Optimal Number of Systematic Biopsy Cores used for Magnetic Resonance Imaging/Transrectal Ultrasound Fusion Targeted Biopsy

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Research Article

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Abstract

Background: In recent years, the effectiveness of magnetic resonance imaging (MRI)–ultrasound fusion targeted biopsy (MRF–TB) has been widely reported. In this study, we assessed the effect of reduction of the number of systematic biopsy (SB) cores on the cancer detection rate (CDR).

Methods: MRI was performed for patients with high prostate-specific antigen (PSA) levels, and the PI–RADS^{TM} (Prostate Imaging-Reporting and Data System version 2) was used to rate the lesions. Patient selection criteria were to satisfy both of the following conditions: PSA level between 4.0 ng/ml and 30.0 ng/ml Patients having one or more MRI lesions with a PI–RADS score of 3 or more. A total of 104 Japanese met this selection criterion. We have traditionally performed 14-core SB following the MRF–TB. In this study, the CDRs of 10-core SB methods, excluding biopsy results at the center of the base and mid-level on both sides, were compared with those of the conventional biopsy method.

Results: We compared CDRs of 14-core and 10-core SBs used in combination. The overall CDR was 55.8% for the former and 55.8% for the latter, indicating no significant difference (p = 1.00). In addition, the CDRs of csPCa were 51.9% for the former and 51.1% for the latter, indicating no significant difference (p = 0.317).

Conclusion: Even a 10-core SB used in combination with MRF-TB yields a good CDR. Reducing the number of biopsy cores leads to lower patient burden and lower testing costs.

Background

Prostate biopsy is essential for diagnosis, risk stratification, and treatment planning in prostate cancer (PCa) management. Only 13–33% of PCa cases are single lesions in the prostate. In most cases, it has been reported that cancer lesions occur in multiple forms[1]. Therefore, the usefulness of systematic biopsies (SBs) was reported to be high. However, it is associated with many limitations. For instance, SB under transrectal ultrasound (TRUS) may underdiagnose clinically significant prostate cancer (csPCa) and over-detect clinically insignificant PCa (cisPCa). The overdiagnosis and overtreatment of PCa have become serious clinical problems, requiring new methods to improve the accuracy of prostate biopsy.

In recent years, the utility of multiparametric magnetic resonance imaging (mpMRI) in csPCa detection has been demonstrated. In particular, the localization of cancer suspected by mpMRI is fused with the TRUS image using software, and targeted biopsy (TB) is performed based on the fusion image; this method is known as “MRI–TRUS fusion targeted biopsy (MRF–TB).” In a meta-analysis, it was reported that MRF–TB has a higher detection rate of csPCa as compared with TRUS biopsy and yields a higher csPCa detection rate with a lower number of biopsy samples [2-5].

Many medical institutions use TB and SB in combination, but the exact number of biopsy cores required remains unknown. The number of biopsy cores is determined at the discretion of the examiner based on the size and position of the lesion and the PI–RADS score. Our facility traditionally performed a 2-core TB

and a 14-core SB for each MRI lesion. However, the greater the number of biopsy cores used, the more the cost and time required for treatment increased [6]. Furthermore, despite the efforts for antimicrobial prevention in recent years, the incidence of infectious complications has continued to increase[7]. Infection is believed to be the root cause of prostatitis, which may be caused by an increase in the average number of core-needle biopsy samples taken during the biopsy procedure. Therefore, by reducing the number of biopsy cores, eventually it may be possible to reduce not only the patient's burden but also the complication events related to infection [6, 8].

In this study, we assessed the performance of retrospectively assigned PI–RADS score for the detection of PCa. Furthermore, we investigated whether it is possible to reduce the number of biopsy cores used in the traditional 14-core SB implemented at our facility.

Patients And Methods

Ethical approval for the collection and analysis of the data was obtained from the Ethics Committee of Tottori University Faculty of Medicine, Yonago, Japan (approval number 20A016). Since this study uses only medical data and other information, the details of the study were disclosed on the website in advance in accordance with the ethical guidelines set by the government. Informed consent is waived by ethics committee. (Tottori University Faculty of Medicine Ethics Review Committee)

Patient Selection

A 1.5- or 3-Tesla prostate MRI was performed for patients with high prostate-specific antigen (PSA) levels, and the PI–RADS^{TM} (Prostate Imaging–Reporting and Data System version 2) was used to rate the lesions. Patient selection criteria were to satisfy both of the following conditions: PSA level between 4.0 ng/ml and 30.0 ng/ml Patients having one or more MRI lesions with a PI–RADS score of 3 or more. All enrolled patients were SB naïve or had a history of one or more prior negative SBs. No patient had a history of prior MRF–TB.

