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Track 4 - Nursing, Supportive Care and Geriatric Assessment Geriatric Assessment

O20

PROGNOSTIC VALUE OF GERIATRIC SCREENING AND ASSESSMENT FOR OVERALL SURVIVAL IN OLDER PATIENTS WITH CANCER

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Introduction: Geriatric screening and assessment in older patients with cancer is expected to be useful for better estimating residual life expectancy and lethality of the malignancy in the context of competing comorbidities and general health problems.

Objectives: The aim of this study is to determine the prognostic value of geriatric screening and assessment components for overall survival (OS) in older patients with cancer.

Methods: Older (70 years or older) patients were included if a new cancer event occurred requiring treatment decision. Geriatric screening with G8 and Flemish version of the Triage Risk Screening Tool (fTRST) was performed in all patients, as well as a geriatric assessment (GA) evaluating living situation, functionality (Activities of Daily Living [ADL]; Instrumental Activities of Daily Living [IADL]), fall history in the past 12 months, cognition (Mini Mental State Examination [MMSE]), depression (Geriatric Depression Scale [GDS]), and nutrition (Mini Nutritional Assessment – Short Form [MNA-SF]). Univariate analyses (log-rank test) were conducted to explore the associations between OS and geriatric screening and assessment components. Multivariate analyses are still being conducted.

Results: Nine hundred thirty-seven patients with heterogeneous diagnoses were included (October 2009 to July 2011) (median age = 76 years (range: 70–95)). Mean time of follow-up was 24.9 months, with 517 deaths during the follow-up period. The presence of a geriatric risk profile based on geriatric screening by G8 (hazard ratio [HR] = 0.37) and fTRST (HR = 0.60) were both related to poorer OS. Functional impairments (ADL [HR = 0.73], IADL [HR = 0.55]), decreased cognitive status (HR = 0.62), at risk for depression (HR = 0.59) and nutritional problems (HR = 0.42) were all significantly unfavorable prognostic assessment scores. OS was not associated with living situation and fall history.

Conclusion: These preliminary results confirm the potential of geriatric screening and assessment data in better predicting OS of older patients with cancer. Further research is necessary to develop a GA based prognostic index.

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Track 1 - Solid Tumours in the Elderly Targeted therapies in elderly cancer patients

O21

EFFECT OF AGE ON THE EFFICACY AND SAFETY OF LENVATINIB FOR THE TREATMENT OF 131I-REFRACTORY DIFFERENTIATED THYROID CANCER IN THE PHASE 3 SELECT STUDY

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Introduction: The Phase 3 SELECT study demonstrated a significant 14.7-month prolongation of median progression-free survival (PFS) in patients with progressive radioiodine-refractory differentiated thyroid cancer (RR-DTC) treated with lenvatinib compared with placebo. Lenvatinib-associated toxicities in the overall study were considerable but managed with dose modifications and medications.

Objectives: The patient with progressive RR-DTC is often older and less tolerant of high-grade adverse events (AEs); hence, this analysis compared the efficacy and safety profile of lenvatinib treatment for patients with RR-DTC in SELECT by age subgroup.

Methods: This prespecified subgroup analysis examined PFS and the incidence of AEs for younger patients (aged ≤65 years: lenvatinib, n = 155; placebo, n = 81) and older patients (aged >65 years: lenvatinib, n = 106; placebo, n = 50) from SELECT. Independent radiologic review was required at screening and upon disease progression. Tumor assessments were conducted every 8 weeks using RECIST v1.1 criteria and safety assessments were performed throughout the study.

Results: The overall study population incidence of any-grade lenvatinib treatment-related AEs (TRAEs) was 97.3%, with 75.9% Grade ≥3 TRAEs. Although the proportion of patients who experienced any-grade TRAEs was similar between age groups, there was an increased incidence of Grade ≥3 TRAEs in older patients (for

patients aged ≤ 65 and > 65 years, respectively, any-grade TRAEs: 96.1% vs 99.1%; Grade ≥ 3 TRAEs: 67.1% vs 88.7%). Serious treatment-emergent AEs were experienced by 51% of all lenvatinib-treated patients in the overall study, and there were 20 (8%) fatal AEs in the lenvatinib arm. Younger patients experienced fewer nonfatal serious AEs (47.7% vs 52.8%) or fatal AEs (6.5% vs 9.4%) compared with older patients. In younger vs older patients, respectively, there was a lower incidence of any-grade asthenia (21.3% vs 30.2%), Grade ≥ 3 hypertension (38.1% vs 50.0%), Grade ≥ 3 proteinuria (7.7% vs 13.2%), and Grade ≥ 3 decreased appetite (3.2% vs 9.4%). Conversely, in patients aged ≤ 65 years vs patients aged > 65 years, there was a greater incidence of any-grade diarrhea (70.3% vs 60.4%) and any-grade palmar-plantar erythrodysesthesia syndrome (36.1% vs 26.4%). In the overall study, 67.8% of patients required a dose reduction, 82.4% had dose interruption, and 14.2% discontinued treatment due to AEs. Dose modifications occurred at a higher frequency in older patients: dose reductions, interruptions, and study-drug discontinuation occurred in 63.9%, 79.4%, and 13.5% of patients aged ≤ 65 years, respectively, and in 73.6%, 86.8%, and 20.8% of patients aged > 65 years, respectively. The PFS benefit with lenvatinib vs placebo was observed in both age groups (for patients ≤ 65 years: median PFS = 20.2 vs 3.2 months; HR 0.19; 95% CI 0.13–0.27; for patients > 65 years: median PFS = 16.7 vs 3.7 months; HR 0.27; 95% CI 0.17–0.43).

