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COMPLEMENTARY MEDICINE & WOMEN'S HEALTH: EVIDENCE FOR INTEGRATION

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ABSTRACTS

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THE IMPROVED SURVIVAL IN PRIMARY NON-METASTATIC BREAST CANCER BY ADDITIONAL THERAPY WITH THE STANDARDIZED EUROPEAN MISTLETOE EXTRACT ISCADOR™

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Objective

To evaluate the therapeutic efficacy on survival and tumor events in patients with primary, non-metastatic breast cancer of long-term post-surgical complementary treatment with a standardized European mistletoe extract (Iscador™) administered in addition to the conventional oncological therapy and compared with the conventional therapy alone.

Material and Methods

We have chosen the design of a multicentre, comparative, retrolective, epidemiological cohort study with parallel groups and randomly selected centres, conducted according to the Good Epidemiological Practice (GEP) rules. Iscador™ was subcutaneously administered in the test group in addition to the conventional therapy, while the control group was treated with conventional therapy alone. All patients were followed for at least three years or until death. The primary endpoint criterion of efficacy was the multivariate adjusted tumor-associated mortality. The secondary endpoints were the adjusted overall survival, tumor-free survival, and metastasis-free survival.

Results

1,438 patients (708 tests and 730 controls) were eligible for the "per protocol" survival analysis. At baseline, the test group had a significantly more advanced disease and worse prognostic factors profile. The median follow up was 66 vs.60 months, with the median test therapy duration of 52 months. After adjusting for baseline imbalance and confounder effects, the adjusted hazard ratios were: 0.08 (0.008-0.88), $p=0.039$ for tumor-associated mortality (TS), 0.07 (95% CI, 0.008-0.65), $p=0.019$ for overall mortality (OS), 0.51 (0.11-2.42), $p=0.396$ for tumor-free survival (DFS) and 0.13 (0.015-1.15), $p=0.067$ for metastasis-free survival (MFS). These results were confirmed in sub-group and sensitivity analyses.

Conclusion

The complementary therapy treatment of primary, non-metastatic breast carcinoma patients with Iscador™ was associated with significantly improved tumor-associated survival and overall survival compared to the control group. The tumor-free survival and metastasis-free survival showed a distinctive nonsignificant trend to beneficial results in the test group.

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AROMATHERAPY IN CHILDBIRTH

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This contribution comprises a presentation of key findings from an evaluative investigation on the use of aromatherapy during labour (Burns et al 1999). The study took place over an eight-year time frame on the delivery suite of a large and busy teaching unit, the John Radcliffe, Oxford. The author was inspired to research the administration of essential oils for two reasons: first to extend the choices available to mothers in offering an option, which would not obviate mobility and self-realisation during labour and birth, that is, maximize her innate physiological coping mechanisms; second to provide midwives with a tool to facilitate them to adopt a less technocratic care model.

It was a challenge introducing aromatherapy in this context, especially as there was no evidence on aromatherapy use intrapartum, although some studies were retrieved from other contexts that could be transferable. After a brief pilot, the study evolved to include a sample of over 8000 women, generating a significant and unique database.

The presentation shall outline the ten essential oils used in the study and rationale for their selection; describe the points during labour when the women used aromatherapy; their and their caregiver ratings of effectiveness and trends that emerged in the modes of administration. Adverse associated effects will be presented, alongside an insight into user and caregiver comments on the experience of receiving and giving aromatherapy. Since publication of the main report on the study and subsequent publications (Burns et al 2000, Burns and Blamey 2000), further analysis has been undertaken to explore the impact of aromatherapy on the uptake of pharmacological analgesia, epidural in particular and this outcome shall be included, comparing it to a control group who gave birth in the unit over the same time as the study (Burns 2002).

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ACUPUNCTURE FOR PAIN AND SYMPTOM CONTROL IN WOMEN WITH CANCER

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Complementary and alternative medicine (CAM) is increasingly popular with the general public and cancer patients are no exception. Between 7% and 64% (average 31.4%) used acupuncture in a survey of 26 surveys on CAM use in cancer patients.¹ Most people access CAM alongside conventional treatment at diagnosis, disease progression, or for palliation of pain and symptoms near the end of life. Only a small minority, use it as a complete alternative to conventional treatment, fortunately, as it is a very risky option.

Acupuncture, the ancient Chinese art of healing has its origins in China several thousand years ago and involves the insertion of a number of fine needles into specifically chosen points to alleviate symptoms and for curative purposes for a number of less serious health problems.

Acupuncture releases multiple endogenous analgesic substances, including β -endorphin, enkephalins and dynorphins, serotonin and oxytocin, and its actions can be blocked by pre-treatment with local anaesthetic injections. It also has widespread autonomic effects and releases endogenous steroids. Though preliminary data shows acupuncture to have immuno-enhancing effects, clinical studies remain sparse in this area.² It is becoming more clear that a course of acupuncture 'up-regulates' analgesic gene production, and this can explain why 'top-ups' are required to maintain this gene expression in a 'switched on' mode and why a regular course of treatments, e.g. six weekly treatments, are necessary initially for chronic pain states.

Acupuncture is used to treat a number of pain and non-pain conditions and is accumulating an increasing evidence base, though the majority of papers are observational to date.³ Breast cancer and several forms of gynaecological cancer e.g. cancer of the cervix and ovarian cancer remain major causes of death, despite the numerous advances in treatment. Unfortunately, lung cancer is increasing in women despite a wide education programme against the dangers of smoking. Female as well as male patients develop many of the other forms of cancer e.g. bowel, kidney, CNS and leukaemias from the age of childhood onwards.

