

Does the power of the laser devices matter for a successful HoLEP procedure? A prospective comparative study

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Abstract

Background: To evaluate the efficiency and safety of medium power (MP) holmium laser devices in the enucleation of the enlarged prostate (HoLEP) adenomas compared to high power (HP) laser devices. **Methods:** Based on the device power used, a total of 120 patients were divided randomly into two groups. While patients in Group 1 were treated with a MP device (50 W) at 39.6-W (2.2J / 18Hz), patients in Group 2 were treated with HP (100W) device at 42W (1.2J / 35Hz). Peri- and postoperative parameters were well evaluated in both groups with an emphasis on enucleation efficiency and hemoglobin decrease in a comparative manner. **Results:** Peri- and postoperative parameters as well as functional results were similar in the two groups. The median enucleation efficiency (EE) values in Group 1 and Group 2 were 1.15 (IQR: 0.33-2.2) and 1.11 (IQR: 0.4-2.8), respectively (p=0.775). Hemoglobin decrease values in Group 1 and Group 2 were 1.3 (IQR: 0.1-4) and 1.4 (IQR: 0.4-3.1), respectively (p=0.736). Significant improve in the postoperative functional parameters were noted again in both groups. **Conclusion:** Our results indicate well that similar to the HP laser devices, effective and safe removal of the enlarged prostate adenomas with MP laser devices (50W) is possible without any technical difficulties, even in patients receiving antithrombotic therapy.

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ABSTRACTBackground: To evaluate the efficiency and safety of medium power (MP) holmium laser devices in the enucleation of the enlarged prostate (HoLEP) adenomas compared to high power (HP) laser devices.**Methods:** Based on the device power used, a total of 120 patients were divided randomly into two groups. While patients in Group 1 were treated with a MP device (50 W) at 39.6-W (2.2J / 18Hz), patients in Group 2 were treated with HP (100W) device at 42W (1.2J / 35Hz). Peri- and postoperative parameters were well evaluated in both groups with an emphasis on enucleation efficiency and hemoglobin decrease in a comparative manner.**Results:** Peri- and postoperative parameters as well as functional results were similar in the two groups. The median enucleation efficiency (EE) values in Group 1 and Group 2 were 1.15 (IQR: 0.33-2.2) and 1.11 (IQR: 0.4-2.8), respectively (p=0.775). Hemoglobin decrease values in Group 1 and Group 2 were 1.3 (IQR: 0.1-4) and 1.4 (IQR: 0.4-3.1), respectively (p=0.736). Significant improve in the postoperative functional parameters were noted again in both groups.**Conclusion:** Our results indicate well that similar to the HP laser devices, effective and safe removal of the enlarged prostate adenomas with MP

laser devices (50W) is possible without any technical difficulties, even in patients receiving antithrombotic therapy. **Keywords:** benign prostatic hyperplasia, high power laser device, holmium laser enucleation of the prostate, medium power laser device **What is already known about this topic?** The necessity of higher power Holmium Laser Enucleation of the Prostate (HP-HoLEP) devices for more effective and safe results is controversial.

What does this article add?

