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PROSPECTIVE RANDOMIZED TRIAL IN LOCALIZED PROSTATIC CANCER. RADIOTHERAPY VERSUS RADIOTHERAPY AND ORCHIDECTOMY

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Between 1986 - 1990, 91 patients (pts.) with localized prostatic cancer in all stages except TO-T2, pNO, grade 1-2, were randomized to treatment with either local radiotherapy (RT) or RT in combination with orchidectomy. All pts. had negative bone scans and underwent open surgery with multiple lymphnode biopsies. Positive nodes were found in 38/91 pts. The median follow-up time is 4.5 years and all pts. have been followed for at least 2 years. In 45 pts. treated with RT only, recurrence, mostly in the form of bone metastases, has been recorded in 26% of pNO pts. and in 72% of pN+ pts. In the 46 pts. treated with RT and orchidectomy, the recurrence rate was 18% in pNO pts. and 20% in pN+ pts. Eleven pts. have died in the RT group and 7 pts. in the RT and orchidectomy group. The results illustrate the importance of lymphnode staging before definitive RT and further that node positive pts. should be treated with chemical or surgical castration, possibly in combination with RT in the locally more advanced cases.

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SELF ASSESSMENT QUESTIONNAIRE FOR EVALUATING LATE SIDE EFFECTS AFTER PELVIC RADIOTHERAPY IN PATIENTS WITH PROSTATE CANCER COMPARED TO AN AGE MATCHED CONTROL POPULATION

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Pelvic irradiation is accompanied by urinary and intestinal reactions as well as disturbances of sexual function. The patients own opinion and experience of these problems can be of great importance for the patients quality of life. In this age population disturbances in the urinary tract, intestine and sexual function are common and radiotherapy induced problems should be evaluated in relation to problems in the agematched population. In the present study problems in the urinary tract, intestine and sexual function has been evaluated with a self assessment questionnaire using the L-A scale. The questionnaire was sent out to 200 patients who had received pelvic radiation with curative intention due to their prostatic cancer and to an age matched population of men in Northern Sweden. Follow-up time after radiation was 48 months. The answer frequency in the patient group and the control group was 93% and 71 % respectively. 60 % of the patients and 80 % of the control group reported high quality of life, although 50 % of the patient group and 25 % of the control group report some kind of problem in the urinary tract. The most common problems in the patient group and the control group, respectively, were urgency (42 % and 19 %), starting problems (33 % resp 22 %) and leakage (32 % resp 11 %). In the patient group and the control group 59 % and 14 % respectively report gastrointestinal problems. Most common problems in the patient group and the control group, respectively, were mucus (38 % resp 4 %), cramp (14 % resp 5 %), leakage (27 % resp 2 %) and blood (36 % resp 2 %). 90 % of the patient groups problem, regarding urinary and intestinal problems are small. Field reduction and pause during radiation did not significantly decrease problems in the patientgroup. Regarding sexual problems there is a tendency to increased problems with sexual activity with more treatment. In conclusion the present study has compared problems in the urinary tract, intestine and sexual problem in patients with prostatic cancer treated with pelvic irradiation with a group of age matched men. Pelvic irradiation induce a fairly high amount of problems of small character. The study supports the on-going efforts to decreased irradiation dose to rectum.

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COMPARISON OF HIGH DOSE ESTRACYT AND MITOMYCIN C IN THE TREATMENT OF HORMONE RELAPSED PROSTATE CANCER.
The final results of EORTC study 30865.

D.W.W. Newling

172 Patients were randomized in this prospective phase III study, all of whom showed evidence of objective progression, following castration or other appropriate hormonal therapy. The patients have received between 1-5 previous therapies and the majority were suffering of pain from metastases. Starting dose estracyt was 560 mg/day which after 2 weeks was increased to 700 mg/day, on which dose the patients remained if they could tolerate the side effects. Mitomycin C was given 6 weekly by injection in a slow running solution drip in a dose of 15 mg/m2. The overall time to progression and survival was equally poor in both arms of this trial. The median time to progression was 5 months, with a median duration of survival of 10 months. Side effects of the treatments lead to withdrawal of some 41% of the patients. The side effects for estracyt were mainly gastrointestinal and occured earlier than the myelo suppressive side effects of Mitomycin therapy. In this group of patients, it would seem that neither of these 2 therapies are appropriate, or can be recommended at the present time.

