

SUMMARIES OF
CLINICAL TRIALS AND STUDIES

SEA  BAND[®]

for the prevention and relief of nausea

Summaries of some clinical trials and studies of the Sea-Band and acupressure on the P6 point for travel sickness, morning sickness, chemotherapy and post-operative nausea.

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Summary of 'Power of pressure' by Anna Woodham

Research into acupressure is continuing, as it is in acupuncture. Two major reviews of high quality trials of acupressure concluded that results were sufficiently positive to call for further studies. All stressed the benefits to patients of a non-invasive, patient-controlled and inexpensive treatment for nausea and vomiting.

At the same time, an explanation to satisfy Western science is evolving. Researchers exploring the mechanism behind acupuncture (and by extension acupressure) are finding evidence that chemical messengers in the nervous system could be the link between acupoint stimulation and a physiological response.

Too few health professionals are aware of the research results and the potential of acupressure wristbands to help relieve nausea and vomiting in travel sickness, morning sickness, post-operative care and chemotherapy. Even in severe cases, the bands may enhance the effect of antisickness drugs and allow dosage to be reduced.

Those practitioners who are aware of the benefits may not recognise that correct positioning on acupoint P6 is vital if the bands are going to work. Yet with a little training, the therapy is simple, effective and cheap. Acupressure has been a neglected adjunct to modern medicine for too long.

Can we afford to continue to ignore it?

Acupressure

What traditional Chinese medicine says

Acupressure is one of several techniques used in traditional Chinese medicine. Developed over 4000 years of critical observation and testing, this system is very different in philosophy and practice to Western science. Western doctors start with a symptom and look for a specific cause or disease. A Chinese medical practitioner will treat the symptom as only one factor in the individual's entire physiological and psychological profile, which must be studied to find 'the pattern of disharmony'.

According to traditional Chinese medicine, illness results from an imbalance in the flow of Chi ('life energy') through the body. The original meaning of Chi (pronounced 'chee' and sometimes spelt 'Qi') was simply air, breath or energy, but it eventually came to mean the vital nourishing and protective energy that sustains everything in the world. Chi is animated by a constant movement of energy between yin and yang, two opposing but complementary forces. When one predominates, the flow of energy is disturbed and disease and emotional instability can result.



Chi circulates through the body along a network of invisible channels beneath the skin called meridians. There are 12 basic meridians, paired on the right and left sides of the body and named after the internal organs to

which they are attached, such as the lungs, large bowel and (in the case of P6) the pericardium.

Pericardium 6 (P6) functions include the movement of energy in the chest, harmonisation of the digestion and stomach, the regulation of blood flow and calming of the mind.

The Chinese use acupressure on it to treat chest pain, irregular and painful periods, pre-menstrual depression, insomnia and because of its influence on the stomach - to relieve nausea and vomiting, acid regurgitation, hiccupping and belching.

What Western Science says

So far there is no scientific evidence to support the existence of 'chi' or 'meridians,' despite studies that show acupuncture and acupressure can be effective in relieving nausea, vomiting and pain. Western doctors prefer to seek other, more medically acceptable, explanations for the phenomenon.

Since the 1970s convincing theories have emerged for the mechanisms behind acupuncture (and by extension acupressure). Initial studies into the pain-relieving properties of acupuncture led researchers to conclude that the most likely answer lay in the involvement of morphine like chemicals known as endorphins and the 'gate control theory' of pain relief. In 1982, researchers showed that needling released endorphins in the central nervous system.

In simple terms, nerves carrying pressure signals reach the brain faster than pain messages. As the brain can receive only so many messages at once, the 'gate' is closed by the time pain signals arrive.

Pressure appears to stimulate nerve fibers running up the spinal cord and ultimately result in production of endorphins. These transmitters, also called 'endogenous opioid peptides', are morphine-like compounds which influence the hormonal and immune systems and inhibit the brain's perception of pain, especially when associated with anxiety and stress.

But why, for instance, should the stimulation of specific points and not others trigger certain responses in the brain and by what means are reactions prompted in another, seemingly unrelated part of the body?

Western physicians have known for many years that pressing, stimulating or injecting various points on the skin can help relieve pain. These points, known as trigger points, or motor points, may be some distance from the site of the pain – a phenomenon known as 'referred pain.' By and large they correlate with traditional acupuncture points. Acupuncture and acupressure are regarded as complementary to drugs or surgery or whatever else the patient requires.