Many Western Medical Acupuncturists use a pragmatic approach to treatment following orthodox diagnosis and use a mixture of appropriate segmental points, trigger points and strong traditional points which have stood the test of time, though a traditional diagnostic approach is sometimes employed.

Acupuncture has been used to reduce acute peri-operative pain in patients having major gynaecological surgery,⁴ (Poulain, personal communication) and around breast surgery.⁵ It also improved early mobility in patients following axillary dissection.⁶ Acupuncture or acupressure have been shown to reduce nausea and vomiting around chemotherapy for breast cancer⁷⁻⁹ and peri-operatively.^{10;11}

Acupuncture has both helped pain and improved the circulation and mobility in patients with breast cancer.¹² Acupuncture can improve mobility to enable the patient

to achieve the correct posture for radiotherapy in selected cases and can reduce the pain and burning around a course of radiotherapy. It can reduce pain, depression, distress levels and interference with lifestyle after only three treatments.¹³ This was also combined with a significant reduction in depression scores after a month's treatment. However, this treatment was given alongside the therapeutic consultations both of which were likely to have a beneficial influence on the patient. Acupuncture has reduced advanced cancer-related breathlessness¹⁴ and semipermanent indwelling needles can help prolong the effects for both dyspnoea and anxiety. Acupuncture and TENS have enhanced graft survival around the flaps of reconstructive surgery in both animals and women.¹⁵⁻¹⁸ Acupuncture can reduce radiation proctitis which can be troublesome after radiotherapy to the cervix¹⁹ or abdomen in patients with gynaecological cancer.

Acupuncture has been found to help hot flushes due to hormonal manipulation for breast cancer in particular,²⁰⁻²³ and "do it yourself" (DIY) needling helping selected patients for up to six years.²⁴ Although acupuncture has been found helpful for women with irritative bladder problems,^{25,26} little work has been performed in patients with cancer and success is likely to be reduced in patients with reduced bladder capacity due to tumours or post-radiotherapy and for those with considerable inflammation.

Safety is of paramount importance in any treatment programme and some of the cautions and contraindications have been reviewed and will be described. Acupuncture should not be used in a lymphoedematous limb or around any spinal instability²⁷ and semipermanent needles are inadvisable in selected cases.

Though acupuncture represents only one form of treatment amongst a wide range of therapies for pain and symptom control, it represents an effective non-drug method for an increasing number of symptoms. It is hoped this field attracts further funding to support randomised controlled trials to compare acupuncture with other standard treatments.

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THE INTEGRATED APPROACH TO INFERTILITY

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Infertility is multi-factorial and needs to be investigated in terms of a number of areas including medical problems, lifestyle, age, nutrition, environmental and occupational hazards. It is vital with infertility to view the patient as a whole person and not just to focus on disease and treatment. This concept of Integrated Medicine is now becoming well recognised. The British Medical Journal in January 2001 (Rees L and Weil A (2001)), Integrated Medicine, *British Medical Journal*, 322, 120-1 discussed this approach whereby different schools of thought i.e. conventional and nutritional can be incorporated together into the diagnosis and treatment of a patient and that the consultation process and holistic approach helps to make patients feel more in control of their problem [Reilly DT and Taylor MA (1993) Review of the postgraduate education experiment. Developing integrated medicine: report of the RCCM research fellowship in complementary medicine. *Complementary and Therapeutic Medicine* 1 (suppl), 29-31].

This integrated approach is particularly important for fertility because of the many factors involved. There is now sufficient evidence from the literature to support the view that nutrition has a valuable part to play in infertility treatment both for men and women.

The evidence from the medical literature shows that many nutrients have an impact on both male and female fertility and the prevention of miscarriages. Along with the usual conventional infertility investigations should go nutritional assessments for nutrient deficiencies and a complete medical history that should highlight lifestyle factors such as smoking and drinking, as well as a previous history of dieting, eating disorders, low financial status and any other dietary restrictions.

To assess the benefits of nutrition, a group of women aged 32-43 were given nutritional assessments and subsequent dietary advice to follow before embarking on IVF treatment. They were asked to take a programme of supplements (including folic acid) and to look at other lifestyle factors including smoking, alcohol and caffeine intake. The women were tracked over 69 fertility treatment cycles. Results included a positive pregnancy rate of 49.3% and an ongoing/delivered rate of 37.7%. The Human Fertilisation and Embryo Authority licenses and collates the statistics for the IVF clinics in the UK and the average IVF live birth rate is 20-25% depending on age.

It is not enough now to just recommend couples to eat a 'well balanced diet' as it is clear from the research that most people are not getting adequate nutrient levels from their food alone. This is of particular concern with women who can be permanently watching their weight, restricting their calories and often on no fat or low fat diets with inadequate intake of essential fatty acids along with other nutrients. It is also not enough to supplement with only individual nutrients such as folic acid as the synergistic effect of nutrients needs to be considered.

Having nutritional assessment alongside routine fertility investigations is vital and may result in natural conception, especially where unexplained infertility, which makes up 30% of all cases, is implicated. This would save on drug treatment that comes under the NHS and may also reduce the need for IVF. There is a heavy burden on the NHS dealing with premature babies and babies with cerebral palsy

resulting from IVF multiple births, so any intervention that can lessen the need for IVF would be welcomed. It also means that if the nutritional approach increases the IVF success rate then it will lessen the number of IVF attempts a couple may need.

