Role of Holmium Laser Enucleation of The Prostate for The Diagnosis of Prostate Cancer in Patients with Gray-Zone PSA Levels.

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Role of Holmium Laser Enucleation of The Prostate for The Diagnosis of Prostate Cancer in Patients with Gray-Zone PSA Levels.

Directed by Professor Jang Hwan Kim

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

ABSTRACT

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Purpose

Even though the safety of the treatment for prostate cancer diagnosed by HoLEP has been reported, the diagnostic value of HoLEP for prostate can cer detection has not been confirmed. Therefore, we investigated the diag nostic potential of HoLEP for detecting prostate cancer.

Patients and Method

Between December 2008 and October 2014, 359 patients (median age, 7 0.9 years; range, 66.2-74.8) were treated simultaneously with HoLEP and transrectal prostate needle biopsy (TPNB). Of these, 199 patients with a no rmal digital rectal examination and serum PSA concentration between 3. 5 and 10.0 ng/ml were included in the study. Univariate and multivariate lo

gistic regression analyses were performed to identify the predictive factor for prostate cancer detected by HoLEP.

Results

Median PSA, prostate volume and PSA density were 4.97 ng/ml (range, 4.20-6.70), 57.40 gm (range, 43.67-77.80) and 0.09 ng/ml^2 (range, 0.07-0.12), respectively. Clinically significant prostate cancer (Gleason score ≥ 6) was detected in 46 cases (23.1%). Of these, 26 (56.5%) were detected by HoLEP pathology, 11 (23.9%) by TPNB pathology, and 9 (19.6%) by both. Univariate and multivariate logistic regression analyses were perfor med in 179 patients, including benign prostatic hyperplasia patients (N=15 3, 76.9%) and patients with cancer detected by HoLEP pathology. PSA den sity was identified as an independent predictor of prostate cancer detecte d by HoLEP in gray-zone PSA.

Conclusion

HoLEP is a viable modality for detecting prostate cancer in selected cases. PSA density was an independent predictor of prostate cancer detected by HoLEP in gray-zone PSA.

Key words : prostate cancer, Holmium laser enucleation of the prostate, prostate-specific antigen

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I. INTRODUCTION

Prostate-specific antigen (PSA) is widely used as a marker for prostate cancer screening in the general population. A transrectal prostate needle biopsy (TPNB) for the detection of prostate cancer is also recommended when PSA values are increased and/or prostate cancer is suspected based on digital rectal exam (DRE).[1]

Since Hodge et al. first suggested sextant prostate biopsy as a modality for the detection of prostate cancer,[2] ultrasound-guided transrectal or transperineal laterally directed 18G core biopsies have become the standard method for detecting prostate cancer. However, because there is always the possibility of a false-negative result,

various modifications to these approaches have been suggested for reducing unnecessary procedures and increasing the cancer detection rate. This is especially true in patients with gray-zone PSA levels, where relatively poor detection rates attributable to the limited specificity of PSA have demanded complementary diagnostic modalities.

Several authors have focused on the detection of transition-zone cancer because this cancer cannot be detected easily by conventional biopsy-based methods. Accordingly, the usefulness and necessity of core biopsies targeting the transition zone have been suggested,[3-5] but several authors have argued that the prostate cancer detection rate using this approach is unsatisfactory.[6,7] Therefore, several studies have suggested diagnostic transurethral resection of the prostate (TURP) instead of a core biopsy targeting the transition zone to increase the rate of cancer detection in selected cases.[8-15]

Since Holmium laser enucleation of the prostate (HoLEP) was introduced as a treatment for benign prostatic hyperplasia (BPH),[16] several studies have reported active surveillance for prostate cancer to be detected incidentally by HoLEP and the feasibility of robot-assisted radical prostatectomy after HoLEP.[17-19] However, the diagnostic potential of HoLEP has rarely reported even though the safety of the treatment for prostate cancer diagnosed by HoLEP has been reported. Accordingly, we investigated the diagnostic potential of HoLEP in patients with serum gray-zone PSA levels (3.5–10.0 ng/ml).

