

Acute adverse effects and related quality of life in prostate cancer patients treated with radiotherapy in the multicentre REQUITE cohort study

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Background: The aim of this investigation was to assess the relationship between acute adverse effects and health related quality of life in prostate cancer patients who underwent radiotherapy (RT).

Methods: Prostate cancer patients undergoing RT were recruited in seven countries between April 2014 and October 2015 for an ongoing multicentre prospective cohort study (www.requite.eu). In this preliminary analysis, RT details as well as quality of life (QoL) data prior to and at the end of RT were available for 382 patients. Acute adverse effects (gastrointestinal/GI, genitourinary/GU) were defined as grade 2 or higher according to CTCAE version 4 criteria. Global Health Status (GHS)/QoL was assessed using the EORTC QLQ-C30 questionnaire. Differences in GHS/QoL between patients with and without acute adverse effects were assessed using the Wilcoxon-Mann-Whitney test. Multiple linear regression was used to investigate associations between common acute adverse reactions and a worsening of quality of life, adjusted for age.

Results: The median age of the patients was 70 years. Twenty-eight percent were post-prostatectomy patients, 68% received neoadjuvant or adjuvant hormone treatment. Sixty-two (16%) and 66 (17%) of the 382 patients developed GI and GU toxicity, respectively. Eighteen (4.7%) suffered from both GI and GU toxicity. Most common acute toxicities included proctitis (9.7%), diarrhea (5.5%), urinary frequency (10.5%), urinary urgency (6.8%) and retention (4.5%). Significant clinical worsening of GHS/QoL (i.e. a drop of more than 10 points on a scale from 0 to 100 at the end of RT) was reported by 111 (29%) patients. Both those without GI and without GU toxicity had a median QoL change of 0 points, whereas both patients with grade ≥ 2 GI and with grade ≥ 2 GU toxicity showed a median change of -8.3 (range GI toxicity yes: -75.0 to 66.7, no: -58.3 to 66.7, $p=0.028$ and range GU toxicity yes: -75.0 to 66.7, no: -66.7 to 66.7, $p\text{-value}=0.015$, respectively). All the individual common acute toxicities except for

diarrhea were associated with a reduction in GHS/QoL (median changes for all individual acute toxicities: -8.33; $p < 0.01$). In multiple linear regression analysis, proctitis was the only common adverse effect significantly associated with a decrease in GHS/QoL ($p = 0.021$).

Conclusion: We showed that patients with GI or GU toxicity had statistically significant lower GHS/QoL scores at the end of RT than patients without experiencing adverse effects. Proctitis may have the strongest impact on worsening of QoL. Updated results of these analyses based on a larger patient cohort will be presented. Besides, there will be further follow-ups at 1 and 2 years after treatment in order to study late adverse effects.

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