

## Original Article

# Complications and specimen quality in transrectal ultrasound guided prostate biopsy: Comparison of 16G and 18G needles

Ahmet Murat Bayraktar<sup>1</sup>, Erkan Olcucuoglu<sup>2</sup>, Eray Hasirci<sup>3</sup>, Ismail Nalbant<sup>4</sup>, Suleyman Yesil<sup>5</sup>

<sup>1</sup>Clinic of Urology, Konya Training and Research Hospital, Konya, Turkey

<sup>2</sup>Clinic of Urology, Türkiye Yüksek İhtisas Training and Research Hospital, Ankara, Turkey

<sup>3</sup>Clinic of Urology, Baskent University Medical Faculty, Ankara, Turkey

<sup>4</sup>Clinic of Urology, Ordu University Medical Faculty, Ordu, Turkey

<sup>5</sup>Clinic of Urology, Gazi University Medical Faculty, Ankara, Turkey

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## ABSTRACT

**Objectives:** To evaluate specimen quality, pathological results, complications and pain in transrectal ultrasound (TRUS) guided prostate biopsy using 16 gauge (G) or 18G biopsy needles

**Design:** Retrospective study

**Setting:** Türkiye Yüksek İhtisas Training and Research Hospital, Ankara, Turkey

**Subjects:** Retrospective analysis of 243 TRUS guided prostate biopsies between March 2011 and April 2016

**Interventions:** Group 1 (n=121) underwent TRUS guided prostate biopsy using a 16 G needle and Group 2 (n=122) underwent TRUS guided prostate biopsy with an 18 G-needle.

**Main outcome measures:** We compared two biopsy needle sizes (16G vs 18G) in relation to sample quality, prostate cancer detection rate, pain, bleeding and infection rates in 243 patients. Core fragmentation and short specimen length (<10mm) rate were the sample

quality criteria. Pain was evaluated using visual analog scale (VAS).

**Results:** There were no statistically significant differences in mean patient ages, prostate-specific antigen values and prostate volumes between groups 1 and 2. Sixteen gauge needles caused significantly less fragmentation of the biopsy cores when compared to 18G needles (p=0.00), but no statistically significant difference between two groups was recorded for pathological results (p=0.72) and shorter specimen length (p=0.567). Haematuria, rectal bleeding and infection were similar in both groups. Mean VAS score of group 1 was significantly greater than that of group 2 (3.19 vs 2.66;p=0.027).

**Conclusion:** Though thicker needles provided better sampling quality, the cancer detection rate was not altered by the needle size. Also, even though complication rates were similar for different needle sizes, the 18G needles were better tolerated.

**KEY WORDS:** biopsy, needle size, prostate, transrectal ultrasound

## INTRODUCTION

The main method of diagnosing prostate cancer is by performing prostate biopsy (PB). While finger-guided and lesion-focused techniques were used in the past, it has recently become a standard diagnostic method to perform systematic prostate biopsies under the guidance of transrectal ultrasound (TRUS) [1]. Over the years, various biopsy schemes have been proposed to make PB more accurate and to avoid error in diagnosis. Currently, with the opinion that sextant biopsy (the first described method) is inadequate

for diagnosis, there is still no consensus about the optimal number of cores and core localization [1,2]. The diagnostic accuracy of PB may be increased by increasing the volume of the tissue and sampling quality [3]. For this purpose, it is recommended to use larger needles that can receive larger volumes of tissue, but it is thought that the risk of complications such as pain and bleeding may increase as a result [4]. Today, 16G and 18G needles are widely used in PB. When compared with 18G needle, 16G biopsy needle can theoretically take larger and better quality samples

*Address correspondence to:*

Ahmet Murat Bayraktar, Konya Training and Research Hospital, Konya, Turkey. Tel: +90 5336095220; Fax: +90 3323241854; E-mail: dram6@yahoo.com.tr

and make more accurate pathologic evaluation due to its larger calibre, but there aren't enough studies in the literature that compare the two different PB needles.

