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Bronchial Asthma and Acupuncture

The evidence for effectiveness



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The Evidence Series of Briefing Papers aims to provide a review of the key papers in the literature, which provide evidence of the effectiveness of acupuncture in the treatment of specific conditions. The sources of evidence will be clearly identified ranging from clinical trials, outcome studies and case studies. In particular this series of briefing papers will seek to present, discuss and critically evaluate the evidence.

BRONCHIAL ASTHMA AND ACUPUNCTURE: THE EVIDENCE FOR EFFECTIVENESS

Summary

This paper reviews a number of clinical trials and outcome studies on the use of acupuncture to treat asthma. None of the trials had a large sample size and they suffer from the problems common to all acupuncture trials, such as what constitutes appropriate treatment and a suitable “control”. The outcome studies avoid some of these problems but many lack rigour or adequate description of measurements used. This paper reviews the trials that appeared most sound in methodological terms, together with those outcome studies that had relatively large samples. The trials are divided into two groups: those treating patients as part of normal clinical management and those treating patients suffering an induced asthma attack. The findings for the first group are inconsistent, particularly as regards objective measures of lung function. There is, however, evidence that acupuncture can improve patients’ subjective experience of their symptoms, reduce their use of medication and improve immunological parameters. The smaller number of trials of induced asthma is more consistently positive. The majority of trials provide an inadequate rationale for the acupuncture points used and few bear any relationship to the way acupuncture is actually practised by British Acupuncture Council members. The outcome studies generally provide a much better picture of the diagnostic criteria used and show more consistently positive results than the trials, but their methodology is often weak. The paper concludes by discussing some of the issues that need to be addressed in developing clinically relevant and methodologically sound research.

Introduction.

It is estimated that asthma affects approximately 10% of the population. Both incidence of the disease and resulting mortality are increasing (Howell, 2000). The definition of “asthma” is not, however, clear-cut. Howell (2000) identified three elements: reversible airways obstruction with episodic attacks of breathlessness accompanied by wheezing; responsiveness to asthma drugs (cromoglycate and/or corticosteroids); bronchial hypersensitiveness. In practice, however, none of these provides an absolute criterion for distinguishing asthma from other breathing problems and asthmatics are defined as those with reversible airways obstruction and/or clear responsiveness to asthma medication. The management of asthma often requires daily use of medication on a prophylactic basis. Severe attacks may require hospitalisation and can lead to death. Asthma thus has high economic and personal costs. Lewith and Watkins (1996) suggested that asthma costs the NHS about £400 million per annum; the Department of Social Security, in the form of sickness benefits, £60 million; the economy as a whole, in terms of lost productivity, £350 million.

Literature Search

A search was carried out using the ARRCBASE, the Acupuncture Research Resource Centre database of articles drawn from the British Library's AMED and the US MEDLINE, using the terms "asthma", "breathlessness" and "acupuncture". Sixty-one references were identified and an additional twenty-two were derived from citations in these papers. Papers were excluded for variety of reasons: no English translation was available; the paper was unobtainable from the British Library; the paper was not primarily concerned with presenting or reviewing clinical evidence; the study involved therapies other than acupuncture or did not use needles.

The remainder could be grouped into three categories: reviews, descriptions of a randomised controlled trial (RCT) and descriptions of an outcome study. Reviews were only included if they had been published after 1990, on the grounds that earlier publications would have been superseded. Some RCTs were excluded on the grounds of their weak methodology. For trials prior to 1990, the system of evaluating methodological quality set out by Kleijnen et al (1991) was used to exclude those which scored below 40. Trials since 1990 were included if fully randomised. Outcome studies were included if they used significantly larger sample sizes than the RCTs. The papers finally selected comprise 6 reviews, 11 controlled trials, and four outcome studies.

Reviews

Two of the reviews (Kleijnen et al (1991) and Linde et al (2000)) focused on the methodological quality of the trials reviewed. Kleijnen et al (1991) reviewed 13 trials, which were evaluated against 18 predefined methodological criteria and scored out of 100. Only 8 studies scored above 50 and no paper scored above 72, leading the authors to conclude that no conclusion as to acupuncture's effectiveness could be drawn due to the poor quality of the trials. A similar conclusion was reached in the most recent review carried out by Linde, Jobst and Panton (Linde et al 2001) as part of the Cochrane Collaboration. This review involved tight selection criteria: of 21 trials identified, only seven were regarded as worthy of inclusion. The aim of the Cochrane collaboration is to provide overall analyses that can show conclusively whether there is evidence in favour of particular medical interventions. The authors argued that the heterogeneous nature of the acupuncture trials precluded such an analysis.

