FEASIBILITY OF USING ACUPRESSURE WRISTBANDS IN A TRIAL

A FEASIBILITY TRIAL COMPARING ACUPRESSURE WRISTBANDS PLUS USUAL CARE VERSUS PLACEBO PLUS USUAL CARE IN AMBULATORY SURGERY PATIENTS AT RISK FOR POST-DISCHARGE NAUSEA AND VOMITING

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TITLE: A Feasibility Trial Comparing Acupressure Wristbands Plus Usual Care Versus Placebo Plus Usual Care in Ambulatory Surgery Patients at Risk for Post-discharge Nausea and Vomiting

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Lay Abstract

Postoperative nausea and vomiting (NV) is a common problem after surgery. In patients going home on the day of surgery, NV can persist or begin after being sent home as post-discharge NV. This places patients at risk for complications like pain and bleeding. Patients undergoing laparoscopically assisted vaginal hysterectomy (LAVH), a procedure to remove the uterus, are more likely than other patients to experience this. Research suggests that wrist acupressure may help prevent NV after surgery, but few have looked at its effect on NV after LAVH patients are sent home. This study explored whether it is possible to conduct a trial looking at the effects of acupressure on post-discharge NV in LAVH patients. Twenty participants were randomly assigned to receive either acupressure wristbands or wristbands without acupressure, alongside usual anti-nausea medications. This study found that it is possible to run a trial exploring acupressure wristbands to prevent post-discharge NV.

Abstract

Introduction/Background: Postoperative nausea and vomiting (NV) can occur after surgery, leading to complications like pain and bleeding. In ambulatory surgery patients, NV can begin or persist after discharge as post-discharge NV and impacts 40-80% of patients at risk for this phenomenon, including those undergoing laparoscopically assisted vaginal hysterectomy (LAVH). Studies suggest pericardium 6 (PC6) acupressure may prevent postoperative NV, but little is known regarding its effect on post-discharge NV. This study examined the feasibility of conducting a randomized controlled trial (RCT) to test the effects of bilateral PC6 acupressure wristbands plus usual care on post-discharge NV in ambulatory LAVH patients.

Methods: A randomized controlled parallel-arm feasibility trial was employed. The primary outcome was feasibility, including rates of consent, randomization, intervention/placebo delivery and continuous wear, and retention. The secondary outcomes were preliminary estimates of PC6 acupressure's effects on post-discharge NV. Twenty participants undergoing ambulatory LAVH were randomized to either a) usual post-discharge NV care (prophylactic antiemetics) plus bilateral PC6 acupressure wristbands, or b) usual care with bilateral placebo wristbands. Wristbands were placed on arrival to the recovery room and worn until 24 hours post-discharge. Follow-up calls were made to gather outcome data.

Results: It was feasible to conduct a trial where a registered nurse delivered wristbands to participants in the recovery room following LAVH. There were ten patients randomized in each group. Three of the five criteria met a priori criteria for feasibility success (rates of randomization, intervention/placebo delivery [continuous wear], and retention). Rates of consent and intervention/placebo delivery in the recovery room did not meet the 90% a priori criteria.

The preliminary estimates of intervention effect suggest acupressure may not impact post-discharge NV.

Conclusions: This feasibility study found that it was feasible to conduct an RCT examining the effects of PC6 acupressure wristbands on post-discharge NV in ambulatory LAVH patients.

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List of Abbreviations

AES	Advanced Encryption Standard
ASPAN	American Society of PeriAnesthesia Nurses
ANOVA	Analysis of variance
BCHS	Brant Community Healthcare System
BGH	Brantford General Hospital
CI	Confidence interval
CIHR	Canadian Institutes for Health Research
CNO	College of Nurses of Ontario
CONSORT	Consolidated Standards of Reporting Trials
CSM	Circulation, sensation, and/or movement
DSU	Day Surgery Unit
FIPS	Federal Information Processing Standard
HiREB	Hamilton Integrated Research Ethics Board
ITA	Investigational Testing Authorization
LAVH	Laparoscopically assisted vaginal hysterectomy
MI	Minimally invasive
NRS	Numerical rating scale
NV	Nausea and vomiting
PACU	Post Anesthesia Care Unit
PADSS	Post Anesthetic Discharge Scoring System
PC6	Pericardium 6
RCT	Randomized controlled trials
REC	Research Ethics Committee
TCM	Traditional Chinese medicine
TVT	Tension-free vaginal tape

Declaration of Academic Achievement

This thesis is a report of the original research that I conducted under the supervision of Drs. Sandra Carroll, Shaunattonie Henry, and Michael McGillion, since September 2022. The committee members provided their expertise toward the study design and methodology, the study proposal, submissions to the Hamilton Integrated Research Ethics Board and Brant Community Healthcare System Research Ethics Committee, and all chapters of this dissertation. My thesis work was supported by Dr. Anne Powell at Brantford General Hospital who acted as a co-investigator on site during the conduct of the study. I completed data analysis under the guidance of my supervisory committee members, with expert consultation from Dr. Kathryn Fisher and Dr. Kalpana Nair.

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Chapter I: Introduction and Background

Postoperative nausea and vomiting (NV) and post-discharge NV are major concerns in the management of ambulatory surgery patients (Chinnappa & Chung, 2008; Gan et al., 2020). Nausea is the unpleasant sensation that occurs in the epigastric area and the back of the throat which may result in vomiting, and vomiting is an observable phenomenon where stomach contents are forcefully expelled through the oral or nasal cavity (Rhodes & McDaniel, 2001). The American Society of PeriAnesthesia Nurses (ASPAN) (2006) defines postoperative NV as, "Nausea and/or vomiting that occur within the first 24-hour period after surgery," (p. 233) and delineates it into three types: 1) early postoperative NV that occurs in the first two to six hours after surgery, 2) late postoperative NV that occurs between six to 24 hours after surgery, and 3) delayed postoperative NV that occurs beyond 24 hours after surgery. Post-discharge NV is a type of postoperative NV that affects ambulatory surgery patients after they are discharged home from healthcare facilities, up to 24 hours after discharge (ASPAN, 2006). Any post-discharge NV that occurs beyond the first 24 hours after discharge is described as delayed post-discharge NV (ASPAN, 2006).

Postoperative NV and post-discharge NV are unpleasant phenomena, with some patients reporting them to be more distressing than postoperative pain (Macario et al., 1999). In addition to distress, postoperative NV can place patients at risk for complications like dehydration, wound dehiscence, pain, and bleeding (ASPAN, 2006; Kovac, 2013; Vance et al., 1973). Similarly, post-discharge NV can delay return to baseline function, decrease quality of life, cause patients to avoid adequate pain management with analgesic prescriptions for fear that it will worsen post-discharge NV, and negatively impact patient satisfaction (Kovac, 2013; Vance et al., 1973; Watcha & White, 1992). Furthermore, postoperative NV and post-discharge NV can create

organizational and systemic challenges such as delayed discharges from recovery and discharge units (which may interrupt the flow of the perioperative setting) and unplanned hospital admissions or readmissions (which may create issues around bed allocation and staffing); these challenges increase financial strain on healthcare systems (Chung & Mezei, 1999; Gan et al., 2020; Parra-Sanchez et al., 2012).

Despite introduction of novel anesthetic agents and antiemetic medications, postoperative NV affects up to 30% of all surgical patients, and post-discharge NV affects between 20 to 40% of patients undergoing ambulatory surgery (Apfel et al., 1999; Apfel et al., 2012; Gan et al., 2020; Maraş & Bulut, 2021). Furthermore, in their study including 1,040 adult patients receiving general anesthesia with volatile anesthetics without antiemetic prophylaxis in Europe, Apfel and colleagues (1999) found that the more risk factors patients meet, the higher the incidence rates of postoperative NV. When patients met all four identified predictors for postoperative NV (female, non-smoker, use of postoperative opioids, and history of postoperative NV or motion sickness), incidence was 78%; the confidence interval (CI) was not reported (Apfel et al., 1999). Specifically, Apfel et al. (1999) used logistic regression analysis and found that the odds of experiencing postoperative NV were higher in females than males (OR = 3.55, 95% CI [2.46, 5.14], $p < .001$), in non-smokers than smokers (OR = 2.05, 95% CI [1.49, 2.82], $p < .001$), in patients who received postoperative opioids than those who did not (OR = 2.10, 95% CI [1.42, 3.10], $p < .001$), and in patients with a history of postoperative NV or motion sickness than those without (OR = 1.91, 95% CI [1.35, 2.70]; $p < .001$). Another study by Apfel et al. (2012) using a validation dataset of 257 adult patients undergoing ambulatory surgery with general anesthesia across 12 surgery centres in the United States found that when patients met all five predictors for post-discharge NV (female, age younger than 50 years, history of postoperative NV, use of

opioids in the post anesthesia care unit [PACU], and nausea in the PACU), incidence was 89% (CI was not reported) (Apfel et al., 2012). Specifically, Apfel (2012) found that the odds of experiencing post-discharge were higher in females than males (*OR* = 1.54, 95% CI [1.22, 1.94], $p < .01$), in patients younger than 50 years of age than older patients (*OR* = 2.17, 95% CI [1.75, 2.69], $p < .01$), in patients with a history of postoperative NV than those without (*OR* = 1.50, 95% CI [1.19, 1.88], $p < .01$), in patients who received opioids in the PACU than those who did not (*OR* = 1.93, 95% CI [1.53, 2.43], $p < .001$), and in patients who experienced nausea in the PACU than those who did not (*OR* = 3.14, 95% CI [2.44, 4.04], $p < .001$). Furthermore, some surgical populations are at higher risk for postoperative and post-discharge NV than others (Cao et al., 2017). Among those who are at high risk for these phenomena are patients undergoing laparoscopic gynecological procedures, with incidence rates between 40% to 80% (Echeverria-Villalobos et al., 2022; Gan et al., 2020).

With high incidence rates and potential detrimental impacts on ambulatory surgery patients' physical and mental wellbeing, implementation of optimized preventative measures for postoperative NV and post-discharge NV are warranted. Including non-pharmacological interventions, such as acustimulation, may be one way to optimize these preventative measures.

Chapter II: Literature Review

Current guidelines from professional organizations for the prevention of postoperative NV and post-discharge NV were explored, followed by an examination of literature around acustimulation and acupressure. A high-level overview of the effects of pericardium 6 (PC6) acustimulation on postoperative NV is first presented, which is followed by a full literature review on the effects of PC6 acustimulation on ambulatory surgery patients' NV, which include some data on post-discharge NV. Lastly, a type of surgery that puts patients at high risk for postoperative and post-discharge NV is identified and explored.

Current Guidelines for Prevention of Postoperative NV and Post-discharge NV

The pathophysiology of postoperative NV and post-discharge NV are complex, and as such, their prevention and management are challenging (Fetzer et al., 2004; Gan, 2009). Professional organizations like the Society for Ambulatory Anesthesia, American Society of Enhanced Recovery, and Society of Obstetricians and Gynecologists of Canada have guidelines for the prevention and treatment of postoperative NV and post-discharge NV, with an emphasis on postoperative NV over post-discharge NV (Gan et al., 2020; McCracken et al., 2008). For prevention of postoperative and post-discharge NV, these organizations recommend identifying patients at high-risk by considering and reducing baseline risk factors, including utilizing regional anesthesia over general anesthesia when possible, minimizing perioperative opioid use, avoiding nitrous oxide and volatile anesthetics, minimizing the use of neostigmine, and providing adequate hydration with intravenous fluids (Gan et al., 2020; McCracken et al., 2008). Combination antiemetic therapy for postoperative NV prophylaxis is recommended for patients at moderate to high risk for postoperative NV and post-discharge NV (Gan et al., 2020; McCracken et al., 2008). The guideline released by the American Society of Enhanced Recovery

and Society for Ambulatory Anesthesia (Gan et al., 2020) recommends the use of at least two prophylactic antiemetic therapies for moderate-risk patients and three for high-risk patients. Among the recommended prophylactic antiemetic therapies include dexamethasone, dimenhydrinate, and 5-hydroxytryptamine-3 receptor antagonists like ondansetron (Gan et al., 2020). For prevention of post-discharge NV, the use of dexamethasone and ondansetron are recommended (Gan et al., 2020; McCracken et al., 2008). With recognition that pharmacologic prophylaxis interventions cannot fully prevent postoperative NV nor post-discharge NV, these organizations include acustimulation, a non-pharmacologic prophylaxis, as a recommendation (Gan et al., 2020; Lee et al., 2015; McCracken et al., 2008).

Acustimulation and Acupressure

Acustimulation is a form of complementary therapy based in Traditional Chinese Medicine (TCM) that may be beneficial to integrate into routine peri-operative practices to prevent postoperative NV and post-discharge NV (Hu, 2016a; Lee et al., 2015). Originating in China about 3,000 years ago, TCM is considered a natural science and a product of multidisciplinary knowledge including, but not limited to, Chinese philosophy, biology, botany, astronomy, and geography (Hu, 2016a; Ma et al., 2021). TCM is grounded in the core principles of wholeness and unity, where the human body is described as "an organic whole in which all constituent parts are structurally inseparable, functionally coordinative and interactive, as well as pathologically inter-influencing" (Hu, 2016a, p. 3) and is intertwined in its internal and external environments (Hu, 2016a). In TCM, qi is a dynamic substance that makes up the human body and maintains its functions (Hu, 2016d). It is carried by systems of meridians and collaterals throughout the body, and its imbalances and disruptions in flow are thought to contribute to ailments (Hu, 2016b, 2016c, 2016d). The stimulation of acupoints located along the meridians

throughout the body via needles, electricity, and/or pressure is thought to improve a variety of health conditions (Hu, 2016b, 2016c). The nature of stimulus is thought to be of less importance, if the correct acupoint is stimulated (Mann, 1987, as cited in Fan et al., 1997, p. 824). Using light to medium pressure to activate the acupoints, acupressure is one of the least invasive methods of acustimulation (Blaser, 2021). Acupressure is often delivered using acupressure wristbands, which have been reported to have minimal and transient side effects, including bruising, swelling, pain, itching, discomfort, paresthesia, and redness at the site (Lee et al., 2015; Nilsson et al., 2015). Nausea and vomiting are among health conditions that may be prevented and treated with acupressure (Blaser, 2021; Lee et al., 2015).

Pericardium 6 Acustimulation and Postoperative NV

There is some evidence to suggest that stimulation at the acupoint, PC6, helps to prevent postoperative NV and post-discharge NV (ASPAN, 2006; Blaser, 2021; Lee et al., 2015). PC6 is located in an easily accessible location on the body, two cun (Chinese inches) proximal to the wrist crease between the flexor carpi radialis muscles and palmaris longus tendons, at a depth of about 0.5 to 1 cm (Carr et al., 2015; Ferrara-Love et al., 1996). One cun is the width of the interphalangeal joint of the person's thumb, and two cun is the distance between the person's second and fourth finger at the proximal interphalangeal joints (Carr et al., 2015; Ferrara-Love et al., 1996). Considering pharmacologic prophylactic interventions only partially prevent postoperative NV and post-discharge NV, clinical guidelines like Gan et al.'s Fourth Consensus Guidelines for the Management of Postoperative Nausea and Vomiting from 2020, developed under the American Society of Enhanced Recovery and Society for Ambulatory Anesthesia, as well as ASPAN'S Evidence-Based Clinical Practice Guideline for the Prevention and/or Management of Postoperative NV/Post-discharge NV from 2006 include PC6 acustimulation as

a possible adjunct to Western medical practices to prevent postoperative NV and post-discharge NV (ASPAN, 2006; Gan et al., 2020). The mechanisms by which acupressure prevents postoperative and post-discharge NV are not well understood in Western medicine literature, but TCM theory suggests that acupressure helps to restore disruptions in movements of blood and qi (Lee et al., 2015; Lv et al., 2013).

