chorioncarcinoma (n = 1) and mixed germ cell tumors (n = 28). 12 patients had primary treatment in NNBRCRC during the period 1990–2006, referred for the 1st line chemotherapy (n = 21), follow-up (n = 3) or salvage therapy after recurrence (n = 20).
Results: The median (range) age at presentation was 21 (14−42) years. 15 women (27%) presented with FIGO surgical stage I disease, 4 (7%) had pelvic metastases (stage II), and 20 (36%) had advanced (stage III/IV) disease. 17 patients had no comprehensive surgical staging. 2 women had evidence of dysgenetic gonads with a 46 XY karyotype. Primary surgery was done in 55 patients. 20 patients (36%) underwent fertility-sparing surgery.
Among the 33 women who received 1st line chemotherapy +/− surgery in NNBRCRC 23 (70%) are alive without evidence of disease at a median follow-up of 68 months. 8 deaths were associated with progressive disease, two patients died of severe chemotherapy complications and intercurrent disease, respectively. It is important to note that only 2 (10%) patients out of 20 treated in our center since 2000 year died of progressive disease. Among the 20 women referred for salvage therapy to NNBRCRC 10 women (50%) are alive without evidence of disease, 9 patients died of progressive disease and one patient died of chemotherapy complications. 3 (5%) patients received no adjuvant treatment after surgery due to stage Ia dysgerminoma with elevated AFP level. All of them are alive without evidence of disease at a median (range) follow-up of 4.2 (2−6.4) years.
Conclusions: Our date confirmed that prognosis of MOGCT is excellent if managed with standard treatment initially, that is possible, as a rule, only in specialized cancer hospitals.

5042 POSTER

Promising results of extended-field radiation therapy and high dose rate brachytherapy with concurrent platinum-based chemotherapy for uterine cervical cancer with para-aortic lymph node involvement

K. Lee[1], S. Lee[1], J. Choi[1], S. Park[2], J. Shin[3], K. Lee[3], C. Park[3].
[1]Gachon University of Medicine and Science Gil Medical Center, Radiation Oncology, Incheon, Korea; [2]Gachon University of Medicine and Science Gil Medical Center, Internal Medicine, Incheon, Korea; [3]Gachon University of Medicine and Science Gil Medical Center, Obstetrics and Gynecology, Incheon, Korea

Background: The purpose of this study is to explore the therapeutic efficacy of the extended-field radiation therapy (EFRT) and high dose rate (HDR) brachytherapy with concurrent platinum-based chemotherapy in the management of uterine cervical cancer with para-aortic lymph node involvement.
Materials and Methods: Thirty-eight patients diagnosed as uterine cervical cancer with gross para-aortic lymph node involvement with or without supra-clavicular, inguinal lymph nodes but no other distant metastases were enrolled in this study from May 1999 to August 2005. EFRT included whole pelvis and retroperitoneal para-aortic lymph node baring area and the radiation dose ranged from 32.4 to 64.4 Gy (median 55.8 Gy). After 36 to 50.4 Gy, the fields were reduced to the gross para-aortic lymph node and pelvis with mid line block. During EFRT, concurrent cisplatin (60 mg/m^2) and 5-fluorouracil (1,000 mg/m^2/24 hr for 5 consecutive days) were repeated in 3 weeks for three cycles. HDR brachytherapy using Ir-192 was delivered at the end of EFRT with doses of 21 to 32 Gy to point A in 5 to 8 fractions.
Results: Median follow-up period is 48 months (7−95 months). Two patients (5.3%) could not complete the planned EFRT because of Grade III gastroenteral complications; severe abdominal pain and diarrhea. Grade III or IV hematologic complications occurred in fifteen patients (39.5%), but all the patients were recovered without serious sequelae. Late complications requiring surgical intervention occurred in two patients (5.3%). The sites of recurrence were locoregional (pelvic and para-aortic regions), 23.7%; distant, 21.1%; and locoregional with distant, 10.5%. The 3-year overall and disease-free survival rates were 62.9% and 60.5%, respectively. There was no recurrence after 3 years of treatment. We could not find any significant prognostic factors in this study.
Conclusions: Our results suggest that EFRT and HDR brachytherapy with concurrent platinum-based chemotherapy could be safe and effective treatment for uterine cervical cancer with para-aortic lymph node involvement.

