Original Article

Prostate cancer detection rate of 16-core TRUS-guided prostate biopsy in Rajavithi Hospital

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Keywords:
Biopsy, prostate, prostate cancer, 16-cores, transrectal ultrasound prostate biopsy

Abstract

Objective: Prostate cancer is one of the most prevalent malignancies in the male Thai population. Early detection of prostate cancer increases the chance of organ confined and potentially curable disease. To date, the grayscale transrectal ultrasound (TRUS) is a common modality for prostate diagnosis and the extended 12-core biopsy is considered adequate for cancer detection. With the aim of increasing the peripheral zone of prostate biopsy sampling, Rajavithi Hospital performed a 16-core TRUS-guided prostate biopsy instead. The objectives of this study are to evaluate the rate of prostate cancer detection and to review the factors associated in 16-core TRUS-guided prostate biopsy in Rajavithi Hospital.

Materials and Methods: TRUS-guided prostate biopsy was performed in 243 patients between October 2019 and September 2021 in Rajavithi Hospital. Using retrospective methods, 200 patients were included in this study. The factors associated with prostate cancer detection were analyzed by independent sample t-test, Mann-Whitney U test, Chi-square test and Fisher's exact test, and Multiple logistic regression methods.

Results: The average age of TRUS-guided prostate biopsy patient in Rajavithi Hospital was 69.28 ± 8.41 years. Prostate cancer was detected in 70 patients (35.0%). Factors significantly associated with a positive diagnosis were: abnormal digital rectal exam (DRE) (74.3%, $p < 0.001$), PSA level > 10 ng/ml (mean 9.87 ng/ml, $p < 0.001$), and PSAD ≥ 15 ng/ml/g (94.3%, $p < 0.001$). Among prostate cancer patients, in the majority of cases the positive tissue was found at lateral core (31.0%), followed by the apical core (28.5%), medial core (27.5%) and anterior core (23.5%). No factors were found to be related to increasing prostate cancer detection tissue in the lateral core with the exception of abnormal DRE.

Conclusion: A 16-core TRUS-guided prostate biopsy may be useful for the detection of prostate cancer in patients with abnormal DRE, high PSA, and high PSAD.

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Introduction

Prostate cancer is the most frequent malignancy in males worldwide [1], a prevalence which is reflectec in the Thai population, accounting for approximately 7.1 new diagnoses in 100,000 male patients.[2] Early prostate cancer detection increases the chance for organ confined[3] and potentially curable disease.[4] Transrectal ultrasound (TRUS) remains a common modality for prostate diagnosis and Grey-scale imaging is frequently used.[5] Originally, TRUS-guided prostate biopsy involved the collection of 6 samples from each anterior/base zone, mid-gland, and apex both sides (sextant biopsy).[6] However, the 6-core biopsy was considered inadequate for cancer detection, and the more lateral zone prostate biopsy was developed[7](extended prostate biopsy). Today the 12-core or double sextant biopsy is recommended as a routine procedure by AUA.[8]

Some studies found that 85.0% of prostate tumors presented on the posterior section of the peripheral zone[9-11] With the aim of improving the efficacy of the detection of prostate cancer from peripheral sampling, Rajavithi Hospital has been carrying out 16-core TRUS-guided prostate biopsies instead (Figure 1). This study was carried out to evaluate any changes in the detection rate of prostate cancer and to review the factors associated with efficacious detection following the introduction of 16-core TRUS-guided prostate biopsy in Rajavithi Hospital.

Materials and Methods

Study population

Between October 2019 and September 2021, 243 patients who had no history of MRI prostate underwent these procedures. 43 patients were excluded from this study because of not attending the TRUS-guided prostate biopsy with 16 core sampling, having a history of prostate cancer or treatment for prostate cancer, having received TRUS-guided prostate biopsy before, and having incomplete data. The remaining 200 patients were included in the analysis (Table 1).

