

Acupuncture Treatment of Patients with Radiation-induced Xerostomia

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Xerostomia is a common and usually irreversible side effect in patients receiving radiation therapy (>50 Gy) for head and neck cancer. Of 38 patients with radiation-induced xerostomia, 20 in the experimental group were treated with classical acupuncture and 18 patients in the control group received superficial acupuncture as placebo. Within both groups the patients showed significantly increased salivary flow rates after the acupuncture treatment. In the experimental group 68% and in the control group 50% of the patients had increased salivary flow rates at the end of the observation period. Among those patients who had had all their salivary glands irradiated, 50% in both groups showed increased salivary flow rates (>20%) by the end of the observation period of 1 year. The study indicates that among the patients who had increased salivary flow rates already after the first 12 acupuncture sessions, the majority had high probability of continual improvement after the completion of acupuncture treatment. The improved salivary flow rates usually persisted during the observation year. The changes observed in the control group were somewhat smaller and appeared after a longer latency phase. Significant differences for salivary flow rates could be observed only within each group, and there were no statistically significant differences between the groups. There were no differences in the improvement of salivary flow rates between those patients who were irradiated within a year before the acupuncture treatment and those who had received radiation therapy several years earlier. The results indicate that acupuncture might be a useful method for the treatment of radiation-induced xerostomia, and that superficial acupuncture should preferably not be used as placebo acupuncture. Copyright © 1996 Elsevier Science Ltd

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INTRODUCTION

Radiation therapy plays an important role in the treatment of head and neck cancer. In radical radiotherapy doses are often ranged between 50 and 70 Gy and most of the salivary glands are exposed to this radiation. This causes severe damage to the salivary-gland tissue, which in turn results in atrophy, fibrosis and reduced or lost salivary flow—xerostomia or hyposiali [1–3]. It is a source of serious problems for the patients, such as difficulties in speaking, chewing and swallowing, taste dysfunction, increased frequency of infection of the oral mucosa and gums and rampant caries.

Many attempts have been made to cure or alleviate xerostomia. Various saliva stimulants, both mechanical and pharmacological, have been used with different results. Such studies have proved that all the examined devices gave certain

symptomatic relief but no long-lasting results [4, 5]. Electrical stimulation by a battery-operated device applied to the tongue and palate has been tried as well [6, 7]. Another method to treat xerostomia could be hyperbaric oxygen therapy. This treatment seems to be successful, even though the reported study was limited to 11 patients only [8]. Pilocarpine treatment has also shown positive results, but limitations exist due to side effects such as sweating, rhinitis, headache, nausea and urinary frequency [9, 10]. The fractionation of radiotherapy may influence late changes in salivary-gland function and hyperfractionation has been reported to be less damaging in this respect [11].

The aim of the present study was to investigate the effect of acupuncture on salivary flow rates in patients with xerostomia after irradiation treatment to the head and neck region.

MATERIALS AND METHODS

41 patients who had had all or some of their salivary glands irradiated during treatment of malignant tumours in the head

Correspondence to M. Blom. Received 3 July 1995; provisionally accepted 9 Aug. 1995; revised manuscript received 14 Nov. 1995. and neck region were initially included in the study. All patients received radiotherapy in fractions of 2 Gy daily, 5 days a week to a total of 50–68 Gy. Treatment was given with 4–6 MV photons using a linear accelerator. The patients were randomly assigned to the treatment group or to the control group. All patients who enrolled in the study had subjectively dry mouth.

38 of the patients completed the acupuncture treatment and were transferred to the 1-year-long observation study. The experimental group comprised 20 patients (6 females and 14 males). Their ages ranged between 35 and 79 years (median 61.5 years). The duration of xerostomia ranged between 5 months and 12.5 years (median 16.5 months). The control group comprised 18 patients (6 females and 12 males). Their ages ranged between 43 and 82 years (median 64 years). The duration of xerostomia ranged between 2 months and 7.5 years (median 13.5 months). 5 patients did not return for the last follow-ups because they did not experience any improvement or they were hospitalised because of metastases. The diagnosis, the size of tumours, the irradiation dosage and irradiation area for both groups are shown in Table 1. Subjective findings of the patients were also collected.

