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PROCEDURE EDUCATION LITERATURE

We recommend that you read this handout carefully in order to prepare yourself or family members for the proposed procedure. In doing so, you will benefit both the outcome and safety of the procedure. *If you still have any questions or concerns, we strongly encourage you to contact our office prior to your procedure so that we may clarify any pertinent issues. "An educated patient is the best patient."*

MEDICAL TREATMENT OF ECTOPIC PREGNANCY WITH METHOTREXATE

Definition

Medical = the use of medicinal compounds or drugs for treatment (non-surgical)

Ectopic pregnancy = a pregnancy that develops outside of the normal location within the uterine cavity Methotrexate = a chemotherapeutic drug that interferes with cell growth

Ectopic pregnancy is a pregnancy outside of the normal *intrauterine* location, most often in the fallopian tube and rarely in the abdominal cavity or cervix. This happens when a fertilized egg establishes itself outside of the uterus and begins to develop there. Ectopic pregnancy is a serious condition and can quickly become life-threatening. Ectopic pregnancy is estimated to occur in between 1% and 2% of all pregnancies and is the leading cause of pregnancy-related death in the first trimester of pregnancy. Ectopic pregnancies cannot result in the birth of an infant.

Ectopic pregnancy occurs when the passage of the fertilized egg (ovum) through the fallopian tube to the cavity of the uterus is blocked or delayed. Risk factors predisposing a woman to ectopic pregnancy include:

- History of pelvic inflammatory disease (PID)
- History of salpingitis (infection within the fallopian tube)
- Chlamydia and gonorrhea
- Previous ectopic pregnancy
- Cigarette smoking
- Tubal sterilization
- Tubal sterilization reversal
- Previous pelvic surgery
- Use of an intrauterine device (IUD) at the time of conception
- Fertility drugs and assisted reproduction procedures
- Congenital abnormalities of the fallopian tube
- Administration of hormones to prevent pregnancy (emergency contraception)

Women with an ectopic pregnancy will sometimes experience symptoms that are typical of early pregnancy: nausea, vomiting, breast tenderness, and the absence of a menstrual period. The most common symptoms of ectopic pregnancy are mild, cramping abdominal or pelvic pain, vaginal bleeding and absence of a menstrual period. As an ectopic pregnancy grows larger, it can cause bleeding from the end of the fallopian tube or burst (rupture) through the wall of the tube. Sudden severe pelvic pain, pain in the shoulder or neck, urge to have a bowel movement, feeling dizzy or fainting, and a rapid heartbeat are all symptoms associated with the rupture of an ectopic pregnancy.

A woman with a suspected ectopic pregnancy will have several tests performed to determine if the pregnancy is within or outside of the uterus. Blood tests to measure levels of human chorionic gonadotrophin (hCG; a pregnancy hormone), progesterone, and blood counts may be performed on several occasions to observe for abnormal changes. Ultrasound examination of the uterus, fallopian tubes, and pelvis will be performed, usually through the vagina.

If it is determined that you have an ectopic pregnancy, you may be a candidate for *medical (non-surgical) management* of the

pregnancy. Medical management of ectopic pregnancy involves the intramuscular injection of Methotrexate, a chemotherapeutic agent that interferes with the growth of new cells and tissue. The goals of medical management are to stop development of the pregnancy and to avoid surgery, thereby sparing the fallopian tube from possible removal.

Women who wish to preserve future fertility will reliably return for follow-up care, have no signs of rupture of the ectopic pregnancy, and have no contraindication to Methotrexate may be offered medical management. Women who are breastfeeding, who have immune disorders, liver disease, low blood counts, lung disease or allergy to Methotrexate are not eligible for medical management. The size of the ectopic pregnancy (measured by ultrasound), presence or absence of heart motion in the embryo and level of the pregnancy hormone hCG will also determine if you are a good candidate for medical management of ectopic pregnancy.

After carefully evaluating the results of your lab testing and ultrasound, your doctor will discuss the available medical and surgical options for treatment. The loss of a pregnancy is difficult in any circumstance; however, it is important to keep your health and well being in mind when making treatment decisions.