Patient evaluation

TRUS-guided prostate biopsies in Rajavithi Hospital were performed under local anesthesia (1% xylocaine). Before the biopsy, a cleansing enema was administered, and the prostate volume was estimated. Core biopsies were obtained using an 18-gauge needle with a spring-loaded biopsy gun from anterior core, medial core, lateral cores, and apex core both sides. Despite the variation in prostate size, asymmetrical shape or abnormal DRE, the 16-cores were still taken as shown in Figure 1 and the lesions were collected from their site. All specimens were labeled by biopsy site and transported, separately in formalin-filled containers to the pathology department.

The Data was retrospectively collected from medical records and analyzed including demographic data, laboratory results, operative record, and pathologic report. Approval was obtained

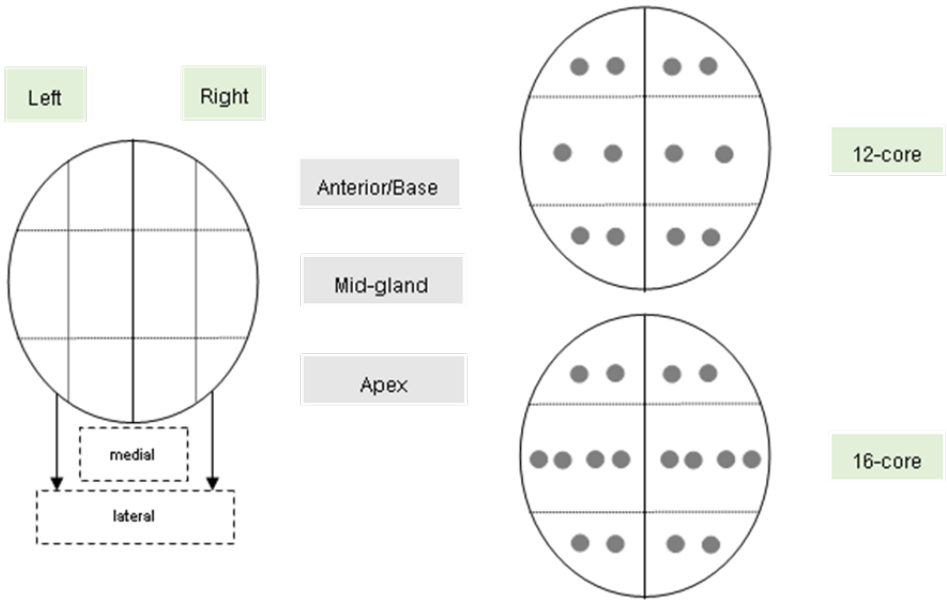

Figure 1. Sampling sites in 12- and 16-core prostate biopsy

Table 1. Demographic and clinical characteristics of participants

Variables	n (%)
Age (years), mean±SD	69.28±8.41
<60	21 (10.5)
60-69	78 (39.0)
70-79	82 (41.0)
>80	19 (9.5)
Family history CA prostate	198 (99.0)
No	2 (1.0)
Yes	
History 5-ARI used ≥ 1 year	
No	176 (88.0)
Yes	24 (12.0)
Abnormal DRE	
No	128 (64.0)
Yes	72 (36.0)
Bilateral	31 (15.5)
Right sided	22 (11.0)
Left sided	18 (9.0)
PSA (ng/ml), (range)	11.92 (7.82-21.96)
≤10	76 (38.0)
>10	124 (62.0)
Size (g), mean±SD	49.96±21.17
<40	66 (33.0)
≥40	134 (67.0)
PSAD (ng/ml/g), (range)	0.27 (0.16-0.67)
<0.15	37 (18.5)
≥0.15	163 (81.5)

DRE = digital rectal examination, PSA = prostate specific antigen, PSAD = prostate specific antigen density, CA = cancer

from the Ethical Review Board, Rajavithi Hospital (Study Number: 65170).