Both these reviews proposed that there was no conclusive evidence that acupuncture has a significant effect on the course of the condition - but equally there is no evidence that it does not. In effect, these reviews are an argument for more rigorous research. Until then, the "jury is out".

The remaining four reviews (Linde et al (1996), Jobst (1995, 1996), Lewith and Watkins (1996)) analysed a range of individual trials, all of which involved some comparison of a treatment group receiving true acupuncture with a control group receiving sham acupuncture. Table 1 summarises their findings.

These reviews highlight the difficulty in reaching agreement, partly because of the heterogeneous nature of the trials themselves and partly because of differences in the subjective interpretation of the reviewers. For example, Linde et al (1996) used a set of assessors to evaluate both the methodological validity of the trials and the appropriateness of

the acupuncture treatments used. Whilst their assessors reached a high level of agreement on the internal validity of the trials, there was little agreement amongst them as to whether the acupuncture treatments given were appropriate; also, the outcome measures used varied

Table 1: Reviews of Acupuncture

Author	Number of trials reviewed	Conclusions
Linde et al (1996)	14	True acupuncture superior to sham: 5 Trend in favour of true acupuncture: 2 No difference between true and sham: 6 Sham acupuncture superior: 1
Jobst (1995, 1996)	16	True acupuncture superior: 10 No difference: 3 Equivocal: 3
Lewith and Watkins (1996)	10	9 positive on at least some outcome measures

considerably. Furthermore they disagreed with Kleijnen et al (1991) in some of their assessments as to whether or not individual trials showed positive results. Similarly, Jobst (1995,1996) differs from Linde et al (1996) in the interpretation of the results of two trials.

In summary, three of the reviews, Kleijnen et al (1991), Linde et al (1996) and Linde et al (2000), argued that the trials did not enable us to come to any conclusions about acupuncture's effectiveness, whilst three, Jobst (1995,1996) and Lewith and Watkins (1996), considered that there was evidence of effectiveness. Jobst (1995,1996) suggested that acupuncture might be used as an addition to conventional medical management of asthma and could lead to a reduction in the need for medication, particularly corticosteroids. Lewith and Watkins (1996) concluded that acupuncture could be useful in the alleviation of short term, acute airways obstruction but that evidence for its long-term efficacy was more open to question - largely, however, because the majority of the trials failed to include any long-term follow-up.

The next sections will review in more detail some of the RCTs discussed in the above reviews as well as outcome studies, which, being uncontrolled, are rarely considered in systematic reviews.

Randomised Controlled Trials

Eleven trials were selected, of which four concern acupuncture administered shortly after the onset of induced asthma, whilst the remainder cover acupuncture provided under normal

clinical conditions. Clearly, the latter are of greatest interest to practitioners since most asthmatics encountered in the treatment room will have their asthma managed through drugs and practitioners may very rarely treat a severe acute attack. Of more interest will be issues such as whether acupuncture can lead to a reduction in medication. Nevertheless, the studies of induced asthma are of interest if they can demonstrate whether acupuncture has an effect.

Trials of treatment given under normal clinical conditions.

Characteristics of trials

The trials detailed in Table 2 all involved patients with a diagnosis of chronic asthma, apart from Jobst et al (1986) where the diagnosis was Chronic Obstructive Pulmonary Disease, and only four of the subjects had signs of asthma. This paper was included since it appears in all the reviews of trials of asthma. The outcome measures used in the studies varied. All but Joos et al (2000) included measures of lung function. Other measures included:

- medication use
- immunological parameters
- heart rate and blood pressure
- walking distance (Jobst et al (1986) only)
 - subjective relief of symptoms
- subjective well-being, quality of life measures.

The details of the outcome measurements used are included in the footnote to Table 2.

Table 2: Controlled Trials for Chronic Asthma

	Design type	Sample size	Number of tx	Treatment (appropriate acupuncture listed first)	Outcome Measures	Conclusion
Christensen et al (1984)	Double blind	17	10 over five weeks	Ren 17, LI4, Dingchuan, Bl 13 vs sham.	Lung function: MPEFR, EPEFR Medication: no. of puffs of β -agonist Subjective: DSA, WSA Immunological: IgE, IgG, IgA, IgM	Modest effect of appropriate acupuncture on both objective and subjective measures of lung function and one immunological parameter. More substantial effect on medication use.
Dias et al (1982)	Double blind	20	Variable	Ren 22, Dingchuan, Lu 7 vs GB 5 & 6	Lung function: PEFR Level of medication usage	Improvements in both groups but control group better than appropriate acupuncture.
Jobst et al (1986)	Single blind	26	13 over three weeks	Individual TCM treatments vs sham	Lung function: PEFR, FEV ₁ , FVC Subjective well-being Subjective measures of breathlessness. Walking distance: six minute walk.	No change in lung function. Significant improvement in well being and walking distance for appropriate acupuncture.

