922 POSTER

NCIC CTG IND102: A phase II study of the oral platinum compound BMS-182751 in patients with advanced and or recurrent squamous cell carcinoma of the cervix

M. Trudeau[1], G. Stuart[1], H. Hirte[1], P. Drouin[1], M. Plante[1], P. Bessette[1], H. Dulude[2], D. Lebwohl[3]. *[1]NCIC CTG, IND Program, Kingston; [2]BMS, Canada; [3]BMS, Wallingford, United States*

Aim: BMS-182751 (JM-216) is an orally bioavailable platinum compound with activity in platinum and platinum resistant preclinical models.

Methods: We conducted a phase II study of BMS-182751 given at a dose of 30 mg/m^2 daily × 14 days every 5 weeks.

Results: 18 patients (pts) with advanced/recurrent squamous cancer of the cervix not amenable to curative therapy with measurable disease who had received no prior chemotherapy for systemic disease were entered, all of whom are evaluable for response and toxicity. Median age was 47 yrs (35–74 yrs); all pts had received prior pelvic irradiation (RT); 4 pts had received cisplatin as a radiosensitizer; PS was 0 (6 pts), 1 (7 pts) and 2 (5 pts); sites of disease included nodes (10 pts), pelvis (5 pts), lung (4 pts) and bone (3 pts). Median number of cycles was 2 (1–5) with 8 pts receiving 3 or more cycles. Toxicity was modest and usually grade 1 or 2 in severity with the most frequent drug related toxicity including nausea (56%), fatigue (50%), anorexia (39%), diarrhea (39%), vomiting (39%), constipation (28%) and altered taste (22%). 6 pts had grade 3 or 4 granulocytopenia and only 1 pt grade 3 or 4 thrombocytopenia. 2 pts had grade 2 or 3 creatinine increases. There were no treatment related deaths. 1 pt with a treatment free interval of 30 years achieved a partial response (PR), while 12 pts had a best response of stable disease (SD).

Conclusions: BMS-182751 is generally well tolerated, but has limited activity in pts with recurrent cervical cancer.

923 POSTER

Telomerase: The molecular marker for cervical cancer screening

V.G. Reddy[1], N. Singh[1], S.K. Jain[2]. *[1]All India Institute of Medical Sciences, Biochemistry, New Delhi; [2]All India Institute of Medical Sciences, Gynecology and Obstetrics, New Delhi, India*

Cervical cancer is one of the commonest cancers in women and is routinely screened by Pap smear. Screening for HPV 16 and 18 has augmented the sensitivity of this test. But still some cases escape. We focused on defining the utility of assaying telomerase activity as a possible screening marker for cervical cancer as telomerase activation is required for cellular immortality and oncogenesis.

With informed consent a total of 50 cases were studied, 20 confirmed carcinoma cervix cases, 20 control cervical samples from hysterectomy specimens and 10 cervical scraping from healthy young women.

We observed that all the cervical carcinoma cases (100%) were telomerase positive. Among the control cervical samples from hysterectomies the one's with any underlying risk factor like HPV-16/18 infection, abnormal cytology or histopathology were telomerase positive while the perfectly normal ones were telomerase negative. The cervical scraping samples, which did not have any underlying high risk factors, were also telomerase negative. The findings suggest that telomerase activity is a better screening marker for the early diagnosis of cervical cancer.

924 POSTER

Are vaginal bleedings in postmenopausal patients an early symptom of malignancies?

B. Gerber, A. Krause, H. Müller, T. Reimer, G. Kundt, J. Markowitzky, K. Friese. *Universität Rostock, Ob/Gyn, Doberaber strasse 142, Postfach 1008 88, D-18055 Rostock, Germany*

Purpose: Vaginal bleedings in postmenopausal patients (pts.) may be an indicator of malignancies, but will mostly disregard by the affected woman. Otherwise conservative management can delay the definitive, histological diagnosis of postmenopausal bleedings. The presented retrospective analysis was conducted to examine the relationship between delayed diagnosis and tumor stage as well as it's value as a prognostic factor.

Methods: Between January 1990 and June 1997 206 pts. with an endometrial cancer (EC) and 72 pts. with a cervical cancer (CC) were treated at our hospital. All together 248 of the 278 pts. stated abnormal vaginal bleedings. The time between the indicated first episode of vaginal bleeding and the definitive histological diagnosis (bleeding interval) was correlated retrospectively with the age, body mass index, hypertension, diabetes, endometrium thickness by transvaginal ultrasound, tumor stage, grading, and also analysed with regard to survival and recurrence. The median follow up time was 50 (min. 19–max. 84) months.

