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## Comparison of traditional Chinese acupuncture, minimal acupuncture at non-acupoints and conventional treatment for chronic sinusitis<sup>☆</sup>

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### KEYWORDS

Randomised controlled trial;  
Acupuncture;  
Sham;  
Minimal acupuncture at non-acupoints;  
Conventional treatment;  
Chronic sinusitis

### Summary

**Objectives:** To compare traditional Chinese acupuncture, minimal acupuncture at non-acupoints and conventional treatment for chronic sinusitis.

**Design:** A three-armed single blind randomised controlled study.

**Setting:** In an outpatient specialist clinic, we recruited 65 patients with symptoms of sinusitis >3 months and signs of sinusitis on computed tomography (CT).

**Interventions:** We randomised patients to one of three study arms: (1) 2–4 weeks of medication with antibiotics, corticosteroids, 0.9% sodium chloride solution, and local decongestants ( $n=21$ ), (2) 10 treatments with traditional Chinese acupuncture ( $n=25$ ), or (3) 10 treatments with minimal acupuncture at non-acupoints ( $n=19$ ).

**Outcome measures:** Change in sinus soft tissue swelling on CT, symptoms of sinusitis, and health-related quality of life (HRQoL), using the two component summary scales of the Short Form 36 and a rating scale.

**Results:** In the conventional treatment group, sinus soft tissue swelling was reduced over 4 weeks ( $p=0.04$ ), and HRQoL improved over 12 weeks ( $p=0.01–0.05$ ). Pairwise comparisons of changes in total symptom score between the groups showed signs of a difference between conventional medication and sham over 4 weeks ( $p=0.06$ ).

**Conclusion:** Sinus soft tissue swelling was reduced in the conventional treatment group over 4 weeks, and HRQoL improved over 12 weeks. Only a non-significant difference in symptom score change over 4 and 12 weeks was shown between conventional medication and traditional Chinese acupuncture.

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## Introduction

The short-term effect of conventional medical treatment for sinusitis is usually adequate, but some patients have limited, only temporary, or no effect of conventional treatment. Hence, some patients have symptoms of chronic sinusitis for many years. Many acupuncturists offer treatment of chronic sinusitis, which is a well-established procedure in traditional Chinese acupuncture. Accordingly, many patients with chronic sinusitis will use acupuncture to try to relieve symptoms.<sup>1</sup> In an American telephone survey, 5% of the population with physician-diagnosed rhino-sinusitis reported having had acupuncture treatment during the previous 12 months.<sup>2</sup>

There is limited documentation on the efficacy of acupuncture in chronic sinusitis, and to our knowledge, no randomised trial has been published on the efficacy of acupuncture in the treatment of sinusitis. A previous study has reported favourable effect of acupuncture in the treatment of children and young adults with chronic maxillary sinusitis, compared with antibiotics and laser acupuncture.<sup>3</sup> Other observational studies have suggested that acupuncture can be effective in sinusitis or sinus pain.<sup>4-6</sup> In these studies there are methodological difficulties, for instance variations in the criteria for establishing the diagnosis of sinusitis, lack of feasible control groups, use of different outcomes, and the samples are small.

In a randomised controlled trial, we compared the effect of conventional medical treatment, traditional Chinese acupuncture and minimal acupuncture at non-acupoints on sinus swelling, symptoms, and health-related quality of life (HRQoL) in chronic sinusitis, where the diagnosis was confirmed with computer tomography (CT).

## Methods

### Patient recruitment and randomisation

We included patients above 17 years of age with sinusitis symptoms for more than 3 months and sinus swelling, fluid retention, or opacification on CT. We excluded patients if they were pregnant, had previously had acupuncture treatment, had been operated on for chronic sinusitis, had polypous sinusitis or pansinusitis, or had recently taken medication that could influence the results of the study. We evaluated more than 500 patients with sinusitis for eligibility to the study. In total, 66 patients were included from August 1996 to December 2000. Ini-

tially we recruited patients from the clinical practice of one otorhino-laryngologist. Because of slow patient recruitment, we advertised the study in the local newspapers and a magazine article.

One otorhino-laryngologist examined and included all patients. He allocated them to one of three groups according to a six-block randomisation algorithm, by first assigning a patient number to each patient. He then phoned one of the acupuncturists to receive information about the group allocation for that particular patient.

The major reasons for exclusion estimated post hoc by the otorhino-laryngologist were: normal CT (30%), heavy allergies (20%), refused conventional medical therapy (10%), trigeminal neuralgia (10%) and did not want a CT scan (5%).

