Laparoscopic TAP Block for Sleeve Gastrectomy: Does Timing Matter

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	CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 02/2012)	DATE: MRN: NAME:
	PROJECT TITLE: **Laparopscopic TAP block for sleeve gastrectomy: Does timing matter?**	

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1. WHY IS THIS RESEARCH BEING DONE?

To make reading this consent form easier, the word “you” refers to you.

You have been asked to take part in a research study because you are having a laparoscopic sleeve gastrectomy. The laparoscopic sleeve gastrectomy is a surgical procedure you undergo to remove a large portion of your stomach for the purposes of weight loss. The purpose of this research study is to determine whether early or late intraoperative transverse abdominus plane block (TAP) block will provide better postoperative pain control.

As part of this study, you will have a procedure called a transverse abdominis plane block (TAP block). This procedure is not experimental. Currently, all of our sleeve gastrectomy patients are receiving this type of analgesia during surgery which involves injecting a numbing medication in between the muscles of the abdomen. Our study is investigating whether injecting the medicine at the beginning of the surgery or at the end of the surgery makes a difference in your pain post-operatively.

On the next page, you will see a diagram of your abdominal wall. The muscles shown in the diagram are what people consider their abdominal muscles on the sides of their abdomen. The diagram is showing a needle been placed through the outside of your body by your surgeon with the tip inserted between two of the innermost abdominal muscles (the area highlighted red). While this is being performed, the surgical assistant is holding the camera **inside** the abdomen looking for the “bulge” noted on the diagram. This bulge is the numbing medication being injected by your surgeon between the innermost abdominal muscles where it will take its effect of numbing your abdominal wall and providing you pain relief after surgery. This is done under sterile conditions to minimize any chance of infection related to the TAP block. It takes about 2 additional minutes to undergo a TAP block, and you will be asleep during this process.

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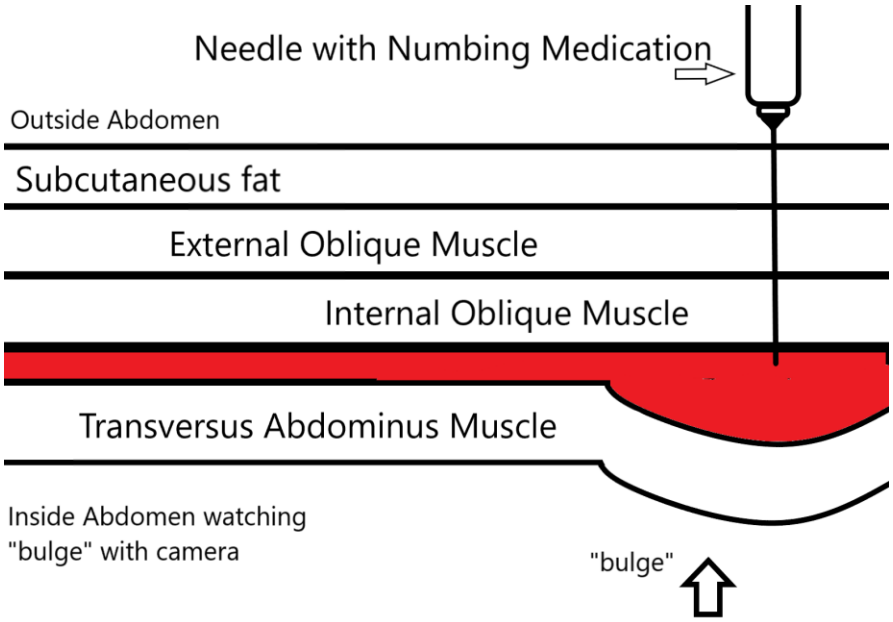
As part of this study, you will be given the drug bupivicaine. It is the numbing medication injected into your abdominal muscles, and it can last up to 9 hours. This drug is approved by the FDA (Food and Drug Administration) for this purpose, and has been used routinely for TAP blocks like the one you will receive. You will receive 90 mls of the drug which has been determined to be a safe amount according to the FDA.



