Abdominal ice packs for pain control and reduction of narcotic use following laparoscopic hysterectomy: a randomized controlled trial.

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Significance
The Center for Disease Control (CDC) released guidelines in 2016 on narcotic prescribing for chronic pain due to growing concern regarding narcotic abuse.[1] The guidelines suggest minimizing narcotic use for acute pain as a strategy to decrease the conversion to long-term use. With more than 600,000 hysterectomies performed annually in the United States,[2] there is a dire need for establishing alternative pain therapies after surgery. We aim to determine the effectiveness of abdominal ice pack use on decreasing narcotic use postoperatively. Ice pack use on the abdominal wall likely inhibits visceral afferent pain fibers via somatic afferent nerve cross-talk.[3,4] Importantly, patient-reported narcotic use has not been well documented so we will plan to accurately document post-discharge use by residual pill counts.

Innovation
Our goal is to quantify narcotic use after hospital discharge following hysterectomy, and evaluate the effectiveness of abdominal ice packs as low cost adjuncts for pain control. We hope to demonstrate the feasibility and effectiveness of ice packs for pain reduction as measured by postoperative narcotic use, patient pain scores, and patient subjective assessment of acceptability. Abdominal ice packs have yet to be studied as pain control adjuncts in laparoscopic surgery, thus this approach is novel.
We will assess narcotic use after discharge by collecting unused pills from patients. This is an innovative approach to document post-discharge narcotic use after laparoscopic hysterectomy, for which there is an absence of published data. Data on narcotic use after hysterectomy may become a basis for future recommendations on appropriate narcotic prescribing following hysterectomy. Demonstrating a clinically significant narcotic use reduction or pain reduction with abdominal ice pack therapy would likely lead to widespread adoption of the practice within gynecology.

Investigators
Tatnai Burnett, PI; Instructor, obstetrics & gynecology. MIGS surgeon with laparoscopic hysterectomy practice.
Gretchen Glaser, Co-I: Gynecologic oncologist with robotic hysterectomy practice.
Shannon Laughlin-Tommaso, mentor: epidemiology and research experience

ABSTRACT
Background
Hysterectomy is one of the most common procedures performed on women in the United States, with approximately 600,000 performed annually.[2] The Center for Disease Control (CDC) released guidelines in 2016 on narcotic prescribing for chronic pain due to growing concern regarding narcotic abuse.[1] The guidelines suggest parameters for narcotic prescribing for acute pain due to its relationship to long-term narcotic use, with a focus on limiting the amount of narcotics prescribed. This is based on evidence suggesting a direct relationship between use of postoperative narcotics in opioid naïve patients and increased risk of continued use in 1 year.[1] In light of the CDC guidelines, alternative means to reduce patient pain and narcotic use after hysterectomy are clinically relevant. In addition, documenting narcotic use patterns after hospital discharge following hysterectomy is vital to understand appropriate prescribing practices.

The use of postoperative cooling for pain has previously been shown to be effective in a variety of procedures, including laparotomy,[5] inguinal hernia repair,[6] total knee arthroplasty,[7] craniotomy,[8] oral surgery,[9] and tonsillectomy,[10] but has yet to be described for laparoscopic surgery. Safety in regards to surgical site infection (SSI) is evidenced by the routine use of postoperative ice packs in orthopedic surgery based on a robust literature demonstrating no increased rate of SSIs in total-knee arthroplasty with hardware placement or anterior cruciate ligament repair procedures.[7,11] Abdominal ice packs placed continuously for 24 hours after laparotomy in one study resulted in both decreased pain scores and reduced use of narcotics during the 24 hour time period, with no incidence of hypothermia.[5]

The primary investigator routinely uses abdominal ice packs following laparoscopic hysterectomy and has observed beneficial effects on pain reduction. In contrast to laparotomy where the wound is a significant pain generator and direct application of ice is intuitive, in laparoscopic surgery much of the pain-generating tissue trauma is intraperitoneal and pelvic in nature, away from the abdominal wall. A plausible mechanism for pain inhibition with abdominal placement of ice packs in this scenario may be found in abdominopelvic neuroanatomy. Cross-talk between neuro pathways has been used to describe referred pain to the abdominal wall via somatic nerve distributions despite originating from visceral afferents.[3] Pain from visceral afferent nerves traveling through the dorsal horn of the spinal cord come in close association with poorly myelinated somatic afferents, causing cross-talk to occur and referred pain in the corresponding dermatome.[4] This viscero-somatic convergence is reported between the ovaries/distal fallopian tubes and the iliohypogastric nerve, the proximal fallopian tubes/uterine fundus and the ilioinguinal/genitofemoral nerves, and the uterine fundus/lower uterine segment and

the lateral femoral cutaneous nerve. The reverse pathway, pain from the somatic afferents referring to the pelvic visceral afferents, has also been described.[4] Accordingly, applying ice to the abdominal wall and its somatic afferents may indeed have the ability to interfere in some fashion with pain signals originating from the pelvic visceral afferents and improve laparoscopic pain control despite the lack of a significant abdominal wound.