In this study, we aimed to compare 18G and 16G PB needles in terms of prostate cancer detection rate; morbidities such as pain, bleeding and infection; and sampling quality in TRUS-guided PB.

## SUBJECTS AND METHODS

Clinical and pathological data from 243 patients who underwent 16 cores TRUS-guided transrectal PB because of elevated prostate-specific antigen (PSA) level between March 2011 and April 2016 were analyzed retrospectively. Patients with total PSA levels between 4 and 10 ng/ml, who had no history of anticoagulant or antiplatelet drug use, bleeding disorder and prostatic surgery were included in the study. Patients with suspicious lesions detected on rectal examination or TRUS were excluded. One hundred and twenty-one patients underwent PB with 16G needle between March 2011 and February 2013 while 122 underwent PB with 18G needle between March 2013 and April 2016.

Prostatic biopsies were performed by two experienced urologists. All patients were started on ciprofloxacin 500 mg twice daily one day before the procedure for prophylaxis and continued until three days after the procedure. All patients were given detailed information about the PB and signed a consent form. PB was routinely performed in the lateral decubitus position following rectal enema. Periprostatic nerve block was performed by injecting a total of 10 ml 2% prilocaine into the junctional area between seminal vesicles and the prostate, including 5 ml on each side. Prostatic volume was then calculated by the ellipsoid formula using 6.5-Hz ultrasound probe. All patients underwent a total of 16 cores PB using 25 cm 16G or 18G biopsy needles from both right and left lobes of the prostate including two lateral peripheral (basal, midgland), three far lateral peripheral (basal, midgland apical) and three medial (basal, midgland, apical). Each sample was sent for pathological examination in separate bottles containing 10% formalin.

Severity of pain during prostatic biopsy was graded from 0 to 10 by using the visual analog scale (VAS). Evaluation of morbidity was generally made one week after the procedure. Hematuria and rectal bleeding was evaluated using Clavien-Dindo classification of surgical complication<sup>[5]</sup> which was systematized for PB by Cicione and colleagues<sup>[6]</sup>. According to this system, rectal bleeding that occurs after biopsy is classified as follows; grade 0: no or very little bleeding; grade 1: bleeding that stops by compressing rectal mucosa without requiring endoscopic treatment, electrolyte infusion or hemostatic medication; and grade 2:

bleeding that requires endoscopic or pharmacological treatment. Fever of 38 °C and above that occurred within 48 hours after the procedure and that required parenteral antibiotic treatment was considered as procedure-induced infection. The following criteria were used to evaluate the sampling quality: having fragmented cores and shorter length of prostatic tissue in non-fragmented cores (core length <10 mm)<sup>[4,6]</sup>.

Data from patients who underwent biopsies with 18G and 16G needles were compared in terms of age, prostatic volume, total and free PSA, treatment induced pain (VAS), the quality of the sampling, detection rate of prostate cancer and morbidity. Since the study is retrospective, there is no ethical committee approval and patient's consent in our study.

## Statistical analysis

Independent sample t-test and chi-square test were used for statistical analysis. All data were analyzed using SPSS (Statistical Package for the Social Sciences, Inc., Chicago, IL, USA) 16.0 for Windows programme.

## RESULTS

Data from a total of 243 patients including 121 patients who underwent biopsy with 16G PB needle (Group 1) and 122 patients with 18G PB needle (Group 2) were analyzed. There was no statistically significant difference between the groups in terms of patient age, prostatic volume, total and free PSA values (Table 1).