Acupuncture treatment (AP)

Acupuncture treatment (AP) and placebo-acupuncture were given in two series of 12 treatments, each lasting 20 min. Each series took 6 weeks (two treatments per week) with a 2week pause between the series. The points that were used are shown in Fig. 1. Five to eight points were chosen among the local and distal points, with regard to the patients' particular complaints and their general health condition. Two to four points were chosen from auricular points, according to traditional Chinese medicine [12]. The needles used were Chinese, sterile acupuncture needles for single use (Cloud & Dragon; diameter 0.30 mm; length 15 and 30 mm). The patients in the experimental group had the needles inserted in acupuncture points which were stimulated manually until the appearance of needling reaction (the Qi). In the control group, superficial needling (placebo acupuncture) was performed; the needles were inserted only superficially (intradermally), without eliciting any further reaction, about 1 cm away from the classical acupuncture point. All the changes in subjective symptoms, as well as the changes in medication during or after treatment, were noted.

Evaluation of the salivary flow rates

Saliva was sampled according to the standard techniques used at the Department of Cariology, Karolinska Institutet [13] at the same time of day for each patient. The vessel used for collecting saliva was weighed before and after each sampling in order to ensure correct measurements. Baseline levels of salivary flow rates for each patient were determined for both resting and paraffin-stimulated saliva on two different occasions before the start of the investigation. Salivary flow rates were measured again, first after the 12th AP and next after the 2-week interval, before the 13th AP. New evaluations of the salivary flow were made immediately after the completion of the acupuncture series; then at 3, 6 and 12 months after the end of the AP. Neither the examiner evaluating salivary flow nor the patients knew whether acupuncture or superficial needling (placebo acupuncture) had been given.

The study was approved by the Human Ethics Committee at Huddinge Hospital, Karolinska Institutet.

Statistical methods

Wilcoxon signed rank test was used for the statistical analysis within each group to compare the changes from baseline levels of salivary flow rates. The differences tested were between baseline levels and results at 2 weeks after the first AP series, immediately after the second AP series and at 3 months, 6 months and 12 months after the end of AP. Mann–Whitney test was used to compare the changes from baseline levels of the salivary flow rates between the two groups at the same time points. To analyse changes in salivary flow rates occurring with time after the last AP, differences in salivary flow rates were also tested between week 14 (immediately after the last AP) and at 3 months, 6 months and 12 months after the last AP.

RESULTS

The salivary flow rates for each patient belonging to the experimental group before, during and after the AP are shown in Table 2 and for each control patient in Table 3. The medians and ranges for both groups are summarised in Table 4. The differences between baseline levels and salivary flow rates at different time points within each group, as well as between the two groups, are shown in Table 5. We observed an improvement in the salivary flow rates in both groups already after the first 12 treatments. In the experimental group the salivary flow rates improved by >20% for both unstimulated and stimulated saliva for more than half of the patients (Tables 1-3 and Figs 3-5). 5 patients whose glands had been only partly irradiated showed very good improvement of the salivary gland function (Table 2). Only 4 of the 20 patients (nos 1, 3, 8, 19) in the experimental group failed to show any objective improvement. When the improved salivary flow suddenly decreased during the treatment or observation period it was usually related to a general decline in the patient's health condition, caused by such factors as depression, stress, common cold, new medication, metastases and cytostatic treatment or surgery. For some patients the salivary flow started to decrease after 6 or 12 months post AP (Tables 2 and 3). The patients in the control group who received superficial acupuncture as placebo also showed positive changes in their salivary flow rates. The changes observed were somewhat smaller and appeared after a longer latency period than in the experimental group. Also in the control group an increase >20% in salivary flow rates was observed for half of the patients. These results persisted during the observation year (Table 3 and Figs 3 and 4).

Differences were found within the two groups but not between the groups. There were significant differences in the experimental group between baseline levels of unstimulated saliva and the results during AP and after the completion of the treatment, throughout the whole observation period (P < 0.05 - 0.01). Within the control group, significant differences were observed (P < 0.05) during the whole period except at the 6 months' observation when no significant difference was found.

