



Can the Penile Cuff Test Predict the Outcome of Holmium Laser Enucleation of the Prostate for Benign Prostatic Obstruction?

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OBJECTIVE	To determine whether the penile cuff test can predict surgical outcomes prior to Holmium laser enucleation of the prostate for benign prostatic obstruction.
METHODS	Men scheduled to undergo Holmium laser enucleation of the prostate were enrolled in this study, and all patients underwent the penile cuff test prior to and 3 months after surgery. Patients were categorized as obstructed, nonobstructed, or uncertain by nomogram. Surgical outcomes were assessed by evaluating changes in their international prostate symptom score, quality of life index, and maximum flow rate preoperatively and 3 months postoperatively. The proportion of patients with good outcomes was compared among nomogram-classified groups, and postoperative changes in position on the nomogram were assessed.
RESULTS	A total of 125 patients were analyzed. After surgery, the overall treatment efficacy and symptomatic treatment efficacy were not different between obstructed and nonobstructed patients. However, the maximum flow rate and quality of life score were significantly higher after surgery in obstructed patients compared to nonobstructed patients. After surgery, 75.7% of patients with obstruction and 63.6% of patients categorized as uncertain for obstruction transitioned to the nonobstructed group, while 77.3% of nonobstructed patients remained in the nonobstructed group.
CONCLUSION	The penile cuff test can be used in patients with bladder outlet obstruction to predict good functional outcome and improved quality of life following treatment with Holmium laser enucleation. After Holmium laser enucleation of the prostate, the majority of patients were classified as nonobstructed. UROLOGY 124: 207–212, 2019. © 2018 Elsevier Inc.

Lower urinary tract symptoms (LUTS) in middle-aged men are largely due to bladder outlet obstruction (BOO) or decreased detrusor contractility, and it is very important to distinguish between these 2 disorders before treatment.¹ The pressure-flow study (PFS) is the current gold standard method to diagnose BOO. The success rate of transurethral resection of the prostate (TURP) is about 30% higher for cases diagnosed by the

PFS as having obstruction (ie, BOO) than for those cases without obstruction.²

The penile cuff test (PCT) was developed to address the disadvantages of the PFS, and has been used to diagnose BOO in several studies.^{3–6} Our previous study confirmed the diagnostic accuracy of the PCT.⁷ However, in order for the PCT to be considered for clinical application, patients diagnosed with BOO using the PCT would need to have better surgical outcomes than nonobstructed patients. In addition, a shift in PCT categorization by nomogram (eg, obstructed, nonobstructed) should be evident after surgery. Two studies from a single institution showed that categorization of BOO cases using PCT improved prediction of TURP outcomes, including a change in position on the nomogram after TURP.^{8,9}

Holmium laser enucleation of the prostate (HoLEP) has become an important treatment modality for BOO. The outcomes of several studies support HoLEP as an alternative to TURP with equivalent or better urodynamic and symptomatic outcomes.^{10–15} Good surgical

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outcomes after HoLEP in patients with BOO diagnosed by the PFS have also been reported.¹⁶

However, no previous study has determined the usefulness of the PCT for effectively selecting candidates for HoLEP. Here, we report the results of a prospective study to determine the usefulness of preoperative patient categorization using a PCT nomogram for improved HoLEP outcome prediction. Following HoLEP, we examined whether PCT nomogram categorization changed after resolution of BOO, and whether isovolumetric bladder pressure was altered.

MATERIALS AND METHODS

Study Participants

Men aged 50 years or older who had an International Prostate Symptom Score (IPSS) of 12 or more and who were scheduled to undergo HoLEP were included in this study. Exclusion criteria were a history of prostate or bladder cancer, neurogenic bladder, urethral stricture, bladder diverticulum, bladder neck contracture, neurologic disorders (eg, stroke, multiple sclerosis, spinal injury, or Parkinson's disease), use of an indwelling catheter, the need for a prostate biopsy due to increased prostate-specific antigen, abnormal findings on transrectal ultrasonography, or any other condition making the patient unsuitable for the study as deemed by the investigator.

