

patients received a course of hormone deprivation for 6 months at least. One biochemical relapse was observed in this cohort of patients. Five patients died during the follow-up period without cancer relapse or toxicity. Acute genitourinary toxicity was observed in 81% of patients with maximal score of 2 in 40.9% of patients. Charlson score greater than 4 did not predict an increase in toxicity. Rectal acute toxicity grade 2 with mucosal discharge was present in 17.6% of patients. Presence of any acute rectal toxicity risk was increased by 2.3 fold in the shorter OTT (cut-point 47 days). Late rectal toxicity Grade 3 was seen in 1 patient, and 5 more patients showed a grade 2 score. Chronic urinary toxicity grades 1-2 were observed in 27.5% of patients, but only 2 patients had grade 2 urinary toxicity.

Conclusion: IMAT with SIB to the prostate was well tolerated, with acceptable rates of acute and early late toxicity. Shorter OTT seems to increase the risk of acute rectal toxicity. Charlson score should not be considered as a predictor factor for toxicity. Additional follow-up is necessary to fully define the long-term toxicity.

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2532

Risk Group and Death From Prostate Cancer Among Men Undergoing Brachytherapy

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Purpose/Objective(s): We estimated prostate cancer-specific mortality (PCSM) risk following brachytherapy with or without neoadjuvant external beam radiation therapy (EBRT) and/or short-course androgen deprivation therapy (ADT) among men with high-, unfavorable intermediate-, favorable intermediate-, and low-risk prostate cancer (PC).

Materials/Methods: The prospective study cohort comprised 6595 consecutively treated men with T1-4, N0M0 PC whose treatment included low-dose-rate brachytherapy between October 16, 1997 and May 28, 2013. Men with low- and favorable intermediate-risk PC were treated with brachytherapy, whereas men with unfavorable intermediate-risk PC were treated with brachytherapy and neoadjuvant ADT (median 4 months) with or without neoadjuvant EBRT, and men with high-risk PC received all 3 treatments. Fine and Gray competing risks regression were used to assess whether PCSM risk was increased in men with high-, unfavorable intermediate- and favorable intermediate- risk as compared with low-risk PC, adjusting for age at and year of brachytherapy, as well as known PC prognostic factors.

Results: After median follow-up of 7.76 years, 820 men died (12.43%): 72 of PC (8.78%). While men with favorable intermediate-risk PC did not have significantly increased PCSM risk as compared to men with low-risk PC (adjusted hazard ratio [AHR] 1.29, 0.57-2.89 95% confidence interval [CI], *P* value .54), men with high- (AHR 3.60, 1.07-12.12 95% CI, *P* value .04), and unfavorable intermediate-risk PC (AHR 2.99, 1.39-6.45 95% CI, *P* value .005) did. Ten-year unadjusted point estimates of PCSM were 8.09% (5.19%-11.81% 95% CI), 2.85% (1.62%-4.63% 95% CI), 1.26% (0.72%-2.07% 95% CI), and 0.83% (0.55%-1.22% 95% CI) for men with high-, unfavorable intermediate-, favorable intermediate-, and low-risk PC, respectively. Please see Table for additional results.

Conclusion: In the setting of high-dose radiation consisting of EBRT and brachytherapy, men with high-risk PC have low absolute estimates of PCSM (<10%) during the first decade following treatment despite receiving only short course ADT. Whether long-term ADT can lower PCSM risk for these men requires additional study. Table. Multivariable Competing Risks Regression Analysis

Poster Viewing Abstracts 2532; Table 1

Clinical characteristic	Number of men	Number of deaths	AHR (95% CI)	<i>P</i> value
Age (years)	6595	72	1.04 (1.01, 1.08)	.01
Year of brachytherapy	6595	72	0.85 (0.78, 0.92)	<.0001
PSA (ng/ml)	6595	72	1.004 (1.00, 1.008)	.07
Gleason 8-10	280	18	2.05 (0.65, 6.47)	.22
7	1395	20	0.85 (0.44, 1.64)	.63
6 or less	4920	34	1.0 (Reference)	-
T-category T3-4	125	9	3.09 (1.16, 8.20)	.02
T2	1599	35	1.83 (1.04, 3.21)	.04
T1	4871	28	1.0 (Reference)	-

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2533

The Effect of Milk of Magnesia on the Consistency of Interfraction Rectal Filling During Prostate Cancer Volumetric Modulated Arc Therapy

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Purpose/Objective(s): To investigate the effect of milk of magnesia (MoM) on interfraction variation in rectal filling and acute rectal toxicity.

