: THE DUTCH EXPERIENCE

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ABSTRACT

Purpose: Subjective and objective results were assessed after laser prostatectomy with the Urolase® fiber at 5 different centers in The Netherlands.

Materials and Methods: Patients were evaluated with the international prostatic symptom score questionnaire, uroflowmetry and post-void residual volume measurements. Urodynamic investigations with pressure-flow analysis were performed at 2 centers.

Results: Data for 233 patients were evaluated. Overall significant improvement in mean international prostatic symptom score, maximum flow, post-void residual and urodynamic parameters was noted. Differences in outcome among the centers may be due to variation of technique or different selection criteria. Postoperative morbidity was significant, with irritative voiding complaints for 4 to 6 weeks in up to 50% of all patients and urinary tract infections in 21.1%.

Conclusions: Laser prostatectomy results in subjective and objective improvement, which is operator independent. Despite the observation that perioperative (intraoperative and immediate postoperative) morbidity seems less severe compared to transurethral resection of the prostate, there is a shift toward greater postoperative morbidity.

Key Words: Lasers, prostatectomy, prostatic hypertrophy, urodynamics

Benign prostatic hyperplasia (BPH) has a high prevalence in men older than 50 years, the majority of whom will eventually have voiding complaints and require treatment.1 Transurethral electroresection of the prostate has proved to be safe and effective, with excellent long-term results. The mortality rate has decreased from 2.5 to 0.2% but morbidity has remained unchanged at 18% within the first 90 days after transurethral resection of the prostate2 and probably is even greater after 1 year. This morbidity rate is a main reason to seek less invasive treatment modalities, causing minimal morbidity while maintaining the same results as after transurethral resection of the prostate. Despite the challenge of numerous alternative operative and nonoperative therapies,3-7 transurethral resection of the prostate and open prostatectomy remain the gold standards in the treatment of BPH, mainly because the clinical outcome of alternative treatments is significantly less successful. A promising, recently introduced alternative treatment of BPH seems to be laser energy.

In 1985 Shanberg et al used laser energy to treat BPH.8 With an end firing, bare fiber used in contact with tissue, causing vaporization, the main purpose was to make prostatic incisions. The incidence of postoperative bleeding was significant and, furthermore, it was difficult to aim the laser beam at the prostatic lobes. Development of a side firing device solved this problem, and after canine feasibility studies Costello et al performed laser prostatectomies in men with a free beam side firing system under cystoscopic guidance.9 McCullough et al performed transurethral ultrasound guided laser ablation of the prostate (TULIP).10 Also, the understanding and acceptance of coagulation as a deeper tissue penetrating effect compared to vaporization allowed for development of an efficient and effective neodymium:YAG laser procedure. Since then, several different free beam, side firing laser fibers for contact or noncontact use have been developed. Besides side firing fiber techniques, other laser applications for interstitial or contact vaporization were developed and are currently under clinical investigation.

A widely used and investigated laser fiber is the side firing, noncontact Urolase fiber. Most studies using this device to treat BPH showed good subjective and objective results.11-14 However, the extent of improvement differed in many studies. We investigated the clinical outcome of laser prostatectomy at different centers in the Netherlands. Is laser prostatectomy operator dependent or can variation in clinical outcome be explained by differences in treatment protocol? The only way to demonstrate effectiveness of treatment for BPH is to perform urodynamic investigations before and after the procedure. There are few studies of urodynamics used to demonstrate effectiveness of laser prostatectomy.15-18 We performed urodynamic investigations before and 6 months after treatment of BPH with the Urolase side firing laser at 2 university centers.