Outcomes

The primary outcomes were the detection rates of prostate using 16-core TRUS-guided prostate biopsy and the associated factors using data from all positive result patients (Figure 2).

Statistical analysis

The demographic and clinical characteristics of the patients were presented as numeric and interquartile range. The associated factors with prostate cancer detection were analyzed by Crude analysis with independent samples t-test, Mann-Whitney U test, Chi-square test and Fisher's exact test.

Any confounders of associated factors data was evaluated with Univariable analysis by simple logistic regression analysis and multivariable analysis by multiple logistic regression.

The demographic and clinical characteristics of patients with prostate cancer in the peripheral zones were presented as numeric and interquartile range and analyzed with independent samples t-test, Mann-Whitney U test, Chi-square test and Fisher's exact test.

Hazard ratios (HRs) with 95% confidence intervals (CIs) were used to assess the strength of the individual variables. Statistical analysis was performed using Stata v.17, and statistical significance was accepted as $p < 0.05$.

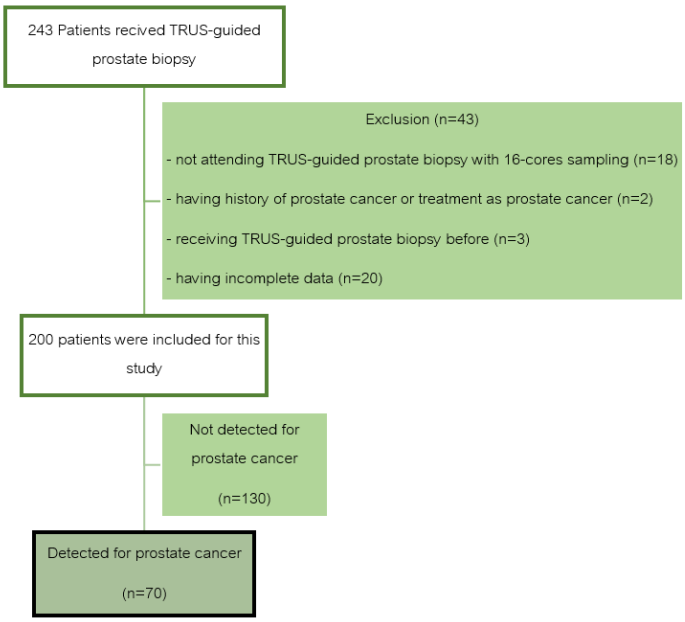

Figure 2. Participants included for the analysis

Results

Between October 2019 and September 2021, Rajavithi Hospital performed 16-core TRUS-guided prostate biopsy on 200 patients with 70 (35.0%) having a positive result for prostate cancer with 62 (31.0%), 57 (28.5%), 55 (27.5%), and 47 (23.5%) positive results being found in the lateral core, apical core, medial core, and anterior core, respectively (Table 2).

Compared with prostate cancer negative patients, patients with prostate cancer had higher average age (67.85 ± 8.03 years vs 71.74 ± 8.60 years) and the majority were likely to have abnormal DRE (74.0% vs 15.4%, $p < 0.001$), PSA > 10 ng/ml (88.6% vs 47.7%, $p < 0.001$), PSAD ≥ 15 ng/ml/g (94.3% vs 74.6%, $p < 0.001$) (Table 3).

Multivariable logistic regression analysis showed that detection of prostate cancer was associated with abnormal DRE (odds ratio [OR] 12.04, 95%Cl 5.42 to 26.73, $p < 0.001$), PSA > 10 ng/ml (OR 5.63, 95%Cl 1.98 to 15.97, $p = 0.001$), and PSAD ≥ 15 ng/ml/g (OR 1.68, 95%Cl 0.40 to 7.04, $p = 0.046$); Table 4.

