Group acupuncture to relieve radiation induced xerostomia: a feasibility study

Richard Simcock,1 Lesley Fallowfield,2 Valerie Jenkins2

ABSTRACT

Background: A distressing complication of radiotherapy treatment for head and neck cancer is xerostomia (chronic oral dryness). Xerostomia is difficult to treat conventionally but there are reports that acupuncture can help. We conducted a feasibility study to examine the acceptability of a standardised group acupuncture technique and adherence to group sessions, together with acceptability of the objective and subjective measurements of xerostomia.

Methods: 12 males with established radiation induced xerostomia were treated in three groups of four. Each received eight weekly sessions of acupuncture using four bilateral acupuncture points (Salivary Gland 2; Modified Point Zero; Shen Men and one point in the distal radial aspect of each index finger (LI1)). Sialometry and quality of life assessments were performed at baseline and at the end of treatment. A semi-structured interview was conducted a week after completing the intervention.

Results: Adherence to and acceptability of the treatment and assessments was 100%. There were objective increases in the amounts of saliva produced for 6/12 patients post intervention and the majority also reported subjective improvements. Mean quality of life scores for domains related to salivation and xerostomia also showed improvement. At baseline 92% (11/12) patients reported experiencing a dry mouth "quite a bit/very much" as compared to 42% (5/12) after the treatment. Qualitative data revealed that the patients enjoyed the sessions.

Conclusion: The pilot study shows that a standardised group technique is deliverable and effective. The tools for objective and subjective assessment are appropriate and acceptable. Further examination in a randomised trial is now warranted.

Xerostomia (the complaint of oral dryness) is a distressing and debilitating complication of radiotherapy used in the treatment of head and neck cancers. Xerostomia causes accelerated oral decay, difficulty eating and reduced quality of life (QoL).1 Xerostomia after radiotherapy arises due to irradiation of normal salivary tissue lying in close proximity to the radiation target volume. If the radiation tolerance of the major salivary glands is exceeded then xerostomia is usually irreversible although some improvement may be seen within the first 18 months, probably due to recovery of minor glands.2 Attempts to reduce the impact of xerostomia have focused on prevention of radiotherapy damage and treatment of established xerostomia. Efforts at prevention have included surgical (transposition of the submandibular glands3) radiotherapeutic (intensity modulated radiotherapy4) and pharmacological5 (Amifostine). Treatment for established xerostomia usually includes salivary analogues. The oral drug Pilocarpine has shown some efficacy in randomised studies6 but its utility is limited by muscarinic side effects of the drug. When Pilocarpine works the effect is seen within 12 weeks.7

Acupuncture has been used in the treatment of xerostomia with some reported successes8–10 and objective improvements in biochemical endpoints.11 A recent functional MRI study showed central nervous system imaging changes during acupuncture for xerostomia.12 There are methodological problems with the existing literature. Standardisation is often not possible due to the common practice of using differing points in each patient; this prevents validation and creates variation between practitioners and subjects. Other studies have used electrostimulation without invasive needles (acupuncture-like TENS).13 Also, the xerostomia in the published acupuncture studies had a number of different aetiologies.

A systematic review of the effect of acupuncture on xerostomia identified only one study of high quality and none of the studies were randomised.14 Despite these problems a Phase 2 study has reported useful benefit in radiotherapy induced xerostomia.15 The protocol was developed by a practitioner using a combination of traditional Chinese and western acupuncture techniques. Importantly, the technique appeared reproducible with similar benefits. This recent trial sought only to demonstrate improvement using the Xerostomia Inventory, a short questionnaire based tool which was applied retrospectively. In view of this preliminary data, we designed a pilot study to test the feasibility, acceptability and adherence to group acupuncture for patients with radiation induced xerostomia using a standardised technique.

METHODS

Patients

Inclusion criteria for the study were head and neck cancer patients age 18 years or over who had been treated with radical radiotherapy at least 18 months previously (minimum one parotid gland within the field of radiotherapy). In addition, patients had no clinical signs of local recurrence, complained of xerostomia and were able and willing to complete QoL questionnaires and attend weekly acupuncture sessions.

Patients were excluded if their xerostomia was caused by reasons other than radiotherapy, for example, Sjogren’s disease, or if they were currently using pilocarpine or other treatment for xerostomia, had previously received acupuncture for xerostomia, or had a history of bleeding...
disorders or vasovagal episodes as a result of injections/phlebotomy.

