

Original Article

Pilot study investigating efficacy of acupressure wristbands for reduction of radiotherapy-induced nausea

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Abstract

Persistent nausea remains one of the most distressing side effects of radiotherapy treatment despite advances in anti-emetic medication.

Stimulation of the Nei-Guan (P6) acupoint on the wrist has been used in Chinese medicine to treat nausea for over 4,500 years. Studies have demonstrated that acupressure wristbands can reduce postoperative nausea, motion sickness, morning sickness and chemotherapy-induced nausea. This pilot study aimed to determine if they could also help reduce radiotherapy-induced nausea. There are no published reports of their use in this setting, thus this preliminary pilot was conducted before engaging in a major study.

A prospective, paired, cross-over study investigated the impact adding acupressure wristbands to the usual anti-emetic care had on radiotherapy-induced nausea. Over the trial period, 30 patients were recruited when they reported radiotherapy-induced nausea to radiotherapists. Their daily nausea levels were assessed for a fortnight using a simple questionnaire and an anti-emetic tablet count. Comparing the 2 weeks data for these patients showed that there was a dramatic drop in their scores when the acupressure wristbands were used. There was a mean score drop of 61% for the combined nausea and vomiting frequency and severity, i.e. a 61% improvement in quality of life.

This study suggested that acupressure wristbands might have a role to play in the treatment of radiotherapy-induced nausea. It is recommended that further studies be conducted to determine their exact role. They potentially offer several benefits when compared to anti-emetic medication. They are easy to use, have no side effects and are more economical since they are reusable. Furthermore, acupressure wristbands place the patient in control of their nausea to some degree. This in turn will make the patients feel less anxious, less depressed and reduce the common feelings of helplessness that often accompanies cancer patients.

Keywords

Acupressure wristbands; radiotherapy-induced nausea; quality of life

INTRODUCTION

One of the most distressing side effects of radiotherapy treatment can be radiotherapy-induced nausea (RIN), sometimes causing vomiting.

Persistent nausea and vomiting can cause dehydration, an imbalance in electrolyte levels and can lead to malnutrition.¹ Patients experiencing RIN will be more tired and anxious, and are more likely to become depressed. The psychological distress caused by RIN will compound the distress felt by cancer patients due to their diagnosis, severely impacting on their quality of life. RIN,

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like all nausea, reduces quality of life drastically. In addition, it has the potential to interrupt radiotherapy treatment, causing a drop in tumour control probability. Although the nausea tends to be less severe than that experienced as a result of chemotherapy agents,² it can be more protracted, lasting for the 5–6 weeks of treatment and beyond. For many years, there has been an extensive array of literature addressing the prevention of chemotherapy-induced nausea but studies in radiotherapy are relatively sparse.

Current treatments for RIN depend on the severity of the nausea. Mild nausea is treated with benzamides such as metoclopramide, combined with neuroleptics such as diazepam. Severe nausea is treated with one of the 5-HT₃ antagonists, such as ondansetron or granisetron. There are several problems associated with this medication. There are some potentially unpleasant side effects, including dizziness, hypotension, depression and insomnia. The efficacy of 5-HT₃ antagonists has been shown to decrease after a week of fractionated radiotherapy.³ In addition, the Italian Group for Anti-emetic Research in Radiotherapy⁴ found evidence to suggest that over 50% of patients receiving radiotherapy supported by prophylactic anti-emetics still experienced nausea. It is clear from existing literature that conventional medicine cannot offer complete protection against RIN. This implies that it may need complementing by alternative forms of therapy.

So what alternatives or complements are there? Many non-pharmacologic treatments for nausea are based on behavioural interventions such as relaxation, imagery, distraction and self-hypnosis techniques.⁵ Other interventions include ginger, music therapy, alterations to diet and acupressure.

Acupressure is a method of treatment that was originally developed before 2500 BC in China. It is similar to acupuncture, in that special points on the body, called acupoints, are stimulated, but pressure is used instead of needles. It is a less invasive form of therapy and is often performed by patients themselves with relative ease and minimal instruction. The theory behind these techniques is that energy (or “chi”) flows along lines (meridians) in the body. The flow of chi can be blocked, causing



Figure 1. Position of Nei-Guan (P6) acupressure point.

various symptoms. Stimulation of the correct acupoint restores balance to the flow of chi.

