ORAL ABSTRACT SESSION: Gynecologic Cancer

**Samedi 2 juin**: Salle E354b

**15h00 à 15h15**  
**ETUDE TARCEVA**  
Ignace B. Vergote  
Abstract N°: #LBA5000

Randomized phase III study of erlotinib versus observation in patients with no evidence of disease progression after first-line platin-based chemotherapy for ovarian carcinoma: A GCIG and EORTC-GCG study.

**15h30 à 15h45**  
**ETUDE AURELIA**  
Eric Pujade-Lauraine, M.D, Ph.D.  
Abstract N°: #LBA5002

A randomized phase III trial evaluating bevacizumab (BEV) plus chemotherapy (CT) for platinum (PT)-resistant recurrent ovarian cancer (OC)
FAG3 TELOMERES
Claire Falandry, MD, PhD
Abstract #9011

Title: Short telomeres (ST) correlate with vulnerability, toxicity and early death in elderly AOC patients receiving carboplatin: a multicenter GINECO trial.

Background: Age induces a progressive decline in the functional reserve and interferes with cancer treatments. As aging is heterogeneous, this decline has to be assessed individually. Telomere attrition leads to tissue senescence. We tested the hypothesis that telomere length (TL) could predict pts vulnerability and outcome during cancer treatment.

Methods: This study was performed in the “Elderly women” GINECO trial designed to evaluate the impact of geriatric covariates on survival in AOC pts over 70 receiving 6 courses of carboplatin. TL was estimated in duplicate using standard Terminal Restriction Fragment analysis from peripheral blood cells at inclusion and tested for its correlation with geriatric covariates and pts outcomes (TC and tolerance, overall survival: OS).

Results: TL (in base pair) was estimated for 109/111 pts (median 5997; extremes [4517-8333]). No significant correlation was found with any pts characteristics. With a cutoff of 5770 bp, TL discriminated two groups with significantly different Treatment Completion (TC) rates: 0.80 (95CI[0.71-0.89]) and 0.59 (95CI[0.41-0.76]), OR=2.8, p=0.02 for long telomere (LT) and short telomere groups, respectively. ST pts were at higher risk of severe adverse events (SAE, OR=2.7; p<0.02) and tended to have more unplanned hospital admissions (OR=2.1; p<0.08). Considering OS, after adjustment on FIGO stage, TL shorter than the median was a nearly significant risk factor of premature death (HR=1.57; p=0.06. Finally, we addressed if TL correlated with our previously validated geriatric vulnerability score (GVS)c including ADL score<6, IADL score<25, albuminemia<35g/l, lymphopenia<1G/L, HADS score≤15 as risk factors of poorer survival. Despite no significant correlation with any of these factors, GVS≥3) and ST tended to be correlated (OR=2.1; p=0.08).

Conclusion: This exploratory study identifies TL as predictive factor of decreased TC, SAE risk, unplanned hospital admissions and OS after adjustment on FIGO stage.
REV
Frédéric Selle, M.D.
Poster Board: #7

Title: Lenalidomide (REV) in asymptomatic late recurrent ovarian cancer (ROC) patients with increasing CA 125: A GINECO phase II trial

Background: REV is a thalidomide analogue, with both immunomodulatory and anti-angiogenic properties that could confer antitumor effect in ROC.

Methods: The aim of this study was to evaluate REV efficacy as single agent in patients (pts) with asymptomatic late ROC (>6mos) with increasing CA 125, in 2nd or 3rd line. Primary endpoint was to estimate the rate of non-progressive disease at 4 mos. Pts were treated with REV 20 mg daily in oral continuous regimen with systematically recommended anti-thrombotic prophylaxis (ATP). Imagery and CA 125 were performed every 8 weeks.