5043 POSTER

10-year-survival data for 138 patients with endometrial carcinoma treated with postoperative vaginal vault brachytherapy: excellent therapeutic ratio for intermediate risk-group and lower cancer-related mortality than from further malignancies

B. Röper[1], A. Heydemann-Obradovic[1], S.T. Astner[1], D. Hölzel[2], B. Schmalfeldt[3], M. Kiechle-Bahat[3], C. Höß[4], M. Molls[1]. *[1]Technical University/Klinikum rechts der Isar, Radiotherapy and Radiation Oncology, München, Germany; [2]Munich Tumour Center, Tumour-registry, München, Germany; [3]Technical University/Klinikum rechts der Isar, Gynaecology, München, Germany; [4]Kreisklinik Ebersberg, Gynaecology, Ebersberg, Germany*

Background: The discussion, in which subgroups of patients with endometrial carcinoma confined to the uterus external-beam radiotherapy (EBRT) can safely be replaced with vaginal vault brachytherapy (VB) is still ongoing. We evaluated the long-term results of VB in stage I-IIIA along with risk factors and causes of death.
Material and Methods: Of 151 pts with endometrial carcinoma treated with VB between 1990 and 2002, 138 met the entrance criteria (85% FIGO I, 12% II, 3% IIIA, TAH-BSO+/−LNE, no EBRT). 18 pts were of low risk (FIGO 2002: IA G1−2, IB G1), 103 intermediate risk (IB G2−3, IC G1−2, IIA-B G1−2) and 17 high risk (IC G3, IIIA). Lymphonodectomy led to >10 excised nodes in 38.4%, 1−9 nodes in 16.7% and none in 44.9%, respectively. HDR-brachytherapy was 3x10 Gy to the surface or 3x5 Gy in 5 mm tissue depths in 95.7% of pts. Update included all available data from living patients, relatives, physicians and tumour-registry Munich.
Results: Median follow-up was 93 months (range 3–185) and 107 mts for 97 survivors. 10 recurrences (3 intermediate, 7 high risk-pts) were vaginal in 1, pelvic in 5 and distant in 7 pts. At 10 years, vaginal control was 99.2% and disease-free survival 91.7% (DFS: low risk 100%, intermediate 97%, high risk 55%). LVSI and deep myometrial invasion were associated with poor DFS in univariate analysis ($p < 0.05$, Chi-Square, logrank), FIGO IIIA and grade 3 in uni- and multivariate analysis ($p < 0.05$, Cox regression). No patient experienced treatment-related toxicity > grade 2 to bladder or GI-tract.
Of 41 deaths, 12 were due to cardiovascular disease, 10 to other malignancies, 8 to endometrial carcinoma, 6 to various reasons and 5 unknown. At 10 years, overall survival was 68.5%, disease-specific survival 92.4%. In 31 patients 35 further malignancies occurred. The actuarial risk to die from these amounted to 9.9% and 17.7% after 10 and 15 years as opposed to 7.6% for endometrial carcinoma.
Conclusions: Vaginal vault brachytherapy provides an excellent therapeutic ratio in low and intermediate risk endometrioid adenocarcinoma, in which EBRT can safely be omitted. As long-term survival is high, minimizing toxicity is an important aim. More aggressive therapeutic concepts should be restricted to high risk patients in order to improve results selectively. Generally, the endpoint “overall survival” is unlikely to resemble treatment effects properly, as leading causes of death are cardiovascular disease and malignancies other than endometrial carcinoma.

5044 POSTER

Quality of life in cervical cancer survivors treated with chemoradiotherapy

N. Assensio[1], A. Opinião[1], M. Roldão[2], M. Diniz[3], J. Oliveira[1], F. Vaz[1].
[1]Instituto Português Oncologia Francisco Gentil, Medical Oncology, Lisboa, Portugal; [2]Instituto Português Oncologia Francisco Gentil, Radiotherapy, Lisboa, Portugal; [3]Instituto Português Oncologia Francisco Gentil, Gynecology, Lisboa, Portugal

Background and Objective: Chemoradiation of the cervix is the standard treatment for locally advanced patients but there is no data concerning survivors of this disease treated with combined therapy. Our objective is to study quality of life in these patients using a validated scale.
Material and Methods: This is a case–control study. Case group – 135 cervical cancer survivors treated with chemoradiation in our institution from November 2000 to September 2002. Median age was 50 years. All women were contacted by telephone and invited to participate in the study. The Portuguese translated version of the Functional Assessment of Chronic illness Therapy-Cervix Cancer Questioner (FACT-Cx, 4th version) was then mailed. Some patients were directly contacted in the gynaecology outpatient service. Control group – healthy women matched for age were recruited in the breast cancer evaluation clinic of our institution.
Results: From January to April 2007, 101 women (62 cancer survivors and 39 controls) answered the FACT-Cx scale. Preliminary data of the first part of the scale (FACT-G) concerning quality of life in general for each item is as follows (cases vs controls): physical well being – 22.7 vs 21.5; social/family well-being – 19.9 vs 19.9; functional well-being – 18.6 vs 19.8,

and emotional well-being – 17.5 vs 23.8. The difference between the two groups concerning emotional well-being will be tested for significance and the remaining items of the scale concerning cervix and gynaecological complaints are also under analysis.
Conclusions: General quality of life in cervix cancer survivors treated with chemoradiation isn't affected. Analysis of the specific part of our scale concerning gynaecological complaints will also be presented.

