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Prostate Cancer

Improved Accuracy in Predicting the Presence of Gleason Pattern 4/5 Prostate Cancer by Three-Dimensional 26-Core Systematic Biopsy

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Abstract

Objectives: To evaluate whether three-dimensional 26-core (3D26) prostate biopsy improves the accuracy in predicting the presence of Gleason pattern 4/5 cancer compared with extended transrectal 12-core (TR12) or transperineal 14-core (TP14) biopsy schemes.

Methods: We studied 143 consecutive men in whom prostate cancer was diagnosed by the 3D26 biopsy and who underwent radical prostatectomy (RP) without neoadjuvant treatment. All histologic grading was reevaluated by a single pathologist according to the 2005 International Society of Urological Pathology Consensus Conference on Gleason Grading. Cancer grade was categorized into high grade (Gleason pattern 4/5 cancer present) and non-high grade (absent) in both biopsy and RP specimens. Since TR12 and TP14 biopsy schemes represent subsets of the 3D26 biopsy, we could compare these schemes directly in an identical patient cohort.

Results: There was a grade agreement between 3D26 biopsy and RP in 132 (92.3%) cancers. Grade concordance between biopsy and RP was significantly better in 3D26 biopsy than in TR12 (83.5%, $p = 0.025$) biopsy. Risk of underestimation of cancer grade by 3D26 biopsy (26.5%) was significantly lower than that by TP14 (51.4%, $p = 0.034$). Grade concordance between 3D26 biopsy and RP was not according to clinical variables including prostate volume, clinical stage, prostate-specific antigen (PSA), and PSA density.

Conclusions: We demonstrated that the 3D26 biopsy can accurately predict the presence of Gleason pattern 4/5 cancer on RP specimens with a high concordance rate of 92.3%, a value significantly higher than that between extended TR12 biopsy and RP specimens.

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1. Introduction

Owing to the widespread use of prostate-specific antigen (PSA) screening, the majority of currently diagnosed prostate cancers are clinically organ-confined [1]. In light of a panel of treatment options including radical prostatectomy (RP), external beam radiotherapy, brachytherapy, androgen-deprivation therapy and active surveillance [2,3], precise risk evaluation is pivotal for proper treatment decision-making. Accurate cancer grading is indispensable for the representative risk stratifications such as the Partin table and the D'Amico's risk grouping in which Gleason score (GS) plays a major role as a prognostic indicator [4,5]. Pan et al [6] reported that the presence of Gleason pattern 4/5 cancer, even as the tertiary pattern, has an adverse impact on oncologic outcome in patients who underwent RP. Therefore presence of Gleason pattern 4/5 cancer should be known before treatment decision-making.

GS determined by the conventional sextant biopsy [7] has been reported to poorly correlate to the final GS on prostatectomy specimens [8,9], suggesting that sextant biopsy is inadequate for assessing the final pathologic feature accurately. In the literature review, extended biopsy protocols have been reported to improve pretreatment prediction of oncologic outcome, including final GS, extraprostatic extension, lymph node metastasis or biochemical recurrence [10-17].

Using a three-dimensional 26-core (3D26) prostate biopsy, we have demonstrated that the three-dimensional combination of transperineal and transrectal approaches outperforms either single transperineal or transrectal approach with regard to cancer detection [18,19].

In the current study, we investigated whether the accuracy in predicting the presence of Gleason pattern 4/5 cancer is improved when the prostate gland is extensively sampled by the 3D26 prostate biopsy.

2. Materials and methods

We evaluated 143 consecutive patients with clinically organ-confined (cT1/2N0M0) prostate cancer diagnosed by the 3D26 biopsy and treated with RP without neoadjuvant therapy between 2002 and 2006 at our institutions. The 3D26 prostate biopsy, a combination of transperineal 14-core (TP14) and transrectal 12-core (TR12) biopsies, is illustrated in Fig. 1. After obtaining informed consent, 3D26 biopsy was performed as described previously [19]. Briefly, under spinal or general anesthesia, transperineal 14 cores (12 cores from the apical peripheral zone and 2 from the transition zone), followed by transrectal 12 cores (conventional sextant cores and additional 6 from the far lateral peripheral zone) were obtained systematically under transrectal ultrasound guidance.

