

PERICARDIUM-6 ACUPRESSURE FOR THE PREVENTION OF POSTOPERATIVE
NAUSEA AND VOMITING

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ABSTRACT

Postoperative nausea and vomiting (PONV) are common problems after general anesthesia. Pharmacological advances have reduced the incidence of PONV however; nausea and vomiting remain the most common postoperative complications of anesthesia. Persistent nausea and vomiting may result in dehydration, electrolyte imbalance, and delayed discharge. Traditional western medicine has been unable to definitively explain why this phenomenon continues to occur. Acupressure at the pericardium-six meridian has been studied in various patient populations and found to be without side effects, however its effectiveness has not been shown. The purpose of this study was to set up a pilot study to retest the claim that acupressure at the pericardium-six meridian can reduce PONV. Ten patients undergoing laparotomy, laparoscopic, or general surgery for gynecological procedures were studied. Acupressure s effectiveness was compared to sham acupressure of the control group. Patients, anesthesia providers, and data collectors were blinded to the control and study groups. Non-invasive acupressure wristbands were applied to both wrists prior to surgery and worn for 24 hours after. Post anesthesia care unit personnel recorded data while the patient was in the hospital. The patient s recorded and quantified nausea and vomiting at home using a visual analogue scale. An anesthesia provider called the patient after surgery to collect data. All data were analyzed using SPSS 8.0. No statistical significance was found in nausea and vomiting scores between the two groups.

Key Words: **Acupressure**, **Postoperative Nausea and Vomiting**, **Pericardium-six Meridian**, **Alternative Medicine**, **Traditional Chinese Medicine**

PERICARDIUM-6 ACUPRESSURE FOR THE
PREVENTION OF POSTOPERATIVE

NAUSEA AND VOMITING

by

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FOREWORD

This research was conducted to provide information to the anesthesia community on the use of acupressure for the prevention of postoperative nausea and vomiting. It was designed not only to inform anesthesia providers on the use of an alternative treatment method but also to aid in patient care and safety during anesthesia.

DEDICATION

I dedicate the creation of this thesis to my wife Danna who without her love, support and encouragement the creation of this thesis would not have been possible.

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CHAPTER I: INTRODUCTION

Background of the Problem

Nausea, retching, and vomiting are among the most common postoperative complaints and can occur after general, regional, or local anesthesia. Postoperative nausea and vomiting (PONV) is not only uncomfortable for the patient it can lead to aspiration, evisceration, electrolyte imbalances, and increased costs to the patient and surgical center. The incidence of PONV varies between 20% and 75% depending on surgical and patient factors (Haigh et al., 1993; Watcha & White, 1992). PONV can delay recovery room discharge by 47-61 minutes (Hirsch, 1994).

Despite the pharmacological advances made over the last decade which have significantly reduced PONV incidences over ether era reports, commonly used antiemetics cannot be considered benign medications. Metoclopramide and droperidol may display side effects such as dysphoric reactions, restlessness, anxiety, and tachycardia (Stein et al., 1997). In Langer's (1998) discussion of the side effects and costs associated with routine prophylaxis with today's antiemetics he states:

PONV is costly, inconvenient, and uncomfortable. Routine prophylaxis may be expensive or have undesirable side effects. Of the studies reviewed, droperidol and ondansetron seem to be the most consistently reliable agents for PONV prophylaxis. Higher doses of droperidol (2.5mg or more) may be more dependable, but sedation and agitation are more prevalent. Routine prophylaxis at this dose would subject too many patients to the risk of unpleasant side effects. Routine prophylaxis with ondansetron would give

fewer side effects, but would be expensive (about \$20.00 per patient) (p.7).

All medications currently used to treat postoperative nausea and vomiting (PONV) have advantages and disadvantages. Sung (1996) states in his article on drugs used for the management of PONV, If used indiscriminately to treat patients who have no problems with PONV, the risks of adverse effects often outweigh the benefits (p.182).

In his article Post-operative Nausea & Vomiting , Langer (1998) reports that time and resources required to treat PONV add to the institutional costs of the procedure and the average day surgery center in the US loses from \$253,000 to \$1,520,000 per year in revenue due to time lost treating PONV. The requirement for a non-invasive, safe, and inexpensive antiemetic therapy is apparent. The traditional Chinese medicinal practice of acupressure may be this desired treatment.

Purpose

Acupressure at the Pericardium six (P6) meridian point offers hope for a non-invasive and safe antiemetic therapy. Investigators have commented on the uniqueness of this type of therapy and the lack of scientific evidence to support its mechanism of action (Vincent & Richardson, 1986). Despite not having grounded scientific rationale for its use, P6 acupressure can be objectively studied. A placebo-controlled, randomized clinical trial can scientifically investigate the effectiveness of P6 acupressure (Vickers, 1996).

Fan and colleagues (1997) studied acupressure as prophylaxis for nausea and vomiting. Two hundred healthy patients undergoing a variety of short surgical procedures participated. One hundred and eight patients were in the acupressure group

and 92 patients were in a control group having pseudo acupressure. A noninvasive AcuBand™ wrist strap was placed on both wrists in all patients. The acupressure group had a spherical plastic bead placed on the anterior surface of the forearm two inches proximal to the distal wrist crease between the tendons of musculus flexor carpi radialis and musculus palmaris longus. This is known as the pericardium six meridian point. The control group members did not wear a spherical plastic bead in their bands. Forty one percent of the control group and twenty-three percent of the acupressure group experienced nausea and vomiting. This is a significant result; unfortunately, other studies have not been as conclusive on acupressure efficacy in preventing postoperative nausea and vomiting (PONV) (Lewis, Pryn, Reynolds, Pandit & Wilton, 1991).

This study and others like it are important not only for the comfort of the postoperative patient but for their safety as well. Stein and colleagues, (1997) compared acupressure to metoclopramide for the prevention of nausea and vomiting during spinal anesthesia for cesarean section. They concluded that acupressure was without side effects and reduced nausea and vomiting; however, it was not as effective as metoclopramide in reducing these symptoms. In comparison to a control group they reported a 52% reduction of nausea in the acupressure group and a 60% reduction in the metoclopramide group. The study shows that a noninvasive technique can reduce nausea and vomiting almost as well as a potentially harmful intravenous medication. The authors noted that they could find no conclusive pathological explanation of why the acupressure was effective. Fan et al. (1997) speculated that the stimulation at this point releases a neurochemical substance which in turn desensitizes the chemoreceptor trigger zone in the brain. This desensitization would prevent PONV caused by intravenous or

inhalation anesthetics. The nature of this substance has not yet been identified.

Statement of the Problem

Postoperative nausea and vomiting are common problems after general anesthesia.

While pharmacological advances have reduced the incidence of PONV, it continues to be the most common postoperative complication of anesthesia (Ferrara-Love, 1996).

Persistent nausea and vomiting may result in dehydration, electrolyte imbalance, and delayed discharge. One of the main reasons for hospital admissions from same day surgery is postoperative nausea and vomiting (PONV) (White, 1996). Retching or vomiting can cause tension on suture lines, venous hypertension, increased bleeding under skin flaps and can increase the risk of aspiration (Watcha & White, 1992).

Traditional western medicine has been unable to definitively explain why this phenomenon continues to occur and is beginning to investigate other health care philosophies for answers (Gin, 1994; O'Brien et al., 1996; Rogers, 1990; Rowbotham, 1992; Weightman et al., 1987). Eastern medicinal practices have become an area of research for the prevention of postoperative nausea and vomiting (Bill & Dundee, 1988; Dundee et al., 1996; Dundee & Ghaly, 1989; Dundee & McMillan, 1991; White, 1997).

Acupressure at the pericardium-six meridian has been studied in various patient populations with varied success. If acupressure were found to be effective, anesthesia providers would have an inexpensive and non-invasive tool for prevention of nausea and vomiting. More research is required to arrive at a definitive conclusion on acupressure's efficacy for the prevention of postoperative nausea and vomiting.

Research Hypotheses

Acupressure at the pericardium-six point is more effective at reducing postoperative nausea than a placebo or no treatment.

Acupressure at the pericardium-six point is more effective at reducing postoperative vomiting than a placebo or no treatment.

Dependent Variables

1. The severity of nausea as measured by nausea scale
2. The incidence of vomiting and/or retching

Independent Variable

P-6 acupressure treatment

Definition of Terms

For the purpose of this study, the following terms have been conceptually and operationally defined:

Acupressure: Constant pressure to specific anatomic areas on the body where the Chi flow comes to the surface of the skin. Pressure is directed at a point in order to release the congestion of Chi, therefore healing disease.