The acupoint Nei-Guan (P6) is used in the treatment of nausea. It is located on the anterior surface of the forearm, three finger widths up from the 1st crease of the wrist, between the tendons of the flexor carpi radialis and palmaris longus muscles (Fig. 1).

One of the easiest ways to stimulate the P6 acupressure point is to use an acupressure wristband. The band is worn on the wrist and a protruding button presses on the P6 point continuously. In this study, a British product called Sea-Bands (Sea Band UK Ltd, Leicestershire) has been used. This is an elasticated fabric band with a plastic button embedded in it. Other types of band commonly in use consist of non-elasticated Velcro straps that can be adjusted to fit. The wristbands were originally developed to combat motion sickness, specifically seasickness, but in recent years have been used in a variety of clinical situations.

A review of the literature was performed to assess the efficacy of acupressure for control of nausea in these other clinical situations. The review was by no means conclusive, and there are a few trials that have determined that P6 acupressure is ineffective. Most of the trials studied suffered from relatively small sample sizes, and reported difficulties

achieving the “blind” conditions that many consider to be an essential part of any scientific study. Contrasting with this, the review discovered considerable evidence supporting the efficacy of P6 acupressure for nausea in a variety of situations, including treatment of morning sickness, motion sickness and postoperative nausea. This may, however, reflect possible publication bias, which is a common problem associated with trials of complementary therapies.

Hu et al.⁶ concluded, “P6 acupressure reduces the severity of symptoms of visually-induced motion sickness and gastric tachyarrhythmia” (p. 631). The few papers concerning controlled trials of acupressure for motion sickness mainly reported success. The author of the one exception⁷ admitted that the test conditions had been too severe for any anti-emetic to deal with. Overall, these controlled trials provided much support for acupressure use.

The evidence in the literature concerning the use of P6 acupressure for morning sickness was also generally supportive. Most of the studied trials reported reduced nausea with acupressure. Steele⁸ studied the use of Seabands for morning sickness and determined that they were effective, cheap and safe.

Harmon et al.⁹ was one of the many studies to report that acupressure was effective in prevention of postoperative nausea and vomiting (PONV). Agarwal¹⁰ found acupressure to be ineffective for PONV in urological endoscopy patients but effective 2 years later for laparoscopic cholecystectomy patients.¹¹ There is a great deal of conflicting evidence in this area.

The potential benefits of acupressure, combined with their success in many trials in a variety of clinical situations implies that they have a significant role to play in the care of patients suffering from RIN.

METHODOLOGY

The study was performed at Derby Cancer Centre at the Derbyshire Royal Infirmary. This can be part of the South Derbyshire Acute Hospitals NHS Trust, which serves a population of fewer than

580,000 people. This relatively small catchment area results in a very small population of eligible patients. The Cancer Centre treats around 90 radiotherapy patients a day with three linear accelerators.

The purpose of the trial was to determine if acupressure wristbands improved nausea levels when combined with the usual care (i.e. anti-emetics) over a period of time. It was felt to be inappropriate to conduct a large scale study with an untested intervention without a short preliminary pilot study. The larger numbers required for a randomised study would have meant a prohibitively long trial due to the slow expected recruitment rate. The trial design had to have sufficient statistical power to detect any improvements with a small cohort.

A paired crossover structure was chosen, with patients acting as their own controls. This was felt to be the most appropriate type of trial design for this study and has the further benefit of being far more sensitive.¹² This is because patient characteristics cannot affect the results. A smaller sample size can be used to achieve the same power as a non-paired trial structure.

Many reviewed studies have found difficulties when comparing acupressure wristbands to placebo wristbands or sham wristbands (in an incorrect position). This is mainly due to the physical nature of acupressure and the widespread use of the bands for travel sickness. Patients were often able to detect whether they had been assigned true acupressure wristbands in the correct place or not. Blinding was felt to be impossible to achieve in this scenario.

