Objective: Conjugated estrogens/bazedoxifene (CE/BZA), a tissue selective estrogen complex, reduced VMS in women in the SMART trials. This study evaluated effects of CE/BZA on VMS and health-related quality of life (HRQOL) in a pooled analysis of SMART-1 and -2. 

Methods: SMART-1 and -2 were randomized, double blind, PBO- and active-controlled, phase 3 studies in nonhysterectomized postmenopausal women. Data were pooled for women (N=435) with moderate/severe (M/S) hot flushes (HFs) given CE 0.45 and 0.625mg/BZA 20mg and PBO for 12 wks. HFs were assessed by daily diary; the Menopause-specific Quality of Life (MENQOL) questionnaire evaluated HRQOL.

Results: At BL, mean (SD) age was 53.8 (4.9) y and BMI was 26.0 (3.9) kg/m2. At 12 wks, CE 0.45 and 0.625mg/BZA 20mg reduced the adjusted mean (SE) change from BL in average number of M/S HFs/d (-7.9 [0.4] and -8.2 [0.4], respectively) vs PBO (-4.1 [0.5]; both P <.001). CE 0.45 and 0.625mg/BZA 20mg reduced the adjusted mean (SE) change from BL in average severity score of HFs/d (-1.0 [0.1] and -1.3 [0.1], respectively) vs PBO (-0.3 [0.1]; both P <.001). CE 0.45 and 0.625mg/BZA 20mg increased the % of women with >=50% (81.2 and 87.1%, respectively) and >=75% (62.4 and 74.8%, respectively) reduction from BL in M/S HFs/d vs PBO (50.6 and 26.4%, respectively; all P <.001), and % of women with >=50% (38.3 and 58.1%, respectively) and >=75% (24.2 and 38.1%) reduction from BL in average severity score of HFs/d vs PBO (11.0 and 5.5%, respectively; all P <.001). CE 0.45 and 0.625mg/BZA 20mg improved HRQOL by reducing the adjusted mean (SE) change in MENQOL vasomotor function (-3.1 [0.2] and -3.7 [0.2], respectively) and total (-1.5 [0.1] and -1.8 [0.1], respectively) scores vs PBO (-1.4 [0.2] and -0.9 [0.1], respectively; P <.001 for both).

Conclusion: In this pooled analysis, CE/BZA relieved VMS in a large population of women with M/S HFs.