### Interventions

The patients were given one of three different treatments; conventional medical therapy, traditional Chinese acupuncture (TCA), or minimal acupuncture at non-acupoints. No treatments were given during the Norwegian allergy season (February–September), because some of the patients were expected to have seasonal allergies.

In the conventional medical treatment group, the treatment was individually tailored for each patient. All patients used a local vasoconstrictor agent (xylometazoline), and 0.9% sodium chloride solution locally for 1 week, and oral corticosteroids for 14 days. In addition, 14 patients used a combination of cefalexin 1500 mg daily for 10 days and 6 patients used azithromycin 500 mg for 7 days.

Both acupuncture groups received 10 treatments with bilateral acupoints over a period of 4 weeks. The acupuncturists giving the treatments had 4–10 years of experience and had training in the treatment of chronic sinusitis.

In the acupuncture group, the patients were given individual TCM diagnoses and individual treatment. Most patients were diagnosed as having one of four TCM diagnoses: (1) retention of damp in the Yangming channel with symptoms of frontal or maxillary headache along with the feeling of pressure and heaviness, and slippery pulse.<sup>7</sup> (2) Damp combined with heat symptoms, such as purulent mucus, thirst and feeling of heat in the head and face. To remove damp/heat from the Yangming channel; LI 4 Hegu, LI 11 Quchi, ST 40 Fenglong and ST 44 Neiting were reduced.<sup>8</sup> (3) Retention of Phlegm in the Shaoyang channel was diagnosed when the patient had headache along with the feeling of pressure and heaviness in the area lateral to the eyes and around the ears, combined with dizziness.<sup>7</sup> (4) Liver Fire symptoms as purulent mucus, red eyes,

feeling of heat in the head and face, thirst, anger, irritation, red tongue and a wiry pulse were often combined with Phlegm.<sup>7</sup> To remove Phlegm/Fire from the Shaoyang channel; GB34 Yanglingquan, LR 2 Xingjian, LI 4 Hegu, and LR 3 Taichong were reduced.<sup>8</sup> All TCA patients were given local acupoints around the affected sinuses.<sup>3,4,9</sup> In addition, we sometimes reduced EX-HN5 Taiyang, when the symptoms affected the lateral area of the eyes.<sup>10</sup>

We used 1.0–1.5 cun needles ( $\varnothing$  0.28 mm, length 25–40 mm). The needles were inserted to the depths of approximately 0.5 cun (facial/hand/feet area) to a maximum of 1.3 cun (arms/legs/trunk area). A good needle sensation, described by patients as soreness, numbness, heaviness or distension, was achieved when needling each acupuncture point.<sup>9</sup> After achieving the needle sensation, the needles were stimulated manually using reducing or reinforcing methods.<sup>9</sup> The needles were left in the acupuncture points for 25 min. During the treatment period, some acupuncture points were added or changed, according to changes in the symptoms.

In the sham treatment group, the patients were given minimal acupuncture at non-acupoints as applied in a previous study.<sup>11</sup> We applied the same sham points during each treatment session. The sham points were located outside the meridians.<sup>11</sup> One point was situated on each shoulder between LI 15 and TE 14, one on each thigh 3 cun above the midpoint of the patella, and two bilateral points were situated 2.5 cun lateral to the umbilicus. For the sham group, we used 0.5 cun needles ( $\varnothing$  0.25 mm, length 13 mm). A shallow, superficial insertion of the needle (maximum depth 0.25 cun) along with a minimum of needle sensation was emphasised. The needles were left in the points for 25 min. In all treatment groups, medication used for other indications remained unchanged during the treatment period.

## Outcome assessment

As study outcomes we used (1) sinus CT-scans, (2) symptoms of sinusitis, and (3) HRQoL. At baseline and after the treatment (4–6 weeks after baseline), the patients had sinus CT scans. An otorhinolaryngologist assessed soft tissue swelling in millimetres and signs of fluid retention and opacification on the CT scans.

The patients reported whether they had five common symptoms of chronic sinusitis using a self-administered questionnaire: (1) mucus production, (2) maxillary headache, (3) stuffed nose, (4) frontal headache, (5) ability to smell, and (5) feeling of illness. The first four items were scored on an or-

dinal scale with the response alternatives none, little, some, much, very much (and recoded on a 0–4 scale). The fifth item had the response alternatives none, little, some, close to normal, normal (recoded on a 4–0 scale). The fifth item had the response alternatives very ill, ill, a little ill, healthy (recoded 3–0). The participants responded to the questionnaire in the physician's office at baseline, at 4 weeks (end of the treatment), 12 weeks and 1 year. The recoded six symptom scores were summed to give an aggregate value representing a "sinusitis symptom score", with a score ranging from 0 (minimal symptoms) to 23 (maximal symptoms).