Male patients who were under active surveillance (i.e., with a prior positive biopsy) and those who underwent MRI prior to the release of the PI–RADS^{TM} were excluded from the analysis. Those who underwent prostate procedures, including surgery (e.g., transurethral resection of the prostate) or radiation therapy, were also excluded. Furthermore, male patients with a region of interest of less than PI–RADS 3 who were administered oral 5α-reductase inhibitors were excluded, as well as those who were deemed unsuitable by the research manager. Finally, a cohort of 104 men was obtained.

For each patient, we recorded the PSA level at biopsy, the digital rectal examination findings, the prostatic volume, the overall PI–RADS and lesion scores, the total number of biopsy cores obtained, the presence of PCa, the Gleason score (GS), and tumor infiltration. In this study, having a GS $\geq$ 7 and/or a maximum cancer core length $\geq$ 5 mm was considered csPCa.

Magnetic Resonance Imaging

All male patients underwent a 1.5- or 3-Tesla prostate MRI. Prior to biopsy, all suspicious lesions found on prostate MRI were scored by a single abdominal radiologist with expertise in prostate imaging. If mpMRI was initially conducted and read by a third-party radiologist, a second reading was performed at our institution, and scoring was based on the PI–RADS guideline recommendations.

Prostate Biopsy

For all biopsy procedures, the TRINITY^{TM} system (Koelis, La Tronche, France) was used under spinal epidural anesthesia with the patient at the lithotripsy position. First, we visualized three-dimensional (3D) volume data from MRI and real-time TRUS images. An elastic image fusion was performed by semi-automatically contouring the MRI image of the entire prostate and suspected lesions onto 3D TRUS images. A biopsy with two biopsy cores targeted to each suspicious lesion identified on MRI was followed by a 14-core SB. If there were three or more MRI lesions, two MRF–TBs (an index lesion and the next suspected lesion) were performed. All biopsy cores were obtained by a single urologist.

Statistical Analysis

We traditionally performed 14-core SB: 6-core at base level (outside, center, inside on both sides), 6-core at mid-level (outside, center, inside on both sides), and 2-core at apex level (center on both sides) (Fig. 1). In this study, we compared how CDRs change when the number of SB used with MRFF–TB is reduced. That is, the CDR in 10-core SB excluding the biopsy results of the central of base and mid-level on both sides was evaluated. We used one-way analysis of variance for comparisons between three groups and the t-test for comparisons between two unpaired groups. Wilcoxon's signed rank test was applied when evaluating between two corresponding groups (e.g., the difference in the CDR between 14-core SB and 10-core SB). For each test result, a corresponding two-sided p value of <0.05 was considered statistically significant. All analyses were performed using SPSS software (IBM, Statistical Package for the Social Sciences ver 23, Chicago, IL USA).

Results

Table 1 shows the descriptive statistics of the study population. The study included 86 biopsy-naïve patients and 18 patients with a prior negative biopsy but with persistently increased PSA levels. The median patient age was 70 years (interquartile range [IQR] 66–74), the median PSA level was 8.62 ng/ml (IQR 6.5–12.6), and the median prostate volume was 44 ml (IQR 30.7–63.5). All patients underwent simultaneous MRF-TB and 14-core systematic transrectal biopsy. No patient had significant prostate biopsy-related complications (Clavien–Dindo grade I) that required hospital admission.

Patient Level

Figure 2 shows the overall CDR and the CDR of csPCa. The combination of SB and TB resulted in the highest CDR. Figure 3 shows the prostate CDR of 14-core and 10-core SB used in combination. The overall CDR was 55.8% for the former and 55.8% for the latter, indicating no significant difference (p =

1.00). In addition, the CDR of csPCa was 51.9% for the former and 51.1% for the latter, indicating no significant difference (p = 0.317).

Lesion Level

In patients with a PI–RADS score of 3, the CDR was 20.0%, the inflammation rate was 26.7%, and the prostatic intraepithelial neoplasia (PIN) rate was 3.3%. In those with a PI–RADS score of 4, the CDR was 56.7%, the inflammation rate was 13.4%, and the PIN rate was 4.5%. In those with a PI–RADS score of 5, the CDR was 77.3%, the inflammation rate was 0.0%, and the PIN rate was 0.0% (Table 2). The higher the PI–RADS score was, the higher the CDR. A PI–RADS score of 4/5 resulted in a significant difference in CDR compared to a PI–RADS score of 3 (Fig. 4). Although patients with a PI–RADS score of 3 had a low CDR, this group also consisted of patients with a high GS (Fig. 5).

