

**ASSESSMENT OF HYPERHTERMIA COMBINED WITH RADIATION IN
TREATMENT OF LOCALLY ADVANCED PROSTATE CANCER: LONG-
TERM RESULTS OF DFCI 94-153.**

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Purpose. Hyperthermia offers potential therapeutic advantage in combination with radiation for treatment of prostate cancer. A phase 2 study was undertaken at the Dana-Farber Cancer Institute (DFCI 94-153) to provide a preliminary assessment of efficacy of transrectal ultrasound hyperthermia in combination with radiation +/- androgen suppression in treatment of locally advanced prostate cancer.

Methods and Materials. Patients with \geq T2b disease who consented to participation on this IRB approved study received 3D conformal radiation therapy in combination with 2 hyperthermia treatments at least 1 week apart during the first 4 weeks of radiation. After 4 patients were accrued, in light of changing practice patterns, 6 months of androgen suppression was allowed. Hyperthermia was administered with a 16 element trans-rectal ultrasound applicator with rectal wall, normal tissue, and intra-prostatic temperature monitoring performed during all treatments.

Results. Thirty-seven patients received a total of 72 hyperthermia treatments between September, 1997 and April, 2002. The mean CEM T₉₀ 43°C for all 37 patients was 8.4 minutes. Median follow-up was 60 months. 1992 AJCC clinical stage: T2b 19, T2c 8, T3a 5, and T3b 5 patients. Median Gleason score was 7 (6-9), and median PSA was 13.3 (2 -65) ng/ml. All patients completed radiation therapy with median dose of 6700 cGy as normalized to 95%. Thirty-three patients received androgen suppressive therapy initiated within 3 months prior to radiation. All but 2 of these patients received 6 months of AST. PSA failure was defined per the ASTRO consensus definition. With a median follow-up of 60 months (range 15-84 months) 65% of patients remain free of biochemical recurrence. Three patients developed metastatic disease of which one patient died of prostate cancer 30 months after treatment. Absolute rate of biochemical control at 24 months, the primary study endpoint, was 78% which compares favorably with a rate of 64% for similar patients on the 4 month androgen deprivation arm of RTOG 92-02 which served as the comparison group for this study.

Conclusion. Transrectal ultrasound hyperthermia combined with radiation for treatment of advanced clinically localized prostate cancer appears promising. Further study of hyperthermia in primary treatment of prostate cancer in combination with optimal radiation and systemic therapies is warranted.