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Introduction

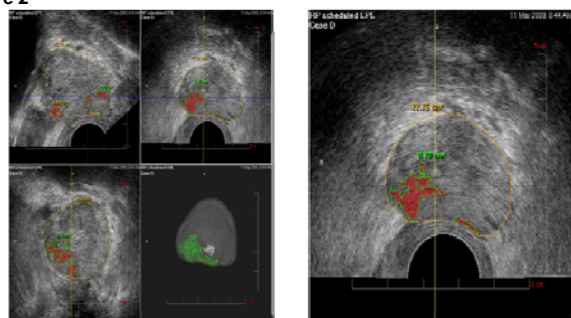
Prostate cancer diagnosis requires histological examination of the prostate tissue. In Palacky University Hospital such tissue is taken by transrectal biopsy under ultrasound control. The routine sampling scheme consists of 8-10 cores taken from the peripheral zone. A bi-planar transrectal probe 8818 with side-fire guide by BK Medical is used.

Prostate HistoScanning™ is an ultrasound based tissue characterization technology that uses as input the native (or RF - radio frequency) ultrasound data recorded during the transrectal ultrasound session (TRUS) (Figures 1 and 2). Volumes found suspicious for cancer during HistoScanning™ analysis constitute the HistoScanning™ Volume (HV) that provides information on the volume and location of cancerous tissues present in the gland.

Figure 1



Figure 2



Objective

This pilot study explored for the first time the potential of HistoScanning™ in the management of patients with a high serum PSA level and previous negative biopsies.

Methods

The study included fifty men, 46 to 77 years old, with a median serum PSA level of 6.9 ng/ml (interquartile range [IQR]: 4.1-10.0); twelve men with one, twenty-seven with two and eleven with three previous negative biopsy sessions. Prior to further biopsy, a TRUS with Prostate HistoScanning™ analysis was undertaken. Patients were then evaluated according to routine practice. Depending on the HistoScanning™ analysis, 1 or 2 additional needles could be directed towards areas outside the routine sampling scheme.

Results

HistoScanning™ Volumes (HV) estimated by Prostate HistoScanning™ decrease with increasing number of previously negative biopsy session(s). (**Table 1**) Eighteen men had at least one positive core at re-biopsy; thirty-two had a negative re-biopsy.

Sixteen men had one and six men had two suspicious HVs \geq 0.20 cc. On average, the volume of the index suspicious HV accounted for 91% of the Total HistoScanning™ Volume (THV).

The median THV was 0.71 cc (IQR: 0.34-9.00) when the re-biopsy was positive, 0.10 cc (IQR: 0.00-0.25) when the re-biopsy was negative (Kruskal-Wallis test: $p < 0.0001$).

Table 1 : Total HistoScanning™ Volume (cc) estimated by Prostate HistoScanning™ grouped according to the number of previously negative prostate biopsy sessions.

#Previous negative biopsy session(s)	No. Patients	25% quartile	Median	75% quartile
1	12	0.28	0.64	0.83
2	27	0.00	0.16	0.34
3+	11	0.04	0.18	0.40

Table 2 : relates the results of the re-biopsy session and THV to the number of previous negative biopsy sessions.

Biopsy session number	2 (1 negative)		3 (2 negative)		4 (3 negative)	
	No	Yes	No	Yes	No	Yes
At least one biopsy positive						
THV (cc) at Prostate HistoScanning						
<0.20	3	0	13	0	7	0
0.20-0.49	1	1	4	5	1	1
0.50-0.99	0	5	1	0	1	1
≥ 1.00	0	2	1	3	0	0
Total	4	8	19	8	9	2

9 / 12 men (75%) with one previous negative biopsy session and 18 / 38 men (47%) with ≥ 2 negative biopsy sessions had a THV ≥ 0.20 cc, (Fisher exact test: $p = 0.07$). For 3 men, still negative at third and fourth re-biopsy sessions (highlighted in green), suspicious areas with a THV ≥ 0.50 cc were visualised in the apex and/or the midline.

Conclusion

The number of negative biopsy sessions is inversely related to the cancer volume, i.e., the smaller the cancer foci, the more frequent the negative biopsy sessions. HistoScanning™ may prove useful for risk stratification of men with negative biopsy session(s) and has the potential to locate tumours in zones difficult to biopsy.