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**Purpose or Objective:** Many patients with advanced cancer develop bone metastases, with pain as a common, devastating consequence. Adequate treatment is important to maintain quality of life. Radiotherapy is the standard treatment for patients with painful bone metastases. Meta-analyses of radiotherapy trials have consistently shown a pain response rate of approximately 60% implying that many patients are treated insufficiently. It would be worthwhile to identify patients who will not respond to radiotherapy as these patients might be candidates for other treatments. Furthermore, better understanding and identification of the patients who do not respond to radiation, might help in the development of innovative treatments as alternative or addition to standard (radiation) treatment options. We studied the relationship between patient and treatment characteristics and pain response in patients with metastatic bone disease, with the aim to construct a prediction model to guide individualized treatment decision-making.

**Material and Methods:** We analyzed all prospectively collected data on pain response from a palliative radiotherapy clinic in an academic hospital. Patients were considered responders if they reported a decrease in pain score of at least 2 points with stable analgesic use within 3 months after treatment. A multivariable logistic regression model was developed with age, gender, primary tumor, Karnofsky performance status (KPS), painful localization, presence of visceral metastases, previous systemic treatment, analgesic use at baseline, and baseline pain score. For variable selection, we started with the full model and applied backward stepwise selection with a selection criterion of  $p < 0.20$ . Performance of the model was quantified using the c-statistic and corrected for optimism. A worst case scenario (assuming no response in patients who were lost to follow up) was added as sensitivity analysis.

**Results:** A total of 1018 patients treated between January 1999 and November 2007 were included. Outcome was recorded in 588 (58%) patients, of which 394 (67%) reported a response. Primary tumor, KPS, baseline pain score, and analgesic use were predictive for response with a corrected c-statistic of 0.59 (Table). Assuming non-response in the 430 patients without follow up (worst case scenario), there was still an association between response and primary tumor, KPS, and baseline pain score.

**Conclusion:** Primary tumor, performance status, baseline pain score, and analgesic use are associated with pain response in patients with bone metastases. However, combining these factors in a prediction model showed poor discrimination limiting its use in clinical practice. Response rates after radiotherapy are moderate, and its prediction is difficult, which shows the need for development of innovative treatments for patients with bone metastases.

#### EP-1433

Comparison of single fraction versus long course RT treating bone metastasis with cobalt machines

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**Purpose or Objective:** To present the observed comparative advantages of the single fraction versus long course radiation therapy in the palliative treatment of bone metastasis, in the conditions of technological resources limited to one national center equipped with only cobalt machines. Purpose: To present the observed comparative advantages of the single fraction versus long course radiation therapy in the palliative treatment of bone metastasis, in the conditions of technological resources limited to one national center equipped with only cobalt machines.

**Material and Methods:** The Radiation Therapy of Mother Theresa University Hospital Center, the unique public center providing RT in the country, performed a study comparing single dose of 8 Gy/1fr. versus 20 Gy/5fr. and 30Gy/10fr. enrolling 110 patients during a time period of five years (2007 - 2012). Factors for the treatment choice between available options were age, pain level, effect of narcotics and need for assistance as well as time and cost effectiveness. Pain relief was assessed based on the patient perception expressed during the follow up visits, 2 weeks, 4 weeks and 12 weeks after the treatment and subsequently every 12 weeks for a period of 48 weeks. Qualitative data from the follow up visits were classified in a scale of 10 points.

**Results:** The complete pain relief was attained for 90 patients or 81.8% out of 110 patients, subject to this study. From this number, 33 patients were treated with single shot, 31 with 20 Gy/5 fraction and 46 with 30Gy/10fr. The percentage of patients benefiting partial pain relief varied from 17.4 to 19.5 which indicate also similar results from the available treatment regimes. Therefore, it wasn't evidenced significant difference between the treatment options as regard to the patients achieving complete or partial pain relief. Further, the toxicity level scored 2-3 grade for all the treatment regimes used. In addition, the patients demonstrated similar median survival from 8 to 10 months for the three options.

**Conclusion:** The findings of the study indicate that single fraction 800cGy/1fr is a treatment option with similar effects with the multiple fractions 20Gy/5fr and 30Gy/10fr. It can be used as more time and cost effective standard treatment especially for patients presenting higher level of pain and more in need for assistance including elder and those more distant from the treatment centers.

#### EP-1434

Phase II study of short-course accelerated palliative radiotherapy for complicated bone metastases

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**Purpose or Objective:** To assess the efficacy of a Short-course Accelerated RadiatiON therapy (SHARON) regimen in the palliative treatment of complicated bone metastases.

**Material and Methods:** A phase II clinical trial was planned based on optimal two-stage Simon's design. Eligibility criteria included patients with an Eastern Cooperative Oncology Group (ECOG) performance status  $\leq 2$ . The primary endpoint was to evaluate the symptoms response rate produced by a radiotherapy regimen based on the delivery of 4 radiotherapy fractions (5 Gy per fraction) with a twice daily fractionation in two consecutive days.

