Transdermal Lidocaine Patch for post-Cesarean pain control for women with obesity: a single-blind randomized controlled trial

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UW-Madison Department of Obstetrics and Gynecology

RESEARCH SUBJECT INFORMATION AND CONSENT FORM	
TITLE:	**Transdermal Lidocaine Patch for post Cesarean pain control for women with body mass index >30: a single-blind randomized controlled trial**

This consent form contains important information to help you decide whether to participate in this research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may discuss this consent form with family or friends. Take as much time as you need to decide if you want to be in this research.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

Before signing this consent form you should be able to answer the following questions.

- Why is this research study being done?
- What will happen to me during the study?
- What are the possible risks to me?
- What other options could I choose instead of being in this study?
- How will my personal health information be treated during the study and after the study is over?
- Will being in this study cost me anything?
- What to do if I have problems or questions about this study?

Please read this consent form carefully.

CONSENT TO BE PART OF A RESEARCH STUDY

Study title: Transdermal Lidocaine Patch for post Cesarean pain control for women with body mass index >30: a single-blind randomized controlled trial

Company or agency sponsoring the study: Department of Obstetrics and Gynecology, University of Wisconsin-Madison

Name, degrees, and affiliation of the Principle Investigator conducting the study: Kathleen M. Antony, MD, MSCI; Division of Maternal-Fetal Medicine; Department of Obstetrics and Gynecology, University of Wisconsin-Madison

1. RESEARCH SUMMARY & INVITATION

Key Information Summary

We are asking you to choose whether or not to volunteer for a research study about the use of a lidocaine skin patch applied at the time of Cesarean delivery for pain management. This key information is to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?
By doing this study, we hope to learn if a lidocaine patch will reduce the dose of opioids received after a Cesarean delivery. Your participation in this research will last about 6 weeks.

On the day of your Cesarean delivery, you will randomly receive either the lidocaine or placebo patch. The placebo patch will look the same as the lidocaine patch, but have no active medicine. The group assignment is random, much like the flipping of a coin, and you will not be told to which group you have been assigned.

After the surgery is complete, the patch will be applied while you are in the operating room. The patch will be removed after 12 hours. You will take a pain control survey at 2 and 6-weeks after giving birth. The study team will collect medical record information about you. For more information, refer to the Detailed Consent that follows.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
You may not personally benefit from this study, but your participation in the study may benefit other women in the future. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
The study risks include an allergic reaction to the patch or lidocaine and a breach of confidentiality. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of this study is Kathleen M. Antony, MD of the University of Wisconsin, Department of Obstetrics and Gynecology. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: 608-417-6099.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact UPH – Meriter Institutional Review Board during business hours, Monday-Friday at 608-417-6411.

You are invited to take part in this research because you will be delivering your baby by Cesarean. Your participation is voluntary.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
The purpose of this study is to find out if a lidocaine skin patch applied near the Cesarean incision after delivery will reduce the total dose of opioids received for pain management. Subjects will wear the patch for 12 hours after their delivery.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?
Women who have a body mass index greater than or equal to 30 before becoming pregnant who will have a Cesarean delivery at UnityPoint-Health Meriter Hospital.

3.2 How many people (subjects) are expected to take part in this study?
60 women are expected to take part in this study.

4. INFORMATION ABOUT STUDY PROCEDURES

4.1 What exactly will be done to me in this study? What kinds of research procedures will I receive if I agree to take part in this study?

On the day of your Cesarean delivery, you will randomly receive either the lidocaine or placebo patch. After the surgery is complete, the patch will be applied by an operating room nurse or physician while you are in the operating room. The patch will be removed after 12 hours.

We will ask you to complete a survey at two weeks and six weeks after the birth of your child. You will receive an email or a call about completing a survey on pain you experienced after your Cesarean surgery. You can complete these surveys on your home computer or a smartphone.

We will also be collecting information from your medical record, including lab test results and medications you are taking. We may need to collect some information about you from your newborn's medical record if it is not available in your records.

4.2 How much of my time will be needed to take part in this study? When will my participation in the study be over?

The placement of the patch will not take any of your time and will not add to your time under anesthesia or in the operating room. Follow-up surveys will be completed at home. Each survey will last approximately 5 minutes. The last survey will be done at 6 weeks post-surgery and will end your study participation.

