

to which Cypriot unit costs were applied. Costs and QALYs were estimated over the remaining lifetime of a cohort of HR+ women aged 60 yrs, discounted at 3.5% annually.

Results: LET and ANA are predicted to increase QALYs by 0.32 and 0.23 per patient compared to TAM, respectively. Lifetime costs increase by CYP 651 and CYP 841, respectively. The mean incremental cost per QALY (ICQ) gained of LET vs TAM is CYP 2,067 (95% CI LET dominates – CYP 6,382), and of ANA vs TAM is CYP 3,633 (95% CI CYP 803–9,340). This suggests (based on the difference in mean values) LET is more cost-effective than ANA, providing a 40% reduction in the cost-effectiveness ratio. The probabilistic sensitivity analysis shows that LET and ANA have around a 100% probability of being cost-effective at a QALY value of CYP 20,000.

Conclusion: Compared to TAM, adjuvant treatment of postmenopausal HR+ women with LET or ANA for 5 years is a cost-effective use of Cypriot health care resources. Comparing mean values LET is more cost-effective than ANA, although the confidence intervals overlap.

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Poster

Patient's Anastrozole Compliance to Therapy Programme (PACT) influence of the addition of a standardized information and reminder service on compliance in comparison to standard clinical care alone in women with early breast cancer

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Introduction: An important requirement for the effectiveness of any therapeutic intervention is optimal compliance. The level of compliance to oral pharmacological therapies in chronic diseases vary, but are predominantly low. In the adjuvant treatment of hormone responsive breast cancer, existing data document that 23% and 50% of patients were non-compliant after the first and fourth year of tamoxifen (TAM) therapy. To date, no data on compliance to aromatase inhibitors (AI) outside of randomized clinical trials (RCTs) has been reported.

Design: PACT program has a two arm, randomized, parallel group design with a primary duration of 12 months and observation extended to 60 months. From July 2006 to September 2008, we intend to enrol 4.674 postmenopausal, receptor positive breast cancer patients assigned to adjuvant AI therapy in accordance with standard local practice and independent of participation in the program. After written informed consent, patients will be randomized to a standardized information and reminder service or to routine clinical care alone. Compliance will be evaluated by self report using standardized, detailed questionnaires at baseline and after each year of treatment. In addition, we will collect the prescription data for each patient from hospital records and physician recall. Finally, we will assess quality of life and patient's satisfaction using standardized questionnaires. Secondary endpoints include persistence on therapy, reasons for non-compliance, influence of baseline characteristics on compliance as well as the influence of compliance on clinical outcome parameters.

Future perspectives: An important goal of any therapeutic intervention is to achieve comparable efficacy in routine clinical practice to that demonstrated in RCTs. The aim of the PACT program is to evaluate whether a simple intervention such as a standardized information and reminder service can lead to a significant increase in compliance in women with primary breast cancer. If successful, such simple measures could greatly improve the efficacy of adjuvant endocrine treatment and would thus have significant impact on individual patient outcomes as well as the health care system.

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Poster

Results of the German IPEP study evaluating the tolerability, efficacy, and acceptance of fulvestrant (Faslodex®) under routine clinical conditions in advanced breast cancer

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Background: Fulvestrant is used in the treatment of postmenopausal women with estrogen receptor-positive, locally advanced or metastatic breast cancer. The questions of the study are whether Fulvestrant is safe, effective and tolerable.

Material and Methods: 848 patients were enrolled in this Fulvestrant In Practice Evaluation Programme (IPEP). Under clinical routine conditions in the participating centers regarding selection of subjects, diagnostic procedures or therapeutic decisions, all relevant data was documented over 9 months of fulvestrant therapy in postmenopausal women with advanced ER+ breast cancer who had relapsed during or after adjuvant anti-estrogen treatment, or with disease progression under palliative anti-estrogen therapy.

Results: Data of 597 (70 %) of patients was evaluable according to protocol. Median age was 64 years, 52% of patients had a co-morbidity, 78% one or more prior palliative therapies. **Safety:** 15.6% had one or more adverse events, mainly hot flushes, gastrointestinal, or musculoskeletal symptoms, 27 patients had a serious adverse event, 20 died during observation. **Efficacy:** after 3 months only 11.5% of patients had progressed; 6% had a complete remission, 16.5% partial remission, 58% stable disease as locally assessed by the investigators. After 9 months, 15% of evaluable patients had progressed, 13% were in complete remission, 28% in partial remission und 42% had stable disease, 2% are not available. **Tolerability:** Tolerability was judged as being good to very good by the majority of both investigators and patients with stable tolerability parameters reported at 3, 6 and 9 months (Patients "very good": 43.5%, "good": 48%. Specialists "very good": 48%, "good": 46%).

Conclusions: Overall, fulvestrant showed very good efficacy with a reported clinical benefit rate of 83% after 9 months, safety and tolerability in this observational study in a patient collective with advanced breast cancer.

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Poster

Local recurrences are not increased in patients who undergo breast conservation after neoadjuvant chemotherapy

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One of the benefits of neoadjuvant chemotherapy is its ability to convert patients ineligible for breast conservative treatment (BCT) to be candidates for this treatment. Although it has not been shown to increase survival, questions have been raised regarding the effectiveness of BCT in terms of local recurrences. The objective of this study is to determine rates of mastectomy conversion to BCT and to evaluate the local recurrences in this group of patients.

Between 1995 and 2005, 214 patients with breast cancer were treated with neoadjuvant chemotherapy at our institution. Median age was 57.2 years old (range, 25 to 94 years old). Clinical stage at diagnosis was I in 2.9%, II in 53.2%, and III in 43.9%. After completion of chemotherapy a multidisciplinary team evaluated the cases eligible for BCT. All patients treated with BCT had negative margins and received radiation therapy as part of the conservative treatment.

Sixty patients (29.3%) candidates for mastectomy received BCT after neoadjuvant chemotherapy. At a median follow up of 50 months (range, 16 to 144 months), 19 patients developed local recurrences, 5 (8.3%) were ipsilateral breast recurrences in the BCT group. Twenty patients (9.8%) developed distant metastasis, 3 (5%) of these in the BCT group. There were 2 patients who developed a metastasis after a local recurrence. Both patients have had a modified radical mastectomy. None of the patients who developed ipsilateral local recurrences had a pathologic complete response after surgery. Variables as tumor size, or vascular invasion were not associated with ipsilateral breast recurrences. Five-year actuarial ipsilateral local recurrences-free survival rate was 92%.

The results of this study not only confirm the advantage of neoadjuvant chemotherapy in allowing BCT in patients who otherwise would require a mastectomy, but also have showed that rates of local recurrences-free survival compare favourably to those for patients with adjuvant chemotherapy. BCT is a safe and feasible treatment in patients with neoadjuvant chemotherapy.