Operational definition: Elasticized bands containing a plastic button to apply sustained pressure on acupoints.

Pericardium six point: A traditional eastern medicine acupoint that is manipulated to prevent and treat nausea and vomiting.

Operational definition: Anterior surface of the wrists, three fingers breadths above the distal skin crease of the wrists joint between the tendons of the palmaris longus and

flexor carpi radialis.

Nausea: Uncomfortable sensation of an impending episode of vomiting. Often associated with prodromal symptoms such as salivation, swallowing, pallor and tachycardia.

Operational definition: A ten-centimeter horizontal visual analogue scale (VAS) will be used to assess the degree of nausea. On the VAS each centimeter will be progressively marked zero through ten. The left or zero end of the scale will be marked, no nausea while the right or ten end will state, worst nausea ever experienced .

Vomiting: A process mediated by central coordination centers which cause the relaxation of the hiatal portion of the diaphragm permitting a transfer of intra-abdominal pressure to the thorax and the expulsion of gastric contents.

Retching: Rhythmic, synchronous, inspiratory movements of the diaphragm and abdominal and external intercostal muscles.

Operational definition: Vomiting and retching will both be recorded as vomiting.

Theoretical Framework

Western medicine is mainly concerned with finding specific agents of disease. In contrast, eastern traditional medicine searches for imbalances in an individual s mind, body or environment that allows an illness to occur (Jackson, 1988). Like western medicine, traditional Chinese medicine has a complete structure underlying its methodology. However, the presentation of a thorough history and explanation is beyond the scope of this thesis. A generic understanding of two key concepts of oriental medicine must be understood before a theory such as acupressure can be utilized in nursing practice. Kaptchuk (1983) explains the first concept:

The Chinese method is thus holistic, based on the idea that no single part can be understood except in its relation to the whole. A symptom therefore, is not traced back to a cause, but is looked at as a part of a totality. If a person has a symptom, Chinese medicine wants to know how the symptom fits into the patient's entire bodily pattern. A person who is well or in harmony, has no distressing symptoms and expresses mental, physical, spiritual balance (p.110).

This concept is not unlike the nursing approach to patient care. Nurses do not just treat a symptom but rather the whole person.

The second concept is that of chi, pronounced chee. Fundamental to Chinese medicine and oriental health care philosophy, Chi is an energy finer than that of electricity or electromagnetic energy; it is the basic or vital energy of life (Teeguarden, 1978, p.45). This energy flows through the body in twelve distinct areas called meridians. The smooth flow of chi along these meridians is essential for the body's harmonious function (Jackson, 1988). It is through the holistic concept of health and the vital force of chi that the theory of acupressure can best be understood and utilized.

Acupressure Theory

Acupressure developed in China thousands of years ago and was used even before acupuncture. According to acupressure theorists, disease signifies an imbalance of the flow of chi along the river-like meridians of the body (Maxwell, 1997). Meridian theory, a part of the acupressure theory, assumes that disorder in a particular meridian unbalances the entire system. Chi stagnation or blockage can be caused by low quality

food, polluted air (anesthetic gases), extreme climatic conditions, extreme emotions, tension, the improper use or disuse of body mobility or by traumatic experiences such as surgery (Teegarden, 1978). Oriental medicine suggests that stimulating certain points on the skin along these meridians can release muscle tension, increase circulation, and allow chi to flow evenly, thus healing disease (Hin, 1994). According to Ortego (1994) there are energy centers or acupoints in the body where the chi flow comes close to the surface of the skin. Acupressure is a way of accessing and releasing blocked or congested energy centers in the body. Pressure is applied to the acupoints where there is a blockage of energy and this redirects and unblocks the chi. Chi is then allowed to flow freely, which results in relaxation and bodymind balance. Working with acupoints on the surface of the body will affect what goes on inside the body, which is the basis of acupressure theory (Kaptchuk, 1983).

For decades nursing education has stressed the importance of assessing the whole person, and the research of alternative approaches to health care, especially holistic, seems to naturally suit the graduate level nurse. In an article written by Maxwell (1997) she revealed the success she has had with simple acupressure skills in her nursing practice, but research data was not collected. Ortego (1994) states in her article on acupressure, Our transforming health care system will undoubtedly look to nursing for alternative choices and directions. Nursing theorists, such as Margaret A. Newman and Martha E. Rogers, offer nurses direction for the practice of alternative care (p.76). These holistic theorists allow oriental health care philosophy and acupressure theory to be used as extensions of nursing theory, and empowers nurses to further investigate these avenues for clinical application.

Assumptions

1. Nausea and vomiting are undesirable experiences.
2. Subjects were honest in their reporting of nausea.
3. Subjects honestly and accurately reported having prior experience with acupressure for relief of nausea and vomiting.

Limitations

1. Only three types of surgical procedures were studied, laparotomy, laparoscopic and general anesthesia for GYN procedures.
2. Sample size was small.
3. Study did not control for variables such as degree and speed of movement following surgery, smells in the post anesthesia care unit, and time of first PO intake after surgery.
4. Study did not have control over the positioning of the bands after the patient enters the operating room or while the patient is at home.

Summary

Postoperative nausea and vomiting is distressing, unpleasant, and in some cases can be dangerous to the patient. Traditional western medicine has not been able to eliminate nausea and vomiting, and drug therapy is often complicated by central nervous system side effects. Acupressure uses noninvasive and nonpharmacological methods to treat nausea and vomiting however results on its efficacy are varied. This holistic and alternative approach is well suited for nursing research.

CHAPTER II: REVIEW OF THE LITERATURE

During a review of the literature, it was apparent that an understanding of the many aspects of postoperative nausea and vomiting (PONV) was necessary to comprehensively test acupressure. Throughout the literature review, the studies on PONV identified similar key topics. The first half of this chapter reviews the factors that increase the risk of PONV, discusses the current proposed physiology behind PONV, and presents current pharmacologic treatment to prevent and relieve these problems. The second half of this chapter will revisit the proposed physiology behind acupressure and review some current studies that have utilized acupressure for PONV.

Factors Increasing Risk of PONV

Patient Factors

PONV is most common in children and occurrence tends to decrease with age (Gin, 1994; Kallar, 1992). The incidence is equal between sexes until puberty, then according to Gin (1994), women can have up to three times the incidence of PONV as compared to men. Kallar (1992) included that a history of motion sickness and previous experience of nausea and vomiting increased the likelihood of developing postoperative emetic symptoms. Cohen, Duncan, DeBoer, and Tweed (1994) found that with lower American Society of Anesthesiologists (ASA) status, I and II s, there was an increased risk of PONV by 1.51 times that of patients who were ASA II or greater. In addition, they found that patients with no preoperative medical conditions were more likely to experience nausea than those with one or more preoperative illnesses. Interestingly, this large multi-center study and another done by Koivuranta, Laara, Snare, and Alahuhta (1997) noted that nonsmokers were more likely than smokers to suffer from PONV. Watcha and

White (1992) added to this list of risk factors any history of vestibular problems, morbid obesity, early pregnancy, excessive anxiety, ingestion of solid food prior to surgery, and conditions which delay gastric emptying such as diabetic gastroparesis, and postoperative pain (Dabbous, 1996).

An additional patient factor studied was the correlation of PONV with the female menstrual cycle. Beattie, Lindblad, Buckley and Forrest (1993) found an increased incidence in PONV in women undergoing laparoscopic tubal sterilization during the first eight days of their menstrual cycle which could not be effectively treated with droperidol. Honkavaara, Lehtinen, Hovorka, and Korttila (1991) reported similar findings and suggest that the increased risk of PONV in women in general may be hormonal and cyclic.

Surgical Factors

Certain types of surgery carry a greater risk of PONV. In adults, high incidences of PONV are found in intra-abdominal surgery, major gynecological surgery, general laparoscopic surgery, orthopedic and ENT surgery (Dershwitz, 1997; Kenny, 1994). Koivuranta, Laara, Snare and Alahuhta (1997) performed a prospective interview-based survey on the incidence of PONV in 1107 surgical patients and found the highest incidence of nausea appeared in the gynecological laparotomy patient with an incidence of 73%, 41% of those patients vomited. They also reported that 70% of joint replacement patients vomited even though only 61% claimed to have been nauseated.

The length of surgery also has been found to affect the incidence of PONV, with increased risk after cases longer than 60 minutes (Watcha & White, 1992). This is

presumed to relate to the increased length of exposure to potentially emetic drugs.