Each biopsy core was separately labeled to analyze the location of cancer positive cores. All prostatectomy specimens were submitted for whole-mount processing with transverse 3- to 5-mm slices cut perpendicular to the rectal surface. To avoid the potential bias from different pathologists, all

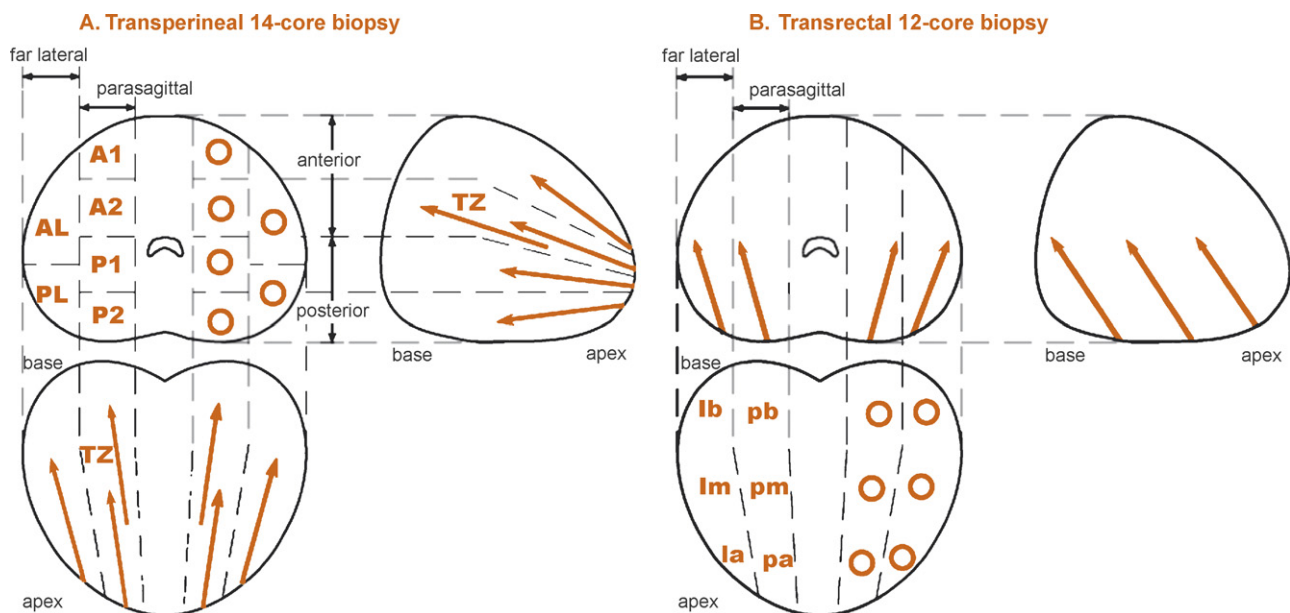


Fig. 1 – Transverse, sagittal, and coronal projections of the three-dimensional 26-core biopsy scheme, a combination of transperineal 14-core and transrectal 12-core biopsies. Transperineal 14-core biopsy comprising 12 cores from peripheral zone and 2 from the transition zone using the fan technique. Transrectal 12-core biopsy comprising conventional 6 sextant cores and 6 cores taken from the far-lateral peripheral zone.

Table 1 – Baseline characteristics of the 143 patients

Variables	
Age (yr)	67 (63–71)
PSA (ng/ml)	7.0 (5.4–10)
Prostate volume* (ml)	29 (22–38)
Clinical stage	
T1cNOMO	107
T2 NOMO	36
No. of positive biopsy core	4 (2–8)
PSA = prostate-specific antigen. Values are expressed as median (interquartile range) except for clinical stage, whose values express the number of patients. * Determined by transrectal ultrasound.	

histologic grading of biopsies and RP specimens were reevaluated by a single pathologist, who was blinded to the cases, according to the 2005 International Society of Urological Pathology Consensus Conference on Gleason Grading [20].

Cancer grade was categorized into high grade if Gleason pattern 4/5 cancer was present and non-high grade if Gleason pattern 4/5 cancer was absent in both biopsy and RP specimens. Therefore, grade concordance in the current study means that biopsy can accurately predict the presence or absence of Gleason pattern 4/5 cancer in RP specimen. Underestimation means that biopsy grade is lower than RP grade, and overestimation means that biopsy grade is higher than RP grade.

