ThT 02

LOW DOSE INVOLVED FIELD IRRADIATION, RISK-ADAPTED CHEMOTHERAPY AND SELECTIVE SPLENECTOMY IN CHILDREN WITH HODGKIN'S DISEASE: RESULTS OF THE WEST GERMAN THERAPY STUDY DAL-HD-82

G. Schellong, J.H. Brämswig and M. Wannenmacher

Between Dec. 1981 and Dec. 1984 207 patients below 16 y. of age (131 boys and 76 girls) from 53 hospitals were enrolled in the therapy study DAL-HD-82 for Hodgkin's disease (HD). It was the aim of this study to reduce chemo- and radiotherapy and to investigate the results of the strategy for selective splenectomy previously developed in the study DAL-HD-78. A nodular surface of the spleen and enlarged lymphnodes at the splenic hilus and/or pancreatic tail were the criteria for selective splenectomy. During surgery these criteria were correctly applied in 174 patients. 96 (39.7 %) with the above changes had a splenectomy. 50 of the removed 69 spleens (72 %) showed histological evidence of HD.

According to the stage of disease 3 different treatment groups were formed receiving 2, 4 and 6 cycles of OPPA/COPP respectively (stage I/IIA, IIB/IIIA, IIIB/IV). Radiation therapy was given as involved field irradiation with a total dose of 35, 30 and 25 Gy depending on the extent of the chemotherapy.

203 patients were treated according to the protocol. Until November 30, 1985 3 patients died from intercurrent disease, 5 patients relapsed. The probability for disease-free survival after 45 months is 96 % for the total and 99 %, 96 % and 87 % for each treatment group.

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ThT 03

MORBUS HODGKIN IN ADULTS: PRELIMINARY RESULTS OF THE HD1, HD2 AND HD3 TRIALS.

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Since 1982 235 of 436 untreated patients (PAT) with Hodgkin's disease from 35 institutions qualified for the prospective trials HD1-3 with the stages: HD1: IA-IIIA with mediastinal mass >1/3 of thoracic diameter, per-continuitatem involvement, excessive involvement of spleen. HD2: IIIA, N. HD3: IIIB/IVAB. First chemotherapy (CT) was COPP, since July 1983 COPP alternating ABVD.
HD1: Randomisation 4 cycles (X) CT + 40 Gy EF radiotherapy (RT) vs. 4 X CT + 20 Gy EF. 21/28 (75%) entered complete remission (CR) after COPP + RT, 20/25 (80%) after COPP/ABVD + RT (not significant). HD2: Randomisation TNI vs. 6 X CT + 20 Gy IF. 13/16 PAT (81%) had CR.
HD3: First 6 X CT. If CR, randomisation: RT (20 Gy IF) vs. 2 X CT as consolidation; if no CR: 20 Gy IF/40 Gy residual tumor (nodal disease) or ABVD after COPP resp. CEVD after COPP/ABVD (extranodal disease or organ involvement) as salvage. 8/26 (31%) had CR after 6 X COPP; 24/38 PAT (63%) obtained CR after 6 X COPP/ABVD, (significant:$p<0.05$). 7/18 PAT not in CR after COPP and 5/14 not in CR after COPP/ABVD had CR by salvage. Finally 17/26 (65%) COPP and 27/38 (71%) COPP/ABVD remained in CR (not significant). CR only after salvage was of short duration.
Whereas COPP/ABVD + RT was not superior to COPP + RT in low stages with risk factors, COPP/ABVD significantly improved the CR rate in advanced stages.

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ThT 04

RANDOMIZED PHASE II STUDIES OF EFFICACY OF DEFINITIVE RADIATION AND HYPERTHERMIA IN PATIENTS WITH ADVANCED MALIGNANT TUMORS.

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Radiation therapy is effective in the treatment of many human cancers. Hypoxic tumor cells are known to be more radio-resistant than euoxic cells. There is only a small difference between tumor control doses and normal tissue radiation tolerance. To overcome this problem different radiosensitizers like misonidazol, hyperbaric oxiganisation and others, havy particles like neutrons as well were used without success.
Selective heating of tumor cells, its effect on hypoxic and S-phase cells, its cytotoxic and radiation sensitizing effect are biologically well known and promising for clinical use.
A multicentric study comparing hyperthermia and irradiation with radiation alone has been started this year. There are three randomized phase II protocolls for patients having advanced head and neck tumors, brondogenic (non oat cell) and cervix carcinoma. The conventional dose range (50-70 Gy, 5x2 Gy/week) was not changed. Hyperthermia is given additionally before radiation 4 times/week up to 50 Gy. All eight participating clinics got the same equipment for hyperthermia (13.56 MHz generators) and temparature control. These protocolls are supported by the German government.

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ThT 05

ADJUVANT TREATMENT OF ENDOMETRIAL CARCINOMA.

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In endometrial carcinoma stage I (FIGO-classification) surgery an radiation are capable of curing 60 to 85% of all cases. The chance of tumor response is determined by the histological type of tumor, morphological grading, myometrial infiltration and presumably by the steroid receptor content. In the past different investigation were started studying the efficacy of an adjuvant progestogen treatment. The results of these studies were very conflic ting. The reason for the varying observations might be the use of relatively low progestogen dosages and the insufficient correlation of the investigations with the mean while well known prognostic factors.
During the last year members of 16 university hospitals (German Endometrial Cancer Research Group-GERG) prepared the study protocol for a prospective randomized trial about the endocrine adjuvant therapy of endometrial carcinoma stage I. Following primary surgery ± radiation the study design includes "no further treatment versus high dose MPA (1000 mg/day orally) versus tamoxifen (40 mg/day orally)". Stratification criteria are the extent of tumor invasion, the morphological grading and the steroid recep tor status. The study should start during January 1986 and include 900 to 1000 patients during the following two years.
Furthermore another protocol is in progress involving the adjuvant drug treatment of endometrial carcinoma stage II In this group, however, only a relatively small number of patients is available. Presumably only 120 to 150patients will enter the study. Therefore the design of the investi gation chosen, is a cohort comprehensive study. After the primary treatment with surgery±radiation the patients receive an adjuvant treatment with high dose progestogens. The disease free survival should be correlated with the extent of tumor invasion, morphological grading and recep tor status.

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