Discussion

In this study, there was no significant difference between the CDR in the combination of 14-core SBs and the CDR using 10-core SBs. Based on this result, our facility has now reduced the number of biopsy cores in SB to 10 and conduct MRI–TRUS fusion biopsy. Further, the combination of SB and MRF–TB had the highest CDR in our study. This result was consistent with those of other reports. Likewise, Calio et al. found that combining SB with MRF–TB significantly reduced surgical GS upgrading compared to SB alone[9]. Additionally, patients with a PI–RADS score of 3 have a low CDR, but a certain number of PCa cases with high GS do exist, necessitating proper precaution. Therefore, in patients with MRI lesions having a PI–RADS score of 3 or higher, we should consider prostate biopsy under MRF–TB.

In recent years, many studies have shown the effectiveness of MRF–TB. It was demonstrated that the csPCa detection rate of men undergoing MRF–TB was higher than that of men undergoing TRUS biopsy [10]. Siddiqui et al. reported that in the prospective single-group cohort of 1,003 men, the number of high-risk cancers detected increased and the number of low-risk cancers detected decreased with the use of MRF–TB[11]. Baco et al. reported comparable detection rates of csPCa between the 2-core MRF-TB and the 12-core SB [12]. Ukimura et al. reported that the TRUS visibility of an MR-suspicious lesion facilitates image-guided biopsies, resulting in higher detection of csPCa [13]. Based on these recent studies, MRF–TB has the potential to be a gold standard diagnostic tool for men suspected of PCa. In addition, MRF–TB has made it possible to determine the GS and cancer localization of csPCa with high accuracy, making it easier to track the cancer progression of individual patients. The detailed information obtained by MRF–TB is expected to be applied to the accurate adaptation of active surveillance, surgical resection with improved curability, and nerve preservation, with further application in focal therapy. TRINITYTM records the 3D position information of the tissue collected by the biopsy and enables 3D display, making it easier to visualize where the cancer tissue is in the prostate. At our institution, in cases where robot-assisted laparoscopic radical prostatectomy (RALP) is to be performed after MRF–TB, it is used to evaluate the localization of cancer in nerve-preserving surgical selection. Moreover, we tried to visually improve the surgical precision by displaying a 3D model on the da Vinci Surgical SystemTM during RALP.

Prostate biopsy is essential for the diagnosis, risk stratification, and treatment planning in PCa. However, the overdiagnosis and overtreatment of cisPCa pose serious clinical and economic problems. For instance, the medical costs associated with prostate biopsy include the costs of testing and radical treatment for cisPCa, and the associated medical costs of erectile dysfunction and dysuria are mainly attributed to treatment. MRF–TB has the potential to resolve these problems. MRF–TB can detect csPCa with a lower number of biopsy cores. A lower number of biopsy cores not only reduces patient discomfort but also minimizes the risk of complications associated with treatment, such as infection. As Onik et al. reported that the localization of csPCa can be diagnosed using mpMRI with a 3-mm slice thickness, it is expected that the use of mpMRI is efficient [14]. If there is no obvious lesion noted on mpMRI, clinical follow-up without prostate biopsy can reduce the problem of overdiagnosis and overtreatment [15]. mpMRI improves the cost-effectiveness of prostate biopsy; however, it should be noted that false negatives can occur in about 20% of cases [16, 17]. Other reports suggested that only 17.4% of cribriform tumors in pure form were visible on MRI [18]. Therefore, in the current imaging diagnostic technology, it is possible that merely performing MRF–TB on MRI lesions may overlook csPCa. Thus, the combined use of SB is considered essential. In fact, it is said that the false-negative rates of csPCa for targeted fusion prostate biopsy were 16.2% and 39.7% for patients with a PI–RADS score of 3 or greater and those with a PI–RADS score of 4 or greater, respectively [19].

Although the effectiveness of MRF–TB has been reported previously, there is a report stating that there is a learning curve in establishing the procedure. Meng et al. reported that the csPCa detection rate increased by 26% (50 to 76%, p=0.025) with time in men with a PI–RADS 4/5 ROI. It is necessary to acquire a certain number of cases in order to achieve stability in performing the procedure. Furthermore, there is no clear standard for the number of MRF–TB cores to be collected for each MRI lesion. The number of TB cores is determined based on the judgment of the examiner according to the size and location of the MRI lesion. According to Porpiglia et al., taking two cores at the center of the index lesion regardless of the diameter may provide more accurate cancer detection and optimize the chances of finding the highest Gleason pattern [20]. On the other hand, there are opinions skeptical of the use of 2-core TB, and Dimitroulis et al. reported that the diagnostic utility does not change despite the use of one or two cores for the target lesion [21].