A Cochrane review that examined literature from 1986 to 2015 found low-quality evidence to suggest PC6 stimulation significantly reduces postoperative NV compared to placebo and moderate-quality evidence to suggest it has similar prophylactic effects to antiemetic drugs, with minimal side effects (Lee et al., 2015). By examining data from 40 randomized controlled trials (RCTs) with a total of 4,742 participants, Lee et al. (2015) concluded that PC6 stimulation significantly reduced the incidence of nausea compared to placebo (*RR* = 0.68, 95% CI [0.60, 0.77]); using data from 45 RCTs examining 5,147 participants, they (2015) concluded that PC6 stimulation significantly reduced the incidence of vomiting compared to placebo (*RR* = 0.60, 95% CI [0.51, 0.71]). This systematic review (2015) further concluded that PC6 acustimulation had similar prophylactic effects as antiemetics drugs on the incidence of nausea based on the data collected from 1,332 participants in 14 RCTs (*RR* = 0.91, 95% CI [0.74, 1.10]) and on the incidence of vomiting from data collected from 1,708 participants in 19 RCTs (*RR* = 0.93, 95% CI [0.74, 1.17]). The confidence intervals are wide, and the heterogeneity of the studies in intervention (e.g., timing of intervention introduction, duration of acustimulation, whether interventions were administered unilaterally or bilaterally), outcomes of interest (severity and/or incidences of nausea and/or vomiting), and target populations (e.g., surgery types and sex) makes it difficult to reach a definitive consensus about the effectiveness of PC6 acupressure (Lee et al., 2015).

There is a growing body of evidence to suggest combining PC6 stimulation with pharmacological prophylactic antiemetics is more effective at preventing postoperative NV than drug therapy alone (Hofmann et al., 2017; Pires et al., 2022; Yang et al., 2015). Hofmann et al. (2017) conducted a two-arm RCT with 110 patients undergoing elective ambulatory surgeries, who were randomly assigned to either the intervention group receiving unilateral PC6 acupressure plus usual pharmacological antiemetics (n = 57), or the placebo group receiving unilateral placebo patches at the PC6 acupoint plus usual pharmacological antiemetics (n = 53). Patients were asked to rate the intensity of postoperative NV on a 11-point scale (0 being no NV and 10 being worst NV ever) in the PACU and day surgery unit (DSU) (Hofmann et al., 2017). This study (2017) also collected data on post-discharge NV, 24 to 48 hours postoperatively, using the same scale. Through an analysis of variance (ANOVA), the authors (2017) indicated statistically significant reductions in the severity of reported postoperative NV in the recovery room ($F_{(1, 91)} = 6.59$, $p = .012$) and discharge area ($F_{(1, 91)} = 18.34$, $p < .001$), as well as severity of reported post-discharge NV ($F_{(1, 91)} = 9.11$, $p = .003$). This study (2017) did not examine postoperative nausea and postoperative vomiting separately. The two-arm RCT by Pires and colleagues (2022) examining 97 adult patients undergoing elective open hysterectomy found that three of 49 patients (6.1%) who received bilateral PC6 acustimulation with prophylactic antiemetic drugs and 14 of 48 patients (29.2%) who received prophylactic antiemetic drugs alone experienced nausea. The chi-square test revealed that bilateral PC6 acustimulation and incidence of nausea were significantly associated in the first 24 hours after surgery (X^2 was not reported, $p = .003$). Two of 49 patients (4.1%) who received bilateral PC6 acustimulation with prophylactic antiemetics and two of 48 patients (4.2%) who received prophylactic antiemetic drugs alone vomited (Pires et al., 2022). The chi-square test revealed that bilateral PC6 acustimulation and

incidence of vomiting were not significantly associated (X^2 was not reported, $p = .98$). Yang et al. (2015) conducted a three-arm RCT examining 157 patients undergoing elective gynecological laparoscopic procedures under general anesthesia, where patients were assigned to one of three groups receiving: acustimulation plus dexamethasone group ($n = 53$), a combination of dexamethasone and tropisetron ($n = 53$), or dexamethasone alone ($n = 51$). The data of three patients in the acustimulation group and one patient in the dexamethasone alone group were not analyzed as patients were either excluded (one refused to continue for unidentified reasons, and the other was converted to open surgery) or lost to follow-up (Yang et al., 2015). In the first 24 hours after surgery, 14 of 50 patients (28%, 95% CI [15%, 41%]) in the acustimulation plus dexamethasone group, 14 of 53 patients (26%, 95% CI [14%, 39%]) in the tropisetron plus dexamethasone group, and 25 of 50 patients (50%, 95% CI [36%, 64%]) in the dexamethasone alone group experienced nausea (Yang et al., 2015). The chi-square test revealed that the groups and incidence of nausea in the first 24 hours after surgery were significantly associated (X^2 was not reported, $p = .021$). Nine of 50 patients (18%, 95% CI [7%, 29%]) in the acustimulation plus dexamethasone group, eight of 53 patients (15%, 95% CI [5%, 25%]) in the tropisetron plus dexamethasone group, and 12 of 50 patients (24%, 95% CI [12%, 36%]) in the dexamethasone alone group vomited (Yang et al., 2015). The chi-square test revealed that the groups and incidence of vomiting in the first 24 hours after surgery were not significantly associated (X^2 was not reported, $p = .503$). The authors (2015) concluded that patients who received acustimulation plus dexamethasone had lower odds of experiencing postoperative NV (at least one episode of or a combination of nausea, retching, or vomiting) within the first 24 hours after surgery than patients who received dexamethasone alone ($OR = 0.39$, 95% CI [0.17, 0.89], $p = .042$). The CIs in this trial were large, and this trial was underpowered. More studies are needed to reach

consensus on whether combining PC6 acustimulation with prophylactic antiemetics are better at preventing postoperative and post-discharge NV than prophylactic drugs alone.

Studies that were published after Lee and colleagues' 2015 Cochrane review echo the heterogenous nature of previous studies and their findings. For example, a meta-analysis conducted in 2020 examined 20 studies to identify the effects of different forms of PC6 acustimulation on postoperative nausea, postoperative vomiting, and postoperative rescue antiemetic use in patients undergoing abdominal surgery (Fu et al., 2020). Fu et al. (2020) found that participants who received PC6 acupressure had significantly lower odds of experiencing postoperative vomiting compared to those who received placebo (*OR* = 0.42, 95% CI [0.25, 0.70]), but not postoperative nausea (*OR* = 0.61, 95% CI [0.35, 1.05]). On the other hand, several RCTs, including those by Pires et al. (2022) and Yang et al. (2015), have supported the opposite, demonstrating statistically significant effect of PC6 acustimulation on the incidence of postoperative nausea but not vomiting, as illustrated previously (Pires et al., 2022; Yang et al., 2015). While existing evidence is contradictory, there is slightly more evidence to support the notion that PC6 acustimulation prevents postoperative nausea, postoperative vomiting, or both, as well as evidence to support that it exhibits similar prophylactic effects to pharmacological antiemetics (Carr et al., 2015; Ertas et al., 2015; Fu et al., 2020; Imtiaz et al., 2022; Kwon et al., 2016; Oh & Kim, 2017; Sahin et al., 2018; Seevaunnamtum et al., 2016; Yang et al., 2015; Yeoh et al., 2016; Zhang et al., 2023). Furthermore, among the uncertainty surrounding the effects of PC6 acustimulation on postoperative NV and post-discharge NV is the optimal timing to introduce the intervention.

The optimal timing to introduce acustimulation to prevent postoperative NV and post-discharge NV is not well understood (Lee et al., 2015). Some earlier researchers have argued that

acustimulation must be initiated prior to the emetic stimulus being introduced to the body (Dundee & Milligan, 1988; Fan et al., 1997). This is based on the hypothesis that acustimulation may release neurochemical substances that desensitizes receptors that trigger nausea and vomiting in the brain (Fan et al., 1997). However, there is some evidence indicating it may be effective when introduced immediately following surgery (Ünülü & Kaya, 2018; Yang et al., 1993). For example, Ünülü and Kaya (2018) examined the effects of unilateral acupressure wristbands on intensity of postoperative nausea and incidence of postoperative vomiting in 97 inpatients undergoing gynecological surgery. In the intervention group (n = 47), acupressure wristbands were placed on the patients after surgery in the recovery room for 12 hours, and the control group (n = 50) received prophylactic antiemetic drugs (Ünülü & Kaya, 2018). They (2018) used an 11-point visual analog scale to measure intensity of nausea (0 being no nausea and 10 being worst nausea). Compared to the control group, the intervention group reported significantly lower intensity of nausea throughout the first 24 hours after surgery, including between 12 to 24 hours after surgery where the median nausea scores (ranges) were 0 (0 to 5) in the intervention group and 2.5 (0 to 6) in the control group (Z^{MW} = -4.59, CI was not reported, p < .001) and between 24 to 48 hours after surgery where the median nausea scores (ranges) were 0 (0 to 3) in the intervention group and 0 (0 to 4) in the control group (Z^{MW} = -2.32, CI was not reported, p = .020) (Ünülü & Kaya, 2018). However, no statistically significant effect was observed on incidence of vomiting between 12 and 24 hours after surgery (10.6% vs. 24.0%; p = .144) or between 24 to 48 hours after surgery (2.1% vs. 4.0%; p = 1.00) (Ünülü & Kaya, 2018). This study did not examine the effects of PC6 acupressure on post-discharge NV, and the intervention group did not receive any prophylactic antiemetics. Further studies are needed to examine the effects of PC6 acustimulation plus prophylactic antiemetic drugs on post-discharge

NV when introduced after the introduction of emetic stimuli. This is important because there may be benefits to patient safety if PC6 acustimulation can be effectively introduced postoperatively. Patients are generally instructed to remove all jewelry, including bracelets, before surgery to help minimize the risk of swelling, loss of circulation, and skin tearing (Sunnybrook Health Sciences Centre, n.d.). Similarly, acupressure wristbands worn in the operating room may introduce these risks. Identifying the effectiveness of acupressure introduced after surgery will contribute to building on the existing body of knowledge on acustimulation, with potential benefits to patients.

As summarized above, much of existing PC6 acustimulation knowledge revolves around preventing postoperative NV in inpatient populations, with less data on its effectiveness at preventing post-discharge NV in ambulatory surgery patients. Post-discharge NV occurs frequently, with incidence rates that are comparable to postoperative NV in high-risk patients (Apfel et al., 2012). Furthermore, discharged patients do not have access to fast-acting intravenous antiemetic medications (Gan et al., 2020). There is a need for fully powered trials to explore the effectiveness of and the best ways to utilize PC6 acustimulation to prevent post-discharge NV.

PC6 Acustimulation in Ambulatory Surgery Patients

To ensure comprehensive understanding of prevention of post-discharge NV using PC6 acupressure in ambulatory surgery patients, a search was conducted using the databases, CINAHL (1981-2023), Ovid MEDLINE ALL (1946-2023), and Ovid Embase (1974-2023). A Health Sciences librarian was consulted to refine search terms to ensure all relevant literature were captured. Additionally, reference lists of relevant articles were used to identify additional studies. Variations of the following search terms were used as keywords and subject headings:

"acupressure", "acupuncture", "acustimulation", "transcutaneous electric nerve stimulator", "electroacupuncture", "acupoint", "acupuncture points", "nausea", "vomit", "emesis", "PONV", "PDNV", "nausea and vomiting", "ambulatory surgery", "ambulatory procedure", "day surgery", "outpatient surgery", "outpatient procedure", "post discharge", and "outpatient service". Searches were limited to publications in English. Using EndNote© software, titles and abstracts were reviewed, and studies not examining acustimulation at PC6 and at least one of postoperative nausea, postoperative vomiting, post-discharge nausea, or post-discharge vomiting in ambulatory patients were removed. Studies that examined acustimulation at PC6 in conjunction with other acupoints to examine effects on postoperative NV and/or post-discharge NV were also removed. Guidelines/recommendations, conference materials, commentaries, and duplicates were removed. No limitations on study designs were placed in this search. Full texts of the remaining studies were reviewed to determine their relevance. Studies were included if 1) the population was ambulatory surgery patients 18 years of age or older, and 2) the study was published in English. This search resulted in nine single RCT studies. The quality of each study was assessed using the Critical Appraisal Skills Programme (CASP) RCT Standard Checklist. The characteristics of each study are outlined in Appendix A.

Evidence on the effectiveness of PC6 acustimulation on preventing postoperative NV and/or post-discharge NV in patients undergoing ambulatory surgeries is conflicting among the nine studies. All studies reported at least one statistically significant finding to support effectiveness of PC6 acustimulation, but the results were heterogenous as the nature and timing of outcome measures varied between studies. There were variations in where the effects were seen (in the recovery area, discharge area, or at home), as well as on what it exerted its

preventative effects (severity and/or incidences and nausea and/or vomiting) (see Appendix A). More research is needed in this area.

There were noted issues in the reporting of the studies. Generally, methods of randomization were poorly reported. Additionally, when acupressure was utilized, it was uncertain if patients were adequately blinded to treatment group (Alkaissi et al., 2002; Fan et al., 1997; Ferrara-Love et al., 1996; Hofmann et al., 2017). Although studies attempted to blind patients to treatment group by using dressings to cover the site and/or placing wristbands on the dorsal aspects of the forearms, it may have been possible for patients to identify their group allocation by sensation and by looking up the location of PC6 acupoint (Alkaissi et al., 1999; Fan et al., 1997; Hofmann et al., 2017). It may also have been possible that participants had existing knowledge of PC6 acupoint's location. Furthermore, reasons for attrition were poorly reported in the examined studies, if at all. This information would be valuable to collect to design a RCT in the future.

There were methodological concerns. In five of the nine studies, postoperative nausea and vomiting were not assessed separately (Al-Sadi et al., 1997; Carr et al., 2015; Fan et al., 1997; Ferrara-Love et al., 1996; Hofmann et al., 2017). This is a problem because existing literature contradicts whether PC6 acustimulation exerts preventative effects on postoperative nausea, postoperative vomiting, both, or neither (Griffiths et al., 2012; Lee et al., 2015). Thus, it is important to assess postoperative nausea and vomiting separately. Furthermore, nausea is a subjective symptom, while vomiting is an objective one (Lee et al., 2015); this necessitates the use of different outcome measures when collecting data. Additionally, in four of the nine studies, only incidences, not severity, of nausea were assessed (Al-Sadi et al., 1997; Alkaissi et al., 1999; Fan et al., 1997; Ferrara-Love et al., 1996), and one study did not assess nausea at all (Yang et

al., 1993). Lastly, although all nine studies looked at ambulatory surgery patients, only six collected data on post-discharge NV (Al-Sadi et al., 1997; Alkaissi et al., 1999; Carr et al., 2015; Hofmann et al., 2017; Larson et al., 2010; White et al., 2002). More research on the effects of PC6 acustimulation on post-discharge NV is needed to assess if ambulatory patients can benefit from this intervention.

To design a study that addressed the limitations of existing studies, a population of ambulatory surgery patients at high-risk for postoperative NV and post-discharge NV was studied. Patients who are at high risk for post-discharge NV would benefit most from the findings of this study. One such population is those undergoing laparoscopically assisted vaginal hysterectomy (LAVH).

