

## Clinical assessment of acupuncture in asthma therapy: discussion paper

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This paper is concerned with reviewing the use of acupuncture for the relief of chronic bronchial asthma, for it is our intention to embark upon a controlled clinical trial of acupuncture therapy in the context of general medical practice. A secondary property of this paper is a discussion of clinical trial methodology as applied to a complementary therapy.

### Acupuncture

Acupuncture is a therapy which has gained some recognition both within the realms of popular practice and, perhaps more importantly, within the realm of medical practice. The practice of acupuncture is a collection of procedures which include the insertion of needles at specific points of the body for both the relief of pain and the treatment of disease, with moxibustion and cupping.

Traditional descriptions of acupuncture are concerned with the flow of vital energy, called *ch'i*, along fixed paths called meridians. These are linked together with each other and the organs of the body. Flow of energy along these paths has a circadian rhythm, so that at times and season it may vary. Energy in this context has a bipolar character; it can be positive called '*yang*', and negative called '*yin*'. The energy within the body, *ch'i*, reflects both the vitality of the universe and society<sup>1</sup>.

For a body to be healthy in this system of description, the flow of *ch'i* in the meridians is normal and balanced. Essentially the process is one of maintaining balance, i.e. becoming healthy or losing health. Diagnosis, too, is seen as a process and takes into account many factors. It includes a patient history of changes in behaviour, appetite and emotions. The state of the skin, eyes, breath and tongue are noted for colour, consistency and odour. There are also special techniques for the evaluation of the flow of energy in the 12 meridians, electrical measurements of skin resistance, and the palpation of skin subcutaneous tissue.

Although the mode of action of acupuncture is not known precisely, there are a number of suggestions which propose that the mechanism is linked with the secretion of endorphins<sup>2</sup>. Yu and Lee<sup>3</sup> suggest that acupuncture relieves that part of the bronchoconstriction which does not arise from the constriction of smooth muscle as a result of chemical mediators. The effect of acupuncture in asthma is mediated through modification of the reflex component of bronchoconstriction. Other writers invoke the proximity of the central nervous system projections of the acupuncture stimulation site and the pain path as the rationale for the selection of treatment loci, humoral-biochemical mechanisms, neuromechanisms, and the

bioelectric mechanism<sup>1</sup>. It has been pointed out, however, that these descriptions are made by 'scientific apologists'<sup>1</sup>.

It is more likely that acupuncture represents many phenomena and that a primary difficulty, as discussed later, lies in a treatment modality that is underpinned by an Oriental philosophy being subjected to an explanation by the differing theoretical understanding of modern Western medicine.

### Asthma

Asthma is a condition characterized by symptoms which are present over long periods of a patients' life. The number of people with asthma in the United Kingdom is estimated to be about two million – a number too great for the hospital services to provide continuing care. Although the condition is often mild and readily treated, for those persons with a chronic condition the illness is composed of recurrent crises and debilitation. Gregg<sup>4</sup> estimates that the incidence of asthma in the population is increasing, and in a form that is frequently more severe than in the past. The general practitioner is in a position to identify the incidence of asthma, to be involved in preventive measures and to offer early treatment. Many persons seen in hospital outpatient departments could be managed just as easily in the context of the general practitioner clinic<sup>5</sup>.

Asthma is often refractory to pharmacotherapy, the side effects of which can be distressing. A low-risk form of treatment such as acupuncture could constitute an advancement in the management of asthma<sup>6</sup>, particularly if used in the context of general medical practice which utilizes elements of patient education and a self-care perspective.

### Clinical controlled trials of asthma

A literature search was carried out using the Medline database through St Mary's Hospital Medical School library. The criteria for the search were English language papers on 'asthma therapy' and 'acupuncture' published in the past ten years. Eight studies were discovered having a controlled trial methodology which used either a 'placebo' or 'no treatment' control group<sup>3,6-12</sup>.

