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의학석사 학위논문

**Application of modified Clavien
classification system to 120W
GreenLight HPS laser for BPH**

전립선 비대증에서 시행하는 HPS
레이저 수술에 대해 Clavien 분류
체계의 적용

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A thesis of the Master's Degree

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February 2013

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College of Medicine
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Application of modified Clavien classification system to 120W GreenLight HPS laser for BPH

지도 교수 손 환 철

이 논문을 의학석사 학위논문으로 제출함

2012년 12월

서울대학교 대학원

임상의과학과

권 오 성

권오성의 의학석사 학위논문을 인준함

2012년 12월

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- ① 본인의 논문을 보존이나 인터넷 등을 통한 온라인 서비스 목적으로 복제할 경우 저작물의 내용을 변경하지 않는 범위 내에서의 복제를 허용합니다.
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논문 제목: Application of modified Clavien classification system to 120W GreenLight HPS laser for BPH: is it useful in case of less invasive procedures?

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ABSTRACT

Introduction: To evaluate the accuracy and applicability of the modified Clavien classification system (CCS) in evaluating complications following modified vaporization-resection for photoselective vaporization of the prostate using 120W GreenLight high performance system (HPS-PVP)

Methods: Medical records of 342 men who underwent HPS-PVP were retrospectively analyzed. Patients were older than 40 years of age with prostate volume $>30\text{mL}$ and IPSS ≥ 8 . Patients with prostatic malignancy, neurogenic bladder, urethral stricture, large postvoid residual volume ($>250\text{ mL}$), previous prostatic surgery and urinary tract infection were excluded. All operations were done by a single surgeon, and patients were followed up for uroflowmetry and IPSS postoperatively. All complications were recorded and classified according to the modified CCS, and methods of management were also recorded.

Results: Mean age was 71.6 ± 7.3 years, and mean prostate volume was $50.0 \pm 17.0\text{ mL}$, and 95 cases (27.7%) had volumes greater than 70 mL. Mean total IPSS score was 21.7 ± 7.9 preoperatively and 12.3 ± 8.1 at the first month postoperatively. Total 59 patients (17.3%) had postoperative complications until the first month after the surgery. Among them, 49 patients (14.3%) showed grade I complications, 9 patients (2.6%) showed grade II complications, and 1 patient (0.3%) showed grade IIIb complication. No one had complications graded higher than IIIb.

Conclusions: Although the modified CCS is a useful tool for communication among clinicians in allowing comparison of surgical outcomes, this classification need to be revised to acquire higher accuracy and applicability in the evaluation of postoperative complications of HPS-PVP.

Keywords: Benign prostatic hyperplasia, Transurethral Vaporesction of Prostate, Transurethral Resection of Prostate, Lasers, Complication

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INTRODUCTION

Although there are many things to be considered for quality assessment of surgical outcomes, previous investigations showed that the Clavien classification system (CCS) for the evaluation of postoperative complications has been accepted as a desirable standardized platform of accuracy and reliability for comparing surgical outcomes among different institutions, surgeons, or operative techniques since 1992 (1). This classification system was based on the therapy used to treat complications that occurred within the first month postoperatively. The CCS was modified according to the reporting manner of perioperative life-threatening and permanently disabling conditions in 2004 (2).

This new grading system has been widely accepted by many urologists to report the perioperative outcomes of laparoendoscopic single-site surgery (LESS) in the upper urinary tract (3), radical cysto-urethrectomy (4), and robot-assisted radical prostatectomy (5). Besides these major oncologic surgeries, the modified CCS has also been validated for grading perioperative complications in patients who underwent transurethral resection of the prostate (TURP) (6,7), percutaneous nephrolithotomy (8,9) or laparoscopic pyeloplasty (10). However, there has been few report on less invasive procedures such as Holmium Laser Enucleation of the Prostate (HoLEP) or photoselective vaporization of the prostate (PVP) using KTP laser. As these less invasive procedures must have a different distribution of complications compared to invasive procedures, the applicability of the modified CCS should be evaluated for less invasive procedures.

