

# Application of the Modified Clavien Classification System to 402 Cases of Holmium Laser Enucleation of the Prostate for Benign Prostatic Hyperplasia

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**Purpose:** We attempted to evaluate the perioperative complications of holmium laser enucleation of the prostate (HoLEP) for benign prostatic hyperplasia by using the modified Clavien classification system (MCCS).

**Materials and Methods:** Targeting 402 patients who underwent HoLEP for benign prostatic hyperplasia performed by a single surgeon between July 2008 and January 2011, we investigated complications that occurred during and within 1 month after surgery and classified them into grade I to grade V on the basis of the MCCS. If two or more complications occurred in one patient, each complication was graded and counted.

**Results:** The mean age, prostate volume, operation time, hospital stay, and average follow-up period of 402 patients who underwent HoLEP were 68.8 years (range, 52–84 years), 53.2 g (range, 23–228 g), 58.2 minutes (range, 20–230 minutes), 4.5 days (range, 2–7 days), and 9 months (range, 4–27 months), respectively; 78 complications occurred in 71 of the patients (morbidity rate, 17.6%). In MCCS grade I, complications occurred in 54 cases (69.2%); in grade II, complications occurred in 19 cases (24.3%); in grade III, complications occurred in 4 cases (5.1%); and in grade IV, 1 patient required intensive care unit care because of cerebral infarction (1.2%). There were no grade V complications.

**Conclusions:** The HoLEP-based MCCS complications classification was performed very quickly. However, MCCS, when compared with other measures of endoscopic prostate surgery experiences, including HoLEP, exposed the lack of accuracy in low grade classification and the inability to include late complications.

**Keywords:** Complications; Holmium; Lasers; Prostate

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## INTRODUCTION

In 1992, Clavien and his colleagues [1] presented guidelines on the classification of complications on the basis of severity grading. This classification method made possible mutual comparisons between dissimilar surgeries [2]. In 2004, large-scale research was performed, and the objectivity of the modified Clavien classification system (MCCS) was announced [3]. Currently, the effectiveness of the MCCS is broadly recognized, and the system is adapted for use in various surgery evaluations beyond hepato-

biliary surgery. Its application in the area of urology has been active recently, including for robot-assisted radical prostatectomy [4], radical cysto-urethrectomy [5], percutaneous nephrolithotomy [6], and laparoscopic pyeloplasty [7]. However, the MCCS has been less actively used in endoscopic benign prostatic hyperplasia (BPH) surgery. An MCCS-based evaluation after surgeries that have recently become popularized, holmium laser enucleation of the prostate (HoLEP), in particular, has yet to be made. Recognizing that, our aim in this research was to evaluate the applicability of the MCCS in reporting and grading the

severity of perioperative complications in patients with BPH who had undergone HoLEP and to compare those results with the MCCS results in transurethral resection of the prostate (TURP) and photoselective vaporization of the prostate (PVP).

## MATERIALS AND METHODS

This study targeted 402 patients who underwent HoLEP for BPH from July 2008 to February 2011 (excluding 35 from a total of 437); the patients' medical records were retrospectively analyzed. Patients were excluded if they had prostate cancer (n=18), had neurogenic bladder (n=7), or had undergone urethral surgery (n=10). Prostate biopsies were performed to exclude prostate cancer when clinically necessary. All procedures were performed by a single surgeon (J.B.L.). Before HoLEP, all patients underwent a digital rectal examination, serum prostate-specific antigen (PSA) measurement, transrectal ultrasonography, uroflowmetry, and residual urine measurement, and International Prostate Symptom Score and quality of life scores were determined. The Versa Pulse Power Suite (Lumenis, Yokneam, Israel) holmium laser was used for enucleation of prostatic adenoma at a laser power of 80 to 100 W. In addition, a 26-Fr resectoscope (Karl Storz, El Segundo, CA, USA) with a laser bridge was used. Tissue morcellation was performed by using a percutaneous nephrolithotomy nephroscope and a VersaCut morcellator (Lumenis). After HoLEP, a 3-way 22-Fr urethral catheter was inserted, and continuous irrigation was carried out. Bladder filling during HoLEP may cause temporary postoperative hypotonicity. Thus, the Foley urethral catheter was generally removed 1 to 2 days later, after which retention was identified by measuring uroflow and postvoid residual, and then discharge was determined. The day after surgery, the hemoglobin, blood urea nitrogen/creatinine, and electrolyte levels were checked with basic blood laboratory tests, and a vital-sign check was carried out 4 times a day during hospitalization. All of these records, treatment information, and postdischarge outpatient prescription information were computerized, and the complication classification was carried out through investigation of them and MCCS classification. According to the MCCS, 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) [3]. All complications were classified by a senior resident (J.I.C.) who was unaware of the clinical details so as to avoid bias from surgeon-related complication misjudgment. Subsequently, the complications recorded were independently classified by a coauthor (W.N.). Any disagreement was resolved by discussion, and the final decision was by consensus. In the case of > 1 complication in the same patient, the categorization was done in > 1