MATERIAL AND METHODS

Each participating center included at least 10 patients who underwent laser prostatectomy with the Urolase fiber. Guidelines for selecting patients for laser prostatectomy were age greater than 50 years, duration of symptoms longer than 3 months, international prostatic symptom score (I-PSS) greater than 12, maximum flow less than 15 ml. per second and voided volume greater than 100 ml. Despite these criteria, 2 centers treated all patients who normally would undergo transurethral resection of the prostate. Therefore, from these 2 centers 3 patients with a maximum flow of more than 15 ml. per second and 7 with an I-PSS of less than 12 underwent laser prostatectomy. Patients in urinary retention, or those with urethral stricture, previous prostate surgery, diabetes mellitus or neurogenic bladder dysfunction were excluded from the study. All patients were evaluated

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with I-PSS and sexual function questionnaires, maximum flow and post-void residual volume preoperatively, and at 3, 6 and 12 months postoperatively. Physical examination (including digital rectal examination), transrectal ultrasound with measurement of prostate volume, laboratory investigations (including prostate specific antigen) and urine cultures were performed preoperatively. Urine was also cultured 2 and 4 weeks after removal of the catheter or in cases suspicious for urinary tract infection. Urine was considered infected when culture yielded more than 10⁵/ml. of a pure organism. All patients with an abnormal digital rectal examination and/or elevated prostate specific antigen underwent transrectal ultrasound guided biopsies of the prostate. Patients with histologically proved adenocarcinoma were excluded from the study.

Urodynamic investigations were performed at 2 centers preoperatively and 6 months postoperatively with an 8F transurethral lumen catheter and an intravesical microtip pressure sensor. Pressure and flow data were recorded digitally with commercially available equipment and urodynamic analysis software. To quantify grade of obstruction different parameters were used, including detrusor pressure at maximum flow (gradation according to the Abrams-Griffith nomogram), interaction of quadratic urethral resistance relation with pressure axis of pressure flow (urethral resistance relation) and linear passive urethral resistance relation (an approximation of the resistance relation by a straight line through minimal detrusor pressure and detrusor pressure at maximum flow, with grading according to the Schafer nomogram).

All patients were treated via the 4-quadrant technique at the 5, 7, and 10 o'clock positions with a power setting of 40 W. for 90 seconds, which has been described previously. An enlarged middle lobe was treated with 1 or 2 laser applications. Each patient was treated with a new fiber. However, at all centers slight modifications were introduced, and additional prostatic tissue was treated after the 4-quadrant applications. Before laser therapy was begun cystourethroscopy was performed and a Ch. 16 suprapubic catheter was introduced. The suprapubic catheter was removed when the patient could void spontaneously with a residual of less than 50 ml. Patients were discharged from the hospital 1 day postoperatively.

The Kruskal-Wallis test was used for statistical comparison of results among the different centers. The Wilcoxon signed rank test was used for statistical comparison between preoperative and postoperative data.

RESULTS

Data from 233 patients treated at 5 centers were evaluated. The distribution among the different centers, and mean values at baseline for age, prostate volume, maximum flow, post-void residual and I-PSS are shown in table 1. Except for age and prostate volume, all other baseline characteristics were statistically different among the centers according to the Kruskal-Wallis test. When baseline characteristics for the 3 centers that used the inclusion criteria were examined there was a difference between the maximum flow and post-void residual but not I-PSS. There was no difference between baseline characteristics for the 2 centers that did not follow the inclusion criteria completely. Data for 200, 180 and 85 patients were available for evaluation at 3, 6 and 12 months. No 12-month data were available from center 3.

Uroflowmetry. Overall, there was an average improvement in mean maximum flow rate plus or minus standard deviation from 7.5 ± 3.2 ml per second (range 2.0 to 23.0) at baseline to 16.4 ± 5.6 (range 4.0 to 45.0) at 3 months, 16.7 ± 5.2 (range 4.5 to 33.0) at 6 months and 16.3 ± 5.7 (range 5.0 to 33.9) at 12 months (table 2). All centers achieved significant improvement in maximum flow rate at 6 months. However, there was a difference in the extent of improvement per center. Two centers treated 3 patients with a maximum flow of more than 15 ml per second. Exclusion of data for these 3 patients from statistical analysis will not change the aforementioned results significantly. Mean individual improvement at 6 months was 160.4% or 10.4 ± 4.5 ml per second (range —5 to 26.5). Only 11 patients (6%) had no improvement in maximum flow rate at 6 months.

