Acupuncture and xerostomia

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COMMENTARY

Xerostomia has Greek origins from ‘xeros’ (dry) plus ‘stoma’ (mouth); an innocuous description that does little to reflect the chronic and miserable state experienced by patients after radiotherapy for head and neck cancer.1 2 Radiotherapy is used as a curative treatment for head and neck cancers (see Figure 1). Incidence of these cancers is increasing (possibly due to rising human papillomavirus infection rates) but cure rates with radiotherapy are also rising.3

Radiotherapy does used far exceed the tolerance of those salivary glands that lie in the path of the radiation beam causing permanent damage and consequent xerostomia.

Xerostomia debilitates and greatly impairs quality of life long after successful cancer treatment. It interferes with taste, chewing, swallowing, speaking, sleeping and accelerates tooth decay. The most common question for the head and neck oncologist in the long-term follow-up of their cured patients is ‘is there anything that will help my dry mouth?’

This burden of xerostomia has prompted major research effort and investment in highly evolved radiotherapy algorithms which potentially avoid salivary damage. Intensity modulated radiotherapy has been demonstrated to reduce xerostomia in a randomised trial4 but the technology is both difficult and expensive to apply universally.5 Xerostomia will continue to affect many more patients in the future despite intensity modulated radiotherapy. The failure of conventional medicine to provide durable relief for this condition5 has led to a revival of complementary approaches. Acupuncture use in this context is intriguing not least because the head and neck cancer patient population have been demonstrated to be very infrequent users of complementary and alternative medicine.7

This timely systematic review by O’Sullivan and Higginson8 examines the current evidence on whether acupuncture is a safe and useful form of treatment for irradiation-induced xerostomia. The review sensibly limits itself to irradiation-induced xerostomia. There is a larger literature looking at acupuncture to relieve xerostomia from all causes but the condition’s pathophysiology will vary according to cause and thus confound treatment approaches. The review was limited to randomised controlled trials and systematic reviews of randomised controlled trials, but due to a paucity of level 1 evidence, was widened to include high quality non-randomised studies. Eighteen publications were identified of which only 11 represented original studies (seven of these published since 2007, reflecting the contemporary interest) but only three of 18 articles were eligible for full text review reflecting a disappointingly poor scientific standard. Lack of control group was the most common exclusion. Selection of control here is difficult. In two of the three randomised studies, sham acupuncture is used to control for therapist interaction but the authors rightly raise concern about the potential for a physiological response from ‘inactive’ points. Lack of a useful standard treatment for xerostomia in this setting justifies ‘usual care’ as a control (as employed in one of the studies). Only one (unselected case series) study has restricted use of acupuncture to patients resistant to pilocarpine, a drug with proven efficacy in this setting.9 Pilocarpine is recommended by less than 40% oncologists in the UK mainly due to worries about side effect profile (unpublished data, Simcock 2010) so may struggle to be accepted as a control arm.

Within the reviewed studies there were simple omissions of study design and reporting including failure to follow STRICTA reporting guidelines and lack of description of randomisation. These are disappointing failings in contemporary acupuncture research.

Radiation induced xerostomia may improve through recovery of minor salivary glands within the first year after treatment. None of the reviewed studies allowed for this and the largest study recruited patients from only 3 months after therapy—the possibility of temporal bias is therefore high.

O’Sullivan and Higginson9 focus on four research questions and objectives for their review: whether patients experienced any (1) objective or (2) subjective relief from acupuncture, (3) the uniformity of acupuncture treatment protocols and (4) whether the frequency and nature of adverse events was acceptable.

Two studies measured saliva and both reported an improvement from baseline but with no difference between study arms.10 11 The reason for improvement in the control arms remains unexplored. The

Figure 1 Patient in immobilisation mask being prepared for radiotherapy treatment on linear accelerator.
review concludes that there is no evidence of objective benefit from acupuncture; however objective evidence of salivary function is not a necessary outcome of successful xerostomia treatment. Assessment of salivary gland function with sialometry may be an important aspect of understanding the mechanism of reduced xerostomia (efficacy) but it is not an essential tool in demonstrating relief from symptoms (effectiveness). Undue focus on function may overshadow useful changes in symptoms. Major salivary gland flow rates are only weakly correlated with xerostomatic scores and in our own experience, only weakly correlated with xerostomia. Major salivary gland flow rates are not a necessary outcome of successful xerostomia treatment. Assessment of salivary gland function with sialometry remains an important outcome measure. Investigators used very specific subjective xerostomia indices, such as the Xerostomia Inventory, in one case reduced to only four questions. This focused approach may miss effects of therapy on global quality of life due to changes in a symptom which affects so much of normal life. Global quality of life measurement in addition to xerostomia domains therefore seems essential.

In assessing the uniformity of the acupuncture protocols the reviewers sadly found none. Acupuncture points used ranged from four to 29 and the number of sessions from four to 24. There was both massive interstudy and considerable intrastudy variability in protocol. An essential principle of scientific study (and one may argue that for complementary and alternative medicine studies the need is even greater) is that in order to build up a body of evidence, one needs to be able to replicate and compare studies. Markedly different protocols are difficult to compare, delaying analysis of components of efficacy. Even those treatments proven to be effective need to demonstrate cost-effectiveness before being adopted into clinical practice—these data will be impossible to provide without clarity around protocols, particularly the number of treatment sessions and therapist time.

Finally, the review highlights the lack of data on safety and adverse events rendering the authors unable to determine the safety of the intervention. This is a failure of research method. Future investigators must accept that an intervention offered with an unknown potential for benefit has an unknown potential for harm and that these data must be collected and reported.

SUMMARY
The life of head and neck cancer survivors may be improved by reducing xerostomia. Given the large amount of noise around acupuncture (61 articles were retrieved on first search in this review) we are left to draw conclusions from three randomised studies in which only 50 patients were analysed with xerostomia as a primary study end point. Closer attention to study detail and reporting are vital. It is with this background that we await the analysis of our own current National Cancer Research Network, Acupuncture for Radiotherapy-Induced Xerostomia study  (with over 100 patients randomised to date) to more fully inform debate on the utility of this therapy.

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