One of the difficulties anticipated was the variability of RIN, with it either spontaneously resolving itself within a couple of days or, more usually, becoming steadily worse as treatment progresses. For this reason, it was decided that the usual care arm should be performed first, since any improvement by the bands could not then be attributed to less severe background nausea. A period of five treatments per intervention was allowed to ensure that there was no spontaneous resolution of symptoms.

It was decided to allow the usual care to continue throughout the trial, with the second arm being

acupressure wristbands plus the usual anti-emetics. This allowed the trial to demonstrate if the wristbands can supplement the anti-emetics, taking care of the residual nausea that often remains. The other possible effect of the bands could be to reduce the patient's need for anti-emetics. A reduction in need for anti-emetics while wearing the wristbands could also be seen as a success. Any increase in medication would, of course, mean that the bands had failed.

MEASUREMENTS

The self-assessment tool actually used in this trial was a daily questionnaire comprising a composite series of four visual analogue scales (VAS). Scales measured frequency and severity of both nausea and vomiting using simple prompts. It was decided that this method of assessment allowed the greatest freedom of expression by the patient, while maintaining as uncomplicated a way as possible of obtaining numerical data.

A pilot of the questionnaires ($n = 4$) showed that patients left to fill them in alone for the first time can make mistakes. Most of the subjects had no difficulty with filling in the questionnaires correctly, unaided, but one subject wrote comments on the line instead of placing a cross along it. Because of this, it was decided that a researcher should oversee the filling in on the first day. It was felt that the patients would soon become very confident with the tool, once the first scale had been marked. On subsequent days, the patients would be left to fill in their own questionnaires unaided.

The other essential measurement taken from the patients was the quantity of anti-emetic medication taken during each assessment period. For simplicity, the patients were asked each day to record the number of tablets taken over 24 h on their daily questionnaires. For the period of the research, patients were advised to take tablets whenever they felt the need, as opposed to regularly. The tablet count was essential to ensure any improvement in nausea was not due to increased medication usage. In addition, a decrease in medication needed could represent a benefit of the wristband, even if the self-assessment detected no improvements.

Other information recorded from the patient was diagnosis, an indication of previous wristband

usage and how often the bands were worn. The diagnosis was recorded in order to see if nausea due to different treatments responded differently to the wristbands. It was thought possible that nausea and vomiting due to irradiation of certain areas, for example the stomach, may be due to different mechanisms and therefore may not be responsive to the bands. The patients were all asked if they had used acupressure wristbands before. This was done in order to determine if previous experience with the bands in other situation influenced response in this situation.

The final piece of information recorded was whether the patient kept the wristband or returned it. This was felt to be important since it shows how the patient viewed the band – as a benefit or a waste of time.

ETHICS

Ethical approval for the project was granted.

RECRUITMENT

Patients saw their consultant if they reported feelings of nausea to the radiotherapists when they attended for daily treatment. The consultant assessed the patient and determined if the nausea was due to their radiotherapy treatment or to their disease. Anti-emetic medication was prescribed as usual. If patients were determined to be suffering from RIN, they would then be offered trial entry by a researcher. Written informed consent was obtained from all patients before entering the study. Patients were only refused trial entry if their nausea was determined by the consultants to be caused by something other than their radiotherapy treatment. The only other stipulation for trial entry was that patients should be undergoing fractionated treatment over a period of 10 days. This was to allow all 10 questionnaires to be administered, allowing adequate baseline measurements to be gathered.

SAMPLE SIZE

A statistician was consulted for determination of sample size. The calculations were based on having a power of 0.8 to detect a 50% difference in nausea and vomiting experience. A sample size of 30

was chosen to allow for an estimated 10% patient withdrawal rate.

RESULTS

Altogether, there were 30 patients recruited for the trial. Out of these, three patients were excluded. One patient became too ill for the trial, being admitted to the ward and having to have continuous anti-emetic medication intravenously. The wristbands were obviously not able to make any discernable difference to the quality of life of the patient. The second patient found that the bands were too tight and refused to carry on with the trial. The third patient took part in the trial for two days and then refused to continue for personal reasons. Results for these patients have been omitted from the analysis.