Although these trials ostensibly used a controlled trial methodology, there were many inconsistencies. First, most of the trials had few subjects; the largest trial had 111 subjects but the rest had no more than 25. Second, there was a large disparity in the age ranges; in one trial the ages ranged from 6 to 71 years. Third, the clinical entities were wide-ranging.

The predominant conclusion of the controlled trials was that at best acupuncture resulted in only

modest improvement in the 'objective' assessment of airways impedance. These objective measures were mainly concerned with expiratory flow rates, airway conductance and thoracic gas volume. A greater perception of symptom relief was made subjectively by the patients using self-report measures and diary techniques, a point that will be discussed further later in the paper.

### Clinical evaluations

Two trials<sup>13,14</sup> were essentially evaluations by clinicians of clinical practice. A range of symptoms associated with asthma were covered, the treatment approach being varied according to the presenting symptoms. The number of treatment sessions was not standardized but varied according to the symptoms and symptomatic improvement.

The criteria for improvement were subjective and included the assessments of both practitioner and patient. Cioppa<sup>13</sup> found that 67% of the patients improved with acupuncture treatment. The conclusions of this research were that acupuncture appears to: (a) relieve muscle spasm; (b) be useful in subacute conditions; (c) be something other than hypnosis; (d) facilitate manipulation; (e) have an *immediate* effect; (f) give complete remission – not only palliation – in many cases; (g) give a sense of well being; (h) be a valuable adjunct to standard practice. Fuller<sup>14</sup> also considered acupuncture to be effective in treating chronic asthma and recommended its use.

The remaining papers were a collection of miscellaneous reports and letters about the clinical application of acupuncture, the relationship to general medical practice, and replies to letters<sup>15–21</sup>.

Hossri<sup>22</sup> described the use of acupuncture massage for the relief of asthma in children. This entails a number of techniques using pressure at acupuncture sites, friction and manipulation. Hossri also used hypnosis in combination with these techniques. Acupressure, the substitute of digital pressure for needling at specific sites, has been used in medicine and dentistry both for the relief of pain and tension<sup>23–25</sup>.

### Discussion

There is a disparity between the claims of acupuncturists as to positive clinical benefit, and the findings of the clinical trials research, which demonstrates little 'objective' change but does emphasize 'subjective' change. Such difficulties bedevil the assessment of alternative or complementary therapies, particularly since there is a confusion between different levels of measurement – i.e. between that which is measurable in terms of quantity such as gas volume, and that which cannot be readily subjected to such quantification such as 'feeling better'.

A more serious critique concerns the controlled trial methodology itself. The trials studied here failed to provide a sample size with sufficient power to make any valid conclusions from the statistics<sup>26</sup>. Furthermore, the trials really did not investigate 'acupuncture'. The process of standardizing the treatment approach removed from the practice itself that which is the essence of the treatment. By restricting needling sites to specific loci, limiting the number of treatment sessions and abdicating the use of traditional diagnostic practices, the trials were really reduced to testing the insertion of needles at particular points. It is therefore not surprising that needling as 'acupunc-

ture' in these trials differed from needling as a 'placebo' or 'sham' acupuncture. What the trials failed to do was realize that even though methodology can be applied, if it is applied without understanding simply as a formula then no significant findings emerge. To do this abdicates both responsibility in science and real discovery. Science is not methodology; methodology serves science.

How can we as scientists say that we have subjected a practice to adequate investigation when we remove from the process that which is essential? When applied rigidly, clinical trials remove the interaction between the subject and the researcher. It is this very interaction which is at the very heart of clinical practice, and which cannot be removed no matter how impersonal we may wish to be. The separation of the disease from the person loses those very qualities which we need to understand. Diseases may be treated as aggregates and submitted to statistical analysis, but it is individual persons in whom those diseases are located and who confront us in our surgeries.