Results: From 05/2009 to 09/2010, 45 pts were included with a median age of 63 years. Pt characteristics were: serous (78%), previous lines (one 73%, two 27%), median platinum-free interval (PFI) (11.3 mos), PFI > 12 mos (42%), measurable disease (73%), and ECOG performance status 0 (84%). Efficacy: Rate of non progressive disease at 4 mos was 38% (95%CI, 23-53), 59% (95%CI, 36-82) and 24% (95%CI, 7-41) for the global population, pts relapsing over 12 mos and those relapsing between 6-12 mos, respectively. Results were independent of the number of previous lines. Median progression-free survival was 3.8 mos (95%CI, 2.1-5.6) and 6.4 mos in the subset of pts with PFI > 12 mos. Response evaluation according to CA 125 (Rustin criteria) was: complete response (CR) 2.4%, partial response (PR) 17%, stable disease (SD) 71%. When using RECIST criteria alone, response evaluation was: 9.5% PR and 45% SD. Median duration of biological response was 6.6 mos. REV efficacy will be correlated to immunological parameters (lymphocyte phenotypes and cytokines). Safety: Grade 3 toxicity in more than 5% of pts was neutropenia (29%) and thromboembolic events (TEE) (3%). TEE occurred only in pts without ATP. Reasons for stopping treatment due to toxicity were TEE (3), allergy (2), arrhythmia (1), dyspnea (1) and neutropenia (1).

Conclusion: REV demonstrated encouraging activity in ROC with good tolerability and manageable adverse events. A phase I of REV combined with platinum-based chemotherapy is currently being conducted.

OCTAVIA
Antonio Gonzalez-Martin, MD
Poster Board: #6

Title: Safety of front-line bevacizumab (BEV) combined with weekly paclitaxel (wPAC) and q3w carboplatin (C) for ovarian cancer (OC): Results from OCTAVIA.

Background: In two randomized phase III trials in OC (GOG218 and ICON7), front-line BEV + q3w PAC + q3w C followed by BEV alone significantly improved progression-free survival (PFS) vs chemotherapy (CT) alone. In the Japanese NOVEL trial, wPAC + q3w C was more effective than q3w PAC + C, but toxicity limited CT delivery. The single-arm OCTAVIA study evaluated front-line BEV + wPAC + q3w C. Methods: Patients (pts) received 6–8 cycles of BEV (7.5 mg/kg, d1) + wPAC (80 mg/m2 d1, 8, 15) + C (AUC6, d1) iv q3w, with BEV q3w continued alone for a total of up to 17 cycles (1 y) as front-line therapy for newly diagnosed OC (FIGO stage I–IIa [grade 3/clear cell] or stage IIb–IV [any grade]). The trial was designed to recruit a pt population similar to that enrolled in ICON7. The primary endpoint was PFS. Secondary endpoints included response rate, duration of response, overall survival, biological progression-free interval, and safety. Previously we reported safety findings from the concurrent CT phase. Here we present final safety results from the entire treatment period. Results: Between Jun 2009 and Jun 2010, 189 eligible pts were enrolled. Baseline characteristics: median age 55 y (range 24–79 y); ECOG 0 74%; FIGO stage I/II/III/IV 10%/10%/63%/17%; serous/clear cell/mixed 65%/6%/6%; 71% optimally debulked. Pts received a median of 6 CT cycles (range 1–8) and 17 BEV cycles (range 0–18). Of the 168 pts who received single-agent BEV, 135 completed 1 y of therapy. In the entire treatment period, BEV was discontinued for adverse events (AEs) in 12% and disease progression (PD) in 10%. The most common grade ≥3 hematologic AEs were neutropenia (60%), anemia (8%), and thrombocytopenia (7%). The incidences of grade ≥3 AEs of special interest for BEV were: hypertension 4.2% (grade 2/3/4: 9.0%/3.2%/1.1%); thromboembolic events 6.3% (grade 3/4: 3.7%/2.6%); bleeding 0.5% (grade 3), wound-healing complications 0.5% (grade 3), and GI perforation 0.5% (grade 4). There was no grade ≥3 proteinuria or fistula/abscess. At the time of data cut-off, 9 pts had died, all from PD.

Conclusions: BEV combined with wPAC is feasible and well tolerated. BEV AEs were no more frequent with wPAC in OCTAVIA than with q3w PAC in ICON7.
Samedi 2 juin de 8h00 à 12h00: S Hall A2

FAG3 ETUDE CLINIQUE
Gilles Freyer, M.D, Ph.D.
Poster Board: #43B

Title: Development of a geriatric vulnerability score (GVS) in elderly advanced ovarian cancer (AOC) patients (pts) treated in first line: a prospective GINECO trial.


