

BRIEFING PAPER No 4

Gynaecology 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.

GYNAECOLOGY AND ACUPUNCTURE: THE EVIDENCE FOR EFFECTIVENESS

Summary

This paper evaluates the evidence for the effectiveness of acupuncture in the treatment of primary dysmenorrhoea, dysfunctional uterine bleeding and chronic pelvic inflammatory disease. The results of the studies indicate that acupuncture can be highly effective for the treatment of primary dysmenorrhoea. It may be a valuable treatment for the other two conditions as well, but as yet little evidence has been collected.

Introduction

Menstrual problems are a common cause for presentation to both the general practitioner and the gynaecology out patients' clinic.

In a British survey (Scrambler and Scrambler 1985), 79 women between the ages of 16 and 44 compiled health diaries and 82% reported at least one distressing symptom associated with menstruation. Ten years later in Canada it was found that gynaecological conditions were one of the most frequently mentioned primary health problems and accounted for at least 8% of patients consulting acupuncturists (Kelner & Welman 1997). Acupuncture has been used in China for gynaecological problems for 2000 years.

Literature Search

A search was made on the specialist acupuncture database, ARRCBASE. ARRCBASE is a composite database, which has been built up by the Acupuncture Research Resources Centre, and incorporates relevant articles from the British Library's AMED and the US Medline databases. Using the terms 'dysmenorrhoea', 'amenorrhoea', 'premenstrual syndrome', 'PMS', 'menorrhagia', 'metrorrhagia' and 'menstruation' 102 references were found. This number was reduced to 11 when foreign language articles, letters, herbal medicine articles and articles concerned solely on treatment were excluded. These 11 articles included 2 randomised controlled trials evaluating acupuncture and dysmenorrhoea and 9 outcome studies of which 5 related to dysmenorrhoea, 3 to uterine bleeding and 1 to pelvic inflammatory disease.

Introduction to the Trials

Whilst the results from outcome studies are useful indicators of *effectiveness*, randomised controlled trials (RCT) are generally considered more rigorous. An evaluation of *efficacy* takes place where an RCT is designed to assess the specific effect of acupuncture treatment while excluding the other non-specific effects of treatment generally.

The 2 controlled trials reviewed both related to dysmenorrhoea (Helms 1987 and Thomas et al 1995). Outcomes were assessed through the analysis of monthly symptom evaluation forms maintained by the patients.

The 9 outcome studies all followed a group of patients treated with acupuncture. Patient response to treatment was assessed by the practitioner and ascribed to one of the following outcome categories: 'clinical cure' with the amelioration of all presenting symptoms, 'marked improvement', 'some improvement', and 'no improvement'. The 'total effective rate' included all those who had obtained benefits from treatment. In a number of the studies, points prescriptions and/or numbers of treatments were standardised. In one trial (Liu et al 1988), biomedical tests were carried out to further validate findings.

Introduction to Primary Dysmenorrhoea

Primary dysmenorrhoea is defined as excessive pain experienced during menstruation in the absence of any underlying pathology, and is therefore idiopathic in origin. "It is a symptom complex with cramping lower abdominal pain radiating to the back and legs, often accompanied by gastrointestinal and neurological symptoms as well as malaise" (Shaw et al 1992). A questionnaire study sent to a representative sample of 19-year-old women in Gothenborg, Sweden, showed the prevalence of dysmenorrhoea in this population to be 72.4%. The same study also found that 51% of these women had been absent from work or school due to the severity of their period pains, with 8% requiring time off work or school with every menstruation (Andersch and Milsom 1982). These figures suggest that there are far-reaching economic and educational consequences from this common gynaecological problem.

The most commonly prescribed medications for dysmenorrhoea are non-steroidal anti-inflammatory drugs and the oral contraceptive pill. Although often effective such interventions do not offer an appropriate treatment strategy in all cases.