4.3 What will happen to my medical information?

Your identifiers will be removed from your medical record data collected for this research. There is a possibility that your de-identified medical information collected for this research, could be used for future research studies or distributed to another investigator for future research without asking for your consent.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The risks of a lidocaine skin patch are not very common. Risks include an allergic reaction to the patch or to lidocaine. Other symptoms may include a localized burning sensation, nausea, dizziness, drowsiness, confusion, blurred vision, ringing in the ears and serious skin reactions such as blistering. If you experience an allergic reaction to the study patch, have pain or irritation, or want to discontinue it for any reason, the patch will be removed.

There is a risk of breach of confidentiality. To prevent a breach, paper research documents will be stored in a locked cabinet in the research coordinator's locked office. Electronic information about you will be stored in a password protected HIPAA compliant secure server designed to securely store protected patient health information.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even when the researchers are careful to avoid

them. If you believe that you have been harmed, notify the researchers listed in Section 10 of this form.

In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, (Kathleen M. Antony) at 608-417-6099 if you are injured or for further information.

5.3 If I take part in this study, can I also participate in other studies?
You may be eligible to participate in other research studies. However, you should discuss participation in more than one study with the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. Your participation in the study may benefit other women in the future. This study may help reduce the total dose of opioids given post-op after Cesarean delivery.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?
There is no alternative. Participation is voluntary. There is no penalty if you choose not to participate. If you decide not to participate, your clinical care or any relationship you have with the UnityPoint Health-Meriter will not be affected in any way.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please notify one of the persons listed in Section 10 “Contact Information” (below).

If you withdraw from the study before your Caesarean, we will not keep any information on you. If you discontinue study participation any time after your Caesarean, we will keep the study information we have about you.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
There are no dangers if you leave the study early.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Will taking part in this study cost me anything? Will I or my insurance company be billed for any costs of the study? If so, which costs? What happens if my insurance does not cover these costs?
Participation will be at no cost to you. No costs related to research procedures will be billed to your insurance company or you.

8.2 Will I be paid or given anything for taking part in this study?
You will receive one package of diapers for your newborn at the time of discharge.

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of the study.

9. CONFIDENTIALITY OF SUBJECT RECORDS

UnityPoint Health - Meriter policies require that private information about you be protected. This is especially true for your personal information.

On the other hand, sometimes the law allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?
Your research information will be stored in a locked cabinet and will not be made a part of your regular medical record. However, if the researcher orders any tests, the order and results may become part of your regular medical record.

All study records will be maintained in locked rooms and access will be limited to essential study personnel. Electronic study records/files will be stored on a secure UW-Madison web-based application and on a UW-Madison or UnityPoint Health-Meriter secure department

server and accessed via networked computers that are password-protected with access provided only to authorized study personnel.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

There are many reasons why information about you may be used or seen by the researchers or others during this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- UnityPoint Health - Meriter IRB, or other officials may need the information to make sure that the study is done properly.
- Organizations that are funding the study may need the information to make sure that the study is done properly.
- Safety monitors or committees may need the information to make sure that the study is safe.
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- UW Madison Research Oversight Offices

The results of this study could be published in an article or presented at a scientific meeting, but would not include any information that would let others know who you are.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:	Dr. Kathleen Antony, MD
Mailing Address:	1010 Mound Street, 4th floor Madison, WI 53715
Telephone:	608-417-6099
Study Coordinator:	Melissa Zernick

Mailing Address: 1010 Mound Street 4th floor
McConnell Hall
Madison, WI 53715
Telephone: 608-417-4218

You may also express a concern about a study by contacting the– UnityPoint Health - Meriter Institutional Review Board at:
608-417-6411
UnityPoint Health - Meriter
202 South Park Street
Madison, WI 53715

When you call or write about a concern, please provide as much information as possible, including the name of the researcher and details about the problem. This will help UnityPoint Health - Meriter officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

☐ This Consent document to be Part of a Research Study.
Note: A copy of this document will be stored in a separate confidential research file. We will also enter this consent into your medical record.

☐ Other (specify): HIPAA authorization for use of protected health information in research.

12. SIGNATURES

Research Subject:

I have discussed this study, its risks and potential benefits, and my other choices. My questions so far have been answered. If I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I will receive a copy of this form at the time I sign it and later upon request.

Signature of Subject: _____ Date: _____

Name (Print legal name): _____

Telephone number:_____

Email address: _____

Person Explaining Consent: _____,

Title:_____Date:_____

Signature of Person Explaining Consent:

_____

Researcher: Enter a signed copy of this consent in the subject's electronic medical record. Use the same method you would use for other signed consent forms.