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Can Smaller Needle Size In Prostate Biopsy Reduce Complications Without Affecting Sample Quality and Cancer Detection Rates?

Prostat Biyopsisinde İğne Kalınlığını Küçültmek, Örnek Kalitesini ve Kanser Tespit Oranlarını Etkilemeden, Komplikasyonları Azaltabilir Mi?

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Abstract

Objective: The aim of this study is to compare the 18G and 20G biopsy needle in transrectal ultrasound guided prostate biopsy (TRUS-PBx) for diagnosis of prostate cancer in terms of sample quality, cancer detection rates, pain and other complications.

Material-Method: 120 patients with PSA (prostate specific antigen) levels of 2.5-10 ng/ml, prostate volumes of 30-80 cc and 50-70 years of age were randomly divided into two groups as those who underwent biopsy with 18G (Group 1) and 20G (Group 2) needles. However, the arm of the study performed with 20G needle biopsy was stopped due to the very low cancer detection rate when the number of patients reached 32. All patients in Group 2 were performed re-biopsy with an 18G needle 3 months later. In all patients, complications and cancer detection rates were evaluated in during and after the procedure.

Results: The cancer detection rates in Group 2 were significantly lower compared to Group 1. The VAS (Visual Analog Scale) 2 score was lower in Group 2 (p=0.008), but there was no statistically significant difference in other VAS scores. In both groups, the rate of side effects and complications related to biopsy were similar. All patients in Group 2 were re-biopsied with an 18G needle. The rate of cancer detection was significantly higher in patients who underwent TRUS-PBx with 18G needle (p=0.0055).

Conclusions: We found that the rate of obtaining sufficient sample for TRUS-PBx and detection of cancer was very low in 20G compared to 18G needle. 20G needle had no superiority to 18G needle in all complications, including pain. We concluded that 20-gauge needle prostate biopsy was not an accurate approach in our study.

Keywords: Biopsy, Histopathology, Prostate Cancer, Visual Analog Pain Scale, Complications.

Özet

Amaç: Çalışmanın amacı; prostat kanseri tanısı için yapılan transrektal ultrason eşliğinde prostat biyopsisinde (TRUS-PBx) standart olarak kullanılan 18G (gauge) biyopsi iğnesi ile 20G biyopsi iğnesini alınan örnek kalitesi, kanser tespit oranları, ağrı ve diğer komplikasyonlar açısından karşılaştırmaktır.

Materyal-Metot: PSA (Prostat Spesifik Antijen) değerleri 2,5-10 ng/ml, prostat hacimleri 30-80 cc, yaşları 50-70 arasında olan 120 hasta, sayıları eşit olacak şekilde rastgele iki gruba ayrıldı. Grup 1'i 18G, grup 2'yi 20G iğne ile prostat biyopsisi yapılanlar oluşturmaktaydı. Fakat 20G iğne biyopsisi ile yapılan çalışmanın kolu, hasta sayısı 32'ye ulaştığında çok düşük kanser tespit oranı nedeniyle durduruldu. Grup 2'deki tüm hastalara 3 ay sonra 18G iğnesi ile yeniden biyopsi yapıldı. Tüm hastalarda, işlemi sırasında ve sonrasında ki komplikasyonlar ile kanser tespit oranları değerlendirildi.

Bulgular: Grup 2'dekilerde kanser tespit oranları grup 1'e kıyasla anlamlı derecede düşüktü. VAS (Visual Analog Scale: Görsel Analog Skalası) 2 ağrı skoru Grup 2'de daha düşüktü (p=0,008) fakat diğer VAS skorlarında istatistiksel olarak anlamlı fark yoktu. Her iki grupta biyopsiye bağlı yan etki ve komplikasyon görülme oranı benzerdi. Grup 2'deki tüm hastalara 18G iğne ile tekrar biyopsi yapıldı. Kanser tespit oranı 18G iğne ile TRUS-PBx yapılanlarda istatistiksel olarak anlamlı derecede yüksekti (p=0,0055).