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LIAROZOLE-HYDROCHLORIDE (R 75251), A NOVEL TREATMENT IN HORMONE-RESISTANT PROSTATIC CANCER : RESPONSE ON PSA

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A total of 100 patients were enrolled in two phase I-II trials with R 75251, a novel imidazole derivative which inhibits the breakdown of retinoic acid. All patients showed progression after at least first line androgen ablation therapy. All patients in the first trial received 300 mg bid as did 2 patients in the second trial (group A, n=33). In the second trial 27 remained on 150 mg bid (group B). Due to insufficient response 37 patients underwent a dose increase (group C). The majority of all increases in dose occured after 1 to 9 weeks. Three patients in the second trial were not evaluable because no data were available. Patients were followed until progression or death. The Hybritech Tandem-R technique was used for all PSA assays. In group A, 15 patients (46%) showed a PSA-response (2 CR, 13 PR); the median survival for responders was 371 d., for stable disease (n= 12) 216 d. and 186 d. for the entire sample. In group B, 4 patients (15 %) had a PSA-response (1 CR, 3 PR) and 9 patients had stable disease; the median survival for all patients was 143 d. In group C, 9 patients (24 %) had a PSA-response (1 CR, 8 PR) and 15 had stable disease; the median survival for all patients was 204 d. The majority of patients in all three groups benefited from a major decrease in pain and urologic symptoms, while general condition improved. PSA-responses were most frequent in the 300-mg group, but clinical responses were equally present in all groups. Toxicity, mainly dermatologic, was often analogous to that encountered with retinoids. Randomised trials with larger patient numbers are warranted to evaluate the survival benefit for PSA responders.

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HIGH DOSE IRRADIATION IN THE TREATMENT OF PROSTATE CANCER. Lo, T.C.M. and Girshovich, L., Lahey Clinic Med Ctr, Burlington, MA, USA Between 1973 and 1989, 519 patients with adenocarcinoma of the prostate were treated with radiotherapy in our Department. After excluding those who received a tumor dose less than 64 Gy, had insufficient follow-up data and had previous prostatectomy, we analysed a total of 395 cases. The median age was 69 years and median follow-up, 61 months. There were 36 Stage A, 216 Stage B, 111 Stage C and 32 Stage D patients. At present, 219 patients are alive with a median survival of 74 months. Sixty-six patients (17%) died from intercurrent disease. The rates of metastasis increased proportionally to stage of disease: 5%, 29%, 44% and 72% for Stages A to D disease respectively. The rates of local recurrence alone, however, were low at 5%, 8%, 11% and 6% for Stages A to D disease respectively. We conclude that high dose radiotherapy is very effective in local control for adenocarcinoma of the prostate but unfortunately many patients will continue to die from metastasis and intercurrent disease.

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CONTINUOUS INFUSION 5 FLUOROURACIL (5FU) FOR HORMONE REFRACTORY PROSTATIC CA.A PILOT STUDY.

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Chemotherapy for stage IV Ca Prostate is disappointing. In a pilot trial we used a continuous infusion of 5FU, 1 gr./m²/24 hrs for 5 days with Mitomycin C 12mg/m² every 6 wks. (or Cis platinum at 70mg per m² given every 3 wks. for bone marrow damage). 16 pts. were treated. Median age 63 yrs.All had bone metastases but 30 had >2 metastatic sites. PSA was increased 15/16 pts. Acid Phos. increased 16/16 pts. Results:No PR., 6/16 had CR(decrease PSA, Acid Phos.), 4/16 had stable disease (marked improvement in pain and performance status).6/16 failed.Duration of response ranged from 2mths. to 14 mths. (median time to progression 5,5 mths.).Toxicity:Granulopenia-3 pts., 2 treated for neutropenic fever,Nausea-9 pts.,Vomiting-2 pts.,Diarrhea-4 patients, Mucositis grade I--4 pts., grade II/III--2 pts., CNS toxicity--1 pt. Conclusion: The treatment seems useful and may lead to the development of better protocols and results.