Motion Sickness

Sea-Band Trial in Motion Sickness

Hospital San Carlo Borromeo, Milan, Italy by Professor G. Canova 1990

INTRODUCTION

The methods normally used to cure motion sickness in children have proved to be only partially efficacious, and not without side effects. This has led us to look for an alternative method to improve efficacy and suppress side effects.

METHOD

Acupressure is found useful in the suppression of nausea in the first three months of pregnancy. The means is a bracelet called Sea-Band, in a stretch fabric, with a pressure button. There is no doubt that this method can only be tried in paediatric because there are no risks of harmful side effects.

We distributed 106 pairs of bracelets with instructions and a questionnaire.

The patients were chosen from the paediatric unit of San Carlo Borromeo Hospital in Milan, they were between 2 and 15 years of age and all had a history of violent travel sickness. The trial took place between Jan. 31 1990 and March 31 1990. 62 questionnaires were returned.

RESULTS

The answers concerned travel exclusively in cars, except for one by ship.

55 cases (88.7%) had excellent results. All the parents had had previous experience of the child being sick.

In 7 cases the results had to be analysed:

In 4 cases (6.4%) vomiting was experienced during the first and second journeys out of a total of five. For the remaining three journeys only nausea was experienced.

Out of those 4:

One boy of 10 years had gastric illness

One girl of 11 had a head problem

One girl of 13 an ovary dysfunction

The parents in those cases mentioned that their children always suffered from serious travel sickness and that they would normally have been sick on every trip.

The other 3 cases (4.8%) suffered from nausea but the parents still reported an improvement on previous experience.

CONCLUSION

In some cases the bands might have been positioned incorrectly but the overall results, in spite of this possibility, are very good. The chosen subjects were very difficult ones who normally suffered intense vomiting even on short journeys.

Considering the very positive results and the obvious absence of harmful side effects, Sea-Bands can be a very useful method of preventing motion sickness in children.

Conducted under the direction of Professor G. Canova.

Pregnancy

The efficacy of Sea-Bands for the control of nausea and vomiting in pregnancy.

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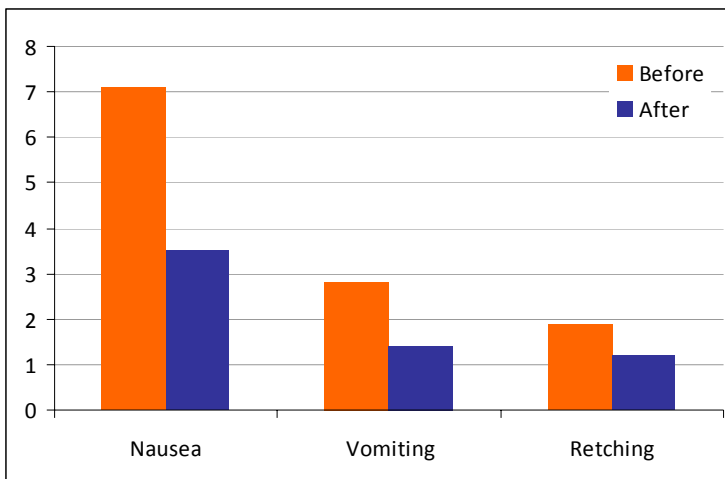
Published in Health Care for Women International, 15:563-575, 1994

SUMMARY

Twenty-seven pregnant women (5-22 weeks gestation) participated in a study to determine the efficacy of Sea-Bands for the control of nausea and vomiting in pregnancy (NVP). NVP was reduced by 50% for these women. Sea-Bands are more effective if applied early in the symptom experience, less if late. Sea-Bands have considerable potential for a drug-free, non-invasive approach to control NVP.

In this article we report the results of a study of the effectiveness of an acupressure wristband known as Sea-Bands in controlling nausea and vomiting in pregnancy (NVP). NVP are familiar phenomena of the first trimester, occurring in an estimated 50-88% of pregnant women (Biggs 1975; Dilorio 1985). There is a cross-cultural taken-for-grantedness associated with these symptoms in early pregnancy based on a general belief that they are self-limiting (only last with pregnancy) and that paying attention to them will only worsen the woman's self-concerns.

