Virtual HDR® Prostate CyberKnife® Radiosurgery: Efficacy, Toxicity and Quality of Life

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Objective(s): In this report we describe the PSA response and toxicity of Virtual HDR® prostate robotic radiosurgery, including full scale EPIC Quality of Life analysis.

Methods: 41 favorable and intermediate prognosis patients received 38 Gy/4 fx using “HDR-like” dose molding and margins as described in our Virtual HDR® CyberKnife® protocol. Median follow-up is 12 months and maximum follow-up is two years. All protocol patients completed the EPIC long form quality of life instrument pre-treatment, with follow-up EPIC long-from analysis available 6 months, 12-months and 18-months post-CK in 27, 20 and 10 patients, respectively.

Results: Efficacy: Biochemical disease-free survival rate: 100%. PSA (median): Pre-treatment: 6.85 ng/ml; Post-CK: 6 months – 1.3 ng/ml; 1 year – 1.1 ng/ml, 18 months - 0.45 ng/ml, 2 years - 0.25 ng/ml. Percent with post-CK PSA nadir < 0.5 ng/ml: 6 months – 22%, 1 year – 40%, 18 months – 60%, 2 years – 100%. Toxicity: Urinary Symptoms: IPSS (median): Pre-CK: 9 (34% on alpha blockers); Post-CK: 2 weeks - 20 (100% on alpha blockers); 1 month - 11 (95% on alpha blockers); 2 months - 9 (67% on alpha blockers); 6 months - 8 (43% on alpha blockers); 1 year - 11 (64% on alpha blockers); 18 months - 12 (27% on alpha blockers). Urinary Toxicity: Obstruction: zero. Self limited late hematuria (grade 2): two cases. Chronic urgency incontinence (grade 2): One case. Gastrointestinal toxicity: Maximum acute rectal toxicity Grade 2: 3 cases; Grade 1: 15 cases; Grade 0: 23 cases; Chronic rectal toxicity at last f/u: Grade 2: 1 case, Grade 1: 3 cases, Grade 0: 37 cases. Grade 3-4 GI or GU complications: Zero EPIC Quality of Life Domain Scores: Urinary: pre-CK - 85.17; Post-CK: 6 months - 86.18; 12 months - 83.03; 18 months - 88.85; Bowel: pre-CK – 94.73; Post-CK: 6 months - 92.73; 12 months – 92.05; 18 months – 91.61; Sexual: pre-CK – 51.93; Post-CK: 6 months - 44.78; 12 months – 39.1; 18 months – 50.0; Hormonal: pre-CK – 88.74; Post-CK: 6 months - 89.69; 12 months - 88.86; 18 months – 93.18.

Conclusion: No patient has relapsed. Median PSA level continues to drop with each successive evaluation, reaching 0.25 ng/ml by 2 years post-CK, with a progressively higher percentage of patients reaching PSA nadir values of < 0.5 ng/ml at each successive follow-up interval out to 2 years. There has been no grade 3 or higher toxicity. Acute grade 1-2 urinary and bowel toxicity peaks 1 - 2 weeks post-CK and typically returns to baseline by 2 months, though an elevated percentage of patients take alpha blockers for up to 18 months post-CK. EPIC long-form quality of life analysis reveals evidence of increasing sexual dysfunction to 12 months post-CK, with a suggestion of at least partial recovery by 18 months. There is no significant change in EPIC bladder, bowel or hormonal domains at any 6-month interval out to 18 months post-CK. A multi-institutional study of “HDR-like” prostate CyberKnife treatment is now underway to evaluate the efficacy, toxicity and quality of life outcome in a larger number of patients.