RUTGERS
Robert Wood Johnson
Medical School

Department of Anesthesiology and
Perioperative Medicine
Rutgers, The State University of New Jersey
125 Paterson Street
New Brunswick, NJ 08901-1977

http://rwjanesthesiology.rwjms.rutgers.edu

p. 732-235-7827
f. 732-235-6131

August 3, 2022

Official Title:
Reducing Nausea and Vomiting During Cesarean Section with Regional Anesthesia: Is the Application of Scopolamine Patch with or without Intra-operative Acupressure Point P6 Stimulation more effective than Intra-operative Acupressure Point P6 Stimulation alone?

Document:
Study Protocol

NCT02960113

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**Title of Project:** **Reducing Nausea and Vomiting During Cesarean Section with Regional Anesthesia: Is the Application of Scopolamine Patch with or without Intra-operative Acupressure Point P6 Stimulation more effective than Intra-operative Acupressure Point P6 Stimulation alone?**

**Principal Investigator**: **Shaul Cohen M.D.**

**Funding Source(s):** **Rutgers Robert Wood Johnson Medical School**

## 1. Purpose/Specific Aims

*1.* The purpose of this study is to compare the effectiveness of reducing intra-cesarean section nausea and vomiting with regional anesthesia in subjects who will receive scopolamine patch with acupressure point P6 stimulation versus subjects that receive just scopolamine patch versus subjects that receive just acupressure point P6 stimulation.

### *1.1 Objectives*

The objective is to randomize subjects who undergo cesarean section with regional anesthesia into one of three groups to compare the efficacy of the therapies. Subjects will receive either (1) scopolamine patch or (2) acupressure point P6 stimulation or (3) scopolamine patch and acupressure point P6 stimulation to reduce intra-cesarean section nausea and vomiting.

### 1.2 *Hypothesis*

We suspect that there will be a difference in outcomes when comparing the three methods research arms and that one or more research arms will have a significantly lower mean rate of nausea and vomiting during cesarean delivery.

## 2. Background and Significance

Cesarean section is a procedure utilized by obstetricians in which an infant is delivered through a surgical incision in the mother's abdomen and uterus. This procedure requires adequate anesthesia usually obtained through one of three modalities: general, spinal, and/or epidural anesthesia. With general anesthesia, the patient is completely unconscious with the utilized agents affecting the entire body. Anesthesia-related maternal complications and mortality are lower when general anesthesia is avoided[1]. Regional anesthesia is the preferred option of healthcare providers when comparing the risks and benefits to the mother and her fetus[2].

Regional anesthesia, including spinal and epidural anesthesia, usually involves injecting varying concentrations and combinations of bupivacaine, ropivacaine, and fentanyl into the

subarachnoid or epidural spaces respectively [3, 4]. With epidural anesthesia, the mother is awake for the procedure and does not feel pain in the anesthetized area. Utilized anesthetic agents are continuously injected into the epidural space around the spinal cord that is usually occupied by fat. With spinal anesthesia, the mother is also awake but utilized agents are directly injected into the cerebral spinal fluid in lower doses than would be normally utilized with epidural anesthesia[5]. The advantages of these methods are effective pain relief without appreciable motor blockade, reduced risk of complications normally seen with general anesthesia, increased infantile APGAR scores at one and five minutes, and earlier bonding of mother with infant. Disadvantages include the inability to perform in mothers with coagulopathies or skin infections overlying the spine, increased reports of pain, and increased nausea and vomiting[4].

Nausea and vomiting are very common and unpleasant events experienced during cesarean section under regional anesthesia and in the postoperative period following cesarean section. These side effects are distressing for both the parturient and her family. In addition, intraoperative vomiting causes significant challenges for the surgeon[6], such as increased procedure length, increased risk of bleeding, increased risk of gastric content aspiration[7], and potential surgical trauma.

To combat the nausea and vomiting seen in all above anesthetic modalities, but to a greater degree in regional anesthesia, a number of pharmacological interventions are currently used with varying degrees of effectiveness in the perioperative period. These medications come from a wide range of drug classes including serotonin and dopamine receptor antagonists, corticosteroids, antihistamines, sedatives and anticholinergics[8].