In the case of paraffin stimulated saliva the differences in the experimental group during the whole period were generally more pronounced (P < 0.01). The differences in the control

Table 1. The relationship between the size of the tumour, the irradiation field and the salivary glands in the experimental and control groups

										Salivar	y glands*		
				(Clinic	o.1			Left			Right	
Patient	Sex	Δ		stage†		Dose	Gl. paro tis	Gl. sub	Gl. sub	Gl. paro	Gl. sub	Gl.	
no.		Age	Primary site			101	(Gy)		mand	ling	tis	mand	ling
Experime	ntal groi	ир											
1	M	56	Oropharynx	2	0	0	64	+	+	+	+	+	+
2	F	60	Tongue	1	0	0	64	+	+	+	+	+	+
3	F	56	Nasopharynx	1	0	0	64	+	+	+	+	+	+
4	M	53	Floor of mouth	2	0	0	64	+	+	+	+	+	+
5	F	70	Tonsil	3	1	0	68	+	+	+	+	+	+
6	M	70	Larynx	2	0	0	66	+	+	+	+	+	+
7	M	67	Lip	+ +			52	+	+	+	+	+	+
8	F	79	Soft palate	3	0	0	52	+	+	+	+	+	+
9	M	49	Nasopharynx	1	0	0	63	+	+	+	+	+	+
10	M	65	Larynx	2	0	0	66	+	+	+	+	+	+
			Oropharynx	1	0	0		+	+	+	+	+	+
11	M	66	Tongue	2	0	Ō	64	+	+	+	+	+	+
12	M	35	CNS (Ependymoma)			·	55	+	_	_	+	_	_
13	M	54	Larynx	2	0	0	64	50% —	+	+	50% —	+	+
14	M	65	Larynx	2	0	0	64	JO 76	+	+		+	+
15	M	52	Larynx	2	0	0	50	50% —	+	+	50°/	+	+
16	M	60	Larynx	2	0	0	64	50% —	+	+	50% —	+	+
17	M	65	Larynx	2	0	0	64	50% —	+	+	50% —	+	+
18	F	63	Parotid gland sin	++	U	U	64		+	+	J0 / ₀ —	_	_
19	F	66	Oropharynx sin	2	0	0	64	+	+	+	_	_	_
20	M	49	Neck metastasis	X	1	0	64	_	-	+	+		
	_	49	Neck metastasis	Λ	1	U	04	_	_		+	+	+
Control g	roup												
21	M	71	Tongue	2	1	0	50	+	+	+	+	+	+
22	M	69	Tongue	2	0	0	64	+	+	+	+	+	+
23	M	73	Oropharynx	3	0	0	64	+	+	+	+	+	+
24	M	71	Oropharynx/Alveolus	2	0	0	64	+	+	+	+	+	+
25	M	64	Oropharynx	2	3	0	64	+	+	+	+	+	+
26	M	62	Tongue	† +			64	+	+	+	+	+	+
27	M	62	Oropharynx	2	1	0	54	+	+	+	+	+	+
28	F	71	Tongue	3	0	0	64	+	+	+	+	+	+
29	\mathbf{F}	60	Oropharynx	2	0	0	64	+	+	+	+	+	+
30	F	58	Palate	4	0	0	64	+	+	+	+	+	+
31	F	54	Tongue	2	0	0	64	+	+	+	+	+	+
32	F	82	Nasal cavity	‡			68	+	+	+	+	+	+
33	M	69	Oropharynx	4	0	0	66	+	+	+	+	+	+
34	M	54	Nasopharynx	1	2	0	66	+	+	+	+	+	+
35	M	71	Nasopharynx	+			66	+	+	+	+	+	+
36	M	64	Larynx	2	0	0	66	50% —	+	+	50% —	+	+
37	M	49	Nasopharynx	1	1	0	64	50°/0 —	+	+	50% -	+	+
38	F	43	Nasopharynx	2	1	0	64	50% —	+	+	50% —	+	+

^{*+,} indicates a salivary gland within the irradiation area; -, indicates a salivary gland outside the irradiation area.

group were significant at week 14, at 6 months (P < 0.05) and at 12 months (P < 0.01). No significant differences were observed at week 8 and at 3 months as compared with baseline levels. There were no significant differences between week 14 and the other control times during the observation period, showing that the results achieved at the end of the AP persisted during the observation year. In this small group there were no differences in the improvement in salivary flow between those

patients who had received radiation treatment within a year before the start of the AP treatment and those who had been irradiated years before.

