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Ten-core versus 16-core transrectal ultrasonography guided prostate biopsy for detection of prostatic carcinoma: a prospective comparative study in Indian population

V. Surya Prakash, G. Chandra Mohan, S. Venkata Krishnaiah, V. Vijaykumar, G. Ramesh Babu, G. Vijaya Bhaskar Reddy, V. S. Mahaboob[1]

Department of Urology and Renal Transplantation, Narayana Medical College and Hospital, Nellore, India
[1]Advanced Research Centre, Narayana Medical College and Hospital, Nellore, India

Purpose: To compare the cancer detection rate in patients with raised serum prostate-specific antigen (PSA) or abnormal digital rectal examination (DRE) results between the 10-core and the 16-core biopsy techniques in an Indian population.
Methods: Between November 2010 and November 2012, 95 men aged >50 years who presented to the Urology Department with lower urinary tract symptoms, elevated serum PSA, and/or abnormal DRE findings underwent transrectal ultrasonography (TRUS)-guided prostate biopsy. A total of 53 patients underwent 10-core biopsy and 42 patients underwent 16-core biopsy.
Results: Of the 53 men in the 10-core group, 8 had cancer, whereas in the 16-core biopsy group, 23 of 42 men had cancer. Detection of prostate cancer was significantly higher in patients who underwent 16-core biopsy than in those who underwent 10-core biopsy ($P<0.001$). Among the 95 men, 44 men had abnormal DRE findings (46.3%), of whom 23 showed cancer (52.27%). Of 51 men with normal DRE findings and elevated PSA, 8 men had malignancy with a cancer detection rate of 15.68%. Among 20 men with PSA between 4.1 and 10 ng/mL, 2 (10%) had cancer. In 31 men with PSA between 10.1 and 20 ng/mL, 3 cancers (9.67%) were detected, and in 44 men with PSA >20 ng/mL, 26 cancers were detected (59.09%).
Conclusions: The cancer detection rate with 16-core TRUS-guided biopsy is significantly higher than that with 10-core biopsy (54.76% vs. 15.09%, $P<0.001$). In patients with both normal and abnormal DRE findings, 16-core biopsy has a better detection rate than the 10-core biopsy protocol. With increasing PSA, there is a high rate of detection of prostate cancer in both 10-core and 16-core biopsy patients.

Keywords: Prostate neoplasms, Prostate-specific antigen, Digital rectal examination, Transrectal ultrasonography, Prostate biopsy

INTRODUCTION

Prostate cancer has been the most common non cutaneous malignancy in United States men since 1984 and now accounts for one-quarter of all such cancers (American Cancer Society, 2008). Its incidence varies widely between countries and ethnic populations, with disease rates differing by more than 100-fold. The incidence is highest in African Americans (272 cases/100,000 men/yr) and lowest in Asian Chinese (1.9 cases/1,00,000) [1]. In the Indian population, the incidence ranges from 5.39 to 6.58/100,000 [2]. Use of serum prostate-specific antigen (PSA), digital rectal examination (DRE), and

Corresponding author: G. Chandra Mohan
Department of Urology and Renal Transplantation, Narayana Medical College and Hospital, Nellore-524003, Andhra Pradesh, India
Email: chandramohan_godala@yahoo.co.in / Tel: +918612317963 / Fax: +91-8612331763
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transrectal ultrasonography (TRUS)-guided biopsy of the prostate have led to increased detection of early-stage prostate cancer and a decrease in mortality. The method introduced by Hodge et al. [3] involving 6 systematic sextant TRUS-guided biopsies has been the gold standard protocol for this purpose. However, it is associated with a relatively high false-negative rate of 15% to 31% [4,5]. Because of concern about the possibility of missing clinically significant tumors, several investigators have considered different regimens involving more extensive sampling of the gland, particularly the far lateral aspects of the peripheral zone of the prostate [6,7]. Although it is evident that increased sampling of the peripheral zone increases the cancer yield, there is no universally accepted technique for prostate gland biopsy. Hence, we planned to study 16-core biopsy in a subset of our study population and compare it with 10-core biopsy.