**TABLE 1.** Baseline characteristics of patients (n=402) who submitted to HoLEP

Characteristic	Mean (range)
Age (y)	68.8 (52.0–84.0)
Prostate volume (mL)	53.2 (23.0–228.0)
PSA (ng/mL)	4.1 (0.15–31.32)
IPSS	25.1 (5.0–35.0)
IPSS (postoperative 1 mo)	10.4 (5.0–19.0)
Qmax (mL/s)	11.7 (1.1–18.0)
PVR (mL)	92 (22–280)
QoL	5.3 (4.0–6.0)
QoL (postoperative 1 mo)	3.8 (1.0–5.0)
Operation time (min)	58.2 (20.0–230.0)
Foley catheter time (d)	2.3 (1.0–6.0)
Follow-up period (mo)	9 (4–27)

HoLEP, holmium laser enucleation of the prostate; PSA, prostate-specific antigen; IPSS, International Prostate Symptom Score; Qmax, maximal flow rate; PVR, postvoid residual urine; QoL, quality of life.

grade.

## RESULTS

The baseline characteristics of the 402 patients are shown in Table 1. Targeting 402 patients who underwent HoLEP for BPH, we classified the complications that occurred during and within 1 month after surgery on the basis of the MCCS; 78 complications occurred in 71 patients. Most complications (54 cases, 69.2%) belonged to grade I: hematuria requiring clot evacuation occurred in 7 cases, urinary obstruction after removal of the urethral catheter that required recatheterization occurred in 9 cases, temporary creatinine elevation occurred in 3 cases, bladder mucosa damage that extended the urethral catheter indwelling period occurred in 13 cases, and temporary urinary incontinence occurred in 22 cases. Grade II included 19 cases, accounting for 24.3% of the 78 complications: low urinary tract infection requiring antibiotic therapy occurred in 3 cases, hematuria requiring transfusion occurred in 5 cases, and postoperative permanent incontinence, urgency, urge incontinence, and dysuria requiring medication occurred in 1 case, 2 cases, 5 cases, and 3 cases, respectively. Grade III included 4 cases, accounting for 5.1% of the 78 complications: remnant chips in the bladder that requiring a second morcellation occurred in 3 cases and severe hematuria requiring transurethral coagulation occurred in 1 case. Grade IV included 1 case, accounting for 1.2% of the 78 cases: 1 patient was transferred to and treated in the intensive care unit for postoperative cerebral infarction. No grade V complications occurred.

The facts that there were no general symptoms and that the low urinary tract infection was localized corresponded to a grade I classification, but the use of antibiotics corresponded to grade II, and thus this complication was classified as grade II. Transfusion was performed when Hg was

**TABLE 2.** Complications classified according to the modified Clavien system

Grade	Complication	Management
I	Hematuria±blood clot retention (n=7)	Bedside bladder irrigation±clot evacuation±catheter traction
	Acute urinary retention after catheter removal (n=9)	Bedside recatheterization
	Transient elevation of serum creatinine (n=3)	Watchful regulation of fluid balance
	Bladder mucosal layer injury (n=13)	Prolongation of Foley catheter period
	Transient incontinence (n=22)	Observation
II	Low urinary tract infection (n=3)	Antibiotics
	Dysuria (n=3)	Antibiotics
	Intraoperative hemorrhage/hematuria (n=5)	Transfusion
	Permanent incontinence (n=1)	Anticholinergics
	Urgency (n=2), urge incontinence (n=5)	Anticholinergics
IIIb	Remnant chips in bladder (n=3)	Remorcellation under GA
	Severe hematuria (n=1)	Transurethral coagulation under GA
IVa	Cerebral infarction (n=1)	Admission to intensive care unit

GA, general anesthesia.