According to the results of a previous study, we defined a good response rate as 87% for bladder outlet obstructed patients and 57% for nonobstructed patients (at least 30% higher in obstructed patients).⁹ The ratio of obstructed to nonobstructed patients required to achieve 80% power at a two-sided 5% significance level was calculated to be 3:1 (63 obstructed and 21 nonobstructed patients).

Study Protocol

This was a prospective study conducted at a single center between January 2014 and June 2017. The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. It was approved by the Institutional Review Board of the Samsung Medical Center. Patients provided written informed consent prior to any procedure.

There were 3 study visits: visit 1 was for screening and setting a baseline, visit 2 was for the HoLEP operation, and visit 3 was for the 3-month, post-op appointment. During visit 1, the patient's eligibility was confirmed according to the above stated inclusion and exclusion criteria. In addition, vital signs, urinalysis, urine culture, serum prostate specific antigen, and IPSS were evaluated, and a TRUS, digital rectal examination, uroflowmetry with postvoid residual, and PCT were performed. During visit 2, the patient underwent HoLEP. During visit 3, uroflowmetry with postvoid residual and PCT were performed, and IPSS was evaluated.

The primary measurement of outcome used for evaluation was the proportion of good responders among bladder outlet obstructed patients and nonobstructed patients 3 months after surgery. Homma's criteria were used to evaluate treatment efficacy. There are 4 domains of Homma's criteria: symptoms, function, anatomy, and quality of life (QOL).¹⁷ The symptom domain was evaluated using the post/pre ratio of IPSS, and the function domain was evaluated with post-pre Q_{max} . The anatomy domain was evaluated using the post-pre prostate volume, while the QOL domain was evaluated using the pre-post QOL index. The efficacy of treatment was graded as excellent, good, fair, or poor. A patient was considered

to be a "good responder" if he had an efficacy grade of good or excellent in each domain. We evaluated the proportion of good responders for all subjects and according to groups of patients categorized based on PCT results. The overall treatment efficacy was measured as the median of the efficacy grades of the symptom, function, and QOL domains. (see [Appendix 1](#)). Secondary outcomes included positional change in the PCT nomogram, change in penile cuff interruption pressure ($P_{cuff.int}$), and change in Q_{max} during the cuff test ($Q_{max.cuff}$) between the baseline measurement and the 3-month, postoperative appointment. All of these metrics were compared between obstructed and nonobstructed patients.

Penile Cuff Test

At baseline, all patients underwent a PCT (Mediplus CT 3000 Cuff Machine). A penile cuff was placed around the penis, and the patient was asked to void into a flowmeter connected to the cuff machine. Once voiding was initiated, the cuff was automatically inflated at 10 cm H_2O/s until the flow was stopped or the safety pressure of 200 cm H_2O was reached. Then, the cuff was deflated rapidly with resumption of flow. This process was repeated until voiding was complete. The PCT parameters were plotted automatically on a nomogram, according to the method proposed by Griffiths.⁴ A single urologist read the maximum value of $P_{cuff.int}$ and $Q_{max.cuff}$ from the continuous plot of flow rate. The inflation cycle was excluded if one of the quality control criteria was not met. For example, data were disregarded if there was no recovery of flow, an erratic flow trace, an ambiguous $P_{cuff.int}$ measurement, or if flow continued above the inflation safety limit (200 cm H_2O).

Statistical Analysis

Patient characteristics and perioperative data were summarized using descriptive statistics according to patient groups as classified based on preoperative PCT results, and between-group differences were assessed by means of a one-way analysis of variance. The number of patients achieving a good outcome was expressed as n (%) [95% confidence interval (CI)]. The proportion of patients in each of the 3 groups classified based on PCT results who achieved a good outcome was then compared with the outcomes in the group as a whole. Then, we compared the proportion of cases with a good outcome between the nonobstructed group and obstructed group, and between the uncertain group and the obstructed group. A Wilcoxon signed-rank test or paired t test were used to compare IPSS, $P_{cuff.int}$, $Q_{max.cuff}$, Q_{max} , and voiding efficacy between baseline and 3 months. All data analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC). P values below .05 were considered statistically significant.

