ATATÜRK ÜNİVERSİTESİ

TIP FAKÜLTESİ

Biomarkers Predicting Postimplantation Syndrome After Endovascular Aortic Repair (EVAR) and Thoracic Endovascular Aortic Repair (TEVAR)

Brief Title: Post-Implantation Syndrome and Laboratory Markers Following EVAR and TEVAR

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INFORMED CONSENT FORM FOR ENDOVASCULAR PROCEDURES

Patient Information:
File Number:
First Name:
Last Name:
Date of Birth:

PROPOSED TREATMENT

My doctor, Dr. …….. and their team have informed me that I have …… disease and that treatment with endovascular methods is possible.

Endovascular treatment involves accessing the artery through the groin or arm under general or regional anesthesia, without making a large incision. This technique entails replacing an aneurysmal arterial segment using one or more strong synthetic tubes or a bifurcated “trouser-shaped” graft, or opening narrowed vessels using specialized balloons and stents.

For aneurysms, the artery is accessed and a graft—prepared based on prior measurements—is advanced upward through the vessel. The position of the graft is monitored using X-rays. Once in the correct position, the graft is deployed. Small hooks around the graft anchor it in place. If a bifurcated graft is used, both groins are accessed and one limb of the graft is inserted from the opposite side and connected to the main graft. Blood flow is checked, and arterial puncture sites are closed. Temporary drains may be placed in the groin to prevent fluid accumulation, and the wounds are then closed.

To treat vascular stenosis or occlusion, access is gained into the vessel without a surgical incision. A balloon and/or stent selected by the surgeon is advanced to the area of narrowing or blockage using X-ray guidance, and the vessel diameter is restored. The procedure is concluded following a control angiogram.

RISKS

The purpose of this explanation is not to frighten or alarm you, but to provide you with a better understanding of the surgery and associated risks. If you have any general or specific questions, please consult your surgeon.

You may experience side effects from the anesthetic drugs used. Common side effects include dizziness, nausea, skin rashes, and constipation.

General risks and limitations associated with endovascular procedures include:

- The surgical wounds may become infected, leading to redness, pain, and swelling, and may require antibiotic treatment.
- Urinary tract infections may develop, requiring antibiotics.
- If general anesthesia is used, small parts of the lungs may collapse, increasing the risk of lung infection, which may necessitate physiotherapy and antibiotic therapy.
- A blood clot (deep vein thrombosis) may form in the leg, causing swelling and pain. If a part of this clot dislodges, it may travel to the lungs (pulmonary embolism), causing shortness of breath. This is rarely fatal.
- You may experience a heart attack due to increased strain on your heart.
  • You may suffer a stroke.
  • Although extremely rare, there is a risk of death during the procedure.
  • Due to technical reasons, the procedure may need to be converted to open surgery.
  • Rarely, blood within the graft or stent may clot after the procedure, requiring further treatment.
  • You may lose enough blood to require a blood transfusion.
  • A hematoma may develop in the groin. This may be absorbed over time, but in rare cases may require a second surgical intervention.
  • Even if the surgery is successful, the underlying disease (arteriosclerosis/atherosclerosis) may continue to progress. Narrowing may occur inside the stent, and symptoms may reappear in the future.
  • If diseased arterial tissue becomes dislodged during surgery, small areas of tissue death may occur in the foot. Circulatory problems and organ dysfunction may develop, possibly leading to life-threatening conditions. In particular, intestinal ischemia may require reoperation.
  • A leakage of blood around the graft (endoleak) may allow continued aneurysm growth. This may require additional minimally invasive or open surgical intervention.
  • The graft may become displaced. If it shifts, becomes blocked, or a leak occurs in the aneurysm, further surgery may be necessary.
  • The original aneurysm may rupture, necessitating emergency surgery.

  • Because this procedure is relatively new, unknown long-term complications may still arise.

• An allergic reaction to the contrast dye used during the procedure may occur, and kidney damage may develop. Dialysis may be required, either temporarily or permanently.
• A previously unknown side effect may still occur.
• If you smoke, have chronic lung disease, are obese, diabetic, have high blood pressure, or known heart disease, these risks may occur at a higher rate.