Controlled Trials

The Helms study (1987) compared acupuncture to sham acupuncture, with 2 groups using medication (NSAID's) acting as the control. 11 patients received acupuncture, 11 sham acupuncture and 21 patients were in the 2 control groups. Those receiving acupuncture and

sham acupuncture received 12 treatments over 3 cycles. The 'real' acupuncture group received a formula of acupuncture points (SP4, P6, KID3, ST36, ST30, REN2, REN4). Helms observed that, whilst sham acupuncture had some therapeutic effects (36.4%), the benefits from treatment with real acupuncture were far superior (90.9%). In addition to a significant decrease in cramping pain, patients receiving 'real' acupuncture also reported improvements in symptoms such as nausea, headache, backache, breast tenderness and fluid retention. At the 6 months follow up, a 41% reduction in analgesic medication was achieved with 'real' acupuncture, the other 3 groups reporting either no change or increased use of medication.

Both studies sought to evaluate outcomes in terms of pain duration and intensity, the amount of medication required (non-steroidal anti-inflammatory drugs - NSAID's), and the patient's subjective assessment of pain and other symptoms. The study by Thomas et al. also measured work hours lost, blood loss and vomiting.

The second study (Thomas et al. 1995) compared different forms of active acupuncture and TENS¹ interventions with sham acupuncture and inactive, placebo TENS as the controls. The patients received an acupuncture treatment (17 patients) or TENS (12 patients) 7 and 3 days prior to the presumed onset of menstruation each month for 4 months. The acupuncture points BL32, SP9, SP6 and REN 4 were used whilst sham acupuncture involved needles being inserted into 4 sites close to the standard acupuncture points. In this study significant improvements were observed with acupuncture and low frequency TENS² ($p < 0.05$ to $p < 0.001$). Although 'real' acupuncture was not found to be statistically superior to either sham acupuncture or TENS, with 'real' acupuncture, some improvements in vomiting and work hours were also recorded.

Outcome Studies

All of the 5 outcome studies were carried out in China and the results were extremely satisfactory. As Steinberger (1980) comments, in China it is accepted that "dysmenorrhoea is a common disease successfully treated by acupuncture in not less than 80% of cases".

A significant feature of 4 of the 5 studies was that patients were first sub-divided into groups according to their Chinese medicine diagnosis. In three cases treatments were then standardised in terms of points used within these groups (Zhang 1984, Wang 1987, Shan 1990). All patients were treated prior to the expected onset of menstruation.

The study by Zhang (1984) involved the treatment of three groups of patients diagnosed with either 'Cold Evil and Blood Stasis' 'Depression of Liver Energy and Stagnation of Vital Energy' 'Deficiency of Vital Energy and Blood'. Treatments were given every other day for the 10 days prior to the expected onset of menstruation for 2 to 3 menstrual cycles. An

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² It is worth noting that low frequency TENS is thought to provide acupuncture-like stimulation. Previous studies have found high frequency TENS to provide immediate relief for dysmenorrhoea during the menses. (Lewers et al., 1989)

unusual yet valid feature of this trial is the inclusion of lifestyle advice. Patients were advised to "observe general relevant hygiene measures, avoid emotional disturbance and catching cold, as well as avoiding raw and cold food."

The second study (Wang 1987) also identified three groups of patients according to Chinese medicine diagnosis and treated them daily for the 8 days prior to menstruation and for 4 days during menstruation. The original paper does not specify the total number of treatments received, although the case study example included in the text refers to a patient who received a second course of treatment. This study involved the use of two point prescriptions, the use of electro and auricular acupuncture points and moxa.

The patients in the study by Shan (1990) fell into two groups, those with 'Cold and Damp Retention' and those with 'Qi and Blood Stagnation'. Patients were treated daily for three days prior to the presumed date of menstruation, if patients responded to treatment a further two courses of treatment were given to consolidate the therapeutic effects.

In the fourth study (Zhu et al 1995) key points were listed, but actual prescriptions were not specified and supplementary points were used according to individual energetic pathology (Zhu et al 1995). Patients were treated every other day, throughout the menstrual cycle, for at up to 5 courses of treatment, with 15 treatments constituting a course.