One of the seminoma patients only wore the bands intermittently and was deemed non-compliant. The patient was a prisoner and was reluctant to be seen wearing the bands. His data was still included in the analysis because he had worn the bands, albeit intermittently. Two of the patients had used acupressure wristbands before the study for travel sickness and had found them useful. These patients also responded well to the acupressure bands for their RIN. Four patients gave the band back, the rest kept them to use again.

Patients recruited into the trial had quite a variety of diagnoses. Most of these patients were having para-aortic irradiation for seminoma (Fig. 2).

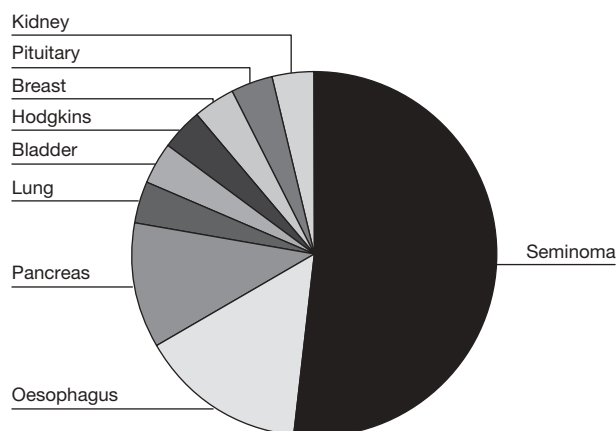


Figure 2. Patient recruitment by diagnosis.

Because patients were only recruited after reporting RIN, this has resulted in a rather unrepresentative sample of radiotherapy patients. It is, however, representative of radiotherapy patients likely to suffer from RIN.

ANALYSIS

All questionnaires for the patients were analysed using a 10 cm-long grid split up into 0.5 cm intervals. Marks on the questionnaires were allocated a score based on their position in the grid in mm. This gave the patients a score ranging from 0 to 100 for each of the four categories of symptoms.

A patient was determined to have noticed benefit from the wristbands if their mean "score" for nausea and vomiting dropped by 10% or more when using them, provided their medication levels did not rise. This was determined with reference to an analysis performed by Sloan of tools measuring quality of life.¹³ Sloan identified the improvement in score necessary to indicate a significant change in quality of life; "A substantial shift (operationally defined here as 10%) should serve as an indication that some aspect of the patient's life, well-being, or attitude has changed."

Patients were also determined to have received benefit if their medication levels dropped, provided their nausea and vomiting mean "score" did not increase. This accounted for patients for whom the wristbands were decreasing reliance on their medication. It was felt that this reflected an improvement in quality of life, even though their symptoms had not visibly improved.

The data was analysed by comparing the two weeks scores with each other to calculate the percentage drop or rise in quality of life due to nausea and vomiting. The patients were categorised by how they modified their medication while wearing the bands. Figures 3–5 show each week's scores for each patient in each of these categories. Wristbands were unable to make any impact on very severe conditions. These results were also noted by Bruce.⁷

85% of the patients felt no need for further medication in the second week. The mean drop in score for these patients was 61%. Figure 6 shows

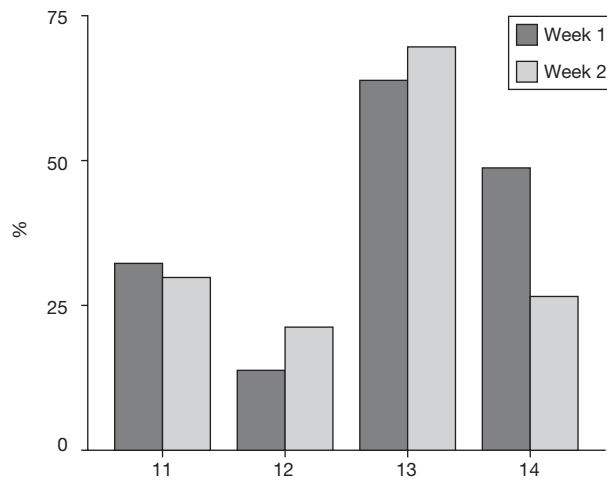


Figure 3. Total nausea and vomiting scores for each intervention (increased medication) (n = 4).