Conclusion: This prespecified subgroup analysis demonstrated improved median PFS with lenvatinib treatment compared with placebo in both younger and older patients with RR-DTC. A higher proportion of older patients reported more Grade ≥ 3 AEs, including increased incidences of hypertension and proteinuria – known class effects of VEGF inhibitors. This analysis highlights the need for close monitoring of toxicities, good communication between patients and physicians, and clear management plans for AEs, especially for older patients.

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Track 3 - New therapies and Basic Science Translational research

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EVALUATION OF CLINICAL AND BIOLOGICAL FRAILTY MARKERS IN OLDER BREAST CANCER PATIENTS

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Introduction: Potential benefits of cancer treatment in older patients must be balanced against risks of toxicity and decline in functionality and quality of life. This is influenced by biological age rather than chronological age, and life expectancy. Clinical geriatric assessment (GA) reflects biological age to a certain extent, but is imperfect in predicting individual outcome, and is time consuming. There is increasing interest in (blood) ageing biomarkers to help in selecting patients who are sufficiently fit for therapy, but none have so far been validated for clinical use.

Objectives: Our aim was to explore the relationship of five potential ageing markers (IL-6, CCL5/RANTES, CCL2/MCP-1, IGF-1, leukocyte telomere length) with calendar age and GA.

Methods: We retrospectively assessed two cohorts of patients with new diagnosis of early or locally advanced breast cancer, for whom a blood sample was collected at diagnosis. The first cohort (N = 162) included patients with age ≥ 70 years, and the second (N = 82) consisted of patients aged 27 to 56 years. Patient scores for each test of the geriatric assessment (in the first group) were gathered from the GA database of our breast centre. Charlson Comorbidity Index and frailty level according to Balducci criteria (fit, vulnerable, frail) were retrospectively calculated. In addition, we developed a new clinical tool, LOFS (Leuven Oncogeriatric Frailty Score), integrating the results from ADL, iADL, MMSE, MNA-14 and CCI tests. Results of each separate GA item were derived to a LOFS subscore (0, +1, +2) and added together, to obtain a final score in a continuous scale ranging from 0 (extreme frailty) to 10 (fit patient). The goal of the LOFS was to create a tool that is as practical in daily use as the Balducci score (based on well validated individual tools), but that evaluates global health status in a continuous way.

Circulating levels of IL-6, CCL5/RANTES, CCL2/MCP-1, and IGF-1 were measured using ELISA technique. Telomere length was assessed by qPCR measurement of T/S ratio on leukocyte DNA.

Statistical analysis was performed by Mann-Whitney U test (for two levels) or Kruskal-Wallis test (for more than two levels). Association between two continuous variables, or between a continuous and an ordinal categorical variable, were analyzed by the Spearman correlation coefficient. Associations between two discrete variables were analyzed using the Fisher exact test.

Results: In the older cohort, 49.4% of patients had ADL dependency and 53.9% showed dependency at iADL. According to Balducci scale, 24.1% scored 'fit', 25.3% 'vulnerable' and 50.6% 'frail'. LOFS was calculated for 130 patients: the median was 8 (Q1 = 7, Q3 = 9).

All biomarkers, except RANTES, showed significant correlation with calendar age as a continuous variable ($p < 0.0001$, see table).

Biomarker	N	Spearman	P
Telomere length	196	-0.396	<.0001
IL-6	238	0.272	<.0001
IGF-1	213	-0.529	<.0001
MCP-1	238	0.412	<.0001
RANTES	238	-0.106	0.1032

Correlation with frailty scores could only be demonstrated for IL-6 ($p = 0.019$ and $p = 0.0131$ for Balducci score and LOFS, respectively).

Conclusion: Our results demonstrate that circulating IL-6 levels are associated with both chronological age and clinical frailty in breast cancer patients. As telomere length, IGF-1 and MCP-1 were clearly correlated with age but not with frailty (neither defined by Balducci criteria, nor by LOFS), they might reflect chronological age rather than biological age or frailty. Further research is needed to assess whether these biomarker predict outcome in addition to GA.

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