These author/practitioners reported a total effective rate of 94% to 100% in the treatment of dysmenorrhoea. Only rare cases was there no relief of symptoms and signs and in the majority of cases (54% to 86%) treatment led to the complete relief of dysmenorrhoea and accompanying symptoms and signs. In the trials by Wang (1987) and Zhang (1984) the follow up after treatment found benefits were maintained for at least 6 months and 3 months respectively. Interestingly, no significant difference in patient response to treatment was found between the various diagnostic sub-groups. (Zhang 1984. Wang 1987. Zhan 1990. Zhu et al, 1995.)

The fifth study (Steinberger & Slogoski 1980) did not involve any differentiation according to Chinese medical diagnoses, as the purpose of this trial was to test a treatment protocol that could be easily replicated by gynaecologists in the author's country of origin. The treatment protocol consisted of the points REN4, LI4, ST36 and SP6. Moxa was used at REN4 in cases of severe pain and at ST36 if nausea and vomiting were present. Patients were treated daily for the five days prior to the presumed onset of one menstrual cycle. Satisfactory results were obtained in more than 80% of cases. 58.3% experienced a complete relief from symptoms, with benefits maintained for at least 6 months after treatment.

Dysfunctional Uterine Bleeding

Dysfunctional uterine bleeding is a common condition occurring in about 10% of women attending gynaecological outpatients' clinics. It is best described as "irregular, heavy, prolonged or frequent bleeding arising from the genital tract which is not due to pregnancy, inflammation, infection or neoplasm." (Varma, 1991)

This condition commonly occurs at the extremes of reproductive life (adolescence and perimenopausally) and is consequently thought to be as a result of abnormalities of ovarian activities. Thus hormonal treatments, such as the contraceptive pill, are used in the majority of cases. In cases of chronic blood loss, which have not responded to such treatments, uterine curettage and hysterectomy may be used.

Outcome Studies

Three studies fall under the heading of uterine bleeding. 2 are concerned with excessive and/or prolonged menstrual flow (Liu 1988 and Zhang & Wang 1994); the third (Tureanu & Tureanu 1994) seeks to evaluate the effectiveness of acupuncture in the treatment of post-oral contraceptive menstrual irregularities and amenorrhoea.

In these 3 studies, the authors present their findings from the treatment of between 20 and 50 cases. All patients were treated according to their Chinese medical diagnosis, and in two of the trials points prescriptions were standardised (Liu 1988, Zhang & Wang 1994).

The study by Liu (1988) diagnosed 5 groups of patients who were treated with the appropriate points formulae and needle technique. Patients received between 7 and 10 daily treatments, with a follow up 3 months after treatment. The 'total effective rate' in the treatment of excessive and/or prolonged menstrual blood loss was 90% with 80% of patients experiencing 'significant benefits'. An interesting secondary feature of the study is the inclusion of blood tests. Haematological indices were assayed in 8 of the patients with uterine bleeding and in 7 donors acting as a normal control. The results showed a significant difference in the blood cell counts between the groups ($p < 0.05$), and confirmed the presence of anaemia in those with bleeding. Post acupuncture tests revealed that blood cell counts had returned to normal levels, a statistically significant improvement ($p < 0.05$). Consequently, this study also concluded that anaemia might be successfully treated with acupuncture.

In the study by Zhang & Wang patients over the age of 37 years were excluded from the study due to the complexity of the disease in menopausal women. They established whether the focus of treatment was to clear an excess, tonify a deficiency or clear heat, and used one points formula for each along with the appropriate needle technique. Patients in this study received at least 10 treatments, with a follow up 6 months after treatment. They report 'complete cure' in 86% of cases, with 100% 'total effective rate'. It is possible that these selection criteria may account for the higher results.