The anticholinergics, namely scopolamine, have been shown to be effective at preventing nausea and vomiting if given before surgery. The mechanism of action is by antagonizing muscarinic cholinergic type 2 receptors, which are largely concentrated in the chemoreceptor trigger zone, nuclei tractus solitarii, and vestibular system[9]. This drug can be given orally, transdermally, subcutaneously, intramuscularly (IM), or intravenously (IV). In our hospital, we use this medicine for prophylactic antiemetic purposes through the transdermal delivery system (TDS), in the form of a patch. Common side effects reported with scopolamine therapy are dry mouth, blurred vision, drowsiness, dizziness, and mydriasis. Rare but serious side effects include disorientation, memory disturbances, dizziness, restlessness, giddiness, hallucinations, delirium, and confusion[10]. The drug can also readily cross the placenta, so it is administered to pregnant women only under observation. It is considered nonteratogenic and is compatible with nursing[11].

As evidenced above, the drugs currently used to prevent intra- and post-cesarean section nausea and vomiting are not without side effects. Other less expensive and safer alternatives have also been used with varying degrees of effectiveness in the treatment of perioperative nausea and vomiting. One non-pharmacological agent, P6 acupressure point stimulation, has been shown to be effective in reduction of post-operative nausea and vomiting. Based on the meta-analysis of 40 trials, involving 4858 patients, it was concluded that there is no differences in risks of postoperative nausea or vomiting after P6 acupressure point

stimulation compared to after administration of antiemetic drugs[12]. Additionally, the application of the acupressure point P6 stimulator has no known risks except for potential mild discomfort of the arm. However, only a few studies have been performed to determine if acupressure point P6 stimulation is effective in reducing intracesarean section nausea and vomiting under regional anesthesia, and the results are inconclusive[13].

In our study, we would like to compare the effectiveness of antiemetic agents or technique which cause less severe adverse reactions to the mother and her fetus. Out of the available pharmacological agents for reduction of intra-cesarean section nausea and vomiting, transdermal scopolamine patch is one of the safest medications. We would like to compare the effectiveness of the transdermal scopolamine patch with acupressure point P6 stimulation versus just transdermal scopolamine patch versus just acupressure point P6 stimulation.

## 3. Research Design and Methods

The design of the study consists of the randomization of subjects undergoing cesarean section with regional anesthesia in one of three groups. The study is not blinded; as the participants will know which method they are being treated with because of the difference in site and nature of the scopolamine patch and acupressure point P6 stimulation. The randomization of patients will be done by a computer to avoid bias before the informed consent form is signed by the patients. The computer will generate three sets of random numbers for the three groups. Once the consent form is signed, the investigator will allocate the patients serially to the groups having those numbers. The randomization will be created before the study begins and will assign 240 subjects into one of the three groups to receive the treatment as follows:

Group I (n=80): Will receive scopolamine patch placement on the skin behind the right ear 1 hour before initiation of the regional anesthesia for the duration of surgery. The time of the application of the patch will be recorded, and the time of the start of the surgery will be recorded. The last time point for evaluation of patient's nausea/vomiting will be when the patient arrives to the post anesthesia care unit. A member of the research team will remove the patch from the patient and properly dispose the patch upon arrival to the post anesthesia care unit.

Group II (n=80): Will receive acupressure point P6 stimulation. This is a stimulation of the chi channel at the master of the heart (MH8 position) at the small depression of the volar surface of the distal right forearm just above the crest of the wrist. The device will be put on the patients in the operating room prior to administration of the regional anesthesia and will be removed after the cesarean section is complete. The device will be removed from the patient in the operating room, before the patient is transported to the recovery room. Patients will receive continuous stimulation at a level that is comfortable for her prior to administration of the standardized regional anesthesia.

Group III (n=80): Will receive both scopolamine patch and acupressure point P6 stimulation, as described above.