This study confirmed the effectiveness of MRF–TB; however, there are some limitations. First, not all patients undergoing MRF–TB were diagnosed with PCa in this study. Furthermore, since not all patients diagnosed with PCa selected to undergo curative prostatectomy, comparison between the biopsy specimen and the whole prostate specimen was incomplete. For these reasons, it was not possible to reliably measure the standard parameters such as actual sensitivity, specificity, diagnostic accuracy, etc. This aspect is considered a major limitation of studies focusing on MRF–TB. Second, improvements in the PI–RADSTM and the collaboration among radiologists, pathologists, and urologists are important factors that have been previously shown to contribute to the enhancement of cancer detection over time. However, it is difficult to quantify these factors [22, 23]. Third, in this study, the comparison is based on the assumption that the number of biopsy cores has been reduced. Therefore, we did not compare actual biopsy results. Forth, when an examiner is performing SB, he/she already has prior knowledge of

suspicious lesions based on either US images or fusion MR images. Therefore, there was a possibility that bias occurred during random sampling.

Despite the limitations, our study has several strengths. First, at our facility, for all male patients who presented with a high PSA value, the possibility of selective bias can be reduced to a certain extent because we performed MRI prior to biopsy when medically possible. Furthermore, since the prostate biopsy was performed by a single examiner, we believe that stability of the procedure can be achieved.

Conclusions

The 2-core MRF–TB had the same CDR as the 14-core SB. The combination of MRF–TB and SB resulted in the highest CDR. However, there was no significant difference in the CDR when the number of SB cores to be used in combination was 14 and 10. Furthermore, it is still a matter of discussion as to whether these 10 SB cores can be considered as optimal biopsy cores. We aim to conduct further investigation in the future with a larger the number of cases.

Abbreviations

CDR: cancer detection rate, cisPCa: clinically insignificant PCa, csPCa: clinically significant PCa, MRI: magnetic resonance imaging, MRF-TB: MRI-TRUS fusion targeted biopsy, PIN: Prostatic intraepithelial neoplasia, PIRADS^{TM}: Prostate Imaging-Reporting and Data System version 2, PSA: prostate specific antigen, PCa: prostate cancer, RALP: Robot-assisted laparoscopic radical prostatectomy, SB: systematic biopsy, TRUS: transrectal ultrasound, TB: targeted biopsy, US: ultrasound

Declarations

Ethics approval and consent to participate

This study was conducted at the Division of Urology, Tottori University Hospital, Yonago, Japan. The study was approved by the Tottori University Ethics Committee (no. 20A016). Informed consent is waived by ethics committee (Tottori University Faculty of Medicine Ethics Review Committee).

Consent for publication: Not applicable

Availability of data and materials: The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

Competing interests: There is no competing interest for this study.

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Authors’ contributions

ST: Project development, data analysis, manuscript writing;

RS and RN: Projectdevelopment, data collection, data analysis;

YK, TY, HI and SM: data analysis;

KH, MH and AT: Project development, Manuscript Revision;

MH: Manuscript Revision.

All authors reviewed and approved the manuscript.

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Tables

Due to technical limitations, table 1 & 2 is only available as a download in the Supplemental Files section.