Anesthetic Factors

A reoccurring theme in the literature is that inexperienced anesthesia providers themselves increase postoperative nausea and vomiting (PONV) (Gin, 1994; Kenny, 1994; Rabey & Smith, 1992). These authors postulated that inexperienced anesthesia providers maintain deeper levels of anesthesia and overzealous inflation of the lungs by mask ventilation that may distend the stomach with anesthetic gases. Cohen and colleagues (1994) quantified the increase risk by reporting that presence of an anesthesia resident increased the risk of PONV 1.15 times those cases done by staff.

Anesthetic technique has been shown to affect the risk of PONV. Regional anesthesia is generally associated with less emesis than general anesthesia (Kenny, 1994). However, regional techniques do not completely obliterate the incidence of PONV. PONV after regional anesthesia is usually caused by the use of spinal opioids or by medullary ischemia from hypotension secondary to sympathectomy from intrathecal or epidural block (Gin, 1994; Watcha & White, 1992; Wetchler, 1992). While there is a decreased risk when spinal and epidural anesthesia are used all surgeries cannot be done using these types of anesthetics (Koivuranta et al., 1997).

The choice of anesthetic induction agent is known to affect PONV. Etomidate and ketamine have been found to increase the risk of PONV when compared to thiopental (Biebuyck, Suter, G.Wilder-Smith & Borgeat, 1994; Gin, 1994; Kallar, 1992). Propofol, on the other hand, significantly decreases the incidences and severity of PONV (Kenny, 1994; Rabey & Smith, 1992; Watcha & White, 1992; Wetchler, 1992).

Currently used inhalation agents, such as isoflurane, enflurane, and halothane do cause PONV; however, to a lesser extent than older agents like ether (Kenny, 1994; Watcha & White, 1992). It is not clear whether these newer agents differ from each other to any significant degree in their potential to cause emesis (Kenny, 1994). Haigh and colleagues (1993) reported a slightly decreased incidence of postoperative nausea and vomiting (PONV) with the use of enflurane, but concluded that the differences between agents was of little clinical significance.

The literature concerning nitrous oxide is contradictory. Watcha and White (1992) reported, evidence at present suggests that nitrous oxide does not significantly affect the incidence of postoperative emesis in adults when halogenated inhalation agents are used (p.164). Kenny (1994) suggested that nitrous oxide has been responsible for a significant degree of PONV. Sound pathologic arguments have been made for the role nitrous could play in increasing risk of PONV, although conclusive evidence has not been demonstrated (Dabbous, 1996; Gin, 1994; Kallar, 1992).

Neuromuscular blocking agents have traditionally been regarded as having no effect on PONV (Kenny, 1994; Rabey & Smith, 1992). However, Haigh and colleagues (1993) reported that the use of pancuronium increased PONV and attributed this to its sympathomimetic effect. Neostigmine is an agent that has traditionally been implicated in causing PONV (Boeke, de Lange, van Druenen, & Langemeijer, 1994; Gin, 1994; Kenny, 1994). Haigh and colleagues (1993) study was not supportive of this established belief. They found that neostigmine, when used to antagonize neuromuscular blockade, had little effect on the risk of PONV.

Opioids have been known to increase the incidence of PONV (Kallar, 1992; Kenny,

1994). Cohen et al. (1994) reported that if an opioid was used intraoperatively patients were 1.32 times more likely to suffer PONV when compared to patients who did not receive an opioid, regardless of anesthetic technique. Opioids have been shown to cause postoperative nausea and vomiting (PONV) regardless of the route of administration, but no one opioid has been shown conclusively to cause more PONV than another (Gin, 1994; Rabey & Smith, 1992). However, as stated earlier postoperative pain also can cause PONV, and studies have shown relieving pain relieves nausea and vomiting (Watcha & White, 1992).

Postoperative Factors

Dershwitz (1997) included severe pain, hypotension/dehydration, premature ambulation, and forcing oral fluid intake as additional factors that increase PONV. Kenny (1994) reported that any type of movement can be a trigger for PONV stating, Use of opioids may sensitize the vestibular system and the combination of opioid pain control and postoperative movement is especially emetogenic (p8). Thirty-eight percent of the 540 patients who experienced nausea associated it with movement in Koivuranta and colleagues 1997 study.

Physiology of PONV

Nausea can be defined as a subjectively displeasing sensation associated with the urge to vomit. Vomiting is the forceful expulsion of gastric contents from the mouth and is brought about by the powerful sustained contraction of the abdominal muscles, descent of the diaphragm, and opening of the lower esophageal sphincter (Dabbous, 1996).

Vomiting is a complicated process involving coordination of the respiratory,

gastrointestinal, and abdominal muscles, mediated by a central coordinating vomiting center thought to reside in the brainstem's reticular formation called the emetic center (Dabbous, 1996; Langer, 1998). Once stimulated, the emetic center sends efferent impulses via the fifth, seventh, ninth, tenth, and twelfth cranial nerves, the phrenic nerves, and the spinal nerves to the esophagus, stomach, and diaphragm (Belatti, 1992). There are two main routes for stimulating the emetic center. First, indirect stimulation can occur from another center, the chemoreceptor trigger zone (CTZ) (Haynes & Bailey, 1996). The CTZ is located in the area postrema (AP) of the brain stem, in the caudal part of the fourth ventricle, and is affected by endogenous and exogenous substances (Grunberg & Hesketh, 1993). Endogenous substances include histamine, serotonin, dopamine, and acetylcholine (Haynes & Bailey, 1996). Exogenous substances include artificially instilled opioids, inhalation anesthetic agents, and other medications. The CTZ is not protected by the blood-brain barrier exposing it to blood borne substances (Dabbous, 1996). Though some of these substances may not be recognized by a specific receptor they can still trigger vomiting through the CTZ relaying information to the emetic center (Dabbous, 1996). The CTZ responds to specific stimuli through adrenergic, cholinergic, histamine, serotonin, dopamine, and opiate receptors (Grunberg & Hesketh, 1993). Most antiemetic medications have antagonistic activity at one of these receptors.

The direct stimulation of the emetic center occurs from signals originating in the pharynx, gastrointestinal tract, mediastinum, and areas of the brain sensing vision and taste (Langer, 1998). For example, distention of the gastrointestinal tract initiates afferent impulses that reach the emetic center via the tenth cranial nerve (Haynes &

Bailey, 1996). The vestibular apparatus is unique in that it projects afferent fibers carried in the eighth cranial nerve to both the CTZ and the emetic center. This passage furnishes an anatomic basis for motion-induced nausea (Dabbous, 1996).

The vomiting reflex may be elicited by a number of different types of stimuli involving a variety of receptor structures and considerable diversities in afferent pathways and central connections (Graham-Smith, 1986). However, most authorities divide the emetic process into three components:

1. The afferent pathways to the central nervous system (CNS) relaying the signals of emetic stimuli
2. The reception, recognition and central processing of these signals leading eventually to integrated emetic efferent signals emerging from the CNS
3. The efferent pathways relaying the signals which lead to the coordinated respiratory, gastro-intestinal and abdominal muscle expulsive movements and the accompanying emetic epiphenomena (Graham-Smith, 1986, p.1).

Central mediating structures vary widely according to the type of primary emetic stimulus (Brizzee & Mehler, 1986). The emetic circuits which have been most completely described to date are those in which the chemoreceptor trigger zone (CTZ) in the area postrema (AP) of the brain stem functions as a key mediating structure. Even in this system, however, there are large gaps in our knowledge of the nerve tracts and central nervous system connections involved.

Current Pharmacological Treatment for PONV

The emetic center in the brain receives input about specific receptor activation from the CTZ (Dabbous, 1996). Antagonism of any one signal can alleviate vomiting

associated with the stimulation of that particular receptor. However, there is no drug available that will antagonize all receptor sites involved in the emetic response. Four major neurotransmitter systems appear to play important roles in mediating the emetic responses: dopamine, histamine (H1), cholinergic muscarinic, and 5HT₃ (Dabbous, 1996, p.507).

The antiemetic actions of phenothiazines are attributed primarily to their ability to block dopaminergic receptors in the CTZ (Dabbous, 1996; Gin, 1994). One of the most widely used antiemetics is prochlorperazine, although according to Kenny (1994) and Sung (1996) there are few good studies on its efficacy. Side effects of this class of antiemetic include significant sedation, lethargy, and orthostatic hypotension thereby delaying postoperative recovery (Dabbous, 1996; Haynes & Bailey, 1996; Watcha & White, 1992). Extrapyramidal reactions also have been associated with phenothiazine antiemetics with side effects ranging from restlessness to oculogyric crisis.

