Management of indwelling labor epidural catheters and pain during cesarean delivery: a prospective single-center patient-reported outcome study

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BAYLOR SCOTT & WHITE RESEARCH INSTITUTE
Baylor Scott & White Medical Center-Temple

CONSENT FORM AND PRIVACY AUTHORIZATION

PROJECT TITLE: Management of indwelling labor epidural catheters and pain during cesarean delivery: a prospective single-center patient-reported outcome study

PRINCIPAL INVESTIGATOR: Michael Hofkamp, M.D.

TELEPHONE NUMBER: 254-724-3370

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering taking part in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future. Taking part in this study is voluntary.

1. WHY HAVE I BEEN ASKED TO TAKE PART IN THIS STUDY?
You are being asked to take part in this research study because you had an epidural (a pain-blocking injection that uses a tiny tube called a catheter to deliver medicine) at the time of your cesarean delivery.

2. WHY IS THIS STUDY BEING DONE AND HOW LONG WILL IT LAST?
This study is being done to determine whether removing a labor epidural catheter and performing a single injection spinal anesthetic or a combined spinal epidural anesthetic provides better pain control for patients who have a cesarean delivery. Your participation in the study will be to complete the written surveys which we estimate will take around three to five minutes. After that, we will collect information from your medical record and enter it into our database. Once you complete the survey there is nothing more for you to do.

3. WHAT WILL I BE ASKED TO DO IN THIS STUDY?
If you decide to take part in this study, you will be asked to complete a four-item survey that asks you about your pain during your cesarean delivery and a 13-item survey that measures how you deal with pain.

4. WHY MIGHT I WANT TO TAKE PART IN THIS STUDY?
If you agree to take part in this study, there will not be direct medical benefit to you. We hope that the information learned from this study will benefit other patients who have cesarean deliveries in the future.

5. WHY MIGHT I NOT WANT TO TAKE PART IN THIS STUDY?

There are no risks or benefits to you for being in this study. We hope that what we learn in this study will help others with your condition in the future. Your other option is to not be in this study.

For a complete description of known risks, refer to the Detailed Information section of the consent form and privacy authorization.

6. WHAT OTHER OPTIONS ARE THERE?

Your other option is to not be in this study. Being in this study is completely voluntary and you do not have to take part.

7. HOW WILL TAKING PART IN THE STUDY AFFECT ME FINANCIALLY?

There is no additional cost to you if you take part in this study and you will not be paid to participate in the study.

What is the Status of the Procedures or Techniques Involved in This Study?

You will be requested to complete the survey and give us permission to collect data from your medical record.

How Many People Will Take Part In This Study?

About 250 people will take part in this study at Baylor Scott & White Medical Center-Temple.

What Will I Be Asked To Do?

You will be asked to allow the researcher to review your medical records and copy the information from these records into their research charts for this project. This information will be reviewed by the researcher and their staff to answer the specific question as outlined above.

You will be asked to complete two questionnaires with a total of 17 questions which will ask you questions about your experience during your cesarean delivery and how you deal with pain. We estimate it will take about three to five minutes to complete all the survey questions. Once you have completed these questionnaires you will give them to the researcher or their staff so that they can review them for their research report.

How Long Will I Be In The Study?

You will be in this study for the time it takes you to complete the survey which we estimate to be three to five minutes.

The researcher may decide to take you off this study if they feel that it is in your best interest, if you are not able to follow the rules of this study, if this study is stopped before it is finished or if new information becomes available that indicates it would be best for you to stop being in this study.

You can stop taking part in this study at any time. If you decide to stop taking part in this study, you should let the researcher or his/her staff know so that they can make sure you are safely taken out of this study.

What Are The Risks of The Study?
The main risk of this study is loss of confidentiality. We will use secure methods to collect and store your data to prevent this from happening.

What About Confidentiality?
You have a right to privacy. This means that all the information about you from this study will only be shown to the people working on this study. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used. All information about you from this research project will be kept in a locked office or other locked area. Information that is kept on computers will be kept safe from access by people who should not see it.