Head and Neck Cancer

Oral presentations (Mon, 24 Sep, 10.45–12.45)
Head and neck cancer

5500 ORAL

Induction chemotherapy for larynx preservation. Updated results of the GORTEC 2000–01 randomized trial comparing docetaxel + cisplatinum + fluorouracil (TPF) versus cisplatinum + fluorouracil (PF)

G. Calais[1], Y. Pointreau[1], M. Alfonsi[2], C. Sire[3], C. Tuchais[4], J. Tortochaux[5], S. Guerif[6]. [1]*Centre Henry S Kaplan, Radiotherapy Department, Tours, France;* [2]*Institut Ste Catherine, Radiotherapy Department, Avignon, France;* [3]*Centre Hospitalier, Radiotherapy Department, Lorient, France;* [4]*Centre Paul Papin, Radiotherapy Department, Angers, France;* [5]*Centre Jean Perrin, Radiotherapy Department, Clermont Ferrand, France;* [6]*Centre hospitalier Universitaire, Radiotherapy Department, Poitiers, France*

Background: Induction chemotherapy (CT) with PF followed by RT in case of objective response is a standard alternative to total laryngectomy for patients with locally advanced larynx and hypopharynx cancer. Data have suggested that T may add to the efficacy of PF. The objective of this randomized phase III trial was to determine whether the addition of T to PF could increase the larynx preservation rate.
Material and Methods: Patients with larynx and hypopharynx cancer for whom surgical procedure required total laryngectomy were randomized to receive PF or TPF. Other inclusion criteria were: adequate organ function, WHO performance status 0 or 1, age between 18 and 70, signed informed consent. Treatment arms were: Arm 1 (PF): P: 100 mg/m^2/d1 and F: 1000 mg/m^2 continuous infusion (CI) d1 to 5, Arm 2 (TPF), T: 75 mg/m^2/d1, P: 75 mg/m^2/d1 and F: 750 mg/m^2 CI d1 to 5. 3 cycles with 21 days interval were planned. Patients with complete or partial response and who recovered normal larynx mobility received RT to a total dose of 70 Gy(35 f and 7 weeks). Non responders to the induction CT underwent total laryngectomy followed by RT. The primary endpoint was 3-year larynx preservation rate. To detect an absolute difference of 15% the sample size was 210 patients.
Results: 220 patients were randomized (108 to PF, 112 to TPF). Patients and T characteristics (age, sex, PS, primary site, TN) were well balanced. The TPF arm showed greater grade 3–4 alopecia (19% vs 2%) and neutropenia (57% vs 35%) while the PF arm showed greater grade 3–4 mucositis (9% vs 4%). Toxic death rate was not different (2%). Compliance to CT was better in the TPF arm. The specified treatment (according to the protocol) was delivered in 81.2% of patients in the TPF arm vs 67.4%. The overall response rate (T and N) was 82.8% in the TPF arm vs 60.8% ($p = 0.0013$). 60.6% of patients achieved a complete endoscopic response vs 46.7%. Larynx preservation was offered for 80% of patients in the TPF arm vs 57.6% in the PF arm. In a multivariate analysis, a high hemoglobin level (>14 gr/l) and a compliance to treatment >80% are associated with a better response rate. With a median follow up of 45 months the 3-year actuarial larynx preservation rate is 74% following TPF induction chemotherapy versus 51% using the PF regimen.
Conclusion: In advanced larynx and hypopharynx carcinomas, when it is used as induction chemotherapy, TPF regimen demonstrated significantly superior overall response rate compared to the PF regimen. Larynx preservation could be achieved for a higher proportion of patients. Results will be updated for the meeting and functionnal results will be presented.

