MGA parameters and awareness of disease, family interference, reading of CF by proxy and probability of receiving less information, as follows:

| | PS | Charlson's score | MMS | GDS | ADL | IADL |
|---|---|---|---|---|---|---|
| Awareness of disease | p = 0.036 | ns | p < 0.001 | p = 0.013 | ns | ns |
| Family interference | p = 0.003 | ns | p = 0.022 | ns | p = 0.025 | p = 0.031 |
| Reading of CF by proxy | p < 0.001 | ns | ns | p = 0.033 | p = 0.033 | p < 0.001 |
| Less information | p < 0.001 | ns | p = 0.041 | ns | p < 0.001 | p < 0.001 |

ns = non significant

**Conclusions:** Our prospective cohort shows that limited and/or attenuated information is still a relevant modality of relation with elderly cancer patients undergoing chemotherapy in Italy, often in connivance with their family. Limited awareness of disease correlates with poor PS and cognitive/affective problems, while family interference is more frequent in patients with cognitive deficit and low functional status. Comorbidity does not appear to play a relevant role in the informed consent process.

**1276** POSTER

**Duration of onset of metastatic bone pain relief with ibandronate: phase III and phase II trial results**

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**Background:** Bone pain is the most common reason for patients with skeletal metastases to seek treatment from their physician. This symptom is difficult to manage and often persists despite bone radiotherapy or analgesic consumption. The onset of metastatic bone pain relief with ibandronate has been evaluated in clinical trials.
**Materials and methods:** In a 96-week, randomized, phase III trial, ibandronate 6mg (n = 154) or placebo (n = 158) was infused over 1–2 hours every 3–4 weeks. In two phase III studies (data pooled), patients received oral ibandronate 50mg (n = 287) or placebo (n = 277) once daily. Bone pain was assessed on a 5-point scale (0 = none to 4 = intolerable). In phase II studies of patients with bone pain due to metastatic urologic cancer (n = 55) or hormone refractory prostate cancer (HRPCA; n = 45), ibandronate 6mg was infused on 3 consecutive days (18mg loading dose), followed by a single 6 mg infusion every 4 weeks. Bone pain was assessed on a visual analog scale (VAS) from 0 = no pain to 10 = maximum pain. Analgesic use was recorded in a diary and functioning by the Karnofsky index.
**Results:** In a phase III trial, intravenous ibandronate 6mg reduced bone pain below baseline within 4 weeks (maximal effect by Week 12). At endpoint, the mean change from baseline was −0.28 vs +0.21 with placebo ($p < 0.001$). Oral ibandronate 50 mg also reduced bone pain below baseline within a few weeks; this was maintained for 2 years (−0.20 vs +0.10 with placebo at Week 96; $p = 0.001$). In the urologic cancer study, 73% of patients (40/55) had pain relief (≥ 3-point VAS reduction) by Day 2 following loading-dose ibandronate, reaching statistical significance on Day 3 (2.5 vs 6.8 at baseline, $p < 0.001$). Eleven patients (20%) became pain-free. Analgesic use reduced by ≥50% in 64% of patients (35/55). In the HRPCA study, 40 patients (89%) had pain relief by Day 3 ($p < 0.001$). In both phase II studies pain scores remained below baseline for >20 weeks with ibandronate maintenance dosing; performance status also improved (regained mobility and independence).
**Conclusions:** Standard-dose ibandronate alleviated bone pain within several weeks, and for up to 2 years. Severe symptoms were reduced within days of the intravenous loading dose, suggesting that ibandronate offers rapid relief to patients who need it the most. Trial findings are corroborated by case report data. Large-scale comparative trials of oral ibandronate and intravenous zoledronic acid for metastatic bone pain are planned.