**Table 1:** Age, prostatic volume, total and free PSA values in two groups

Baseline demographics	Group 1 (n = 121)	Group 2 (n = 122)	p-value
Age (years)			0.33
Mean ± SD	64.38 ± 7.0	65.0 ± 7.94	
Range	48 - 78	56 - 76	
Vp (cc)			0.228
Mean ± SD	52.16 ± 22.01	56.47 ± 20.42	
Range	15 - 115	30 - 150	
Total PSA (ng/ml)			0.441
Mean ± SD	6.90 ± 2.03	7.15 ± 1.88	
Range	4.14 - 9.89	4.06 - 9.96	
Free PSA (ng/ml)			0.22
Mean ± SD	1.37 ± 0.58	1.53 ± 0.76	
Range	0.16 - 3.19	0.26 - 3.04	

Vp: Prostatic volume; SD: Standard deviation; PSA: Prostate specific antigen

After pathological evaluation, benign pathology was detected in 140 (57.6%), prostate cancer in 80 (32.9%) and atypical small acinar proliferation (ASAP) in 23 (9.4%). There was no statistically significant difference between the groups in terms of cancer, benign pathology and ASAP detection rates (p = 0.72) (Table 2).

Mean VAS scores for pain were 3.19 ± 1.58 and 2.66 ± 1.23 in Groups 1 and 2, respectively and the difference

**Table 2:** Pathology reports of two groups (chi-square test)

Pathology n(%)	Group 1 (n = 121)	Group 2 (n = 122)	p-value
Benign	68 (56.1%)	72 (59.01%)	0.72
Prostate cancer	39 (32.2%)	41 (33.6%)	
ASAP	14 (11.5%)	9 (7.37%)	

ASAP: atypical small acinary proliferation

was statistically significant ( $p = 0.027$ ). There was no statistically significant difference between the groups in terms of complications ( $p = 0.842$ ) (Table 3).

**Table 3:** Comparison of the complications in two groups. (chi-square test)

Complication	Group 1 (n = 121)	Group 2 (n = 122)	p-value
Hematuria			0.842
Grade 0	112 (92.56%)	115 (94.45%)	
Grade 1	9 (7.43%)	7(5.73%)	
Grade 2	0	0	
Rectal bleeding			
Grade 0	112 (92.56%)	116 (95.08%)	
Grade 1	9 (7.43%)	6 (4.91%)	
Grade 2	0	0	
Infection	2 (1.65%)	2 (1.63%)	

When compared to 18G needles, 16G needles were found to cause less fragmentation ( $p = 0.00$ ), but the difference in sampling rate of <10 mm length was not statistically significant between the groups ( $p = 0.567$ ) (Table 4).

**Table 4:** Comparison of sampling quality of two groups (chi-square test)

Sample quality	Group 1 (n = 121)	Group 2 (n = 122)	p-value
Fragmentation			0.00
1 core	17 (14.04%)	66 (54.09%)	
2 cores	20 (16.52%)	22 (18.03%)	
3 cores	10 (8.26%)	10 (8.19%)	
4 cores	5 (4.13%)	3 (2.45%)	
5 cores	5 (4.13%)	2 (1.63%)	
6 cores	0	2 (1.63%)	
<10 mm sample			0.567
1 core	46 (38.01%)	36 (29.50%)	
2 cores	19 (15.7%)	17 (13.9%)	
3 cores	5 (4.13%)	10 (8.19%)	
4 cores	0	2 (1.63%)	

## DISCUSSION

Today, TRUS-guided PB is the main diagnostic method used in the diagnosis of prostate cancer. In various studies, as the first identified scheme for PB, sextant biopsy has been reported to overlook the existing cancer in up to 30% of the cases<sup>[2,7]</sup>. Therefore, the common view is that sextant biopsy is inadequate and outdated in the diagnosis of prostate cancer<sup>[1]</sup>. Effectiveness of different biopsy schemes have been

investigated in order to reach the correct diagnosis. While different PB schemes were identified by increasing the number of cores, there is still no biopsy scheme that is generally standardized and accepted. Scattoni *et al*<sup>[8]</sup> investigated the ideal number of cores in PB for the diagnosis of prostate cancer in their study and they concluded the most ideal core number as between 10 to 16 depending on digital rectal examination findings, prostate size and age. In another study, saturation (20 cores and more) biopsy was concluded to be unnecessary for first time biopsies due to increase in morbidity<sup>[9]</sup>. Therefore, it is reasonable to perform saturation biopsy in patients with previously negative biopsies and rising or persistent high PSA levels. Although it is not a generally accepted scheme, it is recommended to take biopsies from between 10 and 18 cores as lateral as possible for the first biopsy<sup>[1]</sup>. In our own practice, we usually carry out a total of 16 cores sampling including six far lateral peripheral, four lateral peripheral and six medial.