Figures

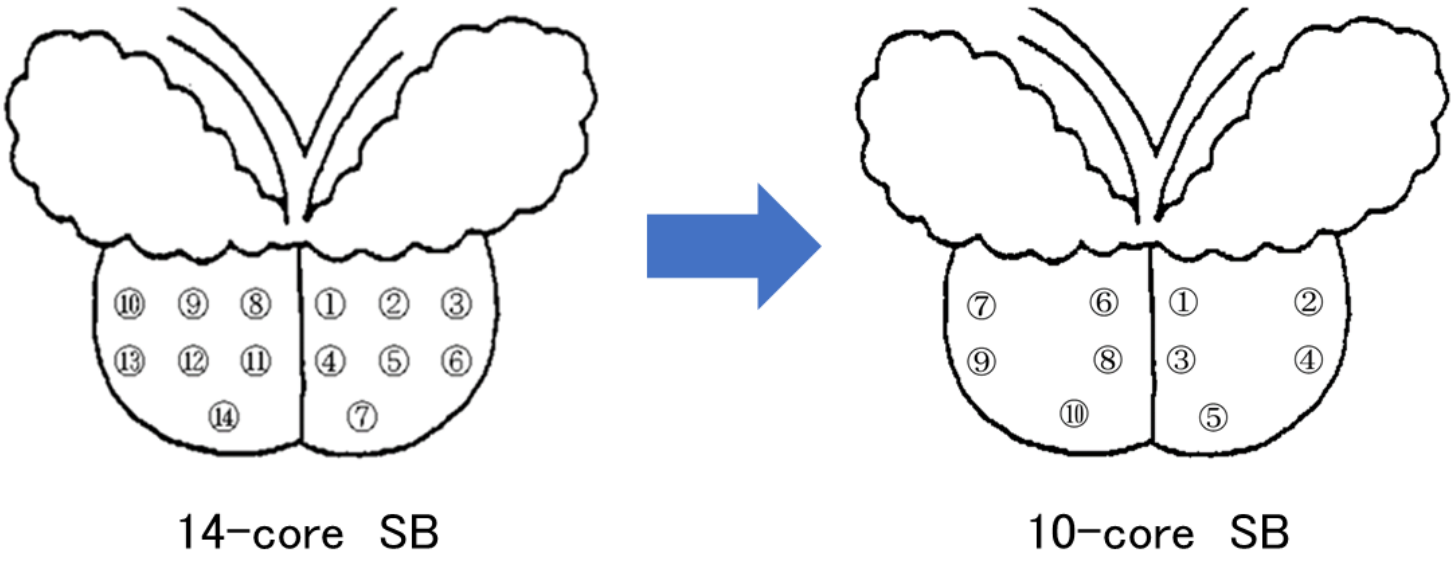


Figure 1

Prostate biopsy site. 14-core SB: 6-core at base level (outside, center, inside on both sides), 6-core at mid-level (outside, center, inside on both sides), and 2-core at apex level (center on both sides). 