Therefore, the aim of this study is to evaluate the accuracy and applicability of the modified CCS in evaluating the complications following the Seoul technique, modified PVP using 120W GreenLight high performance system (HPS-PVP).

MATERIALS AND METHODS

The present study was a retrospective analysis of the medical records of patients who underwent HPS by a single surgeon between January 2008 and September 2011. A total of 353 patients who underwent HPS-PVP were included. Patients were older than 40 years-of-age with prostatic volume >30 mL and IPSS \geq 8. Patients with prostatic malignancy, neurogenic bladder, urethral stricture, large postvoid residual volume (>250 mL), previous prostatic surgery and urinary tract infection were excluded from the analysis. Because patients with these conditions could have voiding problem or bladder dysfunction preoperatively, the postoperative complications might be confused with the underlying abnormalities. According to exclusion criteria, 11 patients were excluded. Finally, the records of 342 patients were analyzed in this study. This study was approved by the Institutional Review Board of Boramae Hospital, and the procedure in this study complies with the Declaration of Helsinki (revised Edinburgh, 2000).

A GreenLight HPS laser that generates up to 120W with a lithium triborate (LBO) crystal was used for the operation. The Seoul Technique, a modified vaporization-resection technique, was used (11). Age, body mass index (BMI), preoperative conditions including past medical history, transrectal ultrasonography, uroflowmetry and American Society of Anesthesiologists (ASA) score were reviewed from the medical records. Patients were followed-up for uroflowmetry and IPSS postoperatively at 2 weeks, 1 month, 3 months, 6 months and yearly from 1 year. All complications that arose within the first month postoperatively were

recorded and classified according to the modified Clavien-Dindo System (2). According to the modified CCS, the complications were graded as I (any deviation from the normal postoperative course without interventions), II (pharmacological treatment, blood transfusion or total parenteral nutrition), IIIa (intervention not under general anesthesia, IIIb (intervention under general anesthesia), IVa (single organ dysfunction), IVb (multiorgan dysfunction) and V (death) 2. For each complication, the managements were also recorded.

Variables were presented as mean \pm standard deviation. All preoperative and postoperative variables were analyzed for statistically significant differences using the independent t-test. To compare pre and postoperative clinical parameters, a paired t-test was used. A $P < 0.05$ was considered statistically significant, and commercially available statistical software (SPSS 14.0, SPSS, Inc, Chicago, IL) was used.

| Grade | Definition |
|--------------|---|
| Grade I | Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside |
| Grade II | Requiring pharmacological treatment with drugs other than such allowed for grade I complications Blood transfusions and total parenteral nutrition are also included |
| Grade III | Requiring surgical, endoscopic or radiological intervention |
| Grade IIIa | Intervention not under general anesthesia |
| Grade IIIb | Intervention under general anesthesia |
| Grade IV | Life-threatening complication (including CNS complications) requiring ICU management |
| Grade IVa | Single organ dysfunction (including dialysis) |
| Grade IVb | Multiorgan dysfunction |
| Grade V | Death of a patient |

Table 1. Modified Clavien classification system

RESULTS

Patients' demographics and perioperative profiles are shown in Table 2. Mean patient age was 71.6 ± 7.3 years. Mean prostate volume was 50.0 ± 17.0 mL, and 95 cases (27.7%) had volumes greater than 70 mL. Mean total IPSS score was 21.7 ± 7.9 preoperatively, which was significantly improved after one month postoperatively (12.3 ± 8.1).

