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significantly higher relapse rate compared to ctx  $\pm$  rtx, but those pts were salvaged by effective ctx.

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#### Radiotherapy for stage I testicular seminoma – A prospective trial

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**Purpose:** With high cure rates of 95–98% for radiotherapy (XRT) of stage I (CS I) testicular seminoma it is the aim of modern treatment strategies to reduce the intensity of adjuvant XRT without compromising locoregional turnour control. We therefore conducted a multicenter prospective trial for limited XRT of CS I seminoma with reduced treatment portals and small total doses. Data on the "per protocol" population have been reported previously. We now present updated results including data of those patients with protocol violations.

**Method:** Patients with histologically proven pure CS I seminoma received adjuvant XRT to the paraaortic lymph nodes only. Treatment portals stretched from the upper border of thoracic vertebra 11 (T11) to the lower border of lumbar vertebra 4. The total dose was 26 Gy in 2 Gy daily fractions. Acute and late side effects of treatment were prospectively scored using the EORTC score.

**Results:** Between 4/91 and 3/94 721 patients were enrolled for the trial. 670 patients were eligible for an interim analysis in 1/99. 483 patients were treated strictly per protocol (PP), 187 patients showed protocol violations (PV). Mean follow up was 55 months. There have been 24 cases of relapse, 18 (3.7%) in the PP and 6 (3.2%) in the PV group. There was no in-field recurrence. 22/24 patients were salvaged with two cases of disease-realted death. Statistical analysis showed no differences in relapse rate nor survival between the study populations. Acute side effects of adjuvant XRT were moderate.

Conclusions: Limited volume XRT for CS I seminoma yields high cure rates with moderate acute side effects.

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#### E<sub>400</sub>P in good prognosis advanced seminoma. The Spanish germ-cell cancer group experience

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**Objective:** To analyse response, toxicity, time to treatment failure (TTF) and survival (OS) in patients (p) with IGCCG good-prognosis advanced seminoma treated with  $E_{400}P$  (cisplatin 25 mg/m²/d and etoposide 100 mg/m²/d  $\times$  4 d).

**Methods:** Since 1994 63 p with were included, 48 p with advanced disease at diagnosis (76%) and 15 p who relapsed after stage I (13 p follow-up, 1 p RT and 1 p carboplatin × 2 after orchiectomy). Mean age was 38 y (19–83), Metastatic sites were retroperitoneum (89%), mediastinum (10%), other lymph nodes (19%) and lung (2%). Royal Marsden stages were II: 84%, III: 14% and IV: 2%. Sixteen p (25%) had high BHCG levels, 16 p had LDH > 2 × N, and 61 p (97%) were classified as MIRC good-prognosis (Fosse et al., Eur J Cancer 33: 1380–87). Number of cycles administered were 3 (7%), 4 (80%), 5 (10%) or 6 (3%); 3 p are still on treatment.

Results: Grade 3—4 toxicities were anemia (3%), thrombocytopenia (3%), neutropenia (32%), mucositis (3%), neutrotoxicity (2%), alopecia (96%) and emesis (4%). Twenty-one p (33%) received prophylactic filgastrim and 53/60 p (85%) received ≥80% of the maximum dose intensity. All p responder (72% CR, 28% residual disease). After a median follow-up of 26 m, treatment failed in 4 p (6%). Failure was defined as viable tumor after CT (1 p), regrowth of a residual mass (0 p), relapse (3 p) or unacceptable toxicity (0 p). These 4 p had MRC good-prognosis and normal BHCG; 3 of them were IIa—b. One p is on 2<sup>nd</sup> CT, the other 3 p achieved a 2<sup>nd</sup> CR (1RT, 2CT). One p died after a 2<sup>nd</sup> relapse. Median TTF and OS have not been reached. Three-year TTF and OS are 92.5% (95%CI: 85.4–99.6%) and 97% (95%CI: 91–100%) respectively. All IIc–IV p are alive and their 3-year TTF is 96%.