We assessed HRQoL at baseline and after 12 weeks with several instruments. We used the Short Form 36 (SF-36) questionnaire for measurement of general health status, focusing on the two summary measures, the physical component summary (PCS) and mental component summary (MCS) scales.<sup>12</sup> These two scales were scored and transformed for comparison with a U.S. general population with mean 50 and S.D. 10.<sup>12</sup> The SF-36 has previously been validated in Norway.<sup>13</sup> In addition, we used a 10 cm visual analog scale from the Euroqol instrument, where patients score their health "today" on a scale from 0 (worst possible) to 100 (best possible).<sup>14,15</sup> The patients in the acupuncture and sham groups also responded to questions about side effects of the acupuncture treatment.

## Statistical analysis

Descriptive statistics are presented with means and S.D., or percentages. We assessed change in sinus soft tissue swelling on CT between baseline and 4–6 weeks and HRQoL from baseline to 12 weeks with paired samples *t*-test.

For group comparisons of sinusitis symptom scores during the first 12 weeks, we used one-way analysis of variance of changes from baseline until 4 and 12 weeks, with post hoc Tukey's test. We compared sinusitis symptom scores between the groups after 1 year using one-way analysis of variance.

We compared baseline age and scores for dropouts and completers after 12 weeks with the *t*-test, using non-valid score on the sum of symptoms scale to denote dropout. This was the time point where we had the largest number of dropouts.

The required sample size was initially estimated to two groups of 22 patients, to detect a group difference of 0.85 S.D. on a visual analog scale, with power 0.8 and a 5% confidence level. As estimate for expected group difference, we used a value suggested by the acupuncturists. The estimate for treatment effect was considered to be conservative, which would reduce the possibility of

a false negative result. Dropouts were not explicitly included in these calculations. Before study starts, the study protocol was adjusted to include a third arm with 22 patients.

The Regional Medical Ethics Committee and The Norwegian Data Inspectorate approved the study.

## Results

There were slightly more women in the conventional treatment group ( $p=0.04$  versus the sham group). The mean duration of sinusitis symptoms varied from 7 years in the acupuncture group to 12.4 years in the sham group, however these differences were statistically not significant. Otherwise the baseline patient characteristics and HRQoL scores were similar in the three groups, as was the dropout rate during the study (Table 1). There was no difference between completers ( $n=43-45$ ) and dropouts ( $n=17-20$ ) after 12 weeks in age, duration of chronic sinusitis, baseline sinus soft tissue swelling, sum of symptoms, Euroqol VAS, or on the SF-36 PCS scale, however, dropouts had lower SF-36 MCS scores than completers ( $p=0.04$ ).

On sinus CT at baseline, three patients in the conventional medicine group had opacification, six in the minimal acupuncture at non-acupoints group, and eight in the TCA group. Only two patients had fluid retention at baseline; both were in the TCA group.

Fifty-seven patients had sinus soft tissue swelling at baseline (Table 1). From baseline to after treatment, there was a reduction in sinus soft tissue

swelling in the conventional treatment group, while there was little change in the two other groups ( $p=0.04$ ) (Table 2).

During the first 4 weeks after study start, there was a trend of improved symptom score in all three groups. This change was somewhat larger in the conventional group compared with the sham acupuncture group ( $p=0.06$ ). Pairwise comparison of changes in total symptom score over the first 12 weeks of the study showed non-significant differences between the groups (Table 3). After 12 months, 15 patients reported having had surgical intervention for chronic sinusitis (conventional group 5, acupuncture 6, sham 4), and there was little difference in symptom score between the groups ( $p=0.32$ ).

In the conventional treatment group, PCS and MCS scores of the SF-36 scale improved during the 12-week period, as did HRQoL scores on the visual analog scale (Table 4). In the sham and TCA groups, there was a non-significant trend towards improvement in HRQoL on the visual analog scale, however no trend towards change on the PCS and MCS scales of the SF-36 (Table 4).

