

# Pilot study to assess the credibility of acupuncture in acute exacerbations of chronic obstructive pulmonary disease

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## ABSTRACT

**Background:** Exacerbation of chronic obstructive pulmonary disease (COPD) is a common reason for hospital admission, and adjunctive non-pharmacological treatments would be welcomed. A pilot study was undertaken to assess the feasibility of conducting a study of acupuncture during an acute exacerbation of COPD. We also examined the credibility of a sham device in this setting and assessed the effect of acupuncture on breathlessness and anxiety.

**Methods:** A prospective, randomised, patient- and assessor-blinded, sham controlled study was conducted on three consecutive days in a district general hospital. Credibility of both acupuncture and the Park sham device were assessed using the Borkovec and Nau questionnaire. Dyspnoea was measured on the modified Borg score and a 10 cm visual analogue scale, while anxiety was measured on a 10 cm visual analogue scale.

**Results:** 11 patients were recruited and nine completed the study. There were no adverse events with either intervention. Acupuncture was well tolerated and credibility scores were similar before and after real and sham acupuncture. Symptoms improved after both treatments, with no significant difference between groups.

**Conclusion:** In this pilot study acupuncture was well tolerated by subjects experiencing an acute exacerbation of COPD. Acupuncture treatment and the Park sham device were both credible. Although recruitment was slow, a further trial with a larger sample size is feasible and recommended.

Chronic obstructive pulmonary disease (COPD) is predicted to be the third highest cause of death worldwide by 2020.<sup>1</sup> Each year in the UK there are around 100 000 hospital admissions due to COPD, often causing prolonged hospital stays and significant morbidity after discharge.

Exacerbations cause a range of problems including increased breathlessness, reduced exercise tolerance and anxiety. Current treatments used during an acute admission (including oxygen, bronchodilators, corticosteroids and antibiotics) all have potential adverse effects<sup>2</sup> and effective non-pharmacological strategies that alleviate symptoms would be welcomed.

Acupuncture has been performed for centuries, particularly in Chinese medicine. Greater understanding of the mechanisms of action and evidence of clinical effectiveness has led to increased use within western medical practice.<sup>3</sup> Widely regarded as a safe treatment, the risk of adverse events is minimal.<sup>4</sup>

Acupuncture has been shown to improve breathlessness and general wellbeing in patients with

stable COPD.<sup>5</sup> Benefit has also been reported in acute asthma<sup>6</sup> and advanced cancer, with reduced dyspnoea and anxiety scores.<sup>7</sup> Acupuncture may reduce the hyperventilation associated with anxiety. Hyperventilation increases dynamic hyperinflation and this in turn worsens dyspnoea.

Prior to carrying out a large randomised trial we conducted a pilot study to assess the credibility of acupuncture using a Western medical approach, as an adjunct to standard treatment during an acute exacerbation of COPD. The study, which took place in a large district general hospital, also assessed the credibility of the Park sham device and the effect of acupuncture on symptoms of dyspnoea and anxiety.

## METHOD

This prospective, randomised, patient- and assessor-blinded study involved treatment and assessment of patients over three consecutive days. Acupuncture points were chosen for their reported effect on anxiety and breathlessness. Upper sternal points may reduce anxiety and LI4 has been shown to improve breathlessness.<sup>6</sup> There is likely to be an acupressure effect from sham devices, so points unlikely to have a local or segmental effect on breathlessness were used in the control group.

The Park sham device has been developed and validated to allow patients to be blinded in acupuncture trials. The device comprises a needle (real or sham) which is inserted through a guide tube on a base adherent to the skin.<sup>8</sup> Acupuncture needles were administered through the guide at the chosen points and inserted to the required depth, the sham needles are blunt and give the appearance of entering the skin, but actually telescope back into their handle. The real and sham needles appear similar and were the same size (0.35 mm×70 mm, stainless steel, Dong Bang Acupuncture Inc., Korea).

All subjects admitted with an acute exacerbation of COPD over a six-month period were considered for the study. The diagnosis of an acute exacerbation had to be made by an independent physician, with previous spirometric confirmation of COPD. Exclusion criteria were the presence of concurrent medical conditions likely to contribute to breathlessness and contraindications to acupuncture (bleeding disorder, anticoagulation or presence of a pacemaker).