Sixteen patients (15 male, one female) attending follow up clinics were invited to join the study. Two proved ineligible, one declined entry and one was unable to attend the evening acupuncture sessions. The 12 participating patients were male and had completed treatment with radical intent (radiotherapy ± surgery and/or chemotherapy) for head and neck cancer at least 18 months previously. All were examined and confirmed to be free of residual or recurrent disease prior to the study. None of the patients had smoked tobacco since their treatment for cancer. All gave written informed consent. The protocol was reviewed and approved by the local ethics committee (Ref: 06/Q1907/53). Further demographics and treatment details are listed in table 1.

**Acupuncture protocol**

The patients were treated in three cohorts. Each cohort had weekly sessions of needling for eight weeks in groups held in the early evening at the Sussex Cancer Centre. Three practitioners gave the acupuncture treatments. Two were medical doctors (an oncologist and general practitioner) and both were members of the British Medical Acupuncture Society regularly performing acupuncture treatments. The third practitioner was a full time acupuncture therapist qualified in both traditional Chinese and western medical acupuncture. The timing of the acupuncture sessions for the pilot study was dependent on the availability of the acupuncture therapists, rather than patient preference. At each session the men were needled to four points bilaterally (three points in the bilateral ears) Salivary Gland 2; Modified Point Zero; Shen Men and one point in the distal radial aspect of each index finger (LI1) according to the protocol outlined by Johnstone and colleagues.15 For auricular needling 0.2×7 mm needles were used and 0.2 mm ×40 mm for the distal point. All needles were sterile and disposable. Points were needled into subcutaneous tissue and were retained in each point for 20 minutes (see fig 1). At 10 minutes retention time the needles were manually rotated to increase the likelihood of de qi although a reported sensation of de qi was not mandated. There were no other co-interventions and sessions were kept to 30 minutes length (allowing a short amount of time before and after needling for preparation and then disposal). Participants were at liberty to talk to each other during needling sessions.

**Sialometry**

The first cohort of men underwent sialometry using the modified Cruttenden-Lashley cup method16 to quantify unstimulated and stimulated flows from each parotid duct. Whole mouth salivation was also measured using change in the mass of pre weighed cotton buds held in the floor of mouth. Participants undergoing this method gave adverse feedback on the discomfort of this process and for the second two cohorts a modified Schirmer strip method was used.17 This method has the advantage of measuring whole mouth salivation as represented by mucosal wetness. The test is inexpensive and easy to administer. Sialometry was performed at baseline, T1 (prior to acupuncture therapy) and again at nine weeks, T2 (one week after the end of the treatment course).

**Quality of life**

QoL was assessed using a validated questionnaire: the European Organisation for Research and Treatment of Cancer (EORTC QLQ-C30 (version 3.0) with the head and neck cancer specific module (EORTC QLQ H&N 35).18 A study specific questionnaire of five questions probed participants use of liquids and their perceptions of oral dryness. These questionnaires were completed at baseline (T1) and one week following the end of treatment (T2). In addition to these questionnaires patients were asked prior to treatment about their expectations of the impact that acupuncture might have on their xerostomia. A semi-structured interview was conducted at the end of the treatment course to explore how they found the intervention. The interview was led by an experienced psychological researcher and explored attitudes towards recruitment, the acupuncture procedure, and outcome and evaluation techniques.

**RESULTS**

There was 100% attendance at all sessions for the 12 men with full compliance with treatment protocol. No adverse events were observed as a result of the acupuncture intervention.
Objective measures

None of the first four subjects produced any unstimulated saliva from either parotid tested using the modified Cruttenden-Lashley cup method. In this group, floor of mouth measurements using weighed cotton buds showed small changes in flow rates (table 2). Patients found this assessment very uncomfortable so for the final eight subjects the Schirmer strip test was used. Results from the test are given in table 3. Fifty percent of this group saw some improvement in Schirmer strip sialometry results but the clinical benefit of this change remains unclear, particularly as those with improved Schirmer strip readings did not always report improvement in symptoms.

Quality of life

The QoL data can be reviewed for an indication of subjective benefits or harms from the intervention. The EORTC QLQ H&N35 scores items and groups from 0–100 (with higher scores representing more problems). Table 4 displays the mean scores at baseline and after eight weeks of acupuncture.

Mean scores from the group from T1 to T2 demonstrated a trend towards improvement in many areas of QoL. The EORTC H&N QLQ H&N35 identifies particular problem domains for subjects by asking them to rate symptoms as “quite a bit”/“very much”. These key symptoms were compared before and after the intervention. In all, 92% (11/12) of the group said that a dry mouth was “quite a bit or very much” a problem for them prior to the intervention as compared to 42% (5/12) at the end of the treatment course. Three subjects reported improvement in problems with sticky saliva and three out of the four patients reporting problems with their sense of smell reported an improvement.

