

The Challenges of a Trial with Acupuncture – ARIX

Dr Richard Simcock, Consultant Clinical Oncologist, Sussex Cancer Centre, described the ARIX Trial – a randomised trial of acupuncture in patients with dry mouth following treatment of head and neck cancer.

Xerostomia – Dr Simcock gave a very clear explanation:

- complaint of oral dryness
- due to salivary hypofunction
- patients report – functional difficulties; accelerated tooth decay; reduced quality of life
- hard to make objective salivary measurement due to changes in salivary function. Saliva changes depending on what we are doing
- various causes of Xerostomia but in this situation long term side effect of radiotherapy treatment

Head and Neck Cancer – approximately 250 people diagnosed per year in Sussex Centre – 53 separate anatomical subsets of the disease. Very sensitive and responsive to radiotherapy, curative dose of 60 to 70 Gy but an organ at risk within the treatment area is the parotid gland, tolerance of 26Gy therefore will be wiped out never to function again. Big news is development of IMRT (Intensity Modulated Radiotherapy) – multiple summated small fields – spares parotid IMRT rates 29%. Main focus for clinician and patient is cure but then following on from this is survivorship and quality of life.

Dr Simcock feels that there is the opportunity in the NHS for all clinicians to undertake research. As acupuncture was part of the trial protocol he went and trained in acupuncture.

He posed the question “What is medicine?” and looked at these areas – acupuncture; chiropractic; homeopathic and herbal medicine offering these thoughts:

- Health warnings that come with complementary therapy
- The disclaimer
- Centuries old wisdom that has not changed over time
- Feeling worse is a sign of getting better
- Evidence is anecdotal and supported by testimonials
- Flattering and appeals to your vanity
- Sounds too good to be true
- Regulation is important but difficult
- Placebo effect – important thing is the effect as patient has problem and placebo has effect therefore not necessary a bad thing

ARIX Trial – Do we believe that acupuncture is helpful for this difficult symptom?
How can we test this question in a robust and scientific way?

- The process > idea > planning > feasibility > determination > compromise
- This was a study of effectiveness rather than efficacy
- Control arm – standard oral care
- Intervention arm - group meeting to have acupuncture – needles in for 20 minutes X 8 times. (Auricular Acupuncture Microsystem Points). (Western Medical Acupuncture ethos: we have got these needles and appear to help so we will do it again)
- Participants had to have radiotherapy at least 18 months ago
- 144 took part
- 1 in 6 patients reported improvement in dry mouth
- ??was part of the effect group support
- Conclusion – acupuncture delivered as a group was safe, acceptable to the group and more effective than oral care
- Now down to acupuncture therapists to develop efficacy

Thank you to Dr Simcock for a very interesting and informative session that included the opportunity for each of us to experience inserting an acupuncture needle into our hand!

Margaret Grayson, ICPV Summer School, July 2014