Materials/Methods: Two groups were retrospectively identified; each consisting of 20 patients with localized prostate cancer treated with volumetric modulated arc therapy (VMAT) to the prostate ± seminal vesicles, to a prescribed dose of 78 Gy in 39 fractions over 8 weeks. The first group was instructed to follow a bowel regimen with antitflatulent diet and MoM started 3 days prior to planning computed tomography (P-CT) scan and continued during radiation therapy, while the second group followed simple dietary advice to achieve an empty rectum. The rectum between the superior and inferior extent of the clinical target volume (CTV) was delineated by a single observer on the P-CT and on 8, weekly cone beam CT images (CBCT). Rectal filling was assessed by measurement of antero-posterior diameter of the rectum at the superior (AP-S), mid (AP-M), and inferior (AP-I) level of the CTV and by calculation of rectal volume (RV) and average cross-sectional rectal area (CSA; defined as the rectal volume divided by length). The differences in these measurements were compared between the 2 groups and data relating to acute Radiation Therapy Oncology Group (RTOG) rectal toxicity was extracted from patients' medical charts.

Results: A total of 360 images, including 40 P-CT and 320 CBCT images from 40 patients were analyzed. In comparison of the 2 groups (MoM vs non-MoM patients), there was no statistically significant difference either in RV (median: 28 cm³ vs 34 cm³, *P* = .99); change in RV between P-CT and CBCTs (mean: 3 cm³ vs 1 cm³, *P* = .99); average CSA (median: 6 cm² vs 6 cm², *P* = .98), change in average CSA between P-CT and CBCTs (mean: 0.1 cm² vs 0.4 cm², *P* = .99); changes in AP-S (mean: 0 cm vs 0.1 cm, *P* = .99); AP-M (mean: 0.2 cm vs 0.2 cm, *P* = .99); or AP-I (mean: -0.5 cm vs -0.1 cm, *P* = .93). In the MoM group, the mean volume of MoM taken by patients was 29 cm³ (range, 15–45 cm³) in the first week and 12 cm³ (range, 0–30 cm³) in the last week. The proportion of patients who took MoM decreased from 100% in the first week to 60% in the last week. Acute RTOG rectal toxicity in MoM/non-MoM groups consisted of G2 diarrhea (n = 2/1), G1 diarrhea (n = 13/4), and G1 proctitis (n = 3/3).

Conclusion: MoM did not appear to reduce the interfraction variation in rectal filling compared to simple dietary advice, although the analysis was limited by small patient numbers. MoM may cause diarrhea and a substantial proportion of patients discontinued its use by the end of radiation treatment.

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2534

Dose Escalation Using a Hydrogel Spacer for Intensity Modulated Radiation Therapy in Prostate Cancer

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Purpose/Objective(s): To quantify dose reduction to organs at risk (OAR) and to assess potential dose escalation in intensity modulated radiation therapy (IMRT) treatment of prostate cancer using an absorbable hydrogel rectal spacer.

Materials/Methods: Imaging and treatment planning for men undergoing IMRT for localized stage T1-T2 prostate cancer was performed before and after implantation of a hydrogel spacer between the prostate and the anterior rectal wall. Pre- and postimplant plans, optimized to satisfy dose-volume criteria for rectum, bladder, and penile bulb, were analyzed to determine the dose (Dx) covering critical percent volumes (x) of these structures. Dx constraints for rectum were 75, 70, 65, 60, and 50 Gy at x = 15%, 20%, 25%, 35%, and 50% volume, respectively. Dx for bladder were 80, 75, 70, and 65 Gy at x = 15%, 25%, 35%, and 50% respectively. Mean penile bulb dose constrained to be ≤52.5 Gy. Dose-volume histograms (DVHs) were recalculated during central review of plans using prostate, rectum, and bladder contours drawn by core lab physicians. The ratio of the dosimetric criteria and Dx values from these DVHs was used to calculate a dose escalation factor (DEF) by which the plan dose could be scaled without violating protocol OAR dose criteria. A comparison of DEF for pre- and postimplant plans was used to assess reduction in OAR doses achieved by use of spacer. For each plan, an overall DEF (minimum DEF satisfying constraints all OARs) and a rectal DEF (satisfies only rectal constraints) were computed.

Results: One hundred and one pairs of plans from 5 clinical sites treating at least 14 spacer subjects each were analyzed. Mean overall DEF was 1.18 (preimplant) versus 1.45 (postimplant) ($P<.0001$). Mean rectal DEF was 1.23 (preimplant) versus 1.63 (postimplant) ($P<.0001$). The average increase in DEF between corresponding pre- and postimplant plans was 24% (overall) and 34% (rectal). The mean (\pm SD) for overall DEF computed individually for the 5 clinical sites were 0.98 ± 0.09 , 1.05 ± 0.09 , 1.23 ± 0.17 , 1.23 ± 0.20 , and 1.29 ± 0.21 (preimplant) and 1.06 ± 0.09 , 1.39 ± 0.28 , 1.45 ± 0.25 , 1.45 ± 0.32 , and 1.67 ± 0.31 (postimplant), respectively ($P<.03$ for all.)