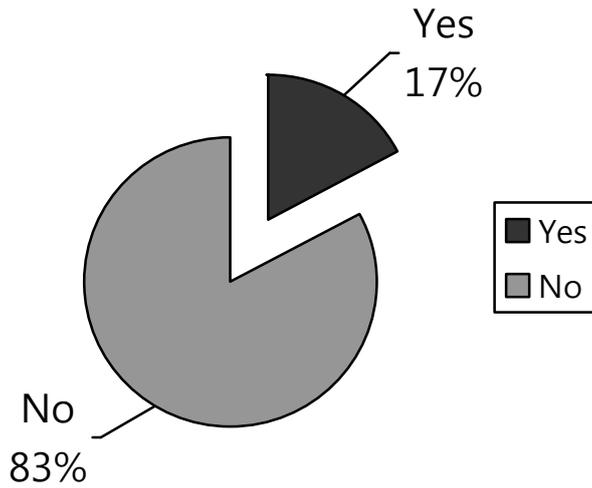
Table 3 shows the distribution of all complications and detailed methods of management for each complication. Among the 342 patients, 59 cases (17.3%) had postoperative complications within 1 month. Most of them (49 cases, 14.3%) showed grade I complications. Non-specific urinary symptoms resolved spontaneously without any medications. Patients complained about mild hematuria, frequency, dysuria, and urgency. But according to the records, the symptoms were too mild to give any medications to treat them and the symptoms were relieved at the next visit. Two patients with grade I complications showed postoperative gross hematuria, which was improved by indwelling of urethral Foley catheter and manual irrigation for several days. Another two patients showed urinary retention after urethral catheters were removed. One of the patients did not void well until the first year postoperatively, and he was not followed up thereafter. Patients with grade II complications (nine cases, 2.6%) showed some transient urinary symptoms (urgency, dysuria or slow stream), which improved after taking medications such as anticholinergic agents, antibiotics and alpha-blockers. One patient (0.3%) showed a grade IIIb complication, which was resolved after transurethral coagulation under general anesthesia. None had complications graded higher than IIIb.

| Mean \pm SD or n (%) | |
|-----------------------------------|-------------------|
| Preoperative profiles | |
| Patient demographics | |
| Age (yr) | 71.6 \pm 7.3 |
| BMI(kg/m ²) | 26.0 \pm 42.7 |
| ASA score, no. (%): | |
| 1 | 112 (32.7%) |
| 2 | 198 (57.9%) |
| ≥ 3 | 32 (9.4%) |
| Comorbidities, no. (%): | |
| Diabetes | 58 (16.9%) |
| Hypertension | 163 (47.5%) |
| PSA (ng/ml) | 4.0 \pm 3.2 |
| Prostate volume (ml) | 50.0 \pm 17.0 |
| Transitional zone volume (ml) | 28.8 \pm 14.4 |
| Symptom scores | |
| Total IPSS | 21.7 \pm 7.9 |
| Voiding symptom subscore | 12.8 \pm 5.0 |
| Storage symptom subscore | 8.8 \pm 3.6 |
| QoL score | 4.2 \pm 1.2 |
| Symptom scores (postop 1 month) | |
| Total IPSS | 12.3 \pm 8.1 |
| Voiding symptom subscore | 5.5 \pm 5.2 |
| Storage symptom subscore | 6.8 \pm 3.7 |
| QoL score | 2.6 \pm 1.7 |
| Voiding diary parameters | |
| Functional bladder capacity (ml) | 382.0 \pm 148.3 |
| Daytime frequency (per day) | 10.7 \pm 3.0 |
| Nocturia (per night) | 2.0 \pm 0.8 |
| Uroflowmetric parameters | |
| Qmax (ml/sec) | 8.7 \pm 3.1 |
| Voided volume (ml) | 178.4 \pm 100.5 |
| PVR (ml) | 93.5 \pm 91.2 |
| Urodynamic parameters | |
| Maximum cystometric capacity (ml) | 363.5 \pm 93.2 |
| Impaired detrusor contractility | 10 (14.7%) |
| BOO index | 42.7 \pm 25.6 |
| Perioperative profiles | |
| Operative time (min) | 60.6 \pm 31.9 |
| Laser energy (joules) | 92349 \pm 75833 |
| Catheter duration (hr) | 21.6 \pm 8.7 |

