

interviewed. All data were statistically analyzed, where some questions enabled multiple statements.

**Results:** The overall response rate was 29.0%. The most gynecological departments were on secondary care (71.8%), tertiary care (23.2%) or university hospital (5.0%) level. The most clinicians performed not more than 5 BOT operations (89.2%) per year. 93.2% of the gynecological departments used additional preoperative diagnostic procedures to the classical bimanual examination and vaginal ultrasound in a case of unclear ovarian tumor: CA-125 or CEA detection (95%), CT-scan (76%), Doppler ultrasound (66%), MRI (36%) or PET-CT scan (1.7%) techniques. In the most university departments (87%), tertiary care (80%), secondary care (68%) and general practitioners' hospitals (64%) a regular fresh frozen section was performed. The surgical treatment of BOT based mostly on laparotomy (48%) and laparoscopy (15%), whereas 19% of the clinics used diagnostic laparoscopy, followed by laparotomy for completion in a second intervention or switch from laparoscopy to laparotomy in the primary surgical session (18%). In younger women clinicians performed much seldom unilateral salpingo-oophorectomy (92%) and only in 53% biopsies of the contra lateral ovary. Generally biopsies of the contra lateral ovary were performed in 4% to 53% of the patients. Chemotherapy was mostly favored in "high-risk" patients with postoperative tumor residual, micro invasion or invasive implants.

**Conclusions:** Thus high grade of insecurity in diagnostic and therapy of BOT exists in some gynecological departments and underlines the need of more educational and study activities.

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POSTER

#### Ovarian germ cell tumours: cancer institute (wia), Chennai, experience over 10 years including quality of life data

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**Background:** Ovarian germ cell tumors are highly curable malignancies which affect young women of childbearing potential. They usually present in early stages and fertility-preserving surgery followed by adjuvant chemotherapy is considered standard of care. The quality of life issues of long-term survivorship are of great importance among the young survivors. The aims of our study were to 1) study the clinical profile and outcome of Malignant Ovarian germ Cell tumors (MOGCT), and 2) analyze the quality of life among long-term survivors.

**Materials and Methods:** Patients diagnosed as MOGCT during the period 1995–2005 was retrospectively analyzed for Clinico-pathological profile, outcome and in 50 Survivors of MOGCT Quality of analysis was conducted using two questionnaires, EORTC QLQ-C30 and EORTC OV 28.

**Results:** Of the 1125 case of Ovarian cancers diagnosed during the study period MOGCT constituted 103 patients (9.1%). The median age at diagnosis was 18 years (7–45). 14.5% of patients were in the premenarcheal age. Mean duration of symptoms were 2.2 months (1–8). Acute abdomen due to torsion was seen in (7.7%). Fertility preservation surgery was performed in 82 patients (79.6%). BEP was administered in 96.2% of the patients who received chemotherapy. Stage distribution for Stage I–IV was 43.8%, 9%, 33.7% and 13.5% respectively. Dysgerminoma was the commonest subtype and constituted 41%. The 5 years and 10 years disease free survival was 80.5% and 78.4% respectively and 5 and 10 years overall survival was 85%. 91.6% patients regained their menstrual cycles in the fertility preserved group. 11 successful deliveries were noted with 50% of the fertility preserved group remaining unmarried. Total QOL score was not statistically significant among fertility preserved and unpreserved group. Both had high scores with a mean of 90.47 and 77.65 respectively. Physical functioning, role functioning and emotional functioning were significantly better in the fertility preserved group. Hormonal symptoms were significantly more in advance stage survivors and the ovaries removed group. There were no statistically significant different scores among early and advance stage survivors.

**Conclusions:** Conservative surgery and BEP based chemotherapy can cure majority of patients with MOGCT. The general psychological health and total quality of life is quite good for survivors of ovarian germ cell tumor survivors.

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POSTER

#### The new approach in early diagnosis and treatment planning of cervical cancer

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**Background:** According to statistical data in Russian Federation there is trend for increasing of incidence of invasive cervical cancer in reproductive age women. It can be explained by stopping of total cytological screening and short time of preinvasive to invasive carcinoma transformation in this age category. It is necessary to revise traditional approach in diagnosis and treatment disease with taking into account the data about role of human papillomavirus (HPV) oncogenic type for malignant progression.

**Materials and Methods:** There are retrospective and prospective clinical and morphological data of 875 patients with preinvasive and invasive cervical carcinoma. We used virusological methods, statistical methods and meta-analyses of literature data.