10-core SB: 4-core at base level (outside, inside on both sides), 4-core at mid-level (outside, inside on both sides), and 2-core at apex level (center on both sides).

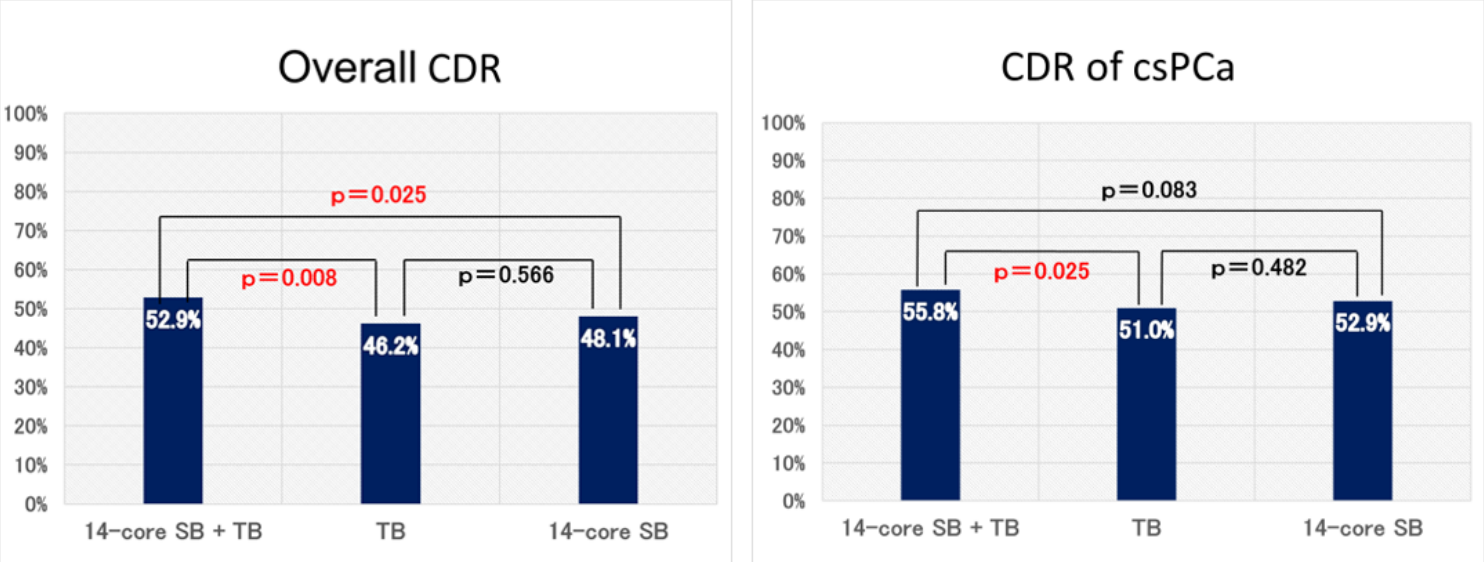
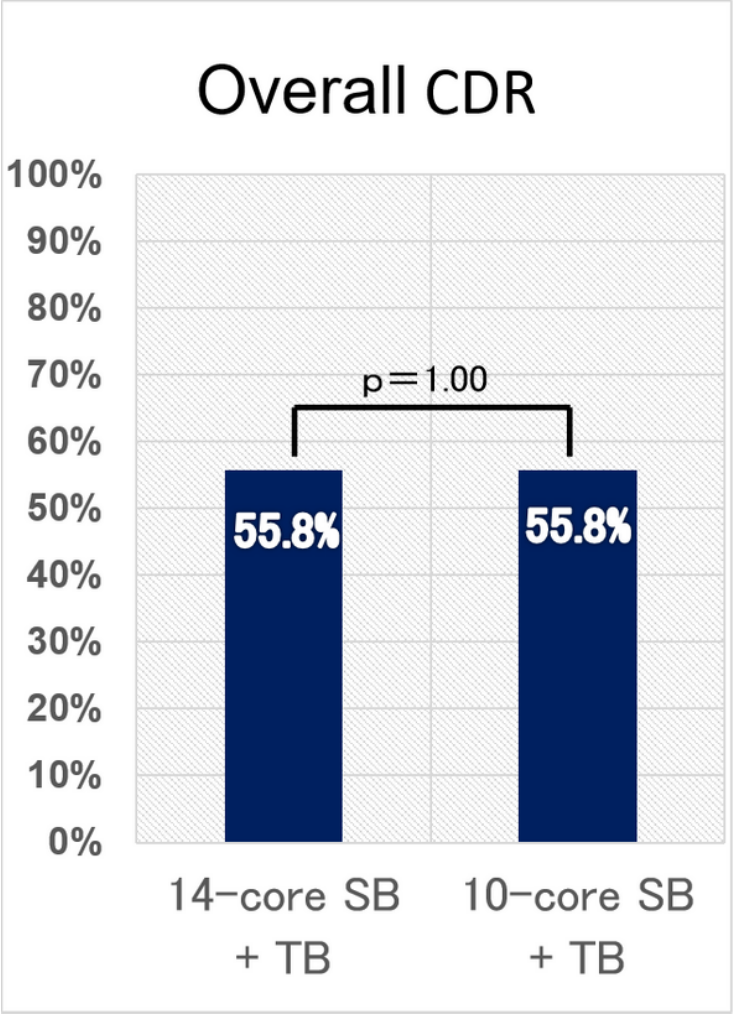