The privacy law requires that Baylor Scott & White Research Institute and your doctors and other health care providers and facilities that have provided services to you, which could include physicians that work for the Scott & White Clinic, HealthTexas Provider Network or Texas Oncology, P.A., Baylor University Medical Center, Baylor-Scott & White Medical Center-Temple and other health care providers depending on where you have received care (collectively, Your Health Care Providers) get your permission before giving any of your health information to other people. There are people who need to review your information to make sure this study is done correctly. These people may look at or copy your information while they are doing this review. When you sign this form you give permission to BSWRI and Your Health Care Providers to give other people information about your health as needed for the research project. These groups include people who work for BSWRI (including the Institutional Review Boards), Baylor Scott and White Health, the US Food and Drug Administration, the Office for Human Research Protections and the Association for the Accreditation of Human Research Protection Programs Even though we usually remove your name from the information, the people who get this information may be able to figure out who you are. The kinds of health information that might be given to these people include results from lab tests or other tests like x-rays. This information might also include notes and other information in your medical records. We may ask for these notes and other information in your medical records from Your Health Care Providers. This means that the records of your care and information about you maintained by Your Health Care Providers may be given to the people mentioned above and, by signing this form, you are agreeing that Your Health Care Providers may release this information to these people.

You do not have to give this permission and it is all right to refuse to sign this form. Your doctor will still treat you and your insurance company will still pay your medical bills (according to their policy) even if you do not give your permission for BSWRI and Your Health Care Providers to release this information. However, since it is important for the people listed above to have access to your information, if you do not sign this form, you cannot be in this study.

If you give permission to BSWRI and Your Health Care Providers to give other people information about your health and the other people are not part of the group that must obey the privacy law,

your health information will no longer be protected by the privacy law. However, we will take all reasonable measures to protect your information from being misused.

If you change your mind and later want to withdraw your permission, you may do so. You must notify BSWRI in writing at 2001 Bryan St, Suite 2200, Dallas, TX 75201. Please be sure to tell us the name of this study and the PI for this study for which you are withdrawing your permission. BSWRI will provide your withdrawal notice to Your Health Care Providers promptly after BSWRI receives your withdrawal notice. While not required, you should also talk to your PI and Your Health Care Providers and make sure they are aware you are withdrawing your permission. If you withdraw your permission, it will not apply to information that was given to others by BSWRI before you withdrew or to information given to others by Your Health Care Providers before Your Health Care Providers receive your notice withdrawing your permission. If you withdraw your permission, you will no longer be able to take part in this study.

You may not be allowed to look at your health information during this study. However, at a later time, you will be able to look at this information. This later time will be sometime after this study is completed.

Unless permission is withdrawn, this permission will not expire at the end of this study.

What are My Rights As a Subject?

Taking part in this study is voluntary. You may choose not to take part or may leave this study at any time. If you agree to take part and then decide against it, you can withdraw for any reason.

Deciding not to be in this study, or leaving this study early, will not result in any penalty or loss of benefits that you would otherwise receive.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

Whom Do I Call If I have Questions or Problems?

If you have concerns, complaints or questions about this study or have a research-related injury, contact the Principal Investigator at 254-724-3370 or by e-mail at Michael.Hofkamp@bswhealth.org.

For concerns, complaints or questions about your rights as a research subject or if you simply wish to speak with someone who is not a part of the research staff, contact the IRB Office at 254-215-9697.

Statement of Person Obtaining Consent:

I have explained to _____(printed name of subject) the purpose of this study, the procedures required and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to taking part in this study. I gave a copy of this consent to the subject.

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

Confirmation of Consent by Research Subject:

You are making a decision about being in this study. You will be asked to give your written consent if you want to be in this study. Giving consent is like giving permission. You should not give your permission to be in this study until you have read and understood all pages in this form. Make sure that all your questions about this study have been answered before you sign this form. When you sign this form, you are giving your permission to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence.

_____ (printed name of person obtaining informed consent) has explained to me the purpose of this study, the study procedures that I will have, and the possible risks and discomforts that may happen. I have read (or have been read) this consent form. I have been given a chance to ask questions about this study and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other options. To the best of my knowledge, I am not in any other medical research. Therefore, I consent to take part as a subject in this study and authorize the activities described in this consent. I also acknowledge that I have received a copy of this consent form.

_____	_____	_____
Signature of Subject	Date	Time