**1277** POSTER

**Quality of life in patients with painful bone metastases: results from the randomized Dutch Bone Metastasis Study on single fraction versus multiple fraction radiotherapy**

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**Background:** The prospectively randomized Dutch Bone Metastasis Study evaluated the palliative effect of 8 Gy single fraction radiotherapy versus 24 Gy in 6 fractions in patients with painful bone metastases. In previous Publication onlyns, the equal effectiveness of both radiotherapy treatment schedules for treating pain was reported. Here, we focus on three specific quality of life (QOL) domains in patients with painful bone metastases.
**Material and methods:** 1157 patients were randomized into the study. Median overall survival was 7 months. Patients filled out 13 weekly and then monthly questionnaires for two years or until death. Questionnaires contained 48 items from EORTC QLQ-C30, Rotterdam Symptom Check List and EURO-QOL. Item scores were summarized by three component scores: physical symptoms, psychological symptoms and functional status. Mixed modeling was used to model the course of QOL during follow up, and to test differences between the two randomization groups, and between primary tumor groups (breast cancer, lung cancer, prostate cancer versus other types of cancer). Differences were expressed as effect sizes d, which can be interpreted as small (d = 0.2), medium (d = 0.5), or large (d = 0.8).
**Results:** In general, patients deteriorated immediately after treatment, subsequently recovered and temporarily improved, but deteriorated sharply in the last months before death. Recovery and improvement were larger in patients with a more prolonged survival. For example, patients with 18 months survival reported less physical symptoms than patients with 6 months survival (figure 1). In addition, patients who received multiple fractions reported more physical symptoms than after a single fraction (d = 0.11, $P < 0.01$), but not more psychological symptoms (d = 0.05, $P = 0.20$) or worse functioning (d = 0.01, $P = 0.80$). Patients with breast cancer reported more psychological symptoms (d = 0.20, $P = 0.02$) and worse functioning (d = 0.19, $P = 0.04$).

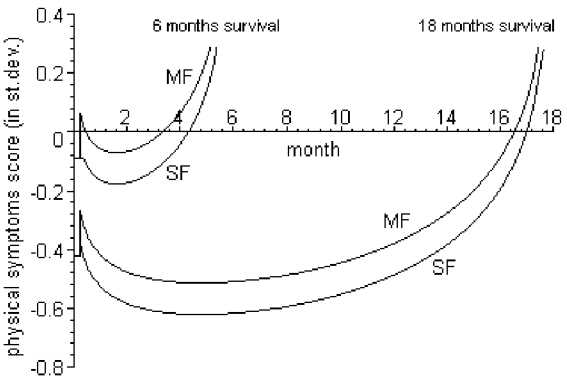


Fig. 1: Mean curve estimates of physical symptoms scores of patients who recieved either single fraction (SF) or multiple fraction (MF) radiotherapy and who survived either 6 or 18 months.

**Conclusions:** The course of QOL of patients receiving single fraction radiotherapy is at least as good as the QOL of patients receiving multiple fractions. Because single fraction radiotherapy provides equal palliation for treating pain it should be the standard palliative treatment for the majority of patients with painful bone metastases. Patients with breast cancer reported worse QOL than others, for that reason, further analyses of specific QOL domains related to direct treatment side effects will be presented at ECCO.

**1278** POSTER

**The efficacy of interleukin-6 and hypothalamus-pituitary-adrenal (HPA) axis function as predictors for the presence of depression in cancer patients**

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**Background:** Inflammation and perturbation of the hypothalamic-pituitary-adrenal (HPA) axis function play a putative role in the ethiology of depression. Patients (pts) with metastatic cancer show elevated prevalence rates for depression. The objective of this study was to illustrate the efficacy of interleukin-6 (IL-6) and HPA axis function in predicting the presence of depression in pts with cancer.
**Methods:** 114 patients with metastatic cancer were assessed by the Hospital Anxiety and Depression Scale (HADS) for Depression and diagnoses was established according to the DSM-IV criteria. A level of ≥ 11 was considered significant on the HADS-D axes for Depression. Plasma concentrations of IL-6 were measured in addition to cortisol levels (8AM and 8PM). The relative diurnal variation of cortisol (cortisol VAR), expressed in percent, was calculated as measure of the circadian function of the HPA