Figure 2

The overall CDR and the CDR of csPCa. The CDR was compared for the combination of SB and TB, and for TB alone and SB alone. We compared the overall CDR and the CDR of csPCa, respectively. The results showed that the combination of SB and TB had the highest CDR, but there was no significant difference in CDR between TB and the 14-core SB.



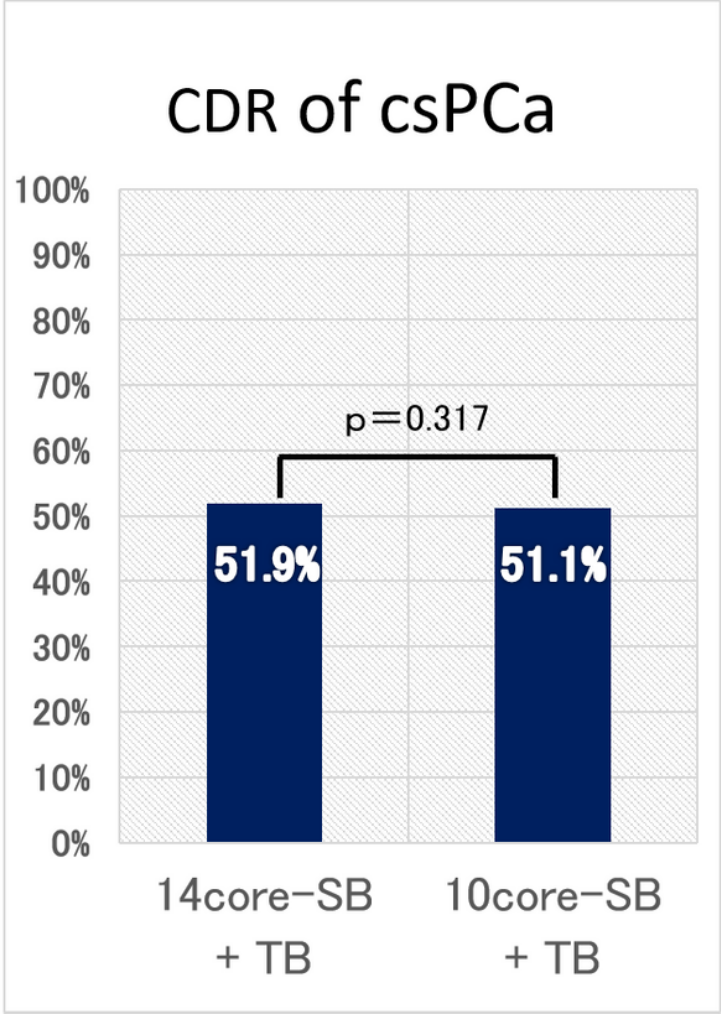


Figure 3

The CDR by number of SB. A combination of 14-core SB and TB and 10-core SB and TB were compared with CDR. No significant differences were found in the overall CDR and CDR of csPCa.

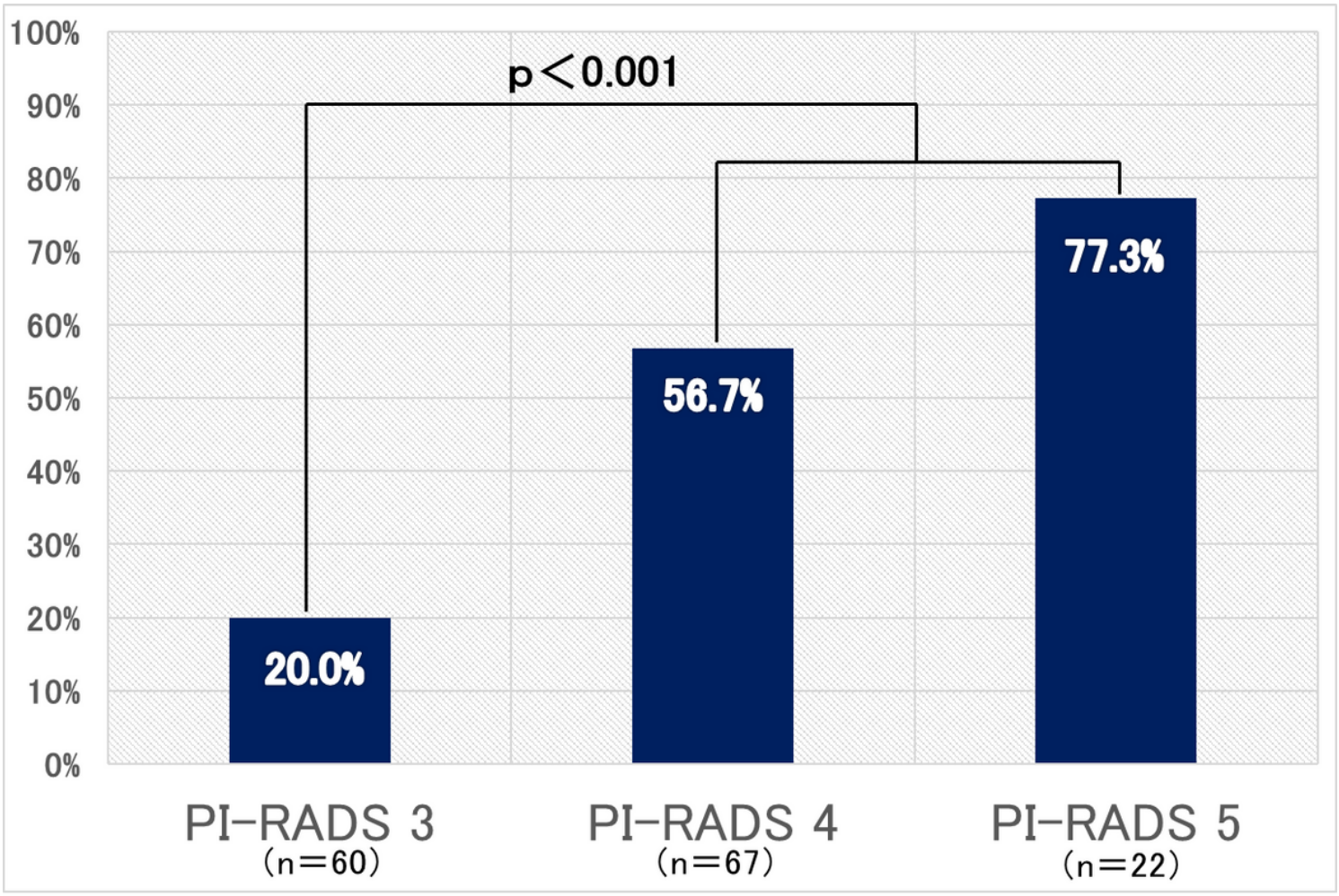


Figure 4

The CDR by PI-RADS score. The CDR for PI-RADS score 3 was 20.0%, the CDR for score 4 was 56.7%, and the CDR for score 5 was 77.3%. Comparing score 3 and 4/5, the CDR was significantly higher in the latter group (p□0.001).