Post-void residual. Overall, there was an average decrease in post-void residual from 110.4 ± 84.5 ml (range 0 to 385) at baseline to 31.8 ± 47.5 (range 0 to 200) at 3 months, 30.2 ± 50.5 (range 0 to 500) at 6 months and 21.3 ± 39.0 (range 0 to 140) at 12 months. All centers achieved a significant decrease in post-void residual at 6 months (table 3). Mean individual decrease in post-void residual at 6 months was 61.7% or 83.9 ± 74.3 ml (range —100 to 345). Only 13 patients (7%) had no decrease in post-void residual at 6 months.

I-PSS. Because not every patient returned the questionnaire during followup, at 3, 6 and 12 months only 191, 178 and 79 patients, respectively, were evaluated. Overall, there was a decrease in symptom score from 21.1 ± 4.8 (range 6 to 32) at baseline to 7.1 ± 5.4 (range 0 to 23) at 3 months, 4.8 ± 5.0 (range 0 to 35) at 6 months and 3.6 ± 3.7 (range 0 to 20) at 12 months. Again, all centers achieved a significant decrease in symptom score (table 4). Mean individual decrease in symptom score at 6 months was 75.5% or 17.1 ± 6.2 (range —9 to 30). Only 5 patients (3%) had no decrease in symptom score at 6 months. Exclusion of data for the 7 patients with an I-PSS of less than 12 from statistical analysis will not change the aforementioned results significantly. There was no significant difference between the 6 and 12-month maximum flow, post-void residual and I-PSS results for all centers (except center 3 because no 12-month data were available).

Sexual function questionnaire. Sexual function was assessed using a questionnaire preoperatively and 6 months postoperatively. There were 127 sexually active patients, defined as those with a good erection for sexual intercourse and antegrade ejaculation. Of these patients 47% had retrograde ejaculation postoperatively and 12.6% complained of erectile function that was insufficient for sexual intercourse or absense.

Pressure-flow studies. Urodynamic investigations were performed in 98 patients preoperatively and 6 months postoperatively. There was improvement in mean detrusor pressure at maximum flow from 77.8 ± 33.5 cm. water (range 28 to 182) to 40.4 ± 20.1 (range 15 to 103). Only 6 patients

<table>
<thead>
<tr>
<th>Center</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. pts.</td>
<td>Mean (range):</td>
<td>59</td>
<td>31</td>
<td>30</td>
<td>60</td>
<td>233</td>
</tr>
<tr>
<td>Age (yr.)</td>
<td>65.0 (51.9-79.2)</td>
<td>66.7 (56.0-79.8)</td>
<td>66.3 (54.3-78.9)</td>
<td>65.0 (52.5-78.4)</td>
<td>68.7 (54.9-82.8)</td>
<td>66.2 (51.2-82.8)</td>
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<td>Prostate vol. (ml.)</td>
<td>43.7 (30-101)</td>
<td>47.2 (37-100)</td>
<td>46.3 (28-96)</td>
<td>51.5 (17-98)</td>
<td>45.4 (30-96)</td>
<td>47.8 (17-101)</td>
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<tr>
<td>I-PSS (range)</td>
<td>21.8 (12-32)</td>
<td>20.9 (9-60)</td>
<td>22.6 (18-31)</td>
<td>17.9 (9-31)</td>
<td>21.8 (15-31)</td>
<td>21.1 (6-32)</td>
</tr>
<tr>
<td>Ml/sec. maximum flow (range)</td>
<td>7.9 (5.0-14.0)</td>
<td>8.7 (4.0-23.0)</td>
<td>5.7 (4.0-12.0)</td>
<td>9.8 (3.0-21.0)</td>
<td>6.1 (4.0-12.0)</td>
<td>7.5 (2.0-23.0)</td>
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<tr>
<td>Ml post-void residual (range)</td>
<td>84.5 (0-365)</td>
<td>120.9 (0-350)</td>
<td>134.8 (0-350)</td>
<td>99.0 (0-350)</td>
<td>115.7 (0-360)</td>
<td>110.4 (0-365)</td>
</tr>
</tbody>
</table>
Table 2. Mean maximum flow at baseline, and at 12, 26 and 52 weeks postoperatively for centers 1 to 5