Various studies have shown Sea-Bands to be effective in controlling NVP. A randomised, clinical trial of 350 pregnant outpatients in the United Kingdom (Dundee et al., 1988) used a three group design: A control group received standard care, one group received pressure on the P6 Point and another group received pressure on a dummy point near the right elbow. Nausea and vomiting were reduced in 8.5% of the experimental Sea-Bands group. Hyde (1989) found that Sea-Bands reduced nausea and improved affect and psychosocial functioning as well as performance of daily activities in a sample of pregnant women. A randomised double-blind cross-over, placebo controlled trial (N=60) demonstrated a 60% positive effect on NVP with Sea-Bands, compared with a 30% effect with placebo (De Aloysio & Penacchioni, 1992). None of these studies examined the experience of NVP with the experience of wearing Sea-Bands.



Mean symptom experience scores on the Rhodes Index of Nausea and Vomiting before and after Sea-Bands

Nausea was the dominant experience and was reduced 50% with Sea-Bands. Vomiting was also reduced 50% and retching by 33%.

Pregnancy

*The effect of acupressure on nausea and vomiting in pregnancy.
A randomised, placebo-controlled study.*

Elizabeth Werntoft, University of Kalmar, Department of Natural Sciences, 2001.

AIM OF THIS STUDY

The aim of this study is to compare the anti-emetic effect of acupressure at P6 in a group of healthy women, first time pregnant with normal pregnancy and NVP with a group of healthy women, first time pregnant with normal pregnancy and NVP getting acupressure at a placebo point. NVP will be followed up in a group of healthy women, first time pregnant with normal pregnancy and NVP without any treatment.

ABSTRACT

Nausea and vomiting occur frequently in pregnancy. This causes discomforts, disability and suffering and results in absence from work and social activities. Acupressure is a non-invasive technique which substitutes the application of pressure for the needles used for acupuncture. Acupressure at the P6 Point located on the surface of the forearm is thought to alleviate nausea and vomiting.

The aim of this study was to compare the anti-emetic effect of acupressure at P6 in a group of healthy women with normal pregnancy and NVP (nausea and vomiting) with a similar group getting acupressure at a placebo point and another similar group without any treatment at all.

These three randomised groups involved 60 women. According to the results of this study it is possible to reduce NVP significantly by acupressure at P6 compared to acupressure at a placebo point or no treatment at all, in healthy women with normal pregnancy. After 3 days of treatment both the group receiving acupressure at the P6 point and the placebo group experienced a 30% decrease in the feeling of nausea compared to how they felt when treatment started. This was statistically significant ($p < 0,05$) effect compared to the group receiving no treatment.

After 14 days of treatment the group receiving acupressure at the P6 point experienced a 50% decrease in the feeling of nausea compared to when treatment started, whereas the placebo group (30% decrease in the feeling of nausea) showed no significant difference from the no treatment group (19% decrease in the feeling of nausea), at this time.

Pregnancy

A double-blind cross-over study to evaluate the effectiveness of acupressure at pericardium 6 (P6) in the treatment of early morning sickness (EMS).

J. Bayreuther, G.T. Lewith and R. Pickering,
Southampton University Medical School 1994

SUMMARY

Background:

Morning sickness affects at least 75% of pregnant women. Typically it occurs in the first 16-18 weeks of pregnancy. Theories as to the cause include psychological factors, metabolic and hormonal changes, but the precise aetiology is unclear. Due to the possible risk of foetal abnormalities the use of drugs in early pregnancy is no longer widely acceptable. Acupuncture at P6 has been used to relieve morning sickness for over 4000 years in China. Recent studies show that acupressure might relieve morning sickness but more detailed investigation is required.

Aims

To assess by means of a blindly evaluated crossover study if acupressure at the P6 wrist point (active) is more effective than at the elbow (placebo) in reducing the nausea and vomiting in pregnancy.

Method

Women were contacted through various Southampton G.P.s and leaflets were given to pregnant women between 18-35 years. The women were randomly allocated to one of two groups, to wear Sea-Bands on both wrists for seven days and then on both elbows for seven days or vice versa. Symptoms were recorded on daily visual analogue cards. There was a questionnaire to be completed at the beginning and end of the two weeks. The credibility of the placebo was also assessed.

Results

Results show a significant decrease in nausea with acupressure at P6 compared to the placebo. Women were initially equally hopeful of both treatments working. They were significantly more confident in recommending acupressure after treatment.

Conclusion

P6 acupressure is a good method of nausea control in pregnancy. A point further up the arm is a credible placebo.

23 patients were entered into a double-blind cross-over study to evaluate the use of P6 acupressure versus sham acupressure in the treatment of early morning sickness (EMS). 16 completed the study. P6 acupressure was considerably more effective than the sham acupressure in the relief of nausea as measured by daily visual analogue scales ($P=0.019$). Two thirds of patients preferred acupressure on P6 compared to the sham point. Sham acupressure was specifically evaluated and found to be a credible placebo.

