

## Sea-Band

### Class 1 Medical Device

#### Review of P6 Acupoint Stimulation for Treating:

- Post-Operative Nausea and Vomiting
- Nausea and Vomiting Due to Chemotherapy
- Nausea and Vomiting due to Pregnancy
- Motion/Travel Sickness

#### A review of the scientific literature, including:

- Independent Expert Opinion
- Guidelines
- Clinical Reviews
- Randomised Controlled Trials

Richard Eggleston BSc MIPharmM MRPharmS MGPharmC DipRegAff  
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Approved Pharma Solutions Ltd.

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## Abbreviations

CINV	Chemotherapy Induced Nausea and Vomiting
EC	European Commission
EEA	European Economic Area (EU + Lichtenstein, Norway and Iceland)
EU	European Union
FDA	Food and Drug Administration (USA)
MDR	Medical Device Regulations
MHRA	Medicines and Healthcare Products Regulatory Agency
NHS	National Health Service (UK)
NICE	National Institute for Health and Clinical Excellence (UK)
N&V	Nausea and Vomiting
NVP	Nausea and Vomiting in Pregnancy
P6AS	P6 Acupoint Stimulation
PONV	Post-Operative Nausea and Vomiting
RCOG	Royal College of Obstetrics and Gynaecology
SAS	Simulation Adaptive Syndrome
TENS	Transcutaneous Electrical Nerve Stimulation
TLESRs	Transient Lower Esophageal Sphincter (LES) Relaxations
UDI	Unique Device Identification
USA	United States of America
UK	United Kingdom

## Summary

P6AS is recommended by independent HEALTHCARE PROFESSIONAL for the treatment of nausea and vomiting due to operations, chemotherapy, pregnancy and motion. Reviews by professional bodies including the Royal Colleges, NICE and the NHS describe its place as an adjunct or alternative to drug-based antiemetic's when patients can't tolerate the side effects, interactions and contraindications of drug treatment.

P6AS was introduced into the UK in the 1980s from the USA following President Nixon's historic visit to China in 1972. The President's physician observed acupoint stimulation in clinical practice and brought it back to the USA.

Acupressure is acupuncture without needles. Acupressure is a simple, non-invasive method of stimulating the acupoint which can be easily self-administered outside the hospital. Sea-Band offers people an unobtrusive, cost-effective and virtually side-effect free way of treating N&V by stimulating the P6 acupoint.

There are over 140 published clinical studies demonstrating the efficacy of P6AS. These studies involved over 15,000 patients. The studies were carried out in the UK, USA, Canada, Australia, Germany, Austria, Switzerland, Norway, Ireland, Italy, Japan and Sweden, as well as the Middle East, Asia and South America.

Independent HEALTHCARE PROFESSIONALS within the NHS routinely offer patients P6AS as an alternative as well as an adjunct to state-of-the-art antiemetic drug combinations for treating nausea and vomiting in primary and secondary care.

Professional guidelines for treating nausea and vomiting due to operations, chemotherapy, pregnancy and at end-of-life recommend a place for P6AS.

P6AS remains a major topic of research in western medicine. Studies now focus on how to identify patients most likely to respond and how best to train them to self-administer acupressure. Many HEALTHCARE PROFESSIONALS and ethical committees now consider it unjustified and certainly unethical to conduct further placebo-controlled studies.

## Introduction

### Problem statement

Nausea and vomiting following operations, chemotherapy or during pregnancy and motion is a debilitating condition.

Anti-emetic drugs are not always effective. All drug treatments have side effects due to their action on the central nervous system (central mode of action). These include dry mouth, blurred vision, headaches, dizziness, drowsiness and somnolence.

Contraindications, restrictions, precautions and drug interactions often make antiemetic drugs unsuitable. For example, those who must avoid drowsiness or who are pregnant, breastfeeding, have digestive problems, urinary retention, prostatic hypertrophy and glaucoma cannot take antiemetic drugs. Many people also simply prefer not to take drugs whenever possible and their views must be respected.

P6AS offers an effective drug free treatment for N&V.

### Legal Basis for CE marked Class 1 Medical Device

The Sea-Band P6AS device was placed on the market in accordance with the UK's Medical Devices Regulations 2002<sup>i</sup>, which brought into force Council Directive 93/42/EEC<sup>ii</sup>.

On 26<sup>th</sup> May 2017 new MDRs came into effect: REGULATION (EU) 2017/745 (MDR) OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC<sup>iii</sup>.

There is a three-year transition period as the new MDRs come into effect. The new MDRs will fully apply equally in all EU Member States from 26<sup>th</sup> May 2020.

During the transition period, devices can remain on the market under the previous EU Directives. However, devices placed on the market after the transition period will need to fully comply with the MDR.

The Sea-Band P6AS device has been reassessed under the new regulations and remains a Class 1 Medical Device in compliance with the MDR.

The Sea-Band P6AS device is approved throughout the EU for treating:

- Motion Sickness
- Travel Sickness
- Morning Sickness
- Post-Operative Nausea
- Chemotherapy Induced Nausea

Sea-Band is also approved as a medical device by the FDA in the USA. Similar P6AS devices are also approved in Europe and the USA.

### Definition of a Medical Device

The MDR define a 'medical device' as: "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means."

In accordance with the definition of a medical device: Sea-Band is a medical device because it is an instrument used for treating N&V.

### Manufacturers legal obligations under the Regulations

The regulations define a 'manufacturer' as a natural or legal person (i.e. company) who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

Therefore, Sea-Band is the manufacturer as defined in the regulations.

As a manufacturer, Sea-Band must meet new obligations set out in the MDR to ensure:

- The MD is classified according to the Rules and risk classification criteria in Annex VIII of the MDR
- The general safety and performance requirements are met, including labelling and technical documentation and Quality Management System per Annex I of the MDR
- The clinical requirements per Annex XIV are met
- Sea-Band have an appropriately qualified and experienced RP in place to ensure compliance per Article 15 of the MDR
- The supply chain is compliant with Good Distribution Practice<sup>iv</sup>
- Product liability insurance is in place per Article 10 of the MDR
- The new vigilance reporting timescales are met, and an annual periodic safety update report is created (Chapter VII, Section 1 and 2 of the MDR)

#### Article 10: General obligations of manufacturers

Sea-Band must:

1. Ensure that the MD is designed and manufactured in accordance with the regulations.
2. Must implement a documented risk management system per Section 3 of Annex I.
3. Carry out a clinical evaluation per Article 61 and Annex XIV, including a post marketing clinical follow-up.
4. Maintain current technical documentation per Annexes II and III.
5. Maintain EU declaration of conformity in accordance with Article 19, and affix the CE marking of conformity in accordance with Article 20.
6. Comply with the obligations relating to the UDI referred to in Articles 27, 29 and 31.
7. Keep the last set of applicable documentations covered by the regulations discoverable for 10 years after the last device is placed on the market.
8. Provide the competent authority with the technical documentation upon request.
9. Maintain the technical documentation within the EU.
10. Ensure that procedures are in place to keep production in conformity with the requirements of this Regulation. Changes in device design or characteristics and changes in the harmonised standards or common specifications by reference to which the conformity of a device is declared shall be adequately considered in a timely manner.
11. Maintain an up to date Quality Management System compliant with the regulations.
12. Maintain a post-market surveillance system in accordance with Article 83.
13. Ensure that the device is accompanied by the information set out in Section 23 of Annex I.
14. Identify the original manufacturer in accordance with Article 30(1).
15. Maintain product liability insurance.

#### Class of Sea-Band P6 Acupoint Stimulation device

According to Annex VIII of the Regulations the product is a Class 1 MD because:

1. Duration of use is transient (Rule 1.1)
2. It is non-invasive (Rule 4.1)
3. The special rules do not apply.

In summary, the Sea-Band Medical Device is non-invasive, non-sterile, does not use a measuring device and is used transiently on healthy unbroken skin to provide mechanical stimulation of the median nerve at the P6 acupoint to treat nausea due to motion, travel, chemotherapy, pregnancy and operations.



## Medical Device Guidelines

The MHRA and EC have issued guidelines for medical devices. Medical devices have a 'medical purpose' which is determined by the definition of a medical device (see above). MHRA guidance states that medical devices must achieve their principal medicinal claim in a mechanical or physical way and not in a metabolic, physiological, immunological or pharmacological way<sup>v</sup>.

EC guidance on the classification of medical devices states that medical devices which are non-sterile, do not have a measuring device or are applied intermittently to intact and healthy skin, are Class I medical devices<sup>vi</sup>.

The Sea-Band device has been approved by the MHRA in accordance with the regulations and the guidelines as a Class 1 Medical Device for supply throughout the EU.

## Origins of P6 Acupressure

Acupressure is acupuncture without needles. Acupressure is a non-invasive way of stimulating acupoints which can easily be self-administered outside hospital.

Acupressure was introduced into the UK from the USA in the 1980's. The clinical application of P6AS was rare in Western medicine before President Nixon's historic visit to China in 1972<sup>vii</sup>. Air Force Major General Dr. Walter R. Tkach was the physician to President's Eisenhower, Kennedy and Nixon. Following his visit to Beijing with President Nixon, Dr Tkach published an article on the medical uses of acupuncture he had observed. This led other physicians to visit China which in turn quickly led to the technique's widespread use in North American clinical practice.

## Clinical Data

Sea-Band carried out extensive reviews of clinical studies, reviews and guidelines describing the safety and efficacy of P6AS (Table 1) <sup>viii ix x xi</sup>.

Cause of nausea and vomiting	Number of clinical studies reviewed	Number of subjects included
Post-operative	83	10,500
Chemotherapy	31	2,456 <sup>1</sup>
Pregnancy	14	1,778
Motion/travel	13	900
<b>Total</b>	<b>141</b>	<b>15,634</b>

*Table 1: Summarising the number of clinical studies and patients included in the reviews carried out by Sea-Band*

The Sea-Band reviews also included thirty clinical reviews and professional guidelines plus guidance published by the NHS and NICE on the use of P6AS for treating N&V due to surgery, chemotherapy, pregnancy and motion sickness in palliative care (Table 2).

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<sup>1</sup> The 31 studies in CINV between 1987 and 2017 included over 2,456 cancer patients undergoing repeat courses of chemo and radio-therapy, including end-of-life palliative care. This represent between 7,000 and 12,000 courses of treatment where P6AS was used.

Cause of nausea and vomiting	Number of Independent Clinical Reviews	Number of Professional Guidelines	Number of NHS guidelines including NICE
Post-operative	2	1	1
Chemotherapy	9	4	3
Pregnancy	5	1	2
Motion/travel		1	1

*Table 2: Summary of the number of Clinical Reviews, Professional Guidelines, NHS Guidelines and NICE Guidelines recommending P6 acupoint stimulation for treating N&V.*

## Summary of evidence supporting use of P6 Acupoint Stimulation for Chemotherapy Induced Nausea and Vomiting

CINV has several physiological mechanisms which account for its anticipatory, acute and delayed nature. This explains why no single antiemetic drug is effective. Hence antiemetic drugs are routinely used in combination to try and address these various mechanisms.

Despite modern combination antiemetic drug regimens, CINV remains a serious problem for cancer patients. Persistent CINV will seriously affect a patient's quality of life, nutrition, hydration and electrolyte balance and can lead to hospital re-admission. Some patients even deciding to abandon potentially lifesaving treatment because of CINV.

The high doses of antiemetic drugs used in CINV mean side effects include extrapyramidal movements which are a contraindication. Adjuvant's which improve the efficacy of drug combinations without additional side effects are welcomed by patients and HEALTHCARE PROFESSIONALS.

Independent cancer care experts within the NHS routinely offer patients P6AS in addition to state-of-the-art antiemetic drug combinations. This is especially useful when treating delayed CINV in out-patients. Effective treatment of delayed CINV helps reduce anticipatory CINV.

Sea Band

Reviews and guidelines from the UK, North America and Europe have confirmed the place of P6AS as an effective adjunct for state-of-the-art antiemetic drug regimens<sup>xii xiii xiv xv xvi xvii xviii xix xx xxi xxii xxiii xxiv xxv xxviii xxix xxx xxxi</sup>. NHS cancer centres now routinely offer P6 acupoint stimulation<sup>xxvi xxvii</sup>.

### Clinical Studies

Appendix 3 presents a horizontal tabulated summary of 29 clinical trials published between 1987 to 2017. These include over 2,456 adult and paediatric cancer patients. This is equivalent to between 7,000 and 12,000 courses of treatment.

### Summary of evidence supporting P6 Acupoint Stimulation for Post-Operative Nausea and Vomiting

N&V is commonly associated with opiate analgesics as well as general, regional, and local anaesthetics and painful procedures.

Studies in PONV suggest there is a central as well as peripheral component to the mechanism of action as efficacy depends on timing in relation to the anaesthetic.

The P6 acupoint is very sensitive to stimulation. Subgroup analysis shows that all forms of P6 acupoint stimulation may be effective. P6AS is also equally effective in adults and children.

### Clinical Studies

Since 1986 more than 80 well controlled studies, including over 10,500 adults and children, have been published which demonstrate the safety and efficacy of using P6AS as an antiemetic adjunct for relieving PONV. These studies are summarised in Appendix 4.

### Independent Clinical Reviews

These studies have been reviewed by the Cochrane Library, NICE and the American Society for Ambulatory Anesthesia; all of which conclude that P6AS offers patients, doctors and nurses a safe and effective low-cost addition to drugs.

National Institute for Health and Clinical Excellence (UK)

In 2012, NICE published its recommendation that women undergoing caesareans should be offered antiemetic treatment with P6 acupressure<sup>xxxii</sup>.

#### Cochrane Library

In 2015, the Cochrane Institute published a rigorous review of randomised controlled studies demonstrating the safety and efficacy of P6 stimulation in adults and children<sup>xxxiii</sup>. The review included 59 studies involving 7,667 patients.

The key findings of the review are:

- Compared to placebo, P6 stimulation significantly reduces nausea, vomiting and the need for rescue medication<sup>2</sup>
- P6 acupoint stimulation is just as effective as metoclopramide, cyclizine, prochlorperazine, droperidol, ondansetron and dexamethasone.
- Combining P6 stimulation with an antiemetic drug is more effective than either alone.
- The side effects associated with P6AS are few, minor, transient and self-limiting compared to the side effects of antiemetic drugs.

#### American Society for Ambulatory Anesthesia

In 2014, the American Society for Ambulatory Anesthesia published its consolidated international guidelines confirming the efficacy of P6 acupressure<sup>xxxiv</sup>.

#### University of Hong Kong

A systematic review and meta-analysis of 30 randomised controlled trials involving over 2,500 patients, published in 2013, showed that P6AS relieves nausea and vomiting<sup>xxxv</sup>.

### Summary of evidence supporting P6 Acupoint Stimulation for Nausea and Vomiting in Pregnancy

NICE, the RCOG and the NHS agree that acupressure offers women an effective drug-free treatment for NVP.

For obvious reasons the safety of anti-emetic drugs during embryogenesis cannot be studied directly in humans. Therefore, none are licensed for treating NVP. P6AS is licensed for treating NVP (morning sickness).

#### Clinical picture of Nausea and Vomiting in Pregnancy

Nausea, retching and vomiting are commonly experienced by women in early pregnancy. It is one of the most common causes of hospital admission among pregnant women. NVP can have a significant adverse effect on a woman's quality of life.

NVP is more common in the first trimester of pregnancy during embryogenesis.

A small percentage of women can progress to HYPEREMESIS GRAVIDUM. HYPEREMESIS GRAVIDUM is characterised by severe and persistent vomiting during pregnancy.

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<sup>2</sup> "rescue medication" is when a patient requires more medication adding to the base level in order to maintain control

HYPEREMESIS GRAVIDUM requires specialist treatment to maintain the woman's nutritional, hydration, metabolic and electrolyte status. There is little consistent evidence supporting the use of anti-emetic drugs in HYPEREMESIS GRAVIDUM<sup>xxxvi</sup>.

### Treatment of Nausea and Vomiting in Pregnancy

Women are commonly offered reassurance and advice about the self-limiting nature of NVP. Advice includes avoiding foods, smells, activities and situations they find nauseating and to eat small frequent, dry and bland meals such as crackers and soda water.

Concern about potential teratogenic effects of drug treatment, following the thalidomide tragedy, have led to a reluctance to prescribe drugs in the first trimester. Because of these concerns, non-pharmacological treatments such as P6AS are recommended as first-line treatment.

### Clinical Studies

Appendix 1 presents the horizontal tabulated summaries of 14 studies from 1988 to 2014 which include 1,778 women.

### Clinical Guidelines

National Institute for Health and Clinical Excellence (UK) Clinical Guidance 62 Antenatal care for uncomplicated pregnancies 2017<sup>xxxvii</sup>

This guideline covers the care that healthy women and their babies should expect from the NHS during their pregnancy. It aims to ensure that pregnant women are offered information and support. Women should be informed that most cases of NVP will resolve spontaneously within 16 to 20 weeks and that nausea and vomiting are not usually associated with a poor pregnancy outcome. If a woman requests or would like to consider treatment, then she should be offered non-pharmacological treatment using P6 wrist acupressure.

