


The Role of Acupuncture in Post-Operative Pain Management in Gynecological Patients

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NCT02855567

Document Date: June 19, 2016

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	Principal Investigator:	Charles Ascher-Walsh
	Primary Contact Name/Contact Info:	Karina Hoan, 9255484100
	Date Revised:	6/19/2016
	Study Number:	1896888

HRP-503 PROTOCOL TEMPLATE

- *Note that, depending on the nature of your research, certain questions, directions, or entire sections below may not be applicable. Provide information if and when applicable, and in cases where an entire section is not applicable, indicate this by marking the section “N/A”. Do not delete any sections.*
- ***For any items below that are already described in the sponsor’s protocol, the investigator’s protocol, the grant application, or other source documents, you may simply reference the title and page numbers of these documents in the sections below, rather than cutting and pasting into this document. Do not refer to the Sample Consent document, or information on the application form in this document.***
- *Keep an electronic copy of this version of the document. You will need to modify this copy when making changes.*


Brief Summary of Research (250-400 words):

There are many benefits to minimally invasive surgery such as smaller incisions, decreased blood loss, less pain, shorter recovery time, and economic enticement. Same-day discharge after laparoscopic surgery has been shown to be safe and cost-effective; however some patients who are otherwise eligible for discharge require an overnight admission for pain management. Hospitalization and the use of high doses of narcotics pose important safety concerns, such as increased risk of hospital borne illnesses and in terms of opioids, respiratory depression and addiction. Given the rising cost of health care there is also an economic incentive to eliminate the need for hospital admission due to post-operative pain.

Acupuncture is a safe, non-addictive alternative therapy, which has been noted to successfully decrease pain. However, to our knowledge, there has never been a study that looks at the difference in post-operative narcotic use in patients undergoing minimally invasive gynecological procedures that receive acupuncture pre-operatively.

In our study, we will recruit female patients over the age of eighteen who have been previously scheduled to undergo a benign gynecological laparoscopic procedure. All patients consented will be eligible for same-day discharge.

Once consented, participants will be randomized into the pre-operative acupuncture (study) or sham acupuncture (control) group using a computer generated randomization system. There will be a total of 50 patients in each group. In the study group, the proposed acupuncture points are LR-3, GB-41, GB-34, TH-5, MH-6. These points are accepted in modern and traditional Chinese acupuncture as aiding in overall painful conditions and with reference to pelvic painful conditions. The PC-6 point is also widely accepted as a major point to reduce nausea and vomiting from any condition, and has been shown in operative and anesthesia literature as well with moderate evidence. Standard acupuncture needles 29 and 30 gauge will be used throughout. On average, it takes three minutes to place five to six acupuncture needles. Due to the rapid placement of the needles, subjects will not be under significantly more anesthesia than patients who do not participate in the study. All points are located on the patients upper and lower extremities and can be easily accessed in lithotomy position. In the study group, the needles will be left in-situ for a total of 15 minutes, as the patient is prepared for surgery. In the control group, the primary surgeon will place five superficial needles in specific predetermined locations on the

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patients' hands and feet. The points, chosen by the lead anesthesiologist, are outside the "meridian" acupuncture points. The needles in the control group will be placed only 1/8 centimeter deep and immediately removed. This poses no increased harm to the patient. Acupuncture needles can leave a very mild sensation over the skin. In order to completely blind the patient, needles must be placed in both groups. All needles will be removed before the first incision is made. All patients will be blinded to their group allocation.

The primary outcome will be narcotic consumption in the first 24 hours. Secondary outcome s will include hospital admission rate and post-operative pain medication in the first 7 days after surgery.

It is our goal to evaluate if acupuncture treatment for pain performed pre-operatively decreases the use of post-operative narcotics and admission rate.

1) Objectives

Research Question: Does the use of acupuncture decrease narcotic consumption in post-operative gynecological patients?


Hypothesis: Narcotic consumption at 24 hours in acupuncture group (study) versus sham acupuncture group (control).

Narcotic abuse and addiction are quickly becoming a very large concern in our health care system. It is our goal to find a safe, effective, and non-addictive alternative for post-operative pain management in order to decrease the amount of narcotics needed.