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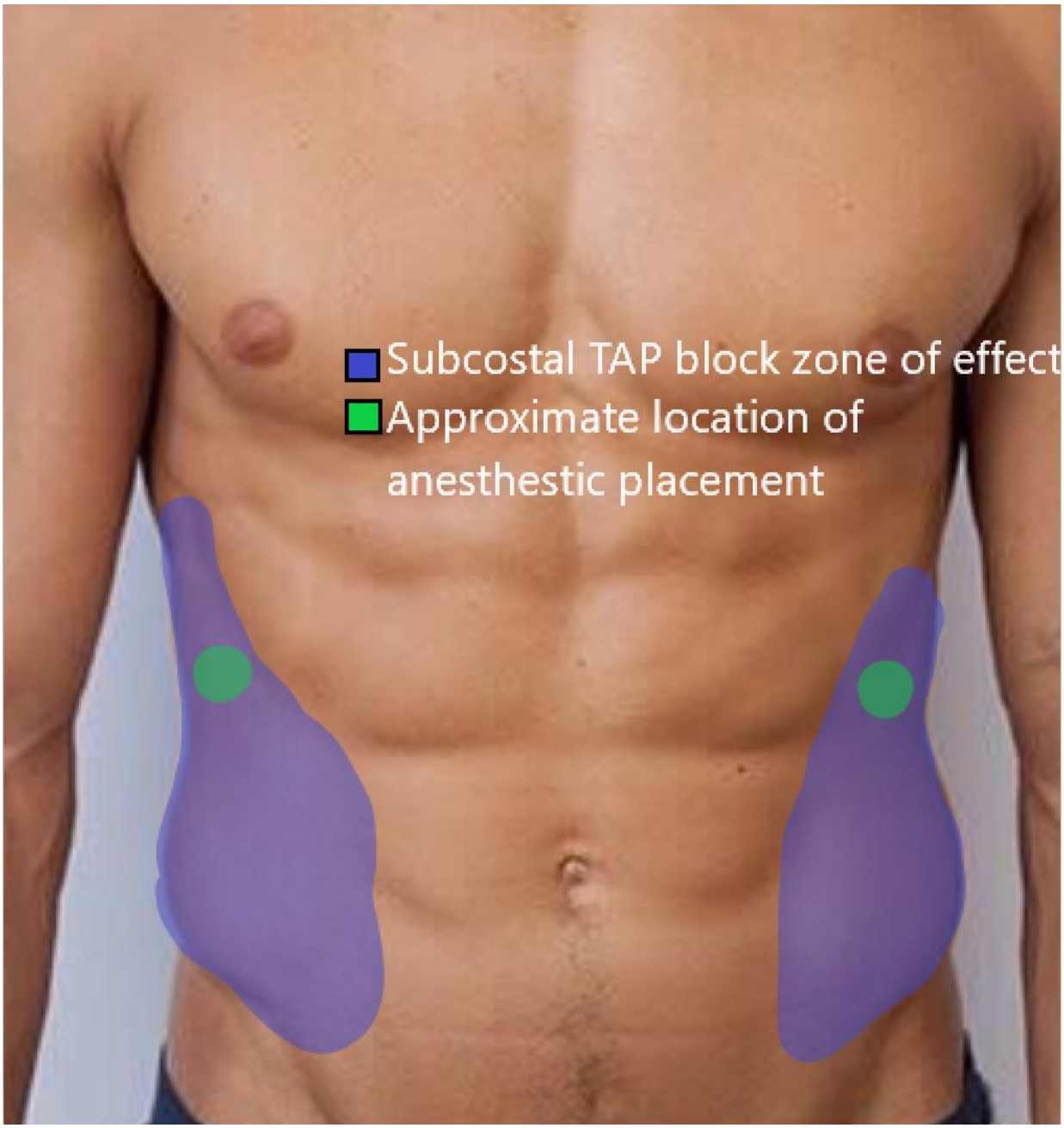

2. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

There will be 2 groups in the study. The group you are assigned to will be chosen by chance (like flipping a coin). One group will be receiving the TAP block at the beginning of the surgery just shortly after being put to sleep. The other group will be receiving the TAP block at the end of surgery just prior to waking up.

