II trial. We observed objective responses at all dl's (n = 26): CR2, PR6, (RR 31%, 95% CI 14–52%), SD 15, PD 3.

Conclusions: The combination of P and oral UFT/LV seems to be a convenient and effective regimen for the second line treatment of MBC.

1295 PUBLICATION

Metastases within the breast from extramammary primary solid tumors: A retrospective analysis

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Purpose: Only few cases of breast metastases (BM) from solid tumors are reported in literature. In our study we evaluated the characteristics and clinical bahavior of 48 cases of BM identified at Institut Gustave Roussy (IGR).

Methods: From 1950 to 1998, seventy-seven cases of BM from solid tumors were identified at IGR. We included in our analysis only patients (pts) with intraparenchymal breast lesions and all cutaneous, subcutaneous or axillary lesions were excluded, as were pts with metastasis from contralateral breast cancer and from non-solid tumors. A total of 48 cases of intraparenchymal BM were analysed. In all cases diagnosis was histologically confirmed.

Results: Forty-one female pts (85%, 27 premenopausal, 14 postmenopausal) and 7 male pts were identify. BM appeared in pts with a known metastatic malignancy in 35 cases (72%), in 9 (19%) BM allowed the diagnosis of an extramammary tumor, in 4 (9%) the breast lesion was diagnosticated during staging of the primary tumor. The median time from diagnosis of primary cancer to detection of BM was 18.5 months (range 0–296), with differences between the histologic types. BM were secondary to carcinomas (54%), malignant melanoma (27%), sarcomas (17%) and neuroblastoma (2%).

Conclusions: BM may occur during the course of the natural history of various malignancies. In the absence of a control cohort it is not possible to draw definitive conclusions about why a higher incidence of BM is observed in the premenopausal population.

1296 PUBLICATION

Standard radiotherapy potentiation with intra-tumoral fluorouracil injectable gel (5-FU gel) in patients with locally advanced or locally recurrent breast cancer

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Purpose: Use of 5-FU as a radiopotentiator has involved the side-effects and inconveniences of continuous intravenous administration. A new site-specific intratumoral delivery system has been designed to provide high drug concentrations for extended periods. 5-FU is formulated in a viscous aqueous gel using purified bovine collagen as a biodegradable carrier matrix. We are examining the effect of dose and schedule of 5-FU gel on safety in patients receiving standard radiation therapy for locally advanced or locally recurrent breast cancer.

Methods: The ongoing Phase I/II study includes patients with breast or chest wall involvement who are receiving radiation therapy to a previously unirradiated field. The open-label, dose-escalation safety study uses 0.2 mL of 5-FU gel/cm^3 of tumor (5-FU dose range, 5 to 40 mg/mL). 5-FU gel is injected once or thrice weekly during a standard course of radiation but not during the radiation boost phase. Treatment-related side-effects will determine maximum tolerated dose.

Results: No dose-limiting, treatment-related side-effects, soft tissue necrosis, or systemic toxicity have been observed to date in patients in the first four treatment groups. All patients have completed treatment except one in whom radiation was discontinued when she developed widespread distant metastases. No drug-related systemic toxicity or soft tissue necrosis has been noted. Skin reactions, including dry and moist desquamation, occurred as expected at these radiation dose levels.

Conclusions: Combined 5-FU gel plus radiation was feasible and well tolerated in the lower levels of a dose-escalation scheme in treating patients with locally advanced or locally recurrent breast cancer. Intratumoral administration of 5-FU gel may prove a practical and effective potentiator of radiation therapy.

1297 PUBLICATION

Thermoradiotherapy (TRT) for locally recurrent breast cancer (LRBC)

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Purpose: The efficacy and side effects of TRT for microscopic residual disease or unresectable/R2-resected LRBC with skin involvement was investigated in extensively pre-treated pat.: 62% radiation therapy (RT) with median 50 Gy (range 40–115 Gy), 64% chemotherapy, 36% hormonal therapy, and 13% miltefosin.

