Medium-Term Outcomes Following Primary Focal Therapy Using HIFU for Localised Prostate Cancer

Introduction and Objectives: A limited number of prospective studies have evaluated the role of focal therapy for localised prostate cancer, demonstrating encouraging short-term cancer control with low rates of genito-urinary side-effects. We evaluated the medium-term (>2 year) outcomes from trial patients followed-up within a prospective registry.
Materials and Methods: Of 118 men with localised prostate cancer (T1c-T3a, Gleason grade ≤4+3, PSA <20) treated (Sonablate® 500 HIFU) in 3 Phase I/II prospective ethics-committee approved trials (hemi, focal, or index lesion ablation), 88 have completed at least 24 months follow-up. Cancer control was assessed using histological outcomes (post-HIFU biopsies of treated or suspicious areas) and biochemical disease-free survival (BDFS) using Stuttgart (PSA nadir + 1.2ng/ml) and Phoenix (PSA nadir + 2ng/ml) criteria. Composite disease-free status was defined as histological absence of disease, or BDFS in the absence of post-operative biopsies. Functional outcomes were assessed using validated patient questionnaires (IPSS, IIEF-15, UCLA EPIC-Urinary).
Results: Median follow-up was 32 months (range 24–69). Mean number of focal treatments was 1.2. There was one non-prostate cancer related death. Absence of any cancer was 72% (52/72), and absence of clinically significant cancer (≤3mm Gleason 3+3) was 86% (62/72) on post-operative biopsy. BDFS was 66% (57/87) and 82% (71/87) using Stuttgart and Phoenix criteria, respectively. Composite disease free status was 80% and 86%, using Stuttgart and Phoenix criteria, respectively. Four men (5%) required salvage radiotherapy or adjuvant hormones. Grade III rectal toxicity occurred in 1 man, with resolution on conservative management. Preservation of continence was 99% (86/87) pad-free, and 85% (56/66) leak-free pad-free. The rate of preserved erectile function was 89% (76/85), including 40% new PDE-5 inhibitor use (32/81).
Conclusions: Our results indicate that the short-term functional benefits of focal therapy seem to extend into medium-term follow-up, alongside encouraging cancer control. Longer-term outcomes are still required.