<table>
<thead>
<tr>
<th>Center</th>
<th>Mean ML/Sec. Maximum Flow (range)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 Wk. (233 pts.)</td>
<td>12 Wks. (200 pts.)</td>
<td>26 Wks. (180 pts.)</td>
</tr>
<tr>
<td>1</td>
<td>7.9 (2.0-14.0)</td>
<td>18.7 (6.5-45.0)</td>
</tr>
<tr>
<td>2</td>
<td>8.7 (4.0-23.0)</td>
<td>16.8 (6.0-34.0)</td>
</tr>
<tr>
<td>3</td>
<td>6.7 (4.0-12.0)</td>
<td>15.0 (10.0-21.0)</td>
</tr>
<tr>
<td>4</td>
<td>9.6 (3.0-21.0)</td>
<td>12.6 (4.0-36.0)</td>
</tr>
<tr>
<td>5</td>
<td>6.1 (4.0-12.0)</td>
<td>15.6 (8.0-22.0)</td>
</tr>
<tr>
<td>Totals</td>
<td>7.5 (2.0-23.0)</td>
<td>16.4 (4.0-45.0)</td>
</tr>
</tbody>
</table>

* At 26 weeks.

Table 3. Mean post-void residual at baseline, and at 12, 26 and 52 weeks postoperatively for centers 1 to 5

<table>
<thead>
<tr>
<th>Center</th>
<th>Mean ML Post-Void Residual (range)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 Wk. (233 pts.)</td>
<td>12 Wks. (199 pts.)</td>
<td>26 Wks. (180 pts.)</td>
</tr>
<tr>
<td>1</td>
<td>86.5 (0-385)</td>
<td>29.8 (0-200)</td>
</tr>
<tr>
<td>2</td>
<td>120.9 (0-350)</td>
<td>34.0 (0-200)</td>
</tr>
<tr>
<td>3</td>
<td>135.8 (0-250)</td>
<td>38.7 (0-150)</td>
</tr>
<tr>
<td>4</td>
<td>99.0 (0-350)</td>
<td>13.9 (0-150)</td>
</tr>
<tr>
<td>5</td>
<td>115.7 (0-250)</td>
<td>34.2 (0-170)</td>
</tr>
<tr>
<td>Totals</td>
<td>110.4 (0-385)</td>
<td>31.8 (0-200)</td>
</tr>
</tbody>
</table>

* At 26 weeks.

Table 4. Mean I-PSS at baseline, and at 12, 26 and 52 weeks postoperatively for centers 1 to 5

<table>
<thead>
<tr>
<th>Center</th>
<th>Mean I-PSS (range)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 Wk. (233 pts.)</td>
<td>12 Wks. (191 pts.)</td>
<td>26 Wks. (178 pts.)</td>
</tr>
<tr>
<td>1</td>
<td>21.3 (12-32)</td>
<td>7.9 (0-23)</td>
</tr>
<tr>
<td>2</td>
<td>20.0 (6-30)</td>
<td>6.7 (0-23)</td>
</tr>
<tr>
<td>3</td>
<td>22.6 (18-31)</td>
<td>4.8 (0-18)</td>
</tr>
<tr>
<td>4</td>
<td>17.9 (9-31)</td>
<td>7.4 (1-19)</td>
</tr>
<tr>
<td>5</td>
<td>21.8 (15-31)</td>
<td>7.2 (1-22)</td>
</tr>
<tr>
<td>Totals</td>
<td>21.1 (6-32)</td>
<td>7.1 (0-23)</td>
</tr>
</tbody>
</table>

* At 26 weeks.

(6.1%) had no decrease in detrusor pressure at maximum flow. There was a similar improvement in the linear passive urethral resistance relation when using the Schäfer nomogram, as well as in urethral resistance relation (table 5). Only 3 patients (3.1%) had no decrease in linear passive urethral resistance relation and 6 (6.1%) had no decrease in urethral resistance relation. The Abrams-Griffith nomogram showed a shift from the obstructed to the equivocal and unobstructed areas (see figure).