Our current findings indicate well that HoLEP surgery can be performed in an effective and safe manner by using MP (50 W) devices. Use of HP-HoLEP devices may lead to unnecessary equipment costs without changing the perioperative functional outcomes and complication rates.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is the main etiology of lower urinary tract symptoms (LUTS) in ageing male.¹ For several decades, transurethral resection of prostate (TURP) has been accepted and applied as the standard endoscopic treatment for symptomatic LUTS in patients not responding to or cannot tolerate medical therapy as well as in those developing BPH-related complications (e.g., bladder stone, urinary retention, or renal insufficiency).² However, following its clinical introduction by Gilling et al. in 1998, Holmium Laser Enucleation of the Prostate (HoLEP) proved itself to be a minimally invasive, size-independent endoscopic management alternative in the effective treatment of LUTS secondary to BPH. Several RCT's have shown comparable (even superior) long-term results to open prostatectomy (OP) and TURP.³⁻⁶ Based on the successful outcomes obtained, HoLEP has been considered as potentially "new gold standard" endo-surgical treatment of BPH.^{7, 8} Complete removal of the obstructing adenomatous tissue via enucleation, simultaneous coagulation of the capsular surface and effective mechanical morcellation are the distinct characteristics of HoLEP which make it superior to other modalities. Despite its excellent outcomes however, HoLEP has still not been widely adopted in urology practice, due to its prolonged learning curve and limited access to HP laser devices.⁹ Although various technical modifications have been described to minimize the learning curve and increase the efficiency of the procedure over the past 20 years^{10, 11}, improved functional outcomes and low complication rates seem to be correlated with the level of experience obtained and the surgical technique applied.¹² Beginning with its first clinical use in 1998, HoLEP procedure was performed with HP holmium laser devices ([?]80W).¹³ During the following years, the popularity of the procedure increased and even more powerful devices (140-150W) were introduced into clinical practice with the perception that a more effective enucleation can be performed with such laser devices creating relatively higher powers. Related with this issue however, HP laser devices are still not available in many urology clinics due to their higher costs and available low-medium power (<80W) laser devices are being used mainly for lithotripsy purposes in many hospitals.¹⁴ Regarding the dilemma concerning the power of the device and its real efficacy in adenoma enucleation, the first study evaluating the efficacy and safety of medium power (MP) (50W) laser was published by Rassweiler et al. in 2008.¹⁵ In the following years, several studies focusing on the efficacy of low power (LP) and MP HoLEP have been performed.^{14, 16-20} Although these limited number of studies have revealed that LP-HoLEP could achieve comparable outcomes with HP-HoLEP, many urologist still prefer using HP-laser devices. Taking the ongoing controversy about the efficacy and safety of LP vs HP laser systems particularly in the removal of large prostatic adenomas as well as the importance of surgeon's experience with particular techniques created rather than the power of laser used into account, in this first prospective, comparative study evaluating the efficacy of both power levels (MP vs HP) with two different laser devices we aimed to demonstrate the applicability of MP laser devices for HoLEP procedure with high efficiency and limiter or no technical difficulties.

METHODS

Study design and patient evaluation:

After receiving the local ethics committee approval, between October 2019 and July 2020, in this prospective and comparative trial, a total of 120 consecutive patients with BPH induced LUTS refractory to medical treatment or developing complications secondary to prostatic obstruction were included and divided into

two groups based on the power of the device used namely Group 1 (50 watt) and group 2 (100 watt) groups. The patients were assigned respective numbers according to the hospital admission time, and these numbers were then classified as odd numbers in group 1 and even numbers in group 2. Exclusion criteria were neurological disorder (e.g. Parkinson's disease, cerebral ischemic event), active urinary infection, active hematuria, prostate cancer and previous urethral or prostatic surgery. Following medical history and digital rectal examination, urine culture, serum prostate specific antigen (PSA, ng/ml), suprapubic ultrasound-determined prostate volume (ml), American Society of Anesthesiologists (ASA) scores, International Prostate Symptom Scores (IPSS), maximum flow rates (Q max), postvoiding residual volumes (PVR), and Quality of Life (QoL) index values were all assessed and recorded prior to the procedure. Transrectal prostate biopsy was performed if indicated and biopsy negative patients were operated at least 4 weeks later. Patients receiving coumadin stopped the medication 5 days before HoLEP and were bridged with low molecular weight heparins during the perioperative period. New oral anticoagulants (such as dabigatran, rivaroxaban, apixaban, and edoxaban) were discontinued 48-72 h before surgery. Patients receiving acetylsalicylic acid and platelet aggregation inhibitors (such as clopidogrel, ticagrelor, and prasugrel) were operated under acetylsalicylic acid treatment. Antithrombotic treatment was resumed as soon as bleeding control was achieved. All preoperative baseline characteristics were recorded.