II. MATERIAL & METHODS

1. Patients and procedures

Three Korean institutions contributed to this study. Between December 2008 and October 2014, 359 patients were simultaneously treated with HoLEP and 12-core TPNB. After receiving institutional review board approval, we conducted a retrospective chart review of 199 patients who had normal digital rectal examination findings and serum PSA concentrations of 3.5 to 10.0 ng/ml. All included patients had moderate or severe lower urinary tract symptoms (LUTS) (International Prostate Symptoms Score: ≥8). Patients with possible urinary tract infections based on urine culture results were excluded from the study.

2. Clinical data and statistical analysis

Age at the time of surgery, preoperative PSA, preoperative prostate volume, transition-zone volume, PSA density, and weight of resected tissue were estimated as variables for analysis. Serum PSA for all included patients was assayed with a Cobas-e411 system (Roche Diagnostics), and prostate volume and transition-zone volume were estimated from transrectal ultrasound (TRUS) results using the prolate ellipsoid formula. PSA density was calculated by dividing serum PSA by total prostate volume.

All included patients were initially divided as 4 groups according to histopathologic results. Each group was BPH group, cancer group detected on TPNB alone, cancer group detected both on TPNB and HoLEP, and cancer group detected on HoLEP alone, respectively. And for analysis of additional cancer detection rate by HOLEP, the total patients were devided as Group 1 for BPH group, Group 2 for cancer group detected on TPNB or both on TPNB and HoLEP. And Group 3 for cancer group detected on HoLEP alone. Group 3 was cancer group who could be diagnosed additionally due to HoLEP.

The Mann-Whitney test was used for comparisons between Group 1 and each cancer group, and the increased detection rate attributable to HoLEP was compared to the detection rate based on biopsy only using the McNemar test, with a P-value < 0.05 considered statistically significant. Univariate and multivariate logistic regression analyses were performed to identify the predictive value of HoLEP for the detection of prostate cancer. Variables with a P-value < 0.1 in univariate logistic regression analyses were included in the multivariate model; variables with a P-value < 0.05 in the multivariate logistic regression analysis were considered statistically significant.

All statistical operations were performed using SPSS Statistics version 20.0.0 (IBM Corp., Armonk, NY, USA). A two-sided P-value < 0.05 was considered statistically significant.

III. RESULTS

The baseline characteristics of the study population are presented in Table 1. The median age was 70.90 years old (range, 66.20-74.80), PSA was 4.97 ng/ml (range, 4.20-6.70), and prostate volume was 57.40 gm (range, 43.67-77.80). Figure 1 shows the distribution of patients according to histopathological results. Clinically significant prostate cancer (Gleason score ≥ 6)[20] was detected in 46 cases (23.1%), including 11 (23.9%) in the cancer group detected by TPNB alone, 9 (19.6%) in the cancer group detected by both TPNB and HoLEP, and 26 (56.5%) in the cancer group detected by HoLEP alone. A comparison of the benign group (Group 1) and each cancer group (Group 2, 3) is presented in Table 2. Mann-Whitney tests revealed a significant difference in PSA, prostate volume, PSA density, transition-zone density, and resected volume between Group 1 and 2. Age and PSA density were also significantly different between Group 1 and 3.

Table 1. Patients characteristics

Age, median (year, range)	70.90 (66.20 - 74.80)
PSA, median (ng /ml, range)	4.97 (4.20 - 6.70)
Prostatic volume, median (gm, range)	57.40 (43.67 - 77.80)
Transition zone volume, median (gm, range)	31.35 (21.00 – 46.13)
PSA density, median (ng/ml/cm3, range)	0.09 (0.07 – 0.12)
Transition zone density, median (ng/ml/cm3, range)	0.17 (0.12 – 0.23)
Resected volume, median (gm, range)	21.00 (15.00 – 43.70)