Among 70 patients diagnosed with prostate cancer 62 had lateral cores positive for cancer. Their average age was 71.95 ± 8.84 years. With the exception of abnormal DRE (80.6% vs 25.4%, $p = 0.003$), our data showed that other factors (a family history of prostate cancer, history 5-ARI use ≥ 1 year, PSA level, prostate size, PSAD level) were not significantly associated with cancer detection using the lateral cores (Table 5).

Discussion

Although there have been many theories about the optimum number of cores for effective cancer diagnosis from prostate biopsy, many studies have supported that the double sextant or 12-core biopsy is optimal for TRUS-guided prostate biopsy.[8] McNeal et al.[9] in 1988 evaluated 88 from 104 prostate glands obtained from radical prostatectomy and reported a positive outcome with regard to the identification of the origin of adenocarcinoma. The pathological results showed 68.0% of tumors arose in the peripheral zone, 24.0% arose in the transitional zone, and 8.0% arose in the central zone. Some studies demonstrated that 85.0% of prostate tumors presented on the posterior portion of peripheral zone.[10-12] In 1998, Chang et al.[13] evaluated the usefulness of adding 4 lateral biopsies from the peripheral zone to routine sextant biopsy of prostate cancer.

Table 2. Pathological characteristics in tissue positive for prostate cancer

	Anterior core	Medial core	Lateral core	Apical core
Total (%)	47 (23.5)	55 (27.5)	62 (31.0)	57 (28.5)
Grade (IQR)	60 (40-80)	50 (30-72.5)	60 (30 -80)	60 (32.5-80)
Grade group (%)				
1	3 (4.3)	7 (10.0)	11 (15.7)	10 (14.3)
2	10 (14.3)	7 (10.0)	11 (15.7)	8 (11.4)
3	3 (4.3)	9 (12.9)	8 (11.4)	7 (10.0)
4	18 (25.7)	18 (25.7)	16 (22.9)	16 (22.9)
5	13 (18.6)	14 (20.0)	16 (22.9)	16 (22.9)
Right sided (IQR)	70 (40-85)	50 (30-80)	70 (50-80)	70 (45-85)
Grade group (%)				
1	3 (4.3)	5 (7.1)	8 (11.4)	9 (12.9)
2	8 (11.4)	7 (10)	8 (11.4)	6 (8.6)
3	5 (7.1)	6 (8.6)	6 (8.6)	6 (8.6)
4	7 (10.0)	11 (15.7)	10 (14.3)	8 (11.4)
5	14 (20.0)	14 (20.0)	15 (21.4)	16 (22.9)
Left sided (IQR)	60 (45-80)	60 (30-80)	60 (30-80)	70 (35-80)
Grade group (%)				
1	1 (1.4)	4 (5.7)	5 (7.1)	3 (4.3)
2	6 (8.6)	6 (8.6)	9 (12.9)	7 (10.0)
3	2 (2.9)	6 (8.6)	5 (7.1)	5 (7.1)
4	15 (21.4)	16 (22.9)	14 (20.0)	14 (20.0)
5	10 (14.3)	12 (17.1)	13 (18.6)	13 (18.6)

IQR = interquartile range

Table 3. Factors associated with prostate cancer detection

Variables	Prostate cancer		P-value
	Yes (n = 70)	No (n = 130)	
Age (years) mean±SD	71.74±8.60	67.95±8.03	0.002
<60	4 (5.7)	17 (13.1)	0.016
60-69	23 (32.9)	55 (42.3)	
70-79	31 (44.3)	51 (39.2)	
>80	12 (17.1)	7 (5.4)	
Family history CA prostate			
No	70 (100)	128 (98.5)	0.543
Yes	0 (0.0)	2 (1.5)	
History 5-ARI used ≥ 1 year			
No	65 (92.9)	111 (85.4)	0.121
Yes	5 (7.1)	19 (14.6)	
Abnormal DRE			
No	18 (25.7)	110 (84.6)	<0.001
Yes	52 (74.3)	20 (15.4)	
PSA (ng/ml) (range)	9.87 (6.99-14.24)	40.40 (13.07-93.84)	<0.001
≤10	8 (11.4)	68 (52.3)	<0.001
>10	62 (88.6)	62 (47.7)	
Size (g) mean±SD	49.74±23.82	50.08±19.67	0.918
<40	27 (38.6)	39 (30.0)	0.219
≥40	43 (61.4)	91 (70.0)	
PSAD (ng/ml/g) (range)	0.22 (0.15-0.31)	0.93 (0.33-1.98)	<0.001
<0.15	4 (5.7)	33 (25.4)	0.001
≥0.15	66 (94.3)	97 (74.6)	

