PO-0719

Excellent 5 year outcome with image guided moderate hypofractionation in prostate cancer: phase I-II study results

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Purpose/Objective: To report 5-year clinical outcomes and late toxicity in prostate cancer patients (pts) treated with Image Guided Radiotherapy (IGRT) Moderate Hypofractionated Simultaneous integrated boost (SIB) by Tomotherapy in a Phase I-II study.

Materials and Methods: 211 pts (78 low-risk [LR], 53 intermediate-risk [IR] and 80 high-risk [HiR]) were treated between 2005 and 2011. IR and HiR pts received 51.8 Gy on pelvic lymph-nodes (LN) and concomitant SIB to prostate up to 74.2 Gy in 28 fr; LR pts were treated to the prostate to 71.4 Gy in 28 fr. Androgen deprivation (AD) was delivered to 33%, 43% and 88% of LR/IR/HiR pts for a median time of 6, 12 and 34 months (m) respectively. The gastrointestinal (GI) and genitourinary (GU) late toxicities were recorded according to the RTOG scoring system. Biochemical relapse free (bRFS) survival (Phoenix definition), cancer-specific (CCS) and overall survival (OS) actuarial curves were assessed. Selected clinical/dosimetry variables were tested as potential predictors of GI/GU toxicity and of BCR/CCS/OS (Cox test).

Results: Median follow was 60m. The 5-year incidence of late toxicity was: GU ≤ G2: 20.2 %; GU ≥ G3: 5.9 %; GI ≤ G2: 17%; GI ≥ G3: 6.3%. The prevalence at the last control was: GU ≤ G2: 71.8%; GU ≥ G3: 28.2%; GI ≤ G2: 86%; GI ≥ G3: 14%. Best predictors of ≥ G3 GU and GI late toxicity were GU acute toxicity (HR: 4.9) and previous surgery (HR: 3.4) respectively. The overall 5-year bRFS was 91.7% (LR: 94.6%; IR: 96.2%; HiR: 91.1%); OS was 88.6% (LR: 90.5%; IR: 87.4%; HR: 87%) and CSS was 97.5% (LR: 98.7%; IR: 95%; HiR: 94.3%). AD and class risk were not correlated with bRFS/OS/CCS.

Conclusions: The combination of pelvic LN irradiation and high dose to the prostate (EQD2=88 Gy) delivered with daily image-guided, intensity-modulated, moderate hypofractionation resulted in an excellent 5-year outcome, even in IR/HiR patients. The 5-year toxicity profile was acceptable with G3 incidences around 6%. The drastically reduced prevalence at the last follow-up for both ≥ G2 and ≥ G3 toxicities shows that symptoms were recovered in most patients.

PO-0720

Patient reported outcomes of overall bowel and urinary bother in the CHHiP trial (CRUK: 8262/A7257)

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Purpose/Objective: Patient reported outcomes (PRO) are important in the assessment of morbidity following treatment for prostate cancer, and may detect more late toxicity from radiotherapy than clinician reported outcomes. The CHHiP trial (Conventional or Hypofractionated High dose intensity modulated radiotherapy in Prostate cancer) randomised patients with early or intermediate risk localised prostate cancer to a standard arm of 74Gy/37v versus experimental arms of 60Gy/20v or 57Gy/19f and included a PRO substudy.

Materials and Methods: PROs of overall bowel bother (primary endpoint) and overall urinary bother (key secondary endpoint) were assessed as single items within UCLA-PCI and EPIC-50 quality of life instruments. These were completed at baseline, pre-radiotherapy (pre-RT), 10 weeks, 6, 12, 18 and 24 months post radiotherapy. All tests were conducted between the control group and each experimental arm. A significance level of 0.001 was used with 99% confidence intervals to allow for multiple testing. A difference in overall bowel or urinary bother score at 24 months was tested using the chi-squared test for trend. Kaplan-Meier methods were used to assess time to ‘small’ bother, with differences between arms assessed using the log-rank test. The odds of an increase in bother from pre-RT to 24 months were modelled using ordered logistic regression.

Results: 2011 patients consented to the PRO substudy. Return rates were 1659 patients (82.5%) pre-RT and 1444 (71.8%) at 24 months. 139 PRO pre-RT and 172 PRO at 24 months dated outside pre-determined acceptable time intervals were excluded from fixed timepoint analyses. A temporary increase in any bother was seen at 10 weeks indicative of acute radiation toxicity (from 408/1498 (27.2%) pre-RT to 741/1308 (56.7%) at 10 weeks). Cross-sectional analysis at 24 months showed no difference between treatment arms (table 1).

Table 1: Overall bowel and urinary bother at 24 months post radiotherapy

<table>
<thead>
<tr>
<th>24Gy</th>
<th>57Gy/20v</th>
<th>57Gy/19f</th>
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<tbody>
<tr>
<td>bowel bother</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>urinary bother</td>
<td>0.0</td>
<td>0.0</td>
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No differences were seen in time to small overall bowel bother (74Gy vs 60Gy: hazard ratio (HR) 1.11 99% CI: (0.85-1.46), p=0.32; 74Gy vs 57Gy: HR 0.97 (0.73-1.28), p=0.77) or small overall urinary bother (74Gy vs 60Gy: HR 0.99 (0.74-