



Fetal Therapy Center

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AMNIOPATCH INFORMATION PACKET

AMNIOPATCH FOR TREATMENT OF PREVIABLE PREMATURE RUPTURE OF MEMBRANES

Premature rupture of membranes (PPROM) means that the bag of waters breaks and amniotic fluid leaks from the vagina before it is time for you to go into labor. Iatrogenic PROM occurs when your bag of waters breaks after a procedure where a needle or other instrument was inserted. Previabile means that the PROM occurred very early in the pregnancy, too early for the pregnancy to be delivered and have a chance for the baby or babies to survive. This patient education guide has been designed to inform you of options available to manage iatrogenic PPRM.

How is PPRM diagnosed?

The diagnosis of PPRM is made with a sterile speculum exam (a sterile speculum is placed in the vagina to examine the fluid leaking out of the vagina). In addition, an abdominal ultrasound evaluation is performed to measure the amount of amniotic fluid in the uterus and to see if the membranes (the linings of the sac) are detached from the wall of the uterus. Severe detachment of the membranes, even without leakage of fluid from the vagina, may be treated with the amniopatch because of the high risk of complete breakage of the bag of waters in this situation.

What is the Amniopatch?

The amniopatch is a technique that could seal the membranes and prevent premature delivery from premature rupture of membranes. This consists of trying to seal the membranes by placing clotting substances inside the amniotic cavity (bag of waters).

Amniopatch Procedure

The amniopatch is typically performed in Labor & Delivery (L&D). After you are admitted, you will have an IV started. Under ultrasound guidance, a needle is inserted through the skin of your abdomen (belly) into the amniotic cavity (bag of waters). This procedure is called amniocentesis. Next, a small amount of fluid will be obtained from the bag of waters and sent to the lab to check for possible infection. Blood clotting cells (Platelets) and clotting factors (Cryoprecipitate) are injected into the amniotic cavity to help seal the membranes. The entire procedure should take no more than 10-15 minutes.

Your own blood may be used to obtain the clotting substances, provided that this can be arranged. Otherwise, blood products from the blood bank will be used to obtain the clotting substances.

What are the Criteria for Treatment of Iatrogenic PPRM with the Amniopatch?

Patients may be offered the amniopatch if they are:

1. 16 weeks pregnant or more
2. Diagnosed with iatrogenic PPRM or detached membranes that do not spontaneously seal (seal on its own)

Patients will not be offered the amniopatch if they have:

1. Active labor or uterine contractions
2. Had a vaginal ultrasound or digital vaginal examination (the doctor examined your cervix with his gloved hand) after you started leaking amniotic fluid.
3. Any signs of intraamniotic infection (infection inside the bag of waters)
 - a. Fever
 - b. Uterine tenderness
 - c. Foul smelling amniotic fluid
 - d. Fetal tachycardia (the baby's heart rate is faster than normal)

Complications

Below is a list of possible complications of the **Amniopatch**.

1) The needle might puncture your bowel, bladder, or blood vessels in your pelvis, or injure the fetus. This would be very unlikely, and is avoided by doing the procedure under ultrasound guidance.

2) There is also a potential risk of infection. This is prevented by doing the amniocentesis with a sterile technique. Infection of the bag of waters usually results from the ruptured membranes itself, as bacteria in the vagina can enter the bag of waters. If you should develop an infection in your bag of waters, it would most likely result from the ruptured membranes themselves rather than from the procedure to help them seal. If infection is present you would have to be delivered.

3) Occasionally, patients can go into labor after amniocentesis. However, the most likely cause of going into labor with ruptured membranes is the ruptured membranes themselves and the setting of infection.

4) There is a very small risk (approximately one in 2000 to 225000) of acquiring an infection from the transfusion of platelets or clotting factors. These risks are kept to a minimum by standard screening procedures done at the blood bank.