LAVH and Postoperative NV/Post-discharge NV Risk Factors

Hysterectomy, the removal of the uterus, is one of the most performed major gynecologic surgical procedures around the world, and it is the sixth most common surgery performed in Canadian hospitals (Garry, 2005; Kelly et al., 2019). Although it can be used to treat malignant conditions, it is most used for non-cancerous indications (Aarts et al., 2015). Some of these indications include endometriosis, abnormal uterine bleeding caused by fibroids, dysmenorrhea, and pelvic organ prolapse (Aarts et al., 2015). LAVH is one approach to hysterectomy, which is a minimally invasive (MI) surgical procedure that uses a combination of vaginal and laparoscopic approaches to remove the uterus (Aarts et al., 2015; Kelly et al., 2019). LAVH can be performed with or without the removal of fallopian tubes (salpingectomy) and/or ovaries (oophorectomy) (Thurston et al., 2019). Furthermore, tension-free vaginal tape (TVT) may be placed under the bladder neck during LAVH to treat or prevent urinary incontinence (Lin et al., 2005).

Although laparoscopic approaches to hysterectomy take longer (140 minutes) to perform than abdominal approaches (135 minutes), they are associated with earlier return to baseline function and reduced risk of complications like bleeding (Aarts et al., 2015; Kelly et al., 2019). The Society of Obstetricians and Gynaecologists of Canada currently recommends MI approaches, like LAVH, to hysterectomy for benign indications and have noted that same-day discharges after MI hysterectomy are safe, cost-effective, and associated with patient satisfaction (Thurston et al., 2019). In Ontario, 163,894 hysterectomies were performed between 2003 and 2014, of which 42.4% were via MI approaches (Kelly et al., 2019). In 2021, Canada's hysterectomy rate was 234 per 100,000 women 18 years of age and older, with increasing rates of MI hysterectomy (Canadian Institute for Health Information [CIHI], n.d.; Chen et al., 2020).

Gynecology surgeries have been reported to place patients at higher risk for postoperative and post-discharge NV compared to other types of surgeries (Cao et al., 2017), as patients meet many of the surgical, anesthetic, and patient risk factors for the phenomena. In particular, hysterectomy is associated with high incidences of postoperative NV and post-discharge NV (Lerman, 1992). Unfortunately, patients who receive LAVH often meet many of the risk factors for postoperative NV and post-discharge NV, such as being female, being younger than 50 years of age (in Ontario, the average age of patients receiving MI hysterectomy is 48 years), experiencing nausea in the recovery room, and having a history of postoperative NV or motion sickness (Apfel et al., 2012; Kelly et al., 2019). Furthermore, LAVH meets many of the surgical and anesthesia-related risk factors for postoperative NV and post-discharge NV, including longer surgery and anesthetic times, as well as the use of laparoscopic approach, general anesthesia with volatile anesthetics, laryngeal mask airway (due to risk of gastric distension), and intraoperative

and postoperative opioids (Al-Sadi et al., 1997; Cao et al., 2017; Gan et al., 2020; McCracken et al., 2008).

There is limited evidence on the effects of PC6 acustimulation, including acupressure, on post-discharge NV in ambulatory patients undergoing gynecological procedures. A fully powered trial could explore this. However, determining the feasibility of conducting these studies before investing extensive resources is beneficial (Thabane et al., 2010). The purpose of this study was to determine the feasibility of conducting a trial that examines the postoperative use of bilateral PC6 acupressure wristbands plus usual care versus placebo wristbands plus usual care to prevent post-discharge NV in patients undergoing ambulatory LAVH.

Chapter III: Methods

This chapter will outline this study's methods, including research questions, outcomes, and study design, as well as details relating to participants and setting, sampling, recruitment, randomization and group allocation, intervention and placebo groups, outcomes of interest, and ethical considerations. This chapter will also present the processes for data collection and analysis.

Research Question and Outcomes

The research question guiding this study was, "What is the feasibility of conducting a trial to deliver bilateral PC6 acupressure wristbands postoperatively plus usual care *versus* placebo wristbands plus usual care in ambulatory patients undergoing LAVH?" The primary outcome of this study was feasibility, including consent rate, randomization rate, delivery of intervention, and retention rate, of a trial that delivers bilateral PC6 acupressure wristbands postoperatively plus usual care *versus* placebo plus usual care to prevent post-discharge NV in ambulatory patients undergoing LAVH. It was hypothesized that the PC6 acupressure intervention would be feasible to deliver postoperatively in a timely manner in ambulatory LAVH patients. The secondary outcomes were used to determine preliminary estimates on the impact of bilateral PC6 acupressure wristbands plus usual care on presence and intensity of post-discharge nausea, as well as presence of post-discharge vomiting in ambulatory patients undergoing LAVH, compared to prophylactic drug therapy alone. It was hypothesized that positive preliminary estimates of effects of the PC6 acupressure intervention plus usual care on presence and intensity of nausea and presence of vomiting would be observed post-discharge.

Study Design

A feasibility study design was employed. This design seeks to uncover if a larger-scale study can be conducted, whether it should be conducted, and if so, how it should be conducted (Eldridge et al., 2016b). Feasibility studies are conducted before fully powered studies to test processes of research plans, assess resource needs, identify possible issues with research plans, and estimate potential intervention effects (Thabane et al., 2010). A parallel arm RCT design was employed. The intervention arm received usual care (preoperative pharmacological prophylaxis) for postoperative NV and post-discharge NV *plus* bilateral PC6 acupressure intervention. The placebo arm received usual care *plus* bilateral placebo wristbands.

Participants and Setting

The inclusion criteria for this study were 1) candidacy for ambulatory LAVH (with or without other surgical procedures including, but not limited to, salpingectomy, oophorectomy, and TVT) under general anesthesia, 2) scheduled for ambulatory LAVH (with or without other surgical procedures) at Brantford General Hospital (BGH), 3) age ≥ 18 years, 4) ability to speak, read, and understand the English language, 5) ability to wear acupressure wristbands on both wrists, and 6) ability to provide informed consent. The exclusion criterion was inability to receive usual care pharmacologic agents (8 mg of dexamethasone preoperatively and 20 mg pyridoxine/ 20 mg doxylamine preoperatively) due to allergies or contraindications.

The study took place at BGH, an acute care hospital with 260 inpatient beds that offers outpatient and inpatient surgical services including laparoscopic gynecological procedures (Brant Community Healthcare System [BCHS], 2019). BGH is the regional centre for several services including gynecology, surgical services, and ambulatory care for Brantford, County of Brant, Six Nations of the Grand River, and Mississaugas of the Credit First Nation (BCHS, 2019). BGH

conducts approximately one to three ambulatory LAVH cases (with or without other surgical procedures including, but not limited to, salpingectomy, oophorectomy, and TVT), two to three times a week. Day surgery patients at BGH encounter the peri-operative settings in the following order: preoperative clinic, Zone 1 (preoperative holding area), the operating room, PACU, and DSU. The details of patient flow through these areas are outlined in Appendix B.

Sampling and Sample Size

Consecutive sampling of patients who met inclusion criteria and were booked for LAVH (with or without other surgical procedures) as of the study's start date were screened using OR Manager and Meditech and recruited (if eligible) until a target sample size of 20 participants was achieved (Curtis & Keeler, 2021). The screening process was supported by the Chief and Medical Director of Obstetrics and Gynecology at the study site. As feasibility/pilot study designs seek to examine feasibility outcomes and measure preliminary estimates of intervention effect as secondary outcomes, a power analysis (sample size calculation) was not conducted (Eldridge et al., 2016a; Thabane et al., 2010). The sample size of 20 participants was chosen based on the average number of ambulatory LAVH cases at BGH. It was determined that under the time and resource constraints of this thesis, the collection and analysis of data for 20 participants would be feasible. Furthermore, it was determined that a sample size of 20 participants should be sufficient to fulfill the study's primary objective of exploring the feasibility of obtaining consent from, randomizing, delivering the intervention to, and retaining ambulatory LAVH patients in a study examining the use of PC6 acupressure wristbands to prevent post-discharge NV.

Recruitment and Consent Procedures

At their preoperative clinic appointments, potential participants meeting inclusion criteria were asked if they would like to be considered for the study by the clinic nurse. Participants were approached by the study nurse before or after they were assessed by the preoperative clinic nurse and/or anesthesiologists. The study nurse approached those who agreed to provide details of the study using the Participant Information Sheet (see Appendix C). The consent form (see Appendix D) was reviewed in lay language to ensure the potential participants had a clear understanding of the study, including its purpose, procedures, risks, and benefits. The study nurse answered questions and written consent to participate in the study were obtained. Then, the Wristband Instruction Sheet (see Appendix E) and Post-discharge Nausea and Vomiting Diary (see Appendix F) were reviewed with participants. Physical copies of these forms, including a copy of the signed consent form, were provided to all consented participants. Those who were interested but could not speak with the study nurse at the preoperative clinic were contacted by telephone using the phone number provided by the potential participants. The study nurse followed the same process of recruitment as when approaching potential participants in person. Those contacted by telephone were given the option to receive the aforementioned forms electronically via email. Honoraria were not provided to participants in this study.

Randomization, Allocation Concealment, and Blinding

After informed consent was obtained, participants were randomized in a 1:1 fashion to the intervention or placebo group. A computer-generated, permuted block randomization sequence was produced by a biostatistician not involved in data collection, and sealed in opaque, consecutively numbered envelopes prior to the start of the study. Generation of random sequences via the use of computers is used in research as an appropriate method of

randomization to reduce selection bias (Kendall, 2003). To conceal allocation and reduce risk of bias, the envelopes remained sealed until the participants were transferred to the PACU after completion of surgery (Kendall, 2003). The study nurse opened the envelopes just before the wristbands (placebo or intervention) were applied. The study nurse who delivered the intervention/placebo and analyzed the data was not blinded to treatment group allocation. However, by using wristbands without acupressure capabilities in the placebo group, this study attempted to blind participants to group allocation.

Usual Care in Intervention and Placebo Groups

As part of standard perioperative care outside of the study, all participants of this study received usual pharmacological prophylactic care for postoperative and post-discharge NV from their preoperative nurses in Zone 1. All LAVH patients without contraindications received 8 mg of dexamethasone (preoperatively) and 20 mg pyridoxine/20 mg doxylamine (preoperatively) as part of usual pharmacological prophylactic care at BGH. The patients received general anesthesia, as determined and administered by the anesthesia team.

Intervention Group: Acupressure Bands

Sea-Bands by Sea-Band Ltd were employed in this study. They are latex-free, reusable acupressure wristbands that have been approved by the Food and Drug Administration for relief of nausea, including postoperative nausea, as well as nausea associated with motion sickness, pregnancy, and chemotherapy (Sea-Band, n.d.). As per *Medical Devices Regulations (SOR/98-282)*, Sea-Bands are considered Class I medical devices. The investigator contacted Card health Care, who distributes Sea-Bands in Canada, to confirm they held the rights for distribution. Furthermore, the Medical Device Establishment License database was accessed to confirm that Card Health Care holds a Class I license. As per Health Canada (2018), under 2.3.5

Requirements of an Investigational Testing Authorization (ITA) application in *Guidance document: Applications for medical device investigational testing authorizations,* there is no requirement to obtain an ITA for a Class I device. The manufacturer suggests that the wristbands be placed on the patients' wrists prior to the establishment of intravenous access so that they are not placed too closely to the PC6 acupoint. However, as this study sought to examine the feasibility of initiating acupressure postoperatively in the PACU, the wristbands were not placed on preoperatively.

Before the commencement of the study, the study nurse completed online acupressure training, as outlined in Appendix G. The intervention group received usual care plus bilateral PC6 acupressure wristbands applied by the study nurse in the PACU, as soon as the participants were deemed stable by the PACU nurse (Modified Aldrete score of at least 5, with a score of 2 in respiration and at least 1 in oxygen saturation, consciousness, and circulation) (Aldrete, 1995). PC6 acupoints on participants were determined by asking the participants to place their second, third, and fourth digits on their inner wrist creases to measure two cun, which, in TCM, is the distance between a person's second and fourth finger at the proximal interphalangeal joints (Carr et al., 2015; Ferrara-Love et al., 1996). Markers were used to indicate this distance. The wristbands were covered by gauze bandage rolls to blind participants to group allocation. To ensure patients were effectively blinded, the study nurse went through the same motions of applying the wristbands to all participants. They were kept on until 24 hours post-discharge and removed by the participants, as per instructions given to them in the preoperative clinic and reinforced in the DSU by the study nurse. Participants were instructed to keep the wristbands and gauze dressings on until the completion of the study. However, they were instructed to take the wristbands and gauze dressings off if normal circulation, sensation, and/or movement (CSM)

were compromised, or intolerable discomfort or side effects were experienced. Participants were provided with the Wristband Instruction Sheet (see Appendix E) that detailed the management of wristbands, including how to check capillary refill, as well as how to remove the wristbands in the unlikely event they experienced intolerable discomfort or side effects.

Placebo Group

The placebo group received usual care plus bilateral sweatbands that had no acupressure capabilities, wrapped in gauze bandage rolls. The bands were placed by the study nurse in the PACU, as soon as the participants were deemed stable by the PACU nurse (Modified Aldrete score of at least 5, with a score of 2 in respiration and at least 1 in oxygen saturation, consciousness, and circulation) (Aldrete, 1995). To ensure patients were effectively blinded, the study nurse went through the same procedure of applying the wristbands to all participants. The placebo wristbands and gauze dressings were kept on until 24 hours post-discharge and removed by the participants, as per instructions given to them in the preoperative clinic and reinforced in the DSU by the study nurse. As with the intervention group, participants were instructed to keep the wristbands and gauze dressings on until the completion of the study. Participants were instructed to take them off if CSM were compromised, or intolerable discomfort or side effects were experienced. Participants were provided with the Wristband Instruction Sheet (see Appendix E).

Primary Outcome Measures and Feasibility Criteria

The primary outcome of this study was feasibility specific to process and resource implications (Thabane et al., 2010). This included assessment of consent rate, randomization rate, delivery of intervention, and retention rate (Thabane et al., 2010). The criteria for feasibility success were defined as: 1) consent rate of 90%, 2) randomization rate of 90%, 3) intervention

delivery in 90% of participants, 4) intervention and placebo wristbands in position for 24 hours after discharge in 80% of participants, and 5) retention rate of 80%. These rates were investigated to better understand the feasibility of the study design from process and resource perspectives (Thabane et al., 2010). Examining rates of consent, randomization, intervention delivery, and retention allowed the assessment of processes that are crucial to the success of a larger RCT, while examining outcomes like delivery of intervention and retention rates allowed the identification of time and resource issues that may occur during a larger RCT if not addressed (Thabane et al., 2010). The reasons for failure to obtain consent, retain, randomize, as well as reasons for intervention delivery difficulties were noted on the data collection sheets and field notes (see Appendices I and J).

Secondary Outcome Measures

Secondary outcomes included intensity of nausea and presence of nausea and vomiting. It was important to evaluate nausea and vomiting separately in this project, as previously explored. There are validated measurement tools for post-discharge NV; however, they evaluate nausea and vomiting together. Thus, to estimate preliminary effects of acupressure wristbands on nausea and vomiting separately, an 11-point numerical rating scale (NRS) (0 = no nausea and 10 = worst nausea imaginable) was used to measure intensity of post-discharge nausea, and proportions of participants were used to measure presence of post-discharge nausea and vomiting. The 11-point NRS is commonly used to assess intensity of postoperative and post-discharge nausea (Hyman et al., 2020; Odom-Forren, 2011).