Hypothesis
The use of abdominal ice packs following laparoscopic hysterectomy will result in improved pain control and reduction in narcotic consumption compared to patients not using ice packs.

Specific Aims
1. Document average patient morphine metabolic equivalents (MME) consumption after laparoscopic hysterectomy from hospital discharge to narcotic self-discontinuation.
2. Evaluate the effect of abdominal ice packs vs routine care on total (MMEs) consumed by patients during the perioperative and entire postoperative period.
3. Evaluate the effect of abdominal ice packs vs routine care on validated pain measures during the first 12 hours after surgery.

Is the Research aiming to answer to an unmet need of the patient (either a specific clinical need or patient satisfaction)? If yes, please explain in detail.
Yes. Reducing postoperative pain and reducing postoperative narcotic use are unmet needs of the patient. Current postop pain regimens for laparoscopic surgery depend heavily on narcotic and non-narcotic medications, thus there is a need for low-cost non-medication alternatives. Furthermore, reducing narcotic use postoperatively may also reduce the risk of future narcotic dependence, which lies at the core of this unmet need.

Research Plan and Methods
Patients ≥ 18 years old undergoing laparoscopic (either conventional or robotic) hysterectomy will be recruited. Patients will be excluded for (a) taking opioid analgesics, including Tramadol, on a daily basis within the two weeks prior to surgery (b) planned ICU admission identified prior to randomization, (c) conversion to laparotomy or any incision ≥4 cm, (d) regional anesthesia or tap block use, and (e) planned same-day discharge. The intent of excluding patients who are opioid tolerant, defined as patients who are chronically receiving opioid analgesics on a daily basis, is to prevent confounding of our specific aims related to total opioid use.[12] Patients will not be excluded due to additional surgical procedures performed or due to malignancy as an indication for surgery. Trial will adhere to CONSORT guidelines.[13]

In the preoperative area, the Brief Pain Inventory-short form (BPI)[14,15] will be administered by study personnel, as the first of two questionnaires. The BPI short form is a validated measure that will allow for quick assessment of baseline and post-operative pain severity and impact on function. Preoperative and intraoperative medications will be standardized using a modified Magic Pathway (multimodal analgesia) with intraoperative narcotic guidelines. All intraoperative and postoperative pain management decisions will be left to the discretion of the subject's surgeon. Following incision closure, the surgeon will determine eligibility for randomization. Subjects will be randomized, using REDcap, by a study coordinator to abdominal ice pack plus routine care or routine Randomization will be stratified into two groups, patients with chronic pelvic pain (pain present for ≥ 6 months, excluding isolated dysmenorrhea) and patients without chronic pelvic pain; there will be no stratification for surgical approach. Blinding will not be possible for patients, physicians, or study coordinator.

A large zip lock bag (size standardized) full of ice chips, placed inside a pillow case, will be placed directly on the abdomen prior to leaving the operating room, for subjects randomized to ice therapy. Ice will be kept on the abdomen continuously for the first 12 hours, however patients will be allowed to remove and replace ice as desired for comfort. Bag will be refilled with ice by hospital staff as needed, and patient will carry the bag home for continued use after discharge. Patient will be encouraged to continue using ice pack through 24 hours and beyond if found to be helpful.

Safety will be carefully monitored in ice pack subjects. Ice packs will always be placed on the abdomen wrapped within a pillow case to reduce the risk of cold burns from ice being directly on the skin. Subjects may remove the ice at any time if discomfort is experienced, limiting the risk of frost bite. Unit nurse will check skin at minimum every 4 hours, and evaluate per the current Nursing Procedural Guideline: Ice Pack Use (immediate removal if skin appears mottled, gray, macerated, blistered, and/or if patient reports extreme burning or numbness). Any skin changes at subject discharge will be recorded as adverse events and prompt a protocol safety review if determined to be secondary to ice pack use (as opposed to skin prep,

bandages, etc.). Safety of a continuous use protocol has previously been demonstrated by Watkins et al, where continuous ice packs were used against an abdominal incision for 24 hours in 27 patients with zero patients experiencing thermal injury. Anecdotally, the primary investigator has be using continuous ice packs as described in this protocol for all laparoscopic hysterectomy patients since mid -2016; conservatively, over 90 patients during that time have used ice packs, with zero thermal injuries noted (the primary investigator personally sees and examines all of his patients on postoperative day 1, after 12-24 hours of ice pack use).