Another feature of the clinical trial methodology was that asthma was seen as a homogeneous clinical entity. There was no consideration that the symptoms were located within persons who perceived their symptoms differentially, or that asthma in a 6-year-old is qualitatively different from that in a 71-year-old.

Asthma appears to be tractable to acupuncture when treated by committed clinicians who use traditional techniques. The clinical trials have not investigated acupuncture as a treatment modality, but 'needling techniques'. The challenge for clinicians and researchers is to examine rigorously the practical effects of acupuncture treatment but from a perspective which involves the whole person and the totality of the treatment process.

### The way forward

It is our intention to carry out a pilot study of acupuncture treatment and education classes in the management of chronic asthma. Our referrals will be taken from hospital outpatients where the patients will be assessed by an external researcher, who will also carry out the post-trial blind assessment. Of 150 patients who will be recruited to the study, 50 will be randomly allocated to an acupuncture treatment; another 50 patients will be allocated to education classes; and the third group of 50 patients will be offered continuing general practitioner contact only. All groups will be asked to complete a diary for the eight-week treatment period, and at a later follow-up period.

The acupuncture treatment method will be determined by the acupuncturist. There will be no definite fixed number of treatment sessions, but it is anticipated that the acupuncturist will attempt to keep within the eight-week timescale. The acupuncture sites will not be controlled, and it is expected that the acupuncturist will use a traditional pulse diagnosis.

The data collected will cover a broad spectrum of information concerned both with the symptoms and illness behaviour, as follows:

(1) impact of asthma upon health (using the Nottingham Health Profile<sup>27,28</sup> and life style data (Social Problem Questionnaire<sup>29</sup>), and locus of control<sup>30</sup>;

- (2) diary recording of events<sup>31-33</sup>, asthma attacks, use of medication/bronchodilator, night-time disturbance, time off work, crisis consultations, GP home visits and scores for wheeze, breathlessness, chest tightness and cough;
- (3) qualitative measures of practitioner, patient and family satisfaction;
- (4) knowledge and skills of patient about the management of asthma;
- (5) peak expiratory flow.

The education classes will consist of direct teaching about allergens and triggers of asthma (physical, psychological and relational); the correct use of medication, where appropriate, and the bronchodilator; and what asthma is in terms of airway impedance. Building on this basis there will be an opportunity for each person to identify through the diaries their own particular triggers.

A number of complementary strategies will be introduced, including dietary understandings, specific breathing technique, the use of relaxation techniques and stress management. It is anticipated that the people involved in this project will be able to personalize these strategies according to their own lifestyles and the contexts in which they become symptomatic.

This pilot study will attempt to meet our earlier criticisms of controlled trials. Acupuncture will not be restricted solely to needling, and a range of data will be collected which will include the physical, the psychological, the relational and the familial.