Participants of this study were asked to rate their most severe post-discharge nausea within 24 hours after discharge on the 11-point NRS scale in the Post-discharge Nausea and Vomiting Diary (see Appendix F). Participants were asked to report the number of vomiting or

retching episodes at least one minute apart in the diary (Hyman et al., 2020). Differentiation between vomiting and retching was not made, as surgical patients may not have any stomach contents to expel. Information entered in each participant's diary were collected during the telephone interviews after 24 hours post-discharge. If they were unable to use the diary, the questions were asked verbally by the study nurse over the phone during the follow-up calls. This produced continuous variable data for intensity of post-discharge nausea and categorical variable data for presence of post-discharge nausea and vomiting.

Data Collection and Follow-up Procedures

Data collection occurred across several settings and stages of participants' surgical journeys to ensure relevant information were captured to understand the feasibility outcomes and preliminary estimates of intervention effect.

Data Collection at the Preoperative Clinic Appointment

During each recruitment day, the study nurse kept field notes of the number of participants screened, deemed eligible, recruited, and approached for consent, as well as reasons for inability to obtain consent (see Appendix I). Once written consent to participate in the study was obtained at the preoperative clinic, the study nurse collected demographic information related to postoperative NV and post-discharge NV risk factors as identified by Apfel et al. in 1999 and 2012, respectively, using the Data Collection Sheet: Initial Contact and Preoperative Clinic (see Appendix H). These were sex and gender, history of previous postoperative NV or motion sickness, smoking status, and month and year of birth (Apfel et al., 1999; Apfel et al., 2012). Information on the other identified risk factors were collected through chart review, as explained below.

At the preoperative clinic, the study nurse explained and provided the Post-discharge Nausea and Vomiting Diary (see Appendix F). Furthermore, verbal and written instructions were provided, in lay language, to participants regarding managing and wearing the wristbands, checking for normal CSM in both hands while wearing the bands, and managing side effects. Contact information including email address, home or work telephone number, and a secondary telephone number were collected, if available, at the preoperative clinic to ensure data collection could be completed during the follow-up calls. Email addresses were also used to distribute the summary of study findings, if requested at the time of obtaining consent.

Data Collection on the Day of Surgery

The study nurse utilized the Data Collection Sheet: Delivery of Intervention to collect the following data: 1) time when the participants were deemed stable by the PACU nurse, 2) time when the wristbands (placebo or intervention) were applied bilaterally, 3) reasons if bands were removed, as well as where and by whom (see Appendix H). The study nurse noted completion of bilateral radial pulse checks, capillary refill check in all digits, intravenous flow checks, and sensation and movement checks on the Data Collection Sheet (see Appendix H).

Data Collection through Chart Review

Physical perioperative charts for each participant were accessed as per BGH's protocols to collect relevant data using the Data Collection Sheet: Chart Review, which included information on the surgery and use of antiemetics and opioids (see Appendix H).

Data Collection through Follow-up Calls

The follow-up calls over the phone were made by the study nurse. Data outlined in the Post-discharge Nausea and Vomiting Diary (see Appendix F) were collected by the study nurse using the Data Collection Sheet: Follow-up (see Appendix H). This included the following: 1)

the most severe post-discharge NRS nausea score on an 11-point scale, within 24 hours post-discharge, 2) number of episodes of vomiting or retching at least a minute apart, within 24 hours post-discharge, 3) use of antiemetics, opioids, or remedies for nausea at home, within 24 hours post-discharge, 4) confirmation that the bilateral wristbands and gauze dressings remained in position for 24 hours after discharge, and 5) reasons for removal, if applicable. If the participants did not complete the diary, the questions were asked verbally over the phone and recorded by the study nurse.

Data Analysis

Data analyses were conducted using descriptive and inferential statistics to gain an understanding of sample and surgical characteristics, feasibility of conducting an RCT study, and secondary outcomes related to post-discharge NV.

Descriptive Data

Sample and surgical characteristics were summarized using descriptive statistics. Mean and standard deviation were used to present age on the day of surgery in years (calculated from month and year of birth, assuming the participants' birthdays fell on the last day of the month) and lengths of surgeries (in minutes). Frequencies were used to describe nominal variables including type of LAVH (with or without other surgical procedures including, but not limited to, salpingectomy, oophorectomy, and TVT), sex and gender (female or male or other), history of motion sickness or postoperative NV (yes or no), smoking status (smoker or non-smoker), use of opioids and antiemetics preoperatively on the day of surgery (yes or no), use of opioids and antiemetics in the operating room (yes or no), use of opioids and antiemetics in the PACU and DSU (yes or no), as well as use of opioids, antiemetics, and remedies for nausea at home (yes or no).

Feasibility Outcomes

To analyze the feasibility outcomes in the study, proportions for consent, randomization, delivery of intervention, and retention and their 95% CIs were compared to the aforementioned success criteria for feasibility. Consent rate was calculated by dividing the number of participants recruited into the study by the number of eligible participants who were approached by the study nurse for written consent. Randomization rate was calculated by dividing the number of participants who were randomly allocated to either usual care plus placebo or usual care plus acupressure intervention by the number of participants who provided written consent. Delivery of intervention was assessed by examining the proportion of participants who received the wristbands after being deemed stable by the PACU nurse, as well as by the proportion of participants who reported keeping their wristbands on until 24 hours after discharge. Retention rate was calculated by dividing the number of participants who completed the study (completed the post-discharge follow-up call) by the number of participants who provided written consent.

Secondary Outcomes

Using inferential statistics, all analyses of secondary outcomes produced estimate preliminary effects of the intervention on post-discharge NV. The analyses of secondary outcomes were performed using R statistical software, version 4.3.3 (2024-02-29) (R Core Team, 2024).

Post-discharge Nausea. Utilizing the scores derived from the 11-point NRS, a two-sided Mann-Whitney U test (α set at .05) was employed to compare the post-discharge nausea scores within 24 hours after discharge between the intervention and placebo groups. The two samples were independent of each other as each participant belonged to only one group. Originally, the use of a one-sided independent samples t-test was proposed to compare the two groups' nausea

scores. However, this non-parametric test was chosen to analyze this secondary outcome as the samples violated the assumptions of normality and equal variance. Furthermore, a two-sided test, rather than a one-sided test, was conducted to allow for comprehensive and conservative analyses of the results (Moyé, 2006). The null hypothesis for post-discharge nausea score was: The intervention group will experience the same post-discharge nausea intensity compared to the placebo group within 24 hours post-discharge. The null hypothesis was rejected if the calculated p-value was less than alpha of .05 (Daniel & Cross, 2013). The nausea scores were treated as "ordinal approximation(s) of a continuous variable" (Ribeiro et al., 2021, p. 5), as researchers have argued that ordinal variables with five or more categories can be used as continuous variables without negatively affecting analyses (Johnson & Creech, 1983; Norman, 2010). Additionally, a Fisher's exact test (α set at .05) was used to determine if there was a difference in the proportions of participants between the groups who experienced nausea within the first 24 hours post-discharge.

Post-discharge Vomiting. A Fisher's exact test (α set at .05) was employed to determine if the proportions of participants who vomited within 24 hours post-discharge were the same in the intervention and placebo groups. The two samples were randomly selected and independent of each other. A two-sided test was employed for reasons explained above. The null hypothesis was: The proportions of participants who vomit within 24 hours post-discharge is the same in the intervention and placebo groups. The null hypothesis was rejected if the calculated p-value was less than alpha (.05) (Daniel & Cross, 2013). This variable was categorical.

Ethical Considerations

Prior to the commencement of this study, a proposal was submitted to the Hamilton Integrated Research Ethics Board (HiREB #16786) and BCHS Research Ethics Committee

(REC) for approval. The three core principles outlined by the Tri-Council were used to consider ethical governance of this study, which are respect for persons, concern for welfare, and justice (Canadian Institutes for Health Research [CIHR] et al., 2018).

To embody the principle of respect for persons, this study honoured participant autonomy by obtaining explicit, informed, ongoing, and uncoerced consent (CIHR et al., 2018; Shivayogi, 2013). To ensure consent was obtained from informed participants, the study nurse used lay language to explain the purpose of the study, what it involved, its foreseeable risks, and potential benefits (CIHR et al., 2018). Furthermore, participants were informed that although this research team was dedicated to providing transparency, they would be blinded to their randomly allocated group until completion of the study (Heale & Shorten, 2017). To ensure consent was ongoing, participants were informed that their consent could be revoked at any time without repercussions. To ensure consent was uncoerced, potential participants were approached by the study nurse who was not involved in providing direct care to patients on the day of surgery. This aimed to minimize the risk of patients consenting to participation out of fear that they would receive poor perioperative care if they declined.

To embody the principle of concern for welfare, this study aimed to protect the physical, mental, and spiritual health of participants (CIHR et al., 2018). Acupressure wristbands are non-invasive, and their previously reported risks are minor and transient, including redness, pain, blistering, skin irritation, discomfort, temporary marks, paresthesia, itchiness, and bruising (Lee et al., 2015; Psi Health Solutions, 2021). In the unlikely event that participants experienced serious or intolerable adverse reactions, the intervention would have been discontinued immediately to ensure protection of physical health and prevent mental harm, such as distress (Gelling et al., 2021). Verbal and written instructions on how to manage minor side effects were

provided to participants at the preoperative clinic appointment and reinforced by the study nurse in the DSU before discharge. This study also protected the welfare of participants by ensuring proper management of data and personal information (Heale & Shorten, 2017). Data remained confidential by assigning study identification numbers to participants and using them on the Data Collection Sheets instead of patient identifiers. Paper data were stored in a locked room at McMaster University. All devices used two-stage password log-in processes. Data were stored on McMaster OneDrive for Business and Sharepoint Online. Bitlocker provided disk-level encryption for all data, while per-file encryption added a unique encryption key for each file. Every step of this encryption used Advanced Encryption Standard (AES) with 256-bit keys and is Federal Information Processing Standard (FIPS) 140-2 compliant. Any identifiers were stored separately from the database. The only paper data that left BGH were consent forms, which were brought to McMaster University and locked in a filing cabinet at the School of Nursing (HSC2J40). No identifiable health information left BGH.

Chapter IV: Results

This chapter includes the results including sample characteristics, feasibility outcomes, and estimated preliminary effects of acupressure wristbands on post-discharge NV.

Characteristics of the Sample

All participants (n = 20) were female. The participants were between the ages of 33 and 65 years, with a mean (*SD*) age of 46 (9) years. About half (12 of 20 participants) had a history of postoperative NV (Table 1). The intervention and placebo groups were similar in baseline characteristics. The groups were similar in the number of risk factors they possessed for post-discharge NV (Table 2). However, there were slightly more participants in the intervention group (7 of 10 participants) who had a history of postoperative NV compared to the placebo group (5 of 10 participants).

Characteristics of Surgery and Medication Use

The groups were also similar in surgical characteristics, which are presented in Appendix J. On average, the intervention group underwent longer surgeries than the placebo group, with the mean (*SD*) length of surgery for the intervention group being 129 (51) minutes and 105 (54) minutes for the placebo group (see Appendix J). The frequencies of opioid and antiemetic use through participants' surgical journeys were similar in both groups (see Appendix J).

The flow of participants through the study is depicted in the Consolidated Standards of Reporting Trials (CONSORT) flow diagram (Figure 1) (Eldridge et al., 2016a). Forty potential participants were screened, and 29 met eligibility criteria. 23 patients were invited to participate in the study. Three patients declined to participate in the study, and 20 participants were successfully recruited and randomized. One participant from each group did not receive wristbands: one participant in the intervention group withdrew from the study prior to surgery

day, and one participant in the placebo group became ineligible intraoperatively when her surgery was converted to a non-laparoscopic procedure.

Table 1

Sample Characteristics: Baseline and History

Variable	**Intervention** ***n*** **= 10**	**Placebo** ***n*** **= 10**	**Sample** ***n*** **= 20**
Mean (*SD*) age, years	46.3 (10.4)	46.0 (8.3)	46.2 (9.2)
Sex			
Female, *n* (%)	10 (100)	10 (100)	20 (100)
Gender			
Female, *n* (%)	10 (100)	10 (100)	20 (100)
History of postoperative NV			
Yes, *n* (%)	7 (70)	5 (50)	12 (60)
NV = Nausea and vomiting; *SD* = Standard deviation			

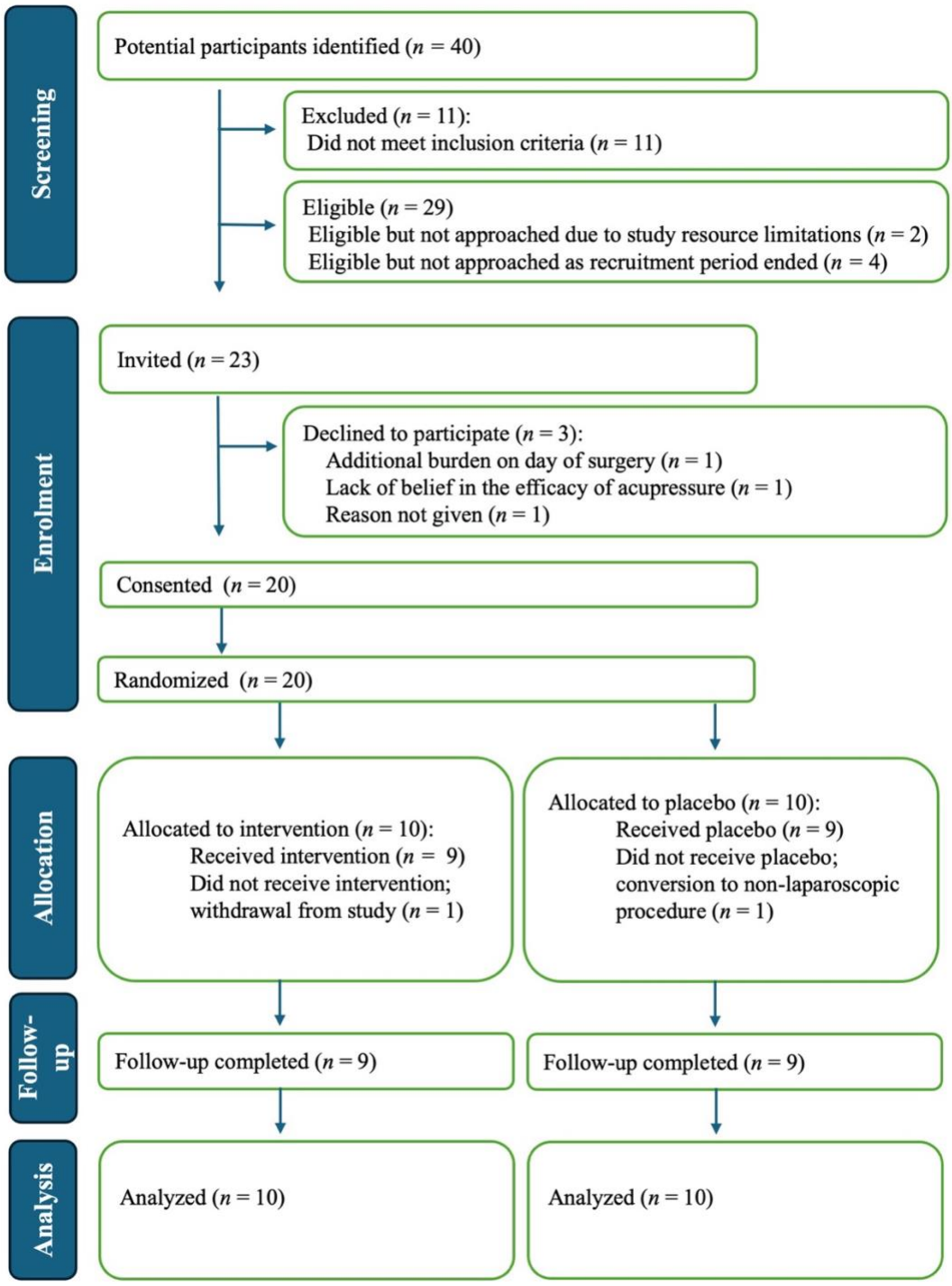
Table 2

Risk Factors for Post-discharge NV

Variable	**Intervention** **n = 10**	**Placebo** **n = 10**	**Sample** **n = 20**
Female, *n* (%)	10 (100)	10 (100)	20 (100)
Age < 50 years, *n* (%)	7 (70)	7 (70)	14 (70)
History of postoperative NV, *n* (%)	7 (70)	5 (50)	12 (60)
Use of opioids in PACU, *n* (%)	8 (80)	7 (70)	15 (75)
Nausea in PACU, *n* (%)	2 (20)	2 (20)	4 (20)
NV = Nausea and vomiting; PACU = Post-anesthesia care unit Risk factors as defined by Apfel et al. (2012)			

Figure 1

CONSORT Flow Diagram



Note. Patient enrolment commenced March 2024 and was completed in May 2024.