5501 ORAL

Cetuximab plus platinum-based therapy first-line in recurrent and/or metastatic (R/M) squamous cell carcinoma of the head and neck (SCCHN): Efficacy and safety results of a randomized phase III trial (EXTREME)

J.B. Vermorken[1], R. Hitt[2], L. Geoffrois[3], J. Erfan[4], A. Kawecki[5], D. Zabolotnyy[6], A. Schueler[7], R. Knecht[8], M. Benasso[9], H. Kienzer[10]. [1]*University Hospital Antwerp, Department of Medical Oncology, Edegem, Belgium;* [2]*Hospital 12 de Octobre, Department of Oncology, Madrid, Spain;* [3]*Centre Alexis Vautrin, Oncology Service, Nancy, France;* [4]*Szalbocs-Szatmar Bereg, Oncoradiology, Nyiregyhaza, Hungary;* [5]*Klinika Nowotworow, Centrum Onkologii, Warsaw, Poland;* [6]*Institute of Otolaringology, Oncology Department, Kiev, Ukraine;* [7]*Merck KGaA, Biostatistics and Data Science, Darmstadt, Germany;* [8]*Universitaetsklinik Frankfurt, Hals-Nasen-Ohrenklinik, Frankfurt, Germany;* [9]*Istituto Nazionale per la Ricerca Sulcrano, Medical Oncology, Genova, Italy;* [10]*Kaiser Franz Josef-Spital, Oncology Department, Vienna, Austria*

Background: The epidermal growth factor receptor (EGFR) inhibitor, cetuximab, an IgG1 monoclonal antibody, is effective in the treatment of R/M SCCHN progressing on platinum-based therapy. This phase III trial assessed the efficacy, safety and QoL of cetuximab in combination with a standard platinum-based regimen in the first-line treatment of R/M SCCHN.
Materials and Methods: In this multicenter phase III trial, patients (pts) with stage III/IV R/M SCCHN, not suitable for local therapy, were randomized to receive a maximum of 6 three-weekly cycles of cisplatin (100 mg/m^2 IV on day 1) or carboplatin (AUC 5, day 1) and 5-FU (1000 mg/m^2/day continuous infusion over the first 4 days of each cycle) either in combination with cetuximab (initial dose 400 mg/m^2 then 250 mg/m^2 weekly) (Group A) or alone (Group B). Cetuximab was administered until disease progression or unacceptable toxicity. Randomization was stratified according to previous chemotherapy (CT) and Karnofsky performance status (KPS) <80 and ⩾80. The primary endpoint of the trial was overall survival time (OS). Secondary endpoints included response rate, progression-free survival time, safety and quality of life (QoL).
Results: 442 pts, from 80 sites in 17 European countries were randomized: Group A: 222 and Group B: 220. Pts were mainly male (399M/43F), with a median age of 57 years [range, 33–80], and a median KPS of 80 [range, 50–100]. The pharynx (47%) and the larynx (25%) were the most common primary tumor sites. Prior therapies included surgery, radiotherapy (RT), induction CT or concomitant CT with RT. The combination of platinum-based chemotherapy and cetuximab significantly prolonged OS: 10.1 months in Group A and 7.4 months in Group B ($p = 0.036$). At the date of 10 February 2006, an interim safety analysis on 429 pts revealed no increases in the incidence of grade 3/4 adverse events commonly known to be due to CT in the cetuximab and CT arm as compared to the CT alone arm. Grade 3/4 skin reactions and infusion reactions, present in Group A (3.3% and 2.3%, respectively) were not found in Group B.
Conclusions: The addition of cetuximab to platinum-based CT in the first-line treatment of R/M SCCHN significantly improved survival by over 2.5 months compared with CT alone. The addition of cetuximab did not modify the characteristic adverse event profile of platinum-based CT. Final analyses on efficacy, safety and QoL will be presented at the meeting.

5502 ORAL

Accelerated weekly concomitant boost postoperative radiation therapy combined to concomitantchemotherapy in patients with locally advanced head and neck cancer

M. Ozsahin[1], B. Pehlivan[1], O. Matzinger[1], F. Luthi[2], L. Bron[3], P. Pasche[3], W. Seelentag[4], S. Bulling[1], R.O. Mirimanoff[1], A. Zouhair[1]. [1]*University Hospital Center and University of Lausanne, Radiation Oncology, Lausanne, Switzerland;* [2]*University Hospital Center and University of Lausanne, Medical Oncology, Lausanne, Switzerland;* [3]*University Hospital Center and University of Lausanne, Otorhinolaryngology, Lausanne, Switzerland;* [4]*University Hospital Center and University of Lausanne, Pathology, Lausanne, Switzerland*

Background: To assess the feasibility and efficacy of accelerated weekly 6 fractionated 66-Gy postoperative radiotherapy (PORT) using a single fraction regimen from Monday to Thursday and a concomitant boost in the Friday afternoon sessions combined with concomitant cisplatin chemotherapy (CT) in patients with locally-advanced head and neck cancer (LAHNC).
Materials and Methods: Between 2001 and 2006, 40 (m/f ratio: 35/5; median age: 60 years) patients with pT1-pT4 and/or pN0-pN3 LAHNC were included in this pilot study. Indications of PORT/CT were positive