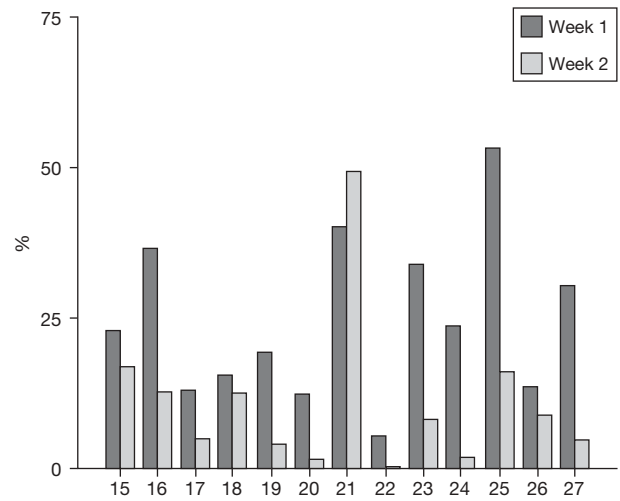


Figure 5. Total nausea and vomiting scores for each intervention (no change to medication) (n = 13).

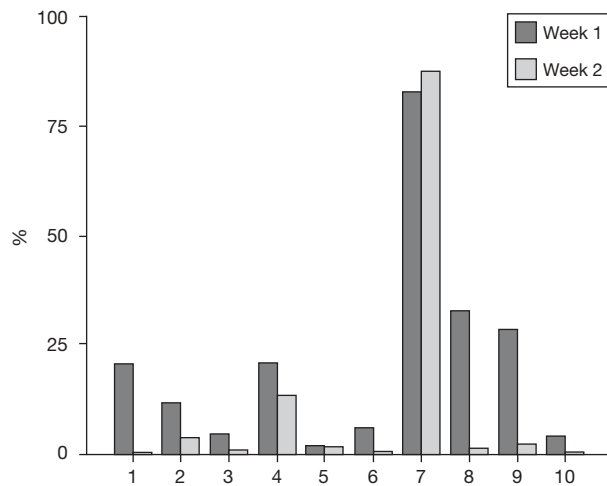


Figure 4. Total nausea and vomiting scores for each intervention (decreased medication) (n = 10).

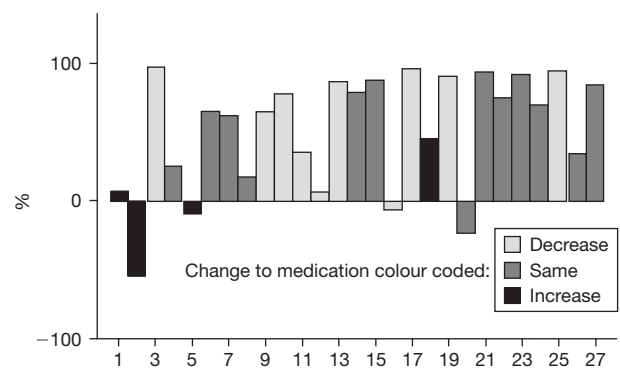


Figure 6. Relative percentage changes in score for each patient (n = 27) related to changes in medication.

this relative change in score between the 2 weeks for each patient. Of the 27 patients, 10 were able to drop their medication levels significantly in the second week while wearing wristbands. Eight patients stopped using anti-emetic medication at all in the second week.

DISCUSSION

Improved quality of life

The results of this study have shown that acupressure wristbands could potentially be an effective

adjuvant therapy for RIN. They have improved the quality of life for patients for whom standard anti-emetic drug therapy is not sufficient. 85% of patients did not increase medication in the second week. The fact that the other patients felt the need for more medication suggests that RIN acts as an accumulative effect. This needs to be tested with a large scale randomised more controlled study.

Comparison with a control group's baseline performance may indicate that the wristbands have an effect even if the tablet count remained the same and the score did not alter. Eight of the patients in the study did not feel the need for any

anti-emetic medication at all in the second week of the trial. A follow-up study needs to compare this data with a control group.