The acupressure point P6 stimulation device is FDA approved for monitoring the magnitude of neuromuscular blocks in general anesthesia. This device stimulates the P6 acupressure point, which as demonstrated in previously published studies, is a safe acupressure point to be stimulated in pregnant women[14, 15]. However, to our knowledge, there are no published studies that have compared the effectiveness of this device versus the scopolamine patch versus the combination of the scopolamine patch and this device in preventing nausea and vomiting in women undergoing cesarean section under regional anesthesia. In this study, we would like to compare these three methods. The device will be used off-label in our study.

As per the RWJUH Obstetric Anesthesia Guidelines (Page 11, Section III B), metoclopramide, ondansetron, scopolamine patch, and acupressure point P6 stimulation may be applied prophylactically or therapeutically for the commonly complaints of nausea and vomiting.

Today, there are five types of procedures that are considered standard of care for obstetric patients undergoing cesarean section with regional anesthesia at the RWJUH. Each doctor gets to choose what he or she wants to do because for now, it is unclear which method is the best. (1) It is acceptable to not give any prophylactic nausea/vomiting therapy at the start of the anesthesia, (2) administer prophylactic metoclopramide and odansetron before beginning the anesthesia, (3) administer scopolamine patch prophylactically before beginning the procedure, (4) stimulate the P6 acupressure point before the start of the anesthesia and continue stimulating it throughout the procedure, or (5) administer scopolamine patch along with acupuncture point P6.

After the subjects have been randomly assigned to one of the three groups, subjects will receive the standardized regional anesthesia consisting of either spinal anesthesia with 10 milligrams of bupivacaine, 20 micrograms of fentanyl and 100 micrograms of epinephrine or epidural anesthesia with 20 milliliters lidocaine 2% along with 20 micrograms fentanyl and 100 micrograms epinephrine. Patients will offer their subjective assessments of the level of nausea on a scale of 0-10 (0 = no nausea, 10 = worst nausea every experienced) (See Appendix II) and objective assessments of whether or not the patients have vomited (See Appendix I) during 4 distinct points during the procedure. The 4 distinct points are as followed: after the administration of the regional anesthesia medications, after eversion of the uterus, after replacement of the uterus, and upon arrival in the post-operative recovery room. An Apfel score, which is used to predict the risk of experiencing post-operative nausea and vomiting, will also be determined with each subject (See Appendix I).

Other data that will be collected throughout the procedure and used for analysis and comparison (See Appendix I) include:

- Age, height and body weight
- ASA classification

- Gestational age
- Did patient have operative blood loss greater than 700cc? (yes or no); amount of blood loss
- If patient was hypertensive (systolic blood pressure above 140); what was the patient's highest blood pressure during the operation?
- If patient was hypotensive (systolic blood pressure below 90); what was the patient's lowest blood pressure during the operation?
- Hypoxia: Did intra-operative pulse oximetry drop <85%? (yes or no); what was the lowest pulse oximetry level of the patient during the operation?
- Efficacy of sensory block for cesarean section
- Nausea and vomiting treatment satisfaction
- Overall satisfaction

Study ID will be used for patient identification.

Of note, if at any point during the operation patients in any group report experience nausea and/or vomiting, they will be given a rescue dose of 4-8 milligrams odansetron with or without 10 milligrams metoclopramide and will be analyzed in their original group based on the statistical principle of intention to treat.

Copies of the subject assessments can be found in Appendix I and II.

***3.1. Duration of Study***

The study will be conducted for the duration of surgery until the parturient arrives at the post anesthesia care unit.

***3.2 Study Sites***

The research will be conducted at Robert Wood Johnson University Hospital, 1 Robert Wood Johnson Place, New Brunswick, NJ, 08901 and Department of Anesthesia, 125 Paterson Street, CAB 3100, New Brunswick, NJ 08901.

***3.3 Sample Size Justification***

This is a randomized unblinded prospective study comparing three different research arms in parallel. There will be three groups each having 80 subjects enrolled for the study. Sample size was determined using online software (Sealed Envelope, binary outcome superiority trial) to obtain power of 90%, two-tailed test at 5% significance level to detect 90% success rate in the combination arm (Scopolamine + acupressure) compared to either of other two arms (70% success rate).

