combined with other chemotherapy (CT) agents was demonstrated in AVADO and RIBBON-1. Subgroup analyses of all 3 trials suggest similar benefit with Bev in pts aged ⩾65 y. Data from the ATHENA study give insight into the tolerability of Bev with standard first-line CT in pts ⩾70 y. To understand better the safety and efficacy of first-line Bev–pac in older pts treated in routine oncology practice, we analysed data in pts ⩾65 y in a German non-interventional study.

Materials and Methods: Pts who had received no prior CT for their mBC received Bev–pac per the European label. Efficacy and safety were documented for up to 1 y (or until progression, death or Bev discontinuation if earlier) with additional long-term follow-up.

Results: By Jan 2011, data were available for 818 pts, of whom 262 (32%) were aged ⩾65 y and 133 (16%) were ⩾70 y. Among those aged ⩾65 y, 16% had mBC at diagnosis, 15% had triple-negative mBC, 29% had ⩾3 metastatic sites, 45% had liver metastases and 36% had lung metastases. Prior therapy included (neo)adjuvant CT in 55% and endocrine therapy for mBC in 26%. ECOG performance status was ⩾2 in 10% of pts. The overall RR in pts ⩾65 y was 57% (complete response in 10%); only 9% had progressive disease as best response. The RR in pts aged ⩾70 y was 57%. Median PFS was 9.2 and 9.3 months in pts aged ⩾65 and ⩾70 y, respectively. Key grade ⩾3 adverse events in pts ⩾65 y were: hypertension in 7% of pts (1% grade 4); cardiac toxicity in 1%, arterial thromboembolic events (ATEs) considered Bev related in 1% and GI perforation in <1%. Further CT lines were reported in at least 37% of pts.

Conclusion: The efficacy and safety of Bev–pac in pts ⩾65 y treated in routine practice is consistent with subgroup analyses of E2100, AVADO, RIBBON-1 and ATHENA. ATEs and cardiac toxicity were infrequent; hypertension was manageable and rarely grade 4. Efficacy data are similar to those reported in the whole population. First-line Bev–pac offers an active, well-tolerated therapy, even in elderly pts who may not be candidates for combination CT. ML21165, sponsored by Roche, is fully accrued.

5073 POSTER

Bevacizumab (Bev) Combined With Paclitaxel (Pac) as First-line Therapy for Metastatic Triple-negative Breast Cancer (TNBC) − Analysis of 147 Patients (pts) Treated in Routine Oncology Practice in Germany

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Background: Both progression-free survival (PFS) and response rate (RR) are significantly improved when Bev is combined with 1st-line chemotherapy for metastatic breast cancer (mBC), as shown in three randomised phase III trials (E2100, AVADO, RIBBON-1). Subpopulation analyses suggest meaningful benefit in pts with TNBC (median PFS 10.6 months with Bev–Pac vs 5.3 months with Pac in E2100; hazard ratio 0.49). To further evaluate the efficacy of first-line Bev–Pac in this setting, we analysed efficacy in the subgroup of pts with TNBC treated in a large German observational study of Bev–Pac in routine oncology practice.

Materials and Methods: Pts with HER2-negative mBC received first-line Bev–Pac according to the European label. Safety and efficacy data were collected for up to 1 year (or until progression, death, or Bev discontinuation if earlier). Study endpoints were safety and efficacy. We conducted an exploratory analysis in the subset of pts with TNBC.

Results: Of the 786 pts with complete data at the time of analysis, 147 (19%) had TNBC. Baseline characteristics and efficacy are shown in the table.

Conclusions: In this ongoing study, first-line Bev–Pac demonstrated a 50% RR, median PFS of 7.9 months, and median OS of 15.2 months in pts with TNBC. This compares favourably with efficacy reported for chemotherapy and/or investigational agents, suggesting that Bev–Pac is an effective first-line option in this difficult to treat population. ML21165, sponsored by Roche, has completed accrual.

	TNBC (n = 147)	Non-TNBC (n = 639)[a]
Median age, years (range)	53 (26−79)	59 (28−87)
Age <40 years, %	9	5
Metastatic at first diagnosis, %	15	20
Disease-free interval <1 year, %	53	17
Tumour grade, %		
1/2	27	57
3	66	32
Unknown	7	11
Metastatic sites, %		
Bone	35	59
Liver	24	48
Lung	46	32
CNS	3	2
Prior (neo)adjuvant chemotherapy, %	79	62
(Neo)adjuvant taxane	38	21
RR, %	50	65
Complete response	12	10
Partial response	39	54
PFS		
Events, n (%)	113 (77)	416 (65)
Median, months (95% CI)	7.9 (7.2−9.0)	10.0 (9.1–10.8)
6-month PFS rate, % (95% CI)	65 (58−74)	75 (72−79)
Overall survival (OS)		
Events, n (%)	81 (55)	224 (35)
Median, months (95% CI)	15.2 (13.8–18.5)	Immature
1-year OS rate, % (95% CI)	65 (57−75)	75 (71−79)

[a]ER, PgR, and/or HER2 status positive/unknown.

5074 POSTER

Evaluation of Serum Testosterone and Dehydroepiandrosterone (DHEA) in Indian Women With Breast Cancer

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Background: Among the endogenous sex steroid hormones, estrogens have been implicated in breast carcinogenesis. However, there have been reports of positive association between serum testosterone levels and pre-menopausal and postmenopausal breast cancer. The hyperandrogenism is usually of an ovarian origin but dehydroepiandrosterone (DHEA) and its sulfate (DHEAS) are major androgens of adrenal origin. The aim of this study was to determine serum testosterone and dehydroepiandrosterone levels in female breast cancer patients and study their relationship with menstrual status, parity, early menarche, late menopause and body mass index.

Materials & Methods: 40 patients with histologically proven, untreated, invasive breast cancer and 50 age matched normal healthy females (controls) were studied. Women who had either received hormone replacement therapy or were on oral contraceptive pills were excluded. All women were consented and the study was approved by the Institute Ethical committee. Blood samples were collected after an overnight fast between 8.00–9.00 AM. Serum was separated and stored. Estimation of serum testosterone and DHEA was done by I^{125} radioimmunoassay. Early menarche was defined as onset of menarche before 12 years, late menopause was described as onset of menopause at the age of 50 or more. Body mass index was calculated by the formula Weight (in kg)/[Height (in m)]^2.

Results: The mean serum testosterone levels were significantly higher ($p = 0.01$) in breast cancer patients (0.37 ng/ml) as compared to controls (0.28 ng/ml). This difference was seen in both premenopausal and postmenopausal women. Serum DHEA levels were higher only in post-menopausal breast cancer patients. Postmenopausal breast cancer patients had higher serum testosterone and DHEA levels than premenopausal breast cancer patients ($p < 0.05$). There was no statistically significant difference in serum testosterone levels between nulliparous and parous women but the serum DHEA levels were higher in nulliparous women as compared to parous women ($p < 0.05$). There was no relationship between serum testosterone and DHEA levels and early menarche, late menopause and body mass index.

Conclusion: The serum testosterone and DHEA levels in Indian women with breast cancer indicate significant differences from their Caucasian