In the third study (Tureanu & Tureanu 1994) patients received individualised treatment according to their Chinese medical diagnosis. A course of treatment involved daily acupuncture for 4 to 5 days prior to and after menstruation. Patients received no more than 3 courses of treatment. This research found acupuncture to be effective in normalising the menstrual cycle and regulating ovulation (as evidenced by mid-cycle luteinizing hormone and cervical mucus values) in patients who had previously used oral contraceptives. In 84.2% of cases significant benefits were achieved through treatment. There was no follow up to gauge the long-term benefits. The authors also observed that those who had used the oral

contraceptive pill for more than 2-3 years, and those patients with a history of menstrual disorders before using oral contraception, required more treatments.

Pelvic Inflammatory Disease

Pelvic inflammatory disease (PID) is a collective term for any extensive bacterial infection of the pelvic organs, especially the uterus, uterine tubes or ovaries. Lower abdominal pain, fever and purulent cervical discharge are the usual presenting symptoms. (Shaw et al. 1992) Chronic PID is usually due to inadequate and/or delayed treatment of a previous episode of PID. The clinical features are fairly characteristic. There is a history of one or more acute attacks of PID, with subsequent secondary dysmenorrhoea and intermittent purulent vaginal discharge. 20% of women also suffer from chronic pelvic pain. (Varma et al. 1991)

The incidence of acute PID in industrialised countries has increased from 20% to 50% over the last decade, and it is estimated that 18 to 20 out of 1000 women between the ages of 15 and 24 years of age acquire PID each year in developed countries. (Westrom 1980) Thus despite the availability of many powerful antibiotics, PID is a major health problem and may lead on to infertility. In cases of chronic PID, where antibiotics have failed to alleviate the symptoms, hysterectomy and bilateral salpingo-oophorectomy are advised. (Varma et al. 1991)

Outcome Study

Patients involved in the one study found (Wang 1989) had not responded to previous courses of antibiotics and/or Chinese herbs. In this study a combination of electro-acupuncture and moxibustion was used in the treatment of 95 patients with chronic PID. The outcomes from patients treated with acupuncture were then compared to the outcomes from 50 patients treated with antibiotics. Results are the practitioners' evaluation of improvement.

Patients treated with Chinese medicine were first sub-divided into groups according to their Chinese diagnosis. The key points used at each treatment within each group were identical. Moxibustion was used for all patients, except at times of acute flare-ups of the disease. Two points prescriptions were used alternately for an average of 23.5 daily treatments.

The total effective rate after acupuncture treatment was 88.4%, with 46% of cases receiving complete relief of all symptoms through treatment. Benefits were sustained for at least 1 year. Wang noted that those patients who had received treatment within the first year of developing pelvic inflammatory disease responded significantly better. The patients receiving antibiotics obtained an overall effective rate of 52%, with only 16% experiencing complete relief. 48% obtained no alleviation of symptoms through treatment. Thus, this study found electro-acupuncture and moxibustion to be significantly superior to antibiotics in the treatment of chronic PID ($p < 0.05$).

Discussion

A positive feature of the less rigorous outcome studies reviewed is that they provided the practitioner/researcher with the possibility of applying appropriately individualised treatment. A criticism is the lack of validated outcome measures and subsequent statistical analysis. However, it should be remembered that the overwhelming majority of these studies were not designed to 'prove acupuncture works.' Rather, the original intention was to promote the use of specific point combinations and techniques, to explore and open for discussion the finer points of acupuncture treatment. Even so these Chinese studies provide us with valuable evidence on the likely effectiveness of acupuncture in the treatment of these disease categories. Interestingly only one trial included lifestyle recommendations, despite their being an important aspect of Chinese medicine (Zhang 1984).

The controlled trials reviewed used simple formulaic acupuncture as a treatment. As diagnoses such as dysmenorrhoea cover a range of Chinese medical diagnoses their use is unlikely to provide an appropriate basis for treatment (Birch 1998). In addition the use of sham acupuncture in a control group may be unsatisfactory as it "*seems to have either an intermediate effect between that of placebo and 'real' acupuncture points or effects similar to those of real acupuncture points*" (NIH, 1997). As a result trials that use sham acupuncture as a control will systematically underestimate therapeutic gains (Vincent & Lewith 1995). Those comparing the acupuncture group to those treated with standard care such as drugs have a particular value for those allocating health care resources.