Primary Outcomes: Feasibility

Three outcome measures met the a priori criteria for feasibility success: randomization rate, intervention/placebo delivery (continuous wear) rate, and retention (study completion) rate (Table 3). All consenting participants (100%, 95% CI [81%, 100%]) were successfully randomized to either the intervention or placebo group. Most participants (17 of 20 participants), 85%, 95% CI [63%, 95%], wore the intervention/placebo wristbands for the entirety of the study. Two did not receive the wristbands, noted below, and one participant took the wristbands off prior to 24 hours after discharge from the hospital, due to swelling in both hands. The retention (study completion) rate was 90%, 95% CI [68%, 98%] (18 of 20 participants), with one participant withdrawing from the study and the other becoming ineligible intraoperatively based on surgical procedure.

This study's consent rate (87%, 95% CI [67%, 96%]) did not meet the a priori criterion for feasibility success (90%). Of the 29 eligible potential participants that were identified, four were not invited due to the sample size being met, and two were not invited due to the availability of the study nurse. Of the 23 patients approached, three declined to partake in the study for the following reasons: one patient stated she felt partaking in the study would be an additional burden on her surgery day, one patient stated she did not believe in the potential efficacy of the intervention, and one patient did not provide a reason. Furthermore, the intervention/placebo wristband delivery rate in the PACU did not meet the a priori criterion for feasibility success at 85%, 95% CI [63%, 95%] (17 of 20 participants), with two consenting participants failing to receive the wristbands, one patient withdrew from the study prior to surgery, and another became ineligible intraoperatively when the surgery was converted to a non-laparoscopic procedure. One patient received the wristbands in the DSU, instead of PACU.

Table 3

Primary Outcomes: Feasibility

Measure	Observed	95% Confidence Interval	A Priori Criteria of Success	Description of Outcome
Consent rate	$\frac{20}{23}$ (87%)	95% CI [67%, 96%]	90%	Proportion of eligible participants approached by the study nurse who provided written consent
Randomization rate	$\frac{20}{20}$ (100%)	95% CI [81%, 100%]	90%	Proportion of consenting participants who were randomly allocated to either usual care plus placebo or usual care plus acupressure intervention
Intervention/ Placebo delivery: Application (in the PACU)	$\frac{17}{20}$ (85%)	95% CI [63%, 95%]	90%	Proportion of consenting participants who received the intervention or placebo wristbands after being deemed stable by the PACU nurse
Intervention/ Placebo delivery: Continuous wear	$\frac{17}{20}$ (85%)	95% CI [63%, 95%]	80%	Proportion of participants who consented, were randomized, and reported continuous wear for 24 hours after discharge from DSU
Retention rate (study completion rate)	$\frac{18}{20}$ (90%)	95% CI [68%, 98%]	80%	Proportion of consenting participants who completed the study (completed the follow-up call)

Secondary Outcomes

Analyses using inferential statistics were conducted to estimate the intervention's preliminary effects on post-discharge NV.

Post-discharge Nausea

The distributions of post-discharge nausea scores were not normal in the placebo (W = .73, p < .01) or intervention (W = .68, p < .01) groups, and equal variances were not assumed, $F(1,16) = 7.49$, p = .01. The non-normal distributions of the groups can be confirmed visually in the histograms (Figures 2 and 3). There were nine data points in each group, which are presented in boxplots (Figure 4). Just under half of the participants who received wristbands (8 of 18 participants, 5 of 9 participants in the placebo group, and 3 of 9 participants in the intervention group) reported experiencing nausea in the first 24 hours post-discharge, as seen in the contingency table (Table 4). This study found that there was no statistically significant difference between the groups in the proportions of participants who experienced nausea within 24 hours post-discharge (p = .64). In the placebo group, the median nausea score was 1 (minimum = 0, maximum = 8). Although not statistically significant, U = 26, p = .17, the intervention group reported lower nausea scores, with a median of 0 (minimum = 0, maximum = 2). The difference between the group medians was 1, 95% CI [0, 7].

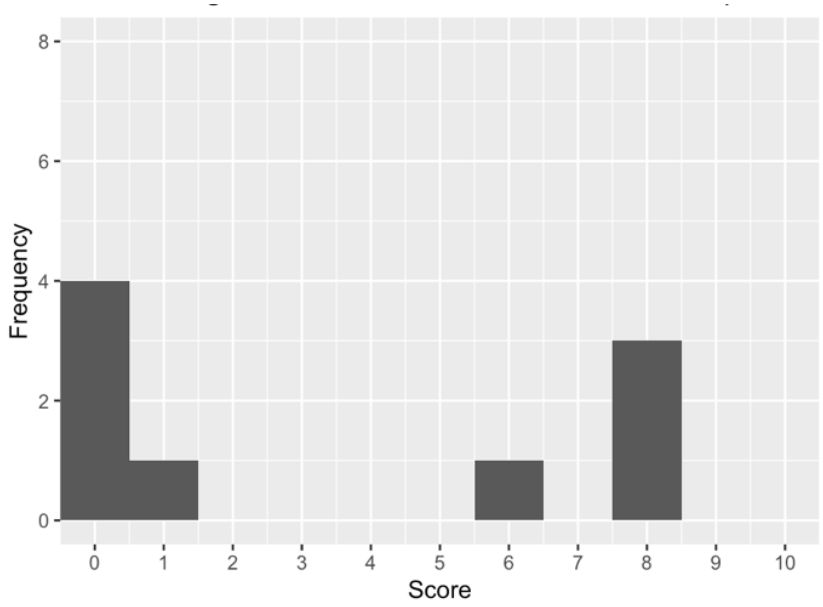
Table 4

Contingency Table for Post-discharge Nausea

	Nausea: Yes	Nausea: No	Total
Intervention	3	6	9
Placebo	5	4	9
Total	8	10	18

Figure 2

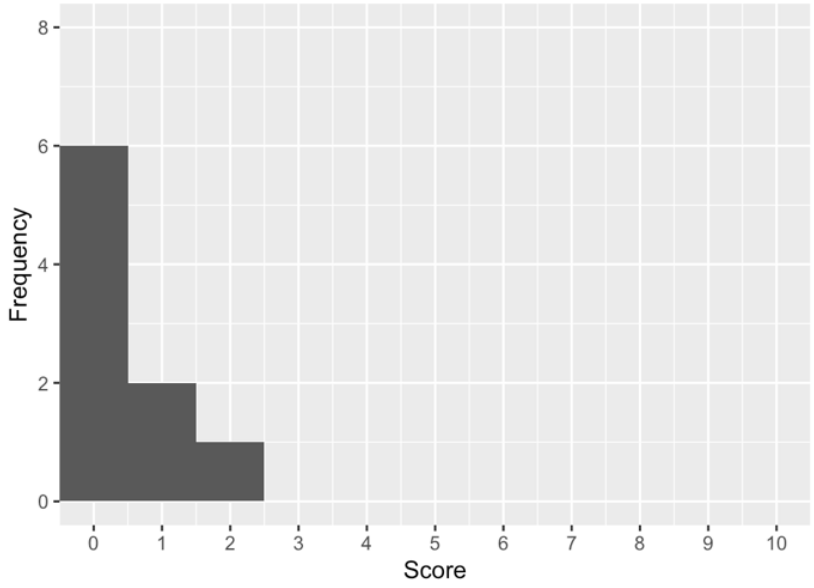
Histogram of Post-discharge Nausea Scores in the Placebo Group



Note. Distribution of participants' nausea scores in the placebo group.

Figure 3

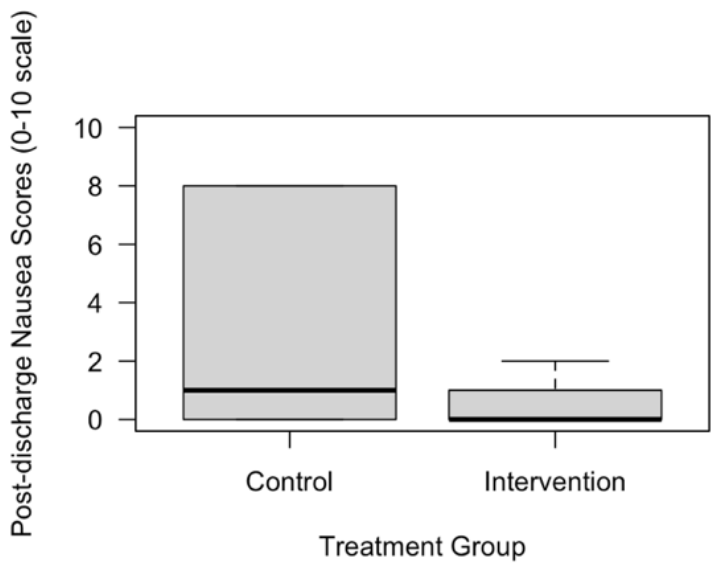
Histogram of Post-discharge Nausea Scores in the Intervention Group



Note. Distribution of participants' nausea scores in the intervention group.

Figure 4

Boxplot of Post-discharge Nausea Scores in Placebo and Intervention Groups



Post-discharge Vomiting

Originally, a comparison of the number of vomiting episodes between the two groups was proposed. However, this study found that most participants did not experience vomiting episodes in the 24-hour period after discharge. Two participants in the control group reported vomiting at least once: one participant reported one episode, and the other reported six episodes. One participant in the intervention group reported vomiting (one episode). A contingency table for post-discharge vomiting is shown in Table 5. With limited data points, it was determined that a comparison of the proportions of participants who vomited in the two groups was more meaningful than a comparison of the number of vomiting episodes. Since the sample sizes were small (n = 9 in each group), the Fisher's exact test was selected over the chi-square test (Daniel & Cross, 2013). There was no statistically significant difference between the two groups in the proportions of participants who vomited (p = 1.00).

Table 5

Contingency Table for Post-discharge Vomiting

	Vomited: Yes	Vomited: No	Total
Intervention	1	8	9
Placebo	2	7	9
Total	3	15	18

Chapter V: Discussion

This study sought to examine the feasibility of conducting an RCT that delivered bilateral PC6 acupressure or placebo wristbands in the PACU plus usual care to prevent post-discharge NV in ambulatory LAVH patients. The primary outcomes were feasibility which included, rates of consent, randomization, delivery of intervention, and retention. The secondary outcomes were preliminary estimates of presence and intensity of post-discharge nausea, as well as presence of post-discharge vomiting. It was hypothesized that this study would be feasible to conduct and that there would be positive preliminary estimates of effects of PC6 acupressure wristbands plus usual care on post-discharge NV. This section explores the study's primary and secondary outcomes, implications for nursing practice and research, strengths, and limitations.

Outcomes

The results suggest that the study design is feasible to conduct, as it met three out of five feasibility criteria: randomization rate, intervention/placebo delivery (continuous wear) rate, and retention (study completion) rate. Two outcomes did not meet the a priori criteria: consent rate and intervention/placebo delivery rate (in PACU). There were no notable issues randomizing consented participants to the acupressure wristbands plus usual care group or the placebo wristbands plus usual care group using a computer-generated, permuted block randomization sequence that was produced by a biostatistician. All consenting participants (100%, 95% CI [81%, 100%]) were successfully randomized in this study. This finding is like that of other feasibility studies using non-pharmacological interventions to prevent or treat NV (Bowe et al., 2022; Tan et al., 2022). For example, a pilot RCT that explored the effect of chewing gum to prevent postoperative NV in patients who underwent elective caesarean section with spinal anesthetic used a randomization method similar to this study and reported a randomization rate

of 99.7% (295 of 296 consenting participants) (Bowe et al., 2022). Another feasibility trial using auricular acupressure in patients with chemotherapy-related NV reported that all 114 consenting participants were successfully randomized using block randomization with a computer-generated sequence (Tan et al., 2022). Other feasibility studies were not randomized trials (Fabbro et al., 2023; Harbell et al., 2024). This study's randomization rate suggests that if a clinical trial were to take place in the future, this method of randomization would be feasible.

The rate of intervention/placebo delivery (continuous wear of wristbands) in this study was 85%, 95% CI [63%, 95%], which surpassed the a priori criterion of 80%. This indicates that it is feasible for participants to continuously wear the wristbands for the duration of the study. Finally, this study's retention rate of 90%, 95% CI [68%, 98%], surpassed the a priori criterion of 80%. This high retention rate may be explained by the minimal risk for serious side effects associated with non-pharmacological interventions. Other recent feasibility or pilot studies involving the use of complementary therapy as an intervention to prevent or treat NV have found similar retention rates (Bowe et al., 2022; Fabbro et al., 2023; Harbell et al., 2024; Tan et al., 2022). This study's retention rate suggests that the study design is manageable.

Two feasibility criteria did not meet the a priori success criteria: consent rate and intervention/placebo delivery (application in PACU) rate. First, this study's consent rate of 87%, 95% CI [67%, 96%], did not meet the a priori criterion of 90%. This finding adds to the wide range of consent rates (48.6% to 99.7%) in existing feasibility studies that used non-pharmacological interventions to prevent or treat NV (Bowe et al., 2022; Fabbro et al., 2023; Tan et al., 2022). Given that this study's consent rate falls in the range of consent rates of other feasibility studies, this study's inability to meet the a priori criterion may reflect an ambitious a priori criterion of 90%, rather than the true feasibility of conducting a larger study. Furthermore,

this study's consent rate suggests that if a larger RCT were to take place, it would take approximately 50 weeks to recruit 120 participants, which is the average sample size of the six studies identified in Chapter II that examined the use of acustimulation on post-discharge NV in ambulatory surgery patients (Al-Sadi et al., 1997; Alkaissi et al., 1999; Carr et al., 2015; Hofmann et al., 2017; Larson et al., 2010; White et al., 2002). Thus, a consent rate of 87%, 95% CI [67%, 96%], is promising.

The intervention/placebo delivery rate in the PACU was 85%, 95% CI [63%, 95%], which did not meet the a priori criterion of 90%. Three participants did not receive their wristbands in the PACU: one withdrew from the study; one converted to a non-laparoscopic procedure, and one was missed in the PACU and received the wristbands in the DSU. This rate is lower than the intervention delivery rate of 90% in the pilot RCT conducted by Bowe et al. (2022), where participants in the intervention group were given packs of 10 chewing gum pieces in the PACU to use at their discretion in the 24-hour postoperative period.