We did not monitor the side effects of the conventional medical treatment, as the side effects of this treatment are well documented.<sup>16</sup> Forty-two patients returned the side effects form after finishing the acupuncture or sham treatment, 25 in the TCA group and 17 in the sham group. In the TCA group, 11 patients (44%) reported side effects, compared with five (29%) in the minimal acupuncture at non-acupoints group. The reported side effects were minor and disappeared within a few hours or

**Table 1** Patient characteristics at baseline according to allocation group, mean (S.D.).

	Acupuncture	Sham	Conventional
<i>n</i>	25	19	21
Women, number (%)	11 (44)	9 (47)	13 (62)
Age	41.1 (14.7)	47.3 (13.7)	41.0 (13.0)
Duration of chronic sinusitis (years)	7.0 (7.8)	12.4 (13.5)	9.7 (10.5)
Number of drop-outs at 4 weeks/12 weeks/1 year	1/5/3	2/3/1	3/4/4
Sinus soft tissue swelling (mm <sup>a</sup> )	13.4 (10.0) <sup>b</sup>	13.2 (12.4) <sup>c</sup>	12.6 (10.1) <sup>d</sup>
SF-36 PCS <sup>e</sup>	40.7 (8.4) <sup>f</sup>	46.1 (7.4) <sup>g</sup>	47.0 (8.5) <sup>f</sup>
SF-36 MCS <sup>e</sup>	47.3 (9.7) <sup>f</sup>	48.5 (8.2) <sup>g</sup>	45.2 (13.3) <sup>f</sup>
Euroqol VAS (0–100 scale)	68.3 (19.4) <sup>f</sup>	72.7 (21.0) <sup>g</sup>	72.4 (14.2) <sup>h</sup>

MCS: mental component summary scale; PCS: physical component summary scale; VAS: visual analog scale.

<sup>a</sup> Sum of 2 maxillary, 2 frontal, ethmoidal and sphenoidal soft tissue swelling measurements.

<sup>b</sup>  $n=22$ .

<sup>c</sup>  $n=18$ .

<sup>d</sup>  $n=20$ .

<sup>e</sup> Compared to reference population with mean 50, S.D. 10.

<sup>f</sup>  $n=17$ .

<sup>g</sup>  $n=15$ .

<sup>h</sup>  $n=16$ .

**Table 2** Change in sinus soft tissue swelling<sup>a</sup> as assessed by CT between baseline and 4 weeks.

	<i>n</i>	Mean (S.D.)	95% CI	<i>p</i>
Acupuncture	22	1.1 (12.0)	−4.2 to 6.4	0.68
Sham	18	1.3 (8.5)	−2.9 to 5.6	0.52
Conventional	20	−6.0 (12.0)	−11.6 to −0.4	0.04

<sup>a</sup> Sum of 2 maxillary, 2 frontal, ethmoidal, and sphenoidal soft tissue sinus swellings measured in mm, a negative change value represents improvement.

**Table 3** Baseline symptom score (sum of 6 symptoms) and change from baseline to 4 and 12 weeks.

	At baseline		From baseline to 4 weeks		From baseline to 12 weeks	
	<i>n</i>	Score	<i>n</i>	Change score <sup>a</sup>	<i>n</i>	Change score
Acupuncture	24	8.5 (2.9)	24	−2.4 (4.2)	16	−2.1 (3.6)
Sham	19	7.6 (3.0)	16	−1.7 (3.5)	15	−1.2 (4.2)
Conventional	20	9.0 (3.5)	18	−4.8 (4.1)	16	−4.1 (5.4)
<i>p</i> (overall)				0.06 <sup>b</sup>		0.20

0–23 scale with 23 as maximal symptoms, mean (S.D.).

<sup>a</sup> A negative change score represents reductions in symptoms.

<sup>b</sup> Post hoc group comparisons with Tukey's test: acupuncture vs. conventional ( $p=0.06$ ); acupuncture vs. sham ( $p=0.84$ ); sham vs. conventional ( $p=0.14$ ).

**Table 4** Change in health-related quality of life from baseline to 12 weeks, mean (S.D.).

	<i>n</i>	Change score <sup>a</sup>	95% CI	<i>p</i>
<i>Acupuncture</i>				
SF-36 PCS	17	1.7 (9.8)	−3.3 to 6.7	0.49
SF-36 MCS	17	−0.7 (6.4)	−4.0 to 2.6	0.66
Euroqol VAS	17	2.6 (15.0)	−5.1 to 10.3	0.49
<i>Sham</i>				
SF-36 PCS	15	−0.6 (6.8)	−4.4 to 3.1	0.72
SF-36 MCS	15	2.3 (6.1)	−1.1 to 5.7	0.17
Euroqol VAS	15	5.2 (23.3)	−7.7 to 18.1	0.40
<i>Conventional treatment</i>				
SF-36 PCS	17	4.9 (8.0)	0.8 to 9.0	0.02
SF-36 MCS	17	6.6 (13.0)	−0.08 to 13.3	0.05
Euroqol VAS	16	9.3 (12.6)	2.5 to 16.0	0.01

VAS: visual analog scale.