Results: Pts. with EC and CC differed significantly with regard to the median age (67 vs. 62 years, p = 0.024). The median bleeding interval of pts. with EC was in tumor stage Ia/b: 12 weeks (25th–75th percentiles: 6–16); Ic: 16 (6–20); II: 16 (12–26) and III/IV: 28 (16–78) weeks. The bleeding intervals of prognostic favorable stages Ia/b were shorter than in stages Ic (p = 0.11), II (p = 0.0001), and III/IV (p = 0.0001). An increasing bleeding interval correlates with increased age (p = 0.032), endometrium thickness (p = 0.001) and tumor stage (p = 0.0001). Disease free survival and overall survival decreased significantly with longer bleeding intervals. By multivariate analysis with regard to disease free survival we confirmed age (p = 0.025) and tumor stage (p = 0.0001) as independent prognostic factors. Pts. with CC revealed median bleeding intervals of 16 weeks in stage Ib and 20 weeks in stages II–IV (p = 0.28).

Conclusion: In patients with endometrial cancer advanced tumor stages correlate with prolonged bleeding intervals. The presented data support the hypothesis that postmenopausal vaginal bleeding represents an early symptom for endometrial cancer. Bleedings due to postmenopausal cervical cancer represent a late symptom.

925 POSTER

Transvaginal color Doppler for predicting pathological response to preoperative chemoradiation in locally advanced cervical carcinoma: A preliminary study

J. Alcazar, M. Jurado, R. Cañón, I. Azinovic. *Clinica Universitaria, Pamplona 31008, Spain*

Purpose: In order to evaluate the role of transvaginal color Doppler ultrasonography (TCD) in predicting pathological response to preoperative chemoradiation in patients with locally advanced cervical cancer.

Methods: Ten patients with histologically proven locally advanced cervical cancer were evaluated by TCD prior to treatment. Tumour volumen, number of vessels within the tumour, lowest resistance index (RI), maximun peak systolic velocity (PSV), and the ratio between the number of vessels and tumour volume (Tumor vascular density, TVD) were calculated. All patients underwent preoperative chemoradiation and radical surgery. Complete pathological response (pathCR) was considered when no residual tumour was found on surgical specimen. Partial pathological response (pathPR) was considered when residual tumour was found.

Results: PathCR was achieved in three patients (30%), whereas 7 (70%) had pathPR. Mean tumoral volume was not statistically different between those with pathCR (33.2 cm^3) and those with pathPR (20.3 cm^3) (p = 0.305). Tumors with pathCR had lower mean number of vessels (3.3 vs 5.3, p = 0.01), lower TVD (0.1 vs 1.1, p = 0.05) and higher RI (0.41 vs 0.29, p = 0.03).

Conclusions: Although these data are preliminary, our results suggest that TCD may be useful for predicting pathological response to preoperative chemoradiation in patients whith locally advanced cervical cancer.

926 POSTER

Stepping source (Ir-192 HDR) versus linear distributed and fixed sources (Co-60 HDR) in brachytherapy of cervical cancer: Our clinical experience

S. Čikarić, S. Stupar-Petrović, I. Marjanov, Lj. Rudan, V. Plešinac, J. Stanković. *Institute for Oncology and Radiology of Serbia, Yugoslavia*

Purpose: A retrospective analysis is reported on the resuls of irradiated 216 patients with cervical cancer of all stages (FIGO) using stepping sorce (Ir-192 HDR: γ rays of 0.35 MeV – Microselectron) versus linear distributed and fixed sources (Co-60 HDR: γ rays of 1.25 MeV – Selectron) in brachytherapy and EBT (x-rays of 6–10 MeV).

Material: Distribution patients by stages was (Ir-192 group versus Co-60 group): St. I – 32 v. 17, St. II – 36 v. 49, St. III – 34 v. 37 St. IV – 6 v. 5 and all stages – 108 v. 108 pts. Squamous cell carcinoma was dominant hystopathological type (cca 95%). There were no patients younger than 20 years and peack incidence occurred in the 45–55 age group.

Methods: We combined transvaginal irradiation (Ir-192 HDR v. Co-60 HDR: 4–5 × 7–8 Gy/.A with uterine tube and 2 vaginal ovoids at radical irradiated group or 2 vaginal ovoids at post-operative irradiated group with doses 4 × 7–8 Gy/0.5 cm) with external beam therapy (36–46 Gy/18–22 fraction with or without central lead shield).

Results: ≥ 4-year survival (Ir-192 group v. Co-60 group) was (corrected