Surgical technique and Equipment:

All procedures were performed by a single experienced surgeon (Tokatli Z.) who had carried out more than 300 HoLEP procedures for various sized prostates. HoLEP was performed with our previously described technique (low tension total retrograde HoLEP technique), as two or three lobes technique depending on prostate morphology (with/without huge median lob).¹¹ A 26-Fr continuous-flow laser resectoscope (Karl-Storz, Germany) in combination with a mechanical tissue morcellator (Versacut; Lumenis Inc) was used for both groups. In group 1, HoLEP procedures were performed by using 50W holmium laser device (Auriga® XL, Boston Scientific, Ratingen, Germany) at 39.6W (2.2 Joule, 18 Hz). In group 2, a 100W Holmium laser (Versapulse, Lumenis Inc., Santa Clara, CA, USA) was used at 42-W (1.2J and 35Hz), comparable with the 50W device.

Perioperative and follow-up data:

All perioperative parameters including weight of removed tissue, enucleation and morcellation time, enucleation and morcellation efficiency, decrease in the hemoglobin level (one day before and 12 hours after surgery), duration of hospitalization and catheterization were all assessed and noted. Postoperative control was performed by evaluating objective parameters (Q max, PVR, PSA reduction) and validated symptom questionnaires, such as the IPSS and QoL index during 3 months visit following catheter removal.

Statistical analysis:

The variables were analyzed with the independent Student's t-test, Chi-Square, and Mann-Whitney U test. The dependence of an outcome variable on two or more independent variables was evaluated by multiple linear regression analysis. p-values less than 0.05 were considered significant.

RESULTS

A total of 120 patients were enrolled into this prospective study (Group 1, n=60; Group 2, n=60). While the median (IQR) age was 66.5 (51-80) years in group 1 it was 67 (52-85) years in group 2 (p = 0.692). There was no statistically significant regarding the preoperative parameters including PSA levels, prostate volume, ASA score, Q max, IPSS, QoL and PVR values between the two groups. While 20 % of the cases in group 1 and 31.7% in group 2 underwent prostate biopsy before HoLEP procedure use of antithrombotic agent was present in 13.3% and 21.7% of the cases in Group 1 and 2 respectively. There was no significant difference between both groups in terms of biopsy and antithrombotic therapy rates (p = 0.144 and p = 0.230, respectively) (Table 1). Preoperative data obtained in both groups are being given in Table 2. Evaluation of these parameters did not show major differences with respect to laser device used. While the median enucleation efficiency values in Group 1 and Group 2 were 1.15 (IQR: 0.33-2.2) and 1.11 (IQR: 0.4-2.8),

median morcellation efficiency in both groups were 4.45 (IQR: 2.2-8) and 4.53 (IQR: 1.1-10), respectively. No statistically significant difference was noted with respect to these parameters in between groups ($p = 0.775$ and $p = 0.204$, respectively). Median values of hemoglobin decrease in Group 1 and Group 2 were 1.3 (IQR: 0.1-4) and 1.4 (IQR: 0.4-3.1), respectively ($p = 0.736$). No blood transfusion was required in any case of the patients in both groups. In our clinical practice, the routine catheterization time is two days, and the hospitalization period is three days. The duration of catheter removal for two patients in the group 1 and three patients in the group 2 was three days due to hematuria. Statistical evaluation of the data obtained revealed no significant difference between Group 1 and Group 2 in terms of catheterization and hospitalization ($p = 0.649$ and $p = 0.649$, respectively) (Table 2). A multiple linear regression analysis was performed to predict Hb decrease biopsy requirement, use of antithrombotic, and the type of laser devices variables (Table 3). Based on this evaluation, a positive and statistically significant correlation was found between biopsy anamnesis and Hb decrease ($p = 0.002$). However, no correlation could be demonstrated between Hb decrease and the type of laser device as well as antithrombotic use on this aspect ($p = 0.906$, $p = 0.637$, respectively). Median preoperative Qmax was 8.3 ml/s and this value increased to 28 ml/s 3 months after surgery ($p < 0.001$). Median baseline PVR value improved from 140 ml to 30 ml during 3 months evaluation ($p < 0.001$). Similarly, significant improvement was noted in IPSS and QoL scores after 3 months following the surgery.