Royal College of Obstetrics and Gynaecology: The Management of Nausea and Vomiting in Pregnancy and Hyperemesis Gravidum 2016<sup>xxxviii xxxix</sup>

The RCOG recommend that women are reassured that P6 acupoint stimulation is safe in pregnancy and can improve NVP. These guidelines are also accredited by NICE.

NHS Choices – Pregnancy and Child - online advice and support for patients 2016<sup>xl</sup>

The NHS website recommends acupressure on the wrist for reducing symptoms of nausea in pregnancy.

## Clinical Reviews

Cochrane Review 2015<sup>xli</sup>

In 2015, the Cochrane Library published its latest review of interventions for NVP. This review did not include patients with the more serious HYPEREMESIS GRAVIDUM. The review looked at several studies using stimulation of the P6 acupressure point. These studies provided evidence for the effectiveness of P6 acupressure.

The review did not find any consistent or strong evidence to support the use of pharmacologically active anti-emetic drugs to relieve NVP. This lack of a clear benefit has important implications when balanced against the risk of serious side effects and birth defects. In view of this lack of a clear effect and potential for side effects, anti-emetic drugs are reserved for second line treatment in HYPEREMESIS GRAVIDUM.

This review also acknowledged the NICE guidelines.

McParlin C et al. Treatments for Hyperemesis Gravidum and Nausea and Vomiting in Pregnancy: A Systematic Review 2016<sup>xlii</sup>

This review looked at 78 studies, 67 of which were randomised, and concluded that P6 acupressure is an appropriate first-line OTC treatment for NVP.

Ebrahimi N et al. Optimal management of Nausea and Vomiting in Pregnancy 2010<sup>xliii</sup>

Optimal management of NVP begins with non-pharmacological approaches including P6 acupressure. The positive impact of these non-invasive, inexpensive and safe methods has been demonstrated. Pharmacological treatments have varying effectiveness.

Helmreich RJ et al Meta-analysis of the efficacy of acustimulation in treating Nausea and Vomiting in Pregnancy. 2006<sup>xliv</sup>

This meta-analysis reviewed 14 trials including 1,655 patients using acupressure, acupuncture or electrical stimulation to treat NVP.

The review confirmed that stimulating the P6 acupoint using acupressure or electrical stimulation is more effective and easier than acupuncture.

The MotheRisk<sup>xlv</sup> Nausea and Vomiting in Pregnancy Survey 2002<sup>xlvi</sup>

This study surveyed 76 women receiving NVP counselling from the MotheRisk Program in North America (USA and Canada). The study found that 61% of women with NVP used complementary and alternative medicines to relieve their symptoms. Acupressure was one of the most popular methods.

The algorithm written by Dr's Einarson, Maltepe, Boskovic and Koren for the treatment of NVP, recommends using P6 acupressure as first-line treatment as well as add on therapy at any stage.



## Summary of evidence supporting P6 Acupoint Stimulation for Motion Sickness

Treatments for motion sickness are more effective if started before travel. Strategies include P6AS, pharmaceuticals and herbal preparations, as well as dietary and behavioural recommendations.

Studies have compared the effectiveness of these remedies under real and simulated conditions.

As with all causes of N&V, there is a high degree of inter as well as intra-subject variability. Hence, the efficacy of travel sickness remedies depends on how the subject is feeling at the time as well as the nature and intensity of the motion, and their ability to adapt.

P6 acupoint stimulation offers travel sickness sufferers an effective drug-free treatment which is also free from central side effects<sup>xlvii</sup>.

### Palliative Care

As well as being a common problem for travellers, motion sickness also affects cancer patients. The malignancy can disrupt their vestibular apparatus and stimulate mechanoreceptors in their viscera. This is a particular problem at the end-of-life<sup>3</sup>. Motion sickness can be induced in a cancer patient by something as simple as moving their head on the pillow. Nausea in these patients adds to their discomfort and adversely affects their hydration and nutrition.

Nursing and NICE palliative care guidelines recommend using simple measures including P6AS before considering drug treatment. Non-pharmacological strategies are very important in the overall management of people at the end-of life<sup>xlviii xlix l li lii liii</sup>. The effectiveness of P6AS for treating motion sickness in cancer patients and palliative care is accepted by HEALTHCARE PROFESSIONALS and patients.

### Field Studies (sea trials)

Gahlinger PM. 2000

Two surveys of passengers crossing the Drakes Passage in the Southern Ocean found that, despite it being one of the roughest seas in the world, 26% of passengers did not want to take drug treatment. Reasons given included a dislike of medication, side effects, drug interactions and contraindications<sup>liv</sup>.

The surveys found:

- That scopolamine was significantly more effective than other treatments.
- There was no significant difference in the efficacy of the other treatments, including P6 acupressure, which were all ranked as effective.
- None of the subjects using acupressure reported adverse effects.
- All subjects using scopolamine reported side effects including drowsiness and dry mouth. Other side effects of drug treatment included blurred vision, difficulty speaking and concentrating. The most frequent side effect reported for meclizine, dimenhydrinate, and cinnarizine was drowsiness with some complaining of somnolence.
- Several subjects taking meclizine complained of neither a benefit nor side effects and thought they were taking a placebo.

Bertolucci LE and DiDario B. 1995

A single-blind, placebo controlled, cross-over study carried out in rough open sea in the North Pacific showed that P6AS significantly decreased the symptoms of seasickness. The study showed that proper positioning and the intensity of stimulation is important. Subjects who began with placebo stimulation at a sham acupoint and then changed to active stimulation, of the P6 acupoint, experienced improvement in symptom control<sup>lv</sup>.

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<sup>3</sup> The end-of-life is defined as the last 12 months of palliative care.

### Clinical Laboratory studies

Studies show that the sensory impulses at the P6 acupoint are conveyed to the central nervous system via peripheral nerves. Nausea is associated with cerebellar activity which is activated by stimulating the P6 acupoint. P6 stimulation also decreases heart rate and increases vagal tone<sup>lvi</sup>. Vagal tone also regulates the stomach. Increased vagal tone reduces the severity motion sickness<sup>lvii</sup>.

Further evidence for P6AS affecting the vagus nerve comes from an Australian single-blind randomised cross-over study in healthy subjects. This showed that P6AS significantly inhibits the frequency of transient lower esophageal sphincter relaxations (TLESRs) in response to mechanical gastric distention. This degree of inhibition is comparable to that seen with pharmacological agents. TLESRs are also mediated by vasovagal neural pathways<sup>lviii</sup>.

### Simulation Laboratory Studies

A randomised study using a driving simulator showed that P6 acupressure significantly reduces the severity of motion sickness<sup>lix</sup>. The study was carried out in the USA using the Sea-Band device approved by the FDA. The study showed that a subject's own perception of susceptibility to motion and simulator sicknesses is a reliable predictor.

Stern and co-workers at the Gastrointestinal Psychology Laboratory of Pennsylvania State University showed that P6AS relieves vection<sup>4</sup> induced motion sickness and reduces gastric tachyarrhythmia which is one of the main symptoms of motion sickness, along with nausea. Further studies by Stern et. al. showed that in cases of severe motion simulation, sufferers must be instructed to press the Sea Band to be effective<sup>lx lxi</sup>.

A Swedish double-blind, randomised, placebo-controlled study found that P6 acupressure increased tolerance to a standardised nauseogenic motion stimuli and reduced the number of symptoms<sup>lxii</sup>.

An American placebo-controlled study investigated the efficacy of P6AS for relieving Simulation Adaptive Syndrome<sup>5</sup> (SAS) in subjects with a history of motion sickness. The study showed that P6AS significantly reduces and prevents SAS-related nausea and physical discomfort<sup>lxiii</sup>. Efforts to counter SAS using antiemetic drugs are limited by the high incidence of drowsiness which will impact the driving skills being evaluated in the simulator. P6AS offers an effective non-invasive and non-drowsy treatment.

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<sup>4</sup> Vection is when a large part of the visual field moves so that viewer feels like he or she has moved but the world has remained stationary. For example, when one is in a train at a station, and a nearby train moves, one can have the illusion that one's own train has moved in the opposite direction. If this feeling persists it sets up a conflict with the vestibular apparatus which causes nausea.

<sup>5</sup> Simulator Adaptation Syndrome is a condition in which nausea, disorientation, dizziness, headache, and difficulty focusing, are exhibited when driving in a simulator.

### Clinical Trials

Appendix 2 presents the horizontal tabulated summary of 13 clinical trials published between 1990 to 2017 describing the use of P6AS for treating motion sickness. These studies include over 900 subjects, some of whom underwent repeat treatment. The studies show that P6AS offers sufferers an effective side-effect free alternative to drug treatment.

### Independent Expert Healthcare Professional Opinion

Pharmacists at Boots and Lloyds Pharmacy chains recommend P6 acupressure for drug and side effect free treatment of travel sickness in children and adults. The medical device is supplied under Boots own brand as well as Sea Band <sup>lxiv lxxv</sup>.

The NHS advice for motion sickness includes visiting your pharmacist who will recommend the best treatment including acupressure bands <sup>lxvi</sup>.

### The place of P6 Acupoint Stimulation in Treating Motion Sickness

The efficacy of all motion sickness remedies, including drugs, herbal (ginger) and behavioural treatments, varies according to the motion and a person's suggestibility, susceptibility and adaptability.

P6AS is approved in the USA by the FDA and EU by the MHRA. It provides drivers and pilots with a non-drowsy treatment. The lack of side effects, interactions and contraindications is also important for pregnant and breastfeeding women as well as those with prostatic hypertrophy, glaucoma and urinary and digestive problems.

P6AS is also an important adjunct to the management of motion sickness in cancer patients at the end-of-life.

### Cost implications of P6 Acupoint Stimulation

The simple design and reusable nature of P6AS makes it a more cost-effective treatment than antiemetic drugs.

Indirect costs are also less as drug related side-effects, contraindications and interactions can delay return to work and in serious cases delay hospital discharge or lead to re-admission.

### Sales

Sea-Band was launched in the EU in the 1980s. Worldwide sales continue to grow and currently stand at over three quarters of a million units per year in Europe alone.

## Conclusion

There are over 140 published clinical studies, including more than 15,600 patients, confirming the effectiveness of P6AS for treating N&V due to surgery, chemotherapy, pregnancy and motion.

These studies have been examined by 16 independent reviews which have formed the basis of 14 clinical guidelines including those by the NHS, RCOG and NICE.

Sea-Band and other similar products are internationally approved as Class I Medical Devices. Self-administered P6 acupressure is easy to use, safe, cost-effective, non-invasive and free from side effects, drug interactions and contraindications.

All antiemetic drugs have side effects such as drowsiness due to their central mode of action which makes them unsuitable for drivers, pilots and pregnant and breastfeeding women.

P6AS is an effective adjunct in post-operative nausea and vomiting. As well as being an effective adjunct for treating chemotherapy induced N&V, cancer patients at the end-of-life with motion sickness also benefit from the drug-free efficacy of P6AS.

Since the 1980's millions of travellers, patients and HEALTHCARE PROFESSIONALS in the UK, EU and USA have been safely and effectively using P6AS.

## Appendix I: Horizontal Tabulation of Randomised Controlled Clinical Trials Nausea and Vomiting in Pregnancy

Horizontal tabulation summarising 14 studies from 1988 to 2014 including 1,778 women, showing the safety and efficacy of P6 acupoint stimulation in treating NVP.

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	No of patients
Dundee JW, Serial FBR, Ghaly RG and Bell PF  P6 acupressure reduces morning sickness  Journal of the Royal Society of Medicine, Volume 81 August 1988, page 456 - 457	Department of Anaesthetics, The Queens University and Royal Maternity Hospital Belfast,  UK	1988	Prospective randomized 3 arm parallel group placebo controlled study	There awes a highly significant ( $P<0.0005$ ) reduction in the severity of sickness in the group receiving P6 acupressure compared to those receiving no treatment.	119
Hyde E  Acupressure Therapy for Morning Sickness – A controlled Clinical trial  Journal of Nurse-Midwifery Vol 34, No 4, July/August 1989	New Haven, Connecticut,  USA	1989	Randomised 2-arm cross-over prospective controlled study	Acupressure relieved morning sickness in 12 of the 16 subjects and significantly reduced anxiety, depression, behavioral dysfunction and nausea.	16
Alloys D and Penacchioni P  Morning Sickness Control in Early Pregnancy by Neiguan Point Acupressure  Obstet Gynecol 1992;80:852-4	Department of Obstetrics and Gynaecology, Bologna University,  Italy	1992	Randomized double blind placebo controlled cross-over study	Acupressure on the P6 acupoint significantly lowers the frequency of morning sickness compared to placebo.	60

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	No of patients
<p>Bayreuther J, Pickering R and Lewith GT</p> <p>A double-blind cross-over study to evaluate the effectiveness of acupressure at pericardium 6 (P6) in the treatment of early morning sickness (EMS)</p> <p>Complementary Therapies in Medicine Volume 2, Issue 2, April 1994, Pages 70-76</p>	<p>Southampton University Medical School</p> <p>UK</p>	1994	Double blind cross-over placebo controlled study	<p>P6 acupressure is significantly more effective than the placebo at relieving morning sickness (<math>P = 0.019</math>).</p> <p>Two thirds of patients preferred P6 acupressure compared placebo.</p>	23
<p>Belluomini J, Lit R, Lee K, and Katz M</p> <p>Acupressure for Nausea and Vomiting of Pregnancy: A randomised, Blind Study</p> <p>Obstet Gynecol 1994;84:245-8</p>	<p>Department of Obstetrics and Gynecology, University of California</p> <p>USA</p>	1994	Placebo controlled randomised subject-blind parallel group	P6 acupressure significantly reduced nausea compared to placebo.	60
<p>Stainton MC and Neff EJA</p> <p>The efficacy of Sea Bands for the control of nausea and vomiting in pregnancy</p> <p>Health Care for Women International, 1994, 15: 6, 563 — 575</p>	<p>Faculty of Nursing, University of Calgary, Calgary, Alberta,</p> <p>Canada</p> <p>School of Nursing, East Carolina University, Greenville, North Carolina,</p> <p>USA</p>	1994	Pre-and post-test longitudinal design.	<p>P6 acupoint stimulation using Sea-Bands reduced the incidence of nausea and vomiting in pregnancy by 50%.</p> <p>Efficacy is improved by early use and offer pregnant women and their unborn children effective drug-free and noninvasive relief from morning sickness.</p>	27

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	No of patients
<p>Steele NM, French J, Gatherer-Boyles J, Newman S, and Leclaire S</p> <p>Effect of Acupressure by Sea-Bands on Nausea and Vomiting of Pregnancy</p> <p>JOGNN, 30,61-70; 2001</p>	<p>Kirkhof School of Nursing, Grand Valley State University, Allendale, Michigan, USA</p>	2001	A multicentre, parallel 2-arm placebo controlled, post-test-only and post-test-repeated observational study.	<p>The group receiving P6 acupressure had significantly less frequent and severe nausea and vomiting of pregnancy, than the placebo group.</p> <p>P6 acupressure using Sea-Bands is a non-invasive, inexpensive, safe, and effective treatment for the nausea and vomiting of pregnancy.</p>	110
<p>Norheim AJ, Pedersen EJ, 2, Fønnebo V and Berge L</p> <p>Acupressure treatment of morning sickness in Pregnancy. A randomised, double-blind, placebo-controlled study</p> <p>Scand J Prim Health Care 2001;19:43-47. ISSN 0281-3432</p>	<p>Institute of Community Medicine, University of Tromsø and the Maternity Unit of the Aker Hospital, Oslo, Norway</p>	2001	Randomised double blind placebo controlled study	<p>There was a strong placebo response, however, P6 acupressure reduced the hours of discomfort hence the use of wristbands can be recommended for morning sickness in early pregnancy, especially before pharmacologically active drugs are considered.</p>	97
<p>Worntoft E, Dykes AK.</p> <p>Effect of acupressure on nausea and vomiting during pregnancy. A randomized, placebo-controlled, pilot study.</p> <p>J Reprod Med. 2001 Sep;46(9):835-9</p>	<p>Department of Nursing, Lund University, Sweden</p>	2001	A randomized, 3-arm, placebo-controlled study	<p>NVP is significantly reduced by acupressure at P6 acupoint as compared to acupressure at a placebo point, or no treatment at all.</p> <p>Relief from nausea appeared one day after starting treatment in both the P6 and placebo groups but lasted for only six days in the placebo group. The P6 group, however, experienced significantly less nausea after 14 days as compared to the other two groups</p>	60
<p>Smith C, Crowther C and Beilby J</p> <p>Acupuncture to treat nausea and vomiting in early pregnancy: a randomized controlled trial.</p> <p>Birth 2002 Mar;29(1):1-9</p>	<p>Department of Obstetrics &amp; Gynaecology, Adelaide University, Adelaide, Australia</p>	2002	Single blind 4-arm randomised placebo controlled study	<p>P6 acupoint stimulation significantly reduces the incidence of nausea and dry retching compared to the no-treatment group.</p>	593