Demographics (i.e., age, gravida, para, BMI) and intraoperative statistics will be documented (surgical time, blood loss, uterine weight, additional procedures, intraoperative complications, use of pre- and/or post-incision local analgesia). During postoperative admission, arrival time to PACU, lowest recorded temperature, pain scores (arrival to PACU, last pain score in PACU, and all inpatient pain scores through 12 hours), and immediate complications will be recorded. Inpatient pain scores will be abstracted from the medical record nurse charting, which per protocol are at minimum every 4 hours.
After between 12 and 24 hours or at hospital discharge (whichever occurs first), subjects will be administered a second survey, reflecting a compilation of the following tools. The ice group will be asked to complete the BPI short form, the Overall Benefit of Analgesia Score (OBAS)[16] measure, and answer questions assessing ice pack tolerability, satisfaction with pain control, and perceived adherence to use (% of time ice pack perceived to be on abdomen during first 12 h). Routine care patients will only complete the BPI short form and OBAS. The OBAS is a 7-item, validated tool specifically designed for post-operative assessment of pain, side effects and satisfaction with analgesia within the first 24 hours following surgery[17].

MMEs will be recorded in split timeframes: starting from subject arrival at PACU to discharge from PACU; arrival to floor until 12 hours s/p surgery; 12 hours s/p surgery until hospital discharge; and from hospital discharge to self-discontinuation. Hospital charts will be used to obtain MMEs while subjects are admitted. Subjects will be instructed to keep unused narcotic medication and bring it with them for accurate use counts at the scheduled post-operative visit, typically six weeks following dismissal. A medication/pain diary will be kept by patients after discharge to include pain scores and all narcotic-type medications consumed, including those not prescribed for the current surgery. The diary will be kept daily until the last dose of narcotic pain medication is needed. Subjects in the treatment arm will additionally record duration of ice pack use during the first 24 hours after hospital discharge. This measure will be incorporated into the diary for ease of completion.

At the scheduled postoperative visit, pill counts will be completed, medication/pain diary collected, and 30-day postoperative complications (surgical site infections, readmissions, etc.) assessed. If patients do not return to Mayo Clinic for a postop exam, a prepaid envelope will be sent to have diary returned by mail and complications/readmissions and pill count assessed by phone with the study coordinator.

Statistics
Descriptive statistics will be applied to demographics, intraoperative, and postoperative data. Comparisons between groups will be performed using a 2-tailed *t*-test or Mann-Whitney U for parametric and non-parametric data as appropriate. A *p*-value of 0.05 will be used to determine statistical significance.

Primary analysis will be an intention-to-treat analysis of total MME use after surgery. Secondary analyses will evaluate effect on pain scores, patient satisfaction with pain control,

No previously published data on narcotic consumption after discharge for any minimally invasive hysterectomy (vaginal, laparoscopic, robotic) could be identified in a literature search. Chart review averaging 3 patients' data demonstrated average use of 150 MMEs after laparoscopic hysterectomy from PACU admission to hospital discharge. Assuming use of 20 oxycodone 5 mg tablets following discharge yields an additional 150 MMEs; total estimated use after laparoscopic hysterectomy is 300 MMEs. Considering a 20% MME reduction as clinically significant (8 x 5mg oxycodone pills), an alpha of 0.05, power of 90%, and SD of 100 MMEs with a 1:1 sampling ratio, 59 subjects per arm (total 118) would be required to demonstrate a statistically significant difference. Addition of a 20% margin for losses to follow up, pre- and post-randomization exclusions, 142 patients would be targeted for recruitment.

Impact
Publication is expected in a high impact factor journal given study design and potential for patient benefit. Results are directly relevant to current Mayo Clinic clinical practice and could immediately be applied to patient care. Additional research on narcotic use and/or ice pack therapy in other gynecologic surgeries could follow, as well as evaluation in specific patient populations such as chronic pelvic pain. This could allow development of an area of clinical expertise for personal

career development. Data from this study, if positive, could tie in to the current enhanced recovery (ERAS) program adding to the current armamentarium. Further evaluation into other laparoscopic procedures may also be considered; grants from organizations such as AAGL and ACOG could be sought to support this expansion. If a difference is noted, then more sophisticated ice packs or cooling systems could be an interest to Mayo Clinic Ventures and an application for device creation could be submitted at next available RFA.

