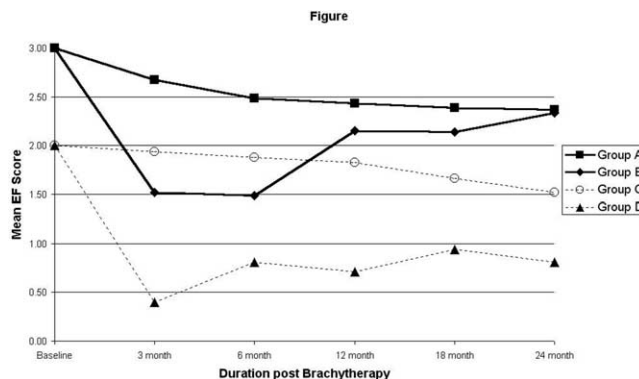


pre-treatment EF and HT on EF at 3, 6, 12, 18, and 24 months post brachytherapy was evaluated. Potency was assessed using the Mount Sinai EF score four point assessment (MS EFS, Stock RG et al, J Urol, 165(2); 436, 2001) prior to implant and at follow-up. Excellent potency (score of 3) was defined as normal EF. Moderate potency (score of 2) was defined as erections sufficient for intercourse but considered suboptimal. A score of 1 was defined as the ability to have erections but insufficient for intercourse. A score of 0 was defined as the complete inability to have erections. Preservation of EF was defined as the percentage of patients with scores of 2 and 3 at each point in time. HT consisted of LHRH agonist with or without an anti-androgen agent administered either as a 3 month neoadjuvant course or a 6 month combined neoadjuvant and adjuvant course (mean 4.9 months). 4 groups were evaluated: group A with a pretreatment EF score of 3 and no HT (n = 344), group B a pretreatment EF score of 3 and HT (n = 131), group C a pretreatment EF score of 2 and no HT (n = 119), and group D a pretreatment EF score of 2 and HT (n = 44). Statistical analyses were performed using Wilcoxon rank sum and Spearman rank correlation tests.

**Results:** Patients with excellent pre-treatment EF (score of 3) who received HT (group B) achieved a statistically significant decline in EF compared with those who underwent brachytherapy alone (group A) at 3, 6, 12, and 18 months ( $p < 0.05$ ). At 12 months, group B patients noted a clinical improvement in EF that was sustained and enhanced resulting in no statistical difference in mean EF scores between groups A and B at 24 months ( $p > 0.50$ ) (See figure). Preservation of EF was 93%, 87%, 87%, 83%, and 83% for group A and 52%, 50%, 80%, 75% and 85% for group B at 3, 6, 12, 18, and 24 months, respectively. Patients with a pretreatment EF score of 2 who received HT (group D) noted a statistically significant reduction in EF compared with those who underwent brachytherapy alone (group C) at all time intervals ( $p < 0.05$ ), which in contrast to the patients with a pretreatment score of 3 did not recover by 24 months (See figure). Preservation of potency was 69%, 69%, 68%, 60% and 58% for group C and 10%, 25%, 19%, 19%, and 19% for group D at 3, 6, 12, 18, and 24 months, respectively. There was no relationship between radiation dose and EF ( $p > 0.20$ ).

**Conclusions:** Men with excellent EF prior to brachytherapy who received HT were observed to have a significant decline in EF that normalized only after 24 months. In contrast, men with moderate EF prior to brachytherapy who received HT were found to have an immediate and sustained decline in EF that did not normalize after 24 months. Men with moderate EF undergoing brachytherapy and receiving HT should be advised of the potential for a significant decline in EF.



**1021 The Role of Prophylactic Tamsulosin ± Dexamethasone in Patients Undergoing Prostate 125I Seed Implants for Prostate Carcinoma. A Randomized Double-Blind Study**

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**Purpose/Objective:** To evaluate the effectiveness of dexamethasone in reducing the peak AUA urinary symptom scores and rate of intermittent self-catheterization (ISC) for patients with prostate adenocarcinoma treated with prophylactic Tamsulosin and prostate 125I seed implant.

