Purpose/Objective(s): There has been continuous discussion about the best treatment for patients with early favorable Hodgkin lymphoma (HL). Open questions included the choice between combined modality treatment and chemotherapy only, the number of chemotherapy cycles needed and the optimal radiation dose. The GHSG thus conducted a randomized study for patients with early-stage favorable Hodgkin lymphoma (HD10) which addressed these questions were.

Materials/Methods: HD10 was an international prospectively randomized multicenter trial comparing 2 and 4 cycles of ABVD as well as 20 Gy or 30 Gy involved field radiotherapy (IFRT) in a 2 x 2 statistical design. Between 5/1998 and 1/2003, a total of 1370 patients from 329 centers were randomized into four arms: 4 x ABVD + 30 Gy; 4 x ABVD + 20 Gy; 2 x ABVD + 30 Gy; 2 x ABVD + 20 Gy. All patients had their initial histology reviewed by a lymphoma expert panel. Documentation was complete in more than 99,1% of cases for this final analysis.

Results: Patients were equally balanced for age, gender, stage, histology, performance status, and risk factors between arms. There were significant differences in major toxicity (WHO grade III/IV) between 4 x ABVD and 2 x ABVD in the overall number of events (52% vs. 33%) including leukopenia (24% vs. 15%) and hair loss (28% vs. 15%). In terms of radiation dose, there also was a difference in grade III/IV toxicity between 30 Gy and 20 Gy IFRT (all events: 8.7% vs. 2.9%), dysphagia (3% vs. 2%), mucositis (3.4% vs. 0.7%). Complete remission was achieved in 97% of patients treated with 4 x ABVD, 97% with 2 x ABVD, 99% after 30 Gy and 97% after 20 Gy. With a median follow-up of 79 - 91 months, there was no significant difference between 4 x ABVD and 2 x ABVD in terms of overall survival at 5 years (OS: 4 x ABVD 97.1%; 2 x ABVD: 96.6%), freedom from treatment failure (FFTF: 93.0% vs. 91.1%) and progression free survival (PFS: 93.5% vs. 91.2%). For the radiotherapy question, there were also no significant differences between patients receiving 30 Gy IFRT and those with 20 Gy IFRT with respect to OS (97.6% vs. 97.5%).

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58 Initial Report of RTOG 9601: A Phase III Trial in Prostate Cancer: Anti-androgen Therapy (AAT) with Bicalutamide during and after Radiation Therapy (RT) Improves Freedom from Progression and Reduces the Incidence of Metastatic Disease in Patients following Radical Prostatectomy (RP) with pT2-3, N0 Disease, and Elevated PSA Levels

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Purpose/Objective(s): To test if long term AAT when combined with RT in these patients with prostate cancer (PC) will improve cancer control outcomes as well as overall survival.

Materials/Methods: Post-RP patients with pT3,N0 or with pT2,N0 (and also positive margins) who have an elevated PSA were entered on a Phase III, double-blinded, placebo-controlled trial of RT alone (64.8 Gy in 36 fractions of 1.8 Gy) Vs RT plus AAT (24 months of bicalutamide, 150mg QD) during and after RT. The primary end-point is overall survival.

Results: From 3/98 to 3/03, 771 eligible patients (median age 65) were randomized to RT plus AAT (387) or RT alone (383). Pretreatment characteristics were balanced. 252 patients (33%) were pT2,N0 and 518 patients (67%) were pT3,N0. 672 patients (87%) had a PSA nadir after RP of < 0.5 ng/mL. 655 patients (85%) had an entry PSA value of <1.6, 115 patients (15%) had an entry PSA of 1.6-3.9. Median follow-up in surviving patients was 7.1 years. The actuarial overall survival at 7 years was 91% for RT plus AAT and 86% for RT alone. Too few "primary end-point events" have occurred as yet to allow a statistical comparison between these groups. PSA progression was defined as a PSA > 0.4 ng/mL in patients whose protocol treatment resulted in an undetectable PSA or, if not, when the PSA rose 0.3 ng/mL above the entry PSA. Freedom From PSA Progression (FFP) estimated at 7 years was 57% for RT plus AAT and 40% for RT alone ($p < 0.0001$); for 226 patients with GS < 7 were 63% and 50% ($p < 0.02$): for 411 GS 7 these were 55% and 39% ($p < 0.0006$), and for 134 GS 8-10 were 56% and 26% ($p < 0.0008$). The cumulative incidence of metastatic PC at 7 years was less in the RT and AAT arm, 7.4% (25 patients),Vs 12.6% (46 patients) in the RT and placebo arm ($p < 0.04$). Late Grade III and Grade IV toxicity were similar in the bicalutamide and placebo arms. By category the combined Grade III plus Grade IV toxicities for RT and AAT and RT alone were: for bladder 5.9% Vs 5.0%, bowel 2.3% Vs 1.4%, cardiac 2.8% Vs 1.8%. Gynecomastia (mostly all Grades I and II) differed significantly, 89% and 15%. In the RT plus AAT arm Grade III was the highest liver toxicity observed which occurred in 3 of 387 patients.

Conclusions: The addition of 24 months of peripheral androgen blockade (AAT) during and after RT significantly improved FFP and reduced the incidence of metastatic PC without adding significantly to radiation toxicity. The significance of benefit in overall survival, as well analysis of risk-stratified subsets, must await longer follow-up.

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59 A Phase II Trial of Stereotactic Body Radiation Therapy for Operable T1N0M0 Non-small Cell Lung Cancer: Japan Clinical Oncology Group (JCOG0403)

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