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.

8063 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 caries 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-Meyer 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 epithelioide (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^2 over 3 hours in combination with pegylated liposomal doxorubicin (PLD) 30 mg/m^2 given every 3 weeks (wks) vs. PLD 50 mg/m^2 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.

8065 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 pos-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 braquitherapy) 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.