Published Reference	Centre and Country	Date of Publication	Study type	Outcome	No of patients
Rosen T, de Veciana M, Miller HS, Stewart L, Rebarber A and Slotnick RN.  A Randomized Controlled Trial of Nerve Stimulation for Relief of Nausea and Vomiting in Pregnancy  The American College of Obstetricians and Gynecologists. VOL. 102, NO. 1, JULY 2003 Page 129 - 135	Department of Obstetrics and Gynecology, New York University School of Medicine, New York, New York.  USA	2003	Multicenter randomised parallel placebo controlled study	P6 acupoint stimulation is significantly more effective than placebo at reducing nausea and vomiting and promoting weight gain in symptomatic women in the first trimester of pregnancy.	230
Neri I, Allais G, Schiapparelli P, Blasi I, Benedetto C and Facchinetti I  Acupuncture versus pharmacological approach to reduce Hyperemesis gravidarum discomfort  Minerva Ginecol 2005 Aug;57(4)471-5	Department of Obstetrics and Gynaecology, University of Modena-Reggio Emilia, Modena,  Italy	2005	Randomised 2-arm parallel group study comparing P6 acupoint stimulation with a combination of IV metoclopramide and PO vitamin B12	Both treatments reduced nausea and vomiting and improved eating. P6 acupoint stimulation was significantly more effective than drugs in improving functioning.	88
KHAVANDIZADEH AGHDAM S and MAHFOUZI B.  EVALUATION OF THE EFFECTS OF ACUPRESSURE BY SEA BAND ON NAUSEA AND VOMITING OF PREGNANCY  IRANIAN JOURNAL OF OBSTETRICS, GYNECOLOGY AND INFERTILITY JUNE-JULY 2010 , Volume 13 , Number 2; Page(s) 39 To 44.	FACULTY OF MEDICINE, AZAD ISLAMIC UNIVERSITY, ARDABIL BRANCH, ARDABIL,  IRAN.	2010	Randomised placebo controlled 2-arm parallel group study using Sea Bands	The severity of nausea and frequency of vomiting is significantly decreased by using Sea Bands.	100
Farquhar S, Ghaemi SZ, Roshandel A, Moshfegh Z, Rostambeigy P and Mohaghegh Z.  The Effect of Acupressure on Nausea and Vomiting during Pregnancy  Researcher 2014;6(6):27-34]. (ISSN: 1553-9865)	Department of Midwifery, Estahban branch, Islamic Azad University, Estahban,  Iran	2014	Placebo controlled three arm randomized stud	The severity and frequency of nausea and vomiting significantly decreased in patients receiving P6 acupressure.	195

## Appendix II: Horizontal Tabulation of Clinical Trials in Motion Sickness

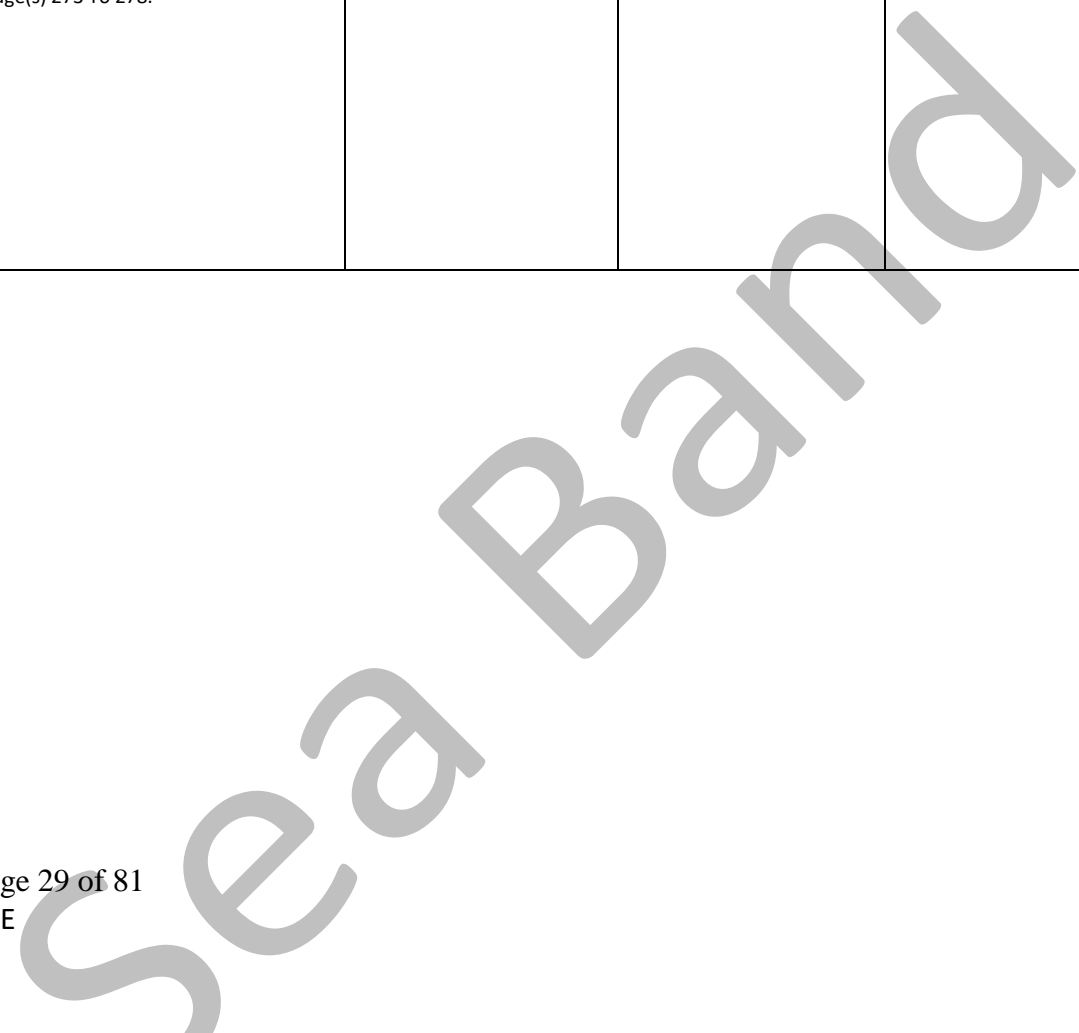
Horizontal tabulated summaries of 13 studies from 1990 to 2017, including over 900 subject's, some of whom underwent multiple treatments, showing the safety and efficacy of P6 acupoint stimulation for relieving Motion Sickness.

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Ourania Fydanaki, Panagiotis Kousoulis, Efthimios Dardiotis, Ioannis Bizakis, and Ioannis Hajjioannou,</p> <p>Electroacupuncture Could Reduce Motion Sickness Susceptibility in Healthy Male Adults: A Double-Blinded Study</p> <p>Medical Acupuncture. October 2017</p>	<p>Department of Ophthalmology, General Air Force Hospital, Hellenic Air Force, Athens.</p> <p>Greece</p>	2017	<p>Randomised 3-arm placebo controlled double blind study</p> <p>A – electrical acupoint stimulation</p> <p>B- sham (placebo) electrical stimulation</p> <p>C – control (no-treatment)</p> <p>Motion stimulus, using a rotating chair. Symptoms were measured using Gianaros Motion Sickness Assessment Questionnaire (MSAQ).</p>	<p>All 3 groups of subjects showed motion sickness symptoms. The mean total symptom score for Group A was 59,375; for Group B it was 74,333 and in Group C was it 93,166.</p> <p>This difference is partially statistically significant when comparing Group A with Group C, especially in a peripheral group of symptoms, as measured by the Gianaros MSAQ.</p>	20

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Cox DJ, Singh H and Cox DM</p> <p>Effectiveness of Acupressure and Acustimulation in Minimizing Driving Simulation Adaptation Syndrome</p> <p>MILITARY MEDICINE, 176, 12:1440, 2011</p>	<p>Department of Psychiatry and Neurobehavioral Sciences, University of Virginia Health System, Charlottesville, Virginia</p> <p>USA</p>	2011	<p>Within subject, placebo controlled repeated-measures randomised crossover study of the efficacy of P6 acupoint stimulation in alleviating symptoms of Simulation Adaptation Syndrome (SAS) in subjects with a history of car, motion and/or sea sickness.</p>	<p>16 subjects reported SAS during placebo treatment. Overall, the analysis of variance condition effect was significant (<math>p &lt; 0.05</math>).</p> <p>Participants in the acustimulation condition reported significantly less physical discomfort (<math>p &lt; 0.005</math>) compared with the placebo.</p> <p>These data show that P6 acupoint stimulation can help to significantly reduce or prevent SAS-related nausea and physical discomfort.</p>	25
<p>Alkaissi, A., T. Ledin, et al. (2005)</p> <p>P6 acupressure increases tolerance to nauseogenic motion stimulation in women at high risk for PONV.</p> <p>Canadian Journal of Anaesthesia 2005 52: 7 pp 703–709</p>	<p>Departments of Anaesthesiology and Intensive Care and Oto-Rhino-Laryngology, University Hospital, Linköping</p> <p>Sweden</p>	2005	<p>Randomised double blind placebo and no treatment controlled study of the effect P6 acupoint stimulation has on the time to nausea using a laboratory motion challenge.</p> <p>The motion challenge was by eccentric rotation in a chair, blindfolded and with chin to chest movements of the head. The challenge was stopped when women reported moderate nausea.</p>	<p>Mean time to moderate nausea was longer in the P6 acupressure group compared to the control group. P6 acupressure = 352 (259-445), mean (95% confidence interval) in seconds, control = 151 (121-181) and placebo acupressure = 280 (161-340); (<math>P = 0.006</math>).</p> <p>Previous severity of motion sickness did not influence time to nausea (<math>P = 0.107</math>). The cumulative number of symptoms differed between the three groups (<math>P &lt; 0.05</math>). Fewer symptoms were reported in the P6 acupressure compared to the control group <math>P &lt; 0.009</math>.</p> <p>P6 acupressure increased tolerance to experimental nauseogenic stimuli, and reduced the total number of symptoms reported.</p>	60

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Zou, D, Chen WH, et al. (2005).                      "Inhibition of transient lower esophageal sphincter relaxations by electrical acupoint stimulation."                      Am J Physiol Gastrointest Liver Physiol 289(2): G197-201</p>	<p>Department of Gastroenterology, Hepatology, and General Medicine, Royal Adelaide Hospital, and Department of Medicine, University of Adelaide                      Australia</p>	<p>2005</p>	<p>Randomised placebo controlled cross-over study of the effect of P6 acupoint stimulation on the oesophageal sphincter.                      Gastric distension is the major trigger for transient lower oesophageal sphincter (LES) relaxations (TLESRs). The aim of this study was to investigate the effect of P6 acupoint stimulation on the TLESRs.                      Oesophageal motility was measured during distension of the proximal stomach with 500 ml of air using a barostat balloon.</p>	<p>P6 acupoint stimulation decreased the rate of TLESRs by 40% from a median of 6/h to 3.5/h (P &lt; 0.02).                      Stimulation of the P6 acupoint significantly inhibits the frequency of TLESRs in response to gastric distention.</p>	<p>14</p>
<p>Wright, L. D. (2005).                      Pain and symptom management. The use of motion sickness bands to control nausea and vomiting in a group of hospice patients.                      American Journal of Hospice &amp; Palliative Medicine 22(1): 49-53.</p>	<p>Hospice of Muskegon-Oceana, Muskegon, Michigan,                      USA.</p>	<p>2005</p>	<p>Open year-long observational study of the efficacy of motion sickness bands for controlling nausea and vomiting in hospice patients.</p>	<p>Twenty-nine of the 33 patients studied showed a positive response to the intervention with a response rate of 88 percent.                      Motion sickness bands were effective in controlling nausea and vomiting and had the added benefits of patient empowerment and financial savings.</p>	<p>33</p>

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>KHOSHNOUDI, M., M. MIRIAN, et al. (2004).                      "EFFECT OF SEA-BAND ON PREVENTION OF NAUSEA &amp; VOMITING IN MILITARY PERSONNEL AT SEA."                      JOURNAL OF MILITARY MEDICINE. Winter 2004, Volume 6, Number 4 (22); Page(s) 273 To 278.</p>	<p>Medicine Institute,                      Baqiyatallah University of Medical Sciences, Tehran,                      Iran</p>	<p>2004</p>	<p>Randomised parallel placebo controlled study of the effectiveness P6 acupoint stimulation using Sea Band for treating seasickness in operational Navy personnel.</p>	<p>Nausea and vomiting was statistically (t-test) significantly reduced in the treatment group.                      Treatment group: nausea 22% and vomiting 14%                      Placebo group: nausea 61% and vomiting 21%.                      Sea Band offers a very cost-effective and non-invasive technique for alleviating motion sickness symptoms.                      Sea Band does not have the central side effects of drug treatments for motion sickness such as drowsiness and headache.</p>	<p>94</p>



Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>SHIOMI M., IMAI K, et al. (2003)</p> <p>"Effect of Acupuncture Stimulation on Optokinetic Motion Sickness Monitored by Electrogastragrams."</p> <p>Journal of the Japan Society of Acupuncture and Moxibustion <b>53</b>(1): 71-80</p>	<p>Japan</p>	<p>2003</p>	<p>Randomised 3-arm study of the effect of P6 acupoint stimulation on motion sickness.</p> <p>1 - electrical stimulation 2 - retaining needle stimulation 3 - no treatment</p> <p>Motion sickness scores and changes in electrogastragrams (EGG) were evaluated.</p> <p>Motion sickness was induced using a rotating optokinetic drum. EGGs were recorded continuously before, during, and after.</p>	<p>P6 acupoint stimulation using a retained needle reduced the severity of nausea and returned more patients to normal EGG activity after drum rotation exposure than in the no treatment group.</p> <p>P6 acupoint stimulation using a retained needle effectively relieves the symptoms of motion sickness possibly by suppressing abnormal gastric myoelectric activities.</p>	<p>36</p>

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Stern, R. M., M. D. Jakerst, et al. (2001)                      Acupressure relieves the symptoms of motion sickness and reduces abnormal gastric activity.                      Alternative therapies in health and medicine 2001 Jul-Aug;7(4):91-4.</p>	<p>Gastrointestinal Psychology Laboratory, Pennsylvania State University                      USA.</p>	<p>2001</p>	<p>Open 3-arm cross-over study:                      1 - P6 acupoint stimulation with Acuband                      2 - Acuband on forearm                      3 - no Acuband</p> <p>Subjects pre-screened for susceptibility to motion sickness tested on 3 separate occasions in a rotating optokinetic drum.</p> <p>Subjective symptoms of motion sickness and abnormal gastric activity, as recorded via electrogastragraphy, were obtained throughout the procedure.</p>	<p>Significantly less motion sickness and abnormal gastric activity was observed when wearing Acuband.</p> <p>P6 acupoint stimulation with Acuband decreases the symptoms of motion sickness and the gastric activity that usually accompanies motion sickness</p>	<p>25</p>

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Gahlinger PM.</p> <p>A comparison of motion sickness remedies in severe sea conditions:</p> <p>Letter to the editor. Wilderness and Environmental Medicine, 11, 136-137 (2000)</p>	<p>Southern Ocean, Drake Passage between Ushuaia, Argentina, and the Antarctic peninsula.</p> <p>Gale force winds and 9m swells.</p>	<p>2000</p>	<p>Ships Physician run open 2 ship surveys in non-adapted subjects receiving either P6 acupoint stimulation, scopolamine, meclizine, dimenhydrinate, and cinnarizine</p>	<p>Scopolamine was significantly more effective than the other treatments which were also effective. There was no difference in efficacy between P6 acupoint stimulation, cinnarizine, meclizine and dimenhydrinate.</p> <p>While no subjects using P6 acupoint stimulation had side effects, all subjects using scopolamine reported side effects including drowsiness and dry mouth. Other scopolamine side effects included blurred vision, difficulty speaking and difficulties concentrating. The most frequent side effect reported for meclizine, dimenhydrinate, and cinnarizine was drowsiness with some complaining of somnolence. Several subjects taking meclizine complained of neither a benefit nor side effects and thought they were taking a placebo.</p>	<p>265</p>



Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Hu, S., R. Stritzel, et al. (1995)</p> <p>P6 acupressure reduces symptoms of vection-induced motion sickness.</p> <p>Aviation, space, and environmental medicine 1995 Jul;66(7):631-4.</p>	<p>Department of Psychology, Humboldt State University, California</p> <p>USA.</p>	<p>1995</p>	<p>Randomised 4-arm study</p> <p>1 – P6 acupressure 2 – dummy-point acupressure 3 – Sham P6 acupressure 4 – control (no treatment)</p> <p>Motion sickness was induced in an optokinetic drum. Subject electrogastrograms and symptoms were recorded.</p>	<p>Subjects in the P6 acupressure group reported significantly less nausea during drum rotation than those in the dummy-point acupressure, sham acupressure, and control groups.</p> <p>The scores for symptoms of motion sickness in the P6 acupressure group were significantly lower than those in the sham acupressure and control group.</p> <p>Subjects in the P6 acupressure group showed significantly less abnormal gastric myoelectric activity and tachyarrhythmia, than those in the sham acupressure and control groups.</p> <p>Subjects in the dummy-point acupressure group did not report significantly fewer symptoms and showed less tachyarrhythmia than those in the sham acupressure and control groups.</p> <p>P6 acupressure reduces the severity of symptoms of visually-induced motion sickness and gastric tachyarrhythmia.</p>	<p>64</p>
<p>Bertolucci, L. E. and B. DiDario (1995)</p> <p>Efficacy of a portable acustimulation device in controlling seasickness.</p> <p>Aviation, space, and environmental medicine 1995 Dec; 66(12): 1155-8.</p>	<p>Maven Laboratories, Inc., Citrus Heights, California</p> <p>North Pacific Ocean off the coast of San Francisco in average to rough seas with 3-6ft swells.</p> <p>USA</p>	<p>1995</p>	<p>Single blind placebo controlled cross over study of P6 acupoint stimulation using Relief Band for sea sickness</p>	<p>Seasickness symptoms were suppressed by P6 acupoint stimulation using Relief Band.</p>	<p>21</p>

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Hu, S., Stern RM, et al. (1992)</p> <p>Electrical acustimulation relieves vection-induced motion sickness.</p> <p>Gastroenterology 1992; 102:1 854-1858</p>	<p>Department of Medicine, Pennsylvania State University</p> <p>USA</p>	1992	<p>2 studies of the effect electrical acustimulation has on gastric myoelectric activity and the severity of motion sickness.</p> <p>Experiment 1: subjects received electrical acustimulation in one of two sessions.</p> <p>Experiment 2: subjects were randomly divided into three groups to receive:</p> <p>1 - acustimulation 2 - sham acustimulation 3 - control.</p> <p>Subjects sat in a rotating optokinetic drum for 15 minutes. Electrogastrograms and subjective symptoms of motion sickness were obtained.</p>	<p>In experiment 1, the mean symptom score and tachyarrhythmia during acustimulation sessions were significantly lower than during no-acustimulation sessions.</p> <p>In experiment 2, the mean symptom score of the acustimulation group was also significantly lower than that of the sham-stimulation group and the control group; tachyarrhythmia in the acustimulation group was significantly less than that of the control group but not the sham-stimulation group.</p> <p>Electrical acupoint stimulation reduces the severity of symptoms of motion sickness and appears to decrease gastric tachyarrhythmia.</p>	61
<p>Sea-Band Trial in Motion Sickness</p> <p>Professor G. Canova 1990</p> <p>Data on file</p>	<p>Hospital San Carlo Borromeo, Milan</p> <p>Italy</p>	1990	<p>Open label study in children aged 2 to 15 who suffered from intense motion sickness even on short journeys</p>	<p>62 questionnaires were returned. 55 (88.7%) had excellent results. All but one journey was by car.</p> <p>Considering the very positive results and the obvious absence of harmful side effects, Sea-Bands is a very useful method of preventing motion sickness in children.</p>	106

### Appendix III: Horizontal tabulated summaries of clinical studies in Chemotherapy Induced Nausea and Vomiting

Horizontal tabulated summaries of 31 studies between 1987 and 2017 including over 2,456 cancer patients in the UK, USA and RoW; showing the safety and efficacy of P6 acupoint stimulation for treating CINV. The studies including RINV and NV in cancer patients undergoing end of life care. Based on 3 to 5 courses of chemotherapy per patient, these data will represent between 7,000 and 12,000 courses of treatment.

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Shen CH and Yang LY</p> <p>The Effects of Acupressure on Meridian Energy as well as Nausea and Vomiting in Lung Cancer Patients Receiving Chemotherapy</p> <p>Biological Research for Nursing volume: 19 issue: 2, page(s): 145-152</p> <p>Article first published online: December 27, 2016; Issue published: March 1, 2017</p>	<p>Kaohsiung Medical University Hospital, Taiwan</p> <p>Republic of China</p>	2017	2-arm parallel group placebo controlled sequential study in lung cancer patients	<p>The group receiving P6 acupressure stimulation had significantly less nausea (<math>p &lt; 0.001</math>) and vomiting (<math>p &lt; 0.006</math>) during the delayed phase, compared to the placebo control group.</p> <p>Acupressure significantly decreased the severity of nausea and vomiting in lung cancer patients undergoing chemotherapy.</p> <p>P6 acupressure is recommend for the relief of nausea and vomiting in patients receiving chemotherapy.</p>	70

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Said ZM, Hussein A and Alkaissi A.</p> <p>Acupressure for Chemotherapy Induced Nausea and Vomiting in Breast-Cancer Patients: A Randomized, Placebo-Controlled Clinical Trial</p> <p>Advances in Life Science and Vol.41, 2016</p> <p>Paper presented at the International Conference of the Society for Acupuncture Research, North Carolina, USA.</p>	<p>An-Najah National University, Nablus.</p> <p>Palestine</p>	2016	<p>3-arm parallel group 5-day outpatient randomised double blind placebo controlled study of the efficacy of P6 acupressure as an antiemetic adjunct for preventing CINV associated with highly emetogenic chemotherapy and its effect on quality of life.</p> <p>Arm 1: received bilateral P6 acupressure            Arm 2: received bilateral placebo stimulation            Arm 3: no stimulation (control)</p>	<p>Arm 1 had a statistically significant reduction in the incidence of delayed nausea 40% (17/42) as compared to the control group 62% (26/42) (p= 0.0495).</p> <p>Requirement of rescue anti-emetics was significantly lower in the arm 1 (55%, 23/42), as compared to control group (76%, 32/42) (p=0.0389).</p> <p>81% (35/42) of the patients in arm 1 were significantly satisfied with P6-acupressure, and 79% (34/42) would recommend P6-acupressure to another patient.</p> <p>P-6 acupressure is an effective adjunct to standard pharmacological anti-emetics for improving the management of CINV in women undergoing treatment for breast cancer.</p>	126
<p>Abusaad FES and Ali WGM</p> <p>Effect of point 6 acupressure on chemotherapy associated nausea and vomiting among adolescents with cancer</p> <p>Journal of Nursing Education and Practice 2016, Vol. 6, No. 4. P122-129</p>	<p>Mansoura University,</p> <p>Egypt</p>	2016	<p>2-arm parallel group study of P6 acupressure as ant anti-emetic adjunct v's pharmacological antiemetic only.</p>	<p>There was a decrease in the total mean score of nausea, vomiting and retching in the P6 group compared to control group with a statistical significant difference between the groups regarding its frequency, severity and duration.</p> <p>40% found P6 acupressure moderately effective, 33.3% effective while only 26.7% stated that it is slightly effective.</p> <p>P6 acupressure has a significant role to play as a non-pharmacological antiemetic adjunct to pharmacological combination antiemetic regimens for CINV.</p>	60

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Genc F and Tan M.</p> <p>The effect of acupressure application on chemotherapy-induced nausea, vomiting, and anxiety in patients with breast cancer.</p> <p>Cambridge University Press. Palliat Support Care. 2015 Apr; 13(2): 275-84.</p>	Giresun University, Turkey	2015	2 arm parallel group controlled study	<p>The mean nausea, vomiting, and retching scores, the total (experience, occurrence, and distress) scores and the mean anxiety scores for patients in the P6 acupressure group were statistically significantly lower compared with the scores of patients in the control group.</p> <p>Applying acupressure at the P6 point is effective in decreasing chemotherapy-induced nausea, vomiting, and anxiety in patients with breast cancer</p>	64
<p>Suh EE</p> <p>The Effects of P6 Acupressure and Nurse-Provided Counselling on Chemotherapy-Induced Nausea and Vomiting in Patients with Breast Cancer</p> <p>Oncology Nursing Forum Vol. 39, No. 1, January 2012</p>	South Korea	2012	<p>RCT, 4-arm balanced parallel study.</p> <ol style="list-style-type: none"> <li>1. placebo,</li> <li>2. counselling,</li> <li>3. P6 acupressure</li> <li>4. P6 acupressure with counselling.</li> </ol>	P6 acupressure with and without nurses counselling is significantly more effective than placebo at managing CINV	120

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Roscoe JA, O'Neill M, Jean-Pierre P, Heckler CE, Kaptchuk TJ, Bushunow P, Shayne M, Huston A, Qazi R and Smith B</p> <p>An Exploratory Study on the Effects of an Expectancy Manipulation on Chemotherapy-Related Nausea</p> <p>J Pain Symptom Manage 2010; 40: 379e 390.</p> <p>U.S. Cancer Pain Relief Committee</p>	<p>University of Rochester, New York and Harvard Medical School, Boston, Massachusetts.</p> <p>USA</p>	2010	<p>5 day parallel 4-arm patient-blind RCT of the effectiveness of adding informational manipulation designed to increase expectation of the efficacy of P6 acupoint stimulation as an adjunct to standard pharmacological anti-emetics in breast cancer patients about to start chemotherapy.</p> <p>Arm 1: neutral expectancy of nausea and efficacy of P6 acustimulation            Arm 2: expected nausea and neutral benefit of P6 acustimulation            Arm 3: neutral expectation of nausea and enhanced efficacy of P6 acustimulation.            Arm 4: expected nausea and enhanced efficacy of P6 acustimulation.</p>	<p>The effectiveness of P6 acupoint stimulation in treating nausea as an anti-emetic adjunct in CINV is improved by targeting expectancy manipulation at patients expecting to experience CINV.</p> <p>Patients receiving the expectancy-enhancing manipulation required less antiemetic medication as outpatients outside the clinic</p>	67
<p>Taspinar A, Sirin A</p> <p>Effect of acupressure on chemotherapy-induced nausea and vomiting in gynecologic cancer patients in Turkey</p> <p>European Journal of Oncology Nursing. Volume 14, Issue 1, February 2010, Pages 49-54</p>	<p>Celal Bayar University</p> <p>Turkey</p>	2010	<p>Prospective study of the efficacy of P6 acupoint stimulation as an adjunct to standard antiemetic regimen for CINV in gynaecological cancer patients.</p>	<p>P6 acupoint stimulation lead to a significant decrease in nausea and use of antiemetic medications (<math>p &lt; 0.05</math>).</p> <p>There was also a clinically significant decline in vomiting and retching which did not reach statistical significance.</p>	34

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Roscoe JA, Bushunow P, Jean-Pierre P, Heckler CE, Purnell JQ, Peppone LJ, Chen Y, Ling MN and Morrow GR.</p> <p>Acupressure Bands Are Effective in Reducing Radiation Therapy-Related Nausea</p> <p>J Pain Symptom Manage 2009; 38: 381-389. 2009</p> <p>U.S. Cancer Pain Relief Committee.</p>	<p>University of Rochester, James P. Wilmot Cancer Center, New York</p> <p>USA</p>	<p>2009</p>	<p>3-arm parallel group RCT to investigate the effectiveness of P6 acupressure bands in controlling radiation therapy-induced nausea in patients who experienced nausea previously and to test whether an informational manipulation designed to increase expectation of efficacy would enhance effectiveness.</p> <p>Arm 1. standard care (control)                      Arm 2: standard care plus acupressure bands and neutral manipulation                      Arm 3: Standard care plus acupressure plus positive manipulation.</p> <p>Patients reported nausea for two days prior to randomization (baseline) and for five days following using a seven-point semantic rating scale (1=not nauseated to 7=extremely nauseated).</p>	<p>Patients in Arms 2 and 3 combined reported a greater reduction in average nausea than patients in Arm 1 (<math>P &lt; 0.01</math>) which equates to a 23.8% decrease in nausea in the band groups compared to a 4.8% decrease in the control group; a difference of 19%.</p> <p>The informational manipulation did not alter efficacy expectations and there was no statistically significant difference in nausea between patients in Arms 2 and 3.</p> <p>Therefore, P6 acupressure bands without positive information are an effective, low-cost, noninvasive, well-accepted, and safe adjunct to standard antiemetic medication.</p>	<p>88</p>

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Gardani G., Cerrone R., Biella C., Galbiati G., Proserpio E., Casiraghi M., Arnoffi J., Meregalli M., Trabattoni P., Dapretto E., Gian L., Messina G., Lissoni P</p> <p>A progress study of 100 cancer patients treated by acupressure for chemotherapy-induced vomiting after failure with the pharmacological approach</p> <p>Minerva Medica 2007 December; 98(6): 665-8</p>	<p>Department of Radiotherapy and Oncology San Gerardo Hospital Monza, Milan</p> <p>Italy</p>	2007	<p>Consecutive study of adjunct P6 acupressure for metastatic solid tumour patients undergoing chemotherapy for advanced neoplastic disease not responding to standard antiemetic's including corticosteroids, anti-dopaminergics and 5-HT 3R antagonists.</p>	<p>Emetic symptoms reduced in 68/100 (68%) patients, without significant differences in relation to tumour histotype.</p> <p>This study confirms the efficacy of P6 acupressure in the treatment of CINV. Therefore, P6 acupressure should be considered as part of the therapeutic strategies for treating CINV.</p>	100
<p>Dibble SL, Luce J, Cooper BA, Israel J, Cohen M, Nussey B, et al.</p> <p>Acupressure for chemotherapy induced nausea and vomiting: a randomized clinical trial.</p> <p>Oncol Nurs Forum 2007 Jul;34(4):813-20</p>	USA	2007	<p>Multicentre RCT 3-arm parallel group study.            Arm 1 P6 acupressure,            Arm 2: placebo P6            Arm 3: no P6.</p>	<p>There were no significant differences between the groups for acute nausea or emesis, but with delayed nausea and vomiting in the acupressure group had a statistically significant reduction in the amount of vomiting and the intensity of nausea over time, when compared with the placebo and usual-care groups.</p> <p>Acupressure at the P6 point is a valuable technique in addition to pharmacological antiemetic management for women undergoing chemotherapy and should be offered to them.</p>	160



Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Perkins P and Vowler SL</p> <p>Does Acupressure Help Reduce Nausea and Vomiting in Palliative Care Patients? Pilot Study</p> <p>Palliat Med. 2008 Mar; 22(2): 193-4. do</p>	<p>Department of Public Health and Primary Care, University of Cambridge</p> <p>UK</p>	2007	<p>Pilot 2-arm blind RCT comparing P6 acupressure as an antiemetic adjunct to placebo in advanced irreversible breast cancer patients at end of life (prognosis of &lt;1y)</p> <p>Full study due for completion in September 2017.</p>	<p>P6 acupressure is an inexpensive and effective antiemetic adjunct which is acceptable to patients.</p>	10
<p>Molassiotisa A, Helinb AM, Dabboura R and Hummerstonc S</p> <p>The effects of P6 acupressure in the prophylaxis of chemotherapy-related nausea and vomiting in breast cancer patients</p> <p>Complementary Therapies in Medicine Volume 15, Issue 1, March 2007, Pages 3-12</p>	<p>Universities of Manchester and Nottingham</p> <p>UK</p>	2007	<p>2 centre 2-arm parallel RCT of acupressure for 5 days following chemotherapy.</p>	<p>Nausea and retching experience, and nausea, vomiting and retching occurrence and distress were all significantly lower in the P6 acupressure group compared to the control group (P &lt; 0.05). The only exception was regrading vomiting experience, which was close to significance (P = 0.06).</p> <p>P6 acupressure has an important role as an adjunct in the management of the complex symptoms of CINV.</p>	36

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Roscoe JA, Jean-Pierre P, Morrow GR, Hickok JT, Issell B, Wade JL and King DK</p> <p>Exploratory Analysis of the Usefulness of Acupressure Bands with Severe Chemotherapy-Related Nausea</p> <p>Journal of the Society for Integrative Oncology, March 2006, Volume 4, Number 1. P1-5</p>	<p>University of Rochester Medical Center, New York</p> <p>USA</p>	<p>2006</p>	<p>3-arm parallel group, multicentre RCT</p> <p>arm 1: P6 acupressure arm 2: P6 acustimulation arm 3: standard care</p>	<p>There was a clinically significant difference between the three groups in the proportion of patients reporting severe nausea (standard care, standard care with acupressure bands (SeaBand®), and standard care with an acustimulation band (ReliefBand®)).</p> <p>The proportion of patients in the acupressure band group who reported severe nausea following their chemotherapy treatment (41%) was significantly less than that of the standard care group (68%) and the acustimulation band group (73%).</p> <p>These findings show that acupressure wristbands are an effective adjuvant therapy for nausea management in cancer patients, especially those experiencing severe nausea following chemotherapy.</p>	<p>86 (follow on from 2003 study)</p>
<p>Shin YH, Kim TI, Shin MS and Juon HS</p> <p>Effect of Acupressure on Nausea and Vomiting During Chemotherapy Cycle for Korean Postoperative Stomach Cancer Patients</p> <p>Cancer Nursing, Vol. 27, No. 4, 2004, p267-274</p>	<p>St. Mary Hospital, Daejeon, Keimyung University,</p> <p>Korea</p> <p>And Department of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health, Baltimore,</p> <p>USA</p>	<p>2004</p>	<p>2-arm parallel non-equivalent control group study.</p> <p>Arm1: P6 acupressure as an adjunct to standard anti-emetic drug treatment with metoclopramide and ondansetron in post-operative gastric cancer patients receiving cisplatin and 5FU.</p> <p>Arm 2: standard antiemetic's</p>	<p>The addition of acupressure to standard antiemetic's reduced the frequency, duration, and severity of CINV.</p>	<p>40</p>