9 or less, and, if medication was given for more than 7 days, the case was considered to fall between postoperative “transient” and “permanent” and thus was classified as grade II. The patient who received intensive care unit care for cerebral infarction had previously been treated with antiplatelet medication because of infarction and was the patient whose medication was suspended for surgery (Table 2).

## DISCUSSION

The rate of post-HoLEP complications by use of the MCCS was 17.6%. The most frequent complications were grade I (69.2%), with grade II complications the next most frequent (24.3%). In the recent dissertation by Mamoulakis et al. [8] that classified complications with MCCS after TURP implementation, the morbidity rate was 15.7%. Grade I complications accounted for 26 of 44 cases (59.1%), and grade II for 13 cases (29.5%). The research by Kwon et al. [9] on MCCS data via high-performance system photoselective vaporization of the prostate (HPS-PVP) found a morbidity rate of 17.3%; grade I included 49 of 59 cases (83.0%), and grade II included 9 cases (15.2%). In all these studies, the majority of complications were grades I and II. However, our study's HoLEP grade III was found to be 5.3%, higher in simple comparison (TURP, 2.3%; HPS-PVP, 0.3%). Of the 4 grade IIIb cases, 3 patients underwent remorcellation herein. Their prostate volume exceeded 170 g, which made it difficult to secure clear vision for morcellation. Mamoulakis et al. [8] reported that antibiotics were used in 9 cases for low urinary tract infection; 2 of the cases had urosepsis symptoms that were classified as grade II, and the rest were grouped into grade I. In the present study, however, all cases treated with antibiotics were classified as grade II, which was a result of our following the principle of MCCS therapeutic consequence. When the grades of symptoms and management differed from each other, we used management as a baseline. Kwon et al. [9] reported on HPS-PVP that no management cases of 45 nonspecific

urinary symptom cases were classified as grade I. Also in their study, 22 cases of mild incontinence, if there was no management after HoLEP, were classified as grade I. But the existence of ambiguity must be acknowledged, because mild incontinence, mild dysuria, mild perineal discomfort, and other mild symptoms may be viewed as sequelae [10].

The HoLEP data here are from the follow-up materials during and 1 month after the surgery. The 2004 MCCS created a suffix “d” to itemize long-term disability [3]. Three urethral stricture patients developed the disease 4 months after surgery and underwent endoscopic internal urethrotomy in our hospital; they were excluded from the cases with complications. Usually, complication classification lasts for about 3 months in order to include MCCS late complications [11]. However, as for the BPH surgery using an endoscope through the urethra, the process of stricture formation is too slow to be easily included.

MCCS prevents down-regulation of complications through therapeutic consequences, and it is an easy tool to use. The system is an objective guideline based on severity grading, which enables cross-data comparison. Another benefit is its adoption of a retrospective analysis method that places less stress on the patients [3]. A prospective study of MCCS reported that the occurrence of complications had dropped from 11% to 7% [11]. Such strong points of MCCS, in fact, have facilitated its wider application in urology [4-7], especially when more objective complication classification tools are required for urology surgery [12,13].

In comprehensive consideration of our experience, classification was very fast, but, if compared with TURP and HPS-PVP, HoLEP surgery was found to show relatively more complications (grade III) that required intervention in case of a large prostate volume. Moreover, in low urinary tract endoscopic surgery, grade I and II classifications still differed from those made by urologists. Furthermore, grade I complications and sequelae were found to be ambiguous to classify. Finally, late complications, such as urethral complications, need to be included.

There were some potential limitations to our study, including the fact that our predictive variables were obtained retrospectively from clinical chart review and thus were inherently incomplete. This factor may have led to inadequate recording of minor, self-limited complications. Although we tried to include the most complete patient-specific information, performance of such a comparison in a prospective study with a large number of patients is needed.

## CONCLUSIONS

HoLEP-based MCCS complication classification was performed very quickly. However, MCCS, when compared with other measures of prostate endoscopic surgery experience, including HoLEP, exposed the lack of accuracy in low grade classification and the inability to include late complications.

## CONFLICTS OF INTEREST

The authors have nothing to disclose.

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