The second way to increase the reliability of prostate biopsy is providing the pathological specimen in adequate quantity and quality. Theoretically, if the needle used for this purpose is longer or larger in caliber, the samples taken in each core would be in larger volume and better quality. Supporting this hypothesis, Dogan *et al*<sup>[10]</sup> reported that tissues obtained in biopsies using longer needles (end cut, 33 mm) were superior in quantity and quality, while cancer detection rate was not different when compared with the needles in the standard size (side notch, 22 mm). However, Özden *et al*<sup>[11]</sup> concluded that taller needles (end-cut, 33 mm) did not provide any advantage in sampling quality compared with the standard needle.

Recently, standard (side-notch) 16G and 18G biopsy needles are widely used in PB. When compared, 16G and 18G needles are equal in length while 16G needle is thicker and has more volume by up to 1.5 times. Therefore, it can theoretically be expected to obtain larger tissues in quality and volume in biopsies with 16G needle. At the same time, increasing the thickness of the biopsy needle may lead to an increase in complications. Helbich *et al*<sup>[12]</sup> compared 16G and 18G needles in breast biopsies and concluded that 16G needle has reached better sampling quantity and quality. In this topic, there are only a few number of studies in the literature. Inal *et al*<sup>[13]</sup> compared their PB outcomes of 103 patients conducted with 16G needle and 101 patients with 18G needle. They concluded better sampling quality in the first group while prostate cancer detection rates, complications and VAS pain scores were not different from the second group. Cicione *et al*<sup>[6]</sup> investigated the effects of PB with 16G and 18G needles on cancer detection rate, sampling quality and morbidity; no significant differences were reported in any of these three criteria.

In our study, 16G needle led to less core fragmentation when compared with 18G. However, there were no significant differences between the number of cores containing samples less than 10 mm. Even though sample quality is better with the 16G needle, there was no statistically significant difference between the two groups in terms of prostate cancer and ASAP detection rates.

We also observed that our patients had difficulty in tolerating PB as the needle size increased. VAS pain scores were significantly higher in 16G needle biopsy group. This can be a result of ineffectiveness of peri-prostatic block on rectal mucosa and contact of the thicker needle with the rectal mucosa. Intrarectal pomads and gels with local anesthetics in addition to the peri-prostatic block can be useful in patients during biopsy with thicker needle. Giannarini *et al*<sup>[4]</sup> concluded less pain scores in patients who underwent PB with peri-prostatic block in combination with intrarectal lidocaine-prilocaine cream, when compared with peri-prostatic block alone.

In this study, complication rates such as hematuria, rectal bleeding and infection were not significantly different between the two groups. Bleeding that required endoscopic or pharmacological treatment (grade 2) were not observed in both groups. Infection that required parenteral antibiotic therapy was observed only in four patients, two in each group. In parallel with our results, previous studies reported no increase in complications in transrectal PB with thicker needles<sup>[6,7,13]</sup>. Giovanni *et al*<sup>[4]</sup> also reported that increase in needle size did not result in a change in the complication rate of transperineal PB.

## CONCLUSION

We conclude that thicker needles did not provide any significant advantage. Though thicker needles provided better sampling quality, the cancer detection rate was not altered by the needle size. Also, even though complication rates were similar for different needle sizes, the 18G needles were better tolerated. Further prospective and randomized trials with larger series are required to determine if 16G needle provides any advantage.

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