Phase III randomized, double-blind, placebo-controlled trial of soy protein and venlafaxine for treatment of hot flashes in men with prostate cancer.

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Author(s):
M. Vitolins, L. Griffin, W. V. Tomlinson, J. Vuky, D. B. Fried, P. T. Adams, D. Moose, B. Frizzell, J. E. Radford, T. R. C. Shah, E. G. Shaw; Wake Forest University Baptist Medical Center, Winston-Salem, NC; Wake Forest University School of Medicine, Winston-Salem, NC; AnMed Health, Anderson, SC; Virginia Mason Medical Center, Seattle, WV; Wake Forest University Health Sciences, Winston-Salem, NC; NSABP; Genesys Regional Medical Center, Flint, MI; Novant Health, Winston-Salem, NC; High Point Regional Cancer Center, High Point, NC; Hendersonville Hem/Onc, Hendersonville, NC; Ann Arbor, Saginaw, MI

Abstract Disclosures

Abstract:

Background: Hot flashes (HFs) occur in approximately 2/3 of androgen-deprived men. There is limited data on treatment from prospective intervention studies. **Methods:** Eligible androgen-deprived men were randomly assigned to 1 of 4 daily regimens (2x2 factorial design) for 12 weeks: placebo pill and casein protein (P), soy protein and placebo pill (S), venlafaxine (Effexor) and Casein Protein (E), or soy plus venlafaxine (SE). The primary endpoint was hot flash symptom severity score (HFSSS), defined as number x severity of hot flashes. The secondary endpoint was quality of life (QoL), assessed using the FACT-P. **Results:** 120 men aged 46-91 (median 69 years) participated. Most were Caucasian (78%) and overweight obese (83%). Groups were similar at baseline (BL). Treatment compliance was 88%. Toxicity was minimal. All groups showed a reduction in HFSSS, but there were no significant differences between

groups (Table). QoL did not change significantly over time and did not differ between groups. **Conclusions:** In androgen-deprived men, neither venlafaxine nor soy protein had a significant effect on HFSSS or QoL, in contrast to findings from Quella et al (1999), which reported a 54% decrease in HF score in men taking venlafaxine. Supported by CCOP Research Base Grant 5 U10 CA081851-11.

Least squares estimates (SE).

Outcome	Visit	P (N = 30)	S (N = 30)	E (N = 30)	SE (N = 30)	P value
HFSSS (%BL)	Week 4	80.5 (12.9)	75.4 (13.6)	75.0 (14.3)	63.1 (13.6)	0.789
	Week 8	58.8 (13.2)	73.9 (14.0)	67.8 (14.7)	66.8 (14.2)	0.873
	Week 12	45.2 (13.8)	68.9 (14.4)	64.9 (15.2)	72.2 (15.3)	0.477
FACT-P	Baseline	111.5 (4.0)	115.7 (4.0)	119.5 (4.1)	119.6 (4.1)	0.474
	Week 12	110.6 (4.2)	120.0 (4.3)	116.2 (4.4)	120.1 (4.4)	0.239