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## Treatment options in resource sparing setting for post-prostatectomy salvage radiotherapy: biochemical nadir and toxicity results from a non-randomized observational study

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**Background:** Limited information is available for hypofractionated radiotherapy after prostatectomy. We aimed to compare hypofractionated and conventionally fractionated radiotherapy regimens in salvage setting for biochemically recurrent prostate cancer after previous prostatectomy and record acute and late toxicity results.

**Methods:** A retrospective analysis was performed in a total of 112 patients with proven PSA recurrence treated with radiotherapy to the prostate bed. Patients were non-randomly, in an alternating fashion, subjected to either 52.5 Gy in 20 fractions of 2.625 Gy over 4 weeks (N=60, hypofractionated group) or 66 Gy in 33 fractions of 2 Gy over 6.5 weeks (N=52, conventionally fractionated group). There was no statistically significant difference in pathologic T-stage and Gleason score distribution between the groups. In the conventionally fractionated group there were more patients with positive margins ( $p=0.01$ ), more prevalent concomitant hormonal therapy (51.9% vs 62.2%,  $p=0.001$ ), but less long-term hormonal therapy (20% vs 84%,  $p<0.001$ ), compared to the hypofractionated arm. Median follow-up was 22 months (range 6-38 months). Treatment failure was defined as biochemical PSA nadir + 0.2. Failure rates between the groups were compared using Cox proportional hazards model. Acute genitourinary and gastrointestinal toxic effects were scored according to RTOG scoring scale from case report forms and patients' self-assessment questionnaires, at baseline, twice during radiotherapy, 3 months and 12 months after completion of radiotherapy.

**Results:** At this early point, 15 patients (25%), and 7 patients (13%) experienced biochemical treatment failure in the hypofractionated group and conventionally fractionated group, respectively (HR 3.3, 95%CI (1.1-6.1)). Due to the different fractionation regimes the dose volume histograms (DVH) have been analyzed in both arms. In the hypofractionated arm the following objectives were followed: bladder V40<80%, V48<50%; rectum V24<80%, V32<70%, V40<60%, V48<50%, V52.5<30%, and in the conventionally fractionated group: bladder V65<50%; rectum V50<50%, V60<35%, V65<25%. There were no difference in acute toxicity outcomes and no correlation between results of the DVH analysis and recorded side effects in both groups. More late grade 2 gastrointestinal and genitourinary side-effects were observed in the conventionally fractionated arm. No grade 3 toxicities were observed.

**Conclusion:** A higher rate of biochemical failures was observed in the hypofractionated regimen compared to the conventionally fractionated regimen (non-significant;  $p=0.1$ ), in salvage radiotherapy of biochemical failure following prostatectomy, despite a higher proportion of patients with positive margins in the latter group. Baseline heterogeneity between the groups and short follow-up preclude any causal conclusions of differential efficacy between these two schedules. Both radiotherapy regimes had similar grade 2 acute and late genitourinary and gastrointestinal toxicities.

We plan to conduct a randomized phase II trial to prospectively compare these two regimens controlling for possible confounders.

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