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BENEFITS OF INFANT MASSAGE FOR WOMEN WITH POSTNATAL DEPRESSION

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Background

Postnatal depression is a major problem, affecting about 10% of those giving birth each year, or about 70,000 in the UK alone. Several studies have shown that women with postnatal depression often, although not necessarily, have problems relating to their new baby. They can seem indifferent, and not smile or talk to their infants as much as other mothers do; alternatively they can be over intrusive and handle their babies roughly. The babies, in turn, often behave in a distressed and abnormal fashion, either with excessive crying or by becoming passive and withdrawn. The effects of this have been shown to persist until the infant is at least 18 months of age. Several studies have also shown that children of women with postnatal depression tend to do less well later, both in terms of their behaviour and their intelligence. This may well be, at least in part, because their mothers have not been able to give them the necessary stimulation and affection in the early months. Postnatal depression itself is readily treatable. However, although individual directed psychotherapy has been claimed to be of help, so far, no simple intervention has been shown to improve the early mother-baby interaction.

Attending a massage class had the potential to be of benefit for early mother–infant interaction as such classes specifically encourage mothers to look at and understand their babies, as well as interacting with them in a pleasurable manner. It has previously been shown that massage by a nurse is beneficial for such babies in a variety of ways. Benefits of massage have been claimed to include improved neuropsychological development, better sleeping patterns and weight gain. Massaged babies have also been claimed to have improved learning and recovery from habituation and relief with constipation and symptoms of colic. Massage and music therapy has also been shown to change the EEG patterns of depressed mothers.

Pilot study

In our pilot study we determined whether attending an infant massage class could help mothers with postnatal depression learn to interact better with their babies. The primary intended outcome was an improvement in the mother-baby relationship. A second possible beneficial outcome was an improvement in the mothers' depression.

First time mothers who gave birth to single healthy babies at Queen Charlotte's and Chelsea Hospital were posted the Edinburgh Postnatal Depression Scale (EPDS) at 4 weeks postpartum. This is a self rating scale which has been well validated as a screening tool for postnatal depression. All those who scored 13 or over, were asked to participate in the trial. They were assigned into either the massage or the control group, depending on the period of their recruitment. Baseline characteristics of the two groups were the same. Those in the massage group joined in the classes already ongoing at Queen Charlotte's.

Twelve in the massage group and 13 in the control group completed the study attending 5 sessions over a period of up to 8 weeks. The infants were on average 9

weeks old at the start of the study. All mothers attended a weekly directed support group session at which they were encouraged to discuss problems and offer mutual support.

The primary assessment was by video recording interaction between mother and baby. The EPDS scores showed that while the depression of control mothers who attended the support group improved over the period, the improvement of the massage group was significantly greater.

The primary measure was the scoring of the video film for mother–baby interaction. This showed that the initial scores for all the mothers were low, indicating poor interaction, as expected. The scores for the mothers in the control group stayed the same for the period of the trial. However the scores for the mothers who attended the massage classes improved greatly. The difference in the change in the mother-baby interaction score between the beginning and end of the trial, in the two groups, is highly statistically significant ($p < 0.001$). All the specific subscales for both mother and infant showed similar patterns.

Aims of current research

In our new research, this study is being repeated on a larger scale ($n=90$) and with a longer follow up, until the child is one year old. The mothers are having a diagnostic interview to assess their depression, and a non depressed control group is also being followed.

Conclusions

The benefit of the massage classes to the mothers and babies was very clear in the pilot study. Although other studies have shown that both counselling and drug treatment can improve mothers' depression, this is the first time that an improvement in mother-baby interaction has been established. However the study was small and only followed mothers up for the period of the trial. The new ongoing study should provide more definitive data concerning both the short and long-term benefits of infant massage for mothers with postnatal depression.

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HOMEOPATHIC MEDICINE IN A COMMUNITY CLINIC FOR PATIENTS WITH SYMPTOMS ASSOCIATED WITH THE MENOPAUSE

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Background

In 1998 Sheffield Community Health obtained a service development grant for 2.5 years to fund a complementary medicine service. Since October 1998 the service has been up and running offering patients homeopathy and aromatherapy through the Menopause clinics at the Central Health Clinic, Sheffield.

Aims/Objectives of service

To provide help for women with symptoms associated with the menopause where HRT is not recommended, not wanted or not successful.

Aims of service evaluation

In May 2001 Kate Thomas – Deputy Director of the Medical Care Research Unit, University of Sheffield and Dr Pat Strong – GP and Homeopath produced the final report: "**Complementary medicine service in a community clinic for patients with symptoms associated with the menopause: Outcome study and service evaluation**"

The aim of the evaluation was to assess how far homeopathy & aromatherapy was able to operate successfully within the menopause clinic and offer beneficial treatment. Beneficial treatment was defined as a measurable reduction of self-reported symptoms associated with the menopause. Secondary aims included

- to assess the demand for the service and the capacity of the service to meet the demand, including the appropriateness of the referrals received
- to estimate the average marginal NHS cost per patient treated by the service.

Description of service

The service is delivered at the Menopause Clinic in Sheffield which is

- situated in the City Centre at Central Health Clinic
- accessed by women living in the Sheffield area either directly or via primary health care team (GP or practice nurse)
- funded by Health Authority then Community Health Trust and now by South East Sheffield Primary Care Trust.

Patients with menopausal symptoms are

- assessed by a member of the clinical staff
- if appropriate a referral is made to one of the homeopaths
- seen by a homeopath for up to 6 sessions – one hour for the first appointment and 15 - 30 minutes for follow up appointment
- remain under the care of the clinical team throughout the treatment period.

Method of evaluation

The service was evaluated using a combination of qualitative and quantitative methods. An audit was undertaken of all patients referred to the Homeopathy/Aromatherapy Service from October 1998 and October 1999. A validated patient generated outcome measure (MYMOP) was employed to assess patient responses to treatment and treatment outcomes. MYMOP entails a one page schedule completed with the therapists at baseline to establish the main concerns of the patient at the time of referral, and measure their perceived severity. It is repeated

at each treatment to measure changes in the patients' perceptions of severity of their main problems.