Conclusion: The average increase in DEF observed between pre- and postimplant plans is consistent with comparison of rectal V70 between control and spacer subjects from prior analysis of this trial, indicating the effectiveness of an implanted tissue spacer in reducing dose to adjacent organs at risk. In this analysis, the increased DEF can also be viewed as a measure of the potential for dose escalation without plan reoptimization and without an increase in toxicity of the rectum, bladder, or penile bulb. The variation of DEF among clinical sites may reflect differences in the degree of plan optimization and dose conformity.

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2535

Permanent Prostate Brachytherapy Monotherapy With I-125 for Low- and Intermediate-Risk Prostate Cancer: Outcome in 966 Patients

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Purpose/Objective(s): To examine outcomes after permanent prostate brachytherapy monotherapy (PPBM) with I-125 for clinically localized prostate cancer (CaP).

Materials/Methods: This study includes 966 consecutive patients (pts) treated with I-125 PPBM between May 1998 and January 2013 with a minimum of 2 years follow-up and at least 1 post-PPBM serum prostate-specific antigen (PSA). A preplanned loose seed applicator approach was used initially (n=440) and afterloading of stranded seeds (n=526) thereafter. All pts had computed tomography (CT)-based postimplant dosimetry (97% <24 hours). Median age was 69 years (range 42-86 years); Gleason (GI) scores were ≤6 (n=781, 81%), 3+4 (n=147, 15%), or 4+3 (n=38, 4%); median PSA was 5.8 ng/mL (IQR 4.2-7.8 mL); and clinical tumor stage was ≤T1c (n=718, 74%), T2a (n=211, 22%), or T2b-c (n=37, 4%). National Comprehensive Cancer Network risk group was low risk (LR) (n=685, 71%) and intermediate risk (IR) (n=281, 29%). Androgen deprivation therapy (ADT) was used in 247 pts (26%), primarily for cytoreduction. Freedom from biochemical failure (FFBF) used the nadir+2 (Phoenix) criteria. Survival estimates used the Kaplan-Meier method. Univariate analysis was performed by log-rank, and multivariate analysis (MVA) by proportional hazards with $\alpha=.05$.

Results: Median follow-up is 69 months (IQR 36-108 months). PSA median follow-up was 51 months (IQR 27-85 months). Median prostate D90 was 159 Gy (tenth to ninetieth percentile: 140-181 Gy) and D90 > 80% in >99% of cases. PSA failure occurred in 45 pts. Overall survival (OS) at 5 and 10 years was 94% (95% confidence interval [CI] 92-95) and 74% (95% CI 69-78). Ten-year CaP-specific survival was 99% versus 96% ($P=.01$) in LR versus IR. FFBF at 5 and 10 years is 97% (95% CI 95-98) and 85% (95% CI 80-90). OS at 5 and 10 years in LR or IR disease was 95% versus 90% and 74% versus 73% ($P=.44$), respectively, and FFBF was 98% versus 93% and 90% versus 74% ($P<.01$). FFBF at 5 and 10 years for pts with GI 3+3 versus 3+4 was 98% versus 95% and 87% versus 80% ($P=.14$), respectively, whereas 5-year FFBF for pts with GI 4+3 was 74% ($P<.01$) (10 years was not reached). OS at 5 and 10 years with or without ADT were both 94% and 74% ($P=.28$), and FFBF with or without ADT at 5 and 10 yrs was 98% versus 96% and 95% versus 82% ($P=.06$), respectively. FFBF at 10 years for pts with prebiopsy PSA <4, 4 to 10, or >10 ng/mL was 94%, 84%, and 67% ($P<.01$), respectively. MVA of FFBF is summarized below.

Conclusion: Excellent long-term CaP-specific survival with I-125 PPBM for LR and IR pts was achieved. Predictors of FFBF include GI score (4+3 vs 3+3 or 3+4), pretreatment PSA, and ADT usage with primary GI 4 strongly influencing and associated with PSA relapse.

Poster Viewing Abstracts 2535; Table

Factors Predictive of FFBF on Multivariate Analysis	Risk Ratio (95% CI)	P value
GI (3+3/4 vs 4+3)	8.4 (3.1-19.4)	.0002
Prebiopsy PSA (continuous)	1.2 (1.1-1.3) per 1 ng/ml PSA	.0011
ADT (yes vs no)	3.5 (1.5-9.3) favors ADT	.0017
D90 (continuous)	0.99 (0.97-1.0)	.0763
T stage (≤T1c vs T2 any)	1.3 (0.7-2.4)	.4471

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