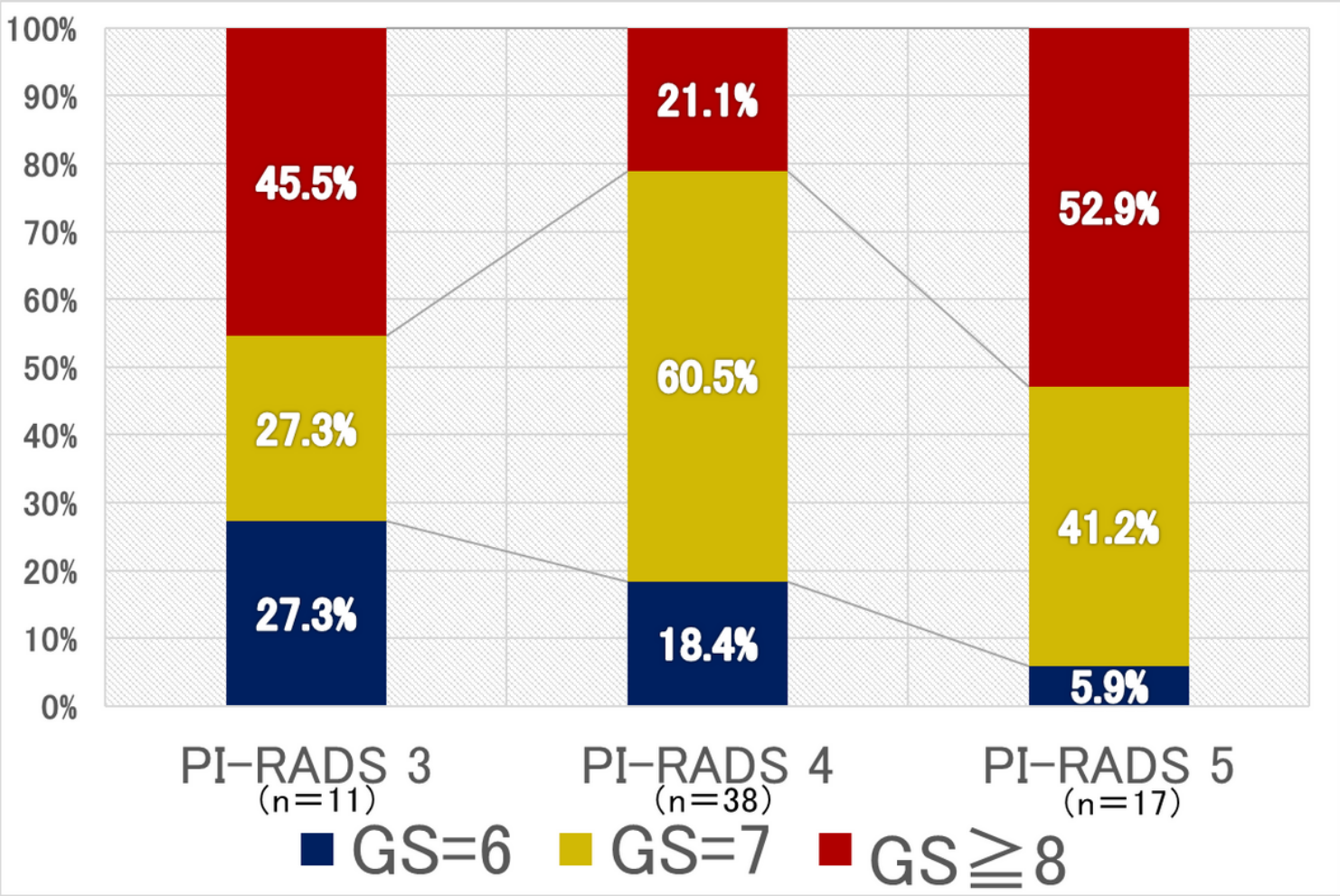


Figure 5

GS assessment by PI-RADS score in prostate cancer-positive patients. PI-RADS score of 5 resulted in a high percentage of GS≧8. On the other hand, even with PI-RADS of 3, a certain percentage had GS≧8 findings.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table1.jpg
- Table2.jpg
- date.xlsx