RESULTS

Baseline Characteristics

A total of 155 patients who underwent HoLEP were initially enrolled in this study. Of these, 18 were lost to follow-up and were dropped from the study, 8 were diagnosed with prostate cancer, and 4 withdrew study consent. Ultimately, full datasets were available for 125 of the 155 enrolled patients (80.6%). The nomogram from the preoperative PCT categorized 70 patients as obstructed, 22 patients as nonobstructed, and 33 patients as uncertain. The baseline characteristics and perioperative outcomes are shown in [Appendix 2](#). The baseline age, prostate specific antigen level, total prostate size, and transition zone size did

not differ significantly among the 3 groups. However, the preoperative IPSS and QOL scores, and maximum flow rate were different among groups. In the perioperative outcomes, there were no differences in operation time or weight of the resected prostate among the groups.

Surgical Outcomes

Surgical outcomes at 3 months postoperatively are described in Table 1. The proportion of good responders was 71.4% in the obstructed group, 63.6% in the nonobstructed group, and 75.8% in the uncertain group. Differences among groups were not significant compared to the proportion of good responders among all patients. There were no statistically significant differences in symptom, function, or QOL efficacy scores between the each of the three groups and the entire study cohort.

When comparing the obstructed and nonobstructed groups, there was no difference in the good responder rate in terms of overall efficacy or symptom efficacy. However, after HoLEP, functional efficacy was significantly higher in obstructed patients (75.7% [95% CI: 65.7-85.8]) than in nonobstructed patients (54.6% [95% CI: 33.7-75.4]). Moreover, the percentage of good responders in the QOL category was significantly higher in the obstructed group than in the nonobstructed group ($P = .012$).

Change in PCT Nomogram Position After HoLEP

Of the 70 patients who had a BOO, 53 (75.7%) were classified as nonobstructed after HoLEP. Of the patients in the uncertain group preoperatively, 63.6% became nonobstructed after surgery, while 77.3% of nonobstructed patients remained in the

nonobstructed category (Table 2). Figure 1 shows the changes in PCT nomogram status after HoLEP.

In patients with preoperative BOO, the $P_{\text{cuff.int}}$ decreased from 136.1 ± 28.2 to 103.9 ± 34.5 cm H_2O ($P < .001$) and the $Q_{\text{max.cuff}}$ increased from 6.1 ± 2.2 to 18.5 ± 10.4 ml/s ($P < .001$) after HoLEP. In upper right and lower left quadrant uncertain patients, the $P_{\text{cuff.int}}$ decreased and $Q_{\text{max.cuff}}$ increased significantly after treatment. In nonobstructed patients, the $Q_{\text{max.cuff}}$ increased and $P_{\text{cuff.int}}$ decreased after surgery, but these changes were not statistically significant (Table 3).

DISCUSSION

Prediction of surgical outcome after HoLEP in male patients with LUTS is desirable in order to avoid unnecessary surgery. In previous studies, the success rate for obstructed patients diagnosed by the PFS was 79%-93%, while that for nonobstructed patients diagnosed by the PFS was 55%-78%.² Although the criteria we used to determine surgical success were not consistent with those of previous studies, we showed a success rate of 71.4% in the obstructed group and 63.6% in the nonobstructed group when we diagnosed BOO using PCT. The overall efficacy among all patients, regardless of PCT categorization, was 71.2%. Unfortunately, we could not predict overall treatment efficacy in patients with or without obstruction.

