1283 POSTER

Extensive clinical experience with Taxotere® (T) is 1st and 2nd line treatment (tt) at 100 mg/m² in locally advanced (LA) or metastatic breast cancer (MBC)

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The efficacy of T single agent as 2nd line tt is clearly established in phase III. A large phase II involving Europe, Middle East, Asia and South America with III participating centers was conducted in 1st and 2nd line tt. T was administered at 100 mg/m² q 3 wk with a 5-day oral corticosteroid premedication. 824 patients (pts) have been treated. 4575 cycles have been administered, median: 6 (1–14). Median age was 51 yrs (26–77), WHO PS 0–1: 78%, PS 2 = 21%. Median organ involved: 2 (1–6). Three subgroups (699 pts evaluable for response so far, LA and MBC) have been identified in 1st and 2nd line with or without prior anthracyclines (A).

	1st line	2nd line: no A	2nd line: prior A
Number of evaluable patients	288	54	357
Overall response (%)	59.4	63	40.6
Median duration of response (months)	9.2	9	6.7
Median TTP (months)	7	7	4.3

Hematological toxicities/pt: neutropenia G 3/4: 50%; febrile neutropenia 3.6%. In conclusion, T as single agent further demonstrates a consistent efficacy in 1st and 2nd line with a manageable toxicity profile.

1284 POSTER

Symptoms – Quality of life (QoL) correlation in postmenopausal patient with metastatic breast cancre (MBC) during hormonal treatment (HT)

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Purpose: Multicenter national study in patients (p) with MBC receiving HT. Specific survey of HT-related symptoms. Assessment of QoL. Identify which were the main symptoms associated either with the disease or the treatment than mostly affect QoL.

Methods: 226 p with MBC under HT were selected during a 9-month period. Two selfadministered questionnaries were used: modified C-PET for symptoms (25 items) and FACT-B for QoL. Intensity of a present symptom was scored from 1 to 4. As a validating external criterion p reported their own QoL using an scale ranging from very bad (0) to excellent (6). Centralised analysis of forms was carried out.

Results: HT distribution in p: 50% antiestrogens, 27% aromatase-inhibitors and 24% progestins. Self-reported QoL shows a mean value of 3.77 with 0.51 SD. 17.7% of p scored their QoL as bad (0–2) with a partial mean value of 1.55. 37.1% of p reported their QoL as good or excellent (5–6) with a partial mean value of 5.2 and 43.6% of p valued their QoL as moderate with a partial mean value of 3.45. The more frequent reported symptoms were tiredness (79%), restlessness (69%), decreased libido (66%), depression (60%), anxiety (58%), muscle cramps (58%), insomnia (57%), constipation (55%), weight gain (55%). P with lower self-reported QoL, showed more symptoms (mean 15) and more intense (mean 1.27), while p with good-excellent QoL showed less symptoms (mean 6.9) and less intense (mean 0.45). Tiredness was highly correlated with p perception of their QoL (R = 0.52). Depressive mood, dizziness, muscle cramps, anxiety, concentration difficulties and loss of appetite were the following symptoms in this analysis (R = 0.49 to 0.40). Loss of libido was present in 66.4% of p with a mean intensity of 3, but it correlated poorly with QoL (R = 0.27). Within domains of FACT-B, general well-being (.79) and functional autonomy (.74) are highly associated with QoL

Conclusions: Existing symptoms and their intensity, physical and functional well being correlates with QoL in this population, decreased sexual interest is frequently seen but it seems not correlate with QoL

1285 PUBLICATION

A phase II trial of taxotere (TXT) 100 or 75 mg/m² as 2nd line chemotherapy (CT) in patients (PTS) with metastatic breast cancer (mbc) with stratification according to prognosis factors

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The study aim is to evaluate the response rate (RR) of TXT as 2nd line CT in pts with MBC after anthracycline failure, with dose chosen according to prognosis factors for response and safety: 100 mg/m² in pts with optimal progn. factors (Gp A) and 75 mg/m² in pts with suboptimal progn. factors with 2 subgroups: GpB: pts with liver functions altered, GpC: WHO PS = 2 or/and thrombocytopenia gr.1 with normal liver functions. 149 pts (A = 55; B = 42; C = 52) were included. Data are available for 119 pts, med. age = 47 y (range 28–70), pts aged <46 y: A: 35%, B: 42%, C: 40%, med PS = 1 (0–2) (% of PS 0/1/2 in GpA: 40/60/0; GpB: 13/58/19); 3 or more organs involved: A:19%, B:29%, C:35%. Pts evaluable for response: Overall: 94/A: 40/B: 22/C: 32. Response Rate: GpA: 46%, GpB: 23%; GpC: 43%, overall: 40%. Overall safety (119 pts, 573 cycles): a) gr. 3–4 acute tox./cycle: neutropenia, 37% (40% GpA vs 34% Gps B&C); anemia, 3%; thrombocytop., none; infection, 2%; vomiting, 1%; skin reactions, none; b) febrile neutrop, 1%/cy; c) gr. 3 chronic tox./pt: neuro-sensory, 3%; -motor 3%; fluid retention, 3% (no gr. 4). No major differences were observed between each group. Dose reduction in pts with poor progn. factors avoid increasing toxicities. Although 75 mg/m² in GpC, the RR is maintained. Results in GpB may be explained by the conjunction of several poor progn. factors: poorer PS compared to GpA, young age and mainly 1/3 pts with 3 or more organs involved, almost always including liver. Final results to be presented at the congress.

1286 PUBLICATION

Epirubicin (E) plus paclitaxel (P) vs epirubicin followed by paclitaxel in metastatic breast cancer (MBC): An ongoing pharmacoeconomic study

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The combination of E (90 mg/sqm bolus i.v.) and P (200 mg/sqm 3 hr infusion) is feasible and very active when used as first line therapy in MBC. However there are pharmacokinetic interferences which might influence both the activity and the toxicity of this regimen (JCO 1997, 2510–2517). On this basis we designed a phase III randomized trial aimed at evaluating the best schedule of administration of E and P in order to optimize their antitumor activity. Previously untreated MBC pts are randomized to receive: 8 courses of E + P (arm A, doses and schedule as previously reported), or 4 cycles of E 120 mg/sqm bolus iv followed by 4 cycles of P 250 mg/sqm 3 hr infusion (arm B). In light of the lower costs and possibly lower toxicity of the sequential regimen (arm B) this could become the preferred one if associated with a reduction not greater than 15% in the proportion of clinical responses. In order to detect this difference with an 80% power, for alpha = 0.05 (one-side test), 133 patients are needed in each arm. In parallel to the clinical trial a prospective pharmacoeconomic study will be performed in order to evaluate the cost-effectiveness (economic efficiency) of the sequential treatment with respect to the combination one. The main hypotesis of this study is that the use of the sequential regimen will lead to a reduction in the use of the health care resources and an improvement in patient,s satisfaction. The primary perspective of the study will be that of society and will include all health care-releted costs. However, two secondary analises will estimate the costs from a narrowed perspective of the payers: the Italian National Health Service and the hospital. So far 126 patients have been randomized in the clinical study and 82 are evaluable for the pharmacoeconomic study.