95%CI: 3.2–29.1%); nine (29%) pts had stable disease and 17 (54.9%) pts progressive disease. The median TTP was 4.6 months (range, 0.8–43.8) and the median OS 14.4 (range, 21–44.8) months.
Conclusions: The GEM/LOHP is a well tolerated and relatively active regimen for patients with heavily pretreated ABC, achieving a tumor growth control in 44% of the patients.

464 PUBLICATION

A pharmaco-epidemiological study of Trastuzumab therapy in metastatic breast cancer

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Introduction: A large pharmaco-epidemiological Brazilian study was conducted to investigate the efficacy, the treatment duration and the mostly prescribed treatments to patients with HER2 positive metastatic breast cancer (MBC).
Methods: Retrospective data was collected in 3 centers and statistical analysis was performed with a two-sided significant level of 5%. Treatment duration and disease-free survival were analyzed using the Kaplan-Meier method and were compared using a log-rank test.
Results: A total of 121 women range from 26 to 88 years (median = 53yo) with proven cancer breast were enrolled between may/2000 and november/2004. The HER-2 status (N = 110) was IHC 3+ = 93, IHC 2+ = 15, IHC 0–1+ = 2. Hormone receptor status (N = 121) was ER+ 47 and PR+ 36. The median time from diagnosis of primary disease to metastasic diagnosis was 2.2 years, range [0–7.8]. The median time from MBC diagnosis and the first prescription of trastuzumab was 159 days [0.0–2978]. 67% of patients used trastuzumab in first line, 21% in second line and 12% in third or others lines. The mostly used strategy therapy in the first-line was trastuzumab associated with vinorelbine (25.2%) and in the second-line were trastuzumab and paclitaxel (21.4%). In the whole population, the median DFS (defined as the time from initiation of trastuzumb to progression or death related to the disease) was 13.5 months, range 7 days to 4 years. CR was observed in 24.5%. No statistical difference on the treatment duration was found comparing patients who received his first course of trastuzumab on first or second-line ($p > 0.05$). The treatment duration in patients who received the first course of trastuzumab on first-line was much higher than among patients who received just on third-line and beyond ($p = 0.01$). The disease free survival for patients who received trastuzumab treatment in first-line was significant higher than patients who received his first course of trastuzumab on second-line ($p = 0.025$) IC: 94% and much higher than the group who received firstly on third and other lines (de $p < 0.0001$). No death was related to trastuzumab events.
Conclusion: We can conclude in this real-life model of analysis that trastuzumab shows greater benefits when used firstly in first-line, as we see in published randomized clinical trials results.

465 PUBLICATION

Male breast cancer: our experience from 1990 to 2004

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Male breast cancer (MBC) is a rare disease which accounts for less than 1% of all breast cancer cases. Approximately 400 new cases of MBC are diagnosed in Italy each year. We performed a retrospective analysis of 48 cases of MBC diagnosed since 1990, in order to analyse the pathological characteristics of the disease. The average age of these patients was 60 years (range 37–84). Forty-two patients had a diagnosis of ductal carcinoma; the others were: papillary 2, intraductal 2, lobular 2. High grade (G2-G3) tumors were present in 27 patients. Three patients were stage IV; 12 patients were stage III and 15 and 13 were stage II and I respectively; 36/48 (75%) patients were oestrogen or progesterone receptor positive, 4/48 (8%) patients were hormone receptor negative; in 8 patients oestrogen and progesterone receptors were not known. Thirty-one of the patients (65%) were treated with chemotherapy and anti-oestrogen therapy; 8 patients (17%) with anti-oestrogen therapy alone. Conservative surgery was performed in one patient only, while all the others underwent mastectomy (97%). Twenty (42%) had recurrences after treatment. Sites of relapse were: 8 visceral (17%), 5 bone (10%), 10 soft tissues (21%); local recurrence occurrence in 2 patients (4%).
BRCA1/2 mutational analysis was performed in 11 patients and two of them from high risk families, were identified as carriers of a BRCA2 mutation.
Conclusion: Thus, in our series, men with breast cancer are slightly younger, more likely to have hormone receptor positive disease, nodal metastases, and advanced stage disease than women with breast cancer. MBC patients should be offered genetic counselling and BRCA genetic testing when members of a high risk family.

466 PUBLICATION

A Phase II trial of gemcitabine (G) and doxorubicin (D) combination as first line treatment of metastatic breast cancer: preliminary results

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Methods: Previously untreated female patients (pts) with visceral metastatic breast cancer and ECOG PS $\leqslant 2$ were included. Pts received D 25 mg/m^2 and G 1250 mg/m^2 on days 1 and 8 for both drugs, every 21 days until progression or severe toxicity.
Results: 32 pts with a median age of 44.1 years (range: 29–67) were enrolled. All pts had stage IV disease. Metastatic sites are detailed in the table below. 31 patients were evaluable for toxicity and 26 patients for response. One patient has voluntary interrupted treatment after one cycle. After 178 cycles, grade 3 and 4 toxicity (WHO) were: neutropenia (4%), febrile neutropenia (0.5%), anemia (1.5%), nausea and vomiting (16%), diarrhea (2%), mucositis (11), reversible alopecia (56%). Among the 26 evaluable patients, response rates were: complete response 27% (7 pts), partial response 23% (6 pts), stable disease 8% (2 pts) and progression 42% (11 pts).

Metastatic sites

Metastatic sites	Number of pts	%
Liver	20	62.5
Lung	13	40.6
Bone	14	43.7
Lymph node	3	9.3
skin	1	3.1
*3 organs involved	2	6.25

Conclusions: The combination of GD in untreated metastatic breast cancer appears to be an active regimen with a safety toxicity profile. Further follow-up is necessary to assess the efficacy of this regimen.

467 PUBLICATION

Pegylated liposomal doxorubicin (PLD) plus cyclophosphamide as 1st-line therapy for metastatic breast cancer in patients previously treated with anthracyclines

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Background: Anthracyclines are among the most active drugs used for the treatment of breast cancer. Utilization in advanced disease however, is limited by their intrinsic dose limiting cardio-toxicity and extensive exposure in the adjuvant setting. Pegylated Liposomal Doxorubicin (Caelyx/Doxil) has been shown to possess similar activity to conventional doxorubicin, with a more favorable toxicity profile and significantly less cardiotoxicity. Cyclophosphamide is commonly used in combination with anthracyclines, thus represents an interesting drug to use with PLD.
Methods: We undertook a multi-center single arm Phase II trial to assess the safety and efficacy of PLD 35 mg/m^2 in combination with cyclophosphamide 600 mg/m^2 every 3 weeks. Eligibility criteria included: Measurable disease, prior anthracyclines exposure > 12 months prior to study entry, adequate organ and bone marrow function.
Results: Fifty-one patients have been enrolled, median age 53 years old (38–77). All patients had previously receive anthracyclines either doxorubicin (64%) or epirubicin (36%) at a median dose of 240 mg/m^2 or 600 mg/m^2, respectively. Some patients also received cyclophosphamide (83%), 5-Fu (30%) and taxanes (20%) as part of their adjuvant therapy. A median of 6 cycles (2–10) of chemotherapy were delivered and no major toxicity has been reported after the first 40 patients. Four patients experience asymptomatic >10% declines in LVEF that was reversible upon discontinuation of PLD. The incidence of hand foot syndrome (HFS) was relatively low (13%); only one patient stopped therapy due to grade 3 HFS. Other toxicities were uncommon and usually did not lead to discontinuation