Butyrophenones, more specifically droperidol, are closely related to the phenothiazines and function as an antagonist at the dopamine receptor (Haynes & Bailey, 1996). Routine use of droperidol is not recommended for patients undergoing outpatient surgery, due to its extrapyramidal side effects (Dabbous, 1996). Despite its alpha-adrenergic receptor blocking activity, droperidol at low doses maintains cardiovascular stability. The combination of droperidol and opioids, especially fentanyl, causes mild hypotension and bradycardia. Respiratory depression induced by droperidol is significant if it is administered in high doses and combined with opioids (Sung, 1996). Despite the potentially harmful side effects droperidol in low doses has been found to be safe and when compared to the latest 5HT₃ blockers droperidol was equally effective and

significantly less expensive (Koivuranta, Laara, Ranta et al., 1997; Sniadach & Alberts, 1997; Tang, Mehernoor, Watcha, & White, 1996).

Antihistamines act on the emetic center and the vestibular pathways (Dabbous, 1996; Watcha & White, 1992). These compounds have been found to be useful in the prophylaxis and therapy of motion sickness and in the control of PONV following middle ear surgery. Kenny (1994) states, only cyclizine has been used extensively for PONV (p.9). He also notes that sedation and dry mouth occur with administration of cyclizine however, this drug has not been associated with extrapyramidal side effects. Walder and Aitkenhead (1995) concluded that cyclizine is as effective as droperidol in the prevention of PONV when included in a patient controlled analgesia (PCA) infusion using morphine.

Anticholinergics, such as scopolamine, are effective both centrally, at the chemoreceptor trigger zone (CTZ), and peripherally as an anticholinergic (Sung, 1996). Transdermal scopolamine has been found to be effective in controlling motion sickness, significantly decreasing the incidence of severe PONV, and decreasing nausea and vomiting after epidural morphine administration (Aronson, 1986; Dabbous, 1996; Sung, 1996; Watcha & White, 1992). Scopolamine is also a CNS depressant and causes amnesia however, at high doses it can be a stimulant (Sung, 1996). Scopolamine has produced side effects such as dry mouth, sedation, visual disturbances, memory dysfunction, dysphoria, and, occasionally, confusion and hallucinations (Kallar, 1992; Watcha & White, 1992).

Metoclopramide is a benzamide with both central and peripheral antiemetic actions (Dabbous, 1996; Watcha & White, 1992). Metoclopramide's antiemetic effects are

attributed to its antidopaminergic properties and antagonism of serotonin receptors in the CTZ (Kenny, 1994; Sung, 1996). It also increases gastrointestinal motility and increases lower esophageal sphincter tone (Dabbous, 1996; Haynes & Bailey, 1996; Watcha & White, 1992). Kenny (1994) lists extrapyramidal reactions, sedation, and significant cardiovascular side effects as potential side effects of metoclopramide.

The serotonin or 5HT₃ antagonist, ondansetron, binds competitively and selectively to serotonin receptors in the CTZ and in the gastrointestinal tract (Bunce & Tyers, 1992; Sung, 1996). Ondansetron appears to be free of CNS side effects. It stimulates gastric emptying better than metoclopramide and very few if any interactions have been found between it and other drugs (Haynes & Bailey, 1996). Ondansetron has been shown to be more effective at preventing emesis than nausea and may fail to prevent postoperative nausea and vomiting (PONV) completely in 30-50% of patients (Gin, 1994; Tramer, Reynolds, Moore, & McQuay, 1997). Ondansetron is considerably more expensive than other antiemetics. Johnstone et al. (1993) reported that ondansetron costs nearly 5000% more than droperidol. According to Fisher (1997) only one of every five patients who would have experienced PONV would benefit from ondansetron.

Drug therapy has not been entirely effective in preventing or treating PONV, and antiemetic drugs often have associated anti-histaminic, anti-cholinergic, or anti-dopaminergic side effects (Gin, 1994). Because of the side effects, cost, and relative ineffectiveness of currently used antiemetics researchers have begun to look at other therapies to prevent PONV. Traditional Chinese medicine (TCM) has used acupressure for thousands of years to combat nausea and vomiting (Beal, 1992a). The second half of this chapter will review the literature on the proposed mechanisms of action behind

acupressure and discuss some of the current studies that have used acupressure for PONV treatment.

Proposed Mechanisms of Action of Acupressure

Beal (1992b) discussed the underlying concepts of TCM, reporting that fundamental to understanding TCMs therapies is the concept of ch i or qi. Beal (1992b) and Edelson (1998) explain that TCM looks at the body as a vessel for ch i, the energy or life force that affects every entity in the universe and is itself affected by any physical, mental, emotional, or spiritual conflict within the body. Ch i is carried throughout the body by meridians or channels and it is seen as a river flowing through our bodies (Beal, 1992b; Edelson, 1998; Maxwell, 1997; Ortego, 1994). Health is seen as a state of balance, specifically balance in the flow of ch i. Energy may be bound up or overabundant in one or more meridians causing a disruption in flow (Beal, 1992b). Disease of any kind signifies an imbalance of flow. Fortunately, along each meridian are acu-points where ch i flow comes to the surface of the skin (Ortego, 1994). Stimulating these points can release muscle tension, increase circulation and allow ch i to flow evenly, thus balancing the individual and restoring health (Maxwell, 1997).

Researchers have attempted to anatomically dissect the meridians suggesting that they follow the routes of vessels or dermatomes (Bensoussan, 1994a). Bensoussan (1994b) concluded that there is little evidence to support the claims that channels and points represent physical entities in a common anatomical sense. He suggested that meridians can be mapped out electrically and that acu-points are areas of high electrical conductivity relative to nearby tissues. It is thought that manipulation of these points alters the electrical field in the immediate vicinity and brings about physiological changes

(Bensoussan, 1994b). However, not everyone agrees with this explanation.

Andersson and Lundeberg (1995, p.273) state, effects [of acupressure] must rest on physiological and/or psychological mechanisms and should have a biological meaning. They go on to say, stimulation of cutaneous or subcutaneous tissue should obtain their effects from the artificial activation of systems which receive a similar stimulation from biological effects in functional situations" (p.272). The authors suggested that acupressure stimulation of the skin sensory receptors activate A-beta and A-delta fibers, which in turn release endogenous opioids from the hypothalamus. They stated that endogenous opioids were essential in the induction of functional changes of different organ systems. In addition, the authors suggest the possibility that effective acupressure treatment may be due to positive placebo effects.

Acupressure for Treatment of PONV

The mechanism by which acupressure at the pericardium-6 meridian point prevents postoperative nausea and vomiting is not yet fully understood (Fan et al., 1997). Nevertheless, researchers have utilized p-6 acupressure for the treatment and prevention of PONV with varying success.

Fry (1986) reported applying acupressure to the front of the wrist of 136 men and 114 women for 30 seconds just prior to induction of general anesthesia. His patients were unaware of this procedure, to avoid placebo effect, and only 11 of these patients were noted to suffer PONV. His control group of 131 men and 119 women had 40 incidences of PONV. This study was flawed because it was unblinded but the idea of a noninvasive treatment for PONV sparked interest in other researches.

Barsoum, Perry and Fraser (1990) compared p-6 acupressure using bilateral

wristbands to placebo acupressure and prochlorperazine in one hundred sixty-two general surgical patients. The researchers reported a significant reduction in nausea in the acupressure group but no statistical difference in vomiting rates was found among all three groups. The authors noted a lack of research in this area and suggested that p-6 acupressure should be investigated further in other clinical situations.

Allen, Kitching and Nagle (1994) studied the effects of p-6 acupressure on 46 women undergoing laparotomy for major gynecological surgery to sham or placebo acupressure and found no statistical difference in the incidence of PONV between the two groups. The p-6 group, however, did receive significantly less rescue antiemetic than the control group, indicating reduction in severity of nausea. This study also used the acupressure wristbands but only applied pressure to one wrist, which may have reduced its effect.

Phillips and Gill (1994) reported that p-6 acupressure was effective for both nausea and vomiting. Their study used 80 gynecological surgery cases, half wore acupressure bands placed on both wrists the other half was without bands. They found that patients wearing the bands had significantly less nausea and vomiting, and if they were sick, it was for a shorter amount of time with fewer requested doses of antiemetics. An unfortunate issue with this study was the drop out of 12 out of 40 treatment patients without explanation.

Ho, Hseu, Tsai, and Lee (1996) reported a reduction of nausea from 43% in their control group to 3% in the acupressure group, and a decrease in vomiting from 27% to 0%. They utilized bilateral wrist p-6 acupressure bands for the prevention of nausea and vomiting after epidural morphine for post-cesarean section pain relief. Sixty parturients were randomly selected, placed into two groups, and a blinded anesthesiologist collected

their data. Additional conclusions were that acupressure is safe, simple, noninvasive and readily acceptable by patients.