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- INDIVIDUAL RISKS
  After deciding to undergo this surgery, the following risks and complications specific to your individual condition may arise:
  .....
  .....
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- PATIENT STATEMENT
  • My surgeon has provided the necessary information regarding the procedure and alternative treatment options, and answered my specific questions.
  • After deciding to proceed with the operation, my surgeon informed me about the possible risks and complications associated with my individual condition.
  • I consent to any additional procedures that may be deemed necessary by my surgeon during the surgery.
- You may experience a heart attack due to the strain on your heart.
  • You may suffer a stroke.
  • Although extremely rare, there is a small risk of death during the procedure.
  • Due to technical reasons, the procedure may need to be converted to open surgery.
  • In rare cases, blood inside the graft/stent may clot after the procedure, requiring additional treatments.
  • You may lose enough blood to require a blood transfusion.
  • Blood may collect in the groin area. This can be reabsorbed over time, but in rare cases may require a new operation.
  • Even if the surgery is successful, the underlying condition (arteriosclerosis/atherosclerosis) may continue to progress. Narrowing inside the stent may occur, and symptoms may recur in the future.
  • If diseased tissue inside the artery becomes dislodged during the operation, small areas of tissue necrosis may develop in the foot. Circulatory disorders in organs and related loss of function may arise, potentially leading to life-threatening situations. In particular, bowel ischemia may require reoperation.

  A blood leak (endoleak) may develop around the graft, allowing the aneurysm to continue enlarging. This may require additional minimally invasive or open surgical procedures.

• The graft may shift from its original position. Regular monitoring is necessary, and if the graft moves, becomes blocked, or leakage develops in the aneurysm, new surgical interventions may be required.
• The original aneurysm may rupture and require emergency surgery.
• Since the procedure is relatively new, unknown long-term complications may still emerge.
• An allergic reaction to the contrast agent used during the procedure may develop, and kidney damage may occur. Temporary or permanent dialysis may be required.
• A previously unknown side effect may also emerge.
• If you smoke, have chronic lung disease, are overweight, have diabetes, high blood pressure, or known heart disease, these risks may occur at a higher rate.

INDIVIDUAL RISKS

After deciding to undergo this surgery, the following risks and complications specific to your individual condition may occur:

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PATIENT DECLARATION

• My surgeon has provided me with necessary information about the procedure and alternative treatment options and has answered my questions on specific matters.
• After deciding to proceed with the surgery, my surgeon informed me about risks and complications that may arise due to my personal condition.
• I consent to any additional procedures that my surgeon deems necessary during the operation.
• I consent to the use of any medications, serums, vaccines, or mechanical or biological prostheses, and any other procedures recognized by contemporary medical science as necessary for the treatment of my condition during and after the operation.
• I give permission for blood transfusion if required.
• I consent to the disposal of any tissues removed during the procedure by hospital authorities. I understand that some tissue or sample materials may be retained as part of my medical record.
• I consent to the planned surgical procedure being performed by Dr. …… and their team.

• I understand that photographs and videos may be taken for medical education purposes during the procedure, and these materials will be used only by medical professionals for educational purposes. I understand that my identity will not be disclosed in any of these materials.
• I have received a copy of this consent form for my records.
• In the event that a needle-stick or injury from a sharp object occurs during surgery and involves a member of the medical team, I consent to the collection of an additional blood sample from me for testing for HIV and other blood-borne diseases for investigational purposes. I understand that I will be informed as soon as possible after surgery if this becomes necessary and that I will be given any required recommendations.
• I have read and understood all four (4) pages of this informed consent form.
• Despite the necessity of this procedure, all possible complications, including unintended consequences of the surgery, loss of any tissue or organ, permanent disability, or even death have been explained to me in detail.

- PATIENT NAME
  DATE
  PATIENT SIGNATURE
- ---
- DECLARATION BY LEGAL REPRESENTATIVE
  (*To be completed if the patient is unable to provide consent*)
  • I have read and understood the necessary explanations regarding the surgery, its outcomes, and its associated risks.
  • As the patient is currently unable to provide consent, I hereby consent to the performance of the operation on their behalf.
- LEGAL REPRESENTATIVE'S NAME DATE
  SIGNATURE
- ---
- PHYSICIAN'S DECLARATION
  • I declare that I have provided the necessary explanations regarding the procedure and its outcomes, and have informed the patient about potential risks associated with the operation.
  • I have given the patient an opportunity to ask questions and have answered them accordingly.
- PHYSICIAN'S NAME DATE
-
- PHYSICIAN'S SIGNATURE
- ---
- WITNESS STATEMENT *(Preferably a relative of the patient)*
  I confirm that I have witnessed the explanation of this form and the conversation between the physician and the patient.

- WITNESS NAME – DATE
  WITNESS SIGNATURE