**Materials/Methods:** A double-blind, placebo controlled, randomized trial for patients undergoing 125I prostate implant (PI) treated with prophylactic Tamsulosin comparing dexamethasone vs. placebo is being performed. Eligibility criteria include patients undergoing PI who are not taking tamsulosin or other alpha-blockers, are not on any form of steroid medication and are not insulin dependent diabetics. Patients receive either dexamethasone (4mg PO once a day for 10 days followed by a 2mg taper PO each day for four days) or placebo starting the day of the implant. All patients receive prophylactic tamsulosin (0.8 mg to be taken PO once a day). All patients start tamsulosin 4 days prior to prostate implant and continue for 60 days. Patients are taken off the study if they develop urinary retention requiring catheterization (ISC), have intolerable urinary symptoms, or wish to discontinue the trial for other reasons. The American Urologic Association (AUA) symptom index questionnaire is being used at baseline and on a weekly basis for 12 weeks to assess the irritative and obstructive urinary symptoms after PI. The percent change from baseline AUA symptom score over the 12 weeks was compared using repeated measures analysis. Chi square analysis was used to compare ISC rates.

**Results:** From 3/19/03 to 3/17/04, 96 of a planned 100 pts. have been enrolled. 58 patients have either completed the 12 weeks of followup, have requested to be removed from the trial or have utilized ISC. Of these 58, 52 completed patients are evaluable for an interim analysis of the effectiveness of treatment, (24 and 28 patients in the dexamethasone and the placebo groups, respectively). The rate of ISC was 29.2% in the dexamethasone arm and 17.9% in the placebo arm ( $p = 0.33$ ). When evaluating the patients who did not utilize ISC, the overall percent change from baseline AUA symptom score was different between the two arms in favor of the placebo group ( $p = 0.0413$ ). Early termination criteria were not met and the trial continues to completion.

**Conclusions:** The preliminary finding of worse toxicity associated with dexamethasone is surprising. It may be related to the fact that the dexamethasone is very effective in relieving post-operative edema resulting in a slightly higher radiation dose to the prostatic urethra yielding more acute radiation-related toxicity. Regardless, this randomized, double blind, placebo controlled trial will continue to accrue the planned total of 100 patients and the final results will be available for the ASTRO 2004 conference.

## 1022 Factors Predicting for Urinary Incontinence Following Prostate Brachytherapy

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**Purpose/Objective:** To define risk factors that predict for urinary incontinence following 125I prostate brachytherapy.

**Materials/Methods:** Urinary incontinence following 125I prostate brachytherapy was evaluated using a patient self-assessment questionnaire based on the NCI Common Toxicity Criteria (version 2). Grade 0 is defined as no incontinence, grade 1 incontinence occurs with coughing, sneezing or laughing, grade 2 is spontaneous incontinence with some control and grade 3 is no control. One hundred and fifty-three patients received monotherapy (145 Gy) 125I implants from October 1996 through December 2001 and 112 (75%) responded to our survey. Median follow-up was 47 months (range 14–74). Patient characteristics included a preimplant prostate specific antigen (PSA) < 10, Gleason score (GS) < 6, and stage < T2b. CT based postimplant dosimetry was analyzed approximately 30 days after the procedure, and dose volume histograms of the prostate and the prostatic urethra were generated based on contoured volumes. Dosimetric parameters evaluated as predictive factors for incontinence included the prostate volume; total activity implanted; number of needles; number of seeds; seed activity; urethral D5, D10, D25, D50, D75, D90 doses; prostate D90 doses; and prostate V100, V200, V300. Clinical parameters evaluated included age, Gleason score, PSA, pre-implant I-PSS and length of follow-up.