The secondary outcome of this study was to estimate the effects of bilateral PC6 acupressure wristbands plus usual care versus placebo plus usual care on the presence of post-discharge NV and intensity of post-discharge nausea in ambulatory LAVH patients, when the wristbands were introduced in the PACU. As a feasibility trial, this study was not powered, and it did not aim primarily to measure effectiveness of acupressure wristbands on post-discharge NV. Thus, no definitive findings regarding the intervention can be reported. However, it is worth some discussion of the study's preliminary estimates of the effects of acupressure wristbands on post-discharge NV and findings in the literature of studies that examined similar outcomes.

In the present study, there was no difference between the intervention and placebo groups in the proportions of participants who experienced nausea within 24 hours post-discharge (*p*

= .64), as this feasibility trial was not designed to detect statistically significant group differences in post-discharge NV. This is a finding similar to that of a double-blinded RCT that was conducted to examine the effectiveness of PC6 electrical acustimulation on postoperative NV and post-discharge NV (Carr et al., 2015). Although they found no statistically significant difference in the presence of nausea in the intervention and placebo groups, they reported four of 29 participants in the intervention group and seven of 27 participants in the control group experienced post-discharge nausea (Carr et al., 2015). Like the present study, Carr et al.'s (2015) study was small with only 56 participants. Other studies have reported the opposite, reporting a statistically significant difference in the proportions of participants who experienced post-discharge nausea between the acustimulation and placebo (or control) groups (Al-Sadi et al., 1997; Alkaissi et al., 1999; White et al., 2002). These studies had more participants than the present study (n = 81, n = 60, n = 100). Larger trials are needed to detect potential effects of PC6 acupressure on the presence of post-discharge nausea.

Furthermore, in the present study, there was no difference between the two groups in nausea scores (U = 26, p = .17). In contrast, other research examining effects of acustimulation (electrical stimulation) on post-discharge nausea reported a significant difference between groups (White et al., 2002). White et al. (2002) undertook a power analysis to calculate their sample size (n = 120) to provide 80% power to detect an absolute difference of 25% between treatment groups. The other studies that looked at post-discharge NV in ambulatory surgery patients did not explore the differences in severity of post-discharge nausea (Al-Sadi et al., 1997; Alkaissi et al., 1999; Carr et al., 2015; Hofmann et al., 2017). The present study's preliminary findings that estimate the effectiveness of PC6 acupressure on post-discharge nausea suggest that PC6 acupressure wristbands have no effect on post-discharge nausea, both in presence and intensity.

However, further research in a fully powered trial is needed to determine the impact of PC6 acupressure wristbands in the LAVH population.

The presence of vomiting was low in this study, with only three of 18 participants who received the intervention or placebo wristbands reporting it. There was no statistically significant difference between the groups in the proportion of participants who vomited within 24 hours after discharge (p = 1.00). This study's preliminary finding on post-discharge vomiting and existing literature suggest that few people experience vomiting after surgery (Al-Sadi et al., 1997; Carr et al., 2015). However, fully powered trials are needed to confirm this.

Lastly, although seven of nine participants reported side effects, most participants tolerated the wristbands for the duration of the study. All reported side effects were transient and self-resolving including itching, indentations or redness left at the acupressure site, swelling, and discomfort. These side effects are in line with previous studies that examined the effectiveness of acustimulation, including acupressure wristbands, on postoperative NV and post-discharge NV (Lee et al., 2015). One randomized double-blinded, placebo-controlled study that examined the effects of Sea-Bands on postoperative NV in patients undergoing craniotomy reported bruising, pain, and paresthesia as side effects, but these were not reported by the participants of the present study (Nilsson et al., 2015).

Implications for Nursing Practice and Contributions to Research

This study found that it was feasible to conduct a trial where a registered nurse delivers acupressure wristbands to study participants in the PACU following LAVH under general anesthesia. Postoperative and post-discharge symptom management is an important component of nursing practice (College of Nurses of Ontario [CNO], 2023). Furthermore, with education, the delivery of complementary therapy, including acupressure, is within the scope of nursing

practice (CNO, 2020). If acupressure wristbands are found to be effective at preventing post-discharge NV in larger trials, registered nurses are well positioned to educate patients and deliver them as a cost-effective intervention with minimal risk of side effects (Hofmann et al., 2017; Lee et al., 2015). In addition, with an understanding of perioperative care, registered nurses play an important role in the advancement of symptom management in surgical patients.

This study addressed a research gap by examining the feasibility of testing the use of acupressure wristbands in ambulatory LAVH patients to prevent post-discharge NV using an RCT design. Few studies have examined post-discharge NV as an outcome, and compared to those that have, this feasibility study is novel in that it was designed to explore the feasibility of conducting a trial that introduces PC6 acupressure wristbands immediately *after* surgery (rather than preoperatively) in combination with prophylactic medications. Furthermore, the few studies that have examined the effects of PC6 acustimulation on post-discharge NV are small with inadequate power. Large trials are needed, and this present study shows it is feasible to conduct such trials. In addition, this feasibility study contributes to nursing research by highlighting lines of inquiry that could benefit from additional investigation. For example, there are several factors that are known to put patients at risk for postoperative NV and post-discharge NV. The randomization of participants in a fully powered study should eliminate the systematic differences in the distribution of risk factors between the groups. However, the intervention may influence the use of rescue antiemetics, and there is a potential for the rescue antiemetics to impact the presence and/or intensity of post-discharge NV. Future work examining this potential covariate is needed.

Lastly, if future researchers are to conduct a fully powered RCT examining the effects of PC6 acupressure wristbands on post-discharge NV, they should consider the clinical significance

of their findings when interpreting their results (Fethney, 2010). While statistical significance speaks to how likely it is for the observed intervention effect of a study to be true, clinical significance is based on clinical judgement, considering multiple factors including the magnitude of intervention effect, ease of implementation, cost-effectiveness, as well as patient acceptability and preferences (LeFort, 1993). Previous researchers examining pharmacological interventions to reduce postoperative NV have used the number-needed-to-treat of five as a benchmark for clinical significance (Tramèr et al., 1997). However, as acupressure wristbands present minimal risk of serious side effects (Lee et al., 2015; Nilsson et al., 2015), future work could involve exploring a new benchmark for clinically significant findings in non-pharmacological interventions for preventing postoperative and post-discharge NV.

Strengths

There were design features that strengthened this study. First, the CONSORT statement extension for randomised pilot and feasibility trials informed this study's methodological considerations and reporting of findings (Eldridge et al., 2016a). The guideline allowed this study to effectively fulfil the purpose of conducting a feasibility trial, which is to assess the feasibility of conducting a future RCT (Eldridge et al., 2016a). As well, this study's methodological decision to conceal allocation and randomize participants reduced the risk for selection and allocation biases (Duceppe & Belley-Coté, 2016). These techniques ensured that the study nurse could not influence the allocation of participants, reducing the risk for creating systematic differences between the groups (Higgins et al., 2011; The Cochrane Collaboration, 2023). Furthermore, participants were blinded to group allocation to reduce the risk for performance bias and improve internal validity (Higgins et al., 2011; Karanicolas et al., 2010). Lastly, field notes were utilized in this study, which led to a deeper understanding of how best to

run a future larger trial. Particularly, they were useful in keeping track of reasons participants declined to join the study and notes/thoughts on how best to deliver the intervention or placebo wristbands, within the context of this organization.

In addition to strengths related to this study's design, there were other factors that contributed towards the feasibility of this trial. The study nurse had a pre-existing relationship with the study site and the members of the healthcare team, including administrative staff, nurses (preoperative clinic, operating room, DSU, and PACU teams), surgeons, and anesthesiologists, which facilitated stakeholder buy-in. This allowed for the successful recruitment of participants as potential participants needed to be approached by the clinical team prior to the study nurse. Furthermore, the study nurse's understanding of the organization's policies and the perioperative setting workflow facilitated development of the protocol, recruitment, and delivery of intervention.

Limitations

This feasibility trial also had some limitations. First, this study took place at one site in a city of about 100,000 residents that is predominantly Caucasian (City of Brantford Economic Development, n.d.). This may not be generalizable to larger cities or those with more diverse populations as culture may have an influence on the attitudes and beliefs toward the practice of acupressure in patients and healthcare professionals. This could impact outcomes such as consent and retention rates. Furthermore, ethnicity can influence the surgical experiences of patients, including incidence rates of NV after surgery, which may ultimately impact outcomes (Alli et al., 2017). The study by Alli et al. (2017) found that non-African ethnicity is an independent risk factor for postoperative NV and call for further research to examine ethnicity as a risk factor for postoperative NV. Another limitation of this this study was a small sample size, which resulted

in the wide CIs of the feasibility outcomes. A feasibility trial with a larger sample size would provide more certainty about the true rates of feasibility (Daniel & Cross, 2013).

Conclusion

This study aimed to determine if conducting an RCT delivering bilateral PC6 acupressure wristbands plus usual care versus placebo wristbands plus usual care to ambulatory LAVH patients was feasible in the PACU. Published trials to date on the use of PC6 acupressure for the prevention of post-discharge NV are small, and large, definitive trials are needed. The findings of this feasibility pilot indicate that a clinical trial is feasible to conduct. However, new questions emerged about the use of the acupressure wristbands. Future research should explore the impact of potential covariates, such as the use of rescue antiemetics, on post-discharge NV in a powered trial. Furthermore, careful consideration of what is clinically meaningful to patients and health professionals when making decisions about the use of PC6 acupressure wristbands is needed.

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Appendices

Appendix A: Summary of Studies

Study	Aim and Design	Outcome Measure	Participants	Treatment Groups	Results	Limitations
Authors: Alkaissi et al. **Year:** 1999 **Country:** Sweden	**Aim:** To investigate the effect of acupressure in prevention of postoperative nausea and postoperative vomiting **Population:** Women undergoing outpatient minor gynaecological surgery **Design:** Three-arm RCT **Blinding:** Double-blind (to	**What was measured:** Number of patients who experienced postoperative NV, nausea only, or vomiting; need for rescue antiemetics; nausea and vomiting after discharge (24 hrs) **Timing of outcome:** Postoperative ward: at 30 min, 60 min, 120 minutes Post-discharge: at 1800 day of surgery, before bed, at breakfast on postoperative day 1, and noon postoperative day 1	**Sample size:** 60 minor gynaecological surgery patients; intervention group (n = 20); placebo group (n = 20); control (n = 20) **Mean age in years:** Intervention: 27 Placebo: 27 Control: 29 **Gender (female):** All **Types of surgery:** Dilatation and curettage, abortion, conization	**Intervention:** Bilateral PC6 Sea-Bands, draped with dressing while in hospital **Placebo:** Bilateral Sea-Bands placed on dorsal aspect of forearms, draped with dressing while in hospital **Control:** No wristbands **Prophylactic pharmacological antiemetics given?** No. **Intervention delivery (when):** Before surgery (timing not specified)	No statistically significant difference between groups for nausea (only) in hospital Acupressure group significantly less vomiting than control group (p < .05) in hospital Acupressure group significantly less need for rescue antiemetics than placebo	Dichotomized VAS for nausea; severity of postoperative and post-discharge nausea not compared Quality of blinding: the dressings that covered the wristbands were removed upon discharge from hospital Duration of intervention delivery not specified Didn't look at prophylactic pharmacologic

	participants and to nurses assessing nausea and vomiting)	**Measurement tool:** Nausea: Visual analogue scale (0-100mm; "no nausea"- "worst possible nausea": turned into dichotomous (>10 mm = nausea and <10 mm= no nausea) Vomiting: Incidence	**Operation time:** Intervention: 30 minutes Placebo: 25 minutes Control: 20 minutes	**Intervention delivery (duration):** Not specified **Prophylactic pharmacological antiemetics given?** No.	group ($p < .05$) Both acupressure group ($p < .05$) AND placebo group ($p < .05$) experienced significantly less incidences of nausea 24 hours after surgery, compared to control group	antiemetics + acupressure
Authors: Al-Sadi et al. **Year:** 1997 **Country:** UK	**Aim:** To examine if acupuncture administered intra-operatively reduces incidences of postoperative NV and post-discharge NV	**What was measured:** Incidences of postop nausea or vomiting **Timing of outcome:** In the recovery ward and day ward, as well as within the first 24 hours after discharge (assessed after at least 24	**Sample size:** 81 laparoscopic gynaecological day surgery patients; treatment group ($n = 40$); placebo group ($n = 41$) **Mean(SD) age in years:**	**Intervention:** Bilateral PC6 acupuncture; site covered with dressing after needle removal **Placebo:** PC6 site covered with the same adhesive dressing as intervention group	Statistically significant reduction in nausea or vomiting at hospital (recovery and day wards) ($p = .005$) and for 24 hours after	Severity of postoperative NV or post-discharge NV not assessed Didn't look at prophylactic pharmacologic antiemetics + acustimulation

	Population: Patients undergoing laparoscopic gynaecological day surgeries (diagnostic or therapeutic) **Design:** Two-arm RCT **Blinding:** To participants and nurses collecting data	hours after discharge over phone) **Measurement tool:** N/A	Treatment group: 34.2(6.1) Placebo group: 35.8(8.0) **Gender:** All female **Types of surgery:** Diagnostic and therapeutic, otherwise not specified	**Intervention delivery (when):** After induction, but before start of surgery (before morphine administration) **Intervention delivery (duration):** Inserted, then rotated for 5s, then left in situ for duration of surgery; removed at end of surgery **Prophylactic pharmacological antiemetics given?** No.	discharge (p = .007) Statistically significant reduction in post-discharge nausea (p = .001) Statistically insignificant reduction in nausea alone (p = .132) and vomiting alone (p = .084) at hospital (recovery and day wards) Statistically insignificant reduction in post-discharge vomiting alone (p = .139)	