***3.4 Subject Selection***

The subjects will be selected from patients presenting to the services of Obstetrics and Gynecology at Robert Wood Johnson University Hospital in New Brunswick, NJ.

### *3.4.1 Inclusion Criteria*

(1) Female subjects ages 18 to 45
(2) Subjects with ASA Class I or II
(3) Subjects with elective primary or repeat cesarean delivery
(4) Subjects who receive spinal and/or epidural anesthesia
(5) English and non-English speaking subjects will be included in the study

### *3.4.2 Exclusion Criteria*

(1) Female subjects <18 years of age
(2) Subjects requiring emergent cesarean delivery
(3) Gestational age < 37 weeks
(4) History of placenta accreta
(5) Multiple gestation pregnancy
(6) ASA status III or higher
(7) Current history of pregnancy induced hypertension, pre-eclampsia, or eclampsia
(8) History of any chronic medication use (other than prenatal vitamins), including inhaler medications
(9) Current urinary tract infection, pneumonia, or otitis media
(10) Coagulopathies or skin infections overlying the spine
(11) History of open angle glaucoma, seizures or psychosis

## 4. Study Variables

### *4.1 Independent Variables or Interventions*

Subjects in Group I will receive prophylactic scopolamine patch. Subjects in Group II will receive acupressure point P6 stimulation. Subjects in Group III will receive both scopolamine patch and acupressure point P6 stimulation. All three interventions are the standard of care at RWJUH.

### *4.1.1 Drug or Device Interventions*

Subjects randomized to Group I will receive scopolamine patch on the skin behind the right ear 1 hour prior to administration of the standardized regional anesthesia. Subjects randomized to Group II will receive acupressure point P6 stimulation to the right forearm. This consists of a device that releases continuous electric shocks at a level that is comfortable for the patient over the P6 acupressure point. Subjects randomized to Group III will receive both scopolamine patch and acupressure point P6 stimulation. The time at which the patch will be placed on the patient will be recorded. All RWJUH policy will be followed for device and drugs storage, access, and control.

### *4.2 Dependent Variables or Outcome Measures*

The study instrument that we will use is an assessment flowsheet to document:

1. ASA class
2. Age
3. Height

4. Gestational Age
5. Apfel Score (1-4)
6. Hypertension (systolic blood pressure greater than 140) (yes or no)
7. Highest Blood Pressure
8. Hypotension (Did blood pressure drop below 90 systolic at any point) (yes or no)
9. Hypoxia (Did intra-operative pulse oximetry drop <85 %?) (yes or no)
10. Lowest Pulse Oximetry (%)
11. Has Patient Vomited During Procedure (yes or no)
12. Did Patient Vomit After Administration of regional anesthesia (yes or no)
13. Did Patient Vomit After Eversion of Uterus (yes or no)
14. Did Patient Vomit After Replacement of Uterus (yes or no)
15. Did Patient Vomit Upon Arrival to Post-Operative Recovery Room (yes or no)
16. Has Patient Had Nausea During Procedure (yes or no)
17. Ranked Nausea After Administration of regional anesthesia (0-10, 0 = no nausea, 10 = worst nausea ever experienced)
18. Ranked Nausea After Eversion of Uterus (0-10, 0 = no nausea, 10 = worst nausea ever experienced)
19. Ranked Nausea After Replacement of Uterus (0-10, 0 = no nausea, 10 = worst nausea ever experienced)
20. Ranked Nausea Upon Arrival to Post-Operative Recovery Room (0-10, 0 = no nausea, 10 = worst nausea ever experienced)
21. Did Patient Have >700cc Blood Loss (yes or no), amount of blood loss___
22. Efficacy of Sensory Block for Cesarean Section (1 = No Complaints, 2 = + Complaints, 3 = + Sedation $N_2O$ or IV, 4 = G/A)
23. Nausea and Vomiting Treatment Satisfaction (0 = Not Satisfied, 10 = Extremely Satisfied)
24. Overall Satisfaction (0 = Not Satisfied, 10 = Extremely Satisfied)

### *4.3 Chart Review Selection*

No subject charts will be reviewed since this is not a retrospective study.

