

the survival time of these elderly patients when surgery is omitted.

Objectives: The aim of this study was to describe survival and to identify baseline factors from patients' medical records associated with a decreased survival.

Methods: A retrospective review of electronic medical records was performed in two teaching hospitals in the Netherlands. Patients diagnosed with CRC without distant metastases (stage I–III) and managed without tumor resection between 2011–2017 were included. The primary outcome was all-cause mortality. The effect of several baseline variables on survival was evaluated with cox proportional hazard regression. An additional regression was performed analyzing patients with complete data on the risk for malnutrition and activities of daily living (ADL) sum score.

Results and Conclusions: Of the 107 stage I–III CRC patients without oncologic surgery, median and mean overall survival time was 255.0 (SE 34.3) and 399.8 (SE 38.6) days. A high Charlson comorbidity index (CCI) hazard ratio (HR) 1.17 (95% confidence interval (CI) 1.05–1.32) and nursing home residency (HR 2.42, 95% CI 1.47–4.00) were associated with decreased survival, corrected for age, gender and disease stage (N=104). High malnutrition risk (HR 2.29, 95% CI 1.38–3.81) and the CCI (HR 1.18, 95% CI 1.04–1.34) were significant predictors of decreased survival in a regression model corrected for age, gender, disease stage and ADL-sum score (N=81).

Survival of patients managed without oncologic surgery with stage I–III CRC is associated with the number of comorbidities, malnutrition risk status and dependent living, but not with age or disease stage.

Disclosure of interest: None declared

Keywords: Colorectal carcinoma, omission of surgery, survival, frailty, elderly patients

P003

PHASE I STUDY OF HAFNIUM OXIDE NANOPARTICLES ACTIVATED BY INTENSITY MODULATED RADIATION THERAPY (IMRT) AS A NEW THERAPEUTIC OPTION FOR ELDERLY OR FRAIL HNSCC PATIENTS

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Introduction: New therapeutic approaches are needed for elderly or frail head and neck squamous cell carcinoma (HNSCC) patients (pts) ineligible for standard of care. NBTXR3, hafnium oxide nanoparticles injected intratumorally, may represent an option. Otherwise inert, NBTXR3 augments the radiation therapy (RT) dose within tumor cells when activated by RT, increasing tumor cell death compared to RT alone.

Objectives: The purpose of this Phase I was to evaluate safety (dose limiting toxicity; DLT) and determine the NBTXR3

recommended phase 2 dose (RP2D) in elderly or frail HNSCC pts.

Methods: Eligible pts had stage III or IV HNSCC of oral cavity or oropharynx, were aged ≥ 70 years or ≥ 65 years and unable to receive cisplatin but eligible for RT [NCT01946867]. A 3+3 dose escalation design was employed, with NBTXR3 dose levels of 5%, 10%, 15% and 22% of baseline tumor volume. Following intratumoral NBTXR3 injection, pts received IMRT (70 Gy; 35 fractions/7 weeks). Primary endpoints were RP2D and DLT. Localization of NBTXR3 and preliminary efficacy (RECIST 1.1) were also evaluated.

Results and Conclusions: Dose escalation is complete; 19 pts received NBTXR3: 3 at 5%, 3 at 10%, 5 at 15% and 8 at 22%. No NBTXR3-related DLTs or SAEs were observed. Four related AEs were reported: one AE at 15% (G1 tumor hemorrhage) and 3 AEs at 22% (G2 oral pain; G1 asthenia, G1 injection site hemorrhage). IMRT toxicity was as expected and post-injection CT scan showed NBTXR3 localized within the injected tumor. DSMB determined RP2D to be 22%. Among 13 evaluable pts at doses $\geq 10\%$, 9 had a complete response of injected tumor.

Results demonstrate that NBTXR3 activated by RT is a well-tolerated therapy with encouraging anti-tumor activity. RP2D expansion is ongoing. NBTXR3 may be an option for elderly or frail pts with locally advanced HNSCC.

Disclosure of interest: None declared

Keywords: Head and neck squamous cell carcinoma (HNSCC), oropharynx, oral cavity, IMRT, hafnium oxide nanoparticles, NBTXR3

P004

EPIDEMIOLOGICAL STUDY ON THE GERIATRIC ASSESSMENT IN PATIENTS WITH HEMATOLOGICAL CANCER: AN UPDATE OF THE REGISTRY OF THE SPANISH GROUP ON HEMATOGERIATRICS

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Introduction: The CGA is the appropriate tool to categorize age-dependent health problems of elderly patients with cancer. We present and update of the epidemiological study currently in progress using the validated GAH scale in the context of real-world clinical practice.