2593 Vardenafil Is More Efficacious Than Tadalafil for Patient’s who Requested an Alternative To Sildenafil Following Prostate Brachytherapy

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Purpose/Objective(s): To evaluate the relative impact of either tadalafil or vardenafil as second-line treatment following sildenafil for the treatment of prostate brachytherapy associated erectile dysfunction.

Materials/Methods: 54 patients with localized prostate cancer and median age of 63 years (range: 42–74) were treated with brachytherapy from 10/1995 to 6/2004. All patients were initially treated for erectile dysfunction (ED) with sildenafil followed by either vardenafil or tadalafil. Median follow-up after brachytherapy with prospective quality of life measures was 4.1 years (range 0.6 to 9.3 years). Erectile function (EF) was assessed using a physician assigned score (0 - no erections, 1 - erections insufficient for intercourse, 2 - erections suitable for intercourse, 3 - normal function) and beginning in June of 2000, the validated five question International Index of Erectile Function (IIEF-5) was used as a complimentary method to quantify late EF. Detailed notes were made regarding pharmacological intervention for EF on a standardized data collection form. The Pearson's chi-square test and Student t-test were used to compare groups.

Results: The median time to the first use of sildenafil from radiotherapy was 1.6 years (range 0.4 to 8.1). 35% (19/54) used sildenafil consistently for ≥12 months during their course of follow-up. 24% (13/54) were given a prescription for vardenafil and 76% (41/54) were given a prescription for tadalafil. 31% (4/13) of patients treated with vardenafil and 32% (13/41) of patients treated with tadalafil reported a physician assigned EF rise of 1 or more in the next follow-up period (p=0.95). 9% (1/11) of men taking vardenafil experienced a decline in IIEF-5 versus 42% (14/33) of men taking tadalafil (p=0.04). In contrast 33% (3/9) patients taking vardenafil and 0% (0/23) using tadalafil experienced a rise in IIEF-5 above 20 (p=0.001). The mean rise in the IIEF-5 of the vardenafil group was 3.7 (95%CI:2.3–9.7) versus 0.4 (95%CI:3.6–4.4) for the tadalafil group (p=0.04).

Conclusions: Approximately 1/3 of patients have a clinically significant response to tadalafil or vardenafil as second line ED treatment following brachytherapy. Based on a hypothesis generating analysis of patient reported questionnaires, vardenafil has a more significant positive impact on sexual health than tadalafil following patient disaffection with sildenafil for brachytherapy induced ED. Further investigation of these agents in radiation-induced ED is warranted.

Author Disclosure: J. L. Park, None; J. A. Cesaretti, Department of Defense, B. Research Grant; National Institutes of Health, B. Research Grant; C.R. Bard, D. Speakers Bureau/Honoraria; J. Kao, Department of Defense, B. Research Grant; National Institutes of Health, B. Research Grant; N.N. Stone, Prologics Inc., E. Ownership Interest; R.G. Stock, C.R. Bard, D. Speakers Bureau/Honoraria.

2594 Efficacy, Toxicity, and Quality of Life Outcomes in a Phase I Study of Hypofractionated Dose-Escalated Thoracic Radiotherapy for Limited-Stage Small Cell Lung Cancer

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Purpose/Objective(s): To determine the maximal tolerated dose of hypofractionated thoracic radiotherapy with concurrent chemotherapy for limited-stage small cell lung cancer patients.

Materials/Methods: Patients received one of three radiotherapy regimens: 50 Gy, 58 Gy or 62 Gy in 25 daily fractions. We planned to accrue six patients to each dose level, with accrual to the next highest dose level occurring sequentially if acute toxicity rates at the previous dose were acceptable. Radiotherapy was given with 4 cycles of concurrent cisplatin and etoposide. All complete/near complete responders were offered prophylactic cranial irradiation. The maximal tolerated dose of radiotherapy was based on the dose which caused unacceptably high rates of radiotherapy-related toxicity. Disease-free and overall survival were calculated from the date of registration onto the trial. Quality of life was assessed before, during, and after radiotherapy using weekly assessment of patients’ Karnofsky Performance Status, Radiation Therapy Oncology Group patient-reported swallowing and physician-reported dysphagia logs, and the European Organization for the Research and Treatment of Cancer QLQ-C30 and QLQ-LC13 questionnaires.

Results: Thirteen patients were accrued. The trial was closed after patients given 58 Gy experienced excessive rates of acute grade 3 esophagitis (3 of 6 patients). There were no treatment-related deaths. Median overall survival and disease-free survival was 10.9 and 9.4 months, respectively, with no significant differences between patients receiving 50 Gy or 58 Gy. Patients’ Karnofsky Performance Status did not significantly change from baseline. There was a significant trend for deterioration of patient-reported swallowing and physician-reported dysphagia for all patients throughout the course of radiotherapy. There was a significant trend for worsening of fatigue and pain from baseline to 6 weeks post-radiotherapy completion for all patients. Compared to patients treated with 50 Gy, patients given 58 Gy had significantly worsened fatigue, insomnia, dysphagia, chest pain, arm/shoulder pain, global health status and social functioning by the end of radiotherapy. At 6 weeks post-radiotherapy completion, patients given 58 Gy reported significantly worsened fatigue and impaired role functioning compared with patients given 50 Gy.

Conclusions: The maximal tolerated dose of thoracic radiotherapy with concurrent chemotherapy on this trial was 50 Gy in 25 daily fractions. Patients treated with chemoradiotherapy on this trial experienced deterioration of their quality of life during their treatments. Dose escalation to 58 Gy on this trial resulted in significantly worsened patient-related quality of life parameters compared to patients given 50 Gy of thoracic radiotherapy.

Author Disclosure: D. Yee, None; B. Danielson, None; R. Halperin, None; J. Hanson, None; T. Nijjar, None; C. Butts, None; M. Smylie, None; T. Reiman, None; W. Roa, None.