### *4.4 Risks of Harm*

Common adverse effects of scopolamine patch include: dry mouth, drowsiness, dizziness, blurred vision, and mydriasis. Rare but serious side effects include disorientation, memory disturbances, dizziness, restlessness, giddiness, hallucinations, delirium, and confusion[10].

The application of the acupressure point P6 stimulator may rarely cause potential discomfort during the intervention.

There is a potential for lost of anonymity; however, every safety measure will be in place to prevent any breeches in confidentiality.

There are no known psychological/emotional, social, legal, and economic risks of harm from the acupressure point P6 stimulation.

### *4.5 Potential for Benefit*

Potential benefits from the use of acupressure point P6 stimulation include:

1. Reduction of intra-cesarean section nausea and vomiting
2. Potential reduction in cost from using medical therapy (scopolamine patch)
3. Potential reduction of negative side effects associated with medical therapy (scopolamine patch)
4. Potential change of standard of care from more costly medical therapy (scopolamine patch) that can cause potential adverse effects to the more cost effective acupressure point P6 stimulation which has very little side effects associated with its use.

## *5. Subject Recruitment and Enrollment Considerations*

### *5.1 Subject Recruitment*

Subjects presenting to the Obstetrics and Gynecology Services for elective cesarean section or repeat cesarean section who will be undergoing spinal, epidural or combined spinal epidural anesthesia will be approached for consideration of the study. The following times will be documented: when the patient is approached, when the consent form is signed, when the patch is applied on the patient, when the acupressure point P6 stimulation device is applied, and when the surgery begins.

### *5.2 Consent Procedures*

The informed consent process will begin after a subject presents to the Obstetrics and Gynecology Services for elective cesarean section. It will take place while the patient is in the holding room. The patient is in the holding room for a significant amount of time prior to the surgery. This is the time when the nurse approaches the patient to get all the patient's necessary medical records into the computer. During this time, the surgeon and anesthesiologist approach the patient to get consent for the operation and for the anesthesia. With the explanation of the anesthesia, the patient will also be explained about the opportunity to participate in the study. If the patient chooses to participate in the study, the patient will receive the same standard of care that she would have received if she were not part of the study. The only difference is that if the patient is not part of the study, each anesthesiologist chooses by him or herself one of the three options that the patient will receive for anti-nausea medication. If the patient chooses to be part of the study, no matter which anesthesiologist will be at the surgery, the choice of which anti-nausea medication that the patient receives will be random. Each individual will be explained this and given the informed consent document to read and consider prior to agreeing to participate. The study investigator will answer all the subjects' questions and ensure the subject has adequate time to consider participation prior to signing the informed consent document. The patient will be told that she can think about it and does not need to sign the consent form at this time if she does not choose to. No study assessments, measurements, or interventions will occur prior to the subject signing the informed consent document.

We are going to obtain consent from subjects to participate in this study prior to the initiation of study interventions.

The following members of the research team will be obtaining consent from patients: Shaul Cohen, MD and Danielle Levin, BA.

Dr. Shaul Cohen will educate all members of the research team how to obtain appropriate consent. He will demonstrate how to obtain the consent until he feels comfortable that the research team members can obtain the consent by themselves.

The details of the study will be communicated to the patients' obstetricians via email prior to beginning the study. The obstetricians will direct their questions regarding the study to Dr. Cohen. Dr. Cohen will speak with the obstetricians in the holding room and explain to them the study.

***5.3 Subject Costs and Compensation***

The subject will not incur additional costs outside of standard of care costs for medication that may be performed for routine standard of care. There will be no compensation for participation in this study.

## 6. Data Handling

All data will be stored in a locked file in the office of the principal investigator with limited access. The link to the protected health information will be stored separately from the study files and will be destroyed after all the data has been collected and analyzed. Up to 400 subjects may sign the informed consent for participating in this trial. This number is to ensure that 80 subjects complete each study group below. Therefore, we will be replacing subjects that do not complete the study as designed.