DISCUSSION

HoLEP procedure was first described by Gilling et al in 1998 and over the last two decades this technique became a valuable alternative in the management of large prostates due to the excellent functional outcomes, low perioperative morbidity as well as long-term durability of its efficiency.³ Following its clinical introduction, the procedure has been performed by using a 100 W Ho:YAG laser device with energy levels of 2 J and frequency settings of 40–50 Hz for a long period of time.^{3, 21} In 2008 however, Rassweiler et al. published the first study regarding the efficacy and safety of a 50-W holmium laser device for HoLEP procedure.¹⁵ Although they were able to demonstrate the safe and effective application of the enucleation technique with this medium power device, majority of the practicing surgeons still tend to use more efficient high power HoLEP devices with this aim. With the false perception that MP devices are not effective and practical for tissue removal, high devices for HoLEP procedure are still being preferred. This approach also is forcing the industry to develop more powerful laser devices (exceeding 100W) which will bring higher cost issue together. Related with this issue again, since 2008, several studies have focused on the use of MP devices (50-80 W) with low energy settings in the effective and safe enucleation based removal of enlarged prostatic tissue which will clearly be more cost effective than the high power devices.^{14, 16, 18, 22} In our present prospective comparative study, by using two different laser devices (50 W vs 100 W) the enucleation efficiency was found to be 1.14 g / min. where there was no statistically significant difference between Group 1 and Group 2 (1.15 vs. 1.11, $p = 0.775$). Similarly, in their original study Minagawa et al., performed HoLEP procedure with a 30 W power device and similar enucleation efficiency has been reported, although the average removed specimen weight was less than the values obtained in our study. Additionally they compared the outcomes on a surgeon's experience based manner and enucleation time was shown to be significantly lower in HoLEP procedure when performed by experienced surgeon. Since the authors had no HP control group in the study, the results were compared with other HoLEP series performed with 100W power setting and the outcomes in terms of enucleation efficiency were acceptable as well as comparable compared with other reports using a HP laser.¹⁴ In another study, regarding the HoLEP procedure performed with 50 W device (2,2J- 18Hz) HoLEP by two experienced surgeons, the EE was again found to be similar to our findings. Again, the authors did not have include a control group and the obtained results were compared with the outcomes of previously performed HP HoLEP series where they found the EE values they found were higher than the results obtained by HP laser devices. They emphasized that the experience of the surgeon was an important factor (rather than the power of the device used) to obtained such higher EE values.¹⁶ In the first randomized controlled trial comparing LP-HoLEP vs standard HP-HoLEP (50W and 100W energy settings), the authors reported no significant difference between 50W and 100W groups in terms of all operative parameters including the EE values.¹⁷ When we evaluate the outcomes of studies comparing different energy settings in the efficiency of