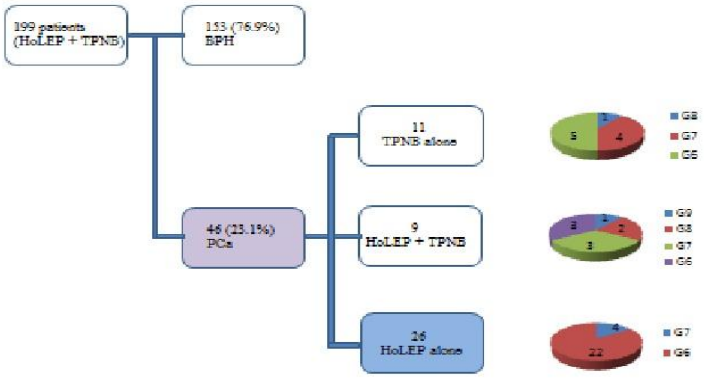

Figure 1. The distribution of patients according to histopathological results.

TPNB had a 10.1% detection rate and detected 43.5% of prostate cancers (20 of 46). The overall cancer detection rate increased from 10.1% to 23.1% by inclusion of HoLEP, an increase that was statistically significant compared with that of TPNB only (p = 0.001, McNemar test).

To identify the predictive factors for the cancer which can be detected additionally by HoLEP, univariate and multivariate logistic regression analysis was performed using Group 1 and Group 3 patients (Table 3). These analyses identified PSA density categorized by median value as an independent predictor of additional cancers detected by HoLEP in gray-zone PSA (odds ratio = 2.516, p = 0.040).

Table 2. Comparison of several factors between Group 1 and Group 2, 3

	Group 1 (N=153)	Group 2 (N=20)	P	Group 3 (N=26)	P
Age, median (year, range)	70.84 (65.84-74.50)	70.26 (64.14-74.95)	0.781	73.35 (67.68-79.37)	**0.045**
PSA, median (ng/ml, range)	4.85 (4.21 – 6.32)	7.44 (5.86-9.03)	**<0.001**	4.96 (3.52-7.65)	0.639
Prostatic volume, median (gm, range)	58.80 (46.50-84.25)	45.95 (31.70-68.58)	**0.008**	48.05 (37.40-76.25)	0.061
Transition zone volume, median (gm, range)	33.05 (22.23-47.08)	22.70 (15.25-40.65)	0.055	23.30 (18.53-43.00)	0.162
PSA density, median (ng/ml/cm3, range)	0.09 (0.07-0.11)	0.15 (0.10-0.22)	**<0.001**	0.09 (0.08-0.13)	**0.047**
Transition zone density, median (ng/ml/cm3, range)	0.16 (0.12-0.22)	0.29 (0.19-0.49)	**<0.001**	0.18 (0.14-0.27)	0.115
Resected volume, median (gm, range)	23.50 (15.00-45.00)	16.50 (10.00-28.55)	**0.042**	22.00 (11.50-43.95)	0.603

Table 3. Predictors for the cancer which can be detected additionally by HoLEP

	Univariate			Multivariate		
	OR	95% CI	P	OR	95% CI	P
Age						
continuous	1.056	1.001-1.114	**0.095**	1.060	0.995-1.129	0.071
categorized <70.9 vs ≥70.9	1.621	0.793-3.312	0.266			
Prostatic volume						
continuous	0.987	0.972-1.001	0.129			
categorized <57.4 vs ≥57.4	0.513	0.251-1.049	0.125			
Transition zone volume						
continuous	0.988	0.967-1.009	0.354			
categorized<31.35 vs ≥31.35	0.600	0.279-1.290	0.273			
PSA						
continuous	1.104	0.911-1.338	0.396			
categorized <4.97 vs ≥4.97	1.217	0.606-2.447	0.643			
PSA density						
categorized <0.09 vs ≥0.09	2.361	1.139-4.894	**0.053**	2.516	1.045-6.068	**0.040**
Transition zone PSA density						
categorized <0.17 vs ≥0.17	1.715	0.797-3.689	0.247			
Resected volume						
continuous	0.996	0.982-1.010	0.604			
categorized <21.0 vs ≥21.0	0.877	0.436-1.762	0.756			

