Symptom Benefit Working group
General Assembly

London, Saturday & Sunday, 16-17 November, 2013
03:00-05:30

Chairs: F Joly, J McAlpine
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Update publications

• The 2 publications of SB Leiden brainstorming have been submitted as companion papers in August to Annals of Oncology
• We are waiting for the reviews (still on process)
PACT in PORTEC 3: Preferences for adjuvant chemotherapy in endometrial carcinoma: what makes it worthwhile to patients and their doctors?

Linda Mileshkin
Aims of Patient preferences sub-study in PORTEC 3

To determine

• the **minimum benefits** patients and their doctors judge sufficient to make **worthwhile the addition of chemotherapy** to pelvic radiotherapy in women with high-risk and advanced endometrial carcinoma, and

• the factors influencing these preferences
Inclusion criteria and questionnaires

**Patients**
- All patients participating in PORTEC-3 in **ANZ sites**
- Patient Questionnaire

**Doctors**
- All gynaecological oncologists, radiation oncologists, and medical oncologists of patients participating in PORTEC-3
- Dr PACT-Q

**Evaluation at T0 and 9 months**
Challenges of preferences studies

- Doctor concern that asking patients about their preferences will cause distress – *rarely a problem*

- Patient Baseline: 79/87 = 91%
- Patient 9 months: 62/70 = 89%
- Dr PACT gyn onc: 39/87 = 49%
- Dr PACT med onc: 56/87 = 64%
- Dr PACT rad onc: 73/87 = 84%

- **Doctors may be uncomfortable** with giving predictions about patient outcomes!
Quality of life in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (AEOC) receiving either pazopanib monotherapy or placebo after first-line chemotherapy: AGO-OVAR16 results

M. Friedlander¹, S. Knoll², W. Meier³, A. Lesoin⁴, J.W. Kim⁵, A. Poveda⁶, M. Buck⁷, G. Scambia⁸, M. Shimada⁹, A. du Bois¹⁰

¹ANZGOG and The Prince of Wales Hospital, Randwick, NSW, Australia; ²GlaxoSmithKline Pharmaceuticals, Collegeville, USA; ³AGO and Evangelisches Krankenhaus, Duesseldorf, Germany; ⁴GINECO and Centre Oscar Lambret, Lille, France; ⁵KGOG and Seoul National University, Seoul, Korea; ⁶GEICO and Fundación Instituto Valenciano de Oncología, Valencia, Spain; ⁷ANZGOG and Sir Charles Gairdner Hospital, Nedlands, Australia; ⁸MITO and Universita Cattolica del Sacro Cuore Policlinico Gemelli, Rome, Italy; ⁹JGOG and Tottori University Hospital, Yonago City, Japan; ¹⁰AGO and Kliniken Essen Mitte, Essen, Germany
Secondary endpoint: evaluate health-related quality of life (HRQOL) as measured by EORTC QLQ-C30, OV28 and EQ-5D (captures health status across five dimensions: mobility, self-care, usual activities, pain/discomfort, anxiety/depression)

- Data were collected at baseline, week 13, months 7, 10, 13, 16, 25 (end of treatment), and 31 (post-treatment)

Pre-specified analyses examined HRQOL differences while on treatment

Maintenance therapy with pazopanib will result in a small but statistically significant decline in global HRQOL and more side effects during the time on treatment, but will be associated with an overall benefit to patients
Conclusions of QoL Substudy

• Predefined QoL endpoint
  ▪ Maintenance therapy with pazopanib results in
    • an improvement in median PFS of 5.6 months
    • a small decrement in overall HRQOL for patients on treatment
    • a significant increase in patient-reported diarrhea

• Post-hoc analyses
  ▪ Progression results in worse HRQOL and initiation of further chemotherapy
  ▪ Quality-adjusted PFS supports the net value of maintenance therapy
WG discussions

- Limitations of post-hoc analyses
  - highlight the importance of including a priori HRQOL hypotheses in future studies

- Limits of the current QoL tools for maintenance therapy
- Necessity to develop some specific questions on the impact of symptoms (induced by maintenance therapy) to daily life
- Opportunities to work with the EORTC-QoL working group to try to add specific questions to the current modules to answer to the question
Ongoing studies

• SB Study
• Ewoc study
• GOG 273 study
• Expression III and IV
Symptom Benefit Study
Update and current status

GCIG Symptom Benefit Study
M Friedlander
Schema – Stage 2-SBS

Target Population
- Informed consent
- ≥18yrs
- Platinum Resistant/Refractory*
- ECOG 0-3
- Life expectancy > 3 months
- Able to commence treatment within 2wks of registration
- Able to complete questionnaires independently

Data Collection
- Baseline
- Each treatment cycle
- One month post completion of treatment or until disease progression

To validate the MOST (QoL questionnaire for pts with palliative CT)

* Amendment included ALL patients receiving 3rd line or greater lines of treatment - including potentially platinum sensitive
• At current rate, total projected accrual would be **963** at study close (31 Dec 2014)
Discussion Points from ANZGOG group

- Suggest that the instrument is called the GCIG-MOST providing that there is needed agreement by GCIG
- The instrument would be made freely available to whoever wishes to use it in clinical trials.
- The MOST instrument and User Manual will be available on GCIG website as well as ANZGOG and PoCOG websites
EWOC-1

Elderly Women Ovarian Cancer
Multicenter, randomized trial of carboplatin +/- paclitaxel in vulnerable elderly patients with stage IIIB-IV advanced ovarian cancer

First ENGOT-GCIG international study of elderly patients in Ovarian Cancer

Participating Groups
GINECO, AGO, MITO, ANZGOG, Canada, JGOG, GOTIC, NSGO
EWOC-1 Flow chart

Patient identification

70 years old
Stage III-IV ovarian cancer
Initial diagnosis

GVS consent

NO

GVS screening

score ADL < 6
score IADL < 25
score HADS > 14
albuminemia < 35g/L
lymphopenie < 1G/L

YES

Vulnerable patient?