Harding et al⁹ predicted the outcome of TURP using the PCT, and reported a good outcome in 87% of patients with obstruction and 56% of patients with

Table 1. Proportion of good responders for all subjects and according to PCT classification

	All Subjects	Pre-op PCT classification					
		Obstructed		Nonobstructed		Uncertain	
	Good Responders (%)	Good Responders (95% CI)	<i>P</i>	Good Responders (95% CI)	<i>P</i>	Good Responders (95% CI)	<i>P</i>
Overall	71.2	71.4 (70.9-82.0)	.966	63.6% (43.5-83.7)	.433	75.8 (61.1-90.4)	.563
Symptoms	76.0	75.7 (65.7-85.8)	.955	68.2 (48.7-87.6)	.391	81.8 (68.7-95.0)	.434
Function*	69.6	75.7 (65.7-85.8)	.266	54.6 (33.7-75.4)	.125	66.7 (50.6-82.8)	.714
QOL*	52.8	55.7 (44.1-67.4)	.625	40.1 (20.4-61.5)	.264	54.6 (37.6-71.5)	.841

CI, confidence interval; PCT, penile cuff test; QOL, quality of life.

* Obstructed vs nonobstructed: $P < .05$

Table 2. Pre- and postoperative position distributions on the PCT nomogram

		Post-op				Total
		Obstructed	Uncertain (Right Upper)	Uncertain (Left Lower)	Nonobstructed	
Preop	Obstructed	6 (8.6%)	3 (4.3%)	8 (11.4%)	53 (75.7%)	70
	Uncertain (Right Uper)	0 (0.0%)	0 (0.0%)	1 (11.1%)	8 (88.9%)	9
	Uncertain (Left Lower)	2 (8.3%)	0 (0.0%)	9 (37.5%)	13 (54.2%)	24
	Nonobstructed	3 (13.6%)	0 (0.0%)	2 (9.1%)	17 (77.3%)	22
	Total	11	3	91	91	125