Morbidity. No complications were encountered during laser prostatectomy. Four patients (1.7%) had urinary retention after removal of the suprapubic catheter and 3 (1.3%) had clot retention. One of the 3 patients required cystourethroscopy with general anesthesia. No bleeding was noted from the prostatic urethra but bleeding occurred at the entry of the suprapubic catheter, which was controlled with electrocautery. No patient with clot retention required blood transfusion. During the first 4 to 6 weeks approximately 50% of the patients complained of irritative voiding symptoms, which consisted mainly of stranguria, urgency and frequency. Urinary tract infection was diagnosed in 21.1% of the patients.

Reoperation. Because of minimal or no improvement after laser treatment transurethral resection of the prostate was performed in 11 patients (4.7%), a second laser treatment in 4 (1.7%) and bladder neck incision in 3 (1.3%). Visual internal urethrotomy was necessary in 1 patient (0.4%) because of urethral stricture. Patients who required transurethral resection of the prostate or a second laser treatment had residual prostatic tissue at cystourethroscopy.

Discussion

Since the first publications of side firing laser fibers for treatment of symptomatic BPH by Costello and McCullough...
et al. reports on laser prostatectomy have increased.\textsuperscript{11-14} Although all of these studies revealed significant subjective and objective results, there seemed to be a difference in extent of improvement. Similar differences among centers were documented in our study. However, because of different baseline characteristics the results of the individual centers are difficult to compare. All participating centers achieved significant improvement in I-PSS and maximum flow but there was a difference in extent of improvement among the centers. A reason for this observation may be an alteration in the way laser energy was applied despite the fact that most patients were treated according to the same protocol. Kabalin and Gill described a significant decrease in amount of coagulation necrosis when the laser application was interrupted for approximately 30 seconds.\textsuperscript{21} In addition, the distance of the fiber tip to the prostatic surface is difficult to standardize and may vary, resulting in different power densities and amounts of coagulation necrosis achieved. Another explanation for differences in results may be variation in interpretation of the uroflowmetry curves. However, in our study all flow curves were reviewed by 2 independent investigators.

To compare the laser procedure to the gold standard transurethral resection of the prostate, a few randomized studies were performed that showed no statistically significant differences in objective and subjective results between the 2 procedures.\textsuperscript{22-25} With regard to morbidity, there appeared to be a shift from perioperative and immediate postoperative morbidity, such as the transurethral resection syndrome, bleeding and the need for blood transfusion, which in the literature is greater for transurethral resection of the prostate, to postoperative morbidity, such as transient voiding complaints, prolonged catheterization and urinary tract infections, which were greater for laser prostatectomy. We must note that complications after transurethral resection of the prostate probably are more severe than those after laser prostatectomy. Approximately 50% of our patients had irritative voiding symptoms lasting 4 to 6 weeks after laser prostatectomy and 21.1% had urinary tract infection. Irritative voiding complaints can be explained partly by the long catheterization period (17 days in our study). On the other hand, several patients with a short catheterization period had irritative voiding complaints for approximately 4 weeks. A previous study showed the same results but did not demonstrate a relationship between irritative complaints and incidence of urinary tract infection.\textsuperscript{26} However, that study showed a relationship between prolonged catheterization and incidence of urinary tract infection, which might also explain the significant incidence of urinary tract infection in our study. Use of a suprapubic catheter in our study, which was removed only when post-void residual was less than 50 mL, could be the reason for this prolonged catheterization. Also, the reoperation rate after 1 year was great in our study, with transurethral resection of the prostate in 4.7% of the cases, second laser treatment in 1.7% and bladder neck incision in 1.3%. Visual internal urethrotomy was necessary in 1 patient (0.4%). These findings are in contrast to other studies by Kabalin,\textsuperscript{11} and Norris\textsuperscript{18} and Leach\textsuperscript{13} et al, who reported only a few patients undergoing a second laser treatment, and only Norris et al reported on 3 patients in whom a transurethral resection of the prostate after initial laser therapy was performed. This fact may be explained by a shorter followup in these studies or a difference in selection criteria. It generally is known that European surgeons usually treat patients with more advanced disease, resulting in treatment of larger prostates, and these patients may be at increased risk for reoperation following laser prostatectomy.

