Urologia / Vol. 76 no. 3, S-15 2009 / pp. S1-3

The accuracy of tissue resonance interaction method probe (Trimprob tm) in non-invasive diagnosis of prostatic cancer. Analysis of the results of 782 patients

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Abstract: *The aim of our study was to evaluate the real utility of the TRIMprob test before TRUS-guided biopsy approach, putting in relation the number of positive tests of the TRIMprob with the number of positive prostate biopsies that were performed successfully. Sensitivity, Specificity, PPV (Positive predicted value), NPV (Negative predicted value) of the TRIMprob test were analyzed with statistical software package for Social Sciences (SPSS Inc, Chicago, Illinois USA). (Urologia 2009; 76: S1-3)*

Key words: *Prostate Cancer Detection, Prostate Biopsy, PSA, Prostate Cancer*

Parole chiave: *Individuazione del cancro della prostata, Biopsia prostatica, PSA, Cancro della prostata*

Introduction and aim of the study

The TRIMprob is a diagnostic device that presents notable practical uses: the test is very quick (it takes in fact 15 minutes), it is not invasive and it yields immediate results; as well as not being invasive for the patient, it does not require any prior preparation on the part of the patient before taking the test. Such uses make the device very easy for everyday practice.

The probe emits electromagnetic radiation with three frequency components: 465, 930 and 1395 MHz; a spectrum analyzer, fed by a receiving antenna, measures signal intensities that are displayed on a computer screen in three different colors: red, green and blue (1, 2) and (3).The interaction between the electromagnetic field emitted by the probe and the cancerous tissue results in a significant decrease of the signal intensity at 465 MHz (red bar), whereas the signal at 930 (green) and at 1395 (blue) do not change.

The aim of our study was to evaluate the real utility of the TRIMprob test before TRUS-guided biopsy approach, putting in relation the number of positive tests of the TRIMprob with the number of positive prostate biopsies that were performed successfully.

Sensitivity, Specificity, PPV (Positive predicted value), NPV (Negative predicted value) of the TRIMprob test were analyzed with statistical software package for Social Sciences (SPSS Inc, Chicago, Illinois USA).

0391-5603/S1-03$15.00/0

Materials and Methods

In 1992 Clarbruno Vedruccio, an Italian physicist, patented a maser for the electromagnetic detection of biologic tissue anomalies (4), (59 and (6). The equipment, named TRIMPROB (Finmeccanica, Rome, Italy) is composed of a non-linear oscillator disposed into a cylindrical probe, a radiofrequency spectrum analyzer, and a dedicated computer software (Fig. 1).

Cases of prostate cancer increase with age, therefore we are dealing with a disease typical of older men that is often underestimated. Hidden prostate cancer is more common than clinical prostate cancer. It has been estimated that 15-45% of male patients who died for other causes had a prostate tumor not clinically present.

In our study the TRIMprob was performed by a single operator who always used the same method with a transperineal approach. The patients who underwent the test were dressed in underwear only, standing with their legs slightly apart while the operator remained behind the patient with the probe in his hand (Fig. 2).

Prostate biopsy was performed under local anesthetic (10 mL of 1% Lidocaine with a 22-gauge needle) and following TRUS-guided approach. All patients underwent 18-core biopsy with a 16-gauge needle. The prostate biopsy with TRU-CUT needle has the advantage of taking a large amount of tissue for the later histological analysis and prognosis (7).

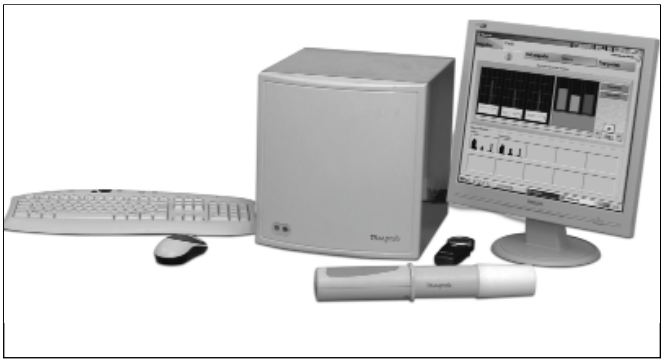

Fig. 1 - *The TRIMPROB device, consisting of a battery-operated probe, a receiver and a control computer with software for data acquisition and calculation.*