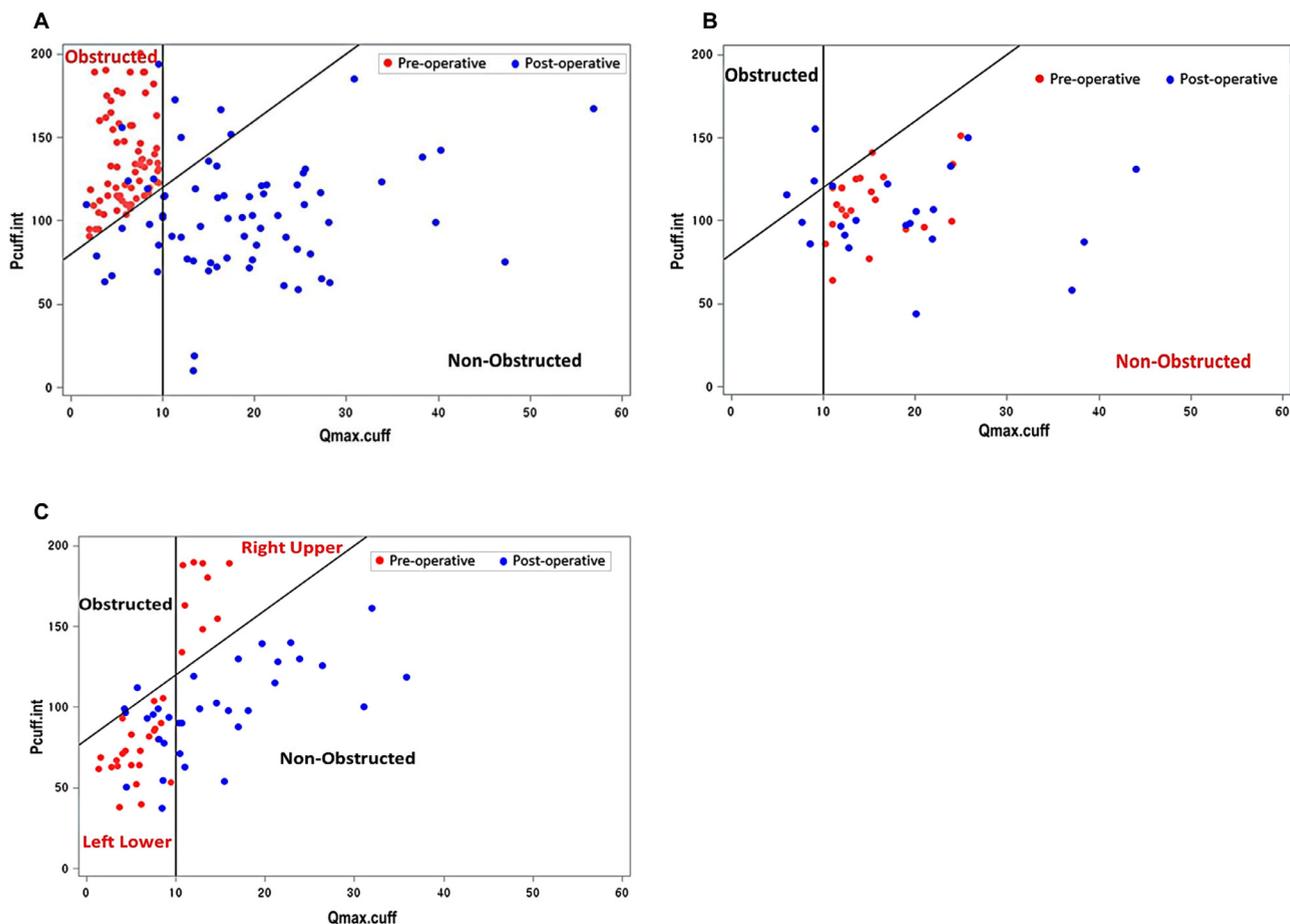


Figure 1. Change in PCT nomogram position after HoLEP in (A) obstructed patients ($n = 70$), (B) nonobstructed patients ($n = 22$), and (C) patients with an uncertain obstruction status ($n = 33$). HoLEP, Holmium laser enucleation of the prostate; PCT, penile cuff test. (Color version available online.)

nonobstruction. They concluded that the PCT improves prediction of outcomes in patients with LUTS undergoing TURP. Losco et al¹⁸ demonstrated that 94% of patients predicted to be obstructed had a good outcome, while 70% of patients predicted to be nonobstructed did not have a good outcome after either TURP or HoLEP ($P < .01$). They used subjective symptom changes from

preoperative to postoperative IPSS as their sole measure of surgical outcome. In contrast, we assessed QOL and Q_{max} as objective outcomes, and investigated subjective symptoms using Homma's criteria in 4 domains. The function domain of Homma's criteria was evaluated using the absolute increase in Q_{max} after operation (post-pre Q_{max}), and a good responder was defined as a patient with a post-

Table 3. Changes in PCT parameters after HoLEP according to preoperative nomogram categorization

	Pre	Post	<i>P</i>
<i>Obstructed (n = 70)</i>			
Pcuff.int	136.1 ± 28.2	103.9 ± 34.5	<.001
Qmax.cuff	6.1 ± 2.2	18.5 ± 10.4	<.001
<i>Nonobstructed (n = 22)</i>			
Pcuff.int	110.7 ± 20.5	104.3 ± 26.5	.359
Qmax.cuff	15.2 ± 4.6	18.6 ± 10.4	.126
<i>Uncertain (Right upper; n = 9)</i>			
Pcuff.int	170.7 ± 21.2	120.0 ± 25.3	<.001
Qmax.cuff	12.7 ± 18.7	18.7 ± 6.9	.042
<i>Uncertain (Left lower; n = 24)</i>			
Pcuff.int	73.3 ± 18.0	90.3 ± 25.0	.005
Qmax.cuff	5.4 ± 2.2	13.1 ± 8.5	.001

HoLEP, Holmium laser enucleation of the prostate; Pcuff.int, pressure that interrupts flow; Qmax.cuff, Qmax during the cuff test.

pre $Q_{\max} \geq 5$ ml/s. The QOL domain was evaluated by the reduction in QOL index score after the operation (pre-post QOL index), and a good responder was defined as a patient with a pre-post QOL score of 3 or higher. Based on functional efficacy, as assessed by Q_{\max} , 76% of the obstructed patients showed a good surgical outcome after HoLEP, while about 55% of nonobstructed patients showed a good surgical outcome after HoLEP. The proportion of patients with an improved QOL after HoLEP was not greater than expected, but there was a significant difference in pre-post QOL scores in about 15% in obstructed patients compared to nonobstructed patients.