IQR = interquartile range, CA = cancer, PSA = prostate specific antigen, PSAD = prostate specific antigen density

Table 4. Multiple logistic regression analysis for factors associated with detection of prostate cancer

Variables	Univariable analysis			Multivariable analysis		
	OR	95%CI	P-value	OR	95%CI	P-value
Age (years)						
<60	1.00	Reference		1.00	Reference	
60-69	1.78	(0.54-5.86)	0.345	1.52	(0.35-6.52)	0.575
70-79	2.58	(0.80-8.38)	0.114	2.70	(0.63-11.59)	0.181
>80	7.29	(1.74-30.56)	0.007	3.21	(0.51-20.16)	0.214
History 5-ARI used ≥ 1 year						
No	1.00	Reference		1.00	Reference	
Yes	0.45	(0.16-1.26)	0.129	0.49	(0.14-1.72)	0.267
Abnormal DRE						
No	1.00	Reference		1.00	Reference	
Yes	15.89	(7.76-32.55)	<0.001	12.04	(5.42-26.73)	<0.001
PSA (ng/ml)						
≤10	1.00	Reference		1.00	Reference	
>10	8.50	(3.77-19.16)	<0.001	5.63	(1.98-15.97)	0.001
Size (g)						
<40	1.00	Reference		1.00	Reference	
≥40	0.68	(0.37-1.26)	0.220	0.40	(0.17-0.98)	0.046
PSAD (ng/ml/g)						
<0.15	1.00	Reference		1.00	Reference	
≥0.15	5.61	(1.90-16.59)	0.002	1.68	(0.40-7.04)	0.476

DRE = digital rectal examination, PSA = prostate specific antigen, PSAD = prostate specific antigen density

Table 5. Demographic and clinical characteristics of patients diagnosed with prostate cancer by detection in the peripheral zone

Variables	Peripheral		P-value
	Yes (n = 62)	No (n = 8)	
Age (years) mean±SD	71.95±8.84	70.13±6.71	
<60	3 (4.8)	1 (12.5)	0.567
60-69	22 (35.5)	1 (12.5)	0.156
70-79	25 (40.3)	6 (75.0)	
>80	12 (19.4)	0 (0.0)	
History CA prostate			
No	62 (100.0)	8 (100.0)	NA
History 5-ARI			
No	58 (93.5)	7 (87.5)	0.465
Yes	4 (6.5)	1 (12.5)	
Abnormal DRE			
No	12 (19.4)	6 (75.0)	0.003
Yes	50 (80.6)	2 (25.0)	
Area (n = 51)			
Bilateral	23 (46.9)	0 (0.0)	0.296
Right sided	13 (26.5)	1 (50.0)	
Left sided	13 (26.5)	1 (50.0)	
PSA (ng/ml) (range)	45.75 (13.41-105)	19.82 (11.07-21.86)	
≤10	7 (11.3)	1 (12.5)	0.078
>10	55 (88.7)	7 (87.5)	1.000
Size (g) mean±SD	51.27±24.10	37.84±18.73	0.134
<40	22 (35.5)	5 (62.5)	0.246
≥40	40 (64.5)	3 (37.5)	
PSAD (ng/ml/g) (range)	1.06 (0.37-2.19)	0.55 (0.29-0.94)	0.104
<0.15	4 (6.5)	0 (0.0)	1.000
≥0.15	58 (93.5)	8 (100.0)	

DRE = digital rectal examination, PSA = prostate specific antigen, PSAD = prostate specific antigen density, CA = cancer

Their study found that the cancer was missed in 77.0% of prostate cancer patients from the sextant biopsies procedure, but detection was successful from lateral biopsies. They concluded that additional lateral biopsies increased the sensitivity for cancer detection.