**Results:** It was found that squamous cell carcinoma prevails in reproductive age women. Endocervical adenocarcinoma often was found in postmenopausal women. Metastasis in lymphatic nodes often occurred in reproductive age women. In this age there were often occurred 16, 18 ? 56 HPV type and complex HPV infection. Episomal form of HPV 16, 18 DNA was found in CIN I and CIN II cases. Integrated form of HPV DNA was found in CIN III ? Ca in situ cases (HPV 16: 50%, HPV 18: 90%). Persistence of HPV 16 and 18, integrated form of HPV DNA and low viral load correlated with malignant progression and could be used as indication for loop excision or conization of cervix uteri in CIN I-II cases. Lymph-vascular space involvement and positive margins were poor factors of prognosis. HPV type and viral load correlated with lymph-vascular space involvement and morphological type and could predispose to metastasis in regional lymphatic nodes. HPV 16 type was independent prognosis factor and could evidence about poor prognosis. Low viral load or integrated form HPV DNA indicated the malignant progression and poor prognosis at I-IIa staging. These factors while choosing of more radical volume for fertility preserving treatment in patients with Ia1 stage of cervical cancer are indication for abdominal radical trachelectomy with lymphadenectomy. If integrated form of HPV 16, 18 types DNA had been found after treatment it could indicate the high risk of disease recurrence.

**Conclusion:** Application of modern high technological methods permits to show up patients with poor prognosis opportunely and plane the volume of treatment more precisely, which is important for reproductive age women.

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POSTER

#### Intraperitoneal cancer cell spreading following diagnostic hysteroscopy for endometrial cancer - a systematic review and meta-analysis

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**Background:** Hysteroscopy is a diagnostic procedure with a high accuracy for the detection of endometrial cancer. Nonetheless, several observational studies underscored a risk associated with the increase in intrauterine pressure during the procedure, suggesting that hysteroscopy may result in seeding of cancer cells into the peritoneal cavity through the fallopian tubes, and eventually upgrade the stage of the disease when limited inside the uterus. In order to clarify whether hysteroscopy is associated with a risk of intraperitoneal endometrial cancer cell dissemination we performed a meta-analysis of available trials.

**Materials and Methods:** We searched the Cochrane Central Trials Registry and PubMed without year and language restriction through March 2009. We considered eligible all retrospective, prospective and randomized controlled studies in which patients were allocated to hysteroscopy (alone or following other diagnostic procedure e.g. D&C, biopsy) versus other diagnostic procedure than hysteroscopy or no procedure. In all eligible trials patients had histologically proven endometrial cancer and underwent hysterectomy with peritoneal washings in order to confirm the presence of endometrial cancer cells within peritoneal fluid. The main outcomes were the rate of positive peritoneal cytology and the rate of disease upstaging.

**Results:** Overall 9 trials were considered eligible; 1 randomized trial, 1 prospective and 7 retrospective cohorts. Five hundred and ninety patients were allocated to hysteroscopy and 1125 to no hysteroscopy. The rate of malignant cytology was significantly higher in the hysteroscopy group OR 1.77, 95% CI 1.13–2.77 p=0.013. The positive peritoneal cytology incidence was also higher when normal saline was used as distention

medium OR 2.8, 95% CI 1.43–5.48  $p=0.003$ . Finally, the rate of disease upstaging solely due to the presence of endometrial cancer cells within the peritoneal cavity was significantly higher in patients that underwent hysteroscopy OR 2.57, 95% CI 1.11–5.93  $p=0.028$ .

**Conclusions:** Our meta-analysis suggests that diagnostic hysteroscopy in patients with endometrial cancer may hint a danger for intraperitoneal cancer cell spreading and upstaging of disease limited inside the uterus. This risk appears to be more prominent when normal saline was used as distention medium.

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## POSTER

### Primary vulvo-vaginal melanoma: management and report of a single institution experience

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**Background:** Primary melanoma of the vulva and vagina is extremely rare. They account for less 3% of all cancer of the urogenital tract in women and less than 10% of all melanoma diagnosed in women. Despite this low incidence, this disease carries a poor prognosis and shows a high tendency to metastasize because the diagnosis is often delayed.

**Objective:** Evaluate clinical outcome and management of patients diagnosed with vulvo-vaginal melanoma.

**Methods:** Retrospective review of patients with vulvo-vaginal melanoma diagnosed from 2000–2006 at Portuguese Institute of Oncology, Oporto. Parameters reviewed included age at diagnosis, family history of melanoma, presenting signs and symptoms, histological pattern, Breslow depth, ulceration status and types of treatment. Statistical analysis were done with SPSS software (version 16.0; SPSS Inc, Chicago) and survival analysis was performed by Kaplan-Meier method. Results: Melanoma site was vulva in 9 patients and vagina in 3 patients. The median age was 74 (range 51–82). Bleeding and nodule were the more frequent first symptom, 5 and 6 patients, respectively. Mean Breslow depth was 3.8 mm (1.2–8.3 mm) and the commonest histological pattern was epithelioid (8 pts). Surgery was performed in 8 patients, 5 were submitted to radiotherapy and 2 to chemotherapy. No family or personal history of melanoma was found. Median follow up was 13 months. The rate of recurrence was nearly 70%: locoregional recurrence vs distant metastasis was 3 vs 7 patients. 2-year disease free survival was 17% and 5-year overall survival was 38%. **Discussion:** Vulvo-vaginal melanoma remains a tumour with a poor outcome, with a short period of time between treatment, recurrence and death. Although the most accepted treatment in vulvar melanoma is the radical local excision, in vaginal melanoma this is not clear. Clinical trials in this area are scarce. Literature as few data concerning adjuvant and palliative treatment and this should be an impulse to think in new clinical research.