<sup>a</sup> A positive change score represents improvement.

days. The most common side effects were: small bleedings around the needles (36% of patients in the TCA group, 29% in the sham group), nerve pain (16% and none, respectively), and dizziness after one of the treatments (4% and 2%, respectively).

## Discussion

In this study of patients with CT-verified chronic sinusitis, we have shown an improvement in sinus soft tissue swelling on CT over 4–6 weeks and HRQoL scores over 12 weeks after conventional treatment with antibiotics, corticosteroids, 0.9%

sodium chloride solution, and local decongestants. There were also signs of improvement in symptoms over 4 weeks in all groups. When comparing changes in symptom scores over 4 weeks between the three groups, we found a non-significant difference between the conventional medicine and the minimal acupuncture at non-acupoints group, and less difference between the conventional medicine and the TCA groups. Our study revealed no differences between the groups after 12 weeks or 12 months, possibly indicating a lacking long-term effect.

To our knowledge, this is the first randomised controlled trial of the effect of TCA in chronic sinusitis. There are few relevant studies with which

we can compare our findings. Pothman et al. compared antibiotics, laser and acupuncture upon chronic maxillary sinusitis in 45 children and young adults.<sup>3</sup> Patients receiving acupuncture reported better results after 6–12 months, than patients in the other two groups. However, the study lacked details about patient selection, allocation procedure, and evaluation method.<sup>3</sup>

In the present study, we used the SF-36 and a standard rating scale for HRQoL assessment. Previous studies have documented the validity and responsiveness of these instruments, although not in the context of interventions for chronic sinusitis. We developed a sinusitis symptom score for this study; however, this scale has not been subject to the same rigorous testing as the HRQoL measures. We based its use in the present study on an assumption of face validity of the items; however, the symptom score might not be responsive to the interventions in the study.

Some weaknesses of our study should be mentioned. The sample size was small, hence reducing the power of the study. Periodicity or seasonality of symptoms or environmental factors might influence our measured outcomes, however, we think it is improbable that this contributed to the main effect of the study.

Choice of placebo intervention for the control group in trials of acupuncture is controversial. In a recent review, 28 controlled studies used 28 different acupuncture placebos.<sup>17</sup> In the present study, we sought to make the minimal acupuncture at non-acupoints look like the TCA, using a penetrating or invasive sham procedure on points that were considered inappropriate for treatment of sinusitis. The patients were blinded to whether they received TCA or minimal acupuncture at non-acupoints. We would expect traditional acupuncture to be superior to minimal acupuncture at non-acupoints,<sup>18</sup> although we could not show that in the present study.

We initially intended to include 66 patients with CT-verified chronic sinusitis within 4–6 months. Recruitment to the study was much slower than expected, and only 10–15% of the examined patients could be included in the project, primarily because the CT scans did not support the diagnosis of chronic sinusitis. However, previous reports have shown little association between CT-based severity staging and patient symptoms.<sup>19–21</sup> Because we only included patients with CT-verified sinusitis, we included a small proportion of all patients presenting symptoms of chronic sinusitis. Hence, one should be careful extrapolating the results of the study beyond patients with CT-verified sinus soft tissue swelling.

The population in our study was different from the population seeking ear–nose–throat specialists for treatment, and also probably different from the population that is diagnosed and treated for sinusitis by acupuncturists. In clinical practice the treatment of sinusitis is initiated without CT scan, and the diagnosis of chronic sinusitis typically implies having had sinusitis symptoms for more than 3 months. The patients included in this study will thus be different from patients regularly treated with conventional medication or acupuncture. Our patients had considerably longer duration of chronic sinusitis, as suggested by a mean duration of symptoms of more than 9 years. In such patients, it is possible that 10 acupuncture treatments was too little and could not show the full potential of acupuncture treatment.

We also chose to treat the patients without electro stimulation or auricular therapy, which might be another limitation of the acupuncture treatment given in this study. On the other hand, it is also possible that many of the patients with a diagnosis of chronic sinusitis without CT might have other diseases, such as inflammation of one or more sinuses of shorter duration, allergies or facial pain, and that these conditions might be more treatable than those in the current study.

In conclusion, we have shown that conventional medical treatment with antibiotics, steroids, local decongestants, and 0.9% sodium chloride solution locally improved soft-tissue swelling over the treatment period of 4 weeks and showed improvement in HRQoL over 12 weeks in patients with CT-verified chronic sinusitis. Only a non-significant difference in symptom score change over 4 and 12 weeks was shown between conventional medication and traditional Chinese acupuncture. After 52 weeks, there was little difference in symptom score between the groups.

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