2) Background

Minimally invasive gynecological surgery has many benefits over traditional open method surgery such as shorter recovery time, less adhesion formation, decreased cost and possibly shorter operative time. (1) With these characteristics, laparoscopy allows for better pain control which in turn leads to decreased hospital stay and less narcotic intake. It has even led to a new era in gynecological surgery marked by the ability to discharge the patient home on the same day as her surgery after procedures that historically required a several-day hospital stay. This decreases hospital costs and limits the exposure of patients to hospital-borne pathogens. In Gynecology and General Surgery, studies have demonstrated that the majority of patients who had same-day discharge as their procedure were highly satisfied to have gone home instead of stay overnight in the hospital. (2) Pain control is essential to achieving same-day discharge and patient satisfaction after a procedure. Currently, narcotics are first-line for post-operative pain control but have become increasingly controversial secondary to the growing epidemic of opioid addiction and abuse. Therefore, it would be beneficial for patients who undergo gynecological surgery to find alternative methods of pain control in an effort to lessen the amount of pain medication required post-operatively. Ideally, this will enhance the benefits of laparoscopy and further decrease hospitalization time and narcotic use.

Acupuncture is a 2000-year-old technique using the application of fine needles in strategic places on the body. It has been proven to be safe, effective and non-addicting. (3) Studies have been performed in other surgical fields that demonstrate the effectiveness of intraoperative acupuncture for controlling post-

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operative pain. A study of transcutaneous electrical acupuncture stimulation during supratentorial tumor resection by Liu et al. showed that patients required less intraoperative analgesics and had better post-operative day one pain control than the patients who received sham intraoperative acupuncture. (4) In another study, by Tsao et al., intraoperative acupuncture was administered at the time of tonsillectomy and was shown to significantly improve subjective post-operative pain and led to earlier oral intake, a marker of pain control, than the study subjects who did not receive intraoperative acupuncture. (5) Wetzal et al. demonstrated that patients receiving auricular acupuncture during total hip arthroplasty required 15% less fentanyl than patients who received placebo acupuncture during the same procedure. (6) In these studies, and several others involving acupuncture during the pre- and post-operative period, acupuncture been used safely and effectively and has been demonstrated to improve patient care in terms of pain control and traditional analgesic intake.

Narcotic abuse and addiction is a fast rising concern in post-operative patients. Past research has shown acupuncture to be effective in post-operative pain control, but no studies have looked specifically at gynecological patients. Our study has the potential to decrease the amount of narcotics prescribed post-operatively to women undergoing gynecological laparoscopic surgery and to decrease the rate of prolonged hospital stays.

1. "Laparoscopic surgery is not inherently dangerous for patients presenting with benign gynaecologic pathology. Results of a meta-analysis." Chapron et al. Human Reproduction. May 2002. 17 (5): 1334-42.
2. "Day-Surgery Laparoscopic Cholecystectomy: Factors Influencing Same-Day Discharge" Psaila et al. World Journal of Surgery. January 2008. 32 (1): 76-81.
3. "Acupuncture" Andrew C. Ahn, MD, MPH. www.uptodate.com
4. "Intraoperative and postoperative anaesthetic and analgesic effect of multipoint transcutaneous electrical acupuncture stimulation combined with sufentanil anaesthesia in patients undergoing supratentorial craniotomy." Liu et al. Acupuncture Medicine. August 2015. 33(4): 270-6.
5. "Intraoperative acupuncture for posttonsillectomy pain: a randomized, double-blind, placebo-controlled trial." Tsao et al. Laryngoscope. August 2015. 125 (8): 1972-8.
6. "The Effect of Auricular Acupuncture on Fentanyl Requirement During Hip Arthroplasty: A Randomized Controlled Trial." Wetzal et al. Clinical Journal of Pain. March/April 2011. 27(3): 262-267.

3) Setting of the Human Research

The research will be conducted in both the private FPA office of the high volume MIS and Urogynecology attendings and the Mt. Sinai Hospital operating room as well as the post-anesthesia care unit (PACU). If the patient is admitted to the hospital the research will be continued on the patient floor. Standard of care is for all patients undergoing gynecologic laparoscopic surgery to have a pre-operative visit 1-3 weeks prior to the surgery and post-operative visits 2 and 6 weeks after surgery. Potential study participants will be provided information about the present study during their pre-operative office visit. On the morning of the procedure patients will check in to the hospital and wait in the pre-operative area. Once it is time for the surgery they will be brought to the holding area. Following surgery patients will spend a minimum of two hours in the post anesthesia care unit and may or may not be admitted to the gynecological service at Mount Sinai Hospital.

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4) Resources Available to Conduct the Human Research

Dr. Ascher-Walsh, Dr Fenske, and Dr Mamik are all high volume surgeons in gynecology. Between the three of them, over 500 laparoscopic gynecological procedures are performed per year, providing an adequately sized pool of subjects to meet the recruitment goals. Using anecdotal evidence from past studies performed by Dr. Ascher-Walsh it is estimated that 85% of patients will choose to participate. Dr Jeffery Ciccone, an Assistant Professor at Mount Sinai and Licensed Acupuncturist, will be available to perform intra-operative acupuncture for the first two gynecological cases three days a week. Given this participation rate and the availability of Dr Ciccone, the study is expected to be completed in 6 months.