enucleation during HoLEP procedure, it is noteworthy that EE has been reported to be lower in studies conducted prior to 2013^{15, 23, 24} compared to studies conducted in 2017 and thereafter. While mean EE values was ranging between 0.45-0.94 in previous studies, it has been found to range between 1.1-1.7 in recent studies.^{16, 17, 20} These findings in turn again emphasize well the importance of accumulated experience over the years by indicating that as surgeons acquire more experience the efficiency of the procedure increases as well independent from the power of the devices used. This has been also confirmed with our findings and we believe that depending on the experience of the surgeon the technique applied for enucleation is the key factor for an effective tissue removal regardless of the device power used. By using 25W vs 40W power settings, in their original study Rassweiler et al., reported an average hemoglobin decrease of 3.1 g / dl and a transfusion rate of 8% in their groups.¹⁵ Although these values were unexpectedly high, acceptable values have been reported in later studies involving patients treated with low and medium power settings. In their retrospective study including the data of more than two thousand patients, Becker et al. used the 100 W energy setting for HoLEP procedure and they reported an average hemoglobin decrease of 0.9 g/dl and a transfusion rate of 0.4%.²⁵ In another study comparing 50W and 100W energy settings, decrease in hemoglobin values were 0.9 g/dl and 0.7 g/dl, respectively.¹⁷ In our study, median hemoglobin decrease values were 1.3 g / dl in Group 1 patients, and 1.4 g / dl in Group 2 respectively. There was no statistical difference between the two groups on this aspect and, even the hemoglobin decrease was lower in Group 1 patients. Multiple regression analysis of our findings demonstrated that, the only independent variable in the prediction of hemoglobin decrease was the presence of biopsy anamnesis. We showed that hemoglobin decrease was higher in patients undergoing biopsy before HoLEP procedure. Regarding the possible underlying causes for the high likelihood of bleeding, acute or chronic inflammatory response may cause granulation in the tissue and these alterations could make it more difficult to separate the adenomatous tissue from the prostatic capsule during HoLEP. In addition to high risk of bleeding, difficulty in the separation of capsule may prolong the operation time and / or worsen of the surgical field visibility. Catheterization and hospitalization time were other important parameters correlating with laser settings used in HoLEP procedure. In our study, catheterization and hospitalization time were similar in the two groups. In a recent study performed by Becker et al., 40W energy setting was used for HoLEP procedure and catheterization, and hospitalization times were found to be similar to those in our study.¹⁶ Lastly, evaluation of the functional outcomes during 3-months follow-up visit in our study showed a significant relief of obstructive symptoms in Group 1 patients with LUTS due to symptomatic BPH. Significant improvement observed in voiding parameters (Qmax, PVR) and validated questionnaires (IPSS, QoL) in Group 1 cases after 3 months following HoLEP procedure and these values were comparable with the results obtained in Group 2 cases. In summary, our study is the first study in the literature comparing the efficacy and safety of two different laser devices (MP vs HP) and we were able to show the efficient use of MP device in order to enucleate the large prostatic adenomas with excellent functional outcomes after 3-months. Our findings obtained with MP device were all comparable with the outcomes of HP devices. In the light of these observations we may claim that if the surgeon is experienced by applying his technique of enucleation in a successful as well as practice manner, outcomes will be acceptable regardless of the power of the device used. This will in turn decrease the traditional huge demand for HP devices to perform HoLEP procedure with the false perception of “high power means higher efficiency” and as a result cost of the devices will be less by allowing the HoLEP procedure to be performed in a widespread manner in all parts of the world. Our study may have several limitations. Since our main purpose was to investigate EE and hemoglobin decrease, lack of the long-term functional results in these patients may be an important drawback. However as the first prospective study performed with this aim (by comparing two different power levels for HoLEP procedures performed by a single experienced surgeon) we believe that our well assessed functional outcomes during the postoperative 3 months into account may also contribute well to the existing information in the literature with reliable clinical implications. However we also believe that further studies with larger series of cases focusing on the role of power levels of the devices in HoLEP procedure are certainly needed. In conclusion, our current findings indicate well that HoLEP surgery can be performed in an effective and safe manner by using MP (50 W) devices. Surgeon’s experience is an important factor on this aspect and HoLEP devices with different maximum powers may provide similar efficiency and reliability. As a result, use of HP-HoLEP devices may lead to unnecessary equipment costs without changing the perioperative functional

outcomes and complication rates. This will certainly limit the common application and acceptance of this valuable technique in all parts of the world due to higher costs.

CONFLICT OF INTEREST

The authors have no potential or financial conflicts of interests to declare.

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