Sonuç: TRUS-PBx için yeterli numune elde etme ve kanser saptama oranını, 18G iğneye kıyasla 20G iğnede çok düşük olduğu bulundu. Ağrı dahil tüm komplikasyonlarda ise her iki iğnenin klinik olarak birbirlerine karşı hiçbir üstünlüğü bulunamadı. Çalışmamıza göre 20G iğne ile prostat biyopsisi almanın doğru bir yaklaşım olmadığı sonucuna varıldı.

Anahtar kelimeler: Biyopsi, Histopatoloji, Prostat Kanseri, Görsel Analog Ağrı Skalası, Komplikasyonlar.

Introduction

Currently prostate biopsy is accepted as gold standard for diagnosis of prostate cancer, risk classification and planning of treatment. This procedure is performed annually more than 2 million cases in Europe and the USA (1). While some of the patients can easily tolerate this procedure, some had severe pain and discomfort (2). Approximately 7-8 years ago, European and American Urology Association guidelines recommended 10-12 core systematic TRUS-PBx as the gold standard for primary diagnosis at high PSA levels, including

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a targeted biopsy from suspected areas detected in the rectal region by DRE (Digital Rectal Examination) or TRUS (3, 4). With the introduction of multiparametric MRI in the diagnosis of prostate cancer, the use of systematic biopsy alone is gradually decreasing. NICE and EAU guidelines recommend systematic biopsy in addition to MRI targeted biopsy for the diagnosis of prostate cancer (5, 6).The technique of TRUS-PBx has been become a gold standard in recent years and 18G needle has been frequently used for this procedure (7). Studies have suggested that the use of a larger caliber needle may improve histologic sampling and increase the accuracy of prostate cancer diagnosis (8). In another study, it was suggested that the use of a smaller calibrated needle can reduce complication rates and pain scores without affecting histological sampling (9). The effects of patient's age, number and localization of biopsy obtained, biopsy volume, and prostate volume and patient position during the procedure on pain severity during TRUS-PBx were evaluated in studies (10).

The aim of this study is to compare 18-Gauge (18G) and 20-Gauge (20G) biopsy needles used in TRUS-PBx for the diagnosis of prostate cancer in terms of sample quality, cancer detection rates, pain and other complications. A prospective, single-blind, and randomized controlled trial was performed to compare the results of patients undergoing prostate biopsy using 18G and/or 20G needles to detect prostate cancer.

Material and Methods

Our study was conducted in a university hospital in the Mediterranean region of Turkey between October 2014 and October 2018. Study was planned as a randomized, prospective and single blind study. Patients with high PSA levels (≥2.5 ng/ml), and patients with suspicious lesion detected in DRE were included in the study. Many of our patients were not examined with prostate MRI before biopsy. However, patients who underwent MRI examination were randomly performed 12 quadrant PBx as in other patients. Ethics committee approval of the study was obtained from University Faculty of Medicine with the decision dated 23.07.2014 and numbered 121. Informed consent forms were obtained from all patients. All of the patients participating in the study were told that the biopsy sample was inadequate, the pathologist was not able to make a full diagnosis, and in cases where the biopsy result was Atypical Small Acinar Proliferation (ASAP) or High Grade Intraepithelial Neoplasia (HGPIN) and a re-biopsy would be performed.

Study Population

A 585 patients underwent prostate biopsy by the same surgeon between October 2014 and October 2018. Patients with exclusion criteria (Table 1) were excluded from the study. Initially, 120 patients with PSA values of 2.5-10 ng/ml, prostate volumes of 30-80 cc, age 50-70 years were planned. The patients were selected as closed envelope method. It was divided into two groups, Group 1 (biopsied with 18G needle) and Group 2 (biopsied with 20G needle), by the physician (n:60 for both groups). The arm of the study conducted with 20G needle biopsy was stopped after the sampling of 32nd patient due to the poor quality of the cores (sample) of the prostate biopsy, high ASAP rate and low cancer detection rate. All patients in Group 2 were performed re-biopsy with an 18G needle 3 months later. Study design is shown in Figure 1.

