

Can HistoScanning™ help in the assessment of patients with raised serum PSA level: A pilot study.

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Objectives:

Prostate HistoScanning™ is an ultrasound based tissue characterization technology that uses native ultrasound data recorded during transrectal ultrasound (TRUS) as input.

This pilot study explored for the first time the potential usefulness of HistoScanning™ for the urological work up of men with elevated serum PSA levels and without any known history of prostate disease.

Materials & Methods:

During a four week pilot study 42 consecutive men of median age 68 years (range 56-85) referred to the Department of Urology at Herlev University Hospital due to an abnormal digital rectal examination and/or high serum PSA (median level was 9.8 ng/mL, interquartile range (IQR): 6.5-13.3 ng/mL, with two patients having levels exceeding 100 ng/mL) underwent routine TRUS during which HistoScanning™ was performed. This was followed with the routine biopsy scheme (usually 6 lateral and 4 medial cores, but depending on PSA, patient age and gland volume, the number could be reduced). Only if HistoScanning™ showed suspicious areas outside the normal 10 core scheme, were additional biopsies performed.

TRUS was performed with 2ProFocus ultrasound scanner and 8818 transducer from BK Medical, Denmark;

HistoScanning™ equipment from Advanced Medical Diagnostics, Waterloo, Belgium.

Results:

HistoScanning™ showed one histoscanning volume (HV) ≥ 0.20 cc in 10 men, and two HV ≥ 0.20 cc in 24 men. On average, the largest HV accounted for 98% of the sum of all HV's (ranging 0.01-7cc) visualised in the prostate gland i.e. the total histoscanning volumes (THV). When all biopsies were negative (19 men) the median THV was 0.30cc (IQR: 0.10-0.91) and when at least one biopsy was positive (23 men) the median THV was 1.79cc (IQR: 0.65-2.45) (Kruskal-Wallis test: $p=0.0007$).

Table 1 shows that no biopsies were positive for THV < 0.20 cc. Tendency of positive biopsies steadily increased with increasing THV.

For 11 (32%) of the 34 men with THV ≥ 0.20 cc, no biopsies were positive. The discrepancy between HistoScanning™ and biopsy could be due to false positive result of HistoScanning™ or false negative result of biopsy.

Spatial correlation between HV and biopsy were allocated to each of the following six areas: the base, left and right, the middle, left and right and the apex, left and right. For 22 men out of 23 with ≥ 1 positive biopsy, a matching between the HV and the biopsy scheme was found. For one man, matching was not found.

Conclusion:

HistoScanning™ may prove useful for assisting in the management of men with raised PSA. These data will be used for developing more elaborate controlled clinical trials.

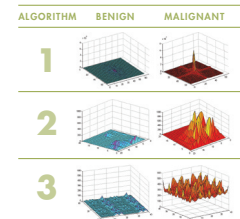
THV (cc)	At least one positive biopsy		Total	≥ 1 positive biopsy
	No	Yes		
<0.20	8	0	8	0%
0.20–0.49	4	4	8	50%
0.50–0.99	4	6	10	60%
≥ 1.00	3	13	16	81%
Total	19	23	42	55%

Table 1

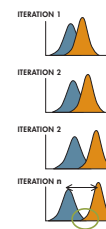
Multiple algorithms trained individually and in composite

A Several algorithms are selected based on their basic tissue differentiation characteristics

TYPICAL SIGNATURE



B Individual and composite differentiation algorithms are trained on patient data sets (scan + histology) to achieve maximum statistical separation



C Trained algorithms are implemented into the system to provide optimised differentiation

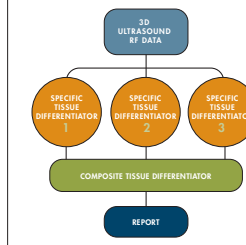


Figure 1. Principles of operation

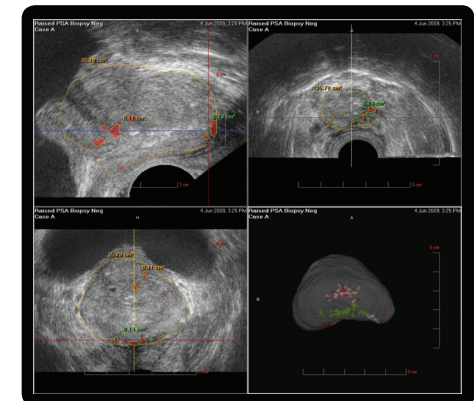


Figure 2. Prostate HistoScanning™ shows differentiated tissue foci with maximum volume at the apex.