Methods: A review was performed of the results from 21 randomized clinical trials listed in the MEDLINE computer data base from 1983 to 1999.

Results: Although neoadjuvant chemotherapy had a high response rate, ten cisplatin-based neodjuvant chemotherapy trials showed no survival benefit over radiation therapy alone. Among nine concurrent chemoradiotherapy trials, three small trials with cisplatin-based chemotherapy and one trial with 5-Fluorouracil failed to demonstrate a survival benefit over radiation therapy alone. However, two trials with hydroxyurea and three large trials with cisplatin-based regimen showed improvement in patient survival. Two GOG studies also confirmed that a cisplatin-based regimen was superior to hydroyxurea for survival with less toxicity.

Conclusion: The data from these randomized trials clearly do not support the use of neoadjuvant chemotherapy prior to definitive irradiation. However, the results of concurrent cisplatin-based chemotherapy and radiotherapy are promising for locally advanced cancer of the cervix.

918 POSTER DISCUSSION 2*

Brachytherapy (BT) in vagina – Cervix clear cell adenocarcinoma (CCA)

A. Gerbaulet, B. Roche, C. Haie-Meder, D. Castaigne, P. Duvillard, C. Lhommé, P. Morice, P. Pautier. *Institut Gustave-Roussy, 94805 Villejuif, France*

Purpose: BT possibilities in conservative approach for young patients (pts) with CCA. Population: 53 pts, FIGO stages rate: I: 34%, II: 35%, III: 17%, IV: 9%. DES exposure: yes: 50%, no: 30%, unknown 20%. Associated malformation +/– adenosis: 60%.

Treatment: radiosurgical treatment combining conservative surgery (pelvic lymphadenectomy + ovarian transposition), ext. beam irradiation (in case of N+ and/or extended disease); BT (mould applicator, miniaturized sources, remote afterloading machine, computerized dosimetry).

Results: At 5 years: total survival 79.8%, DFS 72.2%. DFS according to: * Nodes: N^-: 96.1%, N^+: 60.8%, * Recurrence: no: 100%, yes: 50%, * Stages: I: 100%, II: 92%, III: 40%, IV: 4%. Late complication rate: Gr 1: 25%, Gr 2: 20%, Gr 3: 15%.

5 pregnancies were observed giving birth to 2 children.

Conclusion: Combined radiosurgical treatment can be successfull in CCA when starting with conservative surgery followed by a well personalized BT.

919 POSTER DISCUSSION 2*

Vinorelbine (N) in combination with cisplatin (P) in South African patients with advanced cervical carcinoma

L. Goedhals[1], G. Falkson[1], B.L. Smith[1], C. Falkson[1], A. Lategan[1], J.P. Burillon[2], P. Danel[2], J. Gasmi[2]. [1], *South Africa;* [2]*Inst. de Rech. Pierre Fabre, France*

Cervix carcinoma is among the most common cancer in south african women, and frequently diagnosed at advanced stage at presentation. Cisplatin is the most active drag in this disease. Vinorelbine (Navelbine) a new vinca alkaloid has demonstrated a significant activity as a single agent in the treatment of advanced squamous cervical carcinoma

Purpose: assess the efficacy of NP in terms of response rate and the tolerance.

Methods: eligible patients had histologically confirmed stage III or IV cervical squamous carcinoma; previously untreated; age < 75 yrs; WHO PS < 2, adequate haematopoietic, liver, renal functions and written informed consent. The NP regimen was: vinorelbine 30 mg/m^2 on day 1 & 8, cisplatin 100 mg/m^2 on day 1, every 4 weeks. Assessments were performed by MRI.

Results: Between 7/04/96 and 7/25/98 thirty-six patients were enrolled in this study, median age 46 years (range 26 to 72 ys). 29 patients were evaluable for toxicity; 131 courses of chemotherapy were administered; median 4 range (1 to 6), WHO grade 3 neutropenia, anaemia occurred in 2.5%, and 3.4% of cycle respectively. Only 1.7% neutropenic sepsis was observed. There was 21% WHO grade 3N/V. 28 patients were evaluable for response, the objective clinical response was 52.7%, CR: 8.3%, PR: 44.7%, NC: (19.4%). 24 patients were evaluated by MRI, of which OR rate was increased to 62.5% and CRs were not confirmed.

Conclusion: NP regimen has a significant activity in cervical cancer, the accrual was closed and the final results will be presented at this meeting.