Randomisation

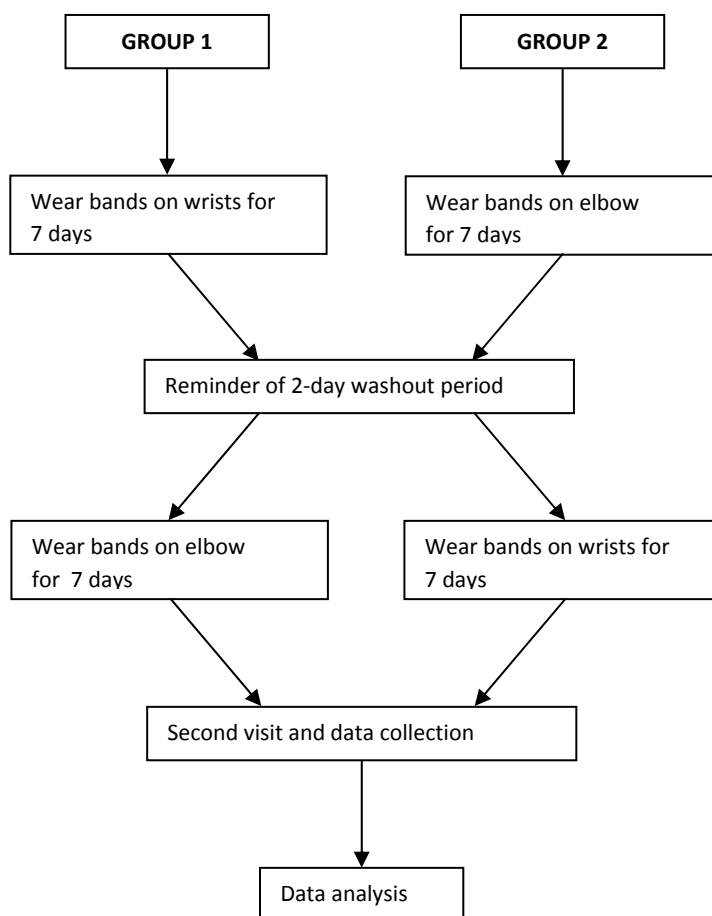


Table 1 Mean levels of nausea			
Test	Mean (w – e)	Confidence interval	P - Value
Paired t-test of treatment at each position	1.69 (1.57)	0.32, 3.06 (2.87, 0.27)	0.019 (0.021)
Two sample t-tests of group difference for each week	1.67 (1.56)	0.24, 3.10 (0.23, 2.91)	0.025 (0.025)
Main results include 15 women, results in brackets include 16 women. Mean w – e indicates the treatment difference			
Table 2 Non-parametric analysis of mean nausea levels			
Test	Mean (w – e)	Confidence interval	P - Value
Wilcoxon test of treatment at each position	1.65 (1.96)	0.14, 3.16 (0.032, 3.42)	0.037 (0.022)
Mean Whitney test of group difference for each week	1.61 (1.55)	-0.01, 3.17 (-0.04, 3.11)	0.049 (0.059)
Main results include 15 women, results in brackets include 16 women. Mean w – e indicates the treatment difference.			

Gynaecological surgery

P6 acupressure may relieve nausea and vomiting after : an effectiveness study in 410 women

Alkaiissi A, Evertsson K, Johnsson VA, Ofenbartl L, Kalman S.

Department of Anaesthesiology and Intensive Care, University Hospital in Linköping, Linköping, Sweden

Canadian Journal of Anaesthesia, 2002 Dec;49(10):1034-9

SUMMARY

PURPOSE: To investigate the effect of sensory stimulation of the P6 point on postoperative nausea and vomiting (PONV) after gynaecological surgery in the everyday clinical setting (effectiveness study).

METHODS:

Four hundred and ten women undergoing general anaesthesia for elective gynaecological surgery were included in a prospective, consecutive, randomized, multicentre, placebo-controlled, double-blind clinical trial with a reference group. One group was given bilateral P6 acupressure (n = 135), a second group similar pressure on bilateral non-acupressure points (n = 139), and a third group (n = 136) served as reference group. Nausea (scale 0-6), vomiting, pain, and satisfaction with the treatment were recorded. Primary outcome was complete response, i.e., no nausea, vomiting or rescue medication for 24 hr. Results were analyzed by applying logistic regression with indicators of treatments, type of operation and risk score for PONV as explanatory variables.