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Roscoe JA, Morrow GR, Hickok JT, Bushunow P, Pierce HI, Flynn PJ et al.</p> <p>The efficacy of acupressure and acustimulation wrist bands for the relief of chemotherapy-induced nausea and vomiting.</p> <p>J Pain Symptom Manage 2003;26(2):731-42.</p>	<p>A University of Rochester, Cancer Center, New York</p> <p>USA</p>	2003	<p>Multicentre RCT 3-arm parallel study as an adjunct to standard antiemetic's for the relief of CINV</p> <p>1) acupressure bands, 2) an acustimulation band, or 3) a no band control condition.</p>	<p>Patients in the acupressure group experienced less nausea compared to controls (P&lt;0.05).</p> <p>Acupressure is a useful adjunct to standard antiemetic treatment for CINV.</p>	739
<p>Treish I, Shord S, Valgus J, Harvey D, Nagy J, Stegal J and Lindley C.</p> <p>Randomized double-blind study of the Reliefband as an adjunct to standard antiemetics in patients receiving moderately-high to highly emetogenic chemotherapy</p> <p>Supportive Care in Cancer, August 2003, Volume 11, issue 8, pp616-521</p>	<p>University of North Carolina Hospitals</p> <p>USA</p>	2003	<p>RCT double blind 2-arm parallel study comparing P6 acupoint stimulation with no stimulation.</p>	<p>Patients wearing the P6 acupoint stimulation experienced less vomiting (<math>p=0.05</math>), retching (<math>p=0.05</math>), and nausea severity (<math>p=0.01</math>).</p> <p>Patients receiving moderately-high to highly emetogenic chemotherapy who experience nausea and vomiting despite standard antiemetics can benefit from P6 acupoints stimulation as an adjunct to antiemetics.</p>	49
<p>Noga S, Tolman A, Roman J, et al.</p> <p>Acupressure as an adjunct to pharmacological control of nausea, vomiting and retching (N/V) during blood and marrow transplantation (BMT): a randomized, placebo controlled, algorithm based study.</p> <p>Proceedings of the American Society of Clinical Oncology. 2002; Vol. 21:361a.</p>		2002			

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Dibble S, Chapman J, Mack K, et al.</p> <p>Acupressure for nausea: results of a pilot study.</p> <p>Oncology Nursing Forum 2000; 27(1): 41–7.</p>	<p>University of California, San Francisco.</p> <p>USA</p>	<p>2000</p>	<p>Single-cycle, RCT to compare differences in nausea experience and intensity in women undergoing out-patient chemotherapy for breast cancer between those receiving usual care plus P6 acupressure and those receiving only usual care. Nausea was measured by the Rhodes inventory of Nausea, Vomiting, and Retching and nausea intensity.</p>	<p>There was a significant difference between the two groups regarding nausea experience (<math>p &lt; 0.01</math>) and nausea intensity (<math>p &lt; 0.04</math>) during the first 10 days of the chemotherapy cycle, with the acupressure group reporting less intensity and experience of nausea.</p> <p>Acupressure at the P6 point decreases nausea in women undergoing chemotherapy.</p>	<p>17</p>
<p>Shen J, Wenger N, Glaspy J, et al.</p> <p>Electroacupuncture for control of myeloablative chemotherapy-induced emesis: A randomized controlled trial.</p> <p>Journal of the American Medical Association 2000; 284 (21): 2755–61.</p>	<p>National Institutes of Health (NIH), Bethesda.</p> <p>USA</p>	<p>2000</p>	<p>Three-arm, parallel-group, RCT with a 5-day study period and a 9-day follow-up.</p> <p>Patients were randomly assigned to receive P6 acupoint stimulation, minimal stimulation or no stimulation with standard triple antiemetic pharmacotherapy and high-dose chemotherapy (cyclophosphamide, cisplatin, and carmustine).</p>	<p>Emesis was reduced in the group receiving acupoint stimulation.</p>	<p>104</p>

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Sergiou K</p> <p>An evaluation of the Sea-Band in alleviating nausea and vomiting in patients receiving chemotherapy</p> <p>Department of Medical Oncology University of Southampton.</p> <p><a href="http://www.p6nauseacontrol.com/dati-clinici-trattamento-oncologico/evaluation-of-the-sea-band-in-alleviating-nausea-and-vomiting-in-patients-receiving-chemotherapy/">http://www.p6nauseacontrol.com/dati-clinici-trattamento-oncologico/evaluation-of-the-sea-band-in-alleviating-nausea-and-vomiting-in-patients-receiving-chemotherapy/</a></p>	<p>Royal South Hants Hospital, Southampton</p> <p>UK</p>	1999	14-day single blind randomised cross-over placebo controlled study of the effectiveness of P6 acupoint stimulation as an adjunct to pharmacological anti-emetic treatment during chemotherapy.	<p>49% of patients found P6 acupressure plus standard anti-emetics provided better control of nausea and vomiting than standard-emetics alone. 17% responded to placebo plus standard antiemetic's and 34% did not find that active or placebo acupressure improved their nausea and vomiting symptoms despite standard anti-emetics.</p> <p>P6 acupressure is an effective adjuvant to conventional anti-emetic therapy for people having chemotherapy, particularly that of a high emetic intensity. It is recommended that it should be offered as part of standard anti-emetic protocols.</p>	105
<p>Pearl ML, Fischer M, McCauley DL, Valea FA and Chalas E.</p> <p>Transcutaneous electrical nerve stimulation as an adjunct for controlling chemotherapy-induced nausea and vomiting in gynecologic oncology patients.</p> <p>Cancer Nurs. 1999; 22:307-311.</p>	<p>Department of Obstetrics and Gynecology, and Surgery, State University of New York</p> <p>USA</p>	1999	Randomized, double-blind, placebo-controlled crossover trial to evaluate the efficacy of transcutaneous electrical P6 nerve stimulation as an adjunct to standard antiemetic therapy for controlling nausea and vomiting induced by cisplatin-based chemotherapy in gynecologic oncology patients.	<p>The severity of nausea was significantly lower in the active cycles during days 2 to 4. Patients averaged less than one episode of vomiting daily in each cycle.</p> <p>Electrical transcutaneous stimulation of the P6 acupoint is an effective adjunct to standard antiemetic agents for controlling CINV.</p>	42

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
McMillan C, Dundee J.  The role of transcutaneous electrical stimulation of neiguan anti-emetic acupuncture point in controlling sickness after cancer chemotherapy.  Physiotherapy 1991; 77: 499–502.		1991			
Dundee JW, Yang J, McMillan C.  Non-invasive stimulation of the P6 (Neiguan) antiemetic acupuncture point in cancer chemotherapy.  Journal of the Royal Society of Medicine 1991; 84(4): 210–3.	Northern Ireland Radiotherapy and Oncology Centre and Department of Anaesthetics, The Queen's University of Belfast  UK	1991	Open case reports of adding P6 acupoint stimulation to the antiemetic regimen of patients not responding adequately to standard antiemetic's alone.	>75% of patients achieved considerable benefit from what was a nontoxic procedure.  The 2-hourly application of Sea Bands prolongs the antiemetic action.	100
Aglietti L, Roila F, Tonato M, Basurto C, Bracarda S, Picciafuoco M, Ballatori E and Del Favero A.  A pilot study of metoclopramide, dexamethasone, diphenhydramine and acupuncture in women treated with cisplatin.  Cancer Chemother Pharmacol. 1990; 26(3): 239-40.	Medical Oncology Division, Ospedale Policlinico, Perugia,  Italy	1990	2-arm parallel study of the efficacy of adding P6 acupoint stimulation to the antiemetic regimen of women receiving cisplatin chemotherapy with a combination of metoclopramide, dexamethasone and diphenhydramine.	P6 acupoint stimulation was shown to increase complete protection from nausea and to decrease the intensity and duration of nausea and vomiting.	26

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients																
<p>Dundee JW and Yang J.</p> <p>Prolongation of the antiemetic action of P6 acupuncture by acupressure in patients having cancer chemotherapy</p> <p>Journal of the Royal Society of Medicine Volume 83 June 1990, pp 360-362</p>	<p>Northern Ireland Radiotherapy Centre</p> <p>UK</p>	1990	<p>The objective of this study was to see if the addition of P6 acupressure to the antiemetic regimen would prolong the antiemetic effect already seen in patients following P6 acupuncture in patients having cancer chemotherapy.</p>	<p><i>Table 7. Comparison of the beneficial antiemetic effects of acupuncture in outpatients and inpatients</i></p> <table border="1"> <thead> <tr> <th></th> <th>Inpatients</th> <th>Outpatients</th> <th>Total</th> </tr> </thead> <tbody> <tr> <td>Good</td> <td>16</td> <td>15</td> <td>35</td> </tr> <tr> <td>Moderate</td> <td>4</td> <td>2</td> <td>2</td> </tr> <tr> <td>Slight or nil</td> <td>0</td> <td>3</td> <td>3</td> </tr> </tbody> </table> <p>P6 acupoint stimulation was very effective for inpatients - even in those receiving highly emetogenic drugs such as cisplatin. Inpatients were monitored and encouraged by the nursing and medical staff to regularly stimulate the P6 acupoint. The absence of this source of prompting might explain the slight difference in efficacy seen in the outpatients as many of the outpatients only stimulated the P6 acupoint when they felt sick, which is too late.</p>		Inpatients	Outpatients	Total	Good	16	15	35	Moderate	4	2	2	Slight or nil	0	3	3	40
	Inpatients	Outpatients	Total																		
Good	16	15	35																		
Moderate	4	2	2																		
Slight or nil	0	3	3																		
<p>Dundee JW, Ghaly RG, Fitzpatrick KT, Abram WP and Lynch GA.</p> <p>Acupuncture prophylaxis of cancer chemotherapy-induced sickness.</p> <p>Journal of the Royal Society of Medicine Volume 82 May 1989</p>	<p>Department of Anaesthetics, The Queens University, Belfast.</p> <p>UK</p>	1989	<p>3 studies:</p> <ol style="list-style-type: none"> <li>1) 15 in an open pilot study</li> <li>2) 10 in a randomized placebo controlled crossover study</li> <li>3) 105 in a definitive study</li> </ol>	<p>Up to 20% of patients stop potentially curative treatment chemotherapy because of nausea and vomiting. Electrical stimulation of the P6 acupoint is an effective adjunct to antiemetic drug treatment in patients having cancer chemotherapy.</p>	130 (includes patients from Dundee 1988)																

Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
<p>Dundee JW</p> <p>Studies with Acupuncture/Acupressure as an Antiemetic</p> <p>Acupuncture in Medicine Aug 1988, 5 (1) 22-24</p>	<p>Department of Anaesthetics, The Queens University, Belfast.</p> <p>UK</p>	<p>1988</p>	<p>Open Pilot study preceding formal observational study. Acupressure added to anti-emetic drug regimen at second course of chemotherapy. 10 patients received placebo.</p>	<p>In view of the limited efficacy of high dose anti-emetic drug regimens, common occurrence of debilitating side effects such as drowsiness and the efficacy and safety of adding P6 acupoint stimulation to anti-emetic drug regimens in chemotherapy it is clinically unethical to carry out further studies using placebo.</p>	<p>108</p>
<p>Dundee J, Chaly R, Fitzpatrick K.</p> <p>Randomized comparison of the antiemetic effects of metoclopramide and electroacupuncture in cancer chemotherapy.</p> <p>British Journal of Clinical Pharmacology 1988;25 (6):678-9.</p>	<p>Department of Anaesthetics, Queen's University of Belfast, Belfast</p> <p>UK</p>	<p>1988</p>	<p>Placebo controlled case reports in 14 inpatients receiving cisplatin of adding P6 acupoint stimulation before chemo and then on the following day at the patients request in addition to standard antiemetics. All had had prolonged and severe sickness after previous chemo.</p>	<p>Eleven patients had complete absence of emetic symptoms for at least eight hours while three had some improvement. P6 acupoint stimulation was performed up to six times with beneficial effects on each occasion. This covered the expected duration of the emetic effect of cisplatin in most patients.</p> <p>Five of the patients had a placebo stimulation which produced no benefit.</p> <p>29 additional outpatients, who had been sick after previous cancer chemotherapy, had one to five P6 acupoint stimulations. 21 of these had complete alleviation of emetic symptoms, four had considerable improvement compared with their previous treatment, and four had some improvement.</p> <p>The beneficial effect of electrical P6 acupoint stimulation lasts for 8 – 10 hours.</p>	<p>43</p>



Published References	Centre and Country	Date of Publication	Study Type	Outcome	No. of patients
Dundee JW, Ghaly RG, Fitzpatrick KT, et al.  Acupuncture to prevent cisplatin-associated vomiting.  Lancet 1987; 1: 1083		1987			
Dundee JW, Ghaly RG, Fitzpatrick KTJ, Lynch GL and Abram P.  Optimising antiemesis in cancer chemotherapy.  British Medical Journal 1987; 294: 179.	Northern Ireland Radiotherapy Centre, and Department of Anaesthetics, Queens University, Belfast  UK	1987	Open observational	Electro-acupuncture was effective and last for 8 to 10 hours. No side effects.  The authors point out that this is this treatment but it is time consuming and that further work is needed to evaluate non-invasive methods of acupuncture which patients could use at home.	71
Dundee JW, Lynas AGA, Ghaly RD.  Alternative Medicine.  Anaesthesia 1987 ;42: 76-7.		1987			

## Appendix IV: Horizontal tabulated summarising of Post-Operative Nausea and Vomiting studies

Summaries of 83 studies from 1986 to 2015 including 10,500 adults and children showing the safety and efficacy of P6AS

These references were reviewed by Doctors' Anna Lee, Simon Chan and Lawrence Fan as part of the Cochrane Library's 2015 update to its series of systematic reviews of P6AS. These studies compared P6 acupoint stimulation to active drug controls such as ondansetron, droperidol, prochlorperazine and metoclopramide as well as drug and P6 in combination and placebo (sham).