A systematic review of the diagnostic value of the PFS after TURP showed that the PFS had diagnostic utility in patients diagnosed with BOO with respect to both IPSS and Q_{\max} .¹⁹ Interestingly, in our study, subjective symptoms according to IPSS did not differ significantly between the obstructed and nonobstructed groups, and both groups showed symptom improvement regardless of PCT categorization, approximately 70% of patients overall. This could be because patients were already in need of surgical treatment due to severe LUTS. The finding that subjective symptoms did not differ between the obstructed and nonobstructed groups after surgery does not necessarily mean that HoLEP is not effective, but could ultimately affect the way treatment is evaluated.

In a previous study, when the PFS was performed after prostate resection for BOO, the detrusor pressure at Q_{\max} decreased and Q_{\max} itself increased.^{11,20} Similarly, we predicted that $Q_{\max.cuff}$ would increase and $P_{cuff.int}$ would decrease after HoLEP. As expected, there was an increase in $Q_{\max.cuff}$ and a decrease in $P_{cuff.int}$. After HoLEP, the mean increase in $Q_{\max.cuff}$ was approximately 12 ml/s for obstructed patients and 3 ml/s for nonobstructed patients. This was reflected in the nomogram by a shift to the right. In addition, the $P_{cuff.int}$ decreased by an average of 30 cm H₂O in obstructed patients and 6 cm H₂O in nonobstructed patients. This was reflected as a downward shift in the nomogram. The extent of the change was not significant in the nonobstructed patients.

About 26% (33/125) of patients were in classified as uncertain with regards to their obstruction status, which is a similar finding to that in our previous study on the diagnostic performance of the PCT.⁷ It remains unclear if surgery is beneficial for these patients. After HoLEP, about 90% of uncertain patients in the upper right quadrant of the nomogram moved to a nonobstructed category, and the overall efficacy was 100.0% (not shown in results). Setting the upper limit of the $Q_{\max.cuff}$ to 10 ml/s in the nomogram might have affected the outcome. In our study, 88.9% of the patients in this area had a $Q_{\max.cuff}$ of 10-15 ml/s. It is not possible to rule out obstruction in patients with a $Q_{\max.cuff}$ of 10-15 ml/s, and our results suggest that the majority of these patients will benefit from surgery. This finding is consistent with the results of a previous PCT study that assessed changes following TURP.⁸ On the other hand, the uncertain group in the lower left quadrant might be heterogeneous. In this group, the $Q_{\max.cuff}$ and

$P_{cuff.int}$ increased significantly after HoLEP, unlike the other categories. Half of these patients moved to the non-obstructed area of the nomogram, but about 40% remained in the left lower quadrant. These patients likely had detrusor underactivity with or without BOO because they had low pressure and a low flow rate. A large retrospective study of the impact of detrusor underactivity on surgical outcomes of prostatectomy showed that the overall improvement in men with detrusor underactivity was less pronounced than in those without detrusor underactivity, while micturition symptoms and Q_{\max} improved regardless of detrusor underactivity at baseline.²¹ The patients in the lower left quadrant showed a significant increase in the Q_{\max} postsurgery when compared with presurgery Q_{\max} , but the overall efficacy was only 66%, and the functional efficacy was 62% (data not shown).

This study had several limitations. First, our study subjects were already selected as patients requiring surgical treatment prior to enrollment in our study. Second, the follow-up period was only 3 months, and thus it remains unclear whether the same results would be obtained after a longer follow-up period.

CONCLUSION

The PCT can be used in patients with BOO to predict good functional outcome and improved QOL following treatment with Holmium laser enucleation. Patients with BOO were more likely to change position on the nomogram to the nonobstructed category with recovery of detrusor contractility than patients classified as uncertain or nonobstructed. However, regardless of categorization according to preoperative PCT results, subjective improvement was similar in all patients after the operation. Although there is no diagnostic method that can completely replace the PFS, the PCT is a viable alternative to the PFS when used prior to surgical treatment for BOO.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.urology.2018.11.012](https://doi.org/10.1016/j.urology.2018.11.012).

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