UROONCOLOGY
Original Article

# Prostate cancer detection rate and Gleason score in relation to prostate volume as assessed by magnetic resonance imaging cognitive biopsy and standard biopsy

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**Cite this article as:** Nepal SP, Nakasato T, Ogawa Y, Naoe M, Shichijo T, Maeda Y, et al. Prostate cancer detection rate and Gleason score in relation to prostate volume as assessed by magnetic resonance imaging cognitive biopsy and standard biopsy. Turk J Urol 2020; 46(6): 449-54.

## ABSTRACT

**Objective:** This study aimed to assess the relationship of the prostate cancer and Gleason scores (GSs) or ISUP Grade system with prostate volume (PV) as assessed by magnetic resonance imaging (MRI) cognitive biopsy and standard biopsy.

**Material and methods:** Data were collected from 659 patients who underwent MRI cognitive biopsy and standard biopsy from January 2014 to January 2018. The biopsies were performed because of increased prostate-specific antigen (PSA) levels (>4 ng/mL) and/or abnormal digital rectal examination findings. Transrectal ultrasound was used to measure PV.

**Results:** Prostate cancer detection rates in patients with increased PVs of ≤40 cc and >40 cc were 68.8% and 51.6% (p<0.001), respectively. ISUP Grade group ≥2 (Gleason score ≥3+4) detection rates for increased PVs of ≤40 cc and >40 cc were 68% and 73%, and 22.3% and 37.8%, respectively, for those with ISUP Grade group ≥4 (Gleason score ≥8) (p=0.003). Among the patients with PV>40 cc, univariate logistic regression showed a significant relationship between ISUP Grade group ≥2 and PSA, free/total PSA, PSA density, and MRI (p<0.05). On multivariable logistic regression, MRI (p=0.014) and PSA (p=0.039) predicted ISUP Grade group ≥2 in patients with PV>40 cc.

**Conclusion:** Although the detection rates of prostate cancer decreased as PV increased, the detection of prostate cancer aggressiveness increased as PV increased. This increase in high ISUP Grade lesions with the rise in PV is due to the use of MRI during prostate biopsy with standard biopsy.

**Keywords:** Gleason score; magnetic resonance imaging cognitive biopsy; prostate cancer; prostate volume; standard biopsy.

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**Submitted:**
17.06.2020

**Accepted:**
20.08.2020

**Available Online Date:**
09.10.2020

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Available online at
www.turkishjournalofurology.com

## Introduction

Prostate cancer is the second leading cause of cancer-related death in men.[1] According to the World Health Organization (WHO), it is the fourth most common type of cancer worldwide, with 1.28 million cases in 2018.[2] According to the 2020 WHO cancer statistics, prostate cancer will account for more than 1 in 5 new cancer diagnoses in America.[1] Asian men aged >60 years are approximately 4 times more likely to develop prostate cancer than their Western counterparts.[3] The incidence of prostate cancer is increasing in Japan because of dietary changes, with the incidence now surpassing those of stomach and lung cancer in men.[4]

Prostate carcinoma is diagnosed by prostate biopsy, which is one of the most common urological procedures, with more than 1 million procedures performed per year in the United States and Europe.[5] Currently, 10–12-core biopsies are recommended.[6] The overall detection rate of prostate carcinoma by standard biopsy is reportedly about 20%–40%. Gleason scores (GSs) based on prostate biopsy are understaged in about half of patients with prostate carcinoma.[7] One contributor to this low detection rate is prostate volume (PV) because cores correspond only to a small portion of prostate tissue. This can lead to inadequate sampling. Thus, as PV increases, the prostate cancer detection rate decreases.[8-12]

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10.5152/tud.2020.20248

Currently, magnetic resonance imaging (MRI)-targeted biopsy is the preferred modality for detecting clinically significant and high-risk tumors, avoiding insignificant prostate cancer. A total of 3 types of MRI-based biopsy techniques are currently in use: direct in-bore MRI biopsy, MRI fusion biopsy, and MRI cognition biopsy/MRI visual biopsy.[6,13] MRI cognition biopsy, in contrast to the former 2, does not require specialized equipment. The operator estimates the prostate lesion using transrectal ultrasound scans (TRUS) according to MRI findings.[13] Compared with TRUS, MRI-targeted biopsy has a higher detection rate as the PV increases.[11,12]