Your participation in this study after receiving the TAP block will last a total of 1-2 days. As part of this study, you will have frequent pain assessment scores after surgery during which you will have to answer a pain scale questionnaire. These pain assessments will be done at regular intervals throughout the afternoon, evening, and early morning after surgery as your pain may change with the different time of day. This is not extra and not experimental and is routinely done to monitor your well-being after surgery.

3. WHAT ARE THE RISKS OF THE STUDY?

As stated previously, the TAP block is routinely performed during this surgery by Dr. Carlin. The risks of this study are limited to the risks of receiving this numbing medication. Known adverse effects of bupivacaine are less likely but include confusion, and headache. Other known adverse effects of the medication that are rare but serious include cardiac arrhythmias and low blood pressure, Some people can be allergic to the drug. The risk of being allergic to the drug is rare but serious. You should tell the person obtaining your consent about any other medical research studies you are involved in right now and divulge any known drug allergies especially to local anesthetics such as Novocain or lidocaine.

4. WHAT OTHER OPTIONS ARE THERE?

You do not have to participate in this study. Should you choose not to participate, your other choices may include:

- Having the sleeve gastrectomy without being in the study and receiving no TAP block; or
- Having the sleeve gastrectomy without being in the study and receiving the TAP block

Talk to your doctor about your choices before you decide if you will take part in this study.

5. WHAT ABOUT CONFIDENTIALITY?

By signing this consent form, you agree that we may collect, use and release your personal and health information for the purpose of this research study.

We may collect and use:
- Your existing medical records.
- New health information created during this study.
- Health insurance and other billing information.

We may release this information to the following people:
- The Principal Investigator (Dr. Carlin) and his associates who work on, or oversee the research activities.
- Government officials who oversee research (Food and Drug Administration).
- Other researchers at other institutions participating in the research.

Once your information has been released according to this consent form, it could be released again and may no longer be protected by federal privacy regulations.

This consent form, test results, medical reports and other information about you from this study may be placed into your medical record. Generally, you are allowed to look at your medical record. During the research study, you will not be allowed to look at your research study information that is not in your medical record.

HFHS or others may publish the results of this study. No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This consent to use and release your personal and health information will expire at the end of this research study.

You do not have to sign this consent to release your medical information and may cancel it at any time. If you decide not to sign this consent or cancel your consent, you cannot participate in this study. If you notify us that you wish to stop participating in this study, we may continue to use and release the information that

has already been collected. To cancel your consent, send a written and dated notice to the principal investigator (Dr. Carlin) at the address listed on the first page of this form.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the Web site will include a summary of the results.

6. WHAT IF I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study. You are not giving up any of your legal rights by signing this consent form.

7. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Dr. A. Carlin or his staff member has explained this research study and has offered to answer any questions. If you have questions about the study procedures, or to report an injury you may call the hospital at (586)-263-2300 and ask the operator to contact Dr. S. Diaz or Dr. K. Seeras. Medical treatment is available to you in case of an injury.

If you have questions about your rights as a research subject you may contact the Henry Ford Health System IRB Coordinator at (313) 874-4464. The IRB is a group of people who review the research to protect your rights.

8. DO I HAVE TO PARTICIPATE IN THIS STUDY?

No, your participation in this research study is voluntary. If you decide to participate, you can stop at any time. If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. There will be no penalties or loss of benefits to which you would otherwise be entitled if you choose not to participate or if you choose to stop your participation once you have started. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study.

9. WHO ELSE CAN STOP MY PARTICIPATION?

The Principal Investigator (Dr. Carlin) can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

10. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

11. WILL I BE PAID TO PARTICIPATE?

There will be no compensation to you for your participation in this study.

12. CONSENT

You have read this consent form or it has been read to you. You understand what you are being asked to do. Your questions have been answered. Any technical terms you did not understand have been explained to you. You agree to be in this study. You will be given a copy of this consent form.

_____ _____ _____
Signature of Subject Date Time

_____
Print Name of Subject

_____ _____ _____
Witness to Signature Date Time

_____
Print Name of Person Obtaining Consent

_____ _____ _____
Signature of Person Obtaining Consent Date Time