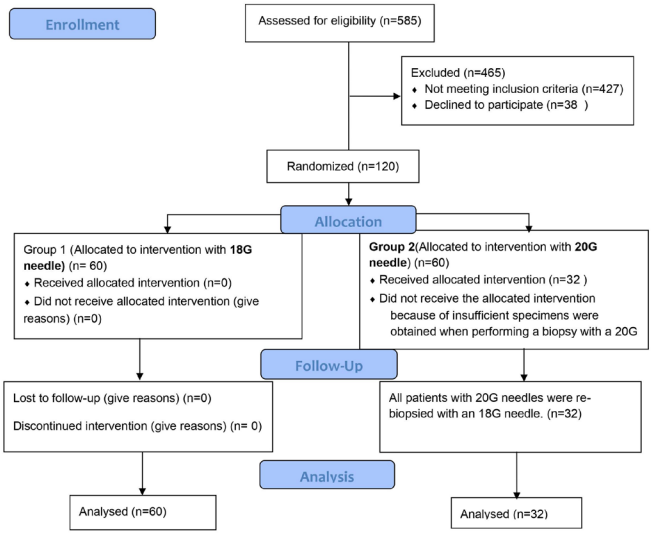

Figure 1. Study design

Table 1. Criteria for exclusion of the patients

- Family history of prostate cancer
- Patients with a history of lower urinary tract infection
- Patients with a history of acute urinary retention
- Patients with any history of prostate surgery and biopsy
- Patients with Anal and rectal disease
- Patients with chronic pain (fibromyalgia, chronic pelvic pain syndrome)
- Diabetic patients
- Patients with bleeding diathesis
- Patients with sensory neuropathy such as sensory neurological deficit
- Oral and parenteral antiaggregant and anticoagulant users
- Chronic analgesic use
- Patients exposed to antimicrobial agents in the last 6 months

Biopsy Technique

All patients were given antibiotic prophylaxis with TMP-SMX (sulfamethoxazole and trimethoprim) 400 mg twice daily dose for the day before the procedure and continued for 5 days after the procedure and single dose ceftriaxone 1gr was administered intravenously one hour before the procedure. No rectal swab samples were taken before the biopsy.

Transrectal Ultrasonography was performed by using General Electric, Logiq C2 brand ultrasound with a 7.5-MHz frequency rectal probe. Prostate volume was calculated by measuring the three dimensions of the prostate with the formula X*Y*Z* 0.52. Biopsy was performed as standard

with 12 core automatic biopsy guns. Of the biopsy needles, the 18G needle had a diameter of 1.3 mm, a length of 25 cm and a sampling groove of 1.9 cm, while a 20G biopsy needle had a diameter of 1.1 mm, a length of 25 cm, and a sampling groove of 1.9 cm. Each patient was instructed to perform rectal enema before the biopsy. Before biopsy, the patient was placed in the left lateral decubitus position abdomen at a 90-degree angle to the lower extremity, and also positioned femur at a 90-degree angle to the tibia. A DRE was performed and the perianal skin and anorectal area of all patients were disinfected with povidon iodine before the biopsy. Then, cotton ball dipped in povidone iodine together with a gel of 15 ml lidocaine 2% was administered intrarectally and kept for 20 minutes. For each biopsy core, the biopsy site from which the sample was taken was specified, the prostate lobe was numbered and identified. Biopsy specimens were sent to pathologist in 10% buffered formalin filled containers.