**Results:** Twenty-nine patients were enrolled in this trial. Characteristics of the patients were: male/female: 16/13; median age: 66 years (range: 46-87). ECOG performance status was  $\leq 2$  in 25 patients (86.2%). With a median follow-up time of 5.0 months (range, 1 to 36 months), 9 G1-2 gastrointestinal (31%), 2 G1 haematological (6.8%) and 6 G1 skin (20.7%) toxicities were recorded. Only 1 patient (3.4%) experienced G3 acute gastro-intestinal toxicity. Of 29 symptomatic patients, 27 showed an improvement or resolution of baseline symptoms (overall palliative response rate: 92.6%). Three-month overall survival was 92.2% (median survival time: not reached). In 25 patients with pain, a significant reduction of this symptom was recorded in terms of Drug Score (mean baseline Drug Score vs mean Drug Score at follow-up: 5.3 vs 4.0;  $p=0.04$ ).

**Conclusion:** Short-course accelerated radiotherapy on complicated bone metastases (20 Gy in twice daily fractions for 2 consecutive days) is tolerated and effective in terms of symptom relief. A phase III comparison against a standard palliative regimen (30 Gy in 10 fractions) has been planned in this patient population.

#### EP-1435

**Radium-223 in castration resistant prostate cancer with bone metastases: preliminary clinical results**

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**Purpose or Objective:** More than 90% of patients with metastatic castration resistant prostate cancer (CRPC) have radiologic evidence of bone metastases. Radium-223 dichloride therapy showed improved overall survival, quality of life and symptom control in patients with symptomatic bone metastases. Aim of the present study is to evaluate clinical course of patients treated in our centre including biochemical and imaging response.

**Material and Methods:** Since November 2014 we started the treatment of symptomatic bone metastatic CRPC patients with Radium-223 dichloride (50kBq/kg, every 4 weeks). Before and after every administration the following parameter were recorded: PSA and alkaline phosphatase (ALP) values, pain numerical rating scale (NRS), performance status (ECOG scale), analgesic therapy and side effects (graded according to the CTCAE v. 4 classification). A whole body scintigraphy was performed before and one month after the treatment.

**Results:** Twenty patients (total: 70 administrations) were treated. All patients showed increased PSA value and reduced ALP values. Performance status, evaluated with ECOG scale, was improved in all patients. Pain control was excellent, with reduction of NRS and analgesic therapies in all patients. Most patients showed only G1 toxicity: anaemia (15 pts), fatigue (3 pts), diarrhea (1 pt), nausea (1 pt), and pain flare-up (6 pts).

Eight patients completed the 6 planned cycles of therapy. Six patients discontinued treatment due to adverse events: anaemia (2 pts), pathological fracture of the femur (1 pt), severe bleeding (2 pts) and complications in uncontrolled diabetes (1 pt). The other patients are still under treatment. Whole body scintigraphy performed one month after the end of the treatment demonstrated in all patients a reduced intensity and number of uptake areas without correlation with PSA values.

**Conclusion:** Treatment with Radium 223 in patients with CRPC and symptomatic bone metastases was tolerated in the majority of patients. High response rates in terms of symptom control and QoL improvement were recorded.

#### EP-1436

**The superior vena cava syndrome (SVCS): role of the radiotherapy**

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**Purpose or Objective:** To determine the results of 55 patients with Superior Vena Cava Syndrome (SVCS) treated with radiotherapy.

**Material and Methods:** Between September 2009 and September 2014, 55 patients with SVCS were treated at Operative Unity of Radiotherapy and Radiobiology, "Hospital Pugliese-Ciaccio", Catanzaro. Of these 21 were women and 34 men, with a median age at diagnosis of 61 years (range 33-77 years). The most predominant symptoms were face or neck swelling (85%), upper swelling extremity (73%), dyspnea (70%), cough (62%), neck and vein distension (45%). Radiotherapy (RT) has been the only treatment in 6 of 11 patients in which the rapidly progressive symptoms has not allowed to submit to a histologic diagnosis. For the patients which the histo-pathological diagnosis was known and for those in which to effect it, the treatment has included both the chemotherapy and the radiotherapy. The fractionation schedule usually has included initial fractions of 300-400 cGy (2-4 fractions) followed by conventional fractionation of 180-200 cGy. The RT total dose delivered is varied by 2000 cGy to 5000 cGy

**Results:** With regard radiotherapy delivered, in 5 (9%) of the 55 patient essays we have observed a complete regression of the SVCS, while in 27 (49%) the response has been partial, stability of illness has been underlined in 15 (27%) patients and disease progression in 8 (15%) patients.

**Conclusion:** In summary, in the SVCS the clinical symptoms often requires an urgent intervention. Survival depend on the status of patient's disease and on the histologic type of the tumor. Radiotherapy is effective in the treatment of the initial SVCS and in the patients that relapsed or with recurrent illness. The radiotherapy produces a good control of the symptoms. There is no necessity of ample fractions in the initial treatment. In the reirradiation, the radiotherapy on mediastinum is one of the most greater components of the palliation. Moreover, in presence laryngeal stridor the radiotherapy can be administered before the histological diagnosis is available.

#### EP-1437

**Radiofrequency, Cementoplasty and Radiotherapy: combined strategy in patients with bone metastases**

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