The study was approved by the University Hospitals Coventry and Warwickshire NHS Trust

**Box 1 Borkovec and Nau Credibility Questionnaire**

1. How confident do you feel that this treatment can alleviate your complaint?
2. How logical does this treatment seem to you?
3. How confident would you be in recommending this treatment to a friend?
4. How successful do you think this treatment would be in alleviating other complaints?

Scale: 1 = not at all; 2 = a little; 3 = moderately; 4 = quite a lot; 5 = extremely

**Box 2 Modified Borg scale**

- |     |                                     |
|-----|-------------------------------------|
| 0   | Not at all                          |
| 0.5 | Very, very slight (just noticeable) |
| 1   | Very slight                         |
| 2   | Slight                              |
| 3   | Moderate                            |
| 4   | Somewhat severe                     |
| 5   | Severe                              |
| 6   |                                     |
| 7   | Very severe                         |
| 8   |                                     |
| 9   | Very, very severe (almost maximal)  |
| 10  | Maximal                             |

Clinical Ethics Committee and all patients provided written informed consent.

**Measurements** Credibility of acupuncture and the Park sham device were measured using the Borkovec and Nau questionnaire (box 1) before and after the course of treatment.<sup>9–10</sup> Dyspnoea was measured using the modified Borg score (box 2)<sup>11–12</sup> and a 10 cm visual analogue scale (VAS). Anxiety was measured on a 10 cm VAS.

**Protocol** Subjects were randomised using an online random number generator. The code was sealed in an opaque envelope, which was opened by the acupuncturist immediately prior to the first treatment. Each subject was informed that they would receive real or sham (pretend) acupuncture.

On the first study day each subject completed the credibility questionnaire and recorded baseline dyspnoea and anxiety measures. Each patient was asked “How would you rate your breathlessness, with zero being no breathlessness and 10 being worst ever breathlessness?” and “How would you rate your anxiety, with zero being no anxiety and 10 being worst ever anxiety?” and asked to make an appropriate mark on two 10 cm scales. They were then shown the modified Borg score and asked to rate their breathlessness from zero to 10.

Patients then received either real or sham acupuncture. All treatment was administered by CAW (a palliative medicine specialist, trained in acupuncture with the British Medical Acupuncture Society with three years experience using acupuncture for symptom control in advanced disease). Real acupuncture was administered to LI4 bilaterally to a depth of 15–20 mm and to two upper sternal points, 2 cm apart in the midline, advanced to the periosteum without manual or electrical stimulation, and with no attempt to elicit *de qi*. Sham treatment was administered over the kneecaps bilaterally and ST25 bilaterally. Needles were left in place for 20 minutes without stimulation.

Treatment was repeated 24 and 48 hours later, with real or sham acupuncture delivered at the same sites on each day. Following the final treatment, credibility, dyspnoea and anxiety were assessed and recorded. To conclude the study, adverse events were assessed by observation and by asking “Did you experience any side effects from the treatment?” Patients were also asked “Do you think you received real acupuncture, sham acupuncture or don’t know?”

**RESULTS**

In all, 45 patient records were assessed, 13 were eligible to participate in the study and 11 subjects were recruited. Two were discharged before the 48 hour intervention period and therefore dropped out of the study. Nine subjects completed the study (five men), with a mean age of 68 years (range 53–78 years). Four received real acupuncture and five received sham acupuncture.

All treatments were well tolerated with no side effects observed or reported. The scores before and after intervention indicate that both acupuncture and sham were credible (table 1).

Mean dyspnoea and anxiety scores improved after both real and sham treatments, but there was no statistical difference between the groups (table 2).

Subjects who received real acupuncture all identified the treatment correctly. Two of the five subjects receiving sham acupuncture thought they had received real treatment and three were unsure.