MATERIALS AND METHODS

This prospective observational study was carried out in our department between November 2010 and November 2012. All male patients above 50 years of age presenting to the urology outpatient department with lower urinary tract symptoms were evaluated by DRE and serum PSA. Patients who had abnormal DRE findings or raised PSA were enrolled in the study (95 patients) and were further evaluated by TRUS-guided biopsy for diagnosing prostate cancer. In patients with normal DRE findings and PSA elevation, repeat PSA testing was done. If both PSA levels were above 4 ng/mL, the patient was subjected to TRUS-guided biopsy. In the initial consecutive 53 patients, a 10-core biopsy was done, and in the remaining 42 patients, a 16-core biopsy was performed. Patients unable or unwilling to give informed consent, patients with mental disorders, and patients with urinary tract infection or a history of previous prostate surgery were excluded from the study. Prior approval was obtained from the Institutional Ethics Committee.

1. TRUS biopsy procedure

TRUS-guided prostate biopsy is done as an outpatient procedure. A proctoclysis enema was given on the day of biopsy. Patients taking anticoagulants and anti-platelets were advised to stop medication 5 days prior to biopsy. Written informed consent was obtained for inclusion in the study. Local anaesthesia was given by per rectal instillation of Lignocaine jelly 5 to 10 minutes before the TRUS biopsy procedure. TRUS imaging of the prostate was done with the patient in the left lateral decubitus position with a Pro Focus UltraView-2202 (BK Medical ApS, Herlev, Denmark) using a biplane transrectal probe (6–12 MHz). Prostate imaging was done simultaneously in the longitudinal and transverse planes, prostate volume was calculated, and any abnormalities in the prostate were noted. The Pro-Mag Ultra automatic biopsy instrument (Angiotech Pharmaceuticals Inc., North Bend, WA, USA) with an 18-G, 20-cm needle was used for prostate biopsy.

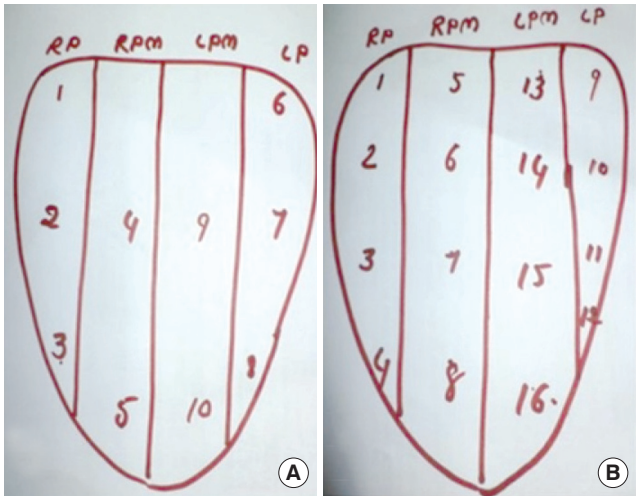

Fig. 1. Prostate biopsy sites. (A) 10 cores, (B) 16 cores. RP, right periphery; RPM, right paramedian; LP, left periphery; LPM, left paramedian.

The sites of the 10 cores (Fig. 1A) were as follows:
right periphery, 3 (1 base, 1 mid, 1 apex); right paramedian, 2 (1 mid, 1 apex); left periphery, 3 (1 base, 1 mid, 1 apex); left paramedian, 2 (1 mid, 1 apex).

The sites of the 16 cores (Fig. 1B) were as follows:
right periphery, 4 (1 base, 2 mid, 1 apex); right paramedian, 4 (1 base, 2 mid, 1 apex); left periphery, 4 (1 base, 2 mid, 1 apex); left paramedian, 4 (1 base, 2 mid, 1 apex).

On TRUS imaging of the prostate, any altered echotexture abnormalities of the prostate were noted and a systematic 10- or 16-core biopsy was done including the abnormal areas in the biopsy region. Tissue bits collected in 10- and 16-core biopsy procedures were placed in tissue paper bits and kept in 4% formalin. Each core was sent in a separate bottle to the pathology department for histopathological examination. Patients were advised to take oral antibiotics (levofloxacin 250 mg+ornidazole 500 mg twice daily) and analgesics (combination of tramadol 50 mg+paracetamol 500 mg twice daily) for 3 days starting from the day of biopsy. The results of the biopsy and the complications of the procedure were studied in the 10- and 16-core groups.

2. Statistical analysis

The statistical analysis was carried out by using SPSS ver. 16.0

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