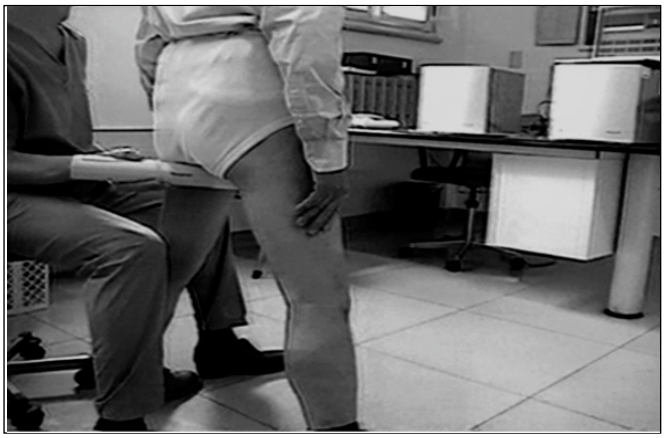

Fig. 2 - *The patients who were tested with the TRIMPROB were dressed only in underwear to reduce the contact between probe and perineum region, standing with their legs slightly apart while the operator remained behind the patient with the probe in his hand.*

Results

From November 2006 to October 2008, 782 patients were selected from ages ranging from 55 to 80, who came in our Urology clinic suffering from urinary tract syndrome. All undertook TRIMprob tests. 550 patients had a normal result whilst the remaining 238 had significant reduction of the frequency type I in one or more prostate regions; these were then invited to take a TRUS-guided biopsy. Of these 238 patients, 6 died for causes not related to prostate-related disease. Only 128 patients who were informed of the study, of median age 62.22 years (range 55-80), with a average PSA total of 5.65 ng/ml (range 0.9-17.8) and not always with a negative rectal exploration, had accepted to undertake a TRUS-guided 18-core biopsy. We have excluded from our study 7 patients having the following histological responses: HGPIN- High Grade Prostate Intraepithelial Neoplasia (3 patients), LG PIN (2 patients), ASAP- Atypical Small Acinar Proliferation (2 patients). We had divided the 128 patients into two groups on the PSA total value: the first group of 34 patients had PSA totals <4 ng/mL (26.6%) and the second group of 94 patients had PSA totals >4 ng/mL(73.4%).

TRUS-guided biopsy was performed as random technique when there were no clear hypoecogenic prostatic areas with 9 cores on the left prostatic lobe and 9 on the right prostatic lobe. Of the 128 TRUS-guided biopsy performed, 54 resulted positive for prostate cancer (42.1%) whilst 74 negative (57.9%).

From these results it emerges that sensitivity and specificity of the TRIMprob test rise for PSA total value > 4ng/ml and the VPN is surprisingly equal to 83.8% (Tab. I).

TABLE I - SENSIBILITY, SPECIFICITY, POSITIVE PREDICTIVE VALUE (PPV) AND NEGATIVE PREDICTIVE VALUE (NPV) OF THE PROSTATE BIOPSY ON A SELECTION OF PATIENTS WITH A NEGATIVE TRIMPROB RESULT

	Total patients (n=128)	**PSA <4 ng/mL** (n=34)	**PSA >4 ng/mL** (n=94)
Sensibility	75%	79.1%	84.1%
Specificity	44.6%	14.4%	67.8%
PPV	37%	17.5%	61.7%
NPV	80.4%	75%	83.8%

Comment

The TRIMprob test, as with other diagnostic investigation, is dependant on the operator and this could result in a limitation of the final statistical results even if multi-clinical studies do not confirm this finding.

Currently, studies that correlate the lowering of the first red bar with the other two bars, that give us information on the hypertrophic prostate (green bar) and vascular alterations (blue bar), have not been conducted.

This information could improve sensitivity and specificity of the TRIMprob test. Possible interference caused by the presence of cancerous tissue in other pelvic organs (rectum and bladder) is theoretically possible but did not seem to be a problem, in fact our patients did not have these related diseases at the moment of diagnosis and neither during the latest follow-up.

Conclusion

The TRIMprob test has a good correlation with the diagnose of prostate cancer for increased PSA values but it cannot be considered a substitute for cyto-histological exams. The results obtained with our study encourage us to integrate the information obtained from this method with common procedures to suggest the undergoing of a prostate biopsy and to eventually focus on bioptical core in the areas with lowering of the frequency type I.

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