Results of evaluation

The patients had a mean age of 50.5 years, and HRT use was 20%.

Patients were asked to complete the MYMOP form at their first visit. Completion requires the patient to select up to two symptoms for which they are seeking some relief, and to rate their general wellbeing.

Reported symptoms included the following problems: flushes, night sweats, tiredness, sleep problems, migraine/headaches, depression, irritability/tension, memory problems/confusion, aching joints/breast pain, mood swings and panic/anxiety.

MYMOP data was collected for 37 homeopathy patients. The results based on the data relating to these 37 cases show that the average MYMOP scores reduced significantly between the baseline and the sixth or final visit for each item ($p < .001$). No correlation was found between MYMOP profile score changes and any of the following factors: age, HRT status, therapy used or first MYMOP symptom identified ($p > .05$ for all correlations and interactions). No serious adverse events were reported by any patients.

The evaluation report established that the homeopathy service

- was highly acceptable to the vast majority of patients
- provided symptomatic relief
- was a valid alternative for relief of distressing menopausal symptoms when HRT is either inappropriate, unacceptable or inadequate

The cost of a completed course of homeopathic treatment was calculated at £80.50 per patient. Average number of appointments was 4.6 – 4.7. Cost is based on marginal NHS costs of therapists' fees, admin support and homeopathic medicines – accommodation and facility costs have not been included in the estimates.

Discussion & conclusion

The positive results of the evaluation indicate that the homeopathy service at the Menopause clinic was associated with clearly identifiable short-term positive benefits in the control of menopausal symptoms as detected by the MYMOP measure. These results suggest that women using the service are experiencing a substantial reduction in the burden of poor health associated with the menopause. Following the results of the service evaluation it became fully integrated into the Sexual & Reproductive Service Directorate. The homeopathy service continues to be funded by the PCT as part of the PMS/Menopause service to the city of Sheffield.

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A full copy of the service evaluation can be obtained from k.j.Thomas@sheffield.ac.uk or downloaded from www.wellforce.co.uk/research

A COHORT ANALYSIS OF PATIENTS TREATED AT THE BRITISH SCHOOL OF OSTEOPATHY EXPECTANT MOTHER'S CLINIC BETWEEN THE YEARS 1985 AND 2000

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Background

In 1984 it was decided that in order to formalise the teaching of the osteopathic care of the pregnant patient, a new clinic needed to be established at The British School of Osteopathy to look at the specific needs of this group. A new case history sheet was designed so as to make retrieval of information easier and so that research could be undertaken to analyse the information so obtained. In this way a trend analysis was achieved in certain key areas that was found to be of both sociological as well as statistical significance.

The clinic runs at the school's main building at London SE1 on Tuesday afternoons and Thursday mornings. Teams of 2 students treat each patient under the direct guidance and supervision of a senior clinical tutor. The majority of the patients are self referred or have been referred by their midwife. Some come from the GP and very few arrive with a letter from their obstetrician.

The Treatments

The treatments consist firstly of a thorough tissue analysis, a postural analysis, and then manipulations applied to the soft tissues and to the joints of the spine and pelvis. The aim of the treatments is, firstly, symptomatic relief and, secondly, to prepare the patient physically for the remainder of her pregnancy and for her labour.

Methods

A cohort analysis of the first 800 patients seen in the clinic after the patient has been discharged or been deemed to be no longer coming for treatment. Each cohort of 100 patients was assessed against each other cohort by seeking the same information from each group. Thus any trends could be identified across the study populations.

Results

The trend analysis showed the following to be true:

1. Most of the patients seen were between 26 and 35 years of age.
2. Most of the patients are primiparous.
3. They present for treatment in the mid trimester but the pain has been there for a few weeks beforehand.
4. Most problems will be Sacro Iliac Joint or Lumbar facet joint pain with muscular and ligamentous pain giving a mixed picture within the analysis.
5. There is usually a previous history of musculo-skeletal pain.
6. The majority of patients gain a high degree of symptomatic relief within 2-6 visits.

7. Only a small number are made worse (>2%) and there are no contra indications from the point of view of the foetus.

Conclusion

From the study we conclude that osteopathic treatment is a safe and effective means of dealing with this group of patients who are difficult to treat with other modalities. It is also cost effective from the point of view of the NHS and Primary Care Groups in particular.

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THE SAFETY AND EFFECTIVENESS OF ACUPUNCTURE FOR WOMEN WITH NAUSEA AND VOMITING IN EARLY PREGNANCY: A RANDOMISED CONTROLLED TRIAL

Smith CA, Crowther CA, Beilby J, Dandoux J.

Background

Nausea and vomiting in pregnancy are common symptoms experienced by women in the first trimester of pregnancy. Nausea affects 70-80% of women, and 50% of women vomit. The Cochrane systematic review of interventions for nausea and vomiting in early pregnancy describes the results from four trials of Pericardium 6 (PC6) acupressure as helpful (Jewell and Young 2002). None of the studies included are of high quality. There is a need to demonstrate both the efficacy and safety of acupuncture in pregnancy.

Hypothesis

To assess whether acupuncture was better than sham acupuncture or no acupuncture with reducing nausea, dry retching and vomiting during early pregnancy. A secondary hypothesis of the trial was:

- acupuncture in early pregnancy for women experiencing nausea and vomiting in early pregnancy has no adverse effects.