The samples were evaluated by a single pathologist. Only one urologist performed all prostate biopsy procedures to prevent mismatch between the processors and to standardize the biopsy technique. The VAS scores were used to measure the severity of pain due to PBx. The VAS score is scored as 0 painless (or no discomfort), while 10 is considered unbearable pain (or unbearable discomfort). For analysis, verbal categories were assigned numbers; the total pain score was evaluated 1-3 as "no pain or mild pain", 4-6 as "moderate pain" and any score greater than 6 as "severe pain". The VAS1 measurement was obtained after the placement of the probe in the rectum, VAS2, during the movement of the needle and biopsy, VAS3; fifteen minutes after biopsy, VAS4; three hours after biopsy, VAS5; twenty-four hours after biopsy, and VAS6; measurements were obtained three days after biopsy. Only one clinical nurse with the previously designed questionnaire interviewed the patients face-to-face and/or by telephone obtained information about other complications such as pain, and blood in the semen, urine or feces after biopsy. The clinical results of prostate biopsy were evaluated as primary (biopsy core quality and prostate cancer detection) and secondary (biopsy related complications, and patient discomfort like pain). Besides histopathologic examination, pathologist also examined the core quality of the specimen as soon as sample arrived.

Presence of the number of cores without prostatic tissue sample more than three or divided into more than three parts, the length of biopsy core smaller than 10 mm, the number of core fragments more than three, the thin or short biopsy material to make the diagnosis difficult, and loss of tissue during paraffin block procedures such as embedding and sectioning were accepted as insufficient sample (i.e. poor quality core). The cases diagnosed as HGPIN or ASAP were reported. Biopsy procedure was repeated in patients with HGPIN or ASAP diagnosis and cases with poor core quality.

Before the procedure, patients performed complete blood counts and their bleeding times were evaluated. Complete blood counts were planned only for patients with severe bleeding after biopsy.

The severity of rectal bleeding of complications were classified to standardize as below; Grade 0; little or no bleeding, Grade 1; bleeding that can be treated by compression to the rectal mucosa (no requirement of endoscopic intervention, electrolyte infusion or hemostatic medication, Grade 2; bleeding require endoscopic intervention or pharmacologic support (11).

The infection was defined as fever that occurred within 48 hours after prostate biopsy and exceeded 38°C.

Statistical Analysis

SPSS (Statistical Package for Social Sciences Inc., Chicago, IL, USA) 22.0 package program was used for statistical analysis. Descriptive statistics were used for the analysis of data, mean and standard deviation for continuous variables and number and percentage were used for categorical data. Data presented a non-parametric distribution and Mann Whitney and Chi-Square tests were used for statistical analysis. P value was accepted as <0.05 for statistical significance.

Results

Age, prostate volume and PSA values of the patients are given in Table 2.

Cancer was diagnosed in 2 (6.25%) of the Group 2 patients and 17 (28.3%) of the Group1 patients. In both PSA ranges of 2.5-4 ng/ml and 4-10 ng/ml, insufficient biopsy specimen and cancer detection rates were found very low in Group 2 and this was statistically significant (PSA: 2.5-4.0 ng/ml, p=0.049 and PSA 4.0-10.0 ng/ml, p=0.0001, respectively) (Table 3). According to re-biopsy results, there was no any insufficient sample and cancer detection rate was found statistically increased (p=0.005). Biopsy and re-biopsy results were shown in Table 4.

Table 2. Patients' baseline clinical characteristics

	Group 1 18G (n=60)	Group 2 20G (n=32)	P value
Age, years Mean (SD)	62 (5)	63 (6)	0.728
Prostate volume, ml, Mean (SD)	48 (15)	50 (19)	0.625
PSA, ng/ml Mean (SD)	6.38 (1.32)	6.85 (1.93)	0.221

Table 3. Prostate cancer detection rates according to needle thickness in varying PSA ranges

PSA	Needle Size	Insufficient Specimen	BPH	Prostate Cancer	ASAP	P value
2.5-4.00 ng/ml	18G (n=7)	0	5 (71.4%)	2 (28.6%)	0	0.049
	20G (n=3)	2 (66.7%)	1 (33.3%)	0	0	
4.00-10.00 ng/ml	18G (n=53)	0	34 (64.2%)	15 (28.3%)	4 (7.5%)	<0.001
	20G (n=29)	15 (51.7%)	4 (13.8%)	2 (6.9%)	8 (27.6%)	