In addition to quantitative data related to the salivary function, qualitative findings were also recorded in both groups. Many patients experienced a decrease of mucus secretion and their saliva became more fluid. There were reports of improved taste, diminished pain in the tongue and

[†]Tumour size (T): <2 cm (1); 2-4 cm (2); >4 cm (3); tumour fixed to adjacent structures (4). Nodal metastases (N): no regional lymph node metastases (0); metastases in a single ipsilateral node of <3 cm diameter (1); metastases in nodes of 3-6 cm diameter (2); metastases in any node >6 cm diameter (3). Distant metastases (M).

[‡]Locoregional recurrence.

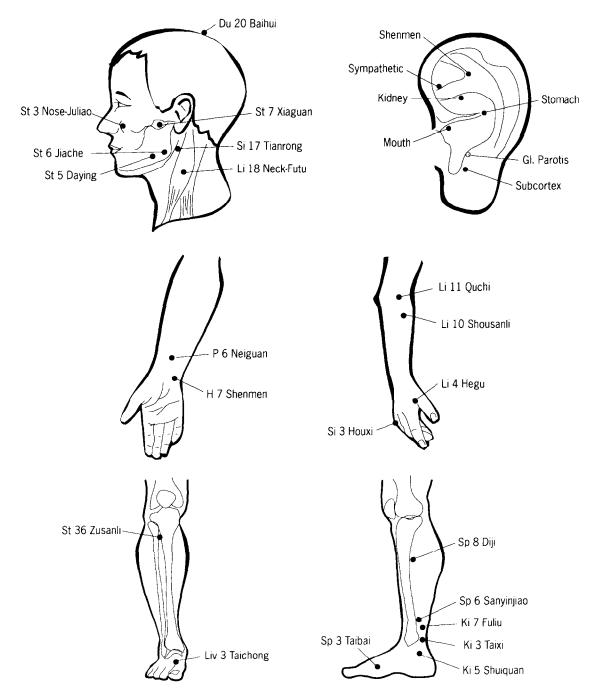


Fig. 1. Acupuncture points used during treatment were localised in the head, ears, hands and legs.



Salivary flow rates were determined at eight time points as indicated by the figures for both the experimental group and the control group.

Fig. 2. Experimental design.

lessened hoarseness. There was also experience of a considerable reduction of nausea and an improvement of appetite and those patients stopped losing body weight. There were also reports of normalised sleep and a general improvement of their

physical and psychic conditions, leading to a better quality of life. Those changes were somewhat slower and weaker in the control group. In a few cases secondary effects of acupuncture treatment, such as tiny haemorrhages at the acupuncture sites, resulting in small haematomas, were noticed. Tiredness sometimes occurred after the first few acupuncture treatments.

DISCUSSION

The present study found that some of the patients in both the experimental and control groups showed improved salivary flow rates, both during and after classical acupuncture and after superficial needle insertion (as placebo). The results indicate that there were no significant differences between the

Table 2. Salivary flow rates for unstimulated and stimulated whole saliva before, during and after acupuncture treatment for each patient in the experimental group