RESULTS:

Complete response was more frequent in the P6 acupressure group than in the reference group (P = 0.0194) conversely, the incidence of PONV was 46% in the reference group, 38% after pressure on a non-acupoint and 33% after P6 acupressure. The decrease from 46% to 33% was statistically significant. When considering vaginal cases separately, the decrease in PONV was from 36% to 20% (P = 0.0168). The corresponding decrease from 59% to 55% in the laparoscopic surgery group was not statistically significant.

CONCLUSION:

P6 acupressure is a non-invasive method that may have a place as prophylactic anti-emetic therapy during gynaecological surgery.

Post-Operative

Evaluation of Acupressure in Reducing Post-Operative Nausea and Vomiting
V. Sdrani, P. Stamatopoulos, Galenus (Greece) 1997; 39:300-308

SUMMARY

The method of acupressure was used, as a pressure on the wrist, to patients that underwent major gynaecological surgeries, in order to estimate its action to post-operative nausea and vomiting. The acupressure was applied to the internal side of the wrists, with elastic strips SEA-BANDS on the P6 point which corresponds to the 6th meridian of the body. The patients were separated in 3 groups. Acupressure was applied to the group OB (v=25) one hour before and six hours after the surgery was evaluated. To the group OA (v=25) the anti-emetic domperidone (4mg) IV (intravenously) was administered before anaesthesia. The group OE (v=25) constituted the control group. Vomiting, nausea and anxiety of patients were estimated during the first, third and sixth hour after surgery was evaluated. The last two were estimated under a range of 5 grades, where the 1st was no nausea and anxiety and the 5th was very intense nausea and anxiety. The statistical analysis of the grades were performed with the method Single Factor ANOVA & the z-test.

The results showed that only 24.4% of the group OB and 23% of OA had vomiting, percentages with statistically considerable difference from those of OE where 64% of patients had vomiting. The nausea was reduced less to the patients of OB (68.4%) and had statistically an important difference from the percentages of OA (52%) and OE (100%).

The study showed that acupressure reduced considerably the post-operative nausea to 75.6% of patients, and less nausea (31.6%) when applied pre-operatively as an alternative anti-emetic treatment to patients undergoing major gynaecological surgeries.

Post-Operative

The use of simple acupressure bands reduces post-operative nausea.

K. Phillips and L. Gill, Wycombe General Hospital, High Wycombe. UK. 1994

INTRODUCTION

Post-operative nausea and vomiting are common symptoms in surgical patients. The major causes are the use of anaesthetic agents, paralytic ileus and administration of opiate analgesics. Anti-emetic drugs are frequently prescribed for the relief of these symptoms.

Acupressure is a variation of acupuncture involving constant pressure on acupuncture points without puncturing the skin. Sea-Bands are bands of elasticated fabric with a small plastic button on the inside surface which exerts a constant pressure on the Neiguan (P6) acupressure point. The bands have been shown to be effective against emesis for patients undergoing cytotoxic chemotherapy, morning sickness in pregnancy and for motion sickness. There is considerable interest in coping with post-operative sickness especially with the move to minimally invasive day-care surgery.

A study to test whether the use of these bands would significantly reduce nausea and vomiting was conducted. Patients were invited to record their experience of nausea and sickness by making a mark on an analogue line to indicate their perceived level of nausea, one end of the line being defined as terribly sick (value = 10) and the other end being not sick at all (value = 0). The type of anti-emetic drugs prescribed and the number of doses administered were also recorded.

SUMMARY

The trial was randomised using 80 gynaecological surgery cases, since these patients are anecdotally regarded as "sicky". 40 of the patients were invited to have sustained acupressure using Sea-Bands and the remaining 40 were matched on age and type of operation and used as a control group. They were not offered any alternative pre-operative treatment.

Those taking part in the study were asked to assess their level of nausea on a linear analogue scale 2 days post-operatively. The level of sickness was assessed by measuring the total reduction in the amount of anti-emetic drugs used post-operatively.

After statistical analysis the study clearly demonstrated that patients wearing the bands had significantly reduced nausea and vomiting, were sick for a shorter time, and had fewer doses of anti-emetics than the control group. Those patients wearing Sea-Bands received 15.5% less doses of anti-emetic drugs.