Although the use of MRI has helped in prostate cancer detection, significant numbers of prostate cancer cases remain undetected. Reportedly, MRI missed 16% of patients with GS≥7.[14] In another study, MRI missed 12% of those with clinically significant prostate cancer.[15]

In our hospital, we routinely perform MRI cognitive biopsy in addition to standard biopsy for diagnosing prostate carcinoma. This study aimed to examine the relationship of prostate cancer detection rates and high-Gleason prostate cancer with PV, as assessed by MRI-targeted and standard biopsies.

## Material and methods

After obtaining institutional review board approval, data were collected from patients who underwent prostate biopsy between January 2014 and January 2018. Patients with prostate-specific antigen (PSA)>4 and/or abnormal digital rectal examination (DRE) findings underwent the biopsy procedure. There were 773 patients who underwent prostate biopsy. We excluded 114 patients who had no MRI performed before the standard biopsy. Of these, 418 (63.4%) patients who had suspicious lesions on the MRI underwent MRI-targeted visual biopsy. All the patients underwent standard biopsy, including 241 (36.6%) patients with no MRI-suspicious lesions.

The use of MRI cognitive biopsy with standard biopsy for prostate cancer diagnosis was our urology department's decision. We believed that both biopsy techniques utilized together would be beneficial and lead to a better detection rate of prostate cancer. We performed MRI cognitive biopsies in our hospital from January 2014 to March 2018. The biopsy was performed by urologists with a minimum of 3 years' experience (postgraduate students and senior urologists).

In our hospital, patients were admitted on the morning of the biopsy and were discharged the day after the procedures if there were no complications. In Japan, patients pay only 30% of the hospital bills with the help of health insurance. Elderly patients, aged from 70 to 74 years, pay only 20% of the hospital admission price, and those aged 75 years and older pay 10% of the admission price. The rest is paid by medical insurance. However, the discount rate for admission fees varies based on the yearly income of the patient. Although patients pay less, our method still creates a financial burden for patients, as they must be admitted for approximately two days. DRE and prostate biopsy were performed by the same clinician.

**Main Points:**

- Combined use of magnetic resonance imaging (MRI) cognitive biopsy and standard prostate biopsy led to higher Gleason score (GS) detection with increase in prostate volume (PV).
- Although the prostate cancer detection decreased with PV, the detection rate was higher than that in previous literature findings.
- Both univariate and multivariate logistic regression analyses indicated MRI to be a significant predictor in detecting Grade group≥2 (GS≥3+4) in patients with PV>40 cc.

**Table 1. Patient characteristics**

| | Median (IQR), mode, or n (%) |
|---|---|
| Age | 71 (11) |
| Abnormal DRE findings | 204 (31) |
| Abnormal DRE with cancer | 150 (73.5) |
| PSA | 8.50 (9.2) |
| | 10† |
| f/t PSA 10 | 16 (10) |
| Free PSA | 1.26 (1.294) |
| PV | 38 (23) |
| PV≤40 | 372 (56.4) |
| PV>40 | 287 (43.6) |
| PSAD | 0.22 (0.27) |
| **MRI** | |
| Suspicious lesions | 418 (63.4) |
| Nonsuspicious lesions | 241 (36.6) |
| Suspicious lesions with cancer | 335 (80.1) |
| Nonsuspicious lesions with cancer | 69 (28.6) |
| Cancer | 404 (61.3) |
| **Gleason score** | |
| Grade 1 | 122 (30.2) |
| Grade 2 + 3 | 169 (41.8) |
| Grade ≥4 | 113 (28) |

IQR: interquartile range: DRE: digital rectal examination; PSA: prostate-specific antigen; PV: prostate volume; PSAD: prostate-specific antigen density; MRI: magnetic resonance imaging; f/t: free/total; †: mode; n (%): sample (percentage).

