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Then we have applied Multidimensional Prognostic Index (MPI), developed on mortality risk, finding that cancer patients have a lower risk in comparison to non cancer patients.

Conclusion: VES-13 criteria and Multidimensional Prognostic Index are shown sensitive to recognize and to discriminate frail patients with or without cancer. We have found that comorbidity and functional status are independent in cancer patients. Cancer patients are less frail showing best scores, with a statistically significant lower mortality risk than non cancer patients.

4001 ORAL

The role of family caregivers of elderly cancer patients in the choice of non disclosure – a GIOGer study

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Background: To investigate the caregiver's role in the choice of non disclosure and in the patient-physician communication.

Materials and Methods: 622 elderly cancer patients and 194 family caregivers of partially Informed (PI) or not-Informed (NI) patients were interviewed. PI patients received only approximate information, aimed at reassurance, NI patients had no access to information. Family caregiver was identified by the patient as the primary source of emotional and social support.

Results: Out of 622 patients, 210 (33.8%) received limited information, 136 patients (64.8%) were partially informed (PI) and 74 (35.2%) not informed (NI). Out of 210 caregivers, 16 refused study participation and 194 were interviewed.

Patients living with their spouse were better informed than patients living with their children. The decision to not inform the patients arose into the family (77% of PI, 86% of NI) due to the psychological frailty of the patient (52.8% NI, 32.8% PI) and considering the direct patient-physician communication at risk of destabilizing emotional strain (66.7% NI, 67.25 PI). PI patients' caregiver consider more destabilizing the information on prognosis (48.4%), while NI patients' caregiver on diagnosis (44.4%). Interviewed caregivers were afraid of increased risk of anxiety and depression in their relatives (55.7%).

Conclusion: The choice of non disclosure was independent from an explicit request of the patient and driven by caregiver's fear and needs. Caregiver preferred to preliminarily define the contents of clinical communication and discuss with the physician social and family contest of the patient. They were not aware that adequate information provides a better opportunity to share anxieties.

Early intervention tailored on caregiver's needs and skills, are needed to avoid the risk of distress of the caregiver and to help medical staff to manage the various aspects of clinical communication.

002 ORA

Surgical treatment of colorectal malignancies in patients aged 80 and older: does age make a difference?

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Background: In the elderly with cancer, clinical decision making is often complicated by the effects of aging. However as life expectancy continues to rise, more people aged 80 and older will present with gastro-intestinal malignancy and may need major surgery. We evaluated our results in colorectal surgery, especially regarding the perioperative mortality, in this oncogeriatric population.

Materials and Methods: Data of 121 patients aged 70–75 and 132 patients aged 80 and older operated upon for colorectal malignancies between 2000 and 2008 were prospectively registered. The registered parameters included: gender, age, tumor location and stage, type of surgery performed, American Society of Anaesthesiologists (ASA)-score, duration of hospitalisation, follow-up, mortality and neoadjuvant treatment. The data were compared between the two age groups and a risk factor analysis for perioperative mortality was performed, stratifying for both age

Results: The perioperative mortality was significantly higher in the 80+ group (n = 18 (13.6%) vs n = 1 (0.8%) in the 70–75 group (P < 0.001). Mean follow up was significantly longer in the 70–75 group 30 ± 23 months versus 18 ± 18 months in the 80+ group (P < 0.001).

In the 80+ group significantly higher tumor stages were found (P = 0.031). More patients in the 70–75 group received radiotherapy (14.0% vs 3.8%, P = 0.008). Type of surgery also differed between groups: more Hartman

and derivative procedures in the octogenarian group and more anterior and rectosigmoid resections in the 70–75 group (P=0.027). In addition, risk factor analysis showed an ASA-score of 4, and higher tumor stage to increase the perioperative mortality in the 80+ group (P=0.020 and P=0.043 respectively), whereas these risk factors were not significant in the 70–75 group.

Conclusions: In octogenarians, high ASA-score and high tumor stage contribute to perioperative mortality when operated upon for colorectal cancer. In these specific patients other therapeutical options should be considered. In case of lower ASA-scores (\leqslant 3) and tumor stage surgical treatment should not be denied to octogenerians. We found that our 80+population seems to be underdiagnosed and undertreated based upon the shorter follow up and more advanced tumor stage at presentation in this group.

To offer the optimal oncological treatment in this geriatric population more extensive preoperative screening is needed.

4003 ORAL

ICE Study: A prospective, multi-centre, controlled, open-label, randomized phase III trial of ibandronate (I) with or without capecitabine (X) in elderly patients (pts) with early breast cancer (GBG 32)

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Background: Data on elderly pts with breast cancer are limited. The CALGB reported data comparing EC or CMF combination therapy versus X monotherapy, suggesting that hormone receptor (HR)-negative pts particularly benefit from polychemotherapy. The ICE study compared X monotherapy plus bisphosphonate versus bisphosphonate alone in elderly pts at increased risk of relapse.

Methods: Pts received either I alone for 2 years (50 mg p.o. daily or 6 mg i.v. every 4 weeks according to pt preference) or the same dose of I for 2 years + X 1000 mg/m² bid on days 1–14 q21 days for 6 cycles. Pts with HR positive disease received endocrine therapy according to local/institution guidelines. The primary objective is to compare disease-free survival (DFS) with either I alone or I + X as adjuvant treatment for primary breast cancer in pts \geqslant 65 years. Secondary objectives are to compare overall survival between the two arms and to assess compliance, toxicity, bone-related events, preference for oral or i.v. I, quality of life, and prognostic and predictive factors. Main inclusion criteria are: female \geqslant 65 years with histologically confirmed breast cancer that is either node-positive or high-risk node-negative (tumour size \geqslant 2 cm, grade > I, and/or ER- and PR-negative); no prior chemotherapy, adequate organ function and a Charlson score \leqslant 2.

A total of 1,394 pts (697 per arm) with 497 events are needed to show an improvement in 5-year DFS from 65% to 71.5% with X, assuming a drop-out rate of 5%. A clinically relevant difference between the treatment arms is detectable at α = 0.05 (two-sided) with 80% power.

Results: Between 06/2004 and 08/2008 1409 pts were recruited in 172 German centers; 703 pts received X+I, 706 pts received I only. The median age was 71 years (range 64–88). 570 pts (80.7%) were HR positive and 133 (19.3%) were HR negative. Lymph nodes were positive in 335 (48.2%) pts and negative in 368 (51.8%) pts. A safety analysis of the first 100 pts treated with X+I demonstrated that >75% of pts received the full dose and cycles of chemotherapy. During the entire recruitment period, no safety-related amendment to the study protocol was required. 305 SAEs were reported, the majority due to gastrointestinal (45), skin (38) and cardiac (43) disorders.

Conclusion: This is the largest adjuvant study in the elderly population and the only one involving a non-chemotherapy arm. So far, there are no safety concerns. First safety data from the entire population will be presented.