Methods

Women were eligible to join the trial if they were less than 14 weeks pregnant, with symptoms of nausea, dry retching or vomiting. Randomisation used a central telephone randomisation service, with 593 women randomly allocated into four groups; 1) traditional acupuncture, 2) PC6 acupuncture 3) sham acupuncture and 4) no acupuncture control. Women attended a weekly treatment session for four weeks. Assessment of women's symptoms was made at day 1, 7, 14, 21 and 26 using the Rhodes index of nausea and vomiting. Pregnancy outcome data were collected from women six weeks after their expected date of delivery. Primary endpoints were women's experience of nausea, dry retching and vomiting. Data were analysed using analysis of variance or the Kruskal Wallis one way ANOVA for data not normally distributed.

Results

At the end of the first week in the trial women receiving traditional acupuncture reported less nausea compared with women in the no acupuncture group ($p < 0.05$). During the second week women receiving traditional acupuncture ($p < 0.001$) and PC6 acupuncture ($p < 0.05$) reported less nausea compared with women in the no acupuncture control group. From the third week women in the sham acupuncture group also reported less nausea compared with women in the no acupuncture control group ($p < 0.01$). These improvements continued into the fourth week ($p < 0.01$). Differences in women's experience of dry retching were first demonstrated at the end of the second week of the trial. Women receiving traditional acupuncture experienced less dry retching compared with women in the no acupuncture control group ($p < 0.01$). During the third week of the trial women in the traditional acupuncture ($p < 0.001$), PC6 acupuncture ($p < 0.01$) and sham acupuncture ($p < 0.001$) all experienced less dry retching compared with women in the no acupuncture control group. No differences in vomiting were found between study groups. No differences were found between the study groups in the incidence of spontaneous abortion, stillbirth or neonatal death.

Conclusion

Acupuncture can be considered a safe and effective, non pharmacological treatment option for women who experience nausea and dry retching in early pregnancy.

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EFFECTIVENESS OF GINGER FOR TREATING NAUSEA AND VOMITING IN EARLY PREGNANCY: A RANDOMISED CONTROLLED EQUIVALENCE TRIAL

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Background

Evidence on the efficacy of ginger has been evaluated in three randomised controlled trials (Fischer et al 1990, Vutyavanich et al 2001 and Willetts et al 2003), a Cochrane systematic review of interventions to treat nausea and vomiting in pregnancy (Jewell and Young 2003) and a systematic review of ginger for nausea and vomiting (Ernst and Pittler 2000). The Cochrane review currently includes one trial and concluded one gram of powdered ginger maybe helpful.

Evidence of effectiveness for treatment of nausea and vomiting in pregnancy exists for a range of treatments for nausea and vomiting in early pregnancy, because of the range of medicines already available it was considered evaluation of ginger in a placebo controlled trial would be unethical. Therefore we chose to use an active comparator of a treatment regularly used for nausea and vomiting for this trial. We carried out a randomised controlled equivalence trial of the effectiveness of one gram of ginger and the recommended dose (25mg three times a day) of vitamin B6 to treat nausea and vomiting in early pregnancy.

Methods

Randomised, controlled equivalence trial involving 291 women less than 16 weeks pregnant. The trial was undertaken at a teaching hospital in Australia. Women took 1g ginger or 75mg vitamin B6 daily for three weeks. Differences from baseline in nausea and vomiting scores were estimated for both groups at day seven, 14 and 21.

Results

Ginger was found to be equivalent to vitamin B6 with reducing nausea, dry retching and vomiting ($p < 0.001$). The majority of women tolerated both medications although more women taking ginger reported belching more frequently compared with vitamin B6 ($p < 0.05$). No differences were found in pregnancy outcome between groups.

Conclusion

For women looking for alleviation of their symptoms the use of ginger will decrease their symptoms to an equivalent amount to vitamin B6.

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ACUPUNCTURE IN THE TREATMENT OF FEMALE INFERTILITY

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Introduction

During the last decade, the popularity of acupuncture among childless couples hoping for pregnancy has increased. An understanding of the physiological principles of acupuncture is important when refuting the argument that the effect of acupuncture is implausible because it relies on concepts of changing the flow of energy in meridians. In acupuncture, the manipulation of a needle in the skin and underlying muscles excites afferent nerve fibers. Information from these afferent nerve fibers—when located in the same segment as the innervation of the pain or organ—is well known to inhibit pain transmission and sympathetic outflow at both the spinal and central levels as well as to modulate the endocrine system and elicit psychological responses. Below, a few applications of electro-acupuncture (EA) have been chosen for discussion.

Acupuncture effects on hormonal disturbances and anovulation

Recently, we conducted a study on women with a well-defined diagnosis of polycystic ovary syndrome (PCOS) and anovulation to elucidate the effect of repeated EA treatments on endocrinological and neuro-endocrinological parameters as well as on anovulation (Stener-Victorin et al. 2000b). The study showed that repeated EA treatments exert long-lasting effects on both endocrinological parameters and anovulation. It appears that acupuncture may have a beneficial effect on women with PCOS and anovulation, and might serve as a complement to first-line therapy in ovulation induction. Both clinical and experimental evidence support this observation. Whether acupuncture improves the pregnancy rate in women with PCOS remains to be shown. Other studies have reported favorable outcomes such as ovulation induction; a regulatory effect on gonadotrophins, estrogens and neuropeptides; and a tendency towards reduced miscarriage rates compared with hormonal treatment (Chen and Yu 1991; Gerhard and Postneek 1992). These studies shed no light on the underlying mechanisms of EA, but the effect was attributed to an inhibition of high activity in the sympathetic nervous system. Recent experimental data indicate that EA modulates activity in the sympathetic nervous system and the endocrine system (Stener-Victorin et al. 2003a; Stener-Victorin et al. 2001; Stener-Victorin et al. 2000a).

