



**(9082) Outcomes for patients treated with or without bevacizumab on SWOG S0819: A randomized, phase III study comparing carboplatin/Paclitaxel or carboplatin/Paclitaxel/bevacizumab with or without concurrent cetuximab in patients with advanced non-small cell lung cancer (NSCLC).**

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**Background:** Bevacizumab (Bev) combined with chemotherapy improves survival in selected patients (pts) with advanced, nonsquamous NSCLC. However, the benefit of Bev has been questioned in certain populations and optimal selection criteria are debated.

**Methods:** SWOG S0819 randomly assigned 1,313 eligible pts with advanced NSCLC to chemotherapy (+/- Bev) with or without cetuximab. Protocol defined criteria for Bev Exclusion (BE) were > 50% squamous cell (SCCA), cavitary lung lesion, hemoptysis (> 1/2 tsp), coagulopathy, CNS metastasis (until 6/2013), non-healing wound or fistula, anticoagulation, platelet inhibitor, or INR > 1.5. Investigators or pts could also choose BE assignment. We conducted subset analyses to compare the baseline characteristics and treatment outcomes for Bev-included (BI) versus BE pts, as well as BE subsets defined by the protocol (BE-Inappropriate) or patient/investigator choice (BE-Choice).



**Results:** BI pts (42.2%) had superior outcomes to BE pts (Table). The reason for BE was ascertained in 94.2%; most commonly SCCA (44.4%), choice (20%), and anticoagulant or platelet inhibitor (19.1%). Multiple reasons were present in 25.6%. There were no significant differences in age, gender, race/ethnicity, PS, or weight loss between BI and BE pts and no differences between BE-Choice and BE-Inappropriate pts. BE-Choice pts had improved PFS but not OS compared to BE-Inappropriate pts.

**Conclusion:** BI pts with advanced NSCLC on S0819 had better survival than BE pts, approximating those of ECOG 4599. The demographics of BI, BE-Choice, and BE-Inappropriate pts were similar; however, BE-Choice pts had survival outcomes more similar to BE-Inappropriate pts than to those treated with Bev. Support: NIH/NCI/NCTN grants SWOG: CA180888, CA180819; ECOG/ACRIN: CA180820; Alliance: CA180821; and in part by Eli Lilly and Company Clinical trial information: NCT00946712

	N	PFS (mo)	HR	OS (mo)	HR
BI	554	5.7	0.61 (0.54-0.68)	12.1	0.72 (0.64-0.81)
BE	759	4.0	P < 0.001	8.5	P < 0.001
BE-Choice	143	4.3	0.78 (0.64-0.94)	8.6	0.84 (0.69-1.04)
BE-Inappropriate	572	3.9	P < 0.01	8.5	P = 0.11