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Suche

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V12-2 - Patient reported outcomes and acute toxicity assessment in REQUITE study patients receiving hypofractionation versus standard fractionation doses

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Background: The aim of the current investigation is to evaluate the occurrence of radiotherapy (RT) related early gastrointestinal (GI) and genitourinary (GU) adverse effects (AEs) in patients receiving hypofractionated RT (>2 Gy/fraction) compared to those receiving conventional fractionation.

Methods: Prostate cancer patients (N=1,809) undergoing RT were recruited in eight countries between 2014-2016 for a multi-center prospective observational study (www.requite.eu). Treatment data as well as toxicity data were available for 1,424 patients (no brachytherapy, no metastases) of whom 409 patients received hypofractionation (HF). Early GI and GU AEs were scored using the maximum of a physician CTCAE scoring and a patient-reported pelvic symptom questionnaire based on LENT/CTCAE. Primary outcome was worsening of RT-related GI or GU symptoms resulting in grade 2 or higher toxicity (binary: grade 2 or 3 vs. grade 0 or 1) at the end of RT.

Multivariable logistic regression was used to investigate associations between HF and common early GI or GU AEs, respectively, at the end of RT for the whole cohort as well as separately by prostatectomy yes/no (438 post-prostatectomy patients including 74 with HF; 985 exclusive RT patients including 335 with HF). Adjustment included age, lymphadenectomy, hormonal therapy, EQD2Gy dose (including treatment time correction 0.7 Gy/day; alpha/beta 10 Gy), radical prostatectomy (if applicable), radiation technique, and for GI additionally hypertension and pelvic irradiation, and for GU diabetes. Excluded through backward selection were alcohol intake, smoking, inflammatory bowel disease, collagen vascular disease, pre-RT TURP.

24. Results: Hypofractionation was associated with significantly higher rates of GI toxicities overall (OR 1.7, 95% CI 1.2-2.3; 678 events) and specifically for proctitis (OR 1.9, 95% CI 1.4-2.6) and sphincter control (OR 2.1, 95% CI 1.2-3.8). HF associated risk was particularly strongly elevated in patients with exclusive RT for certain GI toxicities (GI overall: OR 2.1, 95% CI 1.5-3.1; proctitis: OR 2.3, 95% CI 1.6-3.3; sphincter control: OR 3.4, 95% CI 1.6-7.1). In post-prostatectomy patients, HF was associated solely with increased risk of diarrhea (OR 2.8, 95% CI 1.3-6.2). Urinary symptoms were not significantly associated with HF.

Conclusions: Previous studies on this topic were predominantly randomized trials, whereas our investigation is one of the first based on clinical routine from >10 hospitals in eight countries. Our findings indicate a significant higher risk for certain early GI symptoms after hypofractionation considering dose correction following the linear-quadratic model including time correction. Preliminary findings for late toxicity (24 months) will be presented at the conference.

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