Inter-Operator Reliability of Prostate Histoscanning™ for the Characterisation of Prostate Cancer

Introduction and Objective: For a diagnostic test to be valid, it requires not only high performance characteristics, but must be reliable when applied by different operators. We carried out a pilot study observing the change in Prostate HistoScanning signal when the test is performed by two independent urologists.
Materials and Methods: Ten men with low risk prostate cancer on TRUS guided biopsies, undergoing Prostate HistoScanning had 3D TRUS acquisition performed by two operators. The second operator acquired images using the same equipment independently of the first operator and without alteration of the patient position. The 3D TRUS data volume files were transferred to the Prostate HistoScanning machine at the time of acquisition for processing. An analysis of HistoScanning images for Prostate Volume and Prostate HistoScanning signal was performed for both acquisitions. HistoScanning analysis is a semi-automated process in which the reporter is required to define apex, base, and left and right borders of the prostate. Delineation of the prostate outline, division into sextants, and analysis of ultrasound signal for presence or absence of cancer is automated. Linear regression was used to calculate the correlation in both gland and suspected cancer volume generated by each acquisition. Cohen's kappa statistic was performed to estimate the agreement for presence or absence of a suspicious focus ≥0.5cc in any one sextant. Kappa values indicate a range of agreement (<0 indicates no agreement, 0–0.20 slight, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 substantial, and 0.81–1 almost perfect agreement).
Results: There were 60 sextants from 10 patients analysed. Operators agreed on the presence or absence of a lesion ≥0.5cc within a sextant in 75% of sextants (n=45). Cohen's kappa co-efficient was 0.57 (95% CI: 0.30-0.72). Linear regression for prostate volume between the two acquisitions exhibited strong correlation (R^2= 0.98). For suspected tumour volume, linear regression was also good (R^2= 0.76).
Conclusions: We have shown that outputs from HistoScanning spectral image analysis were stable between two operator-acquired images. The strength of association was greater for prostate volume than it was for tumour volume as reliability in the latter is very sensitive to subtle differences in image quality.