High volume surgeons in the Gynecology department and the co-investigators who are fellows and residents in the Department of Obstetrics and Gynecology at the Mount Sinai School of Medicine will carry out the study. Nursing staff involved in post-operative patient care will be informed of the study protocol and a copy of the protocol will be readily available for reference in the hospital.

Dr Ascher-Walsh, Dr Mamik, and Dr Fenske's offices' will be utilized for presurgery registration and consent of participants. Participating attending and fellows will obtain consent. Dr Ciccone will be responsible for preparing and placing the acupuncture needles in the OR. This will be done immediately after the induction of anesthesia and proper positioning of patients. The needles will be placed in the hands and feet, area's that can be accessed after the patient is appropriately prepped and draped. The needles will be in-situ for approximately 15 minutes, which is the average time acupuncture needles are used for a treatment.

Post operative data collection will be performed by OR nursing staff and Drs. Ascher-Walsh, Mamik, Fenske, Hoan, and Yoselovsky. Data analysis will be performed in the office of the OB-GYN Department by the co-investigators with consultation of the hospital statisticians as needed.

5) Study Design


a) Recruitment Methods

Eligible participants for the study are patients of Dr. Ascher-Walsh, Fenske, or Mamik who are planning to have laparoscopic gynecological procedure. Potential study participants will be provided information about the present study during their pre-operative visit, which occurs 1-3 weeks prior to their surgery. No additional advertisements will be utilized for patient recruitment.

b) Inclusion and Exclusion Criteria

Inclusion criteria: Female patients over the age of 18 scheduled for laparoscopic gynecological procedures of the uterus, fallopian tubes, and/or adnexa benign disease will be included in our study.

Exclusion criteria: Males, women under 18 years of age, women who are pregnant or have suspected or known malignant disease, or women who are immunocompromised will be excluded from our study. Patients with known or persistent abuse of medication, drugs, or alcohol. Patients with chronic pain for greater than 3months will also be excluded.

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(NOTE: You may not include members of vulnerable populations as subjects in your research unless you indicate this in your inclusion criteria.)

c) Number of Subjects: 100

A total of 100 patients will be recruited and there will be 50 in the study group and 50 in the control group. This was determined because we are looking for a difference in narcotic use of 1.5 tablets to be considered significant. Assuming a standard deviation of 2.4 (prior data) , we will need to study 47 experimental subjects and 47 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal and discern a difference of 1.5, with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05.

d) Study Timelines

The anticipated duration of the study is 12 months including recruitment and data analysis. Eligible patients will be offered enrollment in the study during their pre-operative assessment with Dr. Ascher-Walsh, Mamik, or Fenske typically occurring 1-3 weeks prior to surgery. Patients will then be followed throughout their hospital course. Follow up will occur at their post-operative visits 2 weeks after the procedure.

e) Endpoints

The purpose of the present study is to determine the effectiveness of acupuncture in post-operative pain management in laparoscopic gynecological procedures. The endpoints of this study are narcotic use at 24 hours, hospital admission for pain management, and narcotic use for 7 days following surgery. Primary outcome measures narcotic use at 24 hours. Secondary outcome measures are quantity of opioids used for pain management for the first 7 days post operatively and hospital admission.


Safety endpoints that would cause a subject’s participation to end are contact dermatitis from the placement of acupuncture needles. This is a very uncommon response.

f) Procedures Involved in the Human Research

Female subjects who are scheduled to undergo a laparoscopic surgery of the uterus, adnexa or ovaries for benign disease. All procedures will be performed for clinical patient care and not solely for research purposes. Patients will be offered enrollment in the study during their pre-operative visit with Dr. Ascher-Walsh, Dr Mamik, and Dr Fenske and consented by one of the participating fellows.

Once consented, participants will be randomized into the acupuncture (study) or sham acupuncture (control) group using a computer-generated randomization system. The patient will be blinded to the group to which they are assigned.

After general anesthesia induction and proper positioning of the patient, but prior to surgical incision, the acupuncture needles will be placed. In the study group, the proposed acupuncture points are LR-3, GB-41, GB-34, TH-5, MH-6, which are all found on upper and lower extremities. Standard

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acupuncture needles 29 and 30 gauge will be used throughout. As in standard acupuncture treatments, the needles will be left in-situ for a total of 15 minutes. In the control group, the primary surgeon (who has no acupuncture experience) will quickly place 5 needles in random spots on the patients' hands and feet. The needles will be immediately removed. Anesthesiologists will be informed to not make any alterations in their typical anesthesia regimen based due to the placement of acupuncture needles.

