Conclusions: XC combination is useful in patients with MBC because it is no less effective than standard treatments and can be useful in maintaining the QOL of the patients.

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A Spanish Cost-utility Analysis of Nab-paclitaxel Compared to Conventional Paclitaxel Monotherapy for Pretreated Metastatic Breast Cancer: Results From the COSTABRAX Study

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Introduction: In the randomized controlled phase 3 trial CA012 demonstrated that a novel albumin-bound 130nm formulation of paclitaxel (nab®-paclitaxel, Abraxane®) had better efficacy than conventional paclitaxel in metastatic breast cancer (mBC) in patients who failed 1st-line treatment for metastatic disease and for whom standard anthracycline containing therapy is not indicated. The cost-effectiveness of nab®-paclitaxel versus conventional paclitaxel in the Spanish setting is analysed.

Patients and Methods: Clinical data for pretreated patients receiving nab®-paclitaxel 260 mg/m^2 3-weekly (q3w) and conventional paclitaxel 175 mg/m^2 q3w were taken from trial CA012. Since current conventional paclitaxel regimen has changed in Spain to 80 mg/m^2 weekly (q1w), an indirect comparison was carried out to compare nab®-paclitaxel q3w vs. conventional paclitaxel q1w in a secondary analysis. Drug costs, as well as administration, AEs and supportive care costs were taken from Spanish data sources. Long-term efficacy and costs of treatments were extrapolated up to 5 years by means of a Markov model. A panel of 18 Spanish oncologists validated the use of resources and the main model assumptions by completing a questionnaire and attending an in-person meeting. Results are shown as cost per life year gained (C/LYG) and cost per quality-adjusted life year (C/QALY). Costs and effects were discounted at a rate of 3%.

Results: The mean survival was 1.44 and 1.17 years for nab®-paclitaxel q3w and conventional paclitaxel q3w, with total costs of €15,972 and €13,483, respectively. The results of the cost-effectiveness analysis showed that nab®-paclitaxel q3w was associated with a C/LYG and a C/QALY of €9,387 and €15,085, respectively. The indirect comparison showed that nab®-paclitaxel q3w compared to conventional paclitaxel q1w have similar effectiveness and lower costs per patient (€15,972 and €17,146, respectively), which means nab®-paclitaxel has shown to be the most efficient option (dominant) compared to conventional paclitaxel q1w.

Conclusions: The COSTABRAX study performed from the Spanish health perspective showed that nab®-paclitaxel q3w was more effective and a cost-effective option compared to conventional paclitaxel q3w in the treatment of mBC with a C/QALY ratio lower than the generally accepted threshold of 30.000 € by health authorities. Compared to conventional paclitaxel q1w regimen, nab®-paclitaxel q3w was the most efficient option with lower total costs.

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Change of Biomarker Status in Recurrent Breast Cancer

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Background: Breast cancer is a heterogeneous disease and management is based on the disease status and tumor biology. In each patient treatment is tailored considering the factors to drug response mainly Hormonal and Her 2 neu status. Historically the trend has been to continue with hormonal therapy for years if patient's primary tumor is hormone positive. After adequate therapy once a tumor recurs, it was assumed that no change in biological features would occur in the recurrent disease compared to the primary. Studies comparing samples from primary tumor with recurrent loco regional and metastatic disease have demonstrated change in ER, PR and Her 2 neu status. Recurrent disease is a challenge to treat after the exhaustion of first line management. It is important to be sure that patient responds to the treatment given after the recurrence. The aim of this study is to quantify the percentage of tumor that changes receptors for ER, PR and Her 2 neu between original and recurrent disease.

Materials and Methods: Patients with recurrent breast disease presenting to the Breast Unit of Liaquat National Hospital from January 2004–January 2011 were included in this study and were analyzed for biomarker status. Outcome of interest was any change in the biomarker status (ER, PR, Her 2 neu) with respect to primary status.

Results: A total of 58 female patients with biopsy proven recurrent breast carcinoma were included in the study. The mean age was 46 years, with a period of two years and three months as mean time to recurrence. Invasive Ductal carcinoma was the most prevalent recurrent tumor among the study population. There was a change of 25% in ER status (p-value <0.01), change of 36% in PR status (p-value 0.036) and Her 2 neu status changed in 22%(p-value <0.01) which was statistically significant. Of the 42 patients who were triple negative at presentation, 30 patients remained triple negative on recurrence (p-value 0.02). Six of the 16 patients became triple negative upon recurrence(p-value <0.01).

Conclusions: Our study demonstrated that there is indeed a change in biomarker status of patients presenting with recurrent breast carcinoma. There is a need for clinicians to check biomarker status of recurrent breast cancer patients as this may aid in the shift in management plan.

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Design of RESILIENCE: a Phase 3 TRial Comparing CapecitabinE in Combination with SorafenIb or PLacebo for Treatment of Locally Advanced or MetastatIc HER2-Negative Breast CancEr

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Background: Sorafenib is an oral multikinase inhibitor with antiangiogenic and antiproliferative activity. Sorafenib is currently indicated for renal cell and hepatocellular carcinoma, with activity in other tumor types being explored. A double-blind, randomized, phase 2b screening trial (SOLTI-0701) of sorafenib in patients with HER2-negative advanced breast cancer (BC) showed a statistically significant improvement in progression-free survival (PFS) in the sorafenib+capecitabine arm vs the placebo+capecitabine arm: 6.4 vs 4.1 months (hazard ratio = 0.58; 1-sided $P = 0.0006$). Grade 3/4 toxicities were comparable except G3 hand-foot skin reaction/syndrome (HFSR/HFS) (44% vs 14%). These results support a phase 3 trial of sorafenib+capecitabine in advanced BC.

Methods: RESILIENCE is an ongoing multinational, double-blind, placebo-controlled, phase 3 trial designed to assess sorafenib + capecitabine as first- or second-line therapy in advanced HER2-negative BC (ClinicalTrials.gov, NCT01234337). Eligibility criteria include: $\geqslant$18 years of age; $\leqslant$1 prior chemotherapy regimen for advanced BC; resistant to/failed taxane and anthracycline or no indication for further anthracycline; no prior VEGF treatment. Patients are randomized to capecitabine (1000 mg/m^2 PO twice daily [BID], days 1−14 of 21) with sorafenib (PO BID, days 1−21, total dose 600 mg/day) or placebo. Sorafenib 600 mg/day corresponds to the average daily dose during SOLTI-0701 that was effective and had manageable toxicity. Capecitabine and sorafenib/placebo doses can be escalated to 1250 mg/m^2 BID and 800 mg/day, respectively, as tolerated. The protocol outlines strategies to manage toxicities with dose interruption and reduction. Dose re-escalation after reduction is only allowed for sorafenib/placebo. Guidelines detail prophylactic and symptomatic therapy for HFSR/HFS. Radiographic assessment is Q6 weeks for 36 weeks, then Q9 weeks. Primary endpoint is PFS. Secondary endpoints include overall survival, time to progression, overall response rate, and duration of response. Enrollment began in November 2010 and targeted enrollment is ~519 patients.

Conclusions: RESILIENCE will provide definitive PFS data for sorafenib+capecitabine as first- or second-line therapy in HER2-negative advanced BC and will better characterize the benefit-to-risk profile of this regimen.