

## • Research Article

# Efficacy of a traditional Persian medicine preparation for radiation-induced xerostomia: a randomized, open-label, active-controlled trial

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### ABSTRACT

**BACKGROUND:** Xerostomia is one of the most common side effects of radiation therapy among patients with head and neck cancers (HNC). However, conventional medicine lacks an effective treatment for radiation-induced xerostomia.

**OBJECTIVE:** Synthesizing the traditional use of *Alcea digitata* and *Malva sylvestris* with their known beneficial effects from recent studies, we evaluated the efficacy of the herbs in the quality of life (QOL) of HNC patients with radiation-induced xerostomia.

**DESIGN, SETTING, PARTICIPANTS AND INTERVENTIONS:** This study is a randomized, double-arm, open-label active-controlled clinical trial. We evaluated the effect of *A. digitata* and *M. sylvestris* on QOL of HNC patients with radiation-induced xerostomia compared with Hypozalix (artificial saliva). Patients were enrolled from the Imam Hossein Hospital's oncology clinic in Shahid Beheshti University of Medical Sciences, Tehran, Iran.

**MAIN OUTCOME MEASURES:** Primary outcome measures in this trial were changes in patients' QOL assessed by the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, Head and Neck Module (EORTC QLQ-H&N 35).

**RESULTS:** Between-group analysis showed that the intervention group patients obtained significantly lower (better) total EORTC QLQ-H&N 35 scores as compared to the control group at the end of the intervention period ( $P = 0.007$ ). Mean scores of dry mouth of EORTC QLQ-H&N 35 was also significantly lower (better) in the intervention group as compared to the control group ( $P = 0.017$ ).

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**CONCLUSION:** Traditional Persian medicine preparation of hollyhocks and common mallow should be considered as a suitable treatment for xerostomia and improving QOL in HNC patients with radiation-induced xerostomia.

**TRIAL REGISTRATION:** The trial was registered in ClinicalTrials.gov with Identifier: NCT02854358.

**Keywords:** xerostomia; medicine, Persian traditional; hollyhocks; common mallow; cancer

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## 1 Introduction

Head and neck cancer (HNC) refers to cancers originating in the oral and nasal cavity, paranasal sinuses, pharynx, larynx and salivary glands. HNC is one of the most common cancers worldwide, of which 600 000 new cases are diagnosed annually, and has a high level of mortality.<sup>[1,2]</sup>

Although there is a multidisciplinary approach for management and treatment of HNC, radiation therapy is an important treatment, either as an adjunctive method or as the main therapeutic regimen.<sup>[3,4]</sup> Xerostomia is one of the most common side effects of radiation therapy among patients with HNC.<sup>[5,6]</sup>

Xerostomia or mouth dryness is a condition which may be associated with changes in saliva composition and amount.<sup>[7]</sup> Patients with xerostomia often suffer from impairment of taste, difficulties in speech and swallowing, and dental deterioration. Mouth dryness significantly impairs and has an inverse association with the patients' quality of life (QOL).<sup>[8–10]</sup>

Symptom alleviation and prevention of complications are the main therapeutic goals in management of patients with xerostomia.<sup>[11–13]</sup> Treatment strategies include supplemental mucosal lubrication for the replacement of salivary secretions; using buffering acids to decrease the demineralization of teeth; and the application of antimicrobial agents for prevention of secondary infections.<sup>[14,15]</sup> However, most treatments are symptom-directed and are not curative, and there is not an effective, curative, allopathic treatment for radiation-induced xerostomia. Hence, many patients seek out complementary and alternative medicine for this condition.<sup>[16–18]</sup>

Traditional Persian medicine (TPM) is a field of complementary and alternative medicine commonly practiced among Iranian people.<sup>[19–24]</sup> There are several herbal remedies for the treatment of dry mouth in TPM.<sup>[25]</sup> *Alcea digitata* Alef. (hollyhocks) and *Malva sylvestris* L. (common mallow) are amongst the mucilaginous plants that have long been used in TPM to treat symptoms like dry mouth.<sup>[26]</sup> *A. digitata* and *M. sylvestris* both belong to the family of Malvaceae.<sup>[26,27]</sup> These medicinal plants are typically used in TPM for their gastrotonic, anti-tussive,

mucolytic and antiseptic properties. Moreover, common mallow and hollyhocks have been used for the treatment of stomatitis, aphthous lesions and mucosal inflammations since ancient times.<sup>[27–31]</sup> Several studies have shown that gargling of hollyhock extract alleviates oral and pharyngeal irritation.<sup>[32]</sup> Previous studies on hollyhocks and common mallow have shown that they have anti-inflammatory, antimicrobial and antioxidant properties.<sup>[33–35]</sup> Taking into account both the traditional use of *A. digitata* and *M. Sylvestris*, in addition to their scientifically-demonstrated beneficial effects, we decided to design a randomized, controlled clinical trial to evaluate the efficacy of these herbs in enhancing QOL of HNC patients with radiation-induced xerostomia.

## 2 Materials and methods

### 2.1 Trial design

This study is a randomized, double-arm, parallel-group, open-label active-controlled clinical trial, conducted from March 2015 to February 2016. In this trial, the authors evaluated the effect of TPM-based prepared medications containing *A. digitata* and *M. Sylvestris* on the QOL of HNC patients with radiation-induced xerostomia compared with Hypozalix (artificial saliva). No changes were made to methods after the commencement of the trial.

### 2.2 Ethical issues

The trial was registered in ClinicalTrials.gov (Identifier: NCT02854358). The trial was in compliance with the *Declaration of Helsinki* (1989 revision), and also approved by the relevant local research ethics committees (the Office of Research Affairs, the Deputy of Research and Technology and the Shahid Beheshti University of Medical Sciences: reference number 143). All HNC patients who showed symptoms of xerostomia and met the inclusion criteria participated in the study after signing a consent form.

### 2.3 Participants

Inclusion criteria: men and women with HNC aged 20 to 70 years, who had grade 1 or 2 xerostomia (based on the Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0),<sup>[36]</sup> finishing radiotherapy at least two months before the study. According to the CTCAE,

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