IV. DISCUSSION

Several reports have focused on the diagnostic potential of TURP for the detection of prostate cancer.[8-15,21,22] Kitamura et al. reported that, among 139 patients who underwent peripheral-zone and transition-zone biopsy, none was diagnosed as transition-zone cancer only. In addition, these authors reported that none of 18 patients who underwent TURP had clinically significant prostate cancer.[21] Rovner et al. also reported that TURP adds no diagnostic value.[22] Apart from these studies, several reports have suggested that diagnostic TURP could increase the diagnostic rate for prostate cancer in selected cases.[8-15]

Several reports have documented the incidental detection of prostate cancer in patients undergoing HoLEP for BPH.[18,19,23-26] In addition, several authors have reported on the treatment of prostate cancer incidentally detected by HoLEP.[17-19] Elkously et al. and Rivera et al. reported the safety of active surveillance for prostate cancer to be detected incidentally by HoLEP,[18,19] and Gellhaus et al. reported the feasibility of robot-assisted radical prostatectomy in patients with previous HoLEP treatment.[17]

As more vaporization techniques, which cannot identify histopathologic results, have become available for the treatment of BPH, several studies have sought to identify predictive factors for the incidental detection of prostate cancer by HoLEP.[18,23-25]

Bhojani et al. identified age, PSA and HoLEP specimen weight as independent predictors for incidentally detected prostate cancer,[25] and Otsubo et al. reported that prostate volume, PSA and PSA density were independent predictors.[23] In contrast, Elkoushy et al. presented evidence that PSA density and age were independent predictors, but PSA and prostate volume were not.[18] Kim et al. reported that hypoechoic lesion on TRUS was an independent predictor for incidentally detected prostate cancer.

Our study also presents predictors of prostate cancer detection by HoLEP. However, we performed HoLEP and TPNB simultaneously, because we considered the possibility of prostate cancer in all enrolled patients, even though our study followed a retrospective design. In other words, the prostate cancer detected in our study was not incidentally detected cancer. Therefore, to identify the diagnostic potential of HoLEP rather than predictors of incidental cancer, we enrolled patients with gray-zone PSA levels among all patients treated with HoLEP and TPNB.

The histopathologic results of TPNB in our study were somewhat different from the results reported in previous studies. Naughton et al. reported that the cancer detection rate for 12-core TPNB was 27% in cases where PSA was between 2.5 and 20 ng/ml.[27] However, the cancer detection rate for 12-core TPNB in our study was only 10.1%. The mean PSA level and prostate volume in their study were 6.1 ng/ml and 43 g, respectively, compared with the corresponding values of 4.97 ng/ml and 57.40 g in our study. Thus, differences in PSA levels and prostate volume could account for the

difference in cancer detection rate.

The cancer detection rate with HoLEP alone was 13.1%, comparable to the rate of detection with TPNB alone (10.1%). Similar to our results, previous studies have reported a rate of prostate cancer detection by TURP alone of 9.3-28%.[8-15,21,22] However, unlike our study, their procedures were not performed in patients with a specific range of PSA values. Notably, the median PSA of included patients in previous reports was between 6.6 and 16.2 ng/ml, a range that exceeds ours. Even though a direct comparison is impossible because there are no previous reports on diagnostic TURP performed in patients with gray-zone PSA levels, we regard that the diagnostic potential of HoLEP can be more favorable than that of TURP.

Our results based on patient distributions divided by histopathological results showed that a diagnostic modality for transition-zone cancer, which cannot be easily detected by conventional peripheral-zone biopsies, is required for the detection of prostate cancer in patients with large-volume prostates.

