

RANDOMIZED PLACEBO-CONTROLLED TRIAL OF ACUPUNCTURE TO PREVENT RADIATION-INDUCED XEROSTOMIA

BACKGROUND:

To determine if acupuncture can prevent xerostomia among head/neck cancer patients undergoing radiotherapy (XRT).

METHODS:

A two-center, phase III, randomized, placebo-controlled trial comparing true acupuncture (TA) with sham acupuncture (SA) and a wait list control (WLC) group was conducted among patients with naso- (China) or oropharyngeal (US) carcinoma. Patients were treated 3 times per week during their course of XRT. The primary endpoint was determined by the Xerostomia Questionnaire. Patients were followed for 1 year after the end of XRT.

RESULTS:

For combined institutions at the 1-year follow-up (N=358), there was a significant between group difference between TA and WLC (26.6 vs 34.8, $P=0.001$; Cohen's $D= -0.44$), with marginal between group difference between TA and SA (26.6 vs 31.3, $P=0.06$; $D= -0.26$) and no difference between SA and WLC. There was a significant group by institution effect. For patients in China (N=221), there were significant group differences between TA and WLC (20.8 vs 29.6, $P=0.005$; $D= -0.48$) and between TA and SA (20.8 vs 29.9, $P=0.0045$; $D= -0.50$), with no difference between SA and WLC. For patients in the US (N=137) one year after XRT, there were significant between group differences in SA and WLC (31.8 vs 42.2, $P=0.01$; $D= -0.59$) and marginal group difference between TA and WLC (34.7 vs 42.2, $P=0.07$; $D= -0.42$), with no differences between TA and SA. Incidence of clinically significant xerostomia followed a similar pattern. Center differences will be discussed as they relate to culture and the neuroscience of placebo.

DISCUSSION:

Patients in China who received TA concurrently with XRT experienced significantly less xerostomia as compared to SA and standard oral hygiene only. In the US, both TA and SA reduced xerostomia symptoms 1-year after XRT.