Methods: This open prospective trial was designed to confirm the impact of geriatric Co including psycho-geriatric Co on OS of elderly pts (≥70) with stage III-IV AOC treated in first line with 6 courses of carboplatin AUC5/3weeks. Geriatric Co were tested for their impact on OS in uni- and multivariate analyses. The best fitting proportional hazard model (GVS) was developed with the inclusion of major (MaC) and minor Co (miC)

Results: From 08/2007 to 01/2010, 111 pts were included in 21 centres. A majority of pts displayed characteristics of vulnerability: age (median:78, range: 70-93, ≥80:41%), PS≥2: 43%, ≥3 major comorbidities: 27%, ≥4 medications: 69%, ADL score<6: 55%, IADL score<25: 75%, HADS≥15:37%. A total of 74% of pts, however, completed planned chemotherapy. Gr3-4 haematological toxicity was observed in 50% of pts (thrombocytopenia [27%], anaemia [19%], and neutropenia [30%]) and gr3-4 non-haematological toxicity was fatigue (16%), anorexia (13%) and infection (10%). Median OS was 16.2 months (95%CI[14-21]). MaC were: albuminemia<35g/L; ADL score <6; IADL score <25 and miC: lymphopenia<1G/L; HADS≥14. The survival score=exp(0.320*Number[MaC] +0.354*Number[miC]) was validated upon a bootstrap analysis. Using a cutoff of 3, the simplified GVS score = Number[MaC] + Number[miC] discriminated two groups with significantly different OS :11.5 vs 21.7 months; HR=2.94; p<10-4, but also treatment completion rates: 65.4% vs 82.1%; OR=0.41; p=0.04; severe adverse events (SAE): 52.7% vs 28.6%; OR=2.8; p=0.009 and unplanned hospital admissions: 52.8% vs 30.3% OR=2.6; p=0.02.

Conclusion: The GVS identified a group of pts at high risk of severe toxicity, early treatment stopping, unplanned hospitalization and poor outcome. GVS provides a useful tool to identify vulnerable pts in future elderly AOC trials.

FAG3 ETUDE ONCO-Psycho-Geriatrique
Marilène Filbet, MD
Poster Board: #43C

Title: Correlations between depression according DSM-IV-TR (DSM) criteria, three validated scales, oncologist assessment and clinical psychiatric interview in elderly advanced ovarian cancer (AOC) patients (pts) - a GINECO study

Background: Depression is a major outcome in cancer pts. Clinicians typically rely on their clinical impression of depression rather than pts self-reports. Our aim was to explore the association between patient-reported depression, oncologist assessment (OA) and a clinical psychiatric interview (CPI) in elderly AOC pts.

Methods: This analysis was a secondary endpoint of the Elderly Women AOC trial, designed to assess the impact of geriatric covariates, notably depression, on survival in pts over 70 receiving 6 courses of carboplatin. Depression was assessed using the Geriatric Depression Scale-30 (GDS; cut off score of 10/30), the Hospital Anxiety Depression Scale (HADS; cut off score of 15/42), the distress thermometer (DT; cut off score of 4/10) and OA (yes/no). CPI was conducted by psychologists within 10 days after inclusion. The interview guide for CPI (yes/no) was constructed and adapted from three validated scale: GDS, Hamilton Depression Rating Scale Hamilton (HDRS), Montgomery Asberg Depression Rating Scale (MADRS) and the DSM criteria. DSM was considered as the gold standard.

Results: Out of 111 pts, 100 (90.1 %) completed all the assessment (OA, GDS, HADS, DT, CPI). Patients characteristics were: mean age 78, performance status ≥2: 48 (55%). Thirty six pts (36%) were identified as depressed by the CPI versus 17 (17%) by OA, 32 (32%) by the GDS, 36 (36%) by the HADS, 58 (58%) by the DT and 16 (16%) according to DSM. We found a significant correlation between DSM and GDS (r=0.58; p<0.001), DSM and CPI (r=0.53; p<0.001).

Conclusion: The use of validated tools such as GDS and a collaboration between psychologists and oncologists are warranted to better identify emotional disorders in elderly women with AOC.