Fan et al. (1997) observed 200 American Society of Anesthesiologists (ASA) I and II patients undergoing surgeries associated with a high incidence of PONV such as laparoscopic and gynecologic procedures, tonsillectomy, and open cholecystectomy. In a randomized, double-blinded study, they compared real acupressure wristbands to placebo bands worn on both wrists. The acupressure group had a significantly lower incidence of nausea and vomiting. Twenty-five of 108 patients in the treatment group experienced nausea and vomiting versus 38 of 92 patients in the control group. They also concluded that there were no observed side effects or complications due to the placement of the acupressure bands, and all patients felt comfortable while wearing them. A limitation of this study was that it was concluded only six hours after surgery.

Summary

This chapter reviewed the current literature on the risk factors for postoperative nausea and vomiting (PONV), the physiology of PONV, and problems with current pharmacologic treatment. In addition, the proposed mechanisms of action for acupressure and current literature on p-6 acupressure for the relief and prevention of PONV were reviewed. The conclusion of these studies indicates further research needs to be done before a definitive judgment on p-6 acupressure can be made.

CHAPTER III: METHODS

Research Design and Procedures

The ultimate goal of antiemetic prophylaxis is the total protection from nausea and vomiting with therapies that lack adverse side effects (de Mulder, 1992). Acupressure has been shown to be safe and devoid of side effects. However, conflicting results have been reported on its efficacy (Fan et al., 1997; Stein et al., 1997). This study will contribute to the research on the use of acupressure in the prevention of postoperative nausea and vomiting (PONV).

An experimental in design, double blinded, randomized, and placebo controlled study will be conducted to retest the hypothesis that acupressure at the pericardium-6 (p-6) meridian will decrease the incidence of both postoperative nausea and vomiting. Data will be gathered from a sample of surgical patients at Malcolm Grow Air Force Medical Center, Andrews Airforce Base.

Prior to initiation of the study informed consent will be obtained from all participants (see Appendix A). Subjects will be randomized into two groups by drawing one of two cards out of an envelope. One card will be marked one the other two, if the one is drawn every odd numbered subject will be in the control group and even numbered subjects will be in the study sample. Protocol checklists will be numbered from one to fifty in the upper right hand corner signifying a odd or even subject. If the number two is drawn the opposite will be done. The study patients will wear bilateral elastic acupressure wristbands applying pressure on the p-6 acupressure points. The control subjects will receive placebo wristbands consisting of bands without pressure buttons. Both groups will have the bands applied at least 15 minutes prior to induction of general

anesthesia by an anesthesia provider who will not be involved with data collection.

Bands will be loosely covered with gauze and tape so that the groups will not be distinguishable from each other thus blinding the data recorders, subjects and anesthesia providers to the treatment group. The provider applying the bands will check A or B on the protocol checklist, A will be the control group and B will be the study group. Pulse oximetry will be assessed on each hand prior to induction of anesthesia to confirm that blood flow to the digits is not compromised. Subjects will be instructed to leave the bands in place for 24 hours following surgery unless discomfort prevents them from doing so.

All subjects will receive at least 1mg of midazolam as a preoperative medication at least 15 minutes prior to induction of anesthesia. A minimum of 25mcg of fentanyl will be administered approximately five minutes prior to induction to blunt the response to laryngoscopy. Intravenous induction will be accomplished using two to two and a half mg/kg of Propofol followed either by an appropriate dose of succinylcholine or a non-depolarizing neuromuscular blocking agent. Surgical anesthesia will be maintained using isoflurane, oxygen, and nitrous oxide if the provider chooses. Surgical muscle relaxation will be maintained with an appropriate dose of a nondepolarizing neuromuscular blocking agent. Reversal of the block, if required, will be accomplished utilizing 0.035-0.07mg/kg of neostigmine with an appropriate dose of glycopyrrolate. The anesthesia provider may administer any medication that they deem necessary other than antiemetics. Postoperative pain relieve will be accomplished utilizing the anesthesia provider s choice of medications as well as the hospital s standard postoperative regimen.

Sample

Exclusion criteria for this study were:

1. Pregnancy
2. Less than 18 years of age

Inclusion criteria for this study were:

1. Laparotomy, laparoscopic or general anesthesia for GYN surgeries
2. Over the age of 18
3. Literate in the English language

Power analysis revealed that a sample of 27 subjects was needed to attain a 0.80 power level at an alpha of 0.05 in a two sided test given the moderate effect size that is expected in this study (Dr. Levine, personal communication, Feb 13, 1998). An attempt was made to recruit approximately 50 subjects into the study, 25 in each group, to increase the statistical significance of the findings.

Measurement

Demographic data such as age, sex, height, weight, and surgical procedure were collected after the subject agreed to participate in the study. Postoperative vomiting and retching were measured as occurrences over a 24 hour period. Retching was recorded as equal to vomiting and each episode was recorded as a single event within a 24-hour period following surgery. The total number of events were added together at the end of 24 hours. Times of events were evaluated as: (a) during the first hour after surgery, (b) the following four hours, (c) the following seven hours, and (d) during the last 12 hours of the 24 hour assessment period. Time periods a and b were recorded by the PACU staff in the anesthesia provider study protocol (see Appendix B).

Nausea was measured using a 10-centimeter visual analogue scale (VAS) (see Appendix C). The 10-centimeter line on the VAS was marked no nausea and 0 at one end and worst nausea ever experienced and 10 on the other. The subjects were asked to quantify their nausea as a mark on the line that best represents their feelings (Morrow, 1992). According to Rhodes (1997) reliability is the strength of the visual analog scale with a stable phenomena such as postoperative nausea. However, she states that the validity of the scale is unreported. Validity of an instrument is an evaluation of the extent to which the instrument accurately measures the studied variables (Burns & Grove, 1997). Therefore, three expert nurse anesthetists evaluated the VAS for validity before its use. Inter-rater reliability was found to be greater than to 0.80 and was acceptabled. Nausea was measured by the subject and recorded in the anesthesia provider protocol for time periods a and b. Subjects were given a VAS to take home and asked to record time and intensity of episodes occurring during the c and d time periods. An anesthesia provider provided a follow up call to the homes of the subjects to obtain verbal reports of events and VAS scores.

Protection of Human Rights

Institutional review board (IRB) approval from the Uniformed Services University of the Health Sciences (USUHS) and Malcolm Grow were attained prior to this study. Informed consent was obtained from all patients in the study. Strict adherence of exclusion criteria attempted to prevent any untoward effects. The documentation of pulse oximetry in both hands and assessment of the radial pulse bilaterally confirmed blood flow to the digits was not impeded. If a subject vomited or experienceed intolerable nausea an antiemetic was offered and even if taken subjects stayed in the

study.

In studies done by Stein et al. (1997) and Fan et al. (1997) acupressure bands were found to be without side effects or complications. However, subjects may withdraw from the study at any time. Refusing to participate or withdrawing from the study involved no penalty of loss of benefits nor did it affect the care that was provided. Precautions were taken to keep study documents, which identify subjects, by name confidential. To protect confidentiality, each assessment tool was assigned a number so that after verifying information with patient records, subjects could be referred to as their number on the protocol list.

Plan for Data Analysis

The data collected from subjects was analyzed using the Statistical Package for the Social Sciences (SPSS) version 8.0. Frequency and severity of postoperative nausea, as well as the number of vomiting episodes were compared between the two groups. Variables such as age, gender, duration of surgery, and postoperative pain medications were also assessed using SPSS for statistical significance between the groups.

Summary

Acupressure is a safe, noninvasive therapy that if proven to be effective could provide relief from postoperative nausea and vomiting for many patients. Current literature regarding p-6 acupressure is inconclusive. This double-blinded, randomized, placebo controlled study was planned to add scientific evidence to the current literature for or against the use of p-6 acupressure for the relief of postoperative nausea and vomiting. Strict adherence to the research protocol was maintained to ensure the safety and confidentiality of the subjects.

CHAPTER IV: ANALYSIS

During the month of April 1999 ten patients were recruited into the study. The list of variables collected were as follows:

Real vs. Placebo acupressure bands

Age in years

Height in inches

Weight in Kg

Sex

Length of surgery in minutes

Surgical Procedure

History of motion sickness

History of wearing acupressure bands

Number of nausea episodes during the first hour post-op

Average severity of nausea during the first hour post-op

Number of vomiting episodes during the first hour post-op

Number of nausea episodes during hours 2-5 post-op

Average severity of nausea during hours 2-5 post-op

Number of vomiting episodes during hours 2-5 post-op

Number of nausea episodes during hours 6-12 post-op

Average severity of nausea during hours 6-12 post-op

Number of vomiting episodes during hours 6-12 post-op

Number of nausea episodes during hours 13-24 post-op

Average severity of nausea during hours 13-24 post-op

Number of vomiting episodes during hours 13-24 post-op

Number of doses of antiemetic received in recovery room

Was nitrous oxide used during the procedure?