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#### References

- 1 Millman BS. Acupuncture: Context and critique. *Ann Rev Med* 1977;28:223-34
- 2 Guillemin R, Vargo T, Rossier J. Beta endorphin and adrenocorticotrophin are secreted concomitantly by the pituitary gland. *Science* 1977;197:1367
- 3 Yu DY, Lee SP. Effect of acupuncture on bronchial asthma. *Clin Sci Molec Med* 1976;51:503-9
- 4 Gregg I. The quality of asthma in general practice - a challenge for the future. *Family Practice* 1985;2:94-100
- 5 Arnold AG, Lane DJ, Zapata E. Acute severe asthma: Factors that influence hospital referral by the general practitioner and self referral by the patient. *Br J Dis Chest* 1983;77:51-9
- 6 Dias PLR, Subramanian S, Lionel NDW. Effects of acupuncture in bronchial asthma: a preliminary communication. *J R Soc Med* 1982;75:245-8
- 7 Shao JM, Ding YD. Clinical observation of 111 cases of asthma treated by acupuncture and moxibustion. *Journal of Traditional Chinese Medicine* 1985;5:23-5
- 8 Christensen PA, Laurensen LC, Taudorf E, Sorensen SC, Weeke B. Acupuncture and bronchial asthma. *Allergy* 1984;39:379-85
- 9 Berger D, Nolte D. Acupuncture in bronchial asthma: body plethysmographic measurements of acute bronchospasmolytic effects. *Comparative Medicine East and West* 1977;5:265-9
- 10 Tashkin DP, Bresler DE, Kroenig, RJ, Kerschner H, Katz RL, Coulson A. Comparison of real and simulated acupuncture and isoproterenol in metacholine-induced asthma. *Ann Allergy* 1977;39:379-87
- 11 Tashkin DP, Kroenig RJ, Bresler DE, Simmons M, Coulson AH, Kerschner H. A control trial of real and simulated acupuncture in the management of chronic asthma. *J Allergy Clin Immunol* 1985;76:855-64
- 12 Takishima T, Mue S, Tamura G, Ishihara T, Watanabe K. The bronchodilating effect of acupuncture in patients with acute asthma. *Ann Allergy* 1982;48:44-9
- 13 Cioppa FJ. Clinical evaluation of acupuncture in 129 patients. *Diseases of the Nervous System* 1976;37:639-43
- 14 Fuller JA. Acupuncture. *Med J Aust* 1974;ii:340-1
- 15 Allen M. Activity generated endorphins: a review of their role in sports science. *Can J Appl Sport Sci* 1983;8:115-33
- 16 Rebeck AS. The outpatient management of asthma. *Ann Allergy* 1985;55:507-10
- 17 Donnelly WJ, Spyykerboer JE, Thong YH. Are patients who use alternative medicine dissatisfied with orthodox medicine? *Med J Aust* 1985;142:539-41
- 18 Bodner G, Topilsky M, Greif J. Pneumothorax as a complication of acupuncture in the treatment of bronchial asthma. *Ann Allergy* 1983;51:401-3
- 19 Hayhoe S. Effects of acupuncture in bronchial asthma. *J R Soc Med* 1982;75:917
- 20 Marcus P. Effects of acupuncture in bronchial asthma. *J R Soc Med* 1982;75:670
- 21 Rosenthal RR, Wang KP, Norman PS. All that is asthma does not wheeze. *N Engl J Med* 1975;292:372
- 22 Hossri CM. The treatment of asthma in children through acupuncture massage. *Journal of the American Society of Psychosomatic and Dental Medicine* 1976;23:3-16
- 23 Weaver T. Acupressure: An overview of theory and application. *Nurse Practitioner* 1985;10:38-42
- 24 Kurland D. Treatment of headache pain with auto-acupressure. *Diseases of the Nervous System* 1976;37:127-9
- 25 Penzer V. Acupressure in dental practice: Magic at the tips of your fingers. *Journal of the Massachusetts Dental Society* 1985;34:71-5
- 26 Lewith GT, Machin D. On the evaluation of the clinical effects of acupuncture. *Pain* 1983;16:111-27
- 27 Hunt SM, McEwen J, McKenna SP. Measuring health status: a new tool for clinicians. *J R Coll Gen Prac* 1985;35:185-8
- 28 Hunt SM, McEwen J, McKenna SP. Social inequalities and perceived health. *Effective Health Care* 1985;2:151-9
- 29 Corney R, Clare AW. The construction, development and testing of a self report questionnaire to identify social problems - a pilot study. *Psychol Med* 1985;15:637-49
- 30 Lefcourt HM. *Locus of control*. New Jersey: Lawrence Erlbaum, 1982
- 31 Barry DMJ, Marshall TH, Rothwell RPG. Asthma and diary/treatment cards. *NZ Med J* 1985;98:556
- 32 Freer CB. Self care: a health diary study. *Med Care* 1980;18:853-61
- 33 Murray J. The use of health diaries in the field of psychiatric illness in general practice. *Psychol Med* 1985;15:827-40

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