## 8064

## POSTER

### Influence of an independent review on PFS and response assessments in a phase III clinical trial in relapsed ovarian cancer

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**Background:** Independent reviews may help reduce variability and bias, resulting in auditable, more rigorous and uniform evaluation of clinical trial results. A multicenter, randomised Phase III trial compared the efficacy of trabectedin 1.1 mg/m<sup>2</sup> over 3 hours in combination with pegylated liposomal doxorubicin (PLD) 30 mg/m<sup>2</sup> given every 3 weeks (wks) vs. PLD 50 mg/m<sup>2</sup> every 4 wks in advanced relapsed ovarian cancer patients. Primary endpoint was progression free survival (PFS) based on independent radiology review (IRR) per RECIST. Additional PFS analyses were based on independent oncologist (IO) and investigator's assessments (IA). Response rate (RR) was a secondary endpoint. Pts were to be assessed every 8 wks in both arms.

**Methods:** The impact of IRR on PFS and RR in this trial was evaluated through a comprehensive comparison of IRR vs. IO and IA

assessments. IRR was performed by Independent reviewers blinded to study arm allocation following a charter with predefined methodology: two radiologists independently evaluated images; if disagreement, a 3rd radiologist adjudicated. Then, an independent oncologist had access to clinical and laboratory data that was redacted to ensure blinding to treatment arm to establish IO evaluation of PFS events and responses.

**Results:** 672 pts were randomised from 21 countries. In the protocol-specified primary analysis, PFS was significantly better for the trabectedin combination by IRR, IO and IA. The reduction in the risk of progression or death was more pronounced per IA [HR: 0.72;  $p=0.0002$ ] and IO [HR: 0.72;  $p=0.0008$ ] vs. IRR [HR: 0.79;  $p=0.0190$ ]. There were fewer PFS events per IRR (39.7% censored) vs. IA (22.6% censored) and IO (35.6% censored). Overall the IRR-IO-IA concordance (event/censored) for PFS events ranged between 70–92%. Full concordance (event/censored and PFS length) was reached in 45% of pts. However, the discordance between IA and IRR had no significant impact on PFS per IA and IO. The overall response rates with trabectedin + PLD (IA 39%, IO 30% and IRR 28%) supported the primary efficacy finding. Using the different methods of analysis, the results consistently favour the combination. The effect size determined by the IA and IO were greater than by IRR, likely due to availability of clinical data in addition to imaging, as would be the case in the clinic.

**Conclusions:** The independent radiology and oncology reviews added methodological strengths to this phase III trial, increasing reliability and interpretability of the findings and allowing meaningful comparison of results across trials in relapsed ovarian cancer. Overall, significantly better PFS and RR were consistently observed with trabectedin + PLD regardless of the methodology (IRR, IO or IA) adopted to evaluate these efficacy outcomes.

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## POSTER

### Endometrial clear cell adenocarcinoma – a retrospective analysis

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**Background:** Endometrial clear cell adenocarcinoma (ECCA) represents less than 5% of total carcinomas of the endometrium and being usually associated with poor prognosis. Biological features of this tumour remain unclear. The aim of this study was to investigate the clinical findings, treatment and outcomes of patients (pts) with ECCA in the Instituto Português de Oncologia do Porto (IPOP).

**Material and Methods:** Retrospective analysis of consecutive pts admitted in the IPOP with histological diagnosis of ECCA, from 1996 to 2008. The clinical data was obtained from clinical records. SPSS® 16 was used for statistical analysis.

**Results:** A total number of 34 pts were evaluated. ECCA with mixed histologies were excluded. The median age at diagnosis was 65 years (range: 51–78). All pts were post-menopausal. Nulliparity was found in 41.2% pts, obesity in 17.6%, hypertension in 32.4% and diabetes mellitus in 17.6%. Hormone replacement therapy (HRT) or oral contraceptive (OC) was used by 5.9% pts. Stage I (FIGO) was found in 44.1% pts, stage II in 17.6%, stage III in 32.4% and stage IV in 2.9%. A complete surgical staging was obtained in 61.8% of cases. Only 1 patient did not have surgery as part of initial treatment. Adjuvant treatment with chemotherapy and radiotherapy (external radiotherapy and/or brachytherapy) was performed in 10 pts (29.4%), radiotherapy (RT) alone in 12 pts (35.2%) and chemotherapy alone in 3 pts (2.9%). Chemotherapy with carboplatin and paclitaxel was the principal regime, used in 11 pts. Five-years overall survival was 66%. At 118 months (maximum follow-up time) 53% of pts were alive; ten pts (29.4%) relapsed during this period. Patients older than 65 years were associated with poor survival ( $p=0.01$ ). No statistical significant differences were observed for nulliparity, obesity, hypertension, diabetes mellitus, HRT, OC, surgery and FIGO stage.

**Conclusions:** In this study, age at diagnosis was found as prognostic factor. Others prognostic factors were not identified. The 5-year overall survival was longer than the described in the literature. Sample size was an important limitation of this review.