Did the patient find the bands uncomfortable?

Total number of nausea episodes in 24 hours post-op

Average severity of nausea in 24 hours post-op

Total number of vomiting episodes in 24 hours post-op

The statistical technique used to test the null hypothesis, that acupressure has no effect on postoperative nausea and vomiting, was the one-way analysis of variance. This analysis requires that certain assumptions relative to the distribution of the data have been met in order to achieve valid results. These assumptions were:

- Independent random samples have been taken from each population
- The populations are normal
- The population variances are all equal (Norusis, p. 261, 1997).

Independence was assumed with-in the group of study patients because there was not a relationship between the observations in the different groups and between the observations in the same group (Norusis, p. 261, 1997). Acupressure bands or placebo bands were randomly placed on patients undergoing similar operations and conditions did not change over the course of the study.

According to Norusis (p.261, 1997) analysis of variance is not heavily dependent on the normality assumption, As long as the data are not extremely non-normal, you do not have to worry. She does also include the fact that if sample sizes are small, as they are

in this study, the impact of unusual observations can have a big effect on the analysis. An unusual observation made during this study was the length of surgery was significantly longer in the group treated with real acupressure bands, mean of 136.6 minutes versus 56 minutes in the placebo group. The length of surgery difference is assumed to have a significant effect on the one-way analysis of variance results and will be discussed later in this chapter.

In practice, if the number of cases in each of the groups is similar, the equality of variance assumption is not too important (Norusis, p. 261, 1997). This study had an equal number of patients in each group therefore, the equality of variance was assumed to be normal.

Utilizing SPSS for the one-way analysis of variance revealed no statistical significance of any variable other than length of surgery, in postoperative nausea and vomiting scores (See table 1).

Table 1.Statistical Analysis of Data for Selected Variables

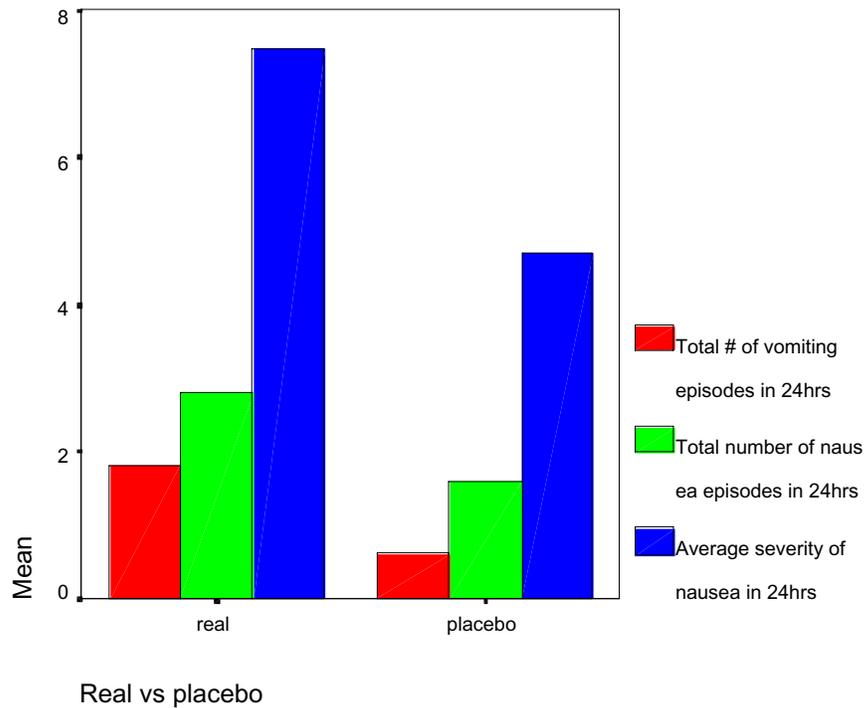
	N	Mean	Std. Deviation	ANOVA Sig.
Surgery Length:				
Treatment	5	135.5min	50.5981	.012
Placebo	5	56.0min	22.1923	
Hx of Motion Sickness:				
Treatment	5	1.6	0.5477	.580
Placebo	5	1.4	0.5477	
# of vomiting episodes in 24hrs				
Treatment	5	1.8	1.4832	0.160
Placebo	5	0.6	0.8944	

Total # of nausea episodes in 24hrs				
Treatment	5	2.8	2.49	.409
Placebo	5	1.6	1.8166	

However, review of the raw data would suggest that wearing the acupressure bands increased the incidence and severity of nausea and caused vomiting (See figure1).

Figure 1.

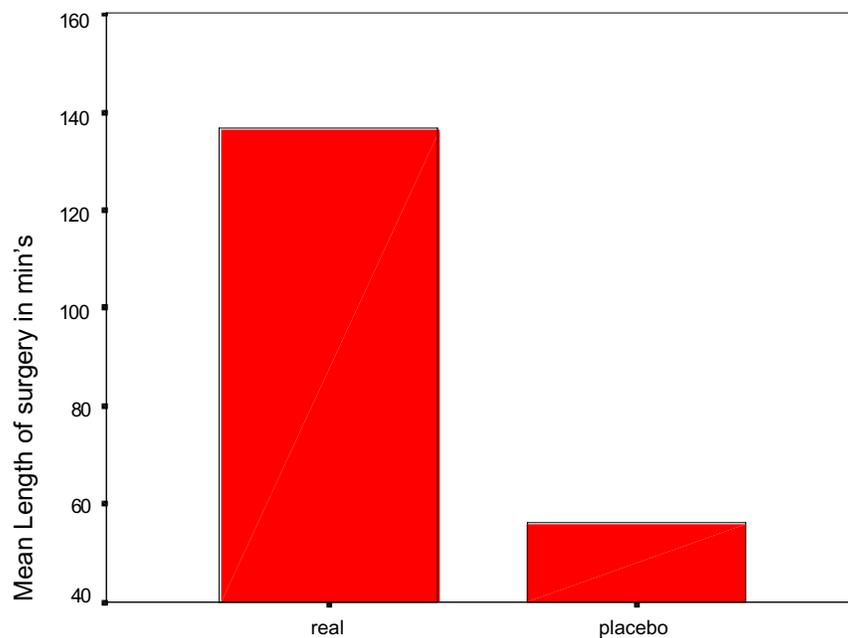
Total Nausea and Vomiting Scores



As stated earlier, evaluation of the variables expressed that the length of surgery was significantly longer in the acupressure treatment group. Statistical analysis of the length of surgery between the two groups using a one-way analysis of variance revealed a significance level of 0.012 (See table 1). To establish that homogeneity of variances had not been violated, for compliance of the one-way analysis of variance criteria, the levine s test was utilized and revealed a significance level of 0.096 establishing the homogeneity of variances in this sample. It was hypothesized that there would be no difference between the two groups in length of surgery. Because of the above results this null hypothesis was rejected.

Figure 2.