Mitchell & Wells (1989)	Single blind	31	8 over 12 weeks	Ren 17, Bl 13, Liv 3 vs Sp 8, Ki 9, GB37.	Lung function: PEFr Medication use Asthma symptoms: patient report No. of Asthma episodes	Improvements in both groups. No statistically significant difference between them. Appropriate acupuncture group had no asthma episodes compared with four in control.
Tashkin et al (1985)	Single blind	25	8 over 4 weeks, then cross over	LI 4, St 36, Du 14, Lu 7, Dingchuan, Waidingchuan vs sham.	Lung function: SG _{aw} , spirometry. Diaries of medication use & subjective symptoms. Heart rate and BP.	Trend to improvement in both groups but not statistically significant.
Biernacki & Peake (1998)	Double blind	23	1 treatment followed by crossover.	Ren 17 vs sham point on the chest wall.	Lung function: FEV ₁ , FVC. Medication use Quality of life questionnaire.	No improvement in lung function, both groups had improved quality of life and reduced medication.

Joos et al (2000)	Single blind	38	12 treatments over 4 weeks	Bl 13, 17, Ren 17, LI 4, Lu7 plus individualised points vs inappropriate points *	Immunological parameters: 14 measures used. General well-being (patient report).	Significant improvement in general well-being and most immunological parameters for appropriate acupuncture.
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* The inappropriate points also included both a set of basic points for all patients (TE3, 19, GB 8, 34) and randomly assigned flexible points (Bl 38, 55, St 4, 6, 32, TE 14, 23, SI 5).

Key to abbreviations: **MPEFR** (morning peak expiratory flow rate), **EPEFR** (evening peak expiratory flow rate), **PEFR** (peak expiratory flow rate), **FEV₁** (forced expiratory volume in one second), **FEF₅₀** or **75** (forced expiratory flow after 50% or 75% vital capacity exhaled), **R_{aw}** (airway resistance), **SG_{aw}** (specific airway conductance), **DSA** (daily severe asthma scale), **WSA** (weekly severe asthma scale), **BP** (blood pressure).

Methodologically, it is extremely problematic to design a double blind trial in which both patient and practitioner are blinded. If the treatment is provided by a trained practitioner, even if they are given sets of points to needle by a different practitioner, they may be able to identify whether points are inappropriate or appropriate for the condition being treated. Where sham points are used, the problem is insurmountable. In practice, therefore, the trials described in Table 2 as “double blind” have blinded the patients and used a blinded evaluator but the practitioner providing the treatment is not necessarily blinded. There may therefore be little difference between trials which describe themselves as double or single blind.

The majority of the trials involved some sort of period during which baseline measurements of parameters such as lung function were drawn up, followed by a treatment period, followed by further measurements. The majority did not involve any long-term follow-up of patients. Two trials (Biernacki and Peake (1998), Tashkin (1985)) used a crossover design, whereby patients were randomly assigned to real or placebo acupuncture, followed by a washout period, followed by a second treatment phase during which they received the alternate form of acupuncture to the one received in the previous treatment phase.

As for the actual treatment given, it is unfortunate that the RCT design has come to be associated with the idea of standard treatments. Whilst this constraint has been more open to question in recent years, only two of the trials below included any individualisation of treatment. In one (Jobst et al (1986)) treatment was fully individualised according to TCM (Traditional Chinese Medicine) syndromes whilst in the other (Joos et al (2000)) both standard and individualised points were used. The control group received either sham acupuncture (points with no defined energetic effect) or what were defined as inappropriate acupuncture points. Researchers differed as to whether they thought the control points should be located reasonably close to the “real” points or at some distance.

All trials except Dias et al (1982) gave a standard number of treatments, which varied from one (real) treatment in Biernacki and Peake (1998) to thirteen in the Jobst et al (1986) study. The number of treatments in the Dias et al (1982) study varied from 2 to 8 (median 6) in the control group and 4 to 12 (median 6) in the treated group.