Patients had 1 or 2 targeted biopsies followed by 10–11-core standard biopsies. In cases of lesions that appeared smaller on MRI, 2 biopsy cores were used, whereas in cases of larger lesions on MRI or multiple lesions, a single core was used. This might have been insufficient in some cases. Before the procedure, the patients were administered 10 mL of 1% lignocaine. Biopsies were performed in the left decubitus position. Random biopsies were taken from the base, midline, and apex regions of the prostate gland. TRUS PV was calculated using the following formula: 0.52 x length x width x height.

MRI examinations were performed on 1.5- and 3-T MRI systems (Siemens Magnetom Avanto 1.5 Tesla and Magnetom *Trio 3 Tesla*, a *Tim* System, Siemens, Germany) using a multichannel phased-array coil and an endorectal coil. The imaging protocol included T1- and T2-weighted imaging, diffusion weighted imaging, and dynamic contrast imaging. Senior radiologists evaluated the MRI lesions. The lesions were categorized dichotomously, i.e., either as suspicious or nonsuspicious.

**Statistical analysis**

Statistical analyses were performed using Statistical Package for the Social Sciences Software v.16.0 (SPSS Inc.; Chicago, IL, USA). Patient characteristics are described using median, mode, and percentages for the numerical variables. The Chi-square and Mann–Whitney U tests were used for comparing the categorical variables and continuous variables, respectively. Univariate and multivariate logistic regression analysis was performed for predicting significant prostate cancer by the independent variables. The independent variables with p<0.25 were included in

**Table 2. Patient data among PV≤40 cc and PV>40 cc**

| | PV≤40 cc | PV>40 cc | p |
|---|---|---|---|
| Age | 71 | 70 | 0.228* |
| DRE | 122 (32.8) | 82 (28.6) | 0.245** |
| Abnormal DRE with cancer | 92 (75.4) | 58 (70.7) | |
| PSA | 7.35 (8.5) | 9.6 (8.6) | <0.001* |
| Free PSA | 1.01 (0.878) | 1.65 (1.417) | <0.001* |
| f/t PSA | 14 (10) | 19 (10) | <0.001* |
| PSAD | 0.27 (0.298) | 0.17 (0.180) | <0.001* |
| MRI | | | 0.005** |
| Suspicious lesions | 253 (68) | 165 (57.5) | |
| Suspicious lesions with cancer | 210 (83) | 125 (75.8) | |
| Nonsuspicious lesions | 119 (32) | 122 (42.5) | |
| Nonsuspicious lesions with cancer | 46 (38.7) | 23 (18.9) | |
| Cancer | 256 (68.8) | 148 (51.6) | <0.001** |
| Gleason score | | | 0.003** |
| Grade 1 | 82 (32) | 40 (27) | |
| Grade 2 + 3 | 117 (45.7) | 52 (35.1) | |
| Grade ≥4 | 57 (22.3) | 56 (37.8) | |

*Mann–Whitney test; **Chi-square test.

IQR: inter-quartile range; DRE: digital rectal examination; PSA: prostate-specific antigen; PV: prostate volume; MRI: magnetic resonance imaging; f/t: free/total; PSAD: prostate-specific antigen density; n (%): sample (percentage).

**Table 3. Gleason score distribution according to MRI findings between PV≤40 cc and PV>40 cc**

| | PV≤40 cc | | PV>40 cc | |
|---|---|---|---|---|
| | Grade 1 | Grade ≥2 | Grade 1 | Grade ≥2 |
| MRI-suspicious lesion with cancer | 60 (28.6) | 150 (71.4) | 27 (21.6) | 98 (78.4) |
| MRI nonsuspicious lesion with cancer | 22 (47.8) | 24 (52.2) | 13 (56.5) | 10 (43.5) |
| | p=0.005 | | p=0.001 | |

Chi-square test. MRI: magnetic resonance imaging; PV: prostate volume; GS: Gleason score.

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multivariate analysis. p<0.05 was considered significant in multivariate analysis.