Preparation

In addition to the tests discussed above, laboratory blood tests to establish pre-treatment levels of liver, kidney, and bone marrow function will be performed prior to administration of Methotrexate. Additionally, blood type and Rh factor will be determined.

Procedure

Methotrexate can be given either in multiple doses (over several days) or in a single dose. Multiple dose and single dose regimens are both very effective in medical management of ectopic pregnancy. Recommendations for treatment will be made based on the specific circumstances of your condition and your doctor's preference.

Post Procedure

Most women will have successful treatment of ectopic pregnancy with medical management. While single-dose treatment is successful for the majority of patients, some women will require more than one dose to complete treatment.

It is important that you continue to be alert to changes in your symptoms. Rupture of the fallopian tube is a serious risk that continues during medical management.

There are many side effects to the drug Methotrexate, some more bothersome than others. These include:

- Nausea
- Vomiting
- Liver dysfunction
- Inflammation of the lips and mouth
- Diarrhea
- Cramping abdominal pain
- Dizziness
- Bone marrow suppression
- Reversible hair loss
- Inflammation of the lungs
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Many women will experience an increase in abdominal discomfort and continued vaginal bleeding. This can be quite normal in women whose treatment will ultimately be successful. However, if you have significant or sudden worsening of pelvic and abdominal pain, heavy vaginal bleeding, dizziness, rapid heartbeat, or fainting, you should seek immediate medical attention.

Your doctor will periodically check blood levels of the pregnancy hormone hCG, to observe for a continued decrease to a non-pregnant level. If the hormone level is not rapidly decreasing, stops decreasing, or rises, then recommendation will be made for either an additional dose of Methotrexate or surgery.

You are instructed to refrain from consumption of alcoholic beverages and vitamins containing folic acid, avoid non-steroidal pain medications (such as ibuprofen and naproxen) and refrain from intercourse until advised otherwise.

Expectations of Outcome

When performed in properly selected patients, medical management of ectopic pregnancy is very effective. Many women will require more than one dose of Methotrexate. Surgery is necessary following failed medical management.

The outlook for future pregnancy is good. Most women who have had one ectopic pregnancy will have a normal pregnancy at some

point in the future. A history of ectopic pregnancy remains a risk factor for subsequent ectopic pregnancy. For this reason, if you become pregnant or have the symptoms of pregnancy, you must see your doctor to confirm an intrauterine pregnancy.

Possible Complications

Medical (non-surgical) management of ectopic pregnancy can be associated with unforeseen problems. They may be immediate or even quite delayed in presentation. While we have discussed these and possibly others in your consultation, we would like you to have a list so that you may ask questions if you are still concerned. It is important that every patient be made aware of all possible outcomes, which may include, but are not limited to:

- Rupture of Fallopian Tube: The most common serious complications of medical management of ectopic pregnancy are rupture of the fallopian tube and internal bleeding. Tubal rupture is a surgical emergency. If you have any symptoms suggestive of rupture (significant or sudden worsening of pelvic and abdominal pain, heavy vaginal bleeding, dizziness, rapid heartbeat, or fainting), you should seek immediate medical attention.
- Treatment Failure: Although medical management is very effective, there are some patients who will have persistent ectopic pregnancies and will require surgical treatment. The surgical approach will depend largely on your condition at the time treatment failure is diagnosed. ***If you have symptoms suggesting any of the above after your discharge from the hospital, you must contact us immediately or go to the nearest emergency room.***
- Medication Side Effects: There are many side effects to the drug Methotrexate, some more bothersome than others. These include nausea, vomiting, liver dysfunction, inflammation of the lips and mouth, diarrhea, cramping abdominal pain, dizziness, bone marrow suppression, reversible hair loss, and inflammation of the lungs.
- Blood Loss/Transfusion: In the case of rupture of the ectopic pregnancy, blood loss can be significant and may require blood transfusion to treat shock or severe anemia.

Patient Signature

Date

Patient Name Patient ID #

Date

Physician Signature

Date

Witness

Date

The information contained in this Medical Informed Consent Form (“Consent Form”) is intended to solely inform and educate and should not be used as a substitute for medical evaluation, advice, diagnosis or treatment by a physician or other healthcare professional. Please call your doctor if you have any questions.