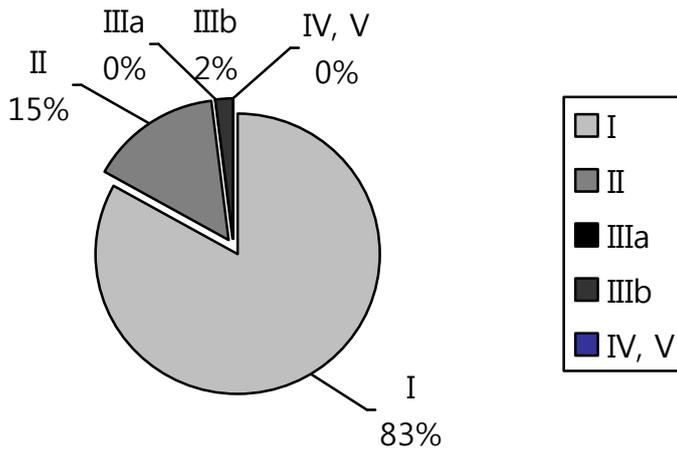
Table 2. Demographics of patients

| Grade | No. of patients | Symptoms and onset of time (POD) | Management | Duration of management |
|-------|-----------------|---|--|----------------------------|
| I | 45 | Non-specific urinary symptoms | Nothing | |
| | 2 | 1: Hematuria (third week) | Catheterization | 1 week |
| | | 1: Hematuria (second week) | | 3 days |
| | 2 | 1: Urinary retention (first day) | Catheterization | 3 days |
| | | 1: Urinary retention (second day) | | 1 year and follow-up loss |
| II | 6 | 1: Urgency (first day) | Anticholinergics | 1 year |
| | | 2: Urgency (third week) | | 1: 2 months 1: 9 months |
| | | 3: Urgency (fourth week) | | 2: 2 months 1: 4 months |
| | 2 | 1: Dysuria and slow stream (first week) | Antibiotics | 1 month |
| | | 1: Urinary tract infection (first day) | | 1 week |
| | 1 | Voiding difficulty (third week) | Alpha blocker | 2 months |
| IIIa | 0 | - | - | - |
| IIIb | 1 | Hematuria (seventh day) | Coagulation under general anesthesia and catheterization | 2 weeks |
| IV, V | 0 | - | - | - |
| Total | 59 | | | |

Table 3. Postoperative complications and management,



(a) Complication rate



(b) Ratio of complication grades in Clavien classification

Figure 1. Postoperative complications

DISCUSSION

The necessity of a standardized guideline for comparing surgical outcomes and grade complications among different hospitals has been repeatedly mentioned since 1992 (1). In particular previous studies investigated the applicability of the CCS in major urologic oncological surgeries in the early years and some modifications have been made after validation in a large patient cohort to become more generalized to elective general surgery (2,3). These procedures had various complications ranging from non-specific minor to life-threatening conditions, therefore, it looks appropriate for grading complications based upon treatments used according to the complications.

In general, the total complication rates were similar in oncological and non-oncological surgeries. Elshal et al. demonstrated that the total complication rate in radical cysto-urethrectomy was 24.7% (46 in 186 patients), 25 cases in grade I to II, 12 in grade III, 6 in grade IV, and 3 in grade V (4). Recently, some efforts have been attempted to utilize the modified CCS practically in non-oncological procedures, as well, and as a result, the modified CCS has been more widely used than during the early years. Greco et al. applied this grading system in LESS procedures of the upper urinary tract and reported that the overall complication rate was 17% (31 of 192 patients), 4 cases in grade I, 22 in grade II, 4 in grade III, and 1 in grade IV (3). Additionally, Tefekli et al. used this grading system in percutaneous nephrolithotomy and demonstrated that the system was helpful to understand the complexity of cases before actual procedures (8). More recently,