920 POSTER DISCUSSION 2*

Concomitant radiotherapy and chemotherapy given by protracted intravenous infusion as preoperative treatment in locally advanced cervical cancer

E. Magnani[1], A. Fabi[1], T. Gamucci[1], B. Saracino[2], R. Rambone[2], D. Mazza[3], G. Vocaturo[3], F. Cognetti[1], G. Arcangeli[2]. [1]*Regina Elena cancer Institute, First Division of Medical Oncology, Rome;* [2]*Regina Elena Cancer Institute, Service of Radiotherapy, Rome;* [3]*Regina Elena Cancer Institute, division of Gynaecological Oncology, Rome, Italy*

Purpose: In order to achieve operability in patients (pts) with locally advanced cervical cancer (LACC) stage IIB–IIIB, on January 1997 we started a prospective phase II study with concomitant radio-chemotherapy as neoadjuvant treatment.

Methods: Twenty-five pts affected with squamous cervical cancer were treated with protracted intravenous infusion (P.I.V.I.) 5FU 200 mg/sqm and CDDP 5 mg/sqm given simultaneously with radiation therapy delivered at 1.5 Gy twice a day (total dose 50 Gy) followed by surgical treatment when feasible. In case of inoperability a boost of 20–26 Gy on tumor bed were delivered. Pts characteristics were: median age 55 (r 34–75), PS 0/1 = 20/5, FIGO stage IIB 21 pts, IIIA 1 pt, and IIIB 3 pts.

Results: All pts are evaluable for toxicity and activity. No case of WHO G3–G4 haematological toxicity occurred. Non haematological toxicity was: G3 diarrhea in 5 pts (20%), G3 emesis in 1 pt (4%) and one case of G3 cardiotoxicity that required hospitalisation; severe proctitis was reported in one case (4%). The overall clinical response is 60%: CR 10 pts (40%), PR 5 pts (20%), NC 8 pts (32%) and PD 2 pts (8%). Out of the 25 treated pts, sixteen underwent surgical treatment: 3 Piver II and 13 Piver III; 14 pts had also a sistematic pelvic lymphadenectomy. A pathological complete response was found in 4/16 pts (25%), while in 6/16 pts (37.5%) only neoplastic microfoci were detected. The remaining 6 pts (37.5%) had a residual macroscopic disease.

Conclusion: P.I.V.I. FU/CDDP with concomitant radiation therapy is a well tolerated regimen in LACC, allowing subsequent radical surgery in a high percentage of cases. A longest follow up is necessary to better define time to progression and overall survival.

921 POSTER DISCUSSION 2*

Recurrent endometrial cancer (EC) after surgery alone: Results of salvage radiotherapy (RT)

B. Jereczek-Fossa, J. Jassem, A. Badzio, A. Kobierska, K. Serkies. *Dept. of Oncology and Radiotherapy, Medical University of Gdansk, Poland*

Purpose: Our aim was to assess the long term results of salvage RT in previously not irradiated EC patients who developed local recurrence after surgery only and to evaluate the impact of patient- and treatment-related factors on treatment efficacy.

Methods: We performed a detailed retrospective analysis of 73 EC patients given RT for local recurrence after the initial surgery. The mean patient age was 63 years. Median time to recurrence was 11 months (range, 1–19 months). Perez modification of the FIGO staging system for primary vaginal carcinoma was employed. There were 5 (7%) stage I patients, 43 (59%) stage II patients, and 25 (34%) stage III patients. 44 patients (60%) received both external beam RT (EBRT) and endovaginal brachytherapy (BRT), 17 (23%) received only BRT, and 12 (17%) – only EBRT. The mean total physical RT dose was 75.9 Gy (range, 8–130 Gy), and the mean normalized total dose (NTD) calculated on the base of the linear-quadratic model was 86.6 Gy (range, 8.5–171.9 Gy). Median follow-up for alive patients was 8.8 years (range, 3–21 years). Uni- and multifactorial analyses were used to evaluate the impact of patient-, tumor- and therapy-related factors on the treatment outcome.

Results: 3- and 5-year overall survival rates were 33% and 25%, respectively. In the unifactorial analysis, lower stage of recurrent disease ($p = 0.000$), combined EBRT and BRT ($p = 0.027$), higher total RT dose ($p = 0.031$) and higher NTD ($p = 0.006$) were significantly correlated with better survival. In the multifactorial Cox test, only stage of recurrent disease ($p = 0.000$) and high total RT dose ($p = 0.047$) were independently correlated with better survival.

Conclusion: Our study shows a limited efficacy of RT in EC patients with local failure after previous surgery. Factors determining the treatment outcome include advancement of the tumor at relapse and RT dose.

*Poster Discussion 2 will be held on Thursday 16 September 1999