

	LDR	HDR	EBRT	p-value
age (years)	68±6	73±4	71±7	<0.001
follow-up (months)	18±8	22±8	14±8	<0.001
urinary function	90±15	79±26	96±7	<0.001
urinary bother	75±23	74±26	84±16	n. s.
leaking urine ≥ once a day	11%	29%	3%	0.004
pain with urination ≥ once a day	11%	26%	0%	0.005
bowel function	89±13	84±18	92±11	0.049
bowel bother	88±18	88±18	91±16	n. s.
rectal urgency ≥ half the time	15%	31%	10%	0.050
sexual function	32±22	21±23	20±21	0.026
sexual bother	51±36	47±37	41±39	n. s.
inability to have an erection	33%	51%	64%	0.015

174 The Role of Prophylactic Tamsulosin (Flomax) in Patients Undergoing Prostate 125-I Seed Implants for Prostate Carcinoma: Final Report of Double-Blind Placebo-Controlled Randomized Study

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Purpose/Objective: To evaluate the effectiveness of prophylactic tamsulosin (Flomax) in reducing the urinary symptoms for patients undergoing 125-I prostate implant.

Materials/Methods: A single institution, double blind, placebo controlled, randomized trial for patients undergoing 125I prostate implant (PI) comparing prophylactic Tamsulosin (Flomax) vs. placebo. Eligibility criteria include patients undergoing PI, who were not taking Tamsulosin (Flomax) or other alpha-blockers prior to PI. The patients received either placebo or Tamsulosin (Flomax)(0.8 mg) to be taken PO once a day). All patients started the medication 4 days prior to prostate implant for duration of 60 days after PI. The American Urologic Association (AUA) symptom index questionnaire was used at baseline and on a weekly basis for 8 weeks to assess the severity of urinary symptoms after PI. For quality assurance purpose, all AUA questionnaires were conducted by one physician (ME). Patients were taken off the study if they developed urinary retention, had intolerable urinary symptoms, or did not wish to continue with the trial. Repeated measures analysis of variance (ANOVA) was done to see if there was a difference in AUA scores between the two treatment arms over the duration of the study period. Unpaired t-tests were done to compare AUA score between the two arms on a week by week basis.

Results: One-hundred eighteen patients were enrolled in this study from 11/2001 to 1/2003 (58 in the tamsulosin arm and 60 patients in the placebo arm). Pretreatment, treatment and post-implant characteristics were comparably matched between the 2 groups. The urinary retention rate was 17% (ten patients) in the placebo group compared to 10% (six patients) in the Tamsulosin (Flomax) group (p=0.3160). Eighty-eight percent (14 patients) of those who developed urinary retention experienced it within 2 weeks after the PI. Intolerable urinary symptoms were reported equally (10 patients in each arm), with 70% of it in the first 2 weeks after PI. There was a significant difference in AUA score in favor of Tamsulosin (Flomax) at week 5 after PI (p=0.0330).

Conclusions: Prophylactic Tamsulosin (Flomax)(0.8 mg/day) did not significantly affect urinary retention rate but had a positive effect on urinary morbidity at week 5 after PI. Currently, we are conducting a similar study comparing prophylactic tamsulosin and dexamethasone vs. tamsulosin alone for patients undergoing prostate brachytherapy in an attempt to improve the obstructive urinary symptoms.