				Salivary flow (g/min)									
		Time lapse between		Before AP	Between AP	After AP							
Patient no.	Age	irradiation and AP		\bar{x} of sample 1 and 2	\bar{x} of sample 3 and 4 (8 w)	Immediate	3 m	6 m	12 m				
1	56	12.5 y	us ss	0	0.02	0	0	0 0	0.0 4 0				
2	60	21 m	us ss	0 0.04	0 0.09	0 0.10	0 0.22	0 0.26	0 0.11				
3	56	19 m	us ss	0 0	0.01 0.01	0 0	0 0	0 0	0				
4	53	15 m	us ss	0 0.10	0.02 0.43	0.06 0.47	0.05 0.48	0 0.46	0.02 0.75				
5	70	4 y	us ss	0 0.02	0 0.03	0 0.05	0 0.07	0.01 0.10	0 0.06				
6	70	8 m	us ss	0 0.02	0 0.04	0.02 0.19	0 0.12	0 0.13	0.04 0.18				
7	67	3 y	us ss	0 0.14	0.01 0.14	0.09 0.29	0.05 0.42	0 0.21	0 0.03				
8	79	5 m	us ss	0	0	0	0 0	0 0					
9	49	10 m	us ss	0 0.13	0 0.14	0 0.11	0 0.18	0.01 0.19	0.01 0.20				
10	65	3 y 8 m	us ss	0	0	0.03 0.01	0.01 0	0.07 0	0.06 0.01				
11	66	1 y	us ss	0 0	0	0.01	0.02 0	0 0	0.01 0				
12	35	10 m	us ss	0 0.12	0.05 0.20	0.04 0.19	0.01 0.12	0.06 0.14	0.11 0.35				
13	54	13 m	us ss	0.01 0.68	0.05 1.14	0 0.80	0.13 1.35	0.16 1.50	0.09 1.28				
14	65	2.5 y	us ss	0.07 0.21	0.13 0.24	0.10 0.40	0.20 0.44	0.29 0.62	0.17 0.55				
15	52	1 y	us ss	0.16 1.01	0.12 1.12	0.28 0.96	0.14 1.00	0.16 1.12	0.42 1.26				
16	60	18 m	us ss	0.01 0.13	0.08 0.29	0.10 0.36	0.14 0.38	0.16 0.40	0.10 0.40				
17	65	3 y	us ss	0 0.25	0.03 0.36	0.04 0.42	0.10 0.50	0.08 0.36	0.05 0.44				
18	63	10 m	us ss	0.06 0.37	0.06 0.39	0.02 0.30	0.08 0.34	0.08 0.21	0.11				
19	66	3 у	us us	0.12 0.86	0.09	0.12 0.92	0.08 0.44	0.06 0.84	0.16 0.84				
20	49	8 m	us ss	0.05 0.57	0.16 0.84	0.20 0.90	0.11 1.04	0.09 1.13	0.04 0.72				

AP, Acupuncture; us, unstimulated saliva; ss, paraffin-stimulated saliva; —, not evaluated; m, months; y, years. Normal values: unstimulated saliva, 0.25-0.35 g/min, (<0.1 g/min, very low); paraffin-stimulated saliva, 1.0-3.0 g/min (<0.7 g/min, very low).

experimental and the control groups in the salivary flow rates when compared to the baseline levels for either unstimulated or paraffin stimulated saliva during all treatment and later during the observation year.

The findings of this study indicate that superficial acupuncture is not reliable as a placebo and it should be treated as a different type of acupuncture treatment with lesser sensoric stimulation in accordance with previous studies [14, 15]. It

Table 3. Salivary flow rates for unstimulated and stimulated whole saliva before, during and after acupuncture treatment for each patient in the control group