Findings

As regards objective outcome measurements, six of the seven trials measured lung function, and, in four, patients experienced improvements in lung function. However, one of these favoured inappropriate acupuncture over appropriate acupuncture and two failed to show a statistically significant change. Only one, therefore, unequivocally favoured appropriate acupuncture. Two of the trials looked at immunological parameters, both of which demonstrated positive benefits for appropriate acupuncture. Joos et al (2000) reported positive changes in a number of immunological parameters, although only the increase in in vitro lymphocyte proliferation rates reached statistical significance when comparing the TCM group with the control group. Christensen et al (1984) reported reduced levels of IgE in the true acupuncture group.

Turning to subjective indicators, six of the trials used measures such as general well-being, quality of life or subjective experience of symptoms. All showed patients experiencing

benefits, with three showing appropriate acupuncture superior to inappropriate and three showing improvements in both groups. The relative importance of objective and subjective measures is debated: Jobst et al (1986) argued that acupuncture was helpful in reducing *disability* since the subjective experience of breathlessness and ability to walk for six minutes improved significantly even without there being a corresponding change in objective measures of lung function.

In relation to all these trials we should bear in mind that they had small sample sizes and only two made any attempt to include some element of individual diagnosis. Both of these (Jobst et al (1986), Joos et al (2000)) included positive outcomes. The problem of diagnosis and point choice will be discussed further later.

Trials of acupuncture for induced asthma attacks.

Three trials looked at the effects of acupuncture on people with a history of asthma, but where bronchospasm had been induced, either by exercise (Fung et al (1986), Chow et al (1983)) or by inhalation of methacholine (Tashkin et al (1977)). A fourth (Yu & Lee (1976)) looked at acupuncture as a treatment for spontaneous asthma attacks, but a sub-group of four patients had an attack induced by histamine inhalation whilst in remission. Table 3 summarises the trial characteristics.

Table 3: Controlled Trials for Induced Asthma

	Design	Sample size	No of tx	Treatment	Outcome measures	Conclusion
Chow et al (1983)	Single blind	16*	1 before exercise*	Auricular points: lung area vs lumbago area.	Lung function: FEV ₁ , FVC.	Neither gave protection against asthma.
Tashkin et al (1977)	Double blind, crossover	12	1 after induced broncho spasm	LI4, Du14, Dingchuan, Waidingchuan, St36, Lu7 vs sham acupuncture	Lung function: FVC, FEV ₁ , FEF ₂₅₋₇₅ , FVC, Sg _{aw} , R _{aw} , V _{tg} . Blood pressure. Heart rate.	Real acupuncture better than sham although isoproterenol was most effective.
Fung et al (1986)	Single blind	19**	1 before exercise	Dingchuan, L6, K3 vs SI14, P4, GB39.	Lung function: FEV ₁ , FVC, PEF _R .	Real acupuncture gave greater protection than sham.
Yu & Lee (1976)	Single blind	20	1 during spontaneous attack. 1 before and 1 after induced attack	St 36 (both groups) vs Dingchuan, vs sham	Lung function: FEV ₁ , FVC, PaCO ₂ Subjective breathlessness Heart rate Expiratory wheeze.	Dingchuan showed significant benefit compared with both sham and St36 during spontaneous asthma attack.

* all aged 8 - 13. Needles left in during exercise. ** all aged 9 - 13.5 years

Abbreviations: as Table 3 + PaCo₂ (arterial carbon dioxide pressure) and V_{tg} (thoracic volume at functional residual capacity).

Findings

Three of the four trials showed positive findings regarding relief of bronchospasm by acupuncture, although Tashkin et al (1977) found that medication had a stronger effect. Yu and Lee (1976) found acupuncture to be beneficial in terms of both subjective and objective parameters for spontaneous asthma attacks, but not effective for histamine-induced attacks. This study is of particular interest because of the comparison of the effect of the extra point Dingchuan with both St 36 and a non-acupuncture site. Nine of the 10 patients in the group treated with Dingchuan experienced relief from breathlessness. This was superior to the non-acupuncture site, which was located 4 cms lateral to Dingchuan. The point St 36 was least effective, with only one out of 20 patients reporting any benefit.

Outcome Studies

Four outcome studies have been included. These are summarised in Table 4.

Findings

Three of the outcome studies are particularly useful because they provided for individualised treatments and explained the diagnostic criteria used in the choice of points. The studies all demonstrated very positive results, but a weakness is that the baseline and outcome measures are often unclear. Where specific measures were referred to, actual statistics were rarely given, instead rather vague categories, such as “markedly improved”, were used. An exception is the experimental group in the Shao Jingming study.

