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Prostate Cancer

Extended 21-Sample Needle Biopsy Protocol for Diagnosis of Prostate Cancer in 1000 Consecutive Patients

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Abstract

Objective: To prospectively evaluate the diagnostic yield of a 21-sample ultrasound-guided needle biopsy protocol as the initial diagnostic strategy for detection of prostate cancer.
Materials and methods: Between December 2001 and October 2005, 1000 consecutive patients underwent 21-sample needle biopsies under local anesthesia, comprising sextant biopsies, 3 additional posterolateral biopsies in each peripheral zone, 3 biopsies in each transition zone (TZ), and 3 biopsies in the midline peripheral zone. Each prostate core was numbered and analyzed separately. The patients were divided into subgroups according to the result of digital rectal examination (DRE), serum prostate-specific antigen (PSA), and prostate volume. We evaluated the cancer detection rate overall and in each subgroup. We compared the results of our biopsy protocol to those from 6-, 12-, and 18-core biopsy protocols by analyzing only those cores from our protocol that would correspond to these biopsy schemes.
Results: Cancer detection rates using 6 biopsy samples (sextant biopsies only), 12 samples (sextant plus lateral biopsies), 18 samples (sextant, lateral, and TZ biopsies), and 21 samples (sextant, lateral, TZ, plus midline biopsies) were 31.7%, 38.7%, 41.5%, and 42.5%, respectively. The 12-sample procedure improved the cancer detection rate by 22% compared with the 6-sample procedure ($p = 0.0001$). The improvement in the diagnostic yield was most marked in patients with a prostate volume $\geq$55 ml (36.9%), in patients with normal DRE (26.6%), and in patients with PSA < 4 (37.5%). The addition of TZ biopsies to a 12-biopsy scheme increased the diagnostic yield by 7.2% overall ($p = 0.023$). Only 10 of 425 (2.3%) patients were diagnosed on the sole basis of midline biopsies.
Conclusions: Patients with suspected localized prostate cancer should be offered at least 12 biopsies in the peripheral zone and far lateral peripheral zone (statistically significant). TZ biopsies have to be considered, because these biopsies improve the diagnostic yield. For patients with abnormal DRE and/or PSA $\geq$ 20 ng/ml, the 6-biopsy scheme seems sufficient (statistically), but 6 far lateral peripheral zone biopsies as well as the TZ biopsies add little incremental value (not significant). Evidence does not support the use of routine midline peripheral zone needle biopsies in the initial biopsy to enhance the detection of prostate cancer.

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1. Introduction

Since its introduction by Hodge et al [1], random, systematic, ultrasound-guided transrectal needle biopsy of prostate has significantly improved the diagnosis and treatment of prostate cancer. This sextant method attempts to sample adequately the cancer-rich peripheral zone by directing the needle along the parasagittal plane, and the basal, median, and apical regions on both sides of the prostate. Studies [2–4] have demonstrated that a traditional sextant technique may miss substantial numbers of cancers and that additional sampling of the lateral peripheral zone may increase the diagnostic yield. Despite such modifications and strategies using 10 to 14 cores, the false-negative rate remains substantial [4]. As a result, saturation biopsy has been adopted in several centers, resulting in cancer detection rates approaching a third when extended biopsy schemes with up to 45 cores were used, even following multiple negative biopsies [5]. The application of local anesthesia has greatly decreased the pain and discomfort associated with transrectal prostate biopsy [6]. It is also possible to perform saturation biopsy with only mild discomfort for the patient. Our group demonstrated that saturation biopsy can be performed safely and effectively in the office using local anesthesia; our initial experience reported an increase of prostate cancer detection using 21 biopsies including the peripheral, middle peripheral, and transition zones [6]. Here we report the cancer detection rate in 1000 consecutive patients who had 21 biopsies at the first procedure.

2. Patients and methods

Between December 2001 and October 2005, 1000 consecutive men prospectively underwent 21-core biopsies of the prostate, because of suspected localized prostate cancer based on abnormal digital rectal examination (DRE) and/or elevated serum prostate-specific antigen (PSA) (>4 ng/ml of 3 ng/ml for patients younger than 60 yr). For all patients it was the first prostate biopsy procedure. Clinical and pathologic data, including patient age, PSA, DRE, prostate volume measured by transrectal ultrasound, Gleason score, and number and location of positive cores were abstracted from the computerized database in our institution. Patient's characteristics are shown in Table 1. All men were instructed to discontinue anticoagulants 5 d before biopsy, but biopsy ensued if they were taking aspirin or nonsteroidal anti-inflammatory drugs. Patients were prescribed enemas 1 d and 3 h before the procedure. A fluoroquinolone antibiotic was prescribed for 7 d after the procedure. All patients were adequately informed of mode of execution of the procedure and its potential complications. All procedures were performed by three senior urologists. All patients received local anesthesia by means of a 22-G spinal needle that was passed through the biopsy guide channel, followed by injection of 5 cc 2% lidocaine into each neurovascular bundle. Ultrasound examination and volume calculations were then performed. A total of 21 biopsies were taken with the use of 18-G biopsy needles and a spring-loaded

Table 1 – Comparison of clinical characteristics of the 1000 patients according to biopsy outcome

	All patients	Positive biopsy	Negative biopsy	*p* value
No. of patients	1000	425 (42.5%)	575 (57.5%)	
Age (yr)				
Mean	65	66	64	NS
Median	65	67	64	
Range	37–90	47–90	37–84	
PSA (ng/ml)				
Mean	13.59	22	7.4	<0.001
Median	6.7	8	6	
Range	0.19–2200	0.84–2200	0.19–78	
PSA density (ng/ml/ml)				
Mean	0.33	0.53	0.18	<0.001
Median	0,18	0,23	0,15	
Range	0.006–36.7	0.03–36.7	0.006–1.6	
Prostate volume (ml)				
Mean	43.8	39.7	46.8	<0.01
Median	35	31	40	
Range	10–200	10–180	10–200	
DRE				
Normal	816 (82%)	312 (38%)	504 (62%)	<0.01
Abnormal	184 (18%)	113 (62%)	71 (38%)	

NS = not significant; PSA = prostate-specific antigen; DRE = digital rectal examination.