EWOC-1 consent

YES

Inclusion and exclusion criteria respect?

YES

EWOC-1 randomization

240 patients

Arm A
 carboplatin AUC 5 + paclitaxel
175mg/m² q21
X 6 cycles

Arm B
 carboplatin AUC 5-6
q21
X 6 cycles

Arm C
 carboplatin AUC 2 + paclitaxel
60 mg/m² weekly q28 (d1, d8, d15) x 6 cycles

Registry
Chemotherapy per investigator choice

Registry should include 500 patients
(Ewoc-1 and non vulnerable patients)

NO

Intervall debulking is allowed

NO
PRIMARY ENDPOINT

To compare the rate of success to deliver 6 courses of chemotherapy without progression at 6 months or unacceptable toxicity* of 3 different regimens in vulnerable elderly patients

* Unacceptable Toxicity = is defined as a major adverse event related to chemotherapy or treatment procedures leading either to early treatment stopping, to an unplanned hospital admission or to death.
EWOC-1 Status

May 2013  French HA and EC approval
Nov 2013  First inclusions in France

- International coordination to be started now
- GCIG Participation: AGO, MITO, NSGO, Canada, JGOG, DGOG
- Interested: KGOG and Shanghai GOG
This is a prospective observational study, not a comparison of treatment regimens.

Clinical Stage I-IV Ovarian, Peritoneal, or Fallopian Tube cancer with confirmed adenocarcinoma at age $\geq 75$, PS 0-3. Investigator decides primary surgery vs. chemotherapy. Physician/patient choice of 2 different chemotherapy regimens.

**Regimen 1**
- Carboplatin AUC 5*
- Paclitaxel 135 mg/m²
- Plus G-CSF every 3 weeks X 4
- *See Appendix I

**Interval surgical cytoreduction (if no prior primary surgery), and/or further chemotherapy at the discretion of the physician**

**Regimen 2**
- Carboplatin AUC 5*
- every 3 weeks X 4
- **See Appendix II**

QOL/geriatric assessments:
- Prior to Cycle 1 and Cycle 3, then 3-6 weeks after completion of Cycle 4**
- All subjects will undergo PK sampling on Day 1 and Day 2 of Cycle #1.

*Patients for whom the physician deems a carboplatin dose of AUC dose of 5 to be unsafe, may be given an AUC of 4.
GOG 273

- Accrual to the first two arms complete (slight overacclual, n=212)
- If possible, first results will be presented at SGO meeting March 22-25, 2014
- Third arm: Carboplatin AUC 5* every 3 weeks Plus Weekly Paclitaxel 60 mg/m2 over 1 hour every 3 weeks X 4 cycles (Day 15 Paclitaxel is optional)
  - the Geriatric Assessment Score (GAS) and tolerance to chemotherapy
ELD1106

- Approved by DCP, protocol under development
- Will explore predictive value of GAS for surgical toxicity
- Goal to have one geriatric assessment that can be used throughout GOG/NRG protocols, surgical and chemotherapy
Expression III
What do primary and recurrent ovarian cancer (OC) patients expect from their doctors and therapy management?
(NOOGGO/ENGOT-ov4 study).

J Sehouli
Numbers of participants in each country, light red columns represent online survey, dark red print survey

Total number: 1839
Conclusions

• This study underlines the high need of ovarian cancer patients to discuss all details concerning treatment options and clinical management with only minor difference between the countries.

• Patients also need more information about side effects of cancer therapies and second opinion opportunities.

• Besides effectiveness of therapy, alopecia and fatigue are the most important side effects bothering the patients.

Final analysis regarding intercultural aspects until the end of the year
EXPRESSION IV-Ovar
What do primary and recurrent ovarian cancer (OC) patients expect from maintenance therapy?
ENGOT-ov22
Aim and design

Aim:
current available drugs for maintenance therapy have:
• different side effects
• administration forms
• schedules

identification of information needs and preferences regarding maintenance therapy among patients with ovarian cancer

Design:
European survey (10-12 countries)
– 200-300 patients / country (all groups of ENGOT intent their participation)
– Internet version and hard copy version
Project

• Survivorship of endometrial cancer
  – Endometrial cancer survey patients
  – Physicians expectations?
Survivorship in Endometrial Cancer:

QoL in long term survivors, needs, and influencing factors

J McAlpine on behalf of the SB Group
Why is it important to do a survivorship study in EM cancer?

• No clear idea of “best” follow-up/surveillance strategies for EM ca patients

• No clear idea of long term survivorship needs of all patients so we could address and support

• Beginning to understand interaction of cancer, comorbidities and BMI....needs further work

• Design interventions?
We need a tool-do we start again?

• Many questionnaires exist-what are the essential components we want to capture? There are some survivorship aspects that may be unique to EM cancer patients...

• Encompassing questionnaire for ovarian cancer survivors being employed by ANZGOG→ can we adapt for EM
Components ANZGOG OvQuest survey

Series of initial questions re demographics, weight and height, prior treatment including how many lines, what drugs, participation in a clinical trial?, IP vs. IV, physicians seen, etc ...

- FACT-O
- FACT-GOG-NTX
- Insomnia severity index
- SPHERE 12
- IPAQ short form
- Supportive care needs survey-SF-34
SB Working group

- Discussion on needs of translational research on survivorships
- Discussion on interventional studies to cope with the sequelae of the treatments (i.e. lymphoedema)
- In conclusion, the group will start with a survey and the results will be presented to the next GCIG meeting