					In hospital, patients receiving placebo were 16 times more likely to experience nausea or vomiting than treatment group After discharge (within 24 hours), patients in placebo group were four times more likely to experience nausea or vomiting than treatment group	
Authors: Carr et al. **Year:** 2015 **Country:** USA	**Aim:** To compare effects of PC6 electrical acustimulation on severity	**What was measured:** Postoperative NV severity (as one construct), post-discharge NV (as	**Sample size:** 56 female laparoscopic cholecystectomy patients; treatment group	**Intervention:** Electrical acustimulation using nerve stimulator electrode at PC6 (unilateral)	No statistical difference between two groups for severity of postoperative	Intervention duration varied depending on length of surgery; some were as short as 40 min

	of postoperative and post-discharge NV and occurrence of vomiting to control group **Population:** Adult female ambulatory laparoscopic cholecystectomy patients **Design:** Double-blind RCT **Blinding:** To participants and PACU RNs (who collected data)	one construct), and presence of vomiting **Timing of outcome:** Postoperative NV: On arrival to PACU, 30 mins after arrival to PACU, 60 mins after arrival to PACU, on discharge from PACU Post-discharge NV:0-6 hours and 6-24 hours, follow-up call made postoperative day 1 **Measurement tool:** Postoperative Nausea and Vomiting Scale (Likert Nausea Scale)	(n=29); placebo group (n=27) **Mean age in years (SD):** 47.6(13.8) **Gender (female):** All **Types of surgery:** Laparoscopic cholecystectomy	**Placebo:** Electrodes were placed at PC6, without electrical stimulation (unilateral) **Intervention delivery (when):** Immediately after induction of general anesthesia **Intervention delivery (duration):** 1 stimulation every 8 seconds for duration of surgery (average 50-60 minutes) **Prophylactic pharmacological antiemetics given?** Yes. All patients received 6mg dexamethasone IV before surgery and ondansetron 4mg IV at end of surgery.	NV nor post-discharge NV Statistically significant difference in presence of vomiting on admission ($p < .001$), at 30 min after arrival to PACU ($p < .01$), and at 60 min after arrival to PACU ($p < .001$)	No sample size calculation Small sample size
Authors: Fan et al. **Year:** 1997 **Country:** USA	**Aim:** To test if patients wearing acupressure bands at PC6 experience	**What was measured:** Presence of nausea and/or vomiting; dose/frequency of	**Sample size:** 200 ASA I or II adult patients (19-59 years old) undergoing short surgical	**Intervention:** Bilateral acupressure bands (AcuBand) at PC6 covered in soft cotton wrapping; initially, spherical	No side effects reported by participants	Did not evaluate postoperative nausea and postoperative vomiting separately

	less postoperative NV than placebo **Design:** Two-arm RCT **Blinding:** To participants and observers who collected data	antiemetics in PACU (for 6 hours) **Timing of outcome:** In PACU (for 6 hours) **Measurement tool:** N/A	procedures associated with high postoperative NV incidences; treatment group (*n* = 108); placebo group (*n* = 92) **Mean age in years:** Treatment group: 37 Placebo group: 36 **Gender (female):** Treatment group: 95.3% Placebo group: 93.5% **Types of surgery:** laparoscopic surgeries (laparoscopic cholecystectomy, laparoscopic tubal ligation, laparoscopic	beads compressed intermittently for a few minutes to activate meridian point **Placebo:** Bilateral acupressure bands (covered in soft cotton wrapping), positioned to dorsal surface of wrists (no known acupressure point or meridian pathway here) **Intervention delivery (when):** Preoperatively (before induction) **Intervention delivery (duration)** Until 6 hours postoperatively **Prophylactic pharmacological antiemetics given?** No. Intraoperative antiemetics were not given either. Data collection ended once participant vomited or experienced nausea	Acupressure group had significantly lower incidence of nausea and/or vomiting compared to control group (*p* = .006)	Post-discharge NV not assessed Severity of postoperative NV not assessed Didn't look at prophylactic pharmacologic antiemetics + acupressure

			lysis of adhesions, diagnostic laparoscopy), gynecologic surgeries (hysteroscopy-D & C, D&C, gynecologic tubal reanastomosis), tonsillectomy, open cholecystectomy			
Authors: Ferrara-Love et al. **Year:** 1996 **Country:** USA	**Aim:** To test the effect of acupressure on incidence of postoperative nausea or vomiting in adult same day surgery patients **Design:** Three-arm RCT **Blinding:** To participants	**What was measured:** Incidences of postop nausea or vomiting and use of rescue antiemetics in the operating room, PACU, and DSU **Timing of outcome:** In PACU: Patients were asked about presence of nausea once awake and every 15 min **Measurement tool:** N/A	**Sample size:** 90 outpatient surgery patients; treatment group (*n* = 30); placebo group (*n* = 30); control, usual care group (*n* = 30) **Mean age in years:** Treatment group: 39 Placebo group: 41 Control group: 35	**Intervention:** Bilateral PC6 Sea-Bands **Placebo:** Wristbands without acupressure **Control:** Usual care only **Intervention delivery (when):** Preoperative (no timing specified) **Intervention delivery (duration):** Removed in DSU area before discharge home	Incidence of nausea or vomiting and use of antiemetics: No difference between groups in operating room and PACU Incidence of nausea: Significantly higher in control than treatment group (*p*	Did not evaluate postoperative nausea and vomiting separately Post-discharge NV not assessed Severity of postoperative NV not assessed Didn't look at prophylactic pharmacologic antiemetics + acupressure

			Gender (female): Treatment group: 46.7% Placebo group: 43.3% Control group: 36.7% **Types of surgery:** Orthopedic, general, plastic, other (not specified)	**Prophylactic pharmacological antiemetics given?** No. Patients were excluded from study if preoperative or intraoperative antiemetics or propofol were given	= .001) and placebo group (*p* = .003) in DSU No statistically significant difference in incidence of nausea between treatment and placebo (*p* = .472), although trend toward reduced incidence of nausea seen in treatment group Frequency of antiemetics required: Statistically significantly higher in control than treatment (*p* = .012) and	

					placebo (p = .040)	
Authors: Hofmann et al. **Year:** 2017 **Country:** USA	**Aim:** To investigate effect of PC6 acupressure on postoperative NV in Phases I and II recovery and post-discharge NV (24 hours) **Population:** Adult ambulatory surgery patients meeting 4/5 risk factors (female, postoperative NV history or motion sickness, non-smoker, and volatile gas general anesthesia)	**What was measured:** Severity of postoperative and post-discharge NV **Timing of outcome:** Postoperative NV assessed on admissions and discharges from Phases I and II; post-discharge NV assessed between 24-48 hours postop over phone **Measurement tool:** 0-10 scale (0= no nausea, 10=severe vomiting or retching)	**Sample size:** 110 adult ambulatory surgery patients; treatment group (n = 57); sham group (n = 53) **Mean age in years(SD):** Treatment= 46.3(13.1) Sham= 46.9(15.0) **Gender (female):** Overall = 95.4% Treatmen t= 100% Sham = 90.6% **Types of surgery:** Laparoscopic cholecystectomy, appendectomy, gynecologic, ENT, vein stripping, and	**Intervention:** Unilateral PC6 acupressure using bead and patches, covered in dressing **Placebo:** Unilateral patch (without acupressure bead) at PC6 **Prophylactic pharmacological antiemetics given?** Yes. **Intervention delivery (when):** 30-60 minutes prior to induction **Intervention delivery (duration):** Until 24 hours postop	Statistically significant lower postoperative NV and post-discharge NV scores in Phase I (p = .012), Phase II (p < .001), and at home (p = .003) in acupressure group, compared to sham	Nausea and vomiting not assessed separately Acupressure was only done unilaterally Method of randomization not clear

	Design: Two-arm RCT **Blinding:** Participants and nurses collecting data		arthroscopic knee			
Authors: Larson et al. **Year:** 2010 **Country:** USA	**Aim:** To examine the effects of ReliefBand (electroacustimulation therapy) wristbands on postoperative NV and postoperative pain **Population:** Outpatient plastic surgery patients **Design:** Two-arm RCT	**What was measured:** Severity of postoperative nausea, incidences of vomiting, need for rescue antiemetics, time to discharge, and impact of symptoms on activities of daily living **Timing of outcome:** 30 minutes, 60 minutes, 120 minutes after surgery; then on postoperative day 1 via phone call **Measurement tool:**	**Sample size:** 122 outpatients undergoing plastic surgery; treatment group (n = 61); sham group (n = 61) **Mean age:** Not reported **Gender (female):** "majority", but not specified **Types of surgery:** Cosmetic and reconstructive face, breast, and body contouring procedures	**Intervention:** ReliefBand at PC6, turned on (tape covered the device to hide if it's on or off) (laterality not specified) **Placebo:** ReliefBand at PC6, turned off (tape covered the device to hide if it was on or off) (laterality not specified) **Intervention delivery (when):** After general anesthesia induced **Intervention delivery (duration):** Deactivated as patient was emerging from general anesthesia	Intervention group reported significantly lower nausea scores at 30 minutes (p < .05) and 120 minutes (p < .05) postoperatively No statistical difference in incidences of vomiting or rescue antiemetic use between groups	Laterality not specified Device only kept on during surgery, and patients did not wear them home Mean age not reported Unclear measurement tool Not much discussion or reported results on nausea scores for post-discharge nausea

	Blinding: To participants	Nausea: on a 1-10 scale (10 being worst), and "Postoperative questionnaire evaluating postoperative NV", not specified		**Prophylactic pharmacological antiemetics given?** Yes, all patients received 4mg ondansetron and 4mg dexamethasone (timing not specified). Patients who had history of motion sickness received meclizine (dose and timing not specified).		
Authors: White et al. **Year:** 2002 **Country:** USA	**Aim:** To compare efficacy of transcutaneous electrical acupoint stimulation (ReliefBand) in preventing postoperative and post-discharge NV to ondansetron used alone or in combination **Population:**	**What was measured:** Severity and incidences of postoperative/post-discharge nausea and incidence postoperative/post-discharge vomiting **Timing of outcome:** On arrival to PACU, at 15 min after initiating treatments, at 30 min after initiating treatments, every 30 min after that until discharge home	**Sample size:** *n* = 120; intervention 1(*n* = 40); intervention 2(*n* = 40); placebo(*n* = 40) **Mean age in years(SD):** Intervention 1: 43(13) Intervention 2: 45(11) Placebo: 46(11) **Gender (female):**	**Intervention 1:** Unilateral (dominant side) PC6 ReliefBand and 2ml IV saline **Intervention 2:** Unilateral (dominant side) PC6 ReliefBand and 4 mg IV ondansetron **Placebo:** Unilateral (dominant side) inactive PC6 ReliefBand and Ondansetron 4mg **Intervention delivery (when):**	Interventions 1 and 2 had significantly lower median nausea scores than placebo ($p < .05$) post-discharge (at the 24 hour follow up) At the 24-hour follow up, intervention 2 had significantly lower	Device wasn't used bilaterally Method of randomization not clear

	Ambulatory patients undergoing plastic surgery procedures **Design:** Double-blind RCT **Blinding:** To participants and those assessing postoperative NV	72-hour postop period, episodes of vomiting and retching were recorded by pts Follow up calls made at 24 hours and 72 hours postoperatively **Measurement tool:** 11-point verbal rating scale for nausea (0= no nausea, 10= worst imaginable nausea)	Intervention 1: *n* = 37 Intervention 2: *n* = 35 Placebo: *n* = 34 **Types of surgery:** Head and neck, breast, abdominal, and extremities	On arrival to PACU **Intervention delivery (duration):** From arrival to PACU until 72 hours after surgery, except when bathing **Prophylactic pharmacological antiemetics given?** Yes. Droperidol 0.625mg after induction	incidences of nausea and vomiting No statistically significant differences in nausea nor vomiting were seen between the groups in the hospital	
Authors: Yang et al. **Year:** 1993 **Country:** Taiwan	**Aim:** To explore the effect of PC6 acupoint injection on postoperative vomiting **Population:** Outpatients undergoing gynecological laparoscopy	**What was measured:** Incidences of vomiting (including dry retching) **Timing of outcome:** Observed in PACU for 3 hours **Measurement tool:** N/A	**Sample size:** 120 female patients undergoing outpatient gynecological laparoscopy **Mean age in years(SD):** Intervention 1 (PC6): 31(6)	**Intervention 1 (PC6):** PC6 injection of 0.2ml 50% glucose in water (doesn't specify if bilateral or unilateral) **Intervention 2 (Drug):** Intravenous droperidol 20 micrograms/kg after induction **Control:** No antiemetic measures	Significantly less incidences of vomiting ($p < .05$) in PC6 injection group than control Significantly less incidences of vomiting (*p*	Did not assess postoperative/ post-discharge nausea (incidence nor severity) Post-discharge NV not assessed Didn't look at prophylactic pharmacologic

	with general anesthesia **Design:** Three-arm RCT **Blinding:** Not reported		Intervention 2 (Drug): 30(5) Control: 31(4) **Gender (female):** All **Types of surgery:** Not specified Average anesthesia time: Intervention 1 (PC6): 51 minutes Intervention 2 (Drug): 54 minutes Control: 55 minutes	**Intervention delivery (when):** Prior to extubation **Intervention delivery (duration):** N/A **Prophylactic pharmacological antiemetics given?** No.	< .05) in Intervention 2 (drug) group compared to control group Statistically insignificant difference between PC6 group and drug group (Intervention 2) in incidences of vomiting Side effect- two patients in PC6 injection group complained of pain at site PC6 acustimulation following emetic stimuli (not before) still worked to	antiemetics + acustimulation Anesthesia time less than half of what an LAVH would take Laterality not specified Blinding not reported

					reduce incidence of vomiting	

Appendix B: Patient Flow through the Peri-operative Setting at BGH

All ambulatory LAVH patients attended their preoperative clinic appointment about one to two weeks prior to their surgery date, as arranged by the surgical offices, to undergo nursing and/or anesthesia assessments, as well as bloodwork. On the day of surgery, all ambulatory LAVH patients went to Zone 1 at BGH, where they prepared for surgery and were assessed by the preoperative nurses, operating room nurses, surgeons, and anesthesiologists before they were brought into the operating room. Once surgery was completed, patients were transferred to the PACU, or Phase I recovery, where they were monitored closely by a registered nurse for about one to two hours. Once they reached a modified Aldrete score of at least eight out of 10 (with a score of two in respirations), they were discharged by the PACU nurse to the DSU, or Phase II recovery. In DSU, patients were given fluids for oral intake and discharge instructions. Ambulatory LAVH patients were discharged home from the DSU when they met discharge criteria, including a Post Anesthetic Discharge Scoring System (PADSS) score of at least nine out of 10, voiding, and postoperative stay (between PACU and DSU) of at least three hours (unless otherwise specified by the surgeon). LAVH patients typically spent about one to three hours in the DSU before they were discharged home.

Appendix C: Participant Information Sheet
Feasibility study on acupressure wristbands and post-discharge nausea and vomiting

Why?

Some patients experience nausea and vomiting after undergoing laparoscopically assisted vaginal hysterectomy (LAVH). Some patients may continue to experience nausea and vomiting after leaving the hospital. This could be a problem because nausea and vomiting experienced at home can be distressing and uncomfortable for you. It is important to explore possible methods to reduce the chances of you experiencing this.

Some studies suggest it may be helpful to use acupressure wristbands which are a simple set of wristbands available in drugstores, in addition to usual care, to prevent nausea and vomiting at home after surgery. We want to explore how feasible it is to have you wear acupressure wristbands beginning in the recovery room until the next day to prevent nausea and vomiting, in addition to receiving usual postoperative care. To do this, we are conducting this study to determine the practicality of conducting the research to apply these acupressure wristbands and to understand how it will affect nausea and vomiting after leaving the hospital.

Who?

We are inviting about 20 people, who are scheduled to receive a LAVH at Brantford General Hospital and go home the same day, to take part in our study.

What?

You will either receive acupressure wristbands plus usual care, or wristbands without acupressure plus usual care after your surgery in the recovery room, depending on the group to which you are randomly assigned. This is like flipping a coin.

The day after surgery, the nurse researcher will call you to ask about your experiences with the wristbands, nausea and vomiting, and any pain or nausea medications/other remedies for nausea you take at home.

When?

On the day of your surgery in the recovery room, the nurse researcher will place either acupressure wristbands or wristbands without acupressure on both of your wrists and cover them with gauze dressing. You will be asked to keep them on until 24 hours after you are discharged from the hospital.

Where?

The study will take place at Brantford General Hospital. You will be asked to keep the wristbands and gauze dressings on at home for the first 24 hours after you are sent home from the hospital.

Appendix D: Consent Form
LETTER OF INFORMATION / CONSENT (Page 1 of 4)

Randomized Parallel-Arm Feasibility Trial Comparing Acupressure as a Prophylactic Antiemetic Plus Usual Care Versus Usual Care in Ambulatory Surgery Patients at Risk for Post-Discharge Nausea and Vomiting

Investigators:

Local Principal Investigator:	**Co-Investigator (BCHS):**	**Student Investigator:**
Dr. Sandra Carroll	Dr. Anne Powell	Aya Tagami, RN
School of Nursing	Chief and Medical Director	School of Nursing
McMaster University	Obstetrics and Gynecology	McMaster University
Hamilton, ON, Canada	Brant Community Healthcare System	Hamilton, ON, Canada
carroll@mcmaster.ca	Brantford, ON, Canada	tagama1@mcmaster.ca
	anne.powell@bchsys.org	

Sponsor: No sponsor

Invitation to participate in research

You are invited to take part in this research study because you are scheduled to receive a laparoscopically assisted vaginal hysterectomy (LAVH) and return home the same day. This study is a student Master's project conducted under the supervision of Dr. Sandra Carroll at McMaster University.