Mamoulakis et al. investigated the applicability of the modified CCS for grading perioperative complications in patients who underwent TURP (6), and the overall perioperative morbidity rate was 15.7%. Grade I complications occurred in 26 cases out of 44 (59.1%) and grade II events in 13 (29.5%). Grade III or higher complications were not so common (9.1%). The modified CCS was demonstrated to be an easily applicable method for grading postoperative TURP complications (6). Carlos et al. compared surgical results of GreenLight HPS 120W laser PVP with TURP. In that study, PVP showed similar safety as TURP (12). And Alexander et al. reported that the 180-W XPS laser therapy for BPH was a safe treatment modality (13). After the introduction of the Seoul technique as a modified method for HPS-PVP, this is the first investigation to report perioperative complications of the surgery using the modified CCS. In this study, the overall complication rate was 17.3%, which was higher than that of previous investigations. However, most of the patients (49 out of 59 cases, 83.1%) showed graded I complications (49 out of 342 patients, 14.3%), 9 patients showed graded II (2.6% from overall patients) and only one patient showed grade IIIb complication (0.3%). None of them had complications graded IVa or higher. Finally, we can conclude that the distribution of all complications in less invasive procedures differs from that of previous investigations, and that we should evaluate complication rates in less invasive procedures from a different point of view.

Because complications rates within the first month after surgery are different from long-term complication rates, it is difficult to identify exactly the actual overall results of the treatment. In this study, one patient with neurogenic bladder could not void by himself for over one year after surgery, while another patient who

suffered from bleeding after 3 weeks postoperatively underwent endoscopic coagulation under general anesthesia and was able to overcome the problem. According to the modified CCS, the former had a grade I complication, while the latter had a grade IIIb complication. However, because the grade IIIb complication was completely resolved, it is difficult to accept that the patient with the grade I complication had a more minor complication from a quality of life perspective. In addition, the classification system does not indicate anything about the degree of disease improvement (14). Therefore, it would be optimal to report the early complications and long-term complications together in order to avoid such misinterpretations. In particular, less invasive procedures have a higher likelihood of having lower grade complications.

So we may consider helpful to add more importance to complications which persist more than 1 month or to make to a new subgrade to predict possible long-term complications. For example we may add new subgrades as Grade IF, IIF, and IIIF for functional problems which may persist longer than a month after surgery. Grade IF is a group of patients who have urinary incontinence or urinary symptoms which do not need any medications. Grade IIF is a group for which medications are necessary. Grade IIIF is a state for which long-term interventions like intermittent catheterization and suprapubic or urethral catheter indwelling are helpful. Otherwise we could classify the complications according to duration of symptoms including long-term complications over a month. Further study with larger group would be helpful to suggest new classification for less-invasive surgeries.

There are a few limitations to this study. The result of this study is from a retrospective analysis so it was difficult to describe some non-specific urinary symptoms postoperatively. And this study is from a single surgeon at a single center. The period used in this study may not affect the complication rates because the technique nearly does not require learning curve. But larger scale studies using data from multiple centers, the accuracy of the findings will be higher and more accurate.

In conclusion, the modified CCS has been a useful tool for evaluating and grading postoperative outcomes but most complications following HPS-PVP have only been classified into either grade I or II. Although this modified CCS is useful for communication among clinicians in allowing comparison of surgical outcomes, this classification need to be revised to acquire higher accuracy and applicability in the evaluation of postoperative complications of HPS-PVP.