In the current study, any subset of the 3D26 biopsy could be compared directly with each other in an identical patient cohort. Cancer detection rate of the 3D26 biopsy was set at 100%.

Rate of grade concordance between 3D26 biopsy and RP specimen was compared among patient subgroups according to clinical variables including prostate volume, clinical stage, PSA, and PSA density. The quartile values of the entire study cohort were used as the cutoff points of prostate volume and PSA density.

Statistical analyses were performed with the use of JMP, version 6.0.2 (SAS Institute Inc, Cary, NC, USA). Values were expressed as median (interquartile range) in continuous variables. The Cochran-Armitage test was used to test for trends. Chi-square test or Fisher exact test was used for

comparison between categorical variables. A *p*-value less than 0.05 was considered to be statistically significant.

3. Results

The baseline characteristics of the 143 patients are listed in Table 1.

Cancer detection rate, grade concordance rate and risk of underestimation of the 3D26 biopsy are shown in Table 2. The rate of high-grade cancers in biopsy was 76.2% (109 of 143) and that in RP was 81.1% (116 of 143). Rate of grade concordance between 3D26 biopsy and RP was 92.3% (132 of 143). Of 11 grade discordance cases 9 were underestimation, and the remaining 2 were overestimation. Risk of underestimation was 26.4% (9 of 34) and that of overestimation was only 1.8% (2 of 109). Analysis of TP14 and TR12 biopsies, subsets of the 3D26 biopsy, are also shown in Table 2. Grade concordance rate between 3D26 biopsy and RP was significantly better than that between TR12 biopsy and RP ($p = 0.025$). The difference between grade concordance rate of 3D26 biopsy and TP14 biopsy did not reach statistical significance ($p = 0.058$). Risk of underestimation of cancer grade by 3D26 biopsy (26.5%) was significantly lower than that by TP14 (51.4%, $p = 0.034$). The difference between risk of underestimation of 3D26 biopsy and TR12 biopsy did not reach statistical significance (47.6%, $p = 0.059$).

Table 3 shows rates of grade concordance between 3D26 biopsy and RP specimen in patient subgroups according to clinical variables. The grading accuracy of the 3D26 biopsy did not vary significantly according to these variables.

4. Discussion

In the current study, we demonstrated that the 3D26 biopsy can accurately predict presence of Gleason

Table 2 – Cancer detectability and grading accuracy according to the biopsy schemes

Biopsy schemes	% cancer detection	Biopsy grade	RP grade		% grade concordance	<i>p</i> value* (vs. 3D26)	% underestimation	<i>p</i> value* (vs. 3D26)
			High	Non-high				
3D26	100 (143/143)	High	107	2	92.3 (132/143)		26 (9/34)	–
		Non-high	9	25				
TP14	88 (127/143)	High	91	1	85.0 (108/127)	0.058	51 (18/35)	0.034
		Non-high	18	17				
TR12	88 (127/143)	High	84	1	83.5 (106/127)	0.025	48 (20/42)	0.059
		Non-high	20	22				

RP = radical prostatectomy; 3D26 = three-dimensional 26-core biopsy; TP14 = transperineal 14-core biopsy; TR12 = transrectal 12-core biopsy.

* Chi-square test.

Table 3 – Grade concordance between 3D26 biopsy and RP specimens in patient subgroups according to clinical variables

Variables	Categories	% grade concordance	p value for trend [*]
Prostate volume ^{**} [ml]	11.8–22.6	86.5 (32/37)	0.71
	23.0–29.1	100 (35/35)	
	29.2–37.8	91.7 (33/36)	
	37.9–100	91.4 (32/35)	
Clinical stage	T1c	92.5 (99/107)	0.87
	T2	91.7 (33/36)	
PSA (ng/ml)	≤4	83.3 (10/12)	0.73
	4.01–10	93.8 (90/96)	
	>10	91.4 (32/35)	
PSA density	0.08–0.18	84.6 (33/39)	0.37
	0.19–0.25	94.1 (32/34)	
	0.26–0.36	91.1 (31/34)	
	0.37–1.30	91.7 (33/36)	

RP = radical prostatectomy; 3D26 = three-dimensional 26-core biopsy; PSA = prostate-specific antigen.
^{*} Cochran-Armitage test for trend.
^{**} Determined by transrectal ultrasound.

pattern 4/5 cancer on RP specimens with a high concordance rate of 92.3%. The current study was designed to allow us to compare the subsets of 3D26, TP14 and TR12 biopsy schemes directly in the same patient population. Accuracy in predicting the presence of Gleason pattern 4/5 cancer was significantly improved by the 3D26 biopsy over TR12 biopsy. To our knowledge, this is the first report demonstrating a biopsy protocol with better grading accuracy than that of extended TR12 biopsy [21].