BPH: Benign Prostatic Hyperplasia, ASAP: Atypical Small Acinar Proliferation

Table 4. Prostate cancer detection with 18G needle in group 20G

	Group 20G	Group 20G (ReBx with 18G)	P value
Insufficient Specimen	17 (53.1%)	0	<0.0001
BPH	5 (15.6%)	16 (50%)	0.0037
Prostate Cancer	2 (6.3%)	11 (34.4%)	0.0055
ASAP	8 (25%)	5 (15.6%)	0.0163

ReBx: Rebiyopsy, BPH: Benign Prostatic Hyperplasia, ASAP: Atypical Small Acinar Proliferation

Table 5. VAS (Visual Analog Scale) scores during and after PBx

	Group 18G (n=60)	Group 20G (n=32)	P value
	VAS, mean (SD)		
VAS1	2.73 (1.339)	2.97 (1.470)	0.440
VAS2	3.68 (1.432)	2.87 (1.238)	0.008
VAS3	2.10 (0.969)	1.97 (1.121)	0.560
VAS4	1.30 (0.696)	1.09 (1.027)	0.257
VAS5	0.77 (0.722)	0.59 (0.837)	0.304
VAS6	0.00	0.00	> 0.9

PBx: Prostate Biopsy, SD: Standard Deviation, VAS1: Measurement was obtained after the placement of the probe in the rectum, VAS2: During the movement of the needle and biopsy, VAS3: Fifteen minutes after biopsy, VAS4: Three hours after biopsy, VAS5: Twentyfour hour after biopsy, VAS6: Measurements were obtained three days after biopsy.

The number of patients reporting hematospermia was 6 (10%) in Group1 and 2 (6.3%) in Group 2. In both groups, none of the cases had severe hematuria, and hemoglobin and hematocrit values were not decreased in Group 2. There was no significant difference between the groups (p=0.251).

Grade 1 and 2 rectal bleeding or rectal bleeding disturbing the patient was not observed in both groups. In both groups, there was no infection and acute urinary retention due to prostate biopsy. Visual pain score (VAS) was used to evaluate pain during and after biopsy. The mean VAS2 (VAS during biopsy) score was 3.68 in Group 2 and 2.87 in Group 1. There was no significant difference in VAS scores between the groups at all times except VAS2 (p=0.008). Although the values were considered statistically significant, they were not clinically significant because the mean VAS2 score in both groups was below 4. VAS scores of both groups are shown in Table 5.

Biopsy procedure was repeated with 18G needle in all Group 2 patients. Sub-group analysis was performed in patients who underwent re-biopsy with 18 G. The effects of 18 G and 20 G needle prostate biopsies on complications were compared in Group 2 patients who underwent both needle size biopsies. All complication rates were similar except for pain. Of all VAS scores, only VAS2 score was found significantly low compared with re-biopsy procedures. Pain score of the first biopsy (20 G) was found as 2.87, whereas pain score of re-biopsy (18G) was found as 3.81 (p=0.007). Although the values were considered statistically significant, they were not clinically significant (in both needle size mean VAS2 score<4). There was no statistically significant difference in other VAS scores (P>0.05).

Discussion

The procedure of TRUS-PBx is a safe procedure that is generally well tolerated by patients used in the diagnosis of prostate cancer. However, it may rarely cause mild complications such as hematuria, hematospermia, pain, and severe complications such as acute prostatitis and sepsis requiring hospitalization (1).

In addition to the high diagnostic value of TRUS-PBx, false negative results are also encountered and re-biopsy may be necessary due to insufficient or poor quality of the tissue sample and the presence of ASAP and multifocal high grade PIN in the samples. In our study, the quality of tissue samples was very low and the frequency of ASAP was higher in the group that was biopsied with 20G needle. The diagnosis of ASAP can be decreased by increasing the quality of the samples (8).

Since 10-12 core tissue sampling has been standardized by previous studies and authors have suggested that the number of cores cannot be decreased but the amount of tissue may be reduced by using a thinner needle such as 20G (12). However, some studies reported that it may be possible to avoid complications such as unnecessary injury by performing fewer biopsies and sampling less tissue during biopsy procedures (8, 9).

