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LOCAL HYPERTHERMIA COMBINED WITH RADIOTHERAPY IN THE TREATMENT OF LOCALLY ADVANCED PROSTATE CANCER.

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To determine the effectiveness of hyperthermia in the treatment of prostate cancer when used in conjunction with radiation therapy, we embarked in January 1990 on a prospective clinical trial applying hyperthermia in addition to curative external beam radiation for locally advanced prostatic cancer in 52 patients (pts) randomized into 2 treatment arms. Group I consisted of 29 pts receiving full-dose radiotherapy (70 Gy) only. Group II included 23 pts receiving radiotherapy combined with local hyperthermia. A much more pronounced drop in PSA levels was noted in Group II (21% vs 147% at 18 months posttreatment). Prostate volume, measured at 12 months post-therapy showed a slight advantage for the combined therapy (82% vs 91%). Prostate biopsies taken at 12 months after treatment became negative in 50% of Group II compared to only 28% of Group I. Our preliminary results indicate an advantage for the combination therapy.

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PIPARUBICIN AND 5 FLUOROURACIL IN THE TREATMENT OF HORMONE RESISTANT METASTATIC PROSTATE CANCER.

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Between 1/1991 and 4/1992, 27 patients with D2 hormone resistant prostate cancer were treated with 5 FU 350 mg/m2/d d1 - 5, PIPARUBICIN 50 mg/m2 d1 every 3 weeks. All patients had histological confirmation and had failed medical or surgical castration. The median age was 67,7 (range 51 - 80). Median PS 80 (range 60 - 90). All patients wre evuable for toxicity and response. Over all 243 courses of chemotherapy were administrated. The patients received a median of 9 cycles (range 3 - 16) Response were determined by reduction > 50 % in their serum PSA, improvement of pain.
25 of 27 patients were evaluable for serum PSA response : 7 pts. (26%) had a reduction in their serum PSA (PR) , 9 patients. (33,3%) had a stable level of PAS (SD), 9 had a progressive level (33,3%). Duration of PSA response (PR + NC) was 9 months (range 3 - 19)
14 patients had bidimensionally measurable disease. In 3 cases (3/14 21%) an objective regression at a measurable site was documented, 4 patients (4/14 28%) had stable disease.
21 patients were evaluable for improvement of pain. 15 pts (56%) had improvement in bone pain.. Duration of pain response was 7 months (range 3 - 18). The overall median survival was 12 months (3 - 20).
27 were evaluable for toxicity. Toxicity was mild with none having grade 3 or 4 leukopenia or thrombocytopenia, 1 grade 3 and 6 grade 2 anemia, 9 grade 2 and 3 grade 3 alopecia. No severe or life-threatening toxicity occured in 243 courses of this chemotherapy.
This combination is an effective outpatient treatment for metastatic hormone resistant prostatic cancer ameliorating quality of life with low toxicity.

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RESULTS OF DEFINITIVE IRRADIATION IN NON METASTATIC PROSTATIC CARCINOMA

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The purpose of this analysis is to evaluate patients treated with ^{60}Cobalt or 25 MV photon beam from 1971 to 1991, regarding efficiency and toxicity. A hundred and ninety patients with a median age of 69 years (53-87) entered the study : 26 T1, 88 T2, 71 T3, 5 T4 (UICC 1987). The breakdown according to WHO histological grade was : grade 1 (27.9 %), grade 2 (27.9 %), grade 3 (48.4 %), not assessed (6.3 %). Thirty three percent of the patients received an adjuvant hormonal treatment before the onset of radiotherapy, either chemical (LHRH analogue) or surgical ; hormonotherapy was decided by the urologists (castration) or by radiation oncologists before entering patients in EORTC 22863 randomized trial. Before 1978 patients were treated with ^{60}Cobalt, with an arctherapy technique, and further with 25 MV photon beam using a four field box technique on the whole pelvis (50 Gy / 25 fr / 5 weeks), followed by a prostatic boost (20 Gy / 10fr). The median follow-up was 48 months (3-206).
Five year overall survivals were 77.9 % for T1/T2 and 68.6 % for T3/T4 (p=0.04). Five year disease free survivals were 63.2 % for T1/T2 and 53.9 % for T3/T4 (p=0.15). Five year actuarial loco-regional control rates were 80.2 % and 75.5 %, without significant difference (p=0.4). WHO Grade 3 acute toxicity occurred for diarrhea (3.7 %), pollakiura (1.1 %) and dysuria (0.5 %). WHO grade 3 late toxicity was mentioned for hematuria (0.5 %), cystitis (0.5 %), diarrhea (0.5 %), urethral stenosis (3.2 %), rectitis (3.2 %), lymphoedema (1.1 %)

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GOSERELIN VERSUS GOSERELIN PLUS MITOMYCIN C IN ADVANCED (STAGE D) PREVIOUSLY UNTREATED PROSTATIC CANCER. A RANDOMIZED STUDY.