5) We have had three fetal deaths after the amniopatch procedure. The fetal deaths could have resulted from the injection of a large amount of platelets, which cause changes in blood pressure and heart rate. The amount of platelet injection has been modified to no more than 35 cc. However, we do not know what should be the safe or effective dose of platelets to use.

6) Patients with a history of PPRM in a previous pregnancy are at an increased risk of PPRM in any future pregnancy. However, PPRM as a result of amniocentesis has not been associated with a risk of PPRM in a future pregnancy. Amniocentesis has not been associated with impairment of future fertility.

Are There Other Treatment Alternatives?

There is presently no other method to seal the membranes. Patients with premature rupture of membranes are usually kept on bed rest at home or in the hospital or terminate the pregnancy.

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All ultrasound evaluations and fetal procedures are performed at **University of Miami/Jackson Memorial Hospital (UM/Jackson)**. The information listed below will familiarize you with the procedure you will follow when you arrive at **UM/Jackson** for evaluation and treatment.

Ultrasound Assessment

Ultrasound evaluations are performed at Jackson Memorial Hospital, also referred to as UM/Jackson, since the hospital serves as the University of Miami's primary teaching hospital. On the day of your appointment, a Jackson Concierge representative will meet you at the hospital near the Diagnostic Treatment Center (DTC). The representative will take you to the fourth floor of Women's Hospital Center, where you will meet the Fetal Therapy Coordinator.

The coordinator will take you to get ultrasound assessments. Following the ultrasound, the doctor will discuss all findings and will review all treatment options with you in addition to the prognosis for your case and follow-up care.

Next, a sample of your blood will be drawn. The blood products are tested and cross-matched to your own blood. There is no waiting period to use these products. After the blood specimen has been drawn, you can return to your hotel/home until the time of the procedure.

You may also choose to use your own blood for the amniopatch procedure. If you choose to donate your own blood you will need to go to a Blood Bank Office located outside of the hospital. The staff at the Blood Bank will make sure it is safe for you to donate your own blood. In particular, they will make sure you are not anemic (low blood count). There is a 24-hour waiting period to prepare the blood products if you choose this option.

Day of Procedure

You are admitted to Labor and Delivery (L&D) for the amniopatch. You check in 2 hours prior to your procedure time. Your husband or significant other can stay with you during the procedure. You have an IV started through which you receive antibiotics. Under ultrasound guidance, a small needle is inserted into the amniotic cavity. A small amount of fluid is obtained from the bag of waters and sent to the lab to check for possible infection. The blood products (platelets and cryoprecipitate) are injected. The procedure takes only a short time and it is relatively painless. Once the procedure is completed, you remain on bed rest for a few hours and then you are discharged to a hotel or home. Occasionally the doctor may recommend that you remain in the hospital.

Follow-Up

On the day after the amniopatch, an ultrasound is performed that checks the amniotic fluid level, the membranes and the status of the baby (babies).

You can usually return home at this time with instructions to stay on bed rest. You will return to the care of your perinatologist and obstetrician. Weekly ultrasounds are recommended for the next month. After that time, ultrasounds are performed as directed by your doctor.

Referral Information

If you are interested in the amniopatch, contact the **Fetal Therapy Coordinator**. She will fax an evaluation form to your doctor to complete and return to us. This information will be needed to determine the best treatment.

All ultrasound reports, prenatal records and insurance information will be requested. Our office will begin the insurance process. The hospital policy, at this time, requires payment prior to the procedure, if your insurance company does not cover the procedure. If your insurance reimburses at a later date, your money will be refunded.

For information regarding the Amniopatch Procedure, please contact:

Tel. 305-585-6636
Fax. 305-325-1282

Transportation and Housing

Patient rates are available at hotels near Jackson Memorial Hospital. Hotel rates and transportation information can be found at:

http://www.uhealthsystem.com/patient_services/international.asp

For additional information about Jackson Memorial Hospital, visit their website at www.jhsmiami.org.

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