Methods: Between 5/1995 and 8/1998, 65 fields in 39 pat. with LRBC were treated with twice weekly local hyperthermia (HT: BSD2000-system, MA150-/MA120-/SA115-applicator) and RT. Twelve fields were treated for microscopic residual disease after local excision, 17 fields after resection with flap-reconstruction of LRBC, and 36 fields for macroscopic nodular skin involvement. Mechanically mapped temperatures (T) were monitored throughout all epicutaneous fields.

Results: All fields received median 7 local HT (range 2–12) and RT with median dose of 60 Gy (range 30–68). Averages maximum and average epicutaneous T were 42.1°C, and 41.0°C, respectively. Average intratumoural T of 41.1°C and max. T of 43.0°C were measured in 9 pat. Median follow up was 23 months (range 4–44), median time to LF 18 months. Actuarial 1 and 2 year local tumour control was 85% and 67% for microscopic disease, and 71% and 0% for macroscopic tumours, $p < 0.02$. Actuarial 1 year local tumour control after <60 Gy vs. ≥60 Gy, and CR vs. PR after TRT was 50% vs. 86% ($p < 0.05$), and 91% vs. 56% ($p = 0.002$), respectively. Necrosis occurred in 3 fields after delayed wound healing or above a silicon implant. Moist desquamation appeared m 15 fields. Median survival after TRT was 24 months, 3/39 pat. died of cancer en cuirass and 13/39 pat. of distant metastases.

Conclusion: Significant predictors of local turnout control in extensively pre-treated pat. with LRBC are resectability, irradiation dose, and response to TRT.

1298 PUBLICATION

Docetaxel (TXT) monotherapy & lenograstim (G-CSF) for advanced breast cancer in the elderly

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With the purpose of evaluate the therapeutic data on elderly advanced breast cancer patients, we report a separate analysis of the p. treated with Docetaxel monotherapy in a phase II trial previously reported.

Methods: Between 6.96 to 12.98 we study 15 p aged >65 (65–81.7 p > 70 y). TXT 75 mg/m^2 for frail 6 p. and 100 mg/m^2 for 9 p every 3 weeks with G-CSF (Lenograstim) since day +2 for 5–7 days. Treatment was given until PD and for at least 3 courses with stable disease. Premedication were anti 5HT3 & Dexametasone 40 mg only before the chemotherapy. P. Characteristics: 8 p were anthracycline resistant (2 p refractory). Prior treatment for advanced disease with 2 or more regimens in 5, one in 6 p and 4 p not pretreated. Radiation completed at least >4 weeks before entry and not given to a site used to assess response in 7 p. Sites of disease: liver 4 p, lung 2 p, bone 6 p, nodes 2 p, thoracic wall 2 p, contralateral breast 1 p. PS (ECOG) 0–1: 9 p, 2: 6 p.

Results: A mean of 6.7 courses (2–13) for a total 101 cycles. Toxicities (n = 15): Anemia G3: 1 p, Neutropenia G3: 1 p (toxic death due to sepsis) G4: 5 p, Diarrhea G2: 2 p, Mucositis G2: 2 p, Alopecia all. Other toxicities: mild fluid retention in 2 p. Responses (n = 14): OR 10/14 (71% CI 95%: 50–92); CR 4/14 (28%): 3 hepatic (14 m, 6 m, 4 m) & supraclavicular (6 + m), 3 were anthracycline resistant; PR 6/14 (43%). With a median follow-up of 11 m 12/15 (80%) are alive; median survival not reached.

Conclusion: Docetaxel & G-CSF offers a very high objective response rate (71% CI 95%: 50–92) in pretreated elderly women with advanced breast cancer, with acceptable hematologic toxicity. Although premedication with dexametasone was limited to 40 mg once, after a mean of 6.7 courses significant fluid retention was not found. Elderly women benefit from active treatment with Docetaxel.