Our study has several limitations. First, the risk classification of all detected cancers was not evaluated. Radiologic studies for clinical staging were performed in only about half of the 46 patients diagnosed with prostate cancer, because the remaining patients did not complete a follow-up visit. Therefore, there is the possibility of over-diagnosis of prostate cancer in the patients in our study. Second, our procedures were performed for therapeutic indications, not for diagnostic indications. Although our

results demonstrate that HoLEP not only has therapeutic advantages but also diagnostic advantages in patients who are considered to have prostate cancer and LUTS, our study should be supplemented by additional studies with a pure diagnostic design. A comparison with diagnostic TURP or transition-zone biopsies would also help to confirm the diagnostic potential of HoLEP.

Even though our study has several limitations as mentioned above, this study has considerable strength because it is the first to report the diagnostic potential of HoLEP and a predictor for the prostate cancer which can be detected additionally by HoLEP.

V. CONCLUSION

Even though the safety of the treatment for prostate cancer diagnosed by HoLEP has been reported, the diagnostic value of HoLEP for the detection of prostate cancer has not been evaluated. In the current study, we found that HoLEP is a viable modality for the detection of prostate cancer in selected cases; and when performed in patients with a relatively high PSA density, it is helpful in detecting prostate cancer. Thus, performing HoLEP in patients with gray-zone PSA and LUTS can be expected to yield not only therapeutic benefits but also diagnostic utility.

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ABSTRACT (IN KOREAN)

회색 지대의 전립선 특이 항원 값이 측정되는 환자에서 전립선암의 진단을 위한 홀륨 레이저를 이용한 전립선 절제술의 역할

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김 기 홍

홀뮴 레이저를 이용한 전립선 절제술 (홀렙)에 의해 진단된 전립선암의 치료의 안정성에 대한 수 차례의 보고가 있어왔음에도, 전립선암에 대한 홀렙의 진단적 가치는 확인된 바가 없었다. 이에 따라 전립선암의 진단을 위한 홀렙의 진단적 가치를 조사하였다.

2008년 12월부터 2014년 10월까지 홀렙과 경직장 전립선 조직 생검이 함께 시행된 259명의 환자 중 직장 수지 검사에서 특이 소견 없으며, 혈청 전립선 특이 항원 값이 3.5 에서 10.0 ng/ml로 확인된 199명의 환자를 대상으로 연구를 진행하였다. 홀렙을 통해 진단되는 전립선암의 예측인자를 확인하기 위하여 단변량 및 다변량 로지스틱 회귀분석을 시행하였다.

혈청 전립선 특이 항원의 중앙값, 전립선 용적 중앙값 및 전립선 특이항원 밀도의 중앙값은 각각 4.97 ng/ml (범위, 4.20-6.70), 57.40 gm (범위, 43.67-77.80) 및 0.09 ng/ml^2 (범위, 0.07-0.12)이었다. 임상적으로 유의한 전립선암(글리슨 점수 ≥6)이 46명 (23.1%)에서 보고되었다. 이 중 26명 (56.5%)는 홀렙에서 암이 진단되었고, 11명 (23.9%)는 경직장 전립선 조직생검에서 암이 진단되었으며, 9명 (19.6%)는 홀렙과 전립선 생검 양측 모두에서 암이 진단되었다. 양성 전립선 비대증으로 보고된 153명 (76.9%)의 환자와 홀렙에서 암이 진단된 환자를 대상으로 단변량 및 다변량 로지스틱 회귀 분석을 시행하였고, 전립선 특이항원 밀도가 회색지대 전립선 특이 항원 값을 갖는 환자에서 홀렙에 의해 진단될 수 있는 전립선 암의 독립적 예측인자로 확인되었다.

본 연구를 통해 홀렙이 전립선암의 진단을 위한 수단이 될 수 있으며, 전립선 특이 항원 밀도는 회색지대 전립선 특이 항원 값을 갖는 환자에서 홀렙에 의해 진단될 수 있는 전립선 암의 독립적 예측인자임을 확인 할 수 있었다.

핵심되는 말 : 전립선암, 홀뮴 레이저를 이용한 전립선 절제술, 전립선 특이 항원