**Results:** Urethral D10 dose and preimplant I-PSS predicted for urinary incontinence on multivariate analysis ( $p = 0.002$  and  $p = 0.003$  respectively). Twenty-eight patients reported grade 1 incontinence (26%) and 5 patients reported grade 2 (5%). Patients with grade 1 and 2 incontinence were analyzed together because of the small number of patients who experienced grade 2. No patients reported grade 3 incontinence. Mean urethral D10 was 314 + 78 Gy in patients with grade 0 compared with 394 + 147 Gy in patients with grades 1,2 incontinence ( $p = 0.002$ ). The incidence of incontinence doubled as the urethral D10 dose increased above 450 Gy. Patients with grade 0 had mean preimplant I-PSS score of 6.6 + 4.5 compared with 10.0 + 6.4 for grades 1, 2 ( $p = 0.003$ ). A significant increase in the incidence of incontinence was noted when the preimplant I-PSS was greater than fifteen. No relationship was noted between incontinence and prostate volume, total activity implanted, or the number of needles used ( $p = 0.83$ ,  $p = 0.89$ ,  $p = 0.36$ , respectively).

**Conclusions:** Urethral D10 dose and preimplant I-PSS are predictive for patients at higher risk of urinary incontinence. To decrease the risk of this complication, an effort should be made to keep the urethral D10 dose as close to the prescribed dose as possible, and the preimplant I-PSS should be thoroughly evaluated in an attempt to select patients with scores less than fifteen.

## 1023 Impact of High-Dose Radiation on Erectile Function in Patients Treated with Intensity-Modulated Radiation Therapy for Prostate Cancer

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**Purpose/Objective:** High-dose external beam radiation has improved outcomes significantly for prostate cancer. There is a concern that these higher doses may compromise quality of life (QOL) and be a factor in the development of post-treatment erectile dysfunction (ED). There are reports that intensity-modulated radiation therapy (IMRT) can reduce the dose received by erectile tissues. In this study, we evaluated the impact of IMRT for localized adenocarcinoma of the prostate (CaP) on sexual function. The effect of sildenafil on ED after IMRT was also studied.

**Materials/Methods:** The records of 194 patients who underwent IMRT for CaP from 3/98 to 12/03 were retrospectively reviewed. Patients were treated to 70 to 78 Gy at 2 to 2.5 Gy/fx. Eighty-six percent were treated to 70 Gy at 2.5 Gy/fx. Potency was assessed with the self-administered International Index of Erectile Function (IIEF5) questionnaire before and after IMRT. This questionnaire consists of 5 questions regarding sexual function with a maximum score of 25 points. ED was defined as a decrease of 5 points or more between the pretreatment and post-IMRT IIEF5 scores. Penile bulb dosimetry (total dose, mean dose, D50, V10, V20, V30, V40, V50, V60, V70, V80, V90, and V100) was available for 87 (54%) patients. To determine if penile bulb dose contributed to ED, penile bulb dosimetry was compared to a decrease in IIEF5 score of 5 points or more using logistic regression.

One hundred sixty-five (85%) patients were sexually active before the start of treatment. Four (2%) of these patients were not sexually active after treatment. Follow-up IIEF5 scores of the remaining 161 patients were used to assess sexual function. Median time to IIEF5 assessment was 24.3 months (range: 0 to 63.6). For the 66 (41%) patients who reported using sildenafil at the time of the post-treatment IIEF5 questionnaire, an IIEF5 score with and without the use of sildenafil was recorded. A paired t-test was done to see if there was an improvement in sexual function with the aid of sildenafil.

**Results:** Sixty-six (41%) out of 161 patients had a decrease in IIEF5 of 5 points or more. The rate of ED for time intervals less than 12 months, 12 to less than 24 months, 24 to less than 36 months, and 36 months or more were 12%, 52%, 44%, and 49% respectively. For the patients who took sildenafil for ED, the mean IIEF5 score without sildenafil was 9.7 vs. 16.4 with the use of sildenafil ( $p < 0.0001$ ). The use of sildenafil increased sexual function by 5 points or more in 73% of the patients. The improvement in ED with the use of sildenafil for time intervals less than 12 months, 12 to less than 24 months, 24 to less than 36 months, and 36 months or more were 70%, 82%, 72%, and 63% respectively.

The median penile bulb volume was 7.0 cc, median mean penile bulb dose was 40.4 Gy, and median D50 was 41.7 Gy. The