Findings: As the extra cost of 2 yrs T + 3 yrs E over 5 yrs T (considering bone density scans) was £3,280, it cost £69,787.2 to prevent one women relapsing (£3,280/4.7%). Our analysis calculated that the average monthly cost of treating a relapse was £752.35. As the mean survival was 32.6 months the mean total cost/patient was £24,526.66. Subtracting this from the initial extra cost of E gives a mean extra cost of £45,260.54 to prevent one patient relapsing. As the median survival of the relapsed women in our analysis was 2.72 yrs and the expected survival if they don't relapse is 18 years, the cost per life year saved was £2,962/yr.
Discussion: Notwithstanding the humanitarian issues, these figures from a single institution suggest it is cost efficient to switch to E at 2 years. As these figures reflect the management of women over the last seven years they are likely to underestimate the future cost. Further modelling of the data in relation to the 25.5% who were HER2+ in terms of the extra cost of herceptin and the longer survival with relapsed disease, together with further detailed subset cost effectiveness analysis will be presented.

2134 POSTER

Clinical benefit of trastuzumab plus vinorelbine as second-line treatment for women with HER2-positive metastatic breast cancer beyond disease progression

P. Chollet[1], X. Durando[1], L. Mauriac[2], C. Delcambre[3], P. Maillart[4], C. Veyret[5], M.A. Mouret-Reynier[1], I. Van Praagh[1], T. Bachelot[6]. *[1]Centre Jean Perrin and UMR INSERM 484, Oncology, Clermont Ferrand, France; [2]Institut Bergonié, Oncology, Bordeaux, France; [3]Centre François Baclesse, Oncology, Caen, France; [4]Centre Paul Papin, Oncology, Angers, France; [5]Centre Henri Becquerel, Oncology, Rouen, France; [6]Centre Léon-Bérard, Oncology, Lyon, France*

Background: The benefits of multiple lines of trastuzumab (Herceptin®; H) therapy have been increasingly reported for women with HER2-positive metastatic breast cancer (MBC). We report the results from the first planned interim analysis of a Phase II, 2 step, multicentre trial evaluating second-line H + vinorelbine (N) in women who received first-line H + taxane therapy for HER2-positive MBC.
Materials and Methods: Women aged ⩾18 years with HER2-positive (IHC3+/2+ and FISH+) MBC who progressed following first-line H + taxane therapy were enrolled. All patients (pts) received H (8 mg/kg iv loading dose followed by 6 mg/kg q3w or 4 mg/kg iv loading dose followed by 2 mg/kg qw) + N (30 mg/m^2 days 1 and 8, q3w) until disease progression (PD). The primary end point was overall response rate (ORR); secondary end points included time to progression, time to treatment failure, overall survival and safety.
Results: To date 17 pts with HER2-positive (16 pts IHC 3+; 1 pt IHC 2+ and CISH+) MBC have been evaluated. Mean age was 54 years (range 42−70). Nine pts had hormone receptor-positive MBC (7 pts ER+/PgR−; 2 pts ER−/PgR+). Prior to enrolling, 12 pts had received previous chemotherapy in the neoadjuvant/adjuvant setting and 6 had undergone adjuvant hormonal therapy. All pts had previously received H in combination with paclitaxel (9 pts) or docetaxel (8 pts) as first-line therapy for MBC. In addition to these treatments for MBC, 3 pts had received hormonal therapy. A median of 6 H + N treatment cycles (range 2−14) were administered, with 2 pts receiving H q3w and 15 pts receiving H qw. The clinical benefit rate was 53% and ORR was 30%, with 2 pts (12%) showing a complete response, 3 pts (18%) experiencing a partial response and 4 pts (23%) achieving stable disease lasting 6 months. Fourteen pts withdrew from the study due to PD. The main serious adverse event was grade 3/4 neutropenia, leading to a delay and dose reduction of N in 4 pts. Only 2 asymptomatic grade 1 cardiac events were reported for the 9 pts for whom cardiac function data were available. No deaths were reported.
Conclusions: First planned interim results indicate that treatment with H + N in pts with MBC who progressed following first-line H + taxane therapy is active and well tolerated. These data provide further evidence for the clinical potential of multiple lines of H in pts with HER2-positive MBC.