Nursing staff will record the kind and dose of pain medications the patient requires in the PACU. This information will also be recorded on the data sheet. After four hours, Dr. Ascher-Walsh will determine if the patients will be discharged home or admitted. Reasons for admission include but are not limited to inadequate pain control, hemodynamic instability, conversion of laparoscopic case to laparotomy, or other adverse outcomes that necessitate close monitoring. Criteria for discharge include adequate pain control, hemodynamic stability, and patient ability to ambulate and tolerate oral intake. Assessment of pain medications used will occur at hours 24 and 48 hours postoperatively either in the hospital or over the phone if the patient was discharged. The patient will continue to keep track of her narcotic use until 10 days post-operatively. The patient will bring her data log of medications taken and her narcotic pill bottles with the remaining tablets to her post-operative visit.

The data will be analyzed and stored by the research team.


g) Specimen Banking

There will be no specimen banking

h) Data Management and Confidentiality

The data will be stored in password-protected spreadsheets in which the subject's identity will be de-identified with a unique coding system. The research data and linking codes will be filed separately. Data will be stored separately from unique identifiers that can link the data to a person's identity. All computer files will be stored on computers connected with the MSSM server, and will also be password protected and viewed only by the research team. Data will be stored indefinitely and will only be accessible by the co investigators. The data will include demographic information (the subject code, age, operation performed, study group) and outcome measure data including pain scale numbers, amount of pain medications taken, and quality of life survey answers.

SPSS will be used for the data analysis. A power analysis was performed using prior data of narcotic use in Dr. Ascher-Walsh's post-operative gynecological patients. This data demonstrated the average number of narcotic tablets consumed at 24 hours is 3, with a standard deviation of 2.4. Overall we are aiming to achieve a decrease of 50% (or 1.5 tablets) for post-operative narcotic use at 24 hours. The number of patients required for such a difference is 47 experimental subjects and 47 control subjects. The Type I error probability associated with this test of this null hypothesis is 0.05. Further Data analysis will be performed using SPSS. The analysis of pain medication use and admission rate will be performed using student t-tests and regression analyses.

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i) Provisions to Monitor the Data to Ensure the Safety of Subjects

1. MSSM Principal Monitor: Dr. Charles Ascher-Walsh (PI)

Academic Title: Director, Division of Gynecology

Phone Number: 212-241-2827

Email: Charles.Ascher-walsh@mssm.edu

2. The choice of principal monitor is appropriate to assess the risks to the participants because he is the lead attending in this study and the attending physician of all of the study participants. He has done a large amount of gynecology research and has ample experience in assessing the safety and well-being of the participants.

3. All adverse events including contact dermatitis will be assessed at the specified endpoints. In addition the efficacy of the acupuncture in reducing pain will be determined.

4. The data will be analyzed after 50 and 100 patients.

5. The study will be terminated if it is determined that there is a significant difference between the study groups in post-operative pain control or if there are multiple incidences of adverse events related to the study protocol.

6. In the past, there has been a very minimal risk of dermatitis with standard acupuncture needles.

7. Standard sterile acupuncture needles will be used.


8. The points in question are safely accessible during positioning for gynecological procedures and do not impose an increased surgical or anesthetic risk. Treatment needles will be placed by a licensed acupuncturist. Control needles will be placed superficially in predetermined locations. These needles will only puncture the skin and then will be immediately removed.

9. The data will be collected and stored in an organized fashion and will be checked by multiple co investigators to ensure that it is complete and accurate.

10. If the patient is negative impacted in any manner, it will be reported to the IRB.

j) Withdrawal of Subjects

Subjects will be able to withdraw from the study at any time, except during the surgical procedure. It is not anticipated that subjects will be withdrawn from the study without their consent. If a

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subject chooses to withdraw early from the research the data collected up to that point of withdrawal will be analyzed using an intention to treat analysis

6) Risks to Subjects

Acupuncture will be given in a sterile fashion and the time it takes for a licensed acupuncturist to place the needles is less than 3 minutes. The needles in the control group will remain in place for fifteen minutes, at which time the patient will be prepped and draped in a normal sterile fashion. The needles in the control group will be placed superficially in the skin and immediately removed. The patient will not have an increased risk of infection or substantial time under anesthesia. Bleeding, cosmetic bruising, and infection are the present risks, but are extremely low and only reported as rare case reports. Pneumothorax has been quoted in the literature with thoracic points, however none of the points used will be in thoracic regions. Nerve damage is theoretical if in close proximity to a peripheral nerve but has not been reported. Foam pads will be placed around the hands and feet in order to prevent the movement of needles, even if external pressure is accidentally placed on the extremities. Lastly, all needles will be removed prior to start of the procedure.