Extended biopsy protocols have been reported to improve both cancer detectability and grading accuracy compared with the conventional sextant biopsy [10–12,16]. However, substantial grade discordance rates of 37%, 24%, and 32% were accompanied with transrectal extended biopsy schemes with 10 cores [11], with a median of 12 cores [10] and a mean of 12.4 cores [16], respectively. In the current study, grade discordance rates of TP14 and TR12 biopsy schemes were 15% and 17%, respectively. Taken together, these results indicate that as far as single transperineal or transrectal approach was taken, even extended 10- to 14-core biopsies have substantial grading error around 15–37%.

As we have reported [18,19], a three-dimensional combination of transrectal and transperineal samplings significantly improve cancer detectability compared with extensive sampling up to 14 cores through a perineal or a rectal route. In the current study we confirmed the superiority of the 3D26 biopsy to TR12 biopsy with regard to grading accuracy. Our result is supported by a recent interesting ex vivo experiment reported by Epstein et al [22]. They showed that when RP specimens were biopsied ex vivo, sufficient prediction of cancer volume and grade can be obtained with

approximately 22 cores. On the basis of the current results, it is dangerous to evaluate risk by limited grade information. Grade information provided by the extended transperineal or transrectal biopsy with a number of sampling sites up to 14 still harbors substantial uncertainty of cancer grading.

In light of the biologic aggressiveness of high-grade prostate cancer, grade underestimation is potentially more dangerous for patients submitted to watchful waiting rather than for those undergoing radical prostatectomy. Thus, an extensive sampling such as the 3D26 biopsy would be beneficial, particularly for those submitted to watchful waiting.

It is possible that grade concordance would differ according to clinical variables. Profound influence of prostate volume on either cancer detectability or grading accuracy by biopsy has been demonstrated recently. Walz et al [23] found that PSA density and transition zone volume are the most significant predictors of prostate cancer on saturation biopsy. Kulkarni et al [24] demonstrated that grade underestimation by biopsy is more likely in larger prostate than in smaller prostate when using transrectal sextant biopsy. In our cohort, however, grade concordance between 3D26 biopsy and RP did not differ according to prostate volume. The discrepancy between Kulkarni's study and ours can be explained by several reasons. First, median prostate volume differed between Kulkarni's cohort and ours (40.8 ml vs. 29 ml). Second, the diagnostic power of conventional sextant biopsy is limited compared with that of the 3D26 biopsy [18,19]. Further investigation is needed to confirm the association between prostate volume and grade migration. Grade concordance did not differ according to

clinical stage, PSA, or PSA density. Taken together, we could not identify a subgroup of patients to be submitted to a less extensive biopsy protocol rather than the 3D26 biopsy, according to prebiopsy clinical variables in our cohort.

Our previous analyses on 3D26 biopsy revealed that, as far as cancer detection rate is concerned, three-dimensional 14-core biopsy (a combination of transperineal 6-core and transrectal 8-core biopsies) can detect more than 95% of cancers in the initial biopsy setting [18], and three-dimensional 16-core biopsy (a combination of transperineal 8-core and transrectal 8-core biopsies) can detect all the cancers in the repeat biopsy setting [19]. Although the current cohort was small, we tried to examine whether the number of sampling cores can be decreased while keeping sufficient cancer detectability and grade accuracy. The rates of grade concordance were evaluated between biopsy schemes that yield the highest cancer detection rate at given number of cores and RP specimens. We found that a combination of transperineal 6-core and transrectal 8-core biopsies can achieve both cancer detectability and grade accuracy greater than the 95% of the 3D26 biopsy. Further investigation is warranted to confirm this preliminary finding, which suggests an optimal biopsy scheme that strikes diagnostic value and number of sampling cores.

Pathologic evaluation in the current study is based on the 2005 International Society of Urological Pathology Consensus Conference on Gleason Grading of Prostatic Carcinoma [20,25]. According to this consensus, fused glands, ill-defined glands with poorly formed glandular lumina, and most of the cribriforms are categorized as Gleason pattern 4. Therefore a part of Gleason pattern 3 components in the former consensus is categorized as Gleason pattern 4 in the new 2005 consensus. Accordingly, the rates of high-grade cancer in both biopsy and RP specimens in the current study might be higher than those with previous grading.