Improvements were seen in response to the direct questions related to use of liquids and the perception of oral dryness (table 5). Five men reported sipping less liquid to relieve a dry mouth at the end of treatment and only one subject reported having to wake in the night to drink to relieve a dry mouth.

Two patients reported improvement in dry mouth that was not identified using the modified Schirmer strip sialometry but the clinical benefit of this change remains unclear, particularly as those with improved Schirmer strip readings did not always report improvement in symptoms.

Table 2  Group 1: measure of saliva flow in ml/min from collection in floor of mouth for patients 1–4

<table>
<thead>
<tr>
<th>Patient ID number</th>
<th>T1: baseline salivary flow (ml/min)</th>
<th>T2: at 9 weeks salivary flow (ml/min)</th>
<th>Change from baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.25</td>
<td>0.05</td>
<td>−0.20</td>
</tr>
<tr>
<td>2</td>
<td>0.02</td>
<td>0.06</td>
<td>+0.04</td>
</tr>
<tr>
<td>3</td>
<td>0.01</td>
<td>0.25</td>
<td>+0.24</td>
</tr>
<tr>
<td>4</td>
<td>0.04</td>
<td>0.00</td>
<td>−0.04</td>
</tr>
</tbody>
</table>

Table 3  Schirmer strip measurements from patients 5 to 12

<table>
<thead>
<tr>
<th>Patient ID Number</th>
<th>T1: Baseline (mm)</th>
<th>T2: At 9 weeks (mm)</th>
<th>Change from baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>4</td>
<td>0</td>
<td>−4</td>
</tr>
<tr>
<td>6</td>
<td>12</td>
<td>10</td>
<td>−2</td>
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<tr>
<td>7</td>
<td>1</td>
<td>19</td>
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<tr>
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<td>12</td>
<td>+5</td>
</tr>
<tr>
<td>9</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>10</td>
<td>20</td>
<td>44</td>
<td>+24</td>
</tr>
<tr>
<td>11</td>
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<td>23</td>
<td>+18</td>
</tr>
<tr>
<td>12</td>
<td>7</td>
<td>3</td>
<td>−4</td>
</tr>
</tbody>
</table>

Table 4  EORTC QLQ C-30 mean score at baseline and after 8 weeks of acupuncture

<table>
<thead>
<tr>
<th>Symptom scales/items</th>
<th>Baseline (n = 12)</th>
<th>After 8 weeks (n = 12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional scales</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical functioning</td>
<td>86</td>
<td>92</td>
</tr>
<tr>
<td>Role functioning</td>
<td>78</td>
<td>92</td>
</tr>
<tr>
<td>Emotional functioning</td>
<td>84</td>
<td>81</td>
</tr>
<tr>
<td>Cognitive functioning</td>
<td>89</td>
<td>82</td>
</tr>
<tr>
<td>Social functioning</td>
<td>74</td>
<td>79</td>
</tr>
<tr>
<td>Symptom scales/items</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>28</td>
<td>23</td>
</tr>
<tr>
<td>Nausea &amp; vomiting</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Pain</td>
<td>13</td>
<td>14</td>
</tr>
<tr>
<td>Dyspnoea</td>
<td>17</td>
<td>11</td>
</tr>
<tr>
<td>Insomnia</td>
<td>39</td>
<td>28</td>
</tr>
<tr>
<td>Appetite loss</td>
<td>19</td>
<td>14</td>
</tr>
<tr>
<td>Constipation</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Financial problems</td>
<td>28</td>
<td>28</td>
</tr>
</tbody>
</table>

Table 5  Number and percentage of patients reporting “very often” or “fairly often” to questions at T1 and T2

<table>
<thead>
<tr>
<th>Question</th>
<th>Baseline (n = 12)</th>
<th>After 8 weeks of acupuncture (n = 12)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. In the last week have you sipped liquids to relieve your dry mouth?</td>
<td>11/12 (92%)</td>
<td>7/12 (58%)</td>
</tr>
<tr>
<td>2. In the last week have you sipped liquids to help you swallow food?</td>
<td>9/12 (75%)</td>
<td>7/12 (58%)</td>
</tr>
<tr>
<td>3. In the last week have your lips felt dry?</td>
<td>10/12 (83%)</td>
<td>4/12 (33%)</td>
</tr>
<tr>
<td>4. In the last week have you woken up at night, needing to drink, because of your dry mouth?</td>
<td>6/12 (50%)</td>
<td>4/12 (33%)</td>
</tr>
</tbody>
</table>
Box 1 Selected comments abstracted from semi-structured interviews

Reflections on the acupuncture:
ID:06 “New experience, felt positive that something will happen.”
ID:09 “I was waiting for something more than I got, not much to feel at all, just tingling when the needle was twiddled.” “A really comfortable thing to do.”
ID:07 “Slight tingle and warmth in left ear, which is the first time I’ve had any feeling in my ear due to nerve damage.”