**Conclusion:**In our experience, E<sub>400</sub>P is a safe regimen for patients with good prognosis advanced seminoma. This regimen could reduce acute and late toxicities observed with the more standard E<sub>500</sub>P or BEP regimens.

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### Identification of prognostic subgroups in patients (PTS) with poor risk germ cell cancer (GCT): A cart analysis

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**Purpose:** Only a few data exist about prognostic criteria within the group of pts who exhibit poor prognostic criteria according to the IGCCCG classification.

**Methods:** We retrospectively analyzed the data of 332 pts with 'IGCCCG' poor risk GCT using the classification-and-regression-tree model (CART). The following variables were included: primary localization, presence of visceral or lung metastases (met.), presence of an abdominal tumor, number of metastatic sites, levels of  $\beta$ -HCG, AFP and LDH. All patients had been treated with cisplatin/etoposide-based CTx within randomized clinical trials.

**Results:** Patient characteristics: gonadal/retroperitoneal (G/R) primary tumor 260 pts (78%), mediastinal primary, tumor 72 pts (22%), visceral met. 205 pts (62%), lung met. 247 pts (74%), abdominal tumor 241 pts (73%), elevated AFP,  $\beta$ -HCG or LDH levels 235 (71%), 253 (76%) and 275 (83%) of pts, respectively. Pts with primary, mediastinal disease and lung met. exhibited the worst 3-year PFS (28%), whereas pts with primary G/R disease and without visceral met. showed the longest 3-year PFS (75%). Pts without visceral met and primary G/R tumor had the most favourable 3-year OS (79%). In contrast, pts exhibiting visceral met. from a primary mediastinal tumor displayed the worst 3-year OS (40%).

**Conclusion:** Different prognostic subgroups can be identified within the group of poor risk GCT. These data may help to estimate detailed individual prognoses and to identify subgroups of high risk pts that may, in turn, be included in new treatment strategies.

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# Acute and late sequelae in conventionally fractionated and hyperfractionated conformal radiotherapy in prostate cancer. Preliminary evaluation

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**Purpose:** To evaluate acute and late toxicities in patients affected by prostate cancer treated with conformal radiotherapy using conventional (STD) or pure hyperfractionated (HFX) regimens.

**Method:** One hundred patients (pts) were treated with 5-field conformal radiotherapy to prostate and seminal vesicles; 85 were evaluable for this analysis. Forty-two pts were treated with STD-CRT at a total dose (ICRU p.p.) of 73.5–75.5 Gy (median: 75.5 Gy; mean: 74.7 Gy); 43 were treated with HFX-CRT at a total dose of 78.3–82 Gy (median: 80.7 Gy; mean: 80.2 Gy). Acute and late toxicities according to RTOG-EORTC criteria were evaluated weekly during CRT, one month after CRT and 3–4 times yearly afterwards.

Results: No significant worsening of acute toxicities was observed using HFX-CRT (grade 2 max. incidence with HFX vs STD: G.l.: 56% vs 62%; G.U.: 33% vs 31%; grade 3 max. incidence with HFX vs STD: G.l.: 0% vs 0%; G.U.: 9% vs 17%). Actuarial probability at 20 months of grade 2 G.U. toxicity was 13% with HFX and 23% with STD, while grade 2 G.l. toxicity was 20% with HFX and 19% with STD. Only one pt, belonging to the STD-CRT group, experienced a grade 3 toxicity (G.U.). Erectile function in pre-radiotehrapy potent patients was maintained at one year in 86% of HFX and 69% of STD pts.

Conclusion: HFX-CRT seems to favourably compare with lower dose STD-CRT with respect to treatment feasibility and acute/late sequelae.

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## Immunotherapy with the bispecific antibody MDX-H210 (anti-HER2 $\times$ anti-CD64) combined with GM-CSF in HER2 positive hormone resistant prostatic cancer

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**Purpose:** Treatment of hormone resistant cancer is palliative in nature and new therapies are urgently needed. We report results following treatment with the bispecific antibody MDX-H210 (anti-HER2  $\times$  anti-CD64)