Conclusion

Whilst three of the four trials of induced asthma showed the acupuncture conferred statistically significant improvements in objective and subjective symptoms, the findings of the trials for asthma as part of normal clinical practice were more mixed. Nevertheless, they demonstrate evidence for the efficacy of appropriate acupuncture for some immunological parameters, for experience of asthma symptoms, level of medication use and quality of life. Findings are more equivocal for improvements in objective measures of lung function with only one, Christensen et al (1984), finding a statistically significant effect in favour of appropriate acupuncture. One, Dias et al (1982),

Table 4: Outcome Studies

	Sample size	Number of treatments	Acupuncture	Outcome measures	Results
Zang Junqi (1990)	192	Single treatment	Lu 6 & Lu 10 with electro acupuncture	Clinical observation of symptoms and signs such as dyspnoea, wheezing but not clear how measured.	76.5% clinical remission or marked improvement.
Lai Xinsheng (1993)	143	Treated for six months	Bl 13, 20, 23, Du 14, Ren 15, 22 (all) Dingchuan or St 40 for excess type. Bl 43, Ren 4 (sometimes with moxa) for deficiency type.	Asthma, chest distress, dyspnoea, cough, expectoration, wheezing and cyanosis. Not clear how measured.	89.8% short-term cure or markedly effective.
Shao Jingming (1985)	111	Daily then alternate days over ten days. Repeated where necessary.	Bl 12, 13, Du 14 (all). Lu 5,9 (cough). Ren 12 St 36 (sputum). Bl 23, Ren 4, Ki 3 (kidney deficiency). Moxa used for cold symptoms, cupping for heat. Dietary restrictions.	Reference to symptoms but not specified. Lung function tests in experimental group *	98.2% were improved or markedly improved
Landa & Fadeeva (1992)	2,500 children not all had asthma	9-12 sessions per course.	Individualised according to eight principles, but no information on actual points used.	Observed improvements in asthma symptoms plus various objective measures: suprarenal and hypophysis functions, immune status, tryptophan exchange, physical development.	Positive effect for 87% of all patients.

* A comparison of the effects of Bl 13, Du 14 and Bl 12 using acupuncture with cupping, acupuncture with moxa and no treatment showed the greatest improvement for acupuncture with cupping. They also compared Bl 13, Du 14 and Bl 12 and found that Bl 13 gave the best results.

found in favour of the control group, which received “inappropriate” acupuncture. This leads some researchers, e.g. Grebski et al (1999), to argue that acupuncture is a useful placebo but that the exact location of the needles is unimportant.

Three counter-arguments can be made. Firstly, as Joos et al (2000) point out, inappropriate acupuncture is not a placebo since it has definite physiological effects. “True” acupuncture would, therefore, have to show a greater effect to achieve statistical significance than if it were being compared with an inert placebo. Secondly, a number of trials showed “real acupuncture” to be

superior and the study by Yu and Lee (1976) indicates that, in an acute attack of asthma, it makes a great deal of difference where the needle is inserted, with the point Dingchuan showing a markedly more positive effect than two other points. Thirdly, the majority of the trials used standardised formulae with no attempt at individual diagnosis. Appropriate points included points on the lung, large intestine, kidney, liver and stomach channels together with Ren 17 and 22 and the Back-shu point of the lung, but there was rarely any clear rationale for the choice. Stomach 36, for example, was used by Tashkin et al (1977, 1985) as a “real point” whereas Yu and Lee (1976) found that it was no better than a sham point. Most traditional acupuncturists would, therefore, regard these trials as of little help in understanding the potential role of acupuncture *as it is actually practised*. The outcome studies bear a closer relationship to the practice of traditional acupuncture and also demonstrate very positive results. However, they suffer from poor design. Further studies are clearly needed which combine both rigorous research methods and good quality acupuncture treatment. There is no reason why outcome studies cannot use well-validated tools to clearly specify the base line and outcome measures rather than using vague terms such as “significant improvement”. It is also argued by many that pragmatic RCTs, where the acupuncture treatment is left to the practitioner’s discretion and the control group receives an alternative form of treatment or no treatment at all, are more useful than placebo-controlled trials because they enable acupuncture to be studied as it is actually practised. “We think it more important to know if acupuncture is of value for the patient than to know that it is ‘more than placebo’” (Linde et al, 1996).

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