To decide if you want to be a part of this research study, it is important for you to understand what is involved and potential risks and benefits. This form gives you detailed information about the study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family. Choosing not to participate will not affect your care.

Why is this study being done?

Some patients experience nausea and vomiting after undergoing LAVH surgery. Some patients may continue to experience nausea and vomiting after leaving the hospital, and it is important to explore possible methods to reduce the chances of you experiencing this. We want to explore how feasible it is to have you wear acupressure wristbands as part of a study, that are placed on in the recovery room until the next day to prevent nausea and vomiting, in addition to receiving usual care by your doctors. To do this, we are conducting this pilot study to determine the practicality of studying these acupressure wristbands and how they might affect nausea and vomiting after leaving the hospital.

How many participants will be in this study?

We are inviting approximately 20 patients to take part in this study.

LETTER OF INFORMATION / CONSENT (Page 2 of 4)

What will happen during the study?

If you choose to participate, the nurse researcher will meet with you at the preoperative clinic and ask you some demographic information such as age (5 minutes). The nurse researcher will explain how to manage and wear your wristbands, how to use your post-discharge nausea and vomiting diary, how to check for normal circulation in your hands while wearing the wristbands, and how to manage potential side effects (15 minutes). You will also be asked to provide your contact information (email, telephone, and mailing address) so the nurse researcher can contact you 24 hours after you are discharged from the hospital.

The study will randomize you (like flipping a coin), on the day of your surgery. You will either receive acupressure wristbands plus usual care, or wristbands without acupressure plus usual care after your surgery. After your surgery in the recovery room, the nurse researcher will place either acupressure wristbands or wristbands without acupressure on both of your wrists and cover them with gauze dressing. You will be asked to keep them on until 24 hours after you are discharged from the hospital. When the research nurse contacts you 24 hours after you are discharged from the hospital, you will be asked about your experiences with nausea and vomiting and any pain or nausea medications/other remedies for nausea you take at home (15 minutes). Your medical record will be accessed by the study nurse to collect information related to your surgery, medications, and care while you are in the hospital.

Are there any risks to doing this study?

The risks involved in participating in this study are minimal. If you are assigned to the acupressure wristband group, you may experience temporary redness, discomfort, pain, itching, swelling, bruising, numbness, and/or imprints at the acupressure sites. If you develop these side effects, they should get better on their own. In the very unlikely event that you experience intolerable discomfort, you can remove your wristbands and seek medical attention if you feel necessary.

Are there any benefits to doing this study?

We cannot guarantee any personal benefits to you from taking part in this study. If you receive the acupressure wristbands, it is possible that you experience less nausea and vomiting after surgery. This study may not benefit you directly, but we hope to learn more about the possibility of introducing acupressure wristbands into the postoperative setting to improve people's experiences with nausea and vomiting at home after undergoing LAVH.

How will we keep your information private?

You are participating in this study confidentially. We will not use your name or any information that would allow you to be identified on study documents. Your name will be replaced with a study number. Only the research team (such as the nurse researcher) will know that you participated in this study unless you choose to tell them. The information/data you provide is

LETTER OF INFORMATION / CONSENT (Page 3 of 4)

kept in a locked desk/cabinet at McMaster University, in the School of Nursing, where only research team members have access. Electronic data will be stored on a McMaster's cloud-based system that encrypts the data. Once the study is completed and published, the data will be destroyed.

What if I change my mind about being in the study?

Your participation in this study is voluntary. If you decide to be part of the study, you can choose to stop (withdraw) at any time, even after signing the consent form or part-way through the study. If you decide to withdraw, there will be no consequences to you. Information you provide up to the point where you withdraw will be kept unless you request that it be removed. Your decision whether or not to be part of the study will not affect your care at Brantford General Hospital. You can withdraw from the study by notifying the nurse researcher, Aya Tagami, in person or via email at tagama1@mcmaster.ca.

How do I find out what was learned in this study?

If you would like a brief summary of the results, please inform the nurse researcher. Once the study has been completed, a short summary will be emailed to you.

Questions about the Study

If you have questions or need more information about the study itself, please contact the nurse researcher at tagama1@mcmaster.ca.

This study has been reviewed by the HiREB (HiREB #16786) and the BCHS Research Ethics Committee (REC). The HiREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please contact the Office of the Chair, HiREB, at 905.521.2100 x 42013, or Dr. Katherine Chorneyko, Chair of the BCHS REC at katherine.chorneyko@bchsys.org .

LETTER OF INFORMATION / CONSENT (Page 4 of 4)

CONSENT

I have read the information presented in the information letter about a study being conducted by Dr. Carroll and Aya Tagami RN, BScN of McMaster University. I have had the opportunity to ask questions about my involvement in this study and to receive additional details I requested.

For the purposes of ensuring proper monitoring of the research study, it is possible that representatives of the Hamilton Integrated REB (HiREB), this institution, and affiliated sites or regulatory authorities may consult your original (identifiable) research data and medical records to check that the information collected for the study is correct and follows proper laws and guidelines. By participating in this study, you authorize such access.

By participating in this study you do not waive any rights to which you may be entitled under the law.

I understand that if I agree to participate in this study, I may withdraw from the study at any time. I will be given a signed copy of this form. I agree to participate in the study.

I would like to receive a summary of the study's results. *Yes* *No*

_____	_____	_____
Name of Participant (Printed)	Signature	Date

Consent form explained in person by:

I have discussed this study in detail with the participant. I believe the participant understands what is involved in the study.

_____	_____	_____
Name and Role (Printed)	Signature	Date

Appendix E: Wristband Instruction Sheet

How do I wear the wristbands?

After your surgery, you will have fabric bands placed on both wrists covered with a white gauze dressing. The bands will either have acupressure or be wristbands without acupressure. You will not be able to tell which type of band you have on with the gauze dressing in place.

Please keep the white gauze dressings on both wrists until 24 hours after you are discharged from the hospital. The research nurse will call you at the 24-hour time point to collect information and to remind you to remove the wristbands.

Please:

- Do not get the white gauze dressings or wristbands wet.
- Do not move or adjust the white gauze dressings or wristbands.
- Do not take the white gauze dressing or wristbands off until 24 hours after you are discharged from the hospital, or when the nurse researcher calls you.

In what situations can I remove the white gauze dressings and wristbands?

You can remove the white gauze dressings and wristbands if you experience side effects that you cannot tolerate such as pain, or if you experience any trouble with circulation, sensation, and/or movement in your hands. These are unlikely.

How do I check for good circulation in my hands?

Press on your nailbeds until it turns white and count how many seconds it takes for the colour to return to your nailbeds. It should take 3 seconds or less for the colour to return. Your hands should feel warm to touch.

When and how do I remove the wristbands?

Please keep the wristbands on until you receive a call from the nurse researcher (unless you experience intolerable or serious side effects). You can remove the wristbands by first unwrapping the white gauze dressing. Then, you can remove the wristbands by sliding them off your wrists. The nurse researcher can talk you through this step over the telephone.

What do I do if I have side effects?

The side effects that you may experience, if any, should get better on their own. If they are intolerable, please remove the wristbands. For minor redness, swelling, and/or pain, you can wrap an ice pack in cloth and apply it to your wrists for 10 minutes at a time. For any serious side effects, like severe pain or issues with your circulation, sensation, or movement with your hands or fingers, please contact the nurse researcher or visit the emergency department.

Appendix F: Post-discharge Nausea and Vomiting Diary
A randomized controlled parallel-arm feasibility trial comparing acupressure as a prophylactic antiemetic plus usual care versus usual care in ambulatory surgery patients at risk for post-discharge nausea and vomiting

Post-discharge Nausea and Vomiting Diary

Study participant ID: _____

Day of surgery: _____

Time to remove your wristbands (24 hours post-discharge): _____

** If you experience any issues with your circulation, sensation, or movement in your hands, or experience intolerable discomfort or side effects, please remove your wristbands and follow the instructions given to you on the "Sea-Band Wristband Instruction Sheet".

In the first 24 hours after being discharged, how bad was your worst nausea at home?

0	1	2	3	4	5	6	7	8	9	10
No nausea										Worst nausea imaginable

Number of vomiting or retching, at least 1 minute apart _____

Narcotic (opioid) medication taken for pain: yes or no

Number of doses: _____

Anti-nausea medication taken: yes or no

Number of doses: _____

Did you use any other remedies for nausea? _____

Did you keep your wristbands on? _____ If no, please tell us why _____

Did you experience any side effects while wearing your wristbands?

Reminder: If you do not experience any serious side effects, like severe pain or issues with your circulation, sensation, or movement with your hands or fingers, please keep your wristbands and gauze wrapping on until you receive a call from the nurse.

Thank you!

Appendix G: Nurse Researcher Training

Before the start of the study, the study nurse underwent acupressure training offered by the University of Minnesota through the global online learning platform, Coursera, that offers online courses and certifications in numerous subjects (Coursera Inc., 2023). This asynchronous 15-hour online course was completed using a 7-day free trial (Coursera Inc., 2023). The course was delivered by a licensed acupuncturist and a registered nurse and was comprised of four modules that covered clinical acupressure fundamentals and basic principles, acupressure for pain, acupressure for gastrointestinal disturbances, and incorporating acupressure into professional practice (Coursera Inc., 2023).

Appendix H
Data Collection Sheet: Initial Contact and Preoperative Clinic (page 1 of 5)

Study Participant ID: _____

Inclusion criteria: Met _____

Exclusion criteria: No exclusion criteria _____

Informed Consent: Yes _____ No _____

If Yes, copy provided to participant _____

Randomization date (same as preoperative clinic date): _____

If could not randomize, why? _____

Sex: _____

Gender: _____

Month and year of birth/calculated age: _____

Antiemetic or opioid medications take at home before surgery: Yes or No

Postoperative NV risk factors (circle all that apply):

Female History of motion sickness or postoperative NV Non-smoker Smoker

Use of postoperative opioids

Post-discharge NV risk factors (circle all that apply):

Female Age < 50 History of postoperative NV Opioid use in PACU Nausea

in PACU

Data Collection Sheet: Initial Contact and Preoperative Clinic (page 2 of 5)

Study Participant ID: _____

Forms

Post-discharge NV diary explained and provided to participant (circle one)?

Yes or No

Wristband instructions explained and provided to participant (circle one)?

Yes or No

Information on how to conduct CSM checks and management of side effects explained and provided to participant (circle one)?

Yes or No

Data Collection Sheet: Delivery of Intervention (page 3 of 5)

Study Participant ID: _____

Time/date participant deemed stable by PACU nurse: _____

Time/date wristbands applied bilaterally: _____

Check once completed:

Bilateral radial pulse check

Capillary refill check in all digits

Intravenous fluid flow check

Sensation and movement check

If bands removed, indicate reason, by whom, and where: _____

Data Collection Sheet: Chart Review (page 4 of 5)

Study Participant ID: _____

LAVH with (list other procedures done in conjunction):

_____

Length of surgery: _____

Usual care prophylactic antiemetics given (circle all that apply)?

8mg dexamethasone (in Zone 1)
20 mg pyridoxine/ 20 mg doxylamine (in Zone 1)
Other:

Antiemetic or opioid medications (name, time, route, and dose) taken on day of surgery preoperatively:

Antiemetic or opioid medications (name, time, route, and dose) given intraoperatively:

Antiemetic or opioid medications (name, time, route, and dose) given in PACU:

Antiemetic or opioid medications (name, time, route, and dose) given in DSU:

Anesthetic agents (name, time, route, and dose) used in the OR:

Data Collection Sheet: Follow-up (page 5 of 5)

Study Participant ID: _____

Date of 24-hour post-discharge follow-up call: _____

Time participant reached: _____

Times of attempts to reach participant:

1. _____
2. _____
3. _____

Most severe nausea NRS score within 24 hours after discharge: _____

Number of vomits or retching, at least one minutes apart, within 24 hours after discharge:

_____

Opioids taken: _____

Anti-nausea medication taken: _____

Other remedies used: _____

Confirmation of bilateral wristband removal (circle one):
Yes or No

Were the bands kept on for the last 24 hours (circle one)?

Yes or No

If no, why?

Any noted side effects by the participant anytime while wearing the wristbands?

Appendix I
Field Notes for Recruitment and Randomization

Recruitment date: _____

Number of participants screened: _____

Number of participants eligible for participation: _____

Number of participants excluded: _____

Reasons for exclusions: _____

Number of participants recruited: _____

Reasons for unsuccessful recruitment:

Number of participants approached for consent: _____

Number of written consents obtained: _____

Reasons for participants declining consent:

Number of successful randomizations: _____

Reasons for unsuccessful randomizations:

Appendix J

Surgery Characteristics and Agents for General Anesthesia

Variable	**Intervention** ***n*** **= 10**	**Control** ***n*** **= 10**	**Sample** ***n*** **= 20**
Length of surgery (minutes): Mean (*SD*)	128.6 (51.3)	105.0 (54.1)	116.78 (52.6)
Surgery Type			
LAVH only, *n* (%)	0 (0)	1 (10)	1 (5)
LAVH + cystoscopy, *n* (%)	1 (10)	0 (0)	1 (5)
LAVH + bilateral salpingectomy, *n* (%)	1 (10)	2 (20)	3 (15)
LAVH + bilateral salpingectomy + cystoscopy, *n* (%)	3 (30)	1 (10)	4 (20)
LAVH + bilateral salpingectomy + cystoscopy + biopsy, *n* (%)	0 (0)	1 (10)	1 (5)
LAVH + bilateral salpingo-oophorectomy, *n* (%)	1 (10)	0 (0)	1 (5)
LAVH + bilateral salpingo-oophorectomy + cystoscopy, *n* (%)	2 (20)	3 (30)	5 (25)
LAVH + left salpingo-oophorectomy + cystoscopy, *n* (%)	0 (0)	1 (10)	1 (5)
LAVH + left salpingo-oophorectomy + right salpingectomy + cystoscopy, *n* (%)	1 (10)	0 (0)	1 (5)
Missing, *n* (%)	1 (10)	1 (10)	2 (10)
LAVH= Laparoscopically assisted vaginal hysterectomy			

Medication and Remedy Use

Location	**Intervention** ***n*** **= 10**	**Control** ***n*** **= 10**	**Sample** ***n*** **= 20**
Opioids Taken			
Preoperatively, at home, *n* (%)	1 (10)	0 (0)	1 (5)
Intraoperatively, *n* (%)	9 (90)	9 (90)	18 (90)
PACU, *n* (%)	8 (80)	7 (70)	15 (75)
DSU, *n* (%)	3 (30)	3 (30)	6 (30)
Postoperatively, at home, *n* (%)	8 (80)	6 (60)	14 (70)
Antiemetics Taken			
Preoperatively, at home, *n* (%)	0 (0)	0 (0)	0 (0)
Intraoperatively, *n* (%)	8 (80)	9 (90)	17 (85)
PACU, *n* (%)	2 (20)	2 (20)	4 (20)
DSU, *n* (%)	1 (10)	1 (10)	2 (10)
Postoperatively, at home, *n* (%)	1 (10)	1 (10)	2 (10)
Home Remedy Used			
Remedy at home for nausea, *n* (%)	0 (0)	1 (5)	1 (5)
DSU= Day surgery unit; PACU= Post-anesthesia care unit			