Complementary therapies in medicine

Complementary Therapies in Medicine (2007) 15, 3–12

The effects of P6 acupressure in the prophylaxis of chemotherapy-related nausea and vomiting in breast cancer patients

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SUMMARY

Background

Nausea, and to a lesser extent vomiting, remain significant clinical problems after the administration of chemotherapy, with up to 60% of patients reporting nausea despite use of anti-emetics. Combining anti-emetics with other non-pharmacological treatments may prove more effective in decreasing nausea than anti-emetics alone. Hence, the aim of the current study was to evaluate the effectiveness of using acupressure in Pericardium 6 (Neiguan) acu-point in managing chemotherapy-induced nausea and vomiting.

Methods

This was a randomised controlled trial. Acupressure was applied using wristbands (Sea-Band™) which patients in the experimental group had to wear for the 5 days following the chemotherapy administration. Assessments of nausea, retching and vomiting were obtained from all patients daily for 5 days. Thirty-six patients completed the study from two centres in the UK, with 19 patients allocated to the control arm and 17 to the experimental arm.

Results

It was found that nausea and retching experience, and nausea, vomiting and retching occurrence and distress were all significantly lower in the experimental group compared to the control group ($P < 0.05$). The only exception was with the vomiting experience, which was close to significance ($P = 0.06$).

Discussion

Results highlight the important role of safe and convenient nonpharmacological complementary therapies, such as acupressure, in the management of the complex symptoms of chemotherapy-related nausea and vomiting.

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Chemotherapy

MINERVA MEDICA 2006;97

Effect of acupressure on nausea and vomiting induced by chemotherapy in cancer patients

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Summary

Aim: Corticosteroids, anti-dopaminergic agents and 5-HT₃ antagonists are the most commonly used drugs in the treatment of chemotherapy-induced vomiting. Acupuncture and acupressure have also appeared to exert anti-emetic effects. The aim of this study was to evaluate the efficacy of acupressure in the treatment of chemotherapy-induced vomiting resistant to the standard anti-emetic therapies.

Methods

The study included 40 consecutive advanced cancer patients with untreatable chemotherapy-induced vomiting. Colorectal cancer, lung cancer and breast cancer were the neoplasm most frequent in our patients. According to tumour histotype, patients received chemotherapeutic regimens the main emetic cytotoxic agents, including containing cisplatin and anthracyclines. Acupressure was made by PC6 point stimulation for at least 6 h/day at the onset of chemotherapy.

Results

The therapeutic approach was well accepted by the overall patients. An evident improvement in the emetic symptomatology was achieved in 28/40 (70%) patients, without significant differences in relation to neither tumor histotype, nor type of chemotherapeutic agent.

Conclusions

This preliminary study seems to suggest that a bioenergetics approach by acupressure on P6 point may be effective in the treatment of chemotherapy-induced vomiting resistant to the conventional pharmacological strategies, as previously demonstrated for vomiting occurring during pregnancy.

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Chemotherapy

An Evaluation of the Sea-Band in Alleviating Nausea and Vomiting in Patients Receiving Chemotherapy.
Katerina Sergio, Department of Medical Oncology, University of Southampton, 1991.

SUMMARY

Aim

To assess by the means of a single blind cross-over model if acupressure by the Sea-Band on P6 wrist point (active) versus acupressure on an ankle point (sham) reduces nausea and vomiting in patients receiving chemotherapy.

Method

Patients receiving chemotherapy at the RHS hospital were asked to participate in the study during their next two treatments. For one treatment they wore the bands on both wrists continuously for seven days, and for the other treatment they wore the bands on both ankles. The ankle and wrist treatments were randomised. While wearing the bands the patients were asked to record their symptoms daily in a diary card. After wearing the bands at both sites the patients were asked to complete a questionnaire concerning their preference for the wrists versus ankle treatments. Throughout the study the patients still received their usual pharmacological anti-emetics.

Results

Patients entered the study	105
Completed the study	67
Patients withdrew	38

Questionnaire analysis found that 49% of patients found P6 acupressure provided better control of nausea and vomiting, 17% found sham acupressure provided better control and 34% found no difference between the two. The diary cards indicated that P6 was more effective than sham acupressure in alleviating sickness, nausea, mood and overall condition in the high emetic intensity group.

Conclusions

P6 acupressure is a good method to complement conventional anti-emetic therapy for people having chemotherapy, particularly that of a high emetic intensity. It is recommended that it should be included in the standard anti-emetic protocol for chemotherapy, subject to further work on it.

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