However, when analyzing the baseline characteristics of patients in whom laser prostatectomy failed and who subsequently required a second laser treatment or transurethral resection of the prostate, we found no significant difference compared to the other patients. Factors, such as differences in prostate tissue texture\textsuperscript{27} or those that influence the power density during laser treatment, probably will explain the differences in clinical outcome.

Previous reports concerning results of laser prostatectomy described only a slight percentage of patients with retrograde ejaculation. In contrast, retrograde ejaculation occurred in 47% of our patients who had normal ejaculation before laser
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CONCLUSIONS

Laser prostatectomy results in significant subjective and objective improvement, which is operator independent. However, minor differences may be noted, possibly due to variation of technique or different selection criteria. Despite the observation that peroperative morbidity seems less severe compared to transurethral resection of the prostate, there is a shift toward greater postoperative morbidity. Pressure-flow analysis shows that laser prostatectomy can relieve bladder outlet obstruction. Future studies should be focused on optimizing dosimetry and improving laser technologies, resulting in minimal morbidity, and probably selecting a subgroup of patients who will benefit the most from this treatment modality.

The urodynamic analysis program was developed at the UIC/BME Research Centre, Department of Urology, Nijmegen, The Netherlands.

REFERENCES


EDITORIAL COMMENT

The Dutch have undoubtedly established themselves as some of the premier laser prostatectomists in the world. The authors and others of their countrymen have provided us with multiple important clinical reports and scientific studies of free beam neodymium:YAG laser prostatectomy, and particularly have enhanced our understanding of the instrumentation and physical mechanisms underlying this operation (reference 17 in article). The authors summarize a large prospective clinical experience with neodymium:YAG laser prostatectomy cumulated from 5 medical centers in The Netherlands. Statistically and clinically significant improvement is documented for all measures of voiding outcome, including complex urodynamic evaluation with pressure-flow studies—the latter invasive data collection is obtained too seldom for any of our BPH therapies. These outcomes from laser prostatectomy are uniformly comparable to those expected from electrocautery resection. As the authors accurately contend, laser prostatectomy is the only treatment modality for BPH today (except, of course, open prostatectomy) that has achieved urodynamic results in large series of patients comparable to those of electrocautery resection. The retrograde ejaculation rate of 47% in this series is the highest yet reported for laser prostatectomy, and speaks perhaps more than any other outcome to the fact that the authors are performing an aggressive, truly debulking prostatectomy with the neodymium:YAG laser.

The authors note irritative voiding complaints in up to 50% of patients. I am only surprised that this proportion is not greater, since all of their patients were treated with a suprapubic catheter for an average of 17 days postoperatively. Suprapubic catheters have been similarly problematic in my experience after laser prostatectomy. For reasons that may not be completely understood, they tend to cause much more bladder irritation than a urethral Foley catheter, and perhaps because of this irritation they tend to stay in much longer postoperatively before an adequate voiding trial is completed. With longer catheterization times come higher rates of infection, documented in more than 21% of patients in this series, and even more irritative symptoms due to the infections. It also is notable that the only significant complication in this series was bleeding from a suprapubic catheter insertion site and not from the laser coagulated prostate, which caused clot retention and required reoperation for fulguration. The only patients in whom I find a suprapubic catheter to be a reasonable management option following laser prostatectomy are those already in chronic retention with a long-term catheter preoperatively, who have muscle and sensory neurogenic bladder dysfunction. This small subset of patients does not experience an acute exacerbation of irritative symptoms with the suprapubic catheter postoperatively, and in these cases the multiple voiding trials that are often necessitated by the detrusor dysfunction are facilitated by the suprapubic catheter.

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