		en: 1		Salivary flow (g/min)								
Patient		Time lapse between	-	Before AP \bar{x} of sample	Between AP \bar{x} of sample							
no.	Age	irradiation and AP		1 and 2	3 and 4 (8 w)	Immediate	3 m	6 m	12 m			
21	71	18 m	us ss	0 0.11	0.05 0	0.04 0.14	0.06 0.01	0 0.12	0.02 0.15			
22	69	18 m	us ss	0 0	0 0	0 0.02	0	0 0.01	0 0.01			
23	73	1 y	us ss	0 0.03	0.01 0.02	0 0	0	0 0.03	_			
24	71	17 m	us ss	0 0.02	0 0	0.04 0	0 0	0 0	0.03 0.01			
25	64	9 m	us ss	0 0	0 0.02	0 0	0 0.02	0 0.10	0 0.05			
26	62	7 y 3 m	us ss	0.01 0	0.02 0.01	0.04 0.02	0.03 0.02	0.09 0.01	0.02 0.07			
27	62	2 m	us ss	0 0	0 0	0 0	0 0	_				
28	71	11 m	us ss	0 0	0 0	0 0	0 0	0 0	_			
29	60	1 y	us ss	0.02 0.02	0.03 0.12	0.04 0.13	0.02 0.16	0.06 0.33	0.05 0.13			
30	58	7 m	us ss	0	0	0 0	0 0	0 0	0 0			
31	54	6 m	us ss	0	0	0	0 0		_			
32	82	6 m	us ss	0	0 0.07	0 0.10	0 0.07	0 0.06	0 0.10			
33	69	15 m	us ss	0	0	0 0	0.03 0	0 0	0 0.03			
34	54	5 y	us ss	0	0 0.42	0.05 0.52	0.08 0.31	0.01 0.30	0.05 0.40			
35	71	3 у	us ss	0	0	0	0 0	0	0			
36	64	2 m	us ss	0.08 0.18	0.13 0.44	0.13 0.51	0.12 0.40	0.19 0.70	0.33 1.34			
37	49	5 y	us ss	0 0.09	0.01 0.11	0 0.12	0.04 0.10	0.02 0.05	0			
38	43	7.5 y	us ss	0 0.2	0 0.01	0.02 0.02	0 0.01	0 0.01	0			

For explanation of symbols see footnote to Table 2.

stimulates skin receptors and after 12–24 treatments it may result in a positive effect on the salivary glands. The use of superficial acupuncture as a placebo is not acceptable as a treatment of control groups in acupuncture studies, and new methods should be developed for that purpose.

We have investigated a part of the mechanism behind the positive effects of superficial acupuncture in an earlier study [16]. There, the effects of different needle stimulation on blood circulation were compared. We used classical acupuncture with manual stimulation to obtain needle sensation (the Qi), low frequency (2 Hz) electro-acupuncture, high frequency (80

Hz) electro-acupuncture and superficial needling on patients with Sjögren's syndrome. Some of those patients showed significant increase of the blood flow in the skin of the cheek, also when superficial acupuncture was used. It seems that the mechanisms involved are more complicated and there are, naturally, individual differences among the patients.

Clinical observation shows that the salivary function in some of the irradiated patients improves spontaneously and that salivary flow rates increase gradually during the first few years after radiotherapy. Afterwards no further increase of salivary flow rates can be expected [17, 18]. Therefore, it

Table 4. Salivary flow rates at different time points in the experimental group and in the control group (medians and ranges)

Medians	and	rangee	for	calivary	flow	ratec	(almin)	

		Unstimu	ılated saliva		Stimulated saliva					
Time weeks/	Expe	erimental	C	Control	Exp	erimental	Control			
months after AP	Median	Range	Median	Range	Median	Range	Median	Range		
Baseline	0.000	0.00-0.16	0.000	0.00-0.08	0.125	0.00-1.01	0.000	0.00-0.18		
8 w	0.020	0.00-0.16	0.000	0.00-0.13	0.170	0.00-1.14	0.005	0.00 - 0.44		
14 w	0.025	0.00-0.28	0.000	0.00-0.13	0.240	0.00-0.96	0.010	0.00-0.52		
3 m	0.035	0.00 - 0.20	0.000	0.00-0.12	0.280	0.00-1.35	0.005	0.00 - 0.40		
6 m	0.035	0.00-0.29	0.000	0.00-0.19	0.210	0.00 - 1.50	0.020	0.00 - 0.70		
12 m	0.040	0.00 - 0.42	0.000	0.00-0.33	0.310	0.00-1.28	0.050	0.00-1.34		

Table 5. Results of statistical analyses of changes in salivary flow within each group and between the two groups at different time points

	D	D:#				
Time weeks/	Experime	ntal group	Contro	Differences† between groups		
months after AP	us	SS	us	SS	us	SS
0–8 w	S (<0.05)	S (<0.01)	S (<0.05)	NS	NS	NS
0-14 w	S(<0.05)	S (<0.01)	S (<0.05)	S (<0.05)	NS	NS
0-3 m	S (<0.05)	S(<0.05)	S(<0.05)	NS	NS	NS
0–6 m	S (<0.05)	S(<0.01)	NS	S(<0.05)	NS	NS
0-12 m	S(<0.01)	S(<0.01)	S(<0.05)	S(<0.01)	NS	NS
14 w-3 m	NS	NS	NS	NS	NS	NS
14 w-6 m	NS	NS	NS	NS	NS	NS
14 w-12 m	NS	NS	NS	NS	NS	NS

NS, non significant difference; S, significant difference; us, unstimulated salivary flow; ss, stimulated salivary flow.