**Table 4. Univariate logistic regression analysis**

| | OR | CI | p |
|---|---|---|---|
| Age | 1.043 | 0.99–1.098 | 0.112 |
| DRE | 1.731 | 0.796–3.763 | 0.166 |
| PSA | 1.026 | 1.004–1.048 | 0.020 |
| Free PSA | 1.259 | 0.98–1.619 | 0.072 |
| f/t PSA | 0.933 | 0.877–0.992 | 0.027 |
| PSAD | 3.988 | 1.202–13.227 | 0.024 |
| MRI | 4.719 | 1.866–11.935 | 0.001 |

DRE: digital rectal examination; PSA: prostate-specific antigen; f/t: free/total; MRI: magnetic resonance imaging; OR: odds ratio; CI: confidence interval; PSAD: prostate-specific antigen density.

**Table 5. Multivariate logistic regression analysis**

| | OR | CI | p |
|---|---|---|---|
| Age | 1.020 | 0.962–1.082 | 0.498 |
| DRE | 1.924 | 0.828–4.469 | 0.128 |
| PSA | 1.022 | 1.001–1.043 | 0.039 |
| MRI | 3.431 | 1.284–9.167 | 0.014 |

DRE: digital rectal examination; PSA: prostate-specific antigen; MRI: magnetic resonance imaging; OR: odds ratio; CI: confidence interval; p<0.05 significant.

**Ethical approval**

This study was approved by the local ethics committee of Showa University (3042-25/2/2020) and in complete agreement with the Declaration of Helsinki. All the patients provided their written informed consent.

## Results

We identified 659 patients who underwent prostate biopsy during the study period. Median age was 71 years, median PSA was 8.50 ng/mL, and median PV was 38 cc. Abnormal DRE findings were observed in 204 patients (31.0%), among whom 150 (73.5%) had carcinoma. Of the 659 patients in the entire cohort, 404 (61.3%) had prostate carcinoma. Of these, 282 (69.8%) had ISUP Grade ≥2 (GS ≥3+4), and 122 (30.2%) had Grade ≤1 (GS≤6). Within 418 patients with MRI-positive lesions, the cancer detection rate was 80.1% (335/418). On the other hand, of 241 MRI-negative lesions, 69 patients (28.6%) had prostate cancer (Table 1).

The prostate cancer detection rate was 68.8% (256/372) with PV≤40 cc and 51.6% (148/287) with PV>40 cc. Patients with PV≤40 cc (68.0% [174/256]) had Grade ≥2, and those with PV>40 cc (73.0% [108/148]) had Grade ≥2 (Table 2).

MRI-negative lesions with Grade ≤1 and Grade ≥2 in PV≤40 cc were 22 (47.8%) and 24 (52.2%), respectively, whereas MRI-

**Table 6. Literature on prostate cancer detection rates and/or aggressiveness in relation to prostate volume**

| Publication | Biopsy method | Prostate volume and detection rate | Prostate volume and Gleason score |
|---|---|---|---|
| Ung et al.[8] | TRUS | ≤45 cc-37.7%; | |
| | | >45 cc-29.6% | |
| Al-Khalil et al.[10] | TRUS | ≤35 cc-66%; | GS≥8 |
| | | ≥65 cc-40% | ≤35 cc-9.1%; |
| | | | ≥65 cc-3.7% |
| de Gorski et al.[11] | MRI fusion | | GS ≥7 or 6 with maximum cancer core length of ≥4 mm |
| | | | <30 cc-77%; |
| | | | 30–38.5 cc-61% |
| | | | 38.5–55 cc-47% |
| | | | 55–160 cc-34% |
| Diaz et al.[12] | MRI fusion | <40 cc-71.1%; | GS≥8 |
| | | ≥40 cc-47.8% | With increase in prostate volume (<40 cc to ≥115 cc) the percentage of patients with GS≥8 were within 20% 40%. |
| Mir et al.[16] | TRUS | | GS ≥7 |
| | | | <30 mL-52% |
| | | | >50 mL-26% |

TRUS: transrectal ultrasound scan; MRI: magnetic resonance imaging; GS: Gleason score.

negative lesions with Grade ≤1 and Grade ≥2 in PV>40 cc were 13 (56.5%) and 10 (43.5%), respectively (Table 3).