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To evaluate the impact of chemotherapy in addition to hormone therapy on survival of patients (pts) with advanced prostatic disease, the G.O.U.P. (Gruppo Onco-Urologico Piemontese) started a prospective multi- institutional randomized trial in June 1990.
The study included previously untreated pts with advanced prostatic cancer (stage AUS D1-D2) with at least one of the following negative prognostic factors: performance status (P.S.)>1 (ECOG); elevated alkaline phosphatase or prostatic acid phosphatase twice the normal value; histological grading: G3.
Pts eligible were randomized to receive either goserelin 3,6 mg s.c. every 4 weeks (arm A), or goserelin + mitomycin C 14 mg/m2 i.v. every 6 weeks (arm B).
54 of the 70 pts entered so far are evaluable for toxicity (25 in arm A and 29 in arm B). Their characteristics are: median age 70 (range 48-86); median P.S.:1 (range 0-2); grading is GX in 1 pt, G1 in 10 pts, G2 in 28 pts, G3 in 15 pts; stage AUS is D1 in 7 pts and D2 in 47 pts.
Toxicity was acceptable in both arms: myelotoxicity was present only in 6 pts (11%) who received Mitomycin C: leukopenia grade 1 (WHO) in 3 pts, grade 2 in 2 pts; thrombocytopenia grade 1 in 2 pts, grade 3 in 3 pts. This study is ongoing.

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SOMATOSTATIN ANALOGUE (SOMATULINE) IN HORMONE RESISTANT PROSTATE CANCER.

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Growth of the R-3327-H rat prostate adenocarcinoma is inhibited by somatuline. We tested somatuline in 40 patients with progressive prostate cancer who had relapsed following conventional therapy. 34 patients had medical or surgical castration, 6 antiandrogens, stilboestrol or castration and an antiandrogen combined. Twenty six patients were treated with slow release formulations of somatuline with doses of between 10-30mg/2 weekly. 14 patients were given the drug by continuous subcutaneous infusion at doses ranging from 1.5-12mg per day. The mean age of the patients was 68.7 years (range 54-88) and they were treated for an average period of 22.4 weeks (range 1-183). Three patients (7.5%) achieved an objective partial remission (PR) and 7 patients (17.5%) were objectively stabilised (SD, NPCP Criteria). 27 patients continued to have progressive disease. 33 patients have died at the time of the current analysis although only one of the responding patients has died. The mean survival from starting somatuline was 39 weeks (median 32 weeks). The mean survival of the responders (PR+SD) was 67 weeks (Range 27-183) and non-responders, 33 weeks (Range 2-109). This difference is statistically significant (P < 0.05). Side-effects were mild to moderate diarrhoea and/or abdominal cramp in 19 patients. This occurred during the first few days of treatment and only persisted in a few patients. Pain and/or induration at the injection site was noted in 10 patients and a generalised urticarial rash in 2 patients. The objective responses to somatuline and the tolerance in this group of poor risk patients is encouraging. Further randomized studies have been started.

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SCREENING FOR EARLY DETECTION OF PROSTATE CANCER

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The role of serum PSA and transrectal ultrasound (TRUS) in the screening for prostate cancer has not yet been defined. 2500 unselected men, age 50-74, were included in a screening program for early detection of prostate cancer. 1500 underwent digital rectal examination only (DRE) and 1000 underwent DRE plus PSA determination. 48 men (out of 1500 in the DRE group) were found to have a suspicious nodule. In 32 of those pts TRUS revealed a hypoechogenic lesion in the prostate and ultrasonic guided biopsies were obtained. In 15 cases adenocarcinoma of the prostate was found. Clinical staging revealed stage B in 11 pts, stage C in 1 pt and stage D in 3 pts. 1000 men underwent DRE and PSA determination. In 115 cases PSA was between 4.1-10 ng/ml. 32 pts had a PSA between 10-20 ng/ml and 7 pts had PSA >20 ng/ml. All pts with a suspicious DRE or PSA above 10 ng/ml, underwent TRUS guided biopsies. Of the 1000 pts, 32 (3.2%) had carcinoma of the prostate. Clinical staging revealed stage B in 27 pts, stage C in 2 pts and stage D in 1 pt. In 23 cases the prostatic tumor could be palpated on DRE. 9 additional pts with a normal DRE were diagnosed as a result of elevated PSA. During screening most of the newly diagnosed cases were found in an early, curable stage.
Keywords: Prostate cancer, screening, PSA.