Applications in human assisted reproduction

Endometrial circulation. Successful in-vitro fertilization (IVF) and embryo transfer (ET) require optimal endometrial receptivity at the time of implantation. Endometrial circulation is considered valuable in assessing endometrial receptivity. In one uncontrolled study it was found that repeated EA treatments increase a low blood flow in the uterine arteries to normal levels (Stener Victorin et al. 1996). This is an interesting finding, but we don't know if acupuncture improves the implantation rate—only that it improves the uterine blood flow. Groups with large numbers of patients will be required to determine this issue.

Embryo transfer and acupuncture. In a recent study, the effect of acupuncture on pregnancy rate in IVF treatment was evaluated by comparing a group of patients receiving acupuncture treatment shortly before and after ET with a control group

receiving no acupuncture (Paulus et al. 2002). Clinical pregnancies were significantly higher in the acupuncture group, compared with the control group. Their conclusion was that acupuncture seems to be a useful tool for improving pregnancy rate after IVF. These observations are interesting. However, the statistics in the study can be criticized since no power calculation was presented. Thus, this result can be misleading and must be interpreted with care. A large number of patients is required to be able to determine whether there is a true difference in pregnancy rate between the groups.

Ovum pick-up and acupuncture analgesia. Optimal pain relief during ovum pick-up (OPU) is an important goal since many women undergoing IVF treatment suffer great stress and anxiety and many need to undergo repeated attempts before success is achieved. In two recent studies, the analgesic effect of EA in combination with a paracervical block (PCB) was compared with conventional pharmacological analgesia during OPU. In both of these trials, EA in combination with PCB was reported to be as effective as conventional pharmacological analgesia without any reported negative side-effects (Stener-Victorin et al. 1999; Stener-Victorin et al. 2003b). There were no differences between the groups regarding pain during OPU. Two hours after OPU, the women who had received EA as analgesia during OPU reported significantly less abdominal pain, nausea, and stress compared with the women who had received conventional pharmacological analgesia (Stener-Victorin et al. 2003b). In addition, the EA group requested significantly lower amounts of additional opiates for pain relief (Stener-Victorin et al. 2003b). Such a reduction is most likely desirable since alfentanil has been found in the follicular fluid shortly after i.v. injection. In the first study, the pregnancy rate was significantly higher in the EA group. For that reason, the study was repeated with a larger number of patients. This time, no significant differences were found between the EA and the alfentanil groups. These studies support the view that EA can be a valuable alternative to conventional analgesics in OPU-assisted reproduction since the pain relief peroperatively is as good as that induced by conventional analgesics.

General conclusion

The definitive role of acupuncture in the treatment of female infertility has yet to be established. The potential impact of acupuncture on the hypothalamic-pituitary-ovarian axis and peripherally on the ovaries and uterus is promising but needs to be further investigated. However, the evidence now appears to be sufficient to allow acupuncture to be added to the arsenal of pain-relief techniques used in conventional medicine and in the treatment of female infertility. Furthermore, it is vital that further research into the underlying mechanisms of the effects of acupuncture is encouraged and that the clinical value of acupuncture is established.

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THE HOMEOPATHIC APPROACH TO SYMPTOMS OF OESTROGEN WITHDRAWAL FOR WOMEN WITH BREAST CANCER

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In the past six years a team of us have been exploring the homeopathic approach and its role in symptom control in the patient with cancer¹. In particular we have been able to explore the benefits of homeopathy for women with breast cancer and difficult menopausal symptoms. The research thus far has suggested statistically significant improvements for these difficult symptoms with significant improvements in anxiety and depression and quality of life over the study periods.

The lead researcher is a Consultant Homeopathic Physician and Senior Lecturer in Palliative Medicine and has been able to offer an integrated service within the National Health Service. Women with a variety of cancers are able to combine their conventional treatments with homeopathic medicines sent to them directly from the homeopathic pharmacy within the trust. Referrals can be made to the designated cancer clinic; from General Practitioners, Hospital Consultants and Senior Nurse Specialists and patients feel their desire to use Complementary Therapies is acknowledged and supported. Communication between the different members of the extended team is valued and encouraged and there have been opportunities to see women on hospital wards to integrate their conventional and complementary therapies at the bedside. Satisfaction has been very high for patients attending the clinic.

Research collaboration has extended across to primary care; the acute trust, local therapists including herbalists, acupuncturists, cranio-sacral therapists and centres of excellence such as the Bristol Cancer Help Centre.

A team of doctors and therapists have also participated in medical undergraduate training in Whole Person Care based within the University, exploring ways of learning about mind body approaches and integrating them into doctors working practices.

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ACUPUNCTURE IN THE TREATMENT OF FEMALE INFERTILITY

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Objective

To evaluate the effectiveness and acceptability of using traditional acupuncture to manage hot flushes and night sweats experienced by women taking Tamoxifen as an adjuvant treatment for breast cancer.

Materials and methods

52 women were given 8 acupuncture treatments administered at weekly intervals, according to traditional acupuncture diagnosis and individualised treatment plans. Participants were recruited from women who had treatment for early breast cancer at the Cancer Treatment Centre at Mount Vernon Hospital (MVH), Northwood, Middlesex, or who were under the care of an oncology consultant at MVH.

Participants needed to be female, age 35+, to have a diagnosis of primary breast cancer, have a good prognosis, and to have been taking Tamoxifen as an adjuvant treatment for a minimum of 6 months. It was also required they be a minimum of six months since completing active anti-cancer treatment (surgery, radiotherapy, and adjuvant chemotherapy). They needed to have been experiencing hot flushes for at least 3 months, and to be reporting an average of at least 4 incidents per 24-hour period.