**DISCUSSION**

In this successful pilot study, acupuncture was well tolerated by subjects admitted to hospital with an acute exacerbation of COPD and the study ran smoothly alongside other standard treatments. There were no adverse events reported and acupuncture was a credible treatment. The study also suggests that the credibility of the Park sham device may have been

**Table 1** Borkovec and Nau Credibility Questionnaire scores

	Real acupuncture		Sham acupuncture	
	Before	After	Before	After
How confident do you feel that this treatment can alleviate your complaint?	4 3 4 2	3 2 4 3	3 5 2 3	3 5 1 3
Mean (SD)	<b>3.3 (1.0)</b>	<b>3.0 (0.8)</b>	<b>3.2 (1.1)</b>	<b>3.2 (1.5)</b>
How logical does this treatment seem to you?	4 4 4 3	3 3 4 3	3 5 3 4	3 5 2 3
Mean (SD)	<b>3.8 (0.5)</b>	<b>3.3 (0.5)</b>	<b>3.8 (0.8)</b>	<b>3.4 (1.1)</b>
How confident would you be in recommending this treatment to a friend?	4 3 4 2	3 3 4 2	3 5 1 4	4 5 1 5
Mean (SD)	<b>3.3 (1.0)</b>	<b>3.0 (0.8)</b>	<b>3.4 (1.5)</b>	<b>4.0 (1.7)</b>
How successful do you think this treatment would be in alleviating other complaints?	4 3 5 2	4 4 4 3	3 5 1 3	4 5 1 4
Mean (SD)	<b>3.5 (1.1)</b>	<b>3.8 (0.5)</b>	<b>3.0 (1.4)</b>	<b>3.6 (1.5)</b>

**Table 2** Breathlessness and anxiety scores before and after acupuncture/sham during an acute exacerbation of COPD. Values are means (SD)

	VAS breathlessness (mm)		Borg score		VAS anxiety (mm)	
	Before	After	Before	After	Before	After
Real acupuncture						
1	73	58	5	4	75	53
2	9	26	2	1	13	5
3	89	98	8	8	90	97
4	88	56	5	2	89	21
Mean (SD)	<b>65 (38)</b>	<b>60 (30)</b>	<b>5 (2)</b>	<b>4 (3)</b>	<b>67 (36)</b>	<b>44 (41)</b>
Sham acupuncture						
1	36	16	3	1	18	19
2	100	53	10	3	70	29
3	0	39	4	2	0	45
4	100	9	9	1	15	0
5	37	32	8	1	72	23
Mean (SD)	<b>55 (40)</b>	<b>30 (18)</b>	<b>7 (3)</b>	<b>2 (1)</b>	<b>35 (34)</b>	<b>23 (16)</b>

VAS, visual analogue scale.

somewhat less in these circumstances, but we believe that, with larger patient numbers, the device will prove credible in a future study, as has been previously reported.<sup>8 13</sup>

Recruitment was more difficult than anticipated and the number of subjects completing the study was disappointing. We expected to recruit more patients over the six-month period, but a concurrent COPD study in the same hospital and a policy emphasising early supported discharge limited the availability of suitable patients.

COPD is a major worldwide healthcare issue and acute exacerbations are common. Dyspnoea and anxiety can cause significant morbidity for patients and effective non-pharmacological approaches to symptom control would be welcomed. The evolution of the illness is such that dyspnoea and anxiety should improve after three days of standard therapy and this small pilot study was not powered to assess whether acupuncture reduces symptoms in an acute exacerbation.

Acupuncture can be applied during an acute exacerbation of COPD and offers a potential adjunct to current treatment. A large study would determine whether it reduces symptoms, and the present data suggest a sample size of approximately 200 patients would be required to show a difference of 10 mm VAS or 1 point on the Borg scale. A recent review suggested that

### Summary points

- ▶ Exacerbation of chronic obstructive pulmonary disease is a common reason for hospital admission
- ▶ Acupuncture has shown some promise as an adjunctive treatment
- ▶ A small pilot study showed acupuncture to be acceptable and well tolerated
- ▶ A larger definitive trial is justified

auricular acupuncture may be beneficial for anxiety and this additional approach could be used in future trials.<sup>14</sup> Increasing discharge support for patients with chronic conditions, such as COPD, suggest that a community rather than in-patient setting may be appropriate.

**Competing interests:** None.

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