Simplicity of use

None of the patients in this study had any difficulty in using the wristbands. Patients found that they only needed one session with the researcher in order to determine the correct position of the bands. Subsequent checks of the position of the bands usually found that they were still correctly positioned. Researcher training was also very rapid. If manual acupressure is to be used, however, this will require more training. The same point needs to be found, but patients need to have a more conscious awareness of when acupressure is required and for how long to apply the pressure.

Absence of side effects

There are no severe side effects produced by acupressure. The only side effects noted by patients in this study were occasional tightness around the wrists. Only patients with larger wrists felt this side effect, and in most cases it was tolerable. The wristbands can be removed temporarily if tightness occurs. In addition, the manufacturers do produce larger diameter wristbands that are suitable for people with thicker wrists. Alternatively, other manufacturers produce adjustable bands, which may be of use in further studies if this problem occurs again. None of the patients in this study reported any other adverse side effects to the wristbands. The side effects of anti-emetic medication have already been discussed. If patients can control their nausea without any of these side effects, it will improve their quality of life dramatically.

Inexpensive

Kirkbride expressed concern about the potential expense of routine use of prophylactic 5-HT₃ antagonists for fractionated treatments.¹⁴ The guidelines that were followed in the department where this study was performed indicated that for most of the cases in the study, the first line anti-emetic used was metoclopramide. Although metoclopramide is relatively inexpensive (72p for 42 tablets (3 per day for 14 days)) when compared

to the cost of a pair of wristbands (£3.75), the wristbands can be used repeatedly, making them more inexpensive once they have been used for five patients. They are washable and durable.

Patient satisfaction

Patients benefit a great deal from being responsible for their own treatment. Giving the patient a wristband and the knowledge that they can treat their own nausea is a very empowering act. Research has shown that how patients view the control of their symptoms affects their mental and physical health.¹⁵ Patients who can take control of their symptoms experience reduced feelings of helplessness and tend to have a more positive outlook. The wristbands had a further benefit to patient satisfaction. A total of 10 out of 27 participating patients in this trial were able to reduce the number of anti-emetic tablets taken when wearing the wristbands. At the start of the trial, several patients reported that they strongly disliked having to take medication. If patients like these are able to control their nausea with fewer tablets, they will experience more satisfaction, as well as feeling more independent.

Other benefits

There are a couple of additional potential benefits afforded by acupressure. Xia found that acupressure raised the body's immunity and controlled the immunosuppression caused by radiation treatments.¹⁶ This would help to prevent patients developing infections due to depressed immune systems. Patients having large areas of haemopoietic tissue irradiated or patients who have had previous chemotherapy will be especially immunosuppressed. As yet, there is little evidence that immunity can be boosted by acupressure and more research is indicated in this area. This is especially important as the role of immunotherapy in cancer management increases. Recent studies have indicated that acupuncture and acupressure both caused a significant decrease in blood pressure and heart rate, suggesting a calming effect.¹⁷ Again, this is important for cancer patients, since reductions in stress levels may improve response to treatment. Yang found that acupressure could regulate the incretory function of malignant tumour patients.¹⁸ This would ease symptoms caused by irregular levels of chemicals in the body due to the tumour.

RECOMMENDATIONS

This study has suggested that acupressure wristbands can help to reduce RIN. There was a good response in this relatively small trial combined with a lack of demonstrable side effects. It is acknowledged that the limitations of time and recruitment rate have affected the extent to which proper controlled conditions could be achieved. This study indicates that acupressure wristbands may have a role to play in the reduction of RIN. It is therefore recommended that this study be followed-up with a randomised controlled trial to determine this role.

The potential benefits of these bands and lack of side effects make them safe for use, and give the patient some control of their side-effect management. If a benefit can be demonstrated, the non-pharmacologic nature of the bands indicates that radiotherapists could offer acupressure wristbands to all patients complaining of nausea as an initial therapy, with anti-emetics being offered if necessary as an adjuvant.

It is recommended that, where wristbands are used, additional rotating pressure should be applied over the Nei-Guan acupoints if nausea persists. Position of the wristbands should be regularly checked if nausea persists. If local expertise is available, wristbands should be replaced with the teaching of the manual acupressure technique. This should include how to accurately identify the correct acupoint and how to perform reducing acupressure to it.

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