Outcome measures included:

Hot Flush and Night Sweat Diaries – this measured frequency and severity of flushes and sweats at 2-hourly intervals for 14 days

Women's Health Questionnaire (WHQ) – this validated tool measures emotional and physical health of mid aged women

Subjective Measures: Hot Flush and Night Sweats Questionnaire – examines the extent to which flushes are distressing, interfere with daily life, and are perceived to be a problem.

Participants were monitored for 30 weeks, and were measured at five points during this period: at baseline, and at 6, 10, 12, and 28 weeks.

Acupuncture Protocol

Participants were treated using traditional acupuncture. At their first treatment appointment, a full consultation (Traditional Diagnosis) was carried out, including pulse and tongue diagnosis. Treatment planning comprised a standard protocol to counteract the effects of the Tamoxifen, and this was combined with acupuncture points selected specifically for each participant, according to her constitution and other presenting symptoms.

Point selection and procedures were chosen from classical texts, modern principles of Traditional Chinese Medicine, and from the Five Elements School of practice.

Results

50 participants completed as per the protocol. Initial quantitative analysis indicates that on completion of 8 acupuncture treatments, the frequency of hot flushes was reduced from a mean of 10.75 to 6.5 per day ($p=0.0001$). At end of treatment (EOT), 89% of participants had a reduction in the frequency of their flushes and 36% had at least a 50% reduction. Measurement one month after treatment shows that 28% of participants were still showing at least a 50% reduction over baseline, with 87% still showing an improvement. The mean reduction in frequency at EOT was 42.4%.

Initial analysis of the Women's Health Questionnaire confirms the reduction in vasomotor symptoms. It also indicates that women experienced an improvement in their somatic symptoms, had improved quality of sleep, and that anxiety and depression levels were reduced. Paired t tests show that the changes between Baseline and EOT are significant in all the aforementioned areas, with the exception of depression.

Preliminary analysis of subjective feedback suggests that women felt this was a beneficial treatment for managing flushes and sweats, and for improving overall quality of life. One participant wrote that the course of treatment "...reduced hot flushes by 50% and the intensity from severe to moderate. Night sweats decreased to 1 per night instead of 3. Some nights had none at all...Generally, I feel a lot healthier and can do a lot more".

Conclusion

This study introduced traditional acupuncture into an NHS setting, and it was well received by patients, consultants, and other healthcare professionals. Acupuncture can play a role in reducing hot flushes and night sweats resulting from treatment with Tamoxifen, and in improving the emotional and physical well-being of patients. Further investigation is warranted, and is being planned.

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WOMEN WITH PRE-MENSTRUAL SYNDROME UNDER HOMEOPATHIC TREATMENT: IMPROVEMENTS IN HEALTH AND QUALITY OF LIFE

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Background

Describing and understanding reality is the main goal of science. To understand the reality of health and illness, one needs to confiscate illness from the narrow context of the physical, and decipher it as a simultaneous event of both body and mind, with individual and environmental aspects. Alternative or holistic medicine is by definition oriented that way, and the validity of its clinical researches should be obtained with results describing multiple variables and points of view regarding the curative process. Referenced that way it may draw nearer to the possibility of describing reality - which is the person as a whole - essentially the goal of our treatments.

Research aim

To convey diverse aspects of the efficacy of homeopathic treatment in premenstrual syndrome (PMS).

Design

Randomised, controlled, double-blind clinical study of classical homeopathy with individualized treatment versus placebo.

Participants: women volunteers, suffering from PMS, otherwise healthy.

Intervention

A single dose of homeopathic medication, prescribed on the basis of a protocol of symptom clusters, with reference to the key symptoms that indicates one of 14 predefined medications in 200c, administered randomly with its parallel masked placebo, on the seventh day of the menses.

Setting: A university hospital outpatient obstetric clinic, Jerusalem, Israel.

Outcome Measures

(a) Evaluation of a daily menstrual distress questionnaire (MDQ) two months before and three months following treatment (1); (b) sick days (c) external medication usage; (d) self-assessments; (e) changes in Psychological traits.

Results

96 women completed the treatment. The results, similar to those found in the pilot study preceding this one (2), are summarized as follows: After the end of 3 months follow-up, more women in the Active treatment group - compared to the Controls - perceived themselves as suffering less (44% vs. 34%), in less need of treatment (1.8 vs. 2.37, $p=0.03$ 1-tailed,) and generally felt that they improved more (1.4 vs. 1.1, $p=0.0035$). 47% vs. 22% felt that they don't need further treatment. The homeopathically treated group improved significantly in PMS scores: 0.35 vs. 0.2, (ANOVA $p=0.05$); reduced sick days by 90% (no change in the Controls, $p=0.007$); Reduced Significantly concomitant medications intake (75% vs. 36%, t-test $p=0.03$); and displayed greater general improvement in health during the rest of the month - the non-PMS period (0.21 vs. 0.08, $p=0.05$).

In addition, social desirability and defensivity (Marlow-Crowne's social desirability scale (3)) increased in the active treatment group compared to the control (non-sig.) and, as it was correlated with high improvement ($r=0.44$, $p=0.005$), this demonstrated women in the active group were able to stand up for themselves more, which is an important quality for PMS sufferers.