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Ertas G, Bengi Sener E, Kaya C, Ozkan F, Ustun YB, Koksal E.</p> <p>Effects of P6 acustimulation with the ReliefBand on postoperative nausea and vomiting in patients undergoing gynecological laparoscopy.</p> <p>Holistic Nursing Practice 2015; 29(1):6–12. [PUBMED: 25470475]</p>	Turkey	2015	Parallel 2-arm randomised Placebo (sham) controlled Double blind	<p>The number of patients and doses of rescue antiemetics required were significantly lower in the ReliefBand (RB) group than in the Placebo (Sham) group. Patient satisfaction scores were significantly higher in the RB group than in the S group.</p> <p>Acustimulation with the P6 ReliefBand decreased the severity of nausea, PONV scores, and antiemetic requirements in the early postoperative period of gynecological laparoscopy patients.</p>	62
<p>Direkvand-Moghadam A, Khosravi A.</p> <p>Effect of acupressure on post-operative nausea and vomiting in cesarean section: a randomised controlled trial.</p> <p>Journal of Clinical and Diagnostic Research 2013;7(10):2247–9. [PUBMED: 24298488]</p>	Iran	2013	Parallel 3-arm randomized trial Single blind Active controlled	Metoclopramide and acupressure was found to be equally effective for reducing emetic symptoms (nausea, retching, and vomiting).	102

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Adib-Hajbaghery M, Etri M, Hosseainian M, Mousavi MS.</p> <p>Pressure to the p6 acupoint and post-appendectomy pain, nausea, and vomiting: a randomized clinical trial.</p> <p>Journal of Caring Science 2013;2(2):115–22. [PUBMED: 25276717]</p>	Iran	2013	Single blind randomized clinical trial comparing Acubands with and without acupressure at PC6 point	P6 acupressure reduced vomiting after appendectomy.	88
<p>El-Deeb AM, Ahmady MS.</p> <p>Effect of acupuncture on nausea and/or vomiting during and after cesarean section in comparison with ondansetron.</p> <p>Journal of Anesthesia 2011; 25(5):698–703. [PUBMED: 21761206]</p>	Egypt	2011	Randomised 3 parallel group comparing placebo, active (ondansetron) and PC acupoint stimulation	P6 acupoint stimulation is as effective as ondansetron in prevention of PONV and in improving patient satisfaction.	450

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>* Ebrahim Soltani A, Mohammadinasab H, Goudarzi M, Arbabi S, Mohtaram R, Afkham K, et al.</p> <p>Acupressure using ondansetron versus metoclopramide on reduction of postoperative nausea and vomiting after strabismus surgery.</p> <p>Archives of Iranian Medicine 2010;13(4):288–93. [IRCT138807152556N1; PUBMED: 20597561]</p> <p>Ebrahim Soltani AR, Mohammadinasab H, Goudarzi M, Arbabi S, Mohammadinasab A, Mohammadinasab F, et al.</p> <p>Comparing the efficacy of prophylactic p6 acupressure, ondansetron, metoclopramide and placebo in the prevention of vomiting and nausea after strabismus surgery.</p> <p>ActaMedica Iranica 2011;49(4):208–12. [IRCT138807152556N1; PUBMED: 21713729]</p>	Iran	2010	Randomised parallel 4 arm efficacy study comparing acupressure wrist bands, ondansetron, metoclopramide and placebo. Single blinding of clinical assessor.	P6 acupressure, ondansetron and metoclopramide were equally effective at significantly reducing PONV.	200
<p>Frey UH, Scharmann P, Löhlein C, Peters J.</p> <p>P6 acustimulation effectively decreases postoperative nausea and vomiting in high-risk patients.</p> <p>British Journal of Anaesthesia 2009;102(5):620–5. [PUBMED: 19246457]</p>	Germany	2009a	Randomised, parallel 4 arm, placebo (sham) controlled, observer blinded	P6 acustimulation decreases PONV, particularly in patients at high risk.	200
<p>Frey UH, Funk M, Löhlein C, Peters J.</p> <p>Effect of P6 acustimulation on postoperative nausea and vomiting in patients undergoing a laparoscopic cholecystectomy.</p> <p>Acta Anaesthesiologica Scandinavica 2009;53(10):1341–7. [PUBMED: 19681777]</p>	Germany	2009b	Parallel 4-arm, double-blind, randomized, placebo (sham) controlled	Acustimulation at the P6 acupoint reduces nausea after laparoscopic cholecystectomy, irrespective of its pre- or post-induction application.	229

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Arnberger M, Stadelmann K, Alischer P, Ponert R, Melber A, Greif R, et al.</p> <p>Monitoring of neuromuscular blockade at the P6 acupuncture point reduces the incidence of postoperative nausea and vomiting.</p> <p>Anesthesiology 2007; 107(6):903–8. [PUBMED: 18043058]</p>	Switzerland and Austria	2007	Parallel-group randomized trial, double blind for both patient and outcome assessor.	P6 acupoint stimulation significantly reduced the incidence of nausea and vomiting. P6 stimulation is as effective as commonly used antiemetic drugs.	220
<p>Amir SH, Bano S, Khan RM, Ahmed M, Zia F, Nasreen F.</p> <p>Electro-stimulation at P6 for prevention of PONV. Journal of Anaesthesiology Clinical Pharmacology 2007;23:383–86.</p>	India	2007	Randomised, 2-arm parallel, observer blind, placebo (“placebo/sham”) controlled, with ondansetron rescue medication	P6 acupoint stimulation is a safe and effective way to prevent nausea and vomiting	40
<p>Butkovic D, Toljan S, Matolic M, Kralik S, Radesi L.</p> <p>Comparison of laser acupuncture and metoclopramide in PONV prevention in children.</p> <p>Pediatric Anesthesia 2005; 15(1):37–40. [PUBMED: 15649161]</p>	Croatia	2005	3-arm, Parallel-group, randomized trial, active and placebo comparator, double blind	Stimulation of the PC6 acupoint point is as effective as metoclopramide in preventing nausea and vomiting in children. Both treatments are significantly more effective than placebo	120
<p>Gan TJ, Jiao KR, Zenn M, Georgiade G.</p> <p>A randomized controlled comparison of electro-acupoint stimulation or ondansetron versus placebo for the prevention of postoperative nausea and vomiting.</p> <p>Anesthesia and Analgesia 2004;99(4):1070–5. [PUBMED: 15385352]</p>	USA	2004	3 arm parallel randomised double blind active (ondansetron) and placebo controlled	Patients in the treatment groups were more satisfied with their management of nausea and vomiting compared with placebo. When used for the prevention of nausea and vomiting, P6-acupoint stimulation or ondansetron was more effective than placebo with greater degree of patient satisfaction. P6-acupoint stimulation was also more effective than ondansetron. This study also showed that P6 stimulation has analgesic effects.	77

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
Alkaiissi A, Evertsson K, Johnsson V, Ofenbartl L, Kalman S.  P6 acupressure may relieve nausea and vomiting after gynecological surgery: an effectiveness study in 410 women.  Canadian Journal of Anesthesia 2002;49:1034–9. [PUBMED: 12477673]	Sweden.	2002	Prospective, consecutive, randomized, multicentre, placebo-controlled, double-blind clinical trial with a reference group	PC6 acupressure was shown to be an effective non-invasive prophylactic antiemetic for some gynaecological surgery.	410
Agarwal A, Bose N, Gaur A, Singh U, Gupta MK, Singh D.  Acupressure and ondansetron for postoperative nausea and vomiting after laparoscopic cholecystectomy.  Canadian Journal of Anesthesia 2002;49(6):554–60. [PUBMED: 12067865]	India	2002	Randomized, prospective, double-blind, parallel are, placebo/sham/ drug controlled study	PC6 acupressure significantly reduces nausea and vomiting and need for rescue antiemetic medication. The efficacy was like that of ondansetron.	150
Harmon D, Ryan M, Kelly A, Bowen M.  Acupressure and prevention of nausea and vomiting during and after spinal anaesthesia for Caesarean section.  British Journal of Anaesthesia 2000;84(4):463–7. [PUBMED: 10823097]	Ireland	2000	Double blind randomised placebo controlled	P6 acupressure significantly reduced the incidence of nausea and vomiting during and after the operation	94
Harmon D, Gardiner J, Harrison R, Kelly A.  Acupressure and the prevention of nausea and vomiting after laparoscopy.  British Journal of Anaesthesia 1999;82(3): 387–90. [PUBMED: 10434821]	Ireland	1999	Double blind randomised placebo controlled study	P6 acupressure significantly reduced the incidence of nausea and vomiting compared to placebo	104

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
Alkaiissi A, Stålnert M, Kalman S.  Effect and placebo effect of acupressure (P6) on nausea and vomiting after outpatient gynaecological surgery.  Acta Anaesthesiologica Scandinavica 1999;43(3):270-4. [PUBMED: 10081532]	Sweeden	1999	Double-blind randomised 3-arm parallel study. One group received acupressure with bilateral stimulation of P6 (A), a second group received bilateral placebo stimulation (P) and a third group received no acupressure wrist band and served as a reference group (R).	Compared to placebo, significantly fewer people receiving P6 acupressure needed rescue medication. Compared to the observation group significantly fewer vomited after acupressure.	60
Duggal KN, Douglas MJ, Peter EA, Merrick PM.  Acupressure for intrathecal narcotic-induced nausea and vomiting after caesarean section.  International Journal of Obstetric Anesthesia 1998; 7:231-6. [EMBASE: 1998371495]	Canada	1998	Parallel-group randomized double blind placebo controlled trial	In women who gave a previous history of nausea or vomiting, there was a statistically significant reduction in both nausea and vomiting/retching in the acupressure group.	263
Ferrara-Love R, Sekeres L, Birche rNG.  Nonpharmacological treatment of postoperative nausea.  Journal of Perianesthesia Nursing 1996;11(6):378-83. [PUBMED: 9069860]		1996	Randomised 3-arm parallel group active (drug) and placebo (sham) controlled	Compared to routine medical treatment, the incidence of nausea is significantly reduced by using placebo bands and further reduced by applying acupressure.	90
Ho CM, Hseu SS, Tsai SK, Lee TY.  Effect of P6 acupressure on prevention of nausea and vomiting after epidural morphine for post-Cesarean section pain relief.  Acta Anaesthesiologica Scandinavica 1996;40(3):372-5. [PUBMED: 8721471]	Taiwan	1996	Randomized, double-blind, parallel 2-arm placebo (sham) controlled trial.	The incidence of nausea and vomiting was significantly decreased in the acupressure group. The prophylactic use of acupressure bands bilaterally on the P-6 acupoint significantly reduces the incidence of nausea and vomiting.	60
Andrzejowski J, Woodward D.  Semi-permanent acupuncture needles in the prevention of postoperative nausea and vomiting.  Acupuncture in Medicine 1996;14: 68-70. [EMBASE: 1997049450]	UK	1996	randomised 2-arm placebo (sham) controlled pilot study	Results from this study suggest that PC6 acupoint stimulation reduces the severity of nausea in the second 24 hours, and has a greater effect on patients who had had motion sickness or nausea and vomiting after a previous anaesthetic	36

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
Allen DL, Kitching AJ, Nagle C.  P6 acupressure and nausea and vomiting after gynaecological surgery.  Anaesthesia and Intensive Care 1994;22(6):691-3. [PUBMED: 7892973]	UK	1994	Randomised 2-arm placebo (sham) controlled studied of the effect of PC6 acupressure	There was a reduction in the requests for anti-emetic rescue medication in the group receiving PC6 acupressure.	46
Ho RT, Jawan B, Fung ST, Cheung HK, Lee JH.  Electroacupuncture and postoperative emesis.  Anaesthesia 1990;45 (4):327-9. [PUBMED: 2140030]	Taiwan	1990	Randomised 4-arm parallel group comparing no treatment, prochlorperazine (antiemetic drug), P6 electro-acupuncture stimulation, P6 transcutaneous electrical stimulation active and no-treatment control	P6 acupoint stimulation is as effective as prochlorperazine.	100
Barsoum G, Perry EP, Fraser IA.  Postoperative nausea is relieved by acupressure.  Journal of the Royal Society of Medicine 1990;83(2):86-9. [PUBMED: 2181138]	England	1990	Randomised 3-arm parallel-group trial comparing P6 acupoint pressure with placebo/sham and prochlorperazine.	Sea Bands acupressure reduces nausea and should be considered for routine use. The severity of nausea was significantly reduced by acupressure in comparison to both controls and drug treatment. There was also a trend towards a lower incidence of vomiting and a reduced need for rescue antiemetic injections in the P6 acupressure group.	162
Fassoulaki A, Papilas K, Sarantopoulos C, Zotou M.  Transcutaneous electrical nerve stimulation reduces the incidence of vomiting after hysterectomy.  Anesthesia and Analgesia 1993;76(5):1012-4. [PUBMED: 8484499]	Greece	1993	Randomised 2-arm parallel placebo/sham controlled single blind observer	The incidence of vomiting postoperatively was significantly less in the P6 acupoint stimulation group	103



Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Gieron C, Wieland B, Von der Laage D, Tolksdorf W.</p> <p>Acupressure in the prophylaxis of postoperative nausea and vomiting. [Published in German]</p> <p>Der Anaesthesist 1993;42(4):221-6.</p> <p>[PUBMED: 8488993]</p>	Germany	1993	Single-blinded (patient), Parallel 2-arm placebo controlled study to see if P6 acupoint stimulation provided additional antiemetic benefit above and beyond standard anti-emetic drug treatment. Both groups received the same standardised antiemetic drug treatment.	<p>The addition of P6 acupressure to a standardised antiemetic drug regimen provided a significant further reduction in nausea compared to placebo.</p> <p>The authors conclude that acupressure is a valuable and effective method of preventing nausea and vomiting without any side-effects.</p>	90
<p>Dundee JW, Fitzpatrick KTJ, Ghaly RG.</p> <p>Is there a role for acupuncture in the treatment of postoperative nausea and vomiting?</p> <p>Anesthesiology 1987;67(3A): A165. [CENTRAL: CN-00652348;]</p> <p>Dundee JW, Ghaly RG, Bill KM, Chestnutt WN, Fitzpatrick KTJ, Lynas AGA.</p> <p>Effect of stimulation of the P6 antiemetic point on postoperative nausea and vomiting.</p> <p>British Journal of Anaesthesia 1989;63(5):612-8. [PUBMED: 2605083]</p> <p>Ghaly RG, Fitzpatrick KT, Dundee JW.</p> <p>Antiemetic studies with traditional Chinese acupuncture. A comparison of manual needling with electrical stimulation and commonly used antiemetics.</p> <p>Anaesthesia 1987;42(10):1108-10. [PUBMED: 3688396]</p>	UK	1989	<p>Parallel 5-arm, randomised, active drug and placebo controlled, single-blind (clinical assessor) study</p> <p>Arms.</p> <ol style="list-style-type: none"> <li>1. Manual P6 stimulation</li> <li>2. Electrical P6 stimulation</li> <li>3. Cyclizine</li> <li>4. Metoclopramide</li> <li>5. No treatment</li> </ol>	<p>Manual and electrical P6 acupoint stimulation was more effective than drug treatment at reducing vomiting and as effective as drug treatment at reducing nausea.</p> <p>P6 acupoint stimulation did not cause side effects while anti-emetic drugs caused drowsiness.</p>	155

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
Dundee JW, Chestnutt WN, Ghaly RG, Lynas AG.  Traditional Chinese acupuncture: a potentially useful antiemetic?  British Medical Journal (Clinical Research edition) 1986;293(6547):583-4. [PUBMED: 3092933]	UK	1986	2 studies, randomised placebo/sham controlled parallel group	P6 acupoint stimulation resulted in a significant reduction in nausea and vomiting. No side effects were attributed to the P6 acupoint stimulation.	125
Iqbal U, Khan A, Sheikh F.  Whether does acupressure (P6) prevent nausea and vomiting in patients undergoing laparoscopic surgery.  Pakistan Journal of Medical and Health Sciences 2012;6(4):973-5. [EMBASE: 2013071896]	Pakistan	2012	Double blind 3-arm parallel group Placebo/sham and no treatment controlled, randomised study	Acupressure significantly reduced vomiting and need for rescue antiemetic's.	60
Kim SI, Yoo IS, Park HN, Ok SY, Kim SC.  Transcutaneous electrical stimulation of the P6 acupoint reduces postoperative nausea after minor breast surgery. [Published in South Korean]  South Korean Journal of Anaesthesiology 2004; 47:834-9. [Identified from Kim KH et al. PLoS ONE 2012 review article]	South Korea	2004	2-arm parallel group randomised placebo/sham controlled double blind	The incidence and severity of nausea was significantly reduced by P6 acupoint stimulation.	66
Kim YH, Kim KS, Lee HJ, Shim JC, Yoon SW.  The efficacy of several neuromuscular monitoring modes at the P6 acupuncture point in preventing postoperative nausea and vomiting.  Anesthesia and Analgesia 2011;112(4):819-23. [PUBMED: 21385974]	South Korea	2011	Parallel group randomised Placebo/sham controlled Double blind	P6 acupoint stimulation significantly reduces nausea and vomiting resulting in more patient satisfaction.	264

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Koo MS, Kim KS, Lee HJ, Jeong JS, Lee JW.</p> <p>Antiemetic efficacy of capsicum plaster on acupuncture points in patients undergoing thyroid operation.</p> <p>South Korean J Anesthesiol 2013;65(6):539-43. [PUBMED: 24427460]</p>	South Korea	2013	<p>4-arm parallel group randomised</p> <p>Placebo/sham controlled</p> <p>Double blind</p>	P6 acupoint stimulation significantly reduced the incidence and severity of nausea and vomiting and the need for rescue antiemetic's	184
<p>Liu YY, Duan SE, Cai MX, Zou P, LY, Li YL.</p> <p>Evaluation of transcutaneous electroacupoint stimulation with the trainof- four mode for preventing nausea and vomiting after laparoscopic cholecystectomy. Chinese</p> <p>Journal of Integrative Medicine 2008;14(2):94-7. [PUBMED: 18679598]</p>	China	2008	<p>Randomised</p> <p>Parallel group</p> <p>Placebo/sham controlled</p> <p>Double blind</p>	P6 acupoint stimulation reduced the incidence and severity of nausea and vomiting.	96
<p>Misra MN, Pullani AJ, Mohamed ZU.</p> <p>Prevention of PONV by acustimulation with capsicum plaster is comparable to ondansetron after middle ear surgery.</p> <p>Canadian Journal of Anesthesia 2005;52(5):485-9. [PUBMED: 15872126]</p>	India	2005	<p>3-arm parallel group</p> <p>Randomised</p> <p>Single blinded - clinical outcome assessor</p> <p>Placebo/sham and active (ondansetron) controlled</p>	Compared to the placebo group - nausea and vomiting as well as the need for antiemetic rescue medication was significantly reduced in both the P6 acupoint stimulation and ondansetron groups. The degree of relief was equal in both groups.	123
<p>Ravi M, Babu G, Somasekharam N, Dinesh M, Asha N, Hamsa J.</p> <p>Comparative efficacy of acupuncture at p6 point with 0.2ml 50% dextrose and inj ondansetron 50ug kg-1 iv for preventing postoperative nausea and vomiting.</p> <p>Journal of Anaesthesiology Clinical Pharmacology 2010; 26:237-9. [EMBASE: 2010376316]</p>	India	2010	<p>2-arm parallel group</p> <p>Randomised</p> <p>Double blind</p> <p>Active comparator using ondansetron</p>	P6 acupoint stimulation was as effective as ondansetron at relieving nausea and vomiting. P6 acupoint stimulation has fewer and less serious side effects.	50