Among the PV>40 cc patient group, on univariate logistic regression between the independent variables and GS≥7, we found PSA (0.020), free/total (f/t) PSA (0.027), PSA density (PSAD) (0.024), and MRI (p=0.001) to be statistically significant (Table 4).

We excluded PSAD because of its high correlation with PSA (Spearman's correlation, r=0.923) and free PSA and f/t PSA because of low number of samples on multivariate logistic regression analysis for predicting detection of clinically significant prostate cancer within the PV>40 cc group. We found MRI (OR=3.46 and p=0.010) and PSA (OR=1.022 and p=0.039) to be statistically significant to predict Grade ≥2 for PV>40 cc controlling for age and DRE (Table 5).

## Discussion

Benign prostatic hyperplasia (BPH) and prostate cancer are commonly observed in elderly patients with urological diseases. According to published studies, prostate cancer detection rates[8,10-12,16,17] and GS[8,10,11,16] decrease or are within similar range[12] as PV increases (Table 6).

With the use of standard prostate biopsy ranging from 6 to 12 cores, Ung et al. found a decrease in the prostate cancer detection rate with an increase in prostate volume (≤45 cc, 37.7%; >45 cc, 29.6%), but they did not perform an analysis of Gleason score detection. [8] Mir et al.[16] used 6-core TRUS biopsy and found Gleason scores ≥7 to decrease with increases in PV (<30 mL, 52%; >50 mL, 26%). de Riese et al.[10] found both the prostate cancer detection rate and Gleason scores ≥8 to decrease with an increase in prostate volume using 12-core prostate biopsy (prostate cancer detection ≤35 cc, 66%; ≥65 cc, 40%; GS≥8 detection ≤35 cc, 9.1%; ≥65 cc, 3.7%).

In a study by de Gorski et al.[11] involving MRI targeted prostate biopsy with 2 or 3 targeted cores, the authors found significant prostate cancer (GS ≥7 or 6 with a maximum cancer core length of ≥4 mm) to decrease with an increase in prostate volume, but MRI targeted biopsy was better than the standard biopsy results of their study. For prostate volumes more than 40 cc, MRI fusion biopsy was found to be better than standard biopsy for detecting significant prostate cancer. Diaz et al.[12] found that prostate cancer detection decreased with prostate volume (<40 cc, 71.1%; ≥40 cc, 47.8%), and they found significant prostate cancer detection (GS ≥8) to be in a similar range of 20% to 40% with an increase in PV (<40 cc to ≥115 cc).

In this study, the detection rate of prostate cancer and ISUP Grade ≥2 (Gleason scores ≥3+4) by MRI-targeted and standard biopsies were 61.3%, and 69.8%, respectively. With the increase in PV, although prostate cancer detection decreased (68.8% for ≤40 cc and 51.6% for >40 cc), the detection rate was higher than those previously reported in literature.[8,10,13,14] In contrast, higher ISUP Grade scores were observed with larger PVs (detection rate of Grade ≥2: 68.0% [174/256] for PV≤40 cc and 73.0% [108/148] for PV>40 cc; Grade ≥4 (GS ≥8) detection rate: 22.3% [57/256] for PV≤40 cc and 37.8% [56/148] for PV>40 cc). With univariate and multivariate logistic regression, MRI was statistically significant for the detection of Grade ≥2 in patients with more than 40 cc of PV. This suggests that utilization of MRI leads to increase in detection of aggressive prostate cancer in higher PVs.

