34.
A MULTICENTER RANDOMIZED STUDY OF TWO REGIMENS IN PALIATIVE RADIOTHERAPY OF BONE METASTASES.

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In this study we compared two methods of radiotherapy in patients with painful bone metastases: 20 Gy in five fraction in five consecutive days vs 8 Gy in one fraction. A total of 115 patients (34 males, 81 females), median age 56 years (23-80), were randomly allocated to one of the treatment arms. In 56 pts. Primary tumor was located in the breast, in 14 pts in the lung, in ten pts in the kidney, in seven pts in the prostate, and in 28 pts in other sites. A total of 146 metastatic bone lesions were irradiated, seventy five (51%) were treated with 20 Gy and seventy one (49%) - with 8 Gy. The most frequent location of metastatic lesions was spine (36%), followed by pelvis (25%), long bones (18%), ribs (12%) and other sites (12%). Treatment techniques included single field (73%) or two parallel opposed fields (27%). Complete pain relief was achieved in 36% of the lesions irradiated with 20 Gy and in 41% of those irradiated with 8 Gy. Partial improvement was observed in 46% and 43% of lesions, respectively. The median time to reappearance of pain in both groups was 5.4 a 4.8 months and 5.0 a 5.4 months respectively. We conclude that a single exposure to 8 Gy is of the same efficacy as 20 Gy in five fractions in pain control of bone metastases and should be recommended as routine management.

35.
HOW OFTEN MEDICAL LITERATURE MAY BE A SOURCE OF INCORRECT CLINICAL DECISION?

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Change in clinical practice results mainly from positive randomized trials (superiority of tested method confirmed by significant result of statistical test). However, the rate of false positive trials might be high among all positive trials - even 30%-50%. This percentage depends mainly on the rate of trials with a real difference in efficacy between tested methods; in lesser extend it depends on a level of type II error (a number of patients in a trial). The probable high rate of false positive trials among all positive trials indicates that a risk of undertaking of incorrect clinical decision based on literature may be also high. In addition, this risk is increased due to publication bias. Therefore, confirmatory trials are often necessary. The other issue, which might be a source of incorrect clinical decision, is lack of data enabling an assessment of generalizability of trial results: 1. a number of eligible but not enrolled patients and the reasons for treatment outside trial; 2. a comparison of a characteristic of patients on trial with a characteristic of eligible, but not enrolled patients; 3. a comparison of results of treatment of patients on trial with results of treatment of eligible, but not enrolled patients 4. data of referral pattern and information on the source population, from which patients were selected.

36.
A PROSPECTIVE, RANDOMIZED STUDY TO COMPARE THE VALUE OF TWO FRACTIONATION SCHEMES OF PALLIATIVE RADIOTHERAPY FOR INOPERABLE NON-SALL CELL LUNG CANCER

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A prospective, randomized study was conducted in eight Polish institutions to compare the value of two fractionation schemes of palliative radiotherapy for inoperable non-small

cell lung cancer. Assessed was the impact of either treatment on the degree and duration of relief of tumor-related symptoms and on patient's performance status. Secondary endpoints included treatment side-effects, objective response and overall survival. One hundred patients were randomly assigned to the dose of 20 Gy/5x/5 days (Arm A) or 16 Gy/2x/8 days (Arm B). There were 90 men and 10 women aged between 47 and 79 (mean 66). Eighty four patients had locally advanced tumor and 16 patients had metastatic disease. Squamous cell carcinoma was diagnosed in 65 patients, adenocarcinoma – in 9 patients, large cell carcinoma – in 1 patient and unspecified non-small cell carcinoma – in 25 patients. Fifty five patients were assigned to Arm A and 45 – to Arm B. Ninety eight patients received assigned treatment whereas two patients died before the end of treatment. The final results of the study will be presented at the conference.

37.
MULTICENTER, RANDOMIZED STUDY ASSESSING THE IMPACT OF AMIFOSTINE ON NORMAL TISSUE RADIATION TOLERANCE DURING HEAD AND NECK CANCER RADIOTHERAPY

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A prospective, randomized multicenter study was conducted to assess the value of amifostine (Ethyol®) as a radioprotectant in head and neck cancer radiotherapy. The aim of the study was to evaluate the impact of the addition of daily amifostine (150 mg/m2) on the degree of early (mucositis, dysphagia, xerostomia) and late (mucosal, cutaneous, salivary gland, mandible and spinal cord) radiation reactions. Assessed were also patients' quality of life, local control and overall survival. Sixty two patients from five Polish institutions were randomly assigned to radiotherapy alone (Arm A - 28 patients) or radiotherapy + amifostine (Arm B – 34 patients). There were 43 men and 19 women. Primary tumor was located in the oral cavity (27 patients), oropharynx (25 patients), nasopharynx (2 patients) and larynx/hypopharynx (8 patients). In 43 patients radiotherapy was used as the sole modality of treatment and 19 patients were irradiated postoperatively. The side effects of amifostine were manageable. In 6 patients amifostine infusion had to be temporarily stopped due to hypotension and in 5 patients its administration was permanently terminated due to hypotension, nausea and vomiting, septicemia or fever and visual disturbances. The early results of the study, focusing on early radiation reactions, will be presented at the conference.

38.
THE OWN EXPERIENCE IN MONITORING THE LATE RADIATION REACTION OF CRITICUAL TISSUES IN HEAD AND NECK REGION

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Purpose: The estimation of scoring system SOMA-LENT in classification the late radiation toxicity in patients with squamous cell cancer irradiated in H&N region.

Material and methods: The material includes 97 patients with oral cavity, pharyngeal and supraglottic cancer $T_{2-4}N_{0-1}$ irradited by conventional method (18 patients), continous accelerated irradiation CAIR (42 patients) and concomitant boost CB (37 patients). Total dose was in range 66-74 Gy. The late radiation toxicity was evaluated by SOMA-LENT system for pharyngeal and oral cavity mucosal membrane, skin, larynx, salivary glands, spinal cord. The estimation was done every 6 months after completing of radiotherapy. In statistical analysis the values were normalisated to maximal intensity of all symptoms in the scale.

Results: The intensity of late radiation toxicity for mucosal membrane was increasing between 12^{th}-18^{th} month after radiotherapy and next decreased from 24 after irradiation. For skin the intensity of late radiation reaction increased to 24 months after treatment. For larynx we noticed two peaks of late radiation toxicity: between 18^{th}-24^{th} month and about 54 month after irradiation. The intensity of late radiation effect