

34.

A MULTICENTER RANDOMIZED STUDY OF TWO REGIMENS IN PALLIATIVE 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-SMALL 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