There are a number of potential explanations for why prostate cancer detection rates decrease with standard core biopsy as PV increases. Owing to the sampling error, the biopsy needle takes only a limited part of the prostate tissue. Thus, in a large prostate, it is difficult to remove the cancerous lesions because the biopsy needle does not cover other areas of the prostate.[8-12] According to Demura et al.[9] BPH around the tumor forms placental growth factor, which stops the vascular endothelial growth factor, thus impeding the blood vessel formation and cancerous growth. As stated by the study by Al-Khalil et al.[10] transitional zone's increase in size squeezes the peripheral zone (PZ), harming the PZ's epithelial cells, thereby reducing the prostate cancer detection rate. Finally, because of the rise in PSA levels, large volume prostate undergoes early prostate biopsy. Thus, there is a decrease in the cancer detection rate (ascertainment bias of PSA). Furthermore, tumor size is small owing to the early detection.[9,17]

In this study, GSs increased as PV increased. Interestingly, this finding is inconsistent with that reported by Al-Khalil et al.[10] and Mir et al.[16] In those studies, the aggressiveness of prostate cancer decreased as PV increased. Moreover, de Gorski et al.[11] reported that when comparing different PVs, the detection rate of clinically significant prostate cancers was higher with MRI-targeted biopsy than with standard biopsy; however, the aggressiveness of prostate cancer decreased as PV increased. Using MRI fusion biopsy, Diaz et al.[12] reported that the detection of high-risk tumors was within 20%–40% as PV increased.

Because we used MRI before the biopsy to diagnose prostate cancer, prostate lesions were identified, and the target biopsy was taken according to visual mapping, thereby reducing the risk of missing prostate tumors. Moreover, standard biopsy was performed to avoid the missing tumors in patients with MRI-negative lesions. This could explain the increased proportion of those with high GSs as PV increased, and the increased detection rate of prostate cancer compared with those previously reported. Our findings highlight the importance of combining MRI-targeted biopsy with standard biopsy.

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Our study has some limitations. First, this study was retrospective in design. Second, there may have been bias because of the small sample size and the data originating from a single institution. A larger scale multicenter study will be needed to confirm our results. Third, MRI cognitive biopsies were not performed by the same clinician, which could have affected the diagnostic accuracy. Fourth, we analyzed the MRI lesions using dichotomous variables (i.e., suspicious or nonsuspicious lesions); the prostate imaging reporting and data system score was not used. The PIRADS was proposed in 2012, and version 2 was announced in 2015. As the PIRADS was changed to Version 2 within the period of this study and the criteria for the PIRADS score differed between the periods of the study, we did not use the PIRADS score in our study.

Finally, we could not calculate the cancer yield per core for one- to two-core MRI cognitive biopsy and 10–11-core standard biopsy because MRI cognitive biopsy and standard biopsy were recorded at the same time without distinction in the biopsy specimens.

In conclusion, the detection of aggressiveness of prostate cancer increased as PV increased after the combined use of MRI cognitive biopsy and standard biopsy. However, the prostate cancer detection rate decreased with increase in PV, although our rates were higher than those reported in previous studies. Our findings highlight the utility of MRI for diagnosing prostate cancer with standard biopsy.

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**Ethics Committee Approval:** Ethics committee approval was received for this study from the ethics committee of Showa University (3042-25/2/2020).

**Informed Consent:** Written informed consent was obtained from patients who participated in this study.

**Peer-review:** Externally peer-reviewed.

**Author Contributions:** Concept – S.P.N., Y.O., T.N., M.N., T.S.; Design – S.P.N., Y.O., T.N., M.N., T.S., T.N., Y.M., J.M., K.O., T.U., T.I., R.K., M.O.; Supervision – Y.O., T.S., Y.M., J.M., K.O., T.U., T.I., R.K., M.O.; Data Collection and/or Processing – S.P.N., Y.M., J.M., K.O., T.U., T.I., R.K., M.O.; Analysis and/or Interpretation – S.P.N., Y.O., T.N., M.N., T.S., T.U., T.I., R.K., M.O.; Literature Search – S.P.N., T.U., T.I., R.K., M.O.; Writing Manuscript – S.P.N.; Critical Review – Y.O., T.S., Y.M., J.M., K.O., T.U., T.I., R.K., M.O.

**Acknowledgments:** We would like to thank Dr. Hideaki Shimoyama, Dr. Yuki Matsui and Dr. Aya Hiramatsu for their help in prostate biopsy.

**Conflict of Interest:** The authors have no conflicts of interest to declare.
**Financial Disclosure:** The authors declared that this study has received no financial support.

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