Reflections on the group acupuncture sessions:
ID:02 “Coming together with other men with similar circumstances was the best part. Enjoyed it all.”
ID:05 “Meeting with others with a similar problem was quite edifying, it was good to meet others with the same trouble, it is the chronic discomfort that gets you down and others who don’t suffer don’t understand, I don’t think the doctors care.”
ID:06 “It was positive to be in a group setting meeting others and sharing experiences of what we have been through. Group therapy sessions is what it has felt like.”
ID:09 “It was a brilliant idea to do it in a group session because everybody shared about their illness. I found out more about my illness in an informal setting.”

Negative reflections:
ID:07 “Nice to be with people with similar medical problems, but I felt down as they were doing much better than me.”

Sialometry:
With Lashley cup
ID:01 “20 minutes is quite a long time to sit holding onto 2 syringes.”
ID:02 “Undignified, can’t talk for 20 minutes… but it’s ok.”
ID:03 “Slightly uncomfortable, felt like a long time, didn’t stick to mouth and kept falling off.”

With Schirmer strip
ID:06 “Not a problem.”
ID:09 “It was an easy way to do it, comfortable, not intrusive.”

proves to be useful under test. The administration of acupuncture to a group of similar patients at once was demonstrated to be an efficient method of delivering the treatment that was acceptable to all parties. An advantage of the group approach was it reduced the amount of therapist time and facilities required, and hence also reducing costs. This has already been demonstrated to be both practical and pragmatic in the treatment of osteoarthritis.21 It became clear from the interviews with subjects that many of the groups found meeting with patients who had had similar healthcare experiences to be an enjoyable and useful experience. It is difficult to comment on whether mixed or single sex group sessions should be employed in future interventions, although in any randomised trial the effect of mixed sex groupings would be controlled for by randomisation. It may be that the effect of creating a therapy environment with a peer group accounted for some of the benefits perceived by the subjects and therefore this design should be preserved in further studies of effectiveness. Likewise an expectation of benefit might have influenced reporting of benefit, although more patients felt that the acupuncture had relieved symptoms than they had predicted at baseline.

Salivary gland hypofunction is an important predictor of xerostomia, however xerostomia can exist in the presence of apparently normal salivary gland function23 partly due to problems in defining “normal” flow rates.24 Salivary flow rates as a measure of salivary gland function do not give information about the enzymatic contents of saliva, which also influence the experience of xerostomia.24 25 Objective measurement of salivary gland function with sialometry may therefore be an important aspect of understanding the mechanism of reduced xerostomia but is not an essential tool in demonstrating relief from the symptom. Other authors have previously shown that major salivary gland flow rates are only weakly correlated with xerostomia scores.2 In this study small changes in production were observed, however these could not be related to the relatively large improvements seen in those domains of QoL related to xerostomia. It is possible that the improvements seen in QoL are independent of salivary flow.

In the symptom domains of the QoL indices related to dry mouth some useful and clinically meaningful improvements were seen. This was reflected in the positive comments made by the subjects in the post-treatment interview. These improvements were seen not only in the subject’s perception of dry mouth as reported in the QoL sub scales but also in physical benefits with reduced consumption of water through the day and less waking at night to take fluid. The smaller improvements in other related physical domains hint at a potential role for the group acupuncture intervention to improve global health related QoL in these subjects.

The study of CAM (including acupuncture) may be divided into studies that explore effectiveness (pragmatic, showing benefit in everyday practice) and efficacy (explanatory and designed to explore causality). This small feasibility study demonstrated that group acupuncture sessions are acceptable and that patients reported relief of many of their symptoms. Two further recent small studies26 27 have also improved salivary flow rates in radiation induced xerostomia; this provides further evidence that acupuncture could be a useful technique.

Chronic xerostomia is a miserable condition with no really effective conventional ameliorative treatments. The pilot study confirms the reproducibility of the acupuncture protocol and shows that the objective and subjective tools to measure xerostomia utilised in the study are acceptable and applicable. A randomised phase III crossover trial with appropriate controls is now being conducted to examine efficacy in this group setting.

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REFERENCES


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