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Cost-effectiveness (CE) of lapatinib plus capecitabine (L+C) in women with ErbB2+ (HER2+) metastatic breast cancer (MBC) who have received prior therapy with trastuzumab (TZ) from the United Kingdom (UK) National Health Service (NHS) perspective

T.E. Delea[1], P. Tappenden[2], O. Sofrygin[1], J. Karnon[2], M. Amonkar[3], D. Browning[4], H. Rudge[4], M. Walker[5]. *[1]Policy Analysis Inc. (PAI), Brookline MA, USA; [2]University of Sheffield, School of Health and Related Research (ScHARR), Sheffield, United Kingdom; [3]GlaxoSmithKline, Global Health Outcomes, Collegeville PA, USA; [4]GlaxoSmithKline, Health Outcomes, London, United Kingdom; [5]GlaxoSmithKline, Global Health Outcomes, London, United Kingdom*

Background: Lapatinib (Tyverb®, Tykerb®) is an oral small molecule dual tyrosine kinase inhibitor that binds intracellularly to the ATP binding site of the EGFR and HER2 receptors. In EGF100151, L+C improved time to progression (TTP) and progression free survival (PFS) vs capecitabine monotherapy (C-only) in women with ErbB2+ (HER2+) MBC who have received prior therapy with TZ. CE of L+C has not been evaluated to date.
Methods: We evaluated CE (ΔCosts/ΔQuality Adjusted Life Years [QALYs]) of L+C vs C-only in women with ErbB2 (HER2+) MBC who have received prior therapy with TZ from the UK NHS perspective using an assumed acquisition cost. Because many patients such in typical clinical practice receive monotherapy with vinorelbine (V-only) or TZ-only or combination therapy with TZ and C (TZ+C) or TZ and V (TZ+V), we also assessed CE of L+C vs these strategies. PFS and overall survival (OS) with L+C and C-only were based on Weibull survival functions estimated using data from EGF100151. Post-progression survival (PPS) for L+C and C-only were calculated as OS − PFS. Lacking data from comparative trials in this population, PFS with TZ+C, TZ+V and TZ-only were estimated from published cohort studies of continued TZ±chemotherapy (TZ±CT) following progression; PPS was assumed to equal that with L+C. PFS and OS with V-only were assumed equal to that with C-only. Drug costs were from the British National Formulary; other costs from NHS reference costs and published studies. Utility values for PFS were from EQ-5D data collected in EGF100151; for PPS, from a UK community-based study of preferences for disease states in MBC. Costs and QALYs were discounted at 3.5% annually.
Results: Results are presented in the table. L+C is dominant (provides more QALYs at a lower cost) vs TZ+V, TZ+C, and TZ-only. In probabilistic sensitivity analyses, the probability (p) that L+C is CE given willingness to pay (WTP) for QALY of £30,000 ranged from. 05 vs C-only to. 95 vs TZ+V.

	L+C	C-only	V-only	TZ+V	TZ+C	TZ-only
Total costs (£)	25,678	11,805	14,094	30,131	27,864	26,753
Total QALYs	0.857	0.686	0.686	0.714	0.714	0.714
CE L+C (£/QALY)		81,129	67,743	Dominant	Dominant	Dominant
p L+C is CE (WTP = £30,000/QALY)		0.05	0.07	0.95	0.89	0.85

Conclusions: The efficacy of L+C has been demonstrated in women with Erb2+ (HER2+) MBC who have received prior therapy with TZ. This study, using indirect comparisons in the absence of head-to-head data, suggests that L+C is a cost effective therapeutic option vs TZ±CT from the UK NHS perspective.

2136 POSTER

Expression profile of TRAIL and its receptors in breast cancer patients with invasive ductal carcinoma

A.D. Sanlioglu[1], A.F. Korcum[2], E. Pestereli[3], G. Erdogan[3], S. Karaveli[3], B. Savas[4], T.S. Griffith[5], S. Sanlioglu[1]. *[1]Akdeniz University School of Medicine Human Gene Therapy Unit, Department of Medical Biology and Genetics, Antalya, Turkey; [2]Akdeniz University School of Medicine, Department of Radiation Oncology, Antalya, Turkey; [3]Akdeniz University School of Medicine, Department of Pathology, Antalya, Turkey; [4]Akdeniz University School of Medicine, Department of Medical Oncology, Antalya, Turkey; [5]University of Iowa, Department of Urology, Iowa City, USA*

Background: TNF-Related Apoptosis Inducing Ligand (TRAIL) selectively induces apoptosis in cancer cells but not in normal cells, and several clinical trials have been started to assess the safety and anticancer properties of TRAIL in patients with cancer. Four different receptors have been identified to bind to TRAIL: two are known as killer receptors [TRAIL-R1 (DR4) and TRAIL-R2 (DR5)], the other two [TRAIL-R3 (DcR1) and TRAIL-R4 (DcR2)] are decoy receptors which counteract TRAIL-induced cell death. Because high levels of DcR2 expression has recently been correlated with carcinogenesis in synoviocytes, prostate and lung, the significance of