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THE ACCURACY OF THE TRIMPROB FOR THE DIAGNOSIS OF PROSTATE CANCER: TWO-YEAR EXPERIENCE

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INTRODUCTION & OBJECTIVES: Evaluation of tissue anisotropy with the TRIMprob is a promising new technology for the early diagnosis of prostate cancer. The objective of this ongoing study was to evaluate the accuracy of the TRIMprob, total PSA and free/total PSA ratio in the diagnosis of prostate neoplasm.

MATERIAL & METHODS: Consecutive patients referred to our outpatient clinics for early diagnosis of prostate cancer were enrolled. All patients had history, physical examination with digital rectal examination of the prostate (DRE), evaluation of total and free serum PSA levels, and TRIMprob test. Evaluation of tissue anisotropy was carried out blinded as to the patient laboratory values and clinical parameters. Indications for prostate biopsy consisted in total serum PSA levels >4.0 ng/ml and/or free/total serum PSA ratio <0.18, and/or positive DRE, and/or positive TRIMprob test. TRIMprob test was considered as positive when the amplitude of the signal at 465 MHz was <50 units in an arbitrary scale from 0 to 255 units. All biopsies were carried out under ultrasound guidance and a minimum of 6 cores were obtained.

RESULTS: 705 patients (66.4 Â±7.5 years of age) enrolled between August 2002 and September 2004 were evaluable for analysis. Mean total serum PSA level was 9.9 Â±11.6 ng/ml, and free/total serum PSA ratio was 13.2 Â± 9.8. Sensitivity, specificity, positive and negative predictive values and accuracy were calculated for the diagnosis of prostate cancer. The following results were obtained:

	Sensitivity	Specificity	PPV	NPP	Accuracy
TRIMprob	0.98	0.78	0.76	0.98	0.86
Total PSA	0.89	0.08	0.39	0.53	0.37
Free/total PSA	0.88	0.30	0.48	0.77	0.42

CONCLUSIONS: The results of this study confirm the highest level of accuracy of TRIMprob test compared to total serum PSA and free/total serum PSA ratio. These data confirm our preliminary results with the TRIMprob and suggest that significant improvement of diagnostic accuracy can be obtained as long as the experience on this new technology increases. We consider that the very high negative predictive value of the TRIMprob test may be particularly useful to identify patients with PSA of 2.5 ng/ml or greater who have a very low risk of having a positive prostate biopsy. Although these data still need to be confirmed by other investigators, we remain confident that the TRIMprob may open the post-PSA era.