Mean Length of Surgery



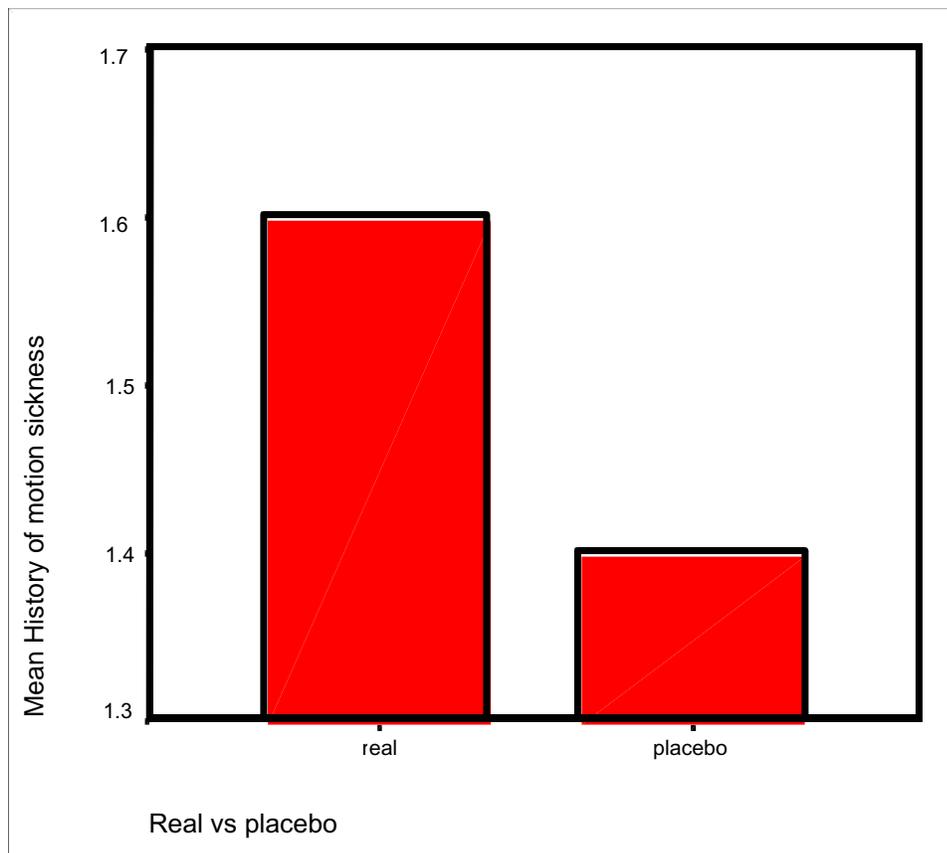
Real vs placebo

This increased length of surgery may provide an explanation for the higher incidence of postoperative nausea and vomiting (PONV) in the treatment group, as acupressure in itself should not cause PONV (See figure 2).

As stated earlier no statistical significance was observed with any other variable. However, the raw data revealed that the treatment group had a greater history of motion sickness than did the placebo group 1.6 incidence versus 1.4. This finding may further explain why the treatment group had a higher incidence of postoperative nausea and vomiting (See figure 3).

Figure 3.

History of Motion Sickness



CHAPTER V: SUMMARY

Restatement of the Problem

Postoperative nausea and vomiting remain problems after general anesthesia. While pharmacological advances have reduced the incidence of PONV, it continues to be the most common postoperative complication of anesthesia (Ferrara-Love, 1996). Persistent nausea and vomiting may result in dehydration, electrolyte imbalance, and delayed discharge. One of the main reasons for hospital admissions from same day surgery is postoperative nausea and vomiting (PONV) (White, 1996). Retching or vomiting can cause tension on suture lines, venous hypertension, increased bleeding under skin flaps and can increase the risk of aspiration (Watcha & White, 1992). Traditional western medicine has been unable to definitively explain why this phenomenon continues to occur and is beginning to investigate other health care philosophies for answers (Gin, 1994; O'Brien et al., 1996; Rogers, 1990; Rowbotham, 1992; Weightman et al., 1987). Eastern medicinal practices have become an area of research for the prevention of postoperative nausea and vomiting (Bill & Dundee, 1988; Dundee et al., 1996; Dundee & Ghaly, 1989; Dundee & McMillan, 1991; White, 1997). Acupressure at the pericardium-six meridian has been studied in various patient populations with varied success. If acupressure were found to be effective, anesthesia providers would have an inexpensive and non-invasive tool for prevention of nausea and vomiting. More research is required to arrive at a definitive conclusion on acupressure's efficacy for the prevention of postoperative nausea and vomiting. This study is to be considered a pilot study for further research to prove or disprove that acupressure at the P-6 meridian reduces

postoperative nausea and vomiting.

Methodology

The ultimate goal of antiemetic prophylaxis is the total protection from nausea and vomiting with therapies that lack adverse side effects (de Mulder, 1992). Acupressure has been shown to be safe and devoid of side effects. However, conflicting results have been reported on its efficacy (Fan et al., 1997; Stein et al., 1997). This study will contribute to the research on the use of acupressure in the prevention of postoperative nausea and vomiting (PONV) and provide a framework for further testing of the acupressure's efficacy.

An experimental design, double blinded, randomized, and placebo controlled study was conducted to retest the hypothesis that acupressure at the pericardium-6 (p-6) meridian would decrease the incidence of both postoperative nausea and vomiting. Data were gathered from a sample of ten surgical patients at Malcolm Grow Air Force Medical Center, Andrews Airforce Base.

Prior to initiation of the study informed consent was obtained from all participants (See Appendix A). Subjects were randomized into two groups by drawing one of two cards out of an envelope. One card was marked one the other two ; if the one is drawn every odd numbered subject was to be in the control group and even numbered subjects in the study sample. Card two was drawn and every odd numbered subject received real acupressure bands and even patients received placebo bands. Protocol checklists were numbered from one to ten in the upper right hand corner signifying a odd or even subject. The study patients wore bilateral elastic acupressure wristbands applying pressure on the p-6 acupressure points. The control subjects received placebo

wristbands consisting of bands without pressure buttons. Both groups had the bands applied at least 15 minutes prior to induction of general anesthesia by an anesthesia provider who was not involved with the anesthesia for the patient. Bands were indistinguishable from each other thus blinding the subjects and anesthesia providers to the treatment group. The provider applying the bands checked A or B on the protocol checklist, A was the control group and B was the study group. Pulse oximetry was assessed on each hand prior to induction of anesthesia to confirm that blood flow to the digits is not compromised. Subjects were instructed to leave the bands in place for 24 hours following surgery unless discomfort prevents them from doing so, all subjects wore the bands for 24 hours and no discomfort was reported.

All subjects received at least 1mg of midazolam as a preoperative medication at least 15 minutes prior to induction of anesthesia. A minimum of 25mcg of fentanyl was administered approximately five minutes prior to induction to blunt the response to laryngoscopy. Intravenous induction was accomplished using two to two and a half mg/kg of Propofol followed either by an appropriate dose of succinylcholine or a non-depolarizing neuromuscular blocking agent. Surgical anesthesia was maintained using a volatile agent, oxygen, and nitrous oxide if the provider desired. Surgical muscle relaxation was maintained with an appropriate dose of a nondepolarizing neuromuscular blocking agent. Reversal of the block was accomplished utilizing 0.035-0.07mg/kg of neostigmine with an appropriate dose of glycopyrrolate; all patients received a reversal dose of neostigmine and glycopyrrolate. The anesthesia provider administered any medication that they deemed necessary other than antiemetics. Postoperative pain relieve was accomplished utilizing the anesthesia provider s choice of medications as well as the

hospital's standard postoperative regimen.

Findings

This pilot study found no statistically significant findings supporting the use of acupressure for the prevention of postoperative nausea and vomiting (PONV). The study was limited because of the small sample size (n=10). A direct correlation between length of surgery and incidence of PONV was revealed in the analysis of variables.

Recommendations

This study should be replicated with a larger sample size and over a longer period of time. The research was limited because only one person was trained to apply the bands and could not be available to recruit every appropriate patient into the study. It was also discovered that during a one month period of time appropriate patient numbers may be limited because of varying surgical cases at one facility. Further recommendations include:

- (1) limiting the study to one type of surgical procedure to offset the varying range of surgical times.
- (2) Excluding patients who have had a history of postoperative nausea and vomiting.
- (3) Excluding patients who have a history of motion sickness.
- (4) Training more than one person to apply the acupressure bands so that accurate placement can be assured after patient positioning for surgery and additional patients can be recruited for the study when one investigator is not available.

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APPENDIX A

SUBJECT CONSENT

Uniformed Services University of the Health Sciences

Bethesda, MD 20814

Malcolm Grow Air Force Medical Center, Andrews Air Force Base, MD 20762

Subject Informed Consent Form

Introduction

You are being asked to take part in a research study of acupressure for the prevention of postoperative nausea and vomiting (PONV). Non-invasive wristbands will be used to apply the treatment. Approximately 50 patients will take part in this study at Malcolm Grow Air Force Medical Center (MGMC). The study will be under the direction of Dr. John P. McDonough, CRNA, Ed.D. and Robert M. Woods, Cpt., USA, SRNA. Your participation in this study begins when you sign this consent form and ends 24 hours after your discharge from the post anesthesia care unit (PACU) or recovery room.

Purpose

The purpose of this study is to retest the claim that acupressure can relieve or prevent PONV. Currently used antiemetic medications can be ineffective, have unwanted side effects, and can be expensive. Several studies have shown that acupressure is effective in decreasing PONV however, more research is needed before conclusions can be made on acupressures efficacy.

Procedures

Before you can take part in this study, an anesthesia provider will obtain your medical history and examine you to see if you meet the requirements of the study. Once an anesthesia provider determines that you can take part in this study and you sign this form, you will have acupressure wristbands placed on both wrists.

All routine procedures for someone scheduled for surgery under general anesthesia will be followed while you are in this study, such as the placement of standard monitoring equipment and frequent monitoring of you heart rate and blood pressure.