The attributes of the improved women were different. In the active treatment group the women suffering most were the ones to improve the most (see figure). The control group did not improve. In general, women who suffered greatly from PMS were highly anxious (Taylor's Manifest Anxiety Scale (3)). In the active group, highly suffering women displayed lower anxiety levels after treatment (from 11.7 to 9.9), while in Controls they stayed the same. The combined test: Wienberger Repressibility index (3,4) tended to be in the Active treatment in reverse correlation with improvement: that is, women who improve became less repressive and so more "open". (Pearson Correlation. r changes from -0.05 to -0.28, $p=0.09$). In Controls – no "opening" occurred. (r did not change: 0.1 to 0.09).

Conclusions

The study has demonstrated repeatedly effectiveness of homeopathic treatment over placebo, associated with amelioration of PMS symptoms but also with improved general well-being, reduced Sick-days and medications. Those were met with the women's self-assessments and psychological measurements. The results demonstrate the limit of placebo to generate deep changes in many aspects of life - in comparison to homeopathic treatment: The placebo effect was shown to be ineffective in reaching deeply into the body or mind: High suffering and fundamental emotional traits were hardly altered by placebo. Using mean changes of the PMS outcome measure was not sufficient in revealing such differences. Further wide-ranged aspects trials are called for.

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BIOGRAPHIES

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MARILYN GLENVILLE is a nutritional therapist who obtained her doctorate from Cambridge University. She is a Fellow of the Royal Society of Medicine and was also an observer on the Food Standards Agency's Expert Group on the safety of Vitamins and Minerals. Dr Glenville is also a steering group member on the Food and Health Forum at the Royal Society of Medicine. She is the author of a number of best selling books including 'Natural Solutions to Infertility' and she practises in a gynaecology clinic in London.

VIVETTE GLOVER was trained as a biochemist at Oxford and did her PhD University College London. She then moved to Queen Charlotte's and Chelsea Hospital, where she worked in the field of biological psychiatry. In more recent years she has applied this expertise to the problems of mothers and babies. She is currently Professor of Perinatal Psychobiology in Imperial College, London. She has published over 350 papers. She is Director of the Fetal and Neonatal Stress Research Group. The aims are to study fetal and neonatal stress responses, methods to reduce them, and long term effects. The effects of psychopathology in the mother, both on the developing fetus and on the neonate are a major focus of interest.

CLARE RELTON qualified as a homeopath in 1994 after four years study at the North West College of Homeopathy in Manchester. She has been in practice as a homeopath since then. Since 1998 she and Dr Pat Strong have provided homeopathic treatment for menopausal women at the Menopause clinic in Sheffield's NHS Central Health Clinic. She also is Director of the Wellforce Complementary Medicine Service in Sheffield – a private clinic specialising in homeopathic medicine.

CAROLINE SMITH has a background in acupuncture, women's health and international health. Before emigrating to Australia Caroline gained her professional qualification in acupuncture. Caroline completed her PhD at the University of Adelaide, her thesis titled randomised trial of acupuncture to treat nausea and vomiting in early pregnancy. Caroline has secured research grants to undertake further randomised controlled trials of acupuncture to treat period pain, induction of labour, the treatment of infertility and an evaluation of ginger to treat nausea and vomiting in pregnancy. Caroline will be taking up a new senior academic appointment at the University of South Australia in July.

ELISABET STENER-VICTORIN is a physiotherapist from Sweden who has worked clinically with acupuncture since 1987, and with lecturing in the subject since 1988. She also works with acupuncture research since 1991 and main focus has been to investigate the effect of electro-acupuncture (EA) in reproductive medicine both in clinical and experimental studies which ended up in a Ph.D. at the department of obstetrics and gynaecology, Göteborg University 2000. After that she has continued as a researcher both at the department of physiology and the department of obstetrics and gynaecology, University of Göteborg, Sweden, investigating the pain relieving effect of EA, the effect of EA on sympathetic nervous system and on immune functions. She has also been in Japan for postdoctoral research in collaboration with professor Mieko Kursosawa, University of Health and Welfare, Basic Medical Research Center, Otawara, Jpan. In addition she is supervisor for students in their research work investigating the effect of acupuncture in different conditions. From January 2002 she work part time as lecturer at the Institute of occupational therapy and physiotherapy, Göteborg University, Sweden. She is chairman in the national committee Physical Therapy Division of Pain and Sensory Stimulation and member in the international committee related to acupuncture research (IARF).

ELIZABETH THOMPSON is the lead clinician for the cancer service from the Bristol Homeopathic Hospital, part of an acute hospital trust. She is an Honorary Senior Lecturer within the Department of Palliative Medicine at Bristol University and is collaborating in a number of research projects investigating complementary and alternative medicines in the cancer setting. Her particular research interests have been the role of homeopathy in symptom control and she clinically offers an integrated approach to supportive cancer care. She has co-authored the chapter on Complementary Therapies in *The Handbook of Palliative Care*.

BEVERLEY DE VALOIS qualified as a professional acupuncturist in 1998, after studying at the College of Integrated Chinese Medicine in Reading, and in China. She works part-time as Research Acupuncturist at the Lynda Jackson Macmillan Centre. She also sits on the British Acupuncture Council Research Committee. She has worked in the cancer sector since 1996, as an aromatherapist with the Macmillan Team at the North Middlesex University Hospital. Beverley is also a Senior Lecturer in the Centre for Complementary Healthcare and Integrated Medicine at Thames Valley University. Her private clinic, the Women's Clinic @ Uxbridge, specialises in complementary healthcare for women.

MICHAL YAKIR is a registered homeopath, Chairwomen of the Israeli Association for Classical Homeopathy and the editor of the Association professional journal. She has MSc in Environmental Biology and completed PHD thesis in homeopathy (first ever) at the Hebrew University Medical School, Jerusalem, Israel. Her 10 years research focuses on women's predicaments - mainly PMS - treatment with homeopathy.