Timeline

In 2016, 586 laparoscopic or robotic hysterectomies were performed at Mayo Clinic Rochester. Rate of preoperative narcotic use in this population is unknown, but 20% estimate would be generous. This would leave about 470 patients for recruitment, and assuming an enrollment of 50% we are left with 235 subjects in a year. As such, 12 months or less for subject recruitment, should be sufficient; 6 months are estimated for protocol development and IRB approval, and another 6 months for data analysis, manuscript preparation, and publication. Total projected time from project initiation to publication would 2 years.

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MAYO CLINIC

Name and Clinic Number

Approval Date: **October 25, 2018**
Not to be used after: **October 24, 2019**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Abdominal ice packs for pain control and reduction of narcotic use following laparoscopic hysterectomy: A randomized controlled trial

IRB#: 17-007182

Principal Investigator: Tatnai Burnett, M.D. and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

MAYO CLINIC

Name and Clinic Number

Approval Date: **October 25, 2018**
Not to be used after: **October 24, 2019**

CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator(s): Dr. Tatnai Burnett **Study Team Contact:** Marnie Wetzstein, RN	**Phone:** (507) 538-5783 **Phone:** (507) 266-4813 **Institution Name and Address:** Mayo Clinic 200 First Street Southwest Rochester, MN 55905	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Subject Advocate (The RSA is independent of the Study Team)	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information
Research Billing	**Rochester, MN:** (507) 266-5670	▪ Billing or insurance related to this research study

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law, and http://www.mayoclinic.org. These web sites will not include information that can identify you. At most, the web sites will include a summary of the results. You can search this web site at any time.

1. Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you are scheduled to undergo a laparoscopic (conventional laparoscopic or robotic laparoscopic) hysterectomy, a surgical procedure to remove the uterus.

The plan is to have about 142 people take part in this study at Mayo Clinic.

2. Why is this research study being done?

The purpose of this study is to evaluate the effect of using ice packs on the abdomen immediately after laparoscopic hysterectomy surgery on pain control.

3. Information you should know

Who is Funding the Study?

Mayo Clinic is funding this study.

4. How long will you be in this research study?

You will be in this study from the time of your surgery until your post-operative examination, which occurs approximately six to eight weeks after surgery.

5. What will happen to you while you are in this research study?

If you are eligible for the study, you will be asked to participate in the following:

We will assign you by chance (like a coin toss) to the routine pain control group or the ice and routine pain control group. You and the Principal Investigator can't choose your study group. You will have an equal chance of being assigned to either group.

> Routine pain control group - You will receive the pain medication routinely provided after surgery.
>
> Ice and routine pain control group - You will use an ice pack on your abdomen continuously for the first 12 hours after surgery and receive pain medicine, as routinely provided after surgery. The ice may be removed during the first 12 hours, as needed, for comfort. Ice may continue to be used after 12 hours, if desired for your comfort.

You will be asked to complete a pain questionnaire just before surgery, which will take approximately two minutes to complete. You will be asked to complete a second pain questionnaire between 12 and 24 hours after surgery, before you are dismissed home. This questionnaire will take approximately five minutes to complete.

You will be provided a simple diary to record your daily pain scores, use of narcotic pain medicine, and if in the ice group, use of ice for post-operative pain control, after discharge from the hospital. We will ask you to record your responses in the diary daily until you are no longer requiring narcotic pain medication and, if in the ice group, are no longer using ice packs. When you return to the clinic approximately 6-8 weeks after surgery, the study team will review your home diary and ask you to count how many narcotic pain pills you have remaining from the prescription provided in the hospital. If you are seeing a provider closer to home for a post-operative visit, a study team member will call you to review the diary and ask you to count the remaining narcotic pain pills.

We will also collect information about your health from you and your medical record up to approximately six-eight weeks after surgery.

6. What are the possible risks or discomforts from being in this research study?

Ice can cause burns when applied directly to the skin or for extended periods of time. To minimize this risk, we will apply the ice pack in a cloth cover to protect your skin. You may remove the ice at any time for discomfort. Further, the nursing staff will monitor your skin during the time the ice packs are used in the hospital.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

8. What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

9. What are the possible benefits from being in this research study?

This study may not make your health better. However, other women undergoing laparoscopic hysterectomy may benefit in the future from what we learn in this research study.

10. What alternative do you have if you choose not to participate in this research study?

You don't have to be in this study to receive treatment for your condition. You can undergo a laparoscopic hysterectomy and receive the routine pain management.

11. What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Pain questionnaires and diary
- Ice packs

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

12. Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

13. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. The data collected for this study will be stored and evaluated on password protected computers on the Mayo Clinic campus. This data will only be accessible to study personnel.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

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ENROLLMENT AND PERMISSION SIGNATURES

Your signature documents your permission to take part in this research.

		: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

		: AM/PM
Printed Name	Date	Time

Signature