One of the limitations of the present study is the relatively small cohort size. Our results should be confirmed in a larger study cohort. Vis et al [26] recently demonstrated that the amount of Gleason pattern 4/5 cancer in both biopsy and RP specimens is an independent and stronger prognostic factor for biochemical and clinical relapse after RP than the Gleason score. In the current study, we analyzed our cohort only from the standpoint of the presence of Gleason pattern 4/5 cancer. Given the significant improvement of grading accuracy, we can expect that extensive sampling would also improve the estimation of the amount of Gleason pattern 4/5

cancer preoperatively. In the current cohort, the 3D26 biopsy was performed under general or spinal anesthesia. To perform three-dimensional biopsy in an outpatient setting and to circumvent risks associated with general or spinal anesthesia, we found local anesthesia such as periprostatic nerve block [27] to be an attractive choice.

5. Conclusions

We demonstrated that the 3D26 biopsy can accurately predict the presence of Gleason pattern 4/5 cancer in RP specimens with a high concordance rate of 92.3%, a value significantly higher than those for extended TR12 biopsy and RP specimens. Grade concordance between 3D26 biopsy and RP specimens did not differ according to prebiopsy clinical variables including prostate volume, clinical stage, PSA, and PSA density.

Conflicts of interest

The authors have nothing to disclose.

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Editorial Comment on: Improved Accuracy in Predicting the Presence of Gleason Pattern 4/5 Prostate Cancer by Three-Dimensional 26-Core Systematic Biopsy

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During the last decade a considerable number of modifications have been made to improve the technique of prostate biopsy.

The authors of this report demonstrated a combination of transperineal 14-core (TP14) and transrectal 12-core (TR12) biopsy technique called three-dimensional 26 prostate biopsy schema (3D26). With the 3D26 biopsy, they found a significantly higher concordance to predict Gleason pattern 4/5 compared to TR12 biopsy alone

($p = 0.025$), but not to TP14 biopsy ($p = 0.058$). Furthermore the 3D26 biopsy schema showed a significantly lower underestimation of Gleason pattern 4/5 compared to TP14 ($p = 0.034$) but not to TR12 ($p = 0.059$) [1]. The 3D26 technique was performed under spinal or general anaesthesia. The vast majority of urologists perform prostate biopsies in an outpatient setting. Under local anaesthesia (eg, periprostatic block) extended transrectal biopsies can be performed safely and cancer detection rates are generally high [2,3]. Jones et al showed at initial biopsy that a saturation biopsy technique does not improve cancer detection (44.6%) as compared to a 10-core biopsy technique (51.7%; $p > 0.9$) [2]. The key to higher prostate cancer (PCa) detection rates when using the Vienna nomogram is the variation in the number of cores according to prostate volume and age [3]. Prostate volume is a known risk factor

for missing PCa on prostate biopsy because of sampling errors from larger prostates [4]. In the present study by Numao et al prostate volume did not influence the biopsy results [1].

Therefore, biopsy techniques requiring spinal or general anaesthesia complicate the role of prostate biopsy in detecting PCa. Even if new biopsy techniques show more precisely high Gleason grades in prostate biopsy and percentage of Gleason grade 4/5 underestimation is improved, it has only a limited role in most patient management protocols because radical prostatectomy is performed in the vast majority of men and thus final histopathologic results are available. However, in patients undergoing active surveillance, prostate biopsy should be as accurate as possible to define predictors of disease as high Gleason grade. Thus, the 3D26 biopsy schema should be limited to this selected patient group. However, if for each prostate biopsy during active surveillance spinal or general anaesthesia is needed, active surveillance loses to minimally invasive treatment.

Currently the aim of prostate biopsy is not always to find as many PCa cases as possible but to detect significant PCa. Gleason pattern remains an important marker for defining significant PCa, thus arguing for a better estimation on prostate biopsy. We should continue to modify our biopsy

techniques to identify significant PCa more accurately based on prostate volume, patient age, and patient health. These biopsy strategies should attempt to identify cancers in those patients in whom definitive treatment would be most beneficial, thus adequate information on Gleason score is of major importance.

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