Currently, despite the beginning use of MRI fusion biopsy technique, TRUS-PBx procedure continues to be used especially in clinics with insufficient technological infrastructure. MRI-targeted prostate biopsy cannot be performed yet because the technological infrastructure of our clinic is insufficient. Moreover, even in the MRI fusion biopsy, a random 12-core biopsy must be performed required as standard in addition to the lesions defined in MRI (13). Needles of 18G thickness are commonly used and 12 core tissue samples are frequently obtained from peripheral zone (12). However, MRI-targeted prostate biopsy cannot be performed in our clinic due to technical impossibilities.

However, it has been shown that the targeted number of biopsy cores can be reduced by using MR fusion biopsy which has become popular in recent years. Baco et al. (14) have not found any difference in cancer detection rates when they compared 2 core biopsies with MR/TRUS guided biopsy and 12 core biopsies randomized. In this way, it has been shown that complications can be reduced by reducing the number of cores without decreasing cancer detection rates.

Cicione et al. (15) found that needle thickness did not alter biopsy specimen quality and consistency between gleason scores detected in prostate biopsies and gleason scores obtained from radical prostatectomy specimens. İnal et al. (16) reported that cancer detection rates of 16G and 18G needles for PBx were similar, but sample quality was better when using 16G needles. It has been also shown that in two different studies, cancer detection rates and non-malignant pathology rates do not increase in prostate biopsies taken with a 16G thick needle (8, 17). Similarly, other studies have concluded that more tissue can be obtained by using longer or thicker biopsy needles, thus improving the quality of the

samples and the detection rates of cancer (18-20). Wan et al. (9) showed that there was no difference in cancer detection rates between the 18G and 20G groups, and in addition, there was no difference between Gleason scores in the prostatectomy specimen. There was slightly difference in diameter [1.02mm (18G) vs 0.81mm (20G)] between 18G and 20 G biopsy needles. However, in our study there were awful significant difference in cancer detection rate between the needles. Biopsy specimen quality was very poor and cancer detection rate was significantly lower in 20G Group. The pathologist was blinded in this study, who said that the tissue samples taken in almost all biopsies taken with 20G needles were quite thin, short and very fragmented. Therefore, all patients in the 20G Group underwent re-biopsy procedure.

The principal cause of pain in prostate biopsy is the entry of the TRUS probe into the rectum and stimulation of the prostate nerve by penetration of the rectal mucosa and prostate capsule by the biopsy needle (21). In a study of comparing 18G and 20G needles in prostate biopsy, Wan et al. (9) found that complications such as pain, hematuria and hematochezia were less frequently observed in the 20G Group, but there was no significant difference in terms of other complications. In other studies, the effect of 16G and 18G needles on all hemorrhagic complications and VAS scores in prostate biopsies was compared, but no significant difference was found (8, 17). In our study, there was no significant difference between VAS scores except VAS2 score during biopsy. VAS2 scores were significantly lower than the 20G Group. Although the values were considered statistically significant, they were not clinically significant because the mean VAS2 score in both groups was below 4.

Postoperative infection related complications of TRUS-PBx include asymptomatic bacteriuria, lower or upper urinary tract infection, and sepsis (22). We have no complication due to infection in both group patients of our study. Unlike another study (9), reduction of biopsy needle size did not lead to a decrease in any of the side effects and complications, including pain.

The limitation of our study was that the biopsy surgeon could not be blinded while the pathologist was blinded, and the number of patients in this group remained low by having to terminate the Group 2 (20G) arm of the study before reaching the planned number of patients.

Conclusion

We observed that TRUS-PBx sample quality and Prostate Cancer detection rate varied according to needle thickness in our study. It was found that the quality of the specimen deteriorated significantly and the detection rate of Prostate Cancer was quite low when using thinner (20G) needles instead of 18G needle with PBx as standard. Therefore, it was concluded that thinning of needle thickness is not a good option to reduce complication rates and side effects.

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