If you take part in this study, you will receive propofol to put you to sleep. Propofol is one of the most commonly chosen drugs used to put people to sleep for surgical anesthesia. To help keep you asleep and free of pain, you will receive isoflurane (an

anesthetic) and fentanyl (a pain reliever).

Once you are in the recovery room and are stable and awake enough, if you are experiencing nausea, you will be asked to rate it on a scale of 0 to 10, with 0 being no nausea and 10 being the worst nausea you have ever experienced. You will be asked to complete this assessment 4 times during the following 24 hours after surgery.

All routine interventions will be taken to ensure that you are comfortable in the PACU after your surgery. If you do experience nausea and/or vomiting you will be offered an intravenous antiemetic medication.

Benefits

Acupressure has been found to be safe and without side effects. The same cannot be said of all the intravenous antiemetic medications. Regardless of whether you receive actual or placebo acupressure, measures will be taken to treat any potential or actual postoperative pain, nausea, and/or vomiting. The true extent of the benefits expected from acupressure such as reduction in nausea and vomiting are unknown. However, the information gained from your participation in this study may benefit future patients. No benefit, however, is guaranteed.

Risks

Acupressure has been tested in clinical studies before. No side effects have been associated with acupressure and wristband testing has been well tolerated by patients. However, if you should experience any discomfort from the wristbands you may take them off at any time. If you do experience nausea and or vomiting you will be offered an intravenous antiemetic medication.

Alternative Procedures

If you do not take part in this study you will receive general anesthesia and the anesthesia provider may decide to use intravenous antiemetics for your procedure. You will not, however, wear the acupressure wristbands.

Confidentiality

Precautions will be taken to keep study documents that identify you by name confidential. Your name will not appear on any documents in the study after your study period is over.

Subject Rights

Your participation in this study is entirely voluntary and you may withdraw from the study at any time. Refusing to participate or withdrawing from the study will involve no penalty of loss of benefits you might otherwise receive nor will it effect the care that you receive while at MGMC. Your anesthesia provider may decide to end your participation in this study at any time, without your approval, if he/she feels it is in your best interest.

By signing this form, you are not waiving any of your legal right.

Additional Information Required by AFI 40-401

Record of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. 562a, and its implementing regulations. DD for 2005, Privacy Act Statement-Health Care Records, contains the Privacy Act Statement for the records. Records may also be examined by the U.S. Food and Drug Administration.

The Department of Defense will provide medical care for DoD eligible members (active duty, dependents, and retired military) for physical injury or illness resulting from participation in this research. Such care may not be available to other research participants, except in the event of an emergency. Compensation may be available through judicial avenues to non-active duty research participants if they are injured. You understand that your entitlements to medical and dental care and/or compensation in the event of injury are governed by federal laws and regulations, and if you desire further information, you may contact Cpt Robert Woods or Dr. John P. McDonough.

In the event that an unanticipated event (clinical or medical misadventure) occurs during your participation in this study, you will be informed. If you are not competent at that time to understand the nature of the event, such information will be brought to the attention of your guardian or next of kin.

The decision to participate in this study is completely voluntary. No one has coerced or intimidated you into participating in this program. You are participating because you want to. Cpt Woods and/or Dr. McDonough have adequately answered any and all questions you have about this study, your participation, and the procedures involved. You understand that Cpt Woods and/or Dr. McDonough will be available to answer any questions concerning procedures throughout this study. You understand that if significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed. Please further understand that you may withdraw this consent at any time and discontinue further participation in this study without prejudice to your entitlements to care. In addition, understand that the investigator for this study may terminate your participation in this study if he feels this to be in your best interest.

Answers to Questions

If at any time you feel that you may have sustained a research-related injury, you may call Cpt Robert M. Woods, SRNA, USA at (401) 379-6784 day or night. You may also call Dr. John P. McDonough, CRNA, Ed.D. at (301) 295-6565 (day) or (301) 315-2338 (night). They will insure that you will receive appropriate medical treatment. If at any time before, during, of after the study you have any questions about the study you may call Cpt Woods and/or Dr. McDonough at one of the above numbers. If you have any questions about your rights as a research subject, you may call USUHS Director, Research Programs (301) 295-3303 or USUHS General Counsel at (301) 295-3028.

I have fully explained this research, including the risks and alternate treatments, to the subject _____. In my judgment, there was sufficient access to information, including risks and benefits, to make an informed decision to participate in this study.

Investigator s signature: _____ Date: _____

Investigator s name (print): Robert M. Woods

You have read the above description of the research study. You have talked it over with the anesthesia provider, have been given the opportunity to ask questions, and have had those questions answered to your satisfaction. You have also been given a copy of this consent form.

You understand that your participation is entirely voluntary and that you may withdraw your consent at any time, without penalty. You know enough about the purpose, procedures, risks, and benefits of the research study to decide that you want to take part in it.

For women able to bear children: You understand that if you are pregnant or breast-feeding I may not take part in this study. You are not breast-feeding and to the best of your knowledge, you are not pregnant.

You willingly give your consent to take part in this study.

Patient s signature

Date and time

Sponsor s social security number

Witness signature

Date and time

#1

A__ B__

APPENDIX B
Anesthesia Provider Protocol

Patient name: _____ Patient home phone

number: _____

Patient age: _____ Patient sex: _____ Patient height: _____

Patient weight: _____ Surgical procedure: _____

ASA _____

Operation start time: _____ Operation end time: _____ Date of

procedure: _____

Please check the appropriate spaces

1. Laparotomy, Laparoscopic, or GA

for GYN surgery? YES _____ NO _____

2. Patient older than 18 years old? YES _____ NO _____

3. Patient literate in the English language? YES _____ NO _____

4. Not pregnant? YES _____ NO _____

5. History of motion sickness? YES _____ NO _____

6. Morbid obesity? YES _____ NO _____

7. Does the patient have diabetes mellitus? YES _____ NO _____

8. Pulse oximetry assessed on each hand prior to
induction of anesthesia? YES _____ NO _____

9. Received at least 1 mg of Midazolam at least

- 10 minutes prior to induction? YES_____ NO_____
10. Receive at least 25mcg of fentanyl at least
Five minutes prior to induction? YES_____ NO_____
11. Induction with 2.0-2.5 mg/kg of Propofol? YES_____ NO_____
12. Succinylcholine or an appropriate dose of
a non-depolarizing neuromuscular blocking agent
used to facilitate intubation? YES_____ NO_____
13. Surgical anesthesia maintained using oxygen,
isoflurane or other agent? YES_____ NO_____
14. Nitrous oxide used? YES_____ NO_____
15. Surgical muscle relaxation maintained with
an appropriate dose of a nondepolarizing
neuromuscular blocking agent? YES_____ NO_____
16. Reversal of neuromuscular blockade with
Neostigmine and glycopyrrolate? YES_____ NO_____
17. Postoperative Pain relief provided for? YES_____ NO_____
18. Has the patient used acupressure bands
For nausea and vomiting in the past? YES_____ NO_____

Additional comments:

PACU Personnel

Please record any episodes of vomiting by date and time and assess nausea using the following visual analogue scale during recording of vital signs.

Number of Vomiting Episodes

Time:_____ Time:_____ Time:_____
Time:_____ Time:_____ Time:_____

Continue time recording here if needed:

Nausea Episodes and Severity

Visual Analogue Scale

0 [-----] 10

No Nausea Worst
Nausea Ever

Experienced

If the patient complains of nausea:

Please have the patient mark on the above line the level of nausea, then record time and number each mark on the scale to correspond to the time recorded

Time:_____ Number:_____ Time:_____ Number:_____
Time:_____ Number:_____ Time:_____ Number:_____
Time:_____ Number:_____ Time:_____ Number:_____
Time:_____ Number:_____ Time:_____ Number:_____

Please continue here if needed:

Did the patient receive an antiemetic? _____YES _____NO

If yes drug, dose and time of each dose:_____

APPENDIX C
Visual Analogue Scale

Patient s home recording tool

0 [-----] 10

No nausea

**Worst nausea ever
experienced**

Please record by time and number score any nausea you experience for 24 hours after you return home from your surgery. Also include by time and date any episodes of vomiting you may have after you return home from surgery.

Vomiting dates and times:

Time/date: _____ Time/date: _____ Time/date: _____

Continue here if needed:

Nausea date, times, and scores:

Time/date: _____ Number score: _____

Time/date: _____ Number score: _____

Time/date: _____ Number score: _____

Continue here if needed:

Did you experience any discomfort from wearing the
Acupressure bands? YES _____ NO _____