## 7. Statistical Analysis

There will be 3 treatment groups each having 80 subjects enrolled for the study. The intergroup analysis for numerical variables will be performed by ANOVA. All categorical variables will be analyzed with Chi-square/Fisher test. Descriptive statistics will provide the quantitative summaries for numerical data in each group.

The difference in end surgical nausea and vomiting will be analyzed using the Mann-Whitney rank sum test. Power analysis determined that 80 patients will be necessary in each group to detect the difference in treatment in nausea and vomiting, assuming a two sided alpha of 0.05 and power of 90%.

## 8. Data and Safety Monitoring

There is no data and safety monitoring committee for this study. Patients will be followed for adverse effects during their participation in this study. We will use Form FDA 3500A mandatory and Form FDA 3500 voluntary reporting forms found on the FDA website, www.fda.gov.

## 9. Reporting Results

### *9.1 Individual Results*

No laboratory data will be collected. Individual results will not be provided to participants enrolled in this study. Data collected will be used for study purposes including any data already collected. Should someone decide to withdraw consent no new data will be collected, but data on hand will continue to be used.

A description of this clinical trial will be available on http://www.clinicaltrials.gov as required by US Law.

### *9.2 Aggregate Results*

Data will be stored on a university computer that is password protected and that has encryption capabilities for a period of 6 years post the end of the study per university policy. Patients can contact the primary investigator to inquire about their data at any time during the study.

### *9.3 Professional Reporting*

We hope to publish reports in case presentations, conferences, and in scientific publications.

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**Reducing Nausea and Vomiting During Cesarean Section with Regional Anesthesia: Is the Application of Scopolamine Patch with or without Intra-operative Acupressure Point P6 Stimulation more effective than Intra-operative Acupressure Point P6 Stimulation alone?**

**By Shaul Cohen M.D.**

1. **Appendix 1:**

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**Study ID number:**
Date:

Time when patient is approached: _____

Time when consent form is signed: _____

Time when scopolamine patch is applied: _____

Time when acupressure point P6 stimulator is applied: _____

Time when surgery begins: _____

Group I: scopolamine patch
Group II: acupressure point P6 stimulation
Group III: scopolamine patch and acupressure point P6 stimulation

ASA Class: (I/II) Age: Height: feet cm Weight: lbs kg

Gestational Age:

Apfel score: _____ (1-4) (add sum from below)
(1 = female gender 1 = non-smoker 1 = history of PONV 1 = history of motion sickness)

Hypertension: > 140 systolic blood pressure: (Y/N) Highest BP _____

Hypotension: < 90 systolic blood pressure: (Y/N) Lowest BP _____

Hypoxia (Did intra-operative pulse oximetry drop <85%?): (Y/N)
Lowest pulse oximetry: _____%

Has patient vomited during procedure: (Y/N)
Has patient had nausea during procedure: (Y/N)

Has patient vomited:
Point 1 - After administration of epidural medications: (Y/N)
Point 2 - After eversion of uterus: (Y/N)
Point 3 - After replacement of uterus: (Y/N)
Point 4 - Upon arrival to post-operative recovery room: (Y/N)

Rate Nausea:
Point 1 - After administration of epidural medications: ____
(0-10, 0 = no nausea, 10 = worst nausea ever experienced)
Point 2 - After eversion of uterus: ____
(0-10, 0 = no nausea, 10 = worst nausea ever experienced)
Point 3 - After replacement of uterus: ____
(0-10, 0 = no nausea, 10 = worst nausea ever experienced)
Point 4 - Upon arrival to post-operative recovery room: ____
(0-10, 0 = no nausea, 10 = worst nausea ever experienced)

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Did patient have more than 700cc blood loss? (Y/N) ___cc

Efficacy of sensory block for C/S _____ (1-4)
(1 = no complaints 2 = + complaints 3 = + sedation N2O or IV 4 = G/A)

Nausea and vomiting treatment satisfaction _____ (0-10, 0 = not satisfied, 10 = extremely satisfied)
Overall satisfaction _____ (0-10, 0 = not satisfied, 10 = extremely satisfied)

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**APPENDIX II:**

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**Nausea Score**