| Surgery | Complication rate (total) | Classification | |
|---|--------------------------------------|-----------------------|-----------------|
| Oncological surgery | | | |
| Radical cysto- urethrectomy (Elshal <i>et al.</i>) | 24.7% (46/186) | Grade I and II | 54.3%(25/46) |
| | | Grade III | 26.1% (12/46) |
| | | Grade IV | 13.0% (6/46) |
| | | Grade V | 6.6% (3/46) |
| | | | |
| Robot-assisted radical prostatectomy (Jeong <i>et al.</i>) | 12% (24/200) | Grade I | 37.5% (9/24) |
| | | Grade II | 37.5% (9/24) |
| | | Grade III | 25% (6/24) |
| | | Grade IV and V | none |
| Non-oncological surgery | | | |
| Percutaneous nephrolithotomy (Tefekli <i>et al.</i>) | 31.4% (255/811) | Grade I | 12.9% (33/255) |
| | | Grade II | 51.8% (132/255) |
| | | Grade III | 30.2% (77/255) |
| | | Grade IV | 4.8% (12/255) |
| | | Grade V | 0.4% (1/255) |
| Laparoscopic pyeloplasty (Greco <i>et al.</i>) | 17% (31/192) | Grade I | 12.9% (4/31) |
| | | Grade II | 71.0% (22/31) |
| | | Grade III | 12.9% (4/31) |
| | | Grade IV | 3.2% (1/31) |
| Transurethral prostatectomy (Mamoulakis <i>et al.</i>) | 15.7% (44/280) | Grade I | 59.1% (26/44) |
| | | Grade II | 29.5% (13/44) |
| | | Grade III or higher | 11.4%(5/44) |

Table 4. Modified Clavien classification in urologic surgeries

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국문 초록

서론: 수술후 합병증 발생을 평가하기 위한 도구로 Clavien 분류 체계가 사용되고 있다. 이를 전립선 비대증에서 시행하는 120W GreenLight HPS 를 사용하는 전립선 기화수술에 적용하고 보완할 만한 부분을 제안해 보고자 한다.

방법: HPS 전립선 기화술을 시행한 342 명의 의료 기록을 후향적으로 분석하였다. 환자군은 나이 40 세 이상, 전립선용적 30ml 이상, 국제 전립선 증상 점수 8 점이상인 경우를 대상으로 하였다. 전립선 악성 종양이 있거나, 신경인성 방광이 동반된 경우, 요도 협착이 있는 경우, 배뇨후 잔뇨가 250ml 이상인 경우, 이전 전립선 수술을 받았거나 요로감염이 동반된 경우는 대상에서 제외하였다. 모든 수술은 한 명의 술자에 의해 이루어졌으며, 환자들은 수술 후 요속 검사, 국제 전립선 증상 설문지로 평가 되었다. 모든 합병증은 Clavien 분류에 따라 구분지어졌다.

결과 : 대상 환자들의 평균 나이는 71.6 ± 7.3 세 이었으며, 평균 전립선 용적은 50.0 ± 17.0ml 였다. 그 중 95 명 (27.7%)은 70ml 이상이였다. 평균 국제 전립선 증상 점수 총점은 수술전 21.7 ± 7.9 점이였으며 수술 후 1 개월 쯤 12.3 ± 8.1 점이였다. 342 명 중

59 명 (17.3%)에서 수술 후 1 개월 째 합병증이 발생한 것으로 확인되었다. 그 중 49 명 (14.3%)은 1 등급의 합병증을 보였으며, 9 명 (2.6%)는 2 등급의 합병증을, 1 명 (0.3%)에서 3b 등급의 합병증을 보였다. 3b 등급을 넘어서는 합병증은 확인되지 않았다.

결론: Clavien 분류 체계는 서로 다른 의료진 사이에서 수술 후 결과를 비교하기 위한 합병증 분류 방법으로는 유용한 도구이다. 그러나 HPS 경요도 전립선 기화술과 같은 비침습적인 수술의 합병증들을 좀 더 정확하게 평가하기 위해서는 보완이 필요할 수 있을 것이라 생각할 수 있다.

주요어 : 전립선 비대증, 경요도 전립선 기화술, 경요도 전립선 절제술, 레이저, 합병증

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