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Improvement in quality of life (QoL) and ECOG in a cohort of 1125 patients (pts) with metastatic breast cancer (MBC) treated with capecitabine (X)

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Background: The oral fluoropyrimidine capecitabine is highly active and well tolerated as single-agent therapy in pts with anthracycline- and/or taxane-pretreated MBC and extends survival when added to docetaxel in MBC. In addition to response rates and survival times, pt preference for oral therapy and QoL are increasingly important considerations in MBC.

Materials and Methods: Women with anthracycline- and/or taxane-pretreated MBC received oral capecitabine 1000 mg/m^2 or 1250 mg/m^2 twice daily on days 1–14 every 3 weeks in a prospective noncomparative multicentre study. QoL was evaluated using EORTC QLQ C-30 (v3.0) and BR-23 questionnaires at 4 timepoints (before cycle 1, weeks 7 and 13, and treatment end). Linear models for repeated measures were used to analyse least square mean QoL data over time. Improvement was defined as a $\geq$10-point improvement and maintenance as a <10-point improvement/worsening from baseline in functional or symptom scores at one or more visits.

Results: Baseline characteristics of the 1125 evaluable pts were: mean age 54.5±12.3 (range 22–90) years; Caucasian (80%); ECOG performance status 0–2 (88%). Patients receiving capecitabine had significant, sustained improvement ($p < 0.0001$ unless stated otherwise) over the study period in the following domains: global health status, role functioning, emotional functioning, social functioning ($p = 0.0004$), cognitive functioning ($p = 0.0257$), fatigue, nausea/vomiting, pain, insomnia, appetite loss, constipation, financial problems, body image, future perspective, systemic therapy side effects, breast symptoms, arm symptoms ($p = 0.0003$), and upset caused by hair loss. The patients with ECOG from 0 to 2, during the treatment had an improuvement at their initial score. Depending on the domain, between 64% and 84% of pts reported improved or maintained QoL during capecitabine therapy.

Conclusions: Patients receiving X had a significant and sustained improvement in 13 of 14 QLQ C-30 domains and 6 of 8 QLQ BR-23 domains, including all QLQ BR-23 symptom scales that are known to be important to women with MBC. These findings highlight the importance of considering QoL and other measurable benefits of oral treatments alongside well-established clinical measures in pts with metastatic disease. The QoL benefits, together with other proven clinical outcomes, suggest that earlier use of Capecitabine in MBC would be beneficial to patients.

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Survival times after metastatic breast cancer improved between 1985 and 2004, but only for patients with a short disease-free interval

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Background: About 30% of breast cancer patients will develop distant metastases following their primary treatment. During the last decades, the treatment of metastatic breast cancer has undergone considerable changes, starting with the introduction of chemotherapy in the sixties and seventies, tamoxifen in the eighties, taxanes and aromatase inhibitors and trastuzumab in the second half of the nineties and later. The aim of this study was to investigate if these changes have resulted in an improvement of the prognosis of patient with metastatic breast cancer.

Methods: We examined the prognosis of patients who developed metastatic disease in a cohort of 1642 patients with primary breast cancer who were treated at the St. Elisabeth Hospital in Tilburg, The Netherlands, between January 1, 1985, and December 31, 2000. Patients with primary metastatic disease were excluded from the study.

Results: After a median follow-up of 6.4 years, 452 patients had developed distant metastases and of these 177 were diagnosed in the period 1985–1994, 126 in the period 1995–1999 and 149 in the period 2000–2004. The metastasis-free interval appeared to be an important prognostic factor. Of the 452 patients, 202 (45%) developed distant disease within 2.5 years after primary treatment, 115 (25%) within 2.5–5.0 years and 135 (30%) more than 5.0 years after primary treatment. The median survival times for these three groups were 0.95 years, 1.64 years and 2.44 years respectively ($P < 0.0001$). Because of the overrepresentation of patients with a short metastasis-free interval in the period 1985–1994, the three periods could only be compared in a meaningful way after stratification according to metastasis-free interval. The stratified analysis demonstrated that the median survival time of patients with a metastasis-free survival interval shorter than 2.5 years, has improved from 0.86 years in the period 1985–1994 to 1.48 years in the period 2000–2004 ($P = 0.04$). No such improvement was observed among patients with a metastasis-free interval of 2.5–5.0 years (median survival 1.5 and 1.6 years, respectively).

Conclusion: The prognosis of patients with metastatic breast cancer and a metastasis-free interval shorter than 2.5 years, has improved significantly since 1994. The lack of an improvement among patients with a longer metastasis-free interval indicates that the new anti-cancer drugs, such as taxanes, aromatase inhibitors and trastuzumab, are more effective in patients with rapidly progressing disease.

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Early use of fulvestrant for the treatment of postmenopausal women with advanced breast cancer – the Nottingham experience

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Fulvestrant (Faslodex®) is an estrogen receptor (ER) antagonist with no agonist activity that binds, blocks and degrades the ER. The Nottingham Breast Unit has been involved in several Phase II and III clinical trials using this drug in the treatment of advanced breast cancer (ABC). Here we focus primarily on clinical data for fulvestrant when used as first-line treatment for advanced disease (at first diagnosis of ABC or following a disease-free interval of >1 year after adjuvant treatment) and as second-line treatment (following one prior endocrine treatment for ABC).

Materials and Methods: We identified 106 patients who had received fulvestrant between January 1993 and April 2005. All patients had either stage 3 or 4 disease and the median age was 70.33 years (range: 44–90 years). Patients received fulvestrant as first- to fifth-line treatment for ABC including 61 patients receiving fulvestrant as first-line and 25 as second-line treatment. Results are presented as clinical benefit (CB) rates (CB = complete response [CR] + partial response [PR] + stable disease [SD] $\geq$24 weeks).

Results: Response to fulvestrant by line of therapy is shown in the Table.

Line of therapy	% of total	Median duration of remission, months (range)	CB, % (n)
First (n = 61)	57.5	13.5 (1–68)	67.2 (41)
Second (n = 25)	23.6	5 (1–77)	44 (11)

For the overall population, best responses to fulvestrant were: CR n = 6, 5.7%; PR n = 17, 16.0%; SD n = 37, 34.9%; and disease progression, n = 46, 43.4%, resulting in a CB rate of 56.6%. In the remaining 20 patients with two or more prior endocrine therapies for ABC the CB rate was 45% and median duration of remission was 7.7 months.

Conclusions: Fulvestrant has significant activity when used as first- and second-line treatment for ABC. The median duration of remission is markedly longer in patients receiving fulvestrant as first-line therapy, supporting its early use. Many of these patients had long durations of response or SD and, therefore, of disease control on fulvestrant.