All surgeries have the risks of bleeding, infection and damage to surrounding structures. With the exception of the aforementioned anesthetic risk, the general surgical risks are no greater in this study than if you have the same surgery without participating in the study. Economic risks due to time away from work or loss of function are also no greater than if the surgery was performed independent of the study. In fact, there may be a reduction in time away from work from the effects of acupuncture.

There always exists the potential for loss of private information; however, there are procedures in place to minimize this risk. These include utilizing a unique coding system that de-identifies subjects and stores data separately from unique identifiers and safeguarding private information in a password-protected database.

If a study subject believes that she has suffered an injury related to this research as a participant in this study, she should contact the Principal Investigator, Dr. Ascher-Walsh. If a subject suffered a complication of surgery related to the study, medical care will be provided by Dr. Ascher-Walsh and consulting physicians as necessary. Generally, this medical care will be billed to the subject and/or her health insurance. In some cases, the costs of this care may be paid for by Dr. Ascher-Walsh.

7) Provisions for Research Related Harm/Injury

If you are injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

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8) Potential Benefits to Subjects

It is important to know that the subject may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be a reduction in pain post operatively. The subject may have a decreased need for opioid pain medications, decreased length of stay in the post anesthesia care unit and lower chance of needing admission to the hospital for pain management.

9) Provisions to Protect the Privacy Interests of Subjects

Subjects will be consented by one of the participating attending physicians or a fellow in a private environment. All aspects of the office visits and surgery will be conducted in private. During surgery care is taken to keep the patient covered with a gown and sheets and to minimize exposure. Post operatively pain will be assessed privately. When the patients are called at home for post-operative follow up the researchers will only speak directly to the patient and will not leave messages or voice mails regarding the study. No general health information or information relating to the study will be discussed in the presence of family or friends accompanying the patient unless explicitly allowed by the subject.

10) Economic Impact on Subjects

There is no cost to the patient for participating in this study beyond those which the patient would pay for the medical care involved. Economic risks due to time away from work or loss of function are also no greater than if the surgery was performed independent of the study.


11) Payments to Subjects

There is no financial incentive to participate.

12) Consent Process

Potential study subjects will be informed and consent obtained in the outpatient setting during their pre-operative visit. The potential subjects will have adequate time to review the material, free of time constraint or a sense of obligation or coercion. Consent will be obtained by Drs. Ascher-Walsh, Mamik or Fenske or by one of the fellows during their pre-operative visit in their private office, not immediately pre-operatively. The consent process will take place in a private room, not in a public area, such as a waiting room or public holding area. Prior studies have shown the average time to appropriately consent a patient during a pre-operative visit is 10 minutes. We will allocate at least 10 minutes to each individual consent process, however more time will be available if needed to address all patient questions and concerns. Patients will be given a copy of the study template and consent document, which will be available in English.

Children

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No children will be included in this study. Women must be over the age of 18 to consent.

Cognitively Impaired Adults

No cognitively impaired adults will be included in this study. Each participant must have the cognitive ability to consent herself.

Non-English Speaking Subjects

English speaking patients will be included. Women that speak any other language will not be included in our study

Waiver or Alteration of the Consent Process

There will not be a waiver or alteration in the consent process.

13) Process to Document Consent in Writing

The consent of all subject will be documented in writing, using the standard PPHS consent template.

14) Vulnerable Populations

Indicate specifically whether you will include (target) or exclude each of the following populations:


<i>Include</i>	<i>Exclude</i>	<i>Vulnerable Population Type</i>
	<i>X</i>	<i>Adults unable to consent</i>
	<i>X</i>	<i>Individuals who are not yet adults (e.g. infants, children, teenagers)</i>
	<i>X</i>	<i>Wards of the State (e.g. foster children)</i>
	<i>X</i>	<i>Pregnant women</i>
	<i>X</i>	<i>Prisoners</i>

15) Multi-Site Human Research (Coordinating Center)

N/A

16) Community-Based Participatory Research

N/A

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17) Sharing of Results with Subjects

The results will not be shared with the subjects.

18) External IRB Review History

There has been no prior IRB review of this study.

19) Control of Drugs, Biologics, or Devices

Our study does not involve drugs, biologics, or devices.