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Rusy LM, Hoffman GM, Weisman SJ.</p> <p>Electroacupuncture prophylaxis of postoperative nausea and vomiting following pediatric tonsillectomy with or without adenoidectomy.</p> <p>Anesthesiology 2002;96(2):300–5.</p> <p>[PUBMED: 11818760]</p>	USA	2002	<p>3-arm parallel group</p> <p>Randomised</p> <p>Double blind</p> <p>Placebo/sham and no-treatment control</p>	<p>This study showed that P6 acupoint stimulation significantly reduces the occurrence of nausea compared with the sham and control groups.</p> <p>The efficacy of P6 acupoint stimulation is like commonly used antiemetic drugs.</p>	120
<p>Sadighha A, Nural N.</p> <p>Acupressure wristbands versus metoclopramide for the prevention of postoperative nausea and vomiting.</p> <p>Annals of Saudi Medicine 2008;28(4): 287–91.</p> <p>[PUBMED: 18596393]</p>	Iran	2008	<p>3-arm parallel group</p> <p>Randomised</p> <p>Patient blinded</p> <p>Placebo/sham control and pharmacological comparator using metoclopramide</p>	<p>P6 acupoint stimulation and metoclopramide both significantly reduced nausea and vomiting to the same degree, but metoclopramide was associated with extrapyramidal side effects and interactions.</p>	156
<p>Schlager A, Offer T, Baldissera I.</p> <p>Laser stimulation of acupuncture point P6 reduces postoperative vomiting in children undergoing strabismus surgery.</p> <p>British Journal of Anaesthesia 1998;81(4):529–32.</p> <p>[PUBMED: 9924226]</p>	Austria	1998	<p>2-arm parallel group</p> <p>Randomised</p> <p>Double blind</p> <p>Placebo/sham controlled</p>	<p>Compared to no treatment at all, P6 acupoint stimulation significantly reduces the incidence of vomiting.</p>	40
<p>Sharma S, Goswami U.</p> <p>Evaluation of acupuncture for anti-emetic prophylaxis.</p> <p>Journal of Anaesthesiology Clinical Pharmacology 2007; 23:401–4.</p> <p>[EMBASE: 2007618554]</p>	India	2007	<p>3 arm parallel group</p> <p>Randomised</p> <p>Group 1 – received ondansetron</p> <p>Group 2 – received P6 acupoint stimulation</p> <p>Group 3 – received both</p>	<p>P6 acupoint stimulation was just as effective as ondansetron.</p> <p>P6 acupoint stimulation had no side effects and was much cheaper than ondansetron.</p> <p>2 patients in the ondansetron group needed rescue antiemetic medication with metoclopramide</p>	60

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Turgut S, Ozalp G, Dikmen S, Savil S, Tuncel G, Kadiogullari N.</p> <p>Acupressure for postoperative nausea and vomiting in gynaecological patients receiving patient controlled analgesia.</p> <p>European Journal of Anaesthesiology 2007;24(1):87–91.</p> <p>[PUBMED: 16895618]</p>	Turkey	2007	<p>2-arm parallel group</p> <p>Randomised</p> <p>Double blind</p> <p>Placebo/sham controlled with metoclopramide as the rescue medication</p>	<p>P6 acupoint stimulation is effective at preventing nausea and vomiting. P6 acupressure stimulation is an effective alternative to standard antiemetic's.</p>	102
<p>Wang SM, Kain ZN.</p> <p>P6 acupoint injections are as effective as droperidol in controlling early postoperative nausea and vomiting in children.</p> <p>Anesthesiology 2002;97(2):359–66.</p> <p>[PUBMED: 12151925]</p>	USA	2002	<p>4-arm, parallel group, randomised, double blind</p> <p>arm 1 – saline + P6</p> <p>arm 2 – droperidol + P6 sham</p> <p>arm 3 – saline + sham</p> <p>arm 4 – saline + P6 sham</p>	<p>P6 acupoint stimulation is as effective as droperidol in controlling nausea and vomiting. Significantly fewer subjects in the acupoint group required intravenous ondansetron as rescue therapy.</p>	187
<p>Wang XQ, Yu JL, Du ZY, Xu R, Jiang CC, Gao X.</p> <p>Electroacupoint stimulation for postoperative nausea and vomiting in patients undergoing supratentorial craniotomy.</p> <p>Journal of Neurosurgical Anesthesiology 2010;22(2):128–31.</p> <p>[PUBMED: 20308818]</p>	China	2010	<p>Randomised, 2-arm stimulation and control parallel group in addition to standard antiemetic therapy using ondansetron and metoclopramide</p>	<p>P6 stimulation significantly reduced nausea and vomiting as an adjunct to standard antiemetic drug treatment.</p>	80

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>White PF, Issioui T, Hu J, Jones SB, Coleman JE, Waddle JP, et al.</p> <p>Comparative efficacy of acustimulation (ReliefBand) versus ondansetron (Zofran) in combination with droperidol for preventing nausea and vomiting.</p> <p>Anesthesiology 2002;97 (5):1075–81.</p> <p>[PUBMED: 12411789]</p>	USA	2002	<p>Randomised double blind placebo and sham controlled</p> <ol style="list-style-type: none"> <li>1. Ondansetron + sham</li> <li>2. P6 + saline</li> <li>3. Ondansetron + P6</li> </ol>	P6 acupoint stimulation was as effective as ondansetron for relieving nausea and vomiting. P6 acustimulation plus ondansetron was more effective than ondansetron alone.	120
<p>White PF, Zhao M, Tang J, Wender RH, Yumul R, Sloninsky AV, et al.</p> <p>Use of a disposable acupressure device as part of a multimodal antiemetic strategy for reducing postoperative nausea and vomiting.</p> <p>Anesthesia and Analgesia 2012;115(1):31–7. [NCT01317082;]</p> <p>PUBMED: 22504214]</p>	USA	2012	Randomised double blind 2-arm parallel group sham controlled in addition to standard antiemetic drug treatment	The addition of P6 acupoint stimulation to standard antiemetic drug treatment provided a further reduction in the incidence of vomiting and an improvement in patient satisfaction	100
<p>Xu M, Zhou SJ, Jiang CC, Wu Y, Shi WL, Gu HH, et al.</p> <p>The effects of P6 electrical acustimulation on postoperative nausea and vomiting in patients after Infratentorial craniotomy. Journal of Neurosurgical Anesthesiology 2012;24 (4):312–6.</p> <p>[PUBMED: 22732720]</p>	China	2012	Randomised parallel group sham controlled study in addition to standard anti-emetic drug treatment	The addition of P6 acupoint stimulation to standard anti-emetic drug treatment produced a further significant improvement in the treatment of nausea and vomiting	130

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Yang LC, Jawan B, Chen CN, Ho RT, Chang KA, Lee JH.</p> <p>Comparison of P6 acupoint injection with 50% glucose in water and intravenous droperidol for prevention of vomiting after gynecological laparoscopy.</p> <p>Acta Anaesthesiologica Scandinavica 1993;37(2):192-4.</p> <p>[PUBMED: 8447210]</p>	Taiwan	1993	Randomised 3-arm parallel group comparing P6 acupoint stimulation with droperidol and no treatment	P6 acupoint stimulation and droperidol were both significantly more effective than the control group at relieving nausea and vomiting	120
<p>Yentis SM, Bissonnette B.</p> <p>Ineffectiveness of acupuncture and droperidol in preventing vomiting following strabismus repair in children.</p> <p>Canadian Journal of Anaesthesia 1992;39(2):151-4.</p> <p>[PUBMED: 1544195]</p>	Canada	1992	Randomised double blind 3 arm parallel study comparing P6 acupoint stimulation and droperidol alone and P6 + droperidol	Droperidol and P6 were equally ineffective. The incidence of restlessness as a side effect was significantly more pronounced in the droperidol group.	90
<p>Zárate E, Mingus M, White PF, Chiu JW, Scuderi P, Loskota W, et al.</p> <p>The use of transcutaneous acupoint electrical stimulation for preventing nausea and vomiting after laparoscopic surgery.</p> <p>Anesthesia and Analgesia 2001;92(3):629-35.</p> <p>[PUBMED: 11226090]</p>	USA	2001	Randomised blind 3-arm parallel group sham and placebo controlled	P6 acupoint stimulation significantly reduced the incidence of nausea.	221

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Zhu HX, Xu YJ, Meng SF, Feng H, Liu Y, Su XJ.</p> <p>[Preventive effect of acupoint injection at neiguan (PC 6) on postoperative nausea and vomiting after laparoscopic gynecologic surgery].</p> <p><i>Article published in Chinese</i></p> <p>Zhongguo zhen Jiu: Chinese Acupuncture and Moxibustion 2010;30(1):72–4.</p> <p>[PUBMED: 20353120]</p>	China	2010	Randomised 3-arm parallel group comparing P6 droperidol injection, IV droperidol and no treatment	P6 acupoint stimulation with droperidol was significantly more effective than IV droperidol or no treatment at all at relieving nausea and vomiting.	120
<p>Agarwal A,Dhiraaj S, TandonM, Singh PK, Singh U, Pawar S.</p> <p>Evaluation of capsaicin ointment at the Korean hand acupressure point K-D2 for prevention of postoperative nausea and vomiting.</p> <p>Anaesthesia 2005;60(12):1185–8.</p> <p>[PUBMED: 16288616]</p>	India	2005	Randomised 2 arm parallel group placebo controlled double blind study	Acupoint stimulation significantly reduced the incidence of nausea and vomiting and the need for rescue medication.	186
<p>Alkaissi A, Ledin T, Odkvist LM, Kalman S.</p> <p>P6 acupressure increases tolerance to nauseogenic motion stimulation in women at high risk for PONV.</p> <p>Canadian Journal of Anesthesia 2005;52(7):703–9.</p> <p>[PUBMED: 16103382]</p>	Sweden	2005	Randomised 3-arm parallel group double blind study comparing active P6, sham and no treatment	P6 acupoint stimulation reduced nausea due to motion sickness.	60
<p>Al-Sadi M, Newman B, Julious SA.</p> <p>Acupuncture in the prevention of postoperative nausea and vomiting.</p> <p>Anaesthesia 1997;52(7):658–61.</p> <p>[PUBMED: 9244025]</p>	UK	1997	Double blind randomised 2-arm placebo controlled study	P6 acupoint stimulation reduced the incidence of nausea and vomiting.	81



Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Cekmen N, Salman B, Keles Z, Aslan M, Akcabay M.</p> <p>Transcutaneous electrical nerve stimulation in the prevention of postoperative nausea and vomiting after elective laparoscopic cholecystectomy.</p> <p>Journal of Clinical Anesthesia 2007;19(1):49–52.</p> <p>[PUBMED: 17321927]</p>	Turkey	2007	Randomized 2-arm parallel group	Acupoint stimulation relieved the symptoms of nausea and vomiting	
<p>Chen HM, Chang FY, Hsu CT.</p> <p>Effect of acupressure on nausea, vomiting, anxiety and pain among post-caesarean section women in Taiwan.</p> <p>Kaohsiung Journal of Medical Sciences 2005;21(8):341–50.</p> <p>[PUBMED: 16158876]</p>	Taiwan	2005	Randomised 2-arm active and no treatment comparative study	Acupoint stimulation significantly reduced the incidence of nausea and vomiting; and, significantly reduced pain and anxiety.	104
<p>Coloma M, White PF, Ogunnaike BO, Markowitz SD, Brown PM, Lee AQ, et al.</p> <p>Comparison of acustimulation and ondansetron for the treatment of established postoperative nausea and vomiting.</p> <p>Anesthesiology 2002;97 (6):1387–92.</p> <p>[PUBMED: 12459663]</p>	USA	2002	<p>Randomised placebo and sham controlled 3 arm parallel group study – all patients received antiemetic prophylaxis with metoclopramide or droperidol. Patients who still developed nausea and vomiting were the randomised to receive one of the following:</p> <ol style="list-style-type: none"> <li>1. Ondansetron and sham P6 stimulation</li> <li>2. Saline and P6 stimulation</li> <li>3. Ondansetron and P6 stimulation</li> </ol>	P6 acupoint stimulation is just as effective as ondansetron. The combination of ondansetron and P6 acupoint stimulation is more effective than either alone.	268
<p>Dundee JW, Ghaly G.</p> <p>Local anesthesia blocks the antiemetic action of P6 acupuncture.</p> <p>Clinical Pharmacology and Therapeutics 1991;50(1):78–80.</p> <p>[PUBMED: 1855355]</p>	UK	1999	Randomised 2-arm parallel group placebo controlled	Local anaesthetic blocked the antiemetic action of P6 acupoint stimulation.	74

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>El-Bandrawy AM, Emara HM, Ghareeb HO.</p> <p>Transcutaneous electrical acupoint stimulation versus acupressure on postoperative nausea and vomiting after abdominal hysterectomy. British Journal of Medicine and Medical Research 2013;3(4):2247–55.</p> <p>[DOI: 10.9734/BJMMR/2013/4005]</p>	Egypt	2013	<p>Randomised 3-arm parallel active controlled study</p> <ol style="list-style-type: none"> <li>1. Electrical P6 + metoclopramide</li> <li>2. Acupressure P6 + metoclopramide</li> <li>3. Metoclopramide only</li> </ol>	Acupressure plus metoclopramide is better than metoclopramide alone and transcutaneous electrical acupoint stimulation of P6 point + metoclopramide appears to be more effective than acupressure + metoclopramide in alleviating nausea and vomiting	150
<p>El-Rakshy M, Clark SC, Thompson J, Thant M.</p> <p>Effect of intraoperative electroacupuncture on postoperative pain, analgesic requirements, nausea and sedation: a randomised controlled trial. Acupuncture in Medicine 2009;27(1):9–12.</p> <p>[PUBMED: 19369187]</p>	UK	2009	Randomised 2-arm parallel group treatment/ no treatment study	P6 acupoint stimulation is not effective if only administered while the patient is under general anaesthetic	107
<p>Fan CF, Tanhui E, Joshi S, Trivedi S, Hong Y, Shevde K.</p> <p>Acupressure treatment for prevention of postoperative nausea and vomiting. Anesthesia and Analgesia 1997;84(4): 821–5.</p> <p>[PUBMED: 9085965]</p>	USA	1997	2-arm parallel group randomised double blind sham controlled	P6 acupoint stimulation is an effective way to relieve nausea and vomiting and therefore a good alternative to drug treatment.	200
<p>Fry ENS.</p> <p>Acupressure and postoperative vomiting. Anaesthesia 1986;41(6):661–2.</p> <p>[PUBMED: 3728942]</p>	UK	1986	2-arm randomised study comparing P6 acupressure with no pressure	P6 acupoint stimulation produced a rapid and significant reduction in nausea and vomiting.	500

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Grube T, Uhlemann C, Weiss T, Meissner W.</p> <p>[Influence of acupuncture on postoperative pain, nausea and vomiting after visceral surgery: a prospective, randomized comparative study of metamizole and standard treatment.]</p> <p>Published in german</p> <p>Schmerz 2009;23(4):370–6.</p> <p>[PUBMED: 19513760]</p>	Germany	2009	Randomised 3-arm study comparing P6 acupoint stimulation with metamizole and no treatment	Repeated P6 acupoint stimulation is effective at relieving nausea, vomiting and pain.	66
<p>Hirs I, Lukic A, Fumic NN, Kekic M, Kotaran J.</p> <p>Acupressure and metoclopramide comparison in postoperative nausea and vomiting prevention on laparotomy patients.</p> <p>Acupuncture and Related Therapies 2013;1(4):42–5.</p> <p>[EMBASE: 2013710528]</p>	Croatia	2013	Randomised six arm parallel group study: group I (epidural analgesia + acupressure), group II (epidural analgesia + metoclopramide), group III (epidural analgesia + sham acupressure), group IV (intravenous analgesia + acupressure), group V (intravenous analgesia + metoclopramide) group VI (intravenous analgesia + sham acupressure).	<p>Compared to placebo acupressure significantly reduced nausea and vomiting in patients receiving intravenous or epidural analgesia.</p> <p>Metoclopramide was similarly effective.</p> <p>Acupressure is a simple, inexpensive and effective way to treat nausea and vomiting regardless of the type of analgesia. It is also without side effects and should be considered as standard treatment.</p>	180
<p>Jin W, Lu Y, Chen SD, Qin JL, Fang JQ, Wang JL.</p> <p>[Efficacy of preventing postoperative nausea and vomiting after thyroid tumor surgery by TAES at neiguan (P1): a clinical observation].</p> <p>Published in Chinese</p> <p>Chinese Journal of Integrated Traditional and Western Medicine 2013;33(9):1199–202.</p> <p>[PUBMED: 24273973]</p>	China	2013	<p>Randomised 4 arm parallel group comparing:</p> <ol style="list-style-type: none"> <li>1. Control group – P6 acupoint injection with saline</li> <li>2. Transcutaneous electrical stimulation</li> <li>3. IV droperidol</li> <li>4. P6 acupoint injection with droperidol</li> </ol>	P6 acupoint stimulation and IV droperidol were equally effective.	120