Unstimulated salivary flow rates

Experimental group n = 20 Control group n = 18 No of patients No of patients 18 18 16 16 14 12 12 10 10 8 w 14 w 3 m 6 m 12 m 14w 3 m 6 m 8 w

Fig. 3. The number of patients who showed changes in unstimulated salivary flow rates >20% from baseline levels during and after acupuncture treatment (AP) ■; 8w=after 12 AP; 14w=directly after the last AP; 3m=3 months after the last AP; 6m=6 months after the last AP; 12m=12 months after the last AP.

Stimulated salivary flow rates

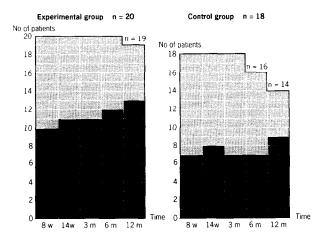
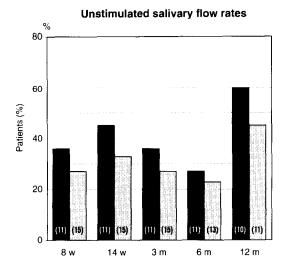


Fig. 4. The number of patients who showed changes in paraffin stimulated salivary flow rates >20% from baseline levels during and after acupuncture treatment (AP) ■;8w=after 12 AP; 14w=directly after the last AP; 3m=3 months after the last AP; 6m=6 months after the last AP; 12m=12 months after the last AP.

^{*}Wilcoxon signed rank test; P values in parentheses.

[†]Mann-Whitney test.



Stimulated salivary flow rates

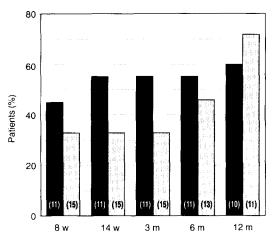


Fig. 5. Improvement of unstimulated and stimulated salivary flow in patients with all salivary glands irradiated; the percentages of patients who showed changes >20% from baseline during and after AP in the experimental group and in the control group () = total number of patients with all salivary glands irradiated; 8w = after 12 AP; 14w = directly after the last AP; 3m = 3 months after the last AP; 6m = 6 months after the last AP; 12m = 12 months after the last AP.

should be pointed out that several patients started the AP treatment years after their radiotherapy was completed and they had suffered from severe xerostomia for a long time without any spontaneous improvements (patients nos 4, 5, 7, 14, 17, 26, 34). Their salivary flow rates began to increase after 6 weeks of AP-treatment but they were not stable immediately and there were fluctuations during the treatment period. However, after the second AP series the salivary flow rate improvements became more stable and did not change significantly from day to day, but remained rather stable during the observation year. The results from the present study show that by means of acupuncture an improved function of the salivary glands can be achieved. It was observed that in most of the cases there was already an increase of the salivary flow rates after the 12th treatment, indicating high probability of further improvement by the completion of 24 AP treatments. The effect of acupuncture on salivary flow in patients with radiation-induced xerostomia is related to

the size of the irradiated area and the patient's history of surgery in the head and/or neck region. Also, the time interval between the irradiation treatment and the beginning of the AP is very important, as well as the general health of the patient and medication. It was found that those patients who were treated with chemotherapy or were operated on during the study showed an immediate decrease in the salivary flow rates. It should be emphasised that acupuncture may give positive effects only when the function of the salivary glands has been disturbed (but not completely destroyed) resulting in reduced metabolism. Naturally, those parts of the glands that have been destroyed by the irradiation cannot be affected by acupuncture or any other treatment.

