Post-Treatment PSA Density at 6 Months Predicts Biopsy-Proven Recurrence After High-Intensity Focused Ultrasound for Localised Prostate Cancer

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PURPOSE / OBJECTIVES

PSA kinetics after focal therapy may reflect treatment completeness and residual tumour activity.
However, robust early post-HIFU biomarkers remain limited.
We evaluated whether PSA density (PSAd) measured six months after treatment predicts biopsy-proven recurrence and high-grade relapse, and compared its performance with baseline (pre-HIFU) PSAd.

MATERIAL & METHODS

This prospective series of **187** men treated with Focal One® HIFU (focal, hemi-ablation, or whole-gland) between **2018 and 2024** was extracted from a **single-centre registry** (>1,900 patients).
For **whole-gland** ablations, PSAd was calculated as PSA divided by total prostate volume; for **partial** procedures (hemi or focal), PSAd was calculated on the **treated volume**.
Post-treatment PSAd was measured at 3–9 months (median 6 months). Recurrence was defined as biopsy-positive disease or salvage therapy and stratified by Grade Group (GG1 vs GG2–3). ROC and Chi-square tests were used to identify optimal thresholds and to compare pre- and post-HIFU predictive
accuracy.

RESULTS

Overall, **81.3 %** had no recurrence and **35 / 187 (18.7 %)** recurred. Regarding management, **89.3 %** required **no second treatment**, 5.9 % underwent repeat HIFU, and the remaining cases received EBRT ± ADT. By recurrence grade, **87.7 %** showed **no progression beyond ISUP-1,** while **8.6 %** recurred as **GG2–3**.
Mean PSAd-6 m was significantly higher in recurrent vs non-recurrent patients (0.029 vs 0.011ng/mL/cm³, $p < 0.001$). The AUC for PSAd-6 m predicting recurrence was **0.81 (95 % CI 0.72–0.91, p< 0.001),** markedly superior to **pre-HIFU PSAd (AUC 0.64, p = 0.012)**.
A threshold of **0.010 ng/mL/cm³** optimally discriminated outcomes, outperforming the conventional 0.015 cut-off, particularly for **high-grade recurrences (GG2–3)** ($\chi^2 = 20.6$, $p < 0.001$). Patients with PSAd-6 m > 0.010 had an 87 % recurrence rate versus 13 % below the threshold.

AT A GLANCE

THE 6-MONTH PSA MAY TELL US MORE THAN BASELINE PSA

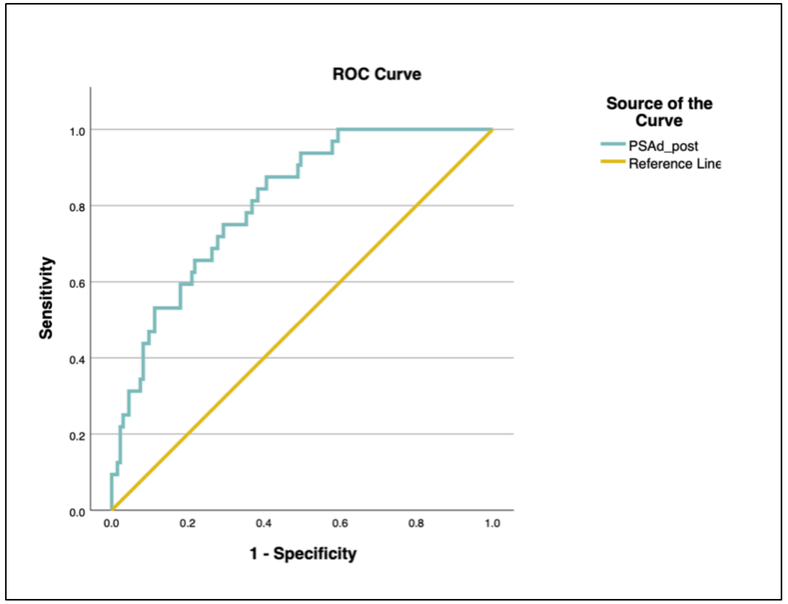
0.81
Post-HIFU PSAd AUC
95% CI 0.72–0.91

0.64
Baseline PSAd AUC
Observed comparison

0.010 ng/mL/cm³
A POTENTIAL EARLY WARNING THRESHOLD

PSA density measured around 6 months after HIFU shows **promising discrimination** of biopsy-proven recurrence, including **higher-grade disease**.

RESULTS



SUMMARY / CONCLUSION

Post-treatment PSA density at six months-calculated on the **treated volume for partial ablations** and the whole gland for total treatments-provides a stronger predictor of oncologic outcome than baseline PSAd.

A **PSAd-6 m ≥ 0.010 ng/mL/cm³** accurately identifies men at high risk of recurrence, including high-grade relapse, and shows superior discrimination (AUC 0.81 vs 0.64). Incorporating this simple biomarker into follow-up could refine post-HIFU surveillance and guide timely re-biopsy or salvage intervention.