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Kabalak AA, Akcay M, Akcay F, Gogus N.</p> <p>Transcutaneous electrical acupoint stimulation versus ondansetron in the prevention of postoperative vomiting following pediatric tonsillectomy.</p> <p>Journal of Alternative and Complementary Medicine 2005;11(3):407–13.</p> <p>[PUBMED: 15992223]</p>	Turkey	2005	<p>Randomised 3-arm parallel group controlled study comparing:</p> <ol style="list-style-type: none"> <li>1. Ondansetron</li> <li>2. P6 acupoint stimulation</li> <li>3. No treatment</li> </ol>	P6 acupoint stimulation and ondansetron are equally effective. There were more side effects in the ondansetron group.	90
<p>Kim KS, Koo MS, Jeon JW, Park HS, Seung IS.</p> <p>Capsicum plaster at the Korean hand acupuncture point reduces postoperative nausea and vomiting after abdominal hysterectomy.</p> <p>Anesthesia and Analgesia 2002;95(4):1103–7.</p> <p>[PUBMED: 12351304]</p>	South Korea	2002	<p>Randomised double blind 3-arm parallel study comparing P6 or KD-2 acupoint stimulation with a control group (no treatment)</p>	P6 acupoint stimulation significantly reduced the incidence of nausea and vomiting and the need for rescue medication	160
<p>Kim NC, Yoo JB, Cho MS, Shin EJ, Hahm TS.</p> <p>[Effects of Nei-Guan acupressure on nausea, vomiting and level of satisfaction for gynecological surgery patients who are using a patient-controlled analgesia.]</p> <p>Published in Lorean</p> <p>Journal of Korean Academy of Nursing 2010; 40:423–32.</p> <p>[EMBASE: 20634633]</p>	South Korea	2002	<p>Randomised 3-arm parallel study:</p> <ol style="list-style-type: none"> <li>1. Control grp no treatment</li> <li>2. Manual acupressure</li> <li>3. Band acupressure</li> </ol>	Manual and band P6 acupressure were both equally effective at relieving nausea and vomiting and more effective than no treatment at all	51

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Korinenko Y, Vincent A, Cutshall SM, Li Z, Sundt TM 3rd.</p> <p>Efficacy of acupuncture in prevention of postoperative nausea in cardiac surgery patients.</p> <p>Annals of Thoracic Surgery 2009;88(2):537–42.</p> <p>[PUBMED: 19632409]</p>	USA	2009	Randomised 2-arm parallel group comparing P6 acupoint stimulation in addition to antiemetic drug treatment with drug treatment alone	P6 acupoint stimulation in addition to antiemetic drug treatment was more effective than drug treatment alone in reducing the incidence of nausea	90
<p>Larson JD, Gutowski KA, Marcus BC, Rao VK, Avery PG, Stacey DH, et al.</p> <p>The effect of electroacustimulation on postoperative nausea, vomiting and pain in outpatient plastic surgery patients: a prospective randomized, blinded, clinical trial.</p> <p>Plastic and Reconstructive Surgery 2010;125(3): 989–94.</p> <p>[PUBMED: 20195124]</p>	USA	2010	<p>Randomised blind 2-arm parallel group study comparing:</p> <ol style="list-style-type: none"> <li>1. Standard antiemetic drug treatment, with</li> <li>2. P6 acupoint stimulation in addition to standard antiemetic drug treatment</li> </ol>	<p>The addition of P6 acupoint stimulation significantly reduced nausea compared to drug treatment alone. In addition, patients receiving P6 acupoint stimulation required significantly less pain medication and were discharged more quickly than patients only receiving antiemetic drug treatment.</p> <p>P6 acupoint stimulation provides patients with added protection against nausea and vomiting and represents a safe and cost-effective addition to current antiemetic drug treatment.</p>	120
<p>Lee MY, Min HS.</p> <p>[Effects of the Nei-Guan acupressure by wrist band on postoperative nausea and vomiting after middle ear surgery].</p> <p>Published in Korean</p> <p>Taehan Kanho Hakhoe Chi 2008;38(4): 503–12.</p> <p>[PUBMED: 18753802]</p>	South Korea	2008	2-arm parallel group study comparing P6 acupoint stimulation with standard antiemetic drug treatment	P6 acupoint stimulation is effective at alleviating nausea	40

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Lee S, Lee MS, Choi DH, Lee SK.</p> <p>Electroacupuncture on P6 prevents opioid-induced nausea and vomiting after laparoscopic surgery.</p> <p>Chinese Journal of Integrated Medicine 2013;19(4):277–81.</p> <p>[PUBMED: 23546631]</p>	South Korea	2013	<p>3-arm parallel group randomised study comparing:</p> <ol style="list-style-type: none"> <li>1. P6 acupoint stimulation before anaesthetic</li> <li>2. P6 acupoint stimulation after surgery</li> <li>3. No P6 stimulation</li> </ol>	<p>P6 acupoint stimulation is effective at preventing nausea and vomiting.</p>	178
<p>Liodden I, Howley M, Grimsgaard AS, Fønnebø VM, Borud EK, Alraek T, et al.</p> <p>Perioperative acupuncture and postoperative acupressure can prevent postoperative vomiting following paediatric tonsillectomy or adenoidectomy: a pragmatic randomised controlled trial.</p> <p>Acupuncture in Medicine 2011;29(1):9–15.</p> <p>[NCT00965367; PUBMED: 21169634]</p>	Norway	2010	<p>2-arm open randomised study comparing P6 acupoint stimulation in addition to standard antiemetic drug treatment, with standard antiemetic drug treatment alone.</p>	<p>P6 acupoint stimulation in addition to antiemetic drug treatment was significantly more effective than antiemetic drug treatment alone in reducing the incidence of retching and vomiting.</p> <p>The effect of acustimulation was pronounced in girls and children aged 1–3 years.</p> <p>P6 acustimulation is an effective adjunct to standard antiemetic drug treatment.</p>	154
<p>Lü JQ, Feng RZ, Pan H, Li N.</p> <p>[A randomized controlled clinical trial for acupuncture stimulation of Neiguan (PC 6) to prevent postoperative nausea and vomiting].</p> <p>Acupuncture Research 2013;38(3):245–8.</p> <p>[PUBMED: 24006673]</p>	China	2013	<p>2-arm parallel group study comparing post-operative P6 acustimulation with no stimulation</p>	<p>P6 acupoint stimulation significantly reduced the incidence of retching and vomiting</p>	60

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>McConaghy P, Bland D, Swales H.</p> <p>Acupuncture in the management of postoperative nausea and vomiting in patients receiving morphine via a patient-controlled analgesia system.</p> <p>Acupuncture in Medicine 1996;14(1):2–5.</p> <p>[EMBASE: 1996251673]</p>	UK	1996	2-arm single blind randomised controlled study comparing P6 acupoint stimulation with dummy elbow stimulation	P6 acupoint stimulation significantly reduced nausea and the need for further antiemetic drug treatment. No adverse events were seen	80
<p>Ming JL, Kuo BI, Lin JG, Lin LC.</p> <p>The efficacy of acupressure to prevent nausea and vomiting in postoperative patients.</p> <p>Journal of Advanced Nursing 2002;39(4): 343–51.</p> <p>[PUBMED: 12139646]</p>	Taiwan	2002	Randomised 3-arm parallel group study comparing: <ol style="list-style-type: none"> <li>1. Finger acupoint stimulation</li> <li>2. Wrist band acupoint stimulation</li> <li>3. No acupoint stimulation – just conversation</li> </ol>	Finger and wrist band acupoint stimulation both significantly reduced the incidence of nausea and vomiting compared to no treatment. No side effects were seen.	150
<p>Noroozinia H, Mahoori A, Hasani E, Gerami-Fahim M, Sepehrvand N.</p> <p>The effect of acupressure on nausea and vomiting after cesarean section under spinal anesthesia.</p> <p>Acta Medica Iranica 2013;51(3):163–7.</p> <p>[PUBMED: 23605600]</p>	Iran	2013	Randomised double blind 2-arm parallel group comparison of P6 acupoint stimulation with no stimulation	P6 acupoint stimulation significantly reduced the incidence of nausea and vomiting.	152
<p>OuyangMW, Qin ZS, Lin CS, GuMN.</p> <p>[Prophylactic effect of acupuncture on nausea and vomiting after laparoscopic operation].</p> <p>Zhongguo zhen Jiu: Chinese Acupuncture and Moxibustion 2009;29(11):915–8.</p> <p>[PUBMED: 19994693]</p>	China	2009	Randomised blinded 2-arm parallel group study comparing P6 acupoint stimulation with no stimulation	P6 acupoint stimulation reduced the incidence of nausea and retching.	100

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Phillips K, Gill L.</p> <p>The use of simple acupressure bands reduces post-operative nausea.</p> <p>Complementary Therapies in Medicine 1994;2:158–60.</p>	UK	1994	Randomised 2-arm parallel group comparison of P6 acupoint stimulation and no stimulation	Patients wearing the bands had significantly reduced nausea and vomiting, were sick for a shorter time. Those patients wearing Sea-Bands also needed 16% less anti-emetic drugs.	80
<p>Shyr MH, Hsu JC, Wu YW, Hui YL, Tan PPC.</p> <p>[P6 acupoint injection reduced postoperative nausea and vomiting].</p> <p>Published in Chinese</p> <p>Ma Tsui Hsueh Tsa Chi Anaesthesiologica Sinica 1990;28(3):357–60.</p> <p>[PUBMED: 2277579]</p>	Taiwan	1990	Randomised 2-arm parallel group comparing P6 acupoint stimulation with no stimulation	P6 acupoint stimulation significantly reduced nausea.	64
<p>Somri M, Vaida SJ, Sabo E, Yassain G, Gankin I, Gaitini LA.</p> <p>Acupuncture versus ondansetron in the prevention of postoperative vomiting.</p> <p>Anaesthesia 2001;56(10):927–32.</p> <p>[PUBMED: 11576093]</p>	Israel	2001	Randomised placebo controlled 3-arm parallel group comparison of P6 acupoint stimulation with ondansetron	<p>This study confirmed the efficacy of P6 acupoint stimulation and ondansetron as a prophylactic therapy for treating vomiting compared to placebo.</p> <p>However, ondansetron is associated with side-effects, including headache, fever, dizziness, abdominal cramps and a transient elevation in plasma aminotransferase and bilirubin levels as well as anaphylactic reactions. Ondansetron is also expensive.</p>	90
<p>Stein DJ, Birnbach DJ, Danzer BI, Kuroda MM, Grunebaum A, Thys DM.</p> <p>Acupressure versus intravenous metoclopramide to prevent nausea and vomiting during spinal anesthesia for cesarean section.</p> <p>Anesthesia and Analgesia 1997;84(2):342–5.</p> <p>[PUBMED: 9024025]</p>	New York	1997	<p>Randomised 3-arm parallel group study comparing:</p> <ol style="list-style-type: none"> <li>1. P6 acupoint stimulation plus saline</li> <li>2. Sham plus metoclopramide</li> <li>3. Sham plus saline</li> </ol>	Patients who received either acupressure or metoclopramide had much less nausea than patients in the placebo group. Acupressure is an effective, non-pharmacologic method for treating nausea.	75



Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Tang W, Ma W, Fu GQ, Yuan L, Shen WD.</p> <p>[Impacts of electroacupuncture at different frequencies on the postoperative nausea and vomiting of patients with laparoscopic surgery.]</p> <p>Published in Chinese</p> <p>Zhonggui zhen Jiu: Chinese Acupuncture and Moxibustion 2013;33(2):159–62.</p> <p>[PUBMED: 23620949]</p>	China	2013	<p>Randomised 4-arm parallel group study comparing P6 acupoint stimulation:</p> <ol style="list-style-type: none"> <li>Stimulation at 2 Hz</li> <li>Stimulation at 2 Hz/100 Hz</li> <li>Stimulation at 100 Hz</li> <li>Control group</li> </ol>	<p>The incidence and severity of nausea and vomiting in group B was lower than that in A, C and D groups.</p> <p>Hence, electro acupoint stimulation at 2/100Hz reduces the incidence and severity of nausea and vomiting.</p>	120
<p>Wang H, Xie Y, Zhang Q, Xu N, Zhong H, Dong H, et al.</p> <p>Transcutaneous electric acupoint stimulation reduces intra-operative remifentanyl consumption and alleviates postoperative side-effects in patients undergoing sinusotomy: a prospective, randomized, placebo-controlled trial. British Journal of Anaesthesia 2014;112(6):1075–82.</p> <p>[PUBMED: 24576720]</p>	China	2014	Randomised 2-arm parallel group double blind	<p>Patients undergoing P6 stimulation required 39% less remifentanyl. The time to extubation and recall in the control group was significantly longer. P6 acupoint stimulation also decreased the incidence of dizziness and pruritus.</p>	60
<p>White PF, Hamza MA, Recart A, Coleman JE, Macaluso AR, Cox L, Jaffer O, Song D, Rohrich R.</p> <p>Optimal timing of acustimulation for antiemetic prophylaxis as an adjunct to ondansetron in patients undergoing plastic surgery.</p> <p>Anesthesia and Analgesia 2005;100(2):367–72.</p> <p>[PUBMED: 5673859]</p>	USA	2005	<p>Randomised double-blind sham controlled 3-arm parallel study comparing acupoint stimulation in addition to ondansetron:</p> <ol style="list-style-type: none"> <li>Preoperative;</li> <li>Postoperatively, and</li> <li>Peri-operatively</li> </ol>	<p>Peri- and post-operative acupoint stimulations was significantly more effective than pre-operative stimulation.</p> <p>Acustimulation is most effective in reducing postoperative nausea and vomiting and improving patients' satisfaction with their antiemetic therapy when it is administered after surgery.</p>	105

Published Reference	Centre and Country	Date of Publication	Study type	Outcome	Number of patients
<p>Zheng LH, Sun H, Wang GN, Liang J, Wu HX.</p> <p>Effect of transcutaneous electrical acupoint stimulation on nausea and vomiting induced by patient controlled intravenous analgesia with tramadol.</p> <p>Chinese Journal of Integrative Medicine 2008;14(1):61-4.</p> <p>[PUBMED: 18219451]</p>	<p>China</p>	<p>2008</p>	<p>Randomised 2-arm parallel group study comparing P6 acupoint stimulation and sham stimulation</p>	<p>P6 acupoint stimulation effectively reduced the incidence of nausea and vomiting.</p>	<p>60</p>

Sea Band

## Appendix V: Authors Curriculum Vitae

### **RICHARD STUART EGGLESTON**

BSc MRPharmS MPharmC PCRegAff

ADDRESS: Mill Farm, Church Street, Bainton, East Yorkshire, YO25 9NJ, UK

Phone +44 (0)77335 22465

EMAIL: [Richard.Eggleston@ApprovedPharmaSolutions.co.uk](mailto:Richard.Eggleston@ApprovedPharmaSolutions.co.uk)

NATIONALITY: British

#### **Present** (2014 – present)

Flamingo Pharma (UK) Ltd

Director

Generic pharmaceuticals

Approved Pharma Solutions Ltd

Director

Pharmaceutical Regulatory Consultancy

RENA Specials Ltd

Director

Pharmaceutical Formulation and Clinical Development

#### **Previously**

- Perrigo International. Board Member and Senior Director of Research and Development and Technical Affairs (1999-2014)
- Janssen Pharmaceutical. Senior Director of European Business Development and Regulatory Affairs (1987-1999)
- Kuwait Cancer Control Centre. Principal Pharmacist (1984-1987)
- St. Georges Hospital, London. Staff Pharmacist (1982-1984)
- Boots the Chemist, Ilford. Pre-registration Pharmacist (1981-1982)

#### **EDUCATION & QUALIFICATIONS**

Postgraduate Education

1982 - Royal Pharmaceutical Society of Great Britain, registered Pharmacist

2000 - University of Wales, Cardiff, Diploma in International Regulatory Affairs

2006 - Leeds University, Yorkshire, Independent Prescribing

#### **Undergraduate Education**

1981 - Portsmouth University, BSc in Pharmacy

#### **Secondary School Education**

1978 - Hornsey Secondary School, East Yorkshire, UK. A Levels in Physics, Chemistry and Biology.

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- <sup>iii</sup> MDR <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=EN>
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- <sup>viii</sup> Sea-Band, Class 1 Medical Device, P6 acupressure stimulation for treating Chemotherapy Induced Nausea and Vomiting (CINV). October 2017. Data on File
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