We conclude that acupuncture may be a valuable method for the stimulation of salivary secretion in many patients with radiation-induced xerostomia. Those patients who show a recurrent decrease in their salivary flow rates during the observation year should undergo further AP of 10-12 sessions to reinforce the function of the salivary glands [19]. It might be preferable to use a different treatment, or no treatment at all, for the control group. Some authors have argued that the comparison of true AP with incorrect AP requires large subject numbers, as incorrect AP itself may have a relatively potent physiological effect [14, 15]. They consider that the use of a wholly inert non-acupuncture placebo, such as mock TNS, is more likely to reveal differences between true AP and the placebo [14, 15]. Further studies on the treatment of xerostomia and the mechanisms behind the effects of acupuncture on salivary flow are in progress.

- Dreizen S, Brown LR, Handler S, Barnet M, Levy M. Radiation-induced xerostomia in cancer patients. *Cancer* 1976, 38, 273–278.
- Karlsson G. The relative change in saliva secretion in relation to the exposed area of the salivary glands after radiotherapy of head and neck region. Swed Dent J 1987, 11, 189–194.
- Spielman A, Ben-Aryeh H, Gutman D, Szargel R, Deutsch E. Xerostomia: diagnosis and treatment. Oral Surg Oral Med Oral Pathol 1981, 51, 144-147.
- Sreebny LM, Banoczy J, Baum BJ, et al. Saliva: its role in health and disease. Int Dent f 1992, 42(4), Suppl 2, 287–304.
- Björnström M, Axell T, Birkhed D. Comparison between saliva stimulants and saliva substitutes in patients with symptoms related to dry mouth. Swed Dent J 1990, 14, 153–161.
- Weiss WW, Brenman HS, Katz P, Bennett JA. Use of an electronic stimulator for the treatment of dry mouth. J Oral Maxilofac Surg 1986, 44, 845–850.
- Steller M, Chou L, Daniels TE. Electrical stimulation of salivary flow in patients with Sjögren's Syndrome. J Dent Res 1988, 67(10), 1334–1337.
- Fontanesi J, Golden EB, Cianci P. Hyperbaric oxygen therapy can reverse radiation-induced xerostomia. J Hyperbaric Med 1991, 6, 215–221.
- Greenspan D. Management of salivary dysfunction. NCI Monographs 1990, 9, 159–161.
- LeVeque F, Montgomery M, Potter D, et al. A multicenter, randomized, double-blind, placebo-controlled, dose-titration study of oral Pilocarpine for treatment of radiation-induced xerostomia in head and neck cancer patients. J Clin Oncol 1993, 11, 1124–1131.
- 11. Leslie MD, Dische S. The early changes in salivary gland function during and after radiotherapy given for head neck cancer. *Radiother Oncol* 1994, **30**, 26–32.
- Essentials of Chinese Acupuncture. Beijing, Foreign Languages Press, 1980, 105–297.
- Ericson T, Mäkinen KK. Saliva—formation, composition and possible role. In Thylstrup A, Fejerskov O, eds. *Textbook of Cariology*. Copenhagen, Munksgaard, 1986, 30-31.

14. Vincent CA, Richardson PH. The evaluation of therapuetic acupuncture: concepts and methods. *Pain* 1986, 24, 1–13.

- 15. Thomas M, Lundeberg T. Importance of modes of acupuncture in the treatment of chronic nociceptive low back pain. *Acta Anaesthesiol Scand* 1994, 38, 63-69.
- Blom M, Dawidson I, Lundeberg T, Angmar-Månsson B. Effects on local blood flux of acupuncture stimulation used to treat xerostomia in patients suffering from Sjögren's Syndrome. J Oral Rehabil 1993, 20, 541–548.
- 17. Greenspan D, Daniels TE. Effectiveness of pilocarpine in postradiation xerostomia. *Cancer* 1987, **59**, 1123–1125.
- 18. Leslie MD, Dische S. Parotid gland function following acceler-

- ated and conventionally fractionated radiotherapy. Radiother Oncol 1991, 22, 133–139.
- Blom M, Dawidson I, Angmar-Månsson B. Acupuncture treatment of xerostomia caused by irradiation treatment of the head and neck region—two case reports. J Oral Rehabil 1993, 20, 491–494.

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