Both controlled trials were very small and could be viewed essentially as pilot studies. Some larger versions would be welcome.

Conclusion

The outcome studies demonstrated that acupuncture could be highly effective in the treatment of dysmenorrhoea, dysfunctional uterine bleeding and pelvic inflammatory disease, often helping over 80% of patients. In the 2 controlled trials significant results were achieved, and in one, acupuncture was shown to be more effective than drug therapy (Helms 1987). Altogether then, there is a growing body of evidence to support the value of acupuncture as a treatment for these gynaecological conditions.

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STUDY	SAMPLE SIZE	CONTROL	STATS	OUTCOME MEASURES	FORM OF ACUPUNCTURE REPORTED	NUMBER OF TX'S	RESULTS	FOLLOW UP
Helms JM 1987 Dysmenorrhea	11	NSAIDs & sham (at non-acupoints)	Yes	Monthly symptom evaluation form, questionnaire, pain intensity scale	Formula: SP4, KID3, ST36, ST30, REN 2,4, P6	12 tx.s over 3 cycles	91% improved, with 41% reduction in NSAID's at 6mth follow up	6 months
Liu W, 1988 DUB	30	NONE	No	Practitioner's evaluation Haematological indices	Formula according to TCM diagnosis	7 to 10 daily tx.s	Total effective rate 90%, significant benefits 80%	3 months
Steinberger & Slagowski 1980 Dysmenorrhea	48	NONE	No	Practitioner's evaluation	Formula: REN4, ST36, SP6, LI4	5 daily prior to one cycle	Total effective rate 80%, clinical cure 58%	6 months
Thomas et al 1995 Dysmenorrhea	17	Placebo TENS & sham (close to points)	Yes	Monthly symptom evaluation form, pain intensity scale (VAS scales)	Different formulaic mode each month: (SP6, SP9, BL32, REN4) manual, electro-ac.(LF), electro-ac. (HF), and sham	7 days and 3 days prior to bleed for 4 months	Significant improvements with all modes p<0.05 to p<0.001	3 months
Tureanu & Tureanu 1994 DUB	38	NONE	No	Practitioner's evaluation, mid-cycle LH values and cervical mucus studies	Individualised tx. according to TCM diagnosis	4 to 5 daily pre- & post-menstruation over a max. of 3 cycles	Total effective rate 84%, Clinical cure 84%	No
Wang X, 1987 Dysmenorrhea	100	NONE	No	Practitioner's evaluation	Individualised tx. according to TCM diagnosis	12+	Total effective rate 94%, clinical cure 54%	6 months
Wang XM, 1989 PID	95	Antibiotics	Yes	Practitioner's evaluation	Formula, according to TCM diagnosis	10+	Total effective rate 88%, clinical cure 46%	1 year
Zhan C 1990 Dysmenorrhea	32	NONE	No	Practitioner's evaluation	Formula, according to TCM diagnosis	3 daily prior to menstruation for a max. of 3 cycles	Total effective rate 97%, clinical cure 62.5%	No
Zhang & Wang 1994 DUB	50	NONE	No	Practitioner's evaluation	Formula: BL29, DU20, LI4, BL40, LU6 and extra point on Pericardium channel Needle technique by TCM diagnosis	10+	Total effective rate 100%, clinical cure 86%	6 months
Zhang Y 1984 Dysmenorrhea	49	NONE	No	Practitioner's evaluation	Formula, according to TCM diagnosis	8+	Total effective rate 98%, clinical cure 86%	3 months
Zhu & Zhu 1995 Dysmenorrhea	30	NONE	No	Practitioner's evaluation	Individualised tx. according to TCM diagnosis including key points: REN3, SP6, ST36	15+	Total effective rate 100%, clinical cure 60%	No

DUB = dysfunctional uterine bleeding

PID = pelvic inflammatory disease

Tx. = treatment