Miyoshi et al[14] in 2013 compared 12- with 16-core biopsies in patients with PSA levels 4.0 - 20.0 ng/ml. and reported that prostate cancer detection rate was higher in the 16-core biopsy group, especially in patients with a prostate volume > 30 g and a PSAD < 0.2 ng/ml/g without any significant complication rate between these two groups. With the aim of collecting more tissue from the lateral site of the prostate gland in PSA ≥ 4 ng/ml patients as a screening procedure or confirmation of prostate cancer, 16-core biopsies were carried out in our Hospital to extend peripheral zone sampling. The aim of this retrospective study was to demonstrate an improvement in prostate cancer detection rate using 16-core TRUS-guided prostate biopsy in Rajavithi Hospital.

Between October 2019 and September 2021, our department performed 16 core TRUS-guided prostate biopsy on 200 patients. The prostate cancer detection rate was 70 out of 200 patients (35.0%). The age range was 71.74 ± 8.60 years and those who presented with an abnormal DRE (74.0%, $p < 0.001$), PSA > 10 ng/ml (88.6%, $p < 0.001$), or PSAD ≥ 15 ng/ml/g (94.3%, $p < 0.001$) were found to have a significantly higher chance of having prostate cancer. This study showed that the prostate sampling site that tested positively the most frequently was the lateral core (31.0%) followed by the apical core (28.5%), medial core

(27.5%) and anterior core (23.5%). Our data didn't indicate any factors increased the possibility of prostate cancer detection in the lateral core significantly with the exception of abnormal DRE.

A PSA > 3 ng/dl is an indication for prostate cancer screening in either a male 55 to 69 years old (AUA 2018)[15] or 45 to 75 years old (NCCN 2019).[16] Additional indications for initial prostate biopsy are patient specific risk factors, suspicious DRE findings/prostate nodules (5.0%-30.0% cancer risk), symptoms suggestive of prostate cancer, or having suggestive findings of metastasis prostate cancer.[17] Our results demonstrate that positive samples for prostate cancer at the lateral core (31.0%) were the most frequent so 16-core TRUS-guided prostate biopsy, which collects more tissue from the lateral site of the prostate gland, may be more effective over 12-core in terms of detecting prostate cancer. This is especially true in patients with abnormal DRE, high PSA (> 10 ng/ml), and high PSAD (≥ 15 ng/dl). Other factors which may have a bearing such as age and prostate size, were found to be insignificant in this study but this may be due to the small sample size. This could also be said about the relationship between abnormal DRE and prostate cancer detection at lateral core.

In addition to the possibility of increasing the detection of prostate cancer by TRUS-guided prostate biopsy, the risk benefits to the patient should also be considered, a limitation to this study as we didn't capture the risks or complications associated with prostate cancer biopsy. A second limitation was there was no comparative method with different cores from TRUS-guided prostate biopsy in this study. Third, the sample size and the patient population with prostate cancer were insufficient to stratify some possible characteristics.

Conclusion

From our data, we can conclude that 16-core TRUS-guided prostate biopsy is a potential procedure for the detection of prostate cancer in patients with abnormal DRE, high PSA (> 10 ng/ml), and high PSAD (≥ 15 ng/dl). Further studies with a larger sample size and also randomized clinical trials are warranted to add weight to this conclusion.

Conflicts of Interest

The authors declare no conflicts of interest.

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