

Understanding your Renal Stent Procedure – A patient Guide (COVER PAGE)

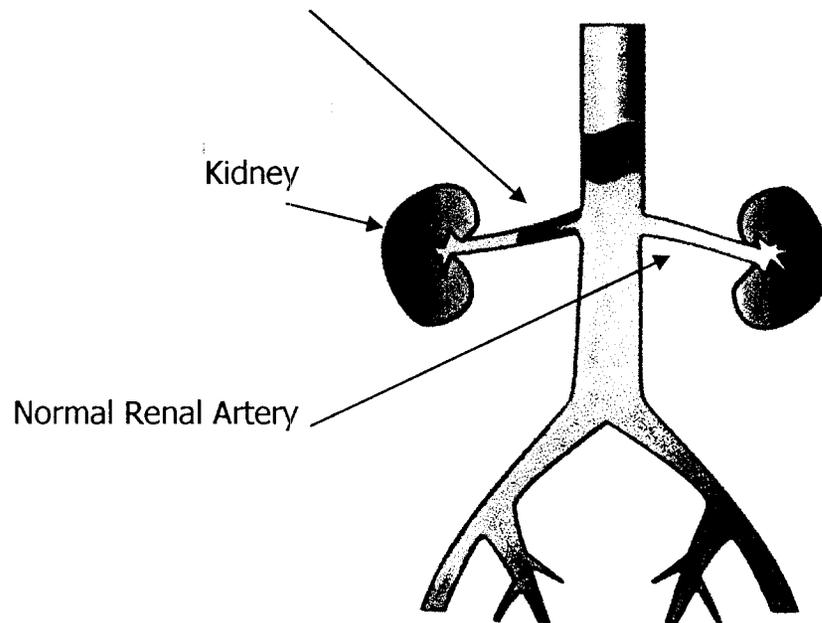
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THE KIDNEY AND THE RENAL ARTERIES

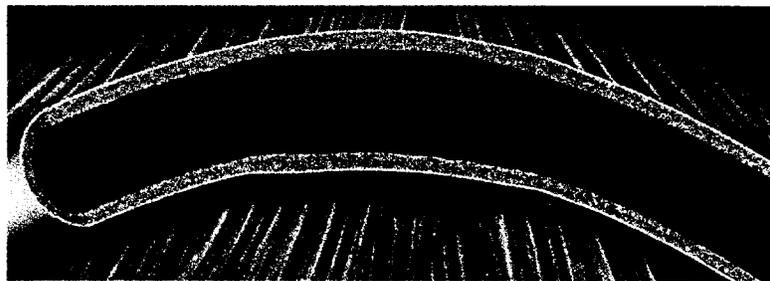
The kidney is one of two organs that functions as a filter to remove waste materials and excess fluids from the blood, excretes urine and help regulate the water, electrolyte (salts), and acid-base (pH) content of the blood. For that reason, the kidneys receive almost one third of the blood flow and plays a major role in regulating your blood pressure. The arteries that carry the blood to your kidneys are called renal arteries.

Diseased Renal Artery

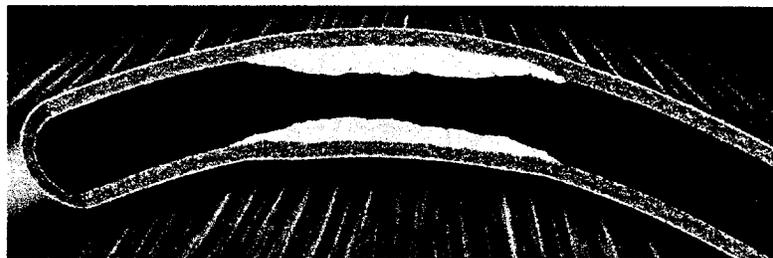


RENAL ARTERY DISEASE

Renal artery disease is peripheral artery disease that occurs in the blood vessels leading to the kidneys. As we age, fatty deposits and/or calcium (also referred to as plaque) build up on the inside of our arteries. This build up is a disease process known as atherosclerosis. Atherosclerosis is a progressive disease that involves the hardening and narrowing of the arteries due to this buildup of plaque and can progress from causing artery stenosis (a narrowing) to the total occlusion (no blood flow) of the artery. If the narrowing in the renal artery is significant, the kidney incorrectly senses that the blood pressure is too low and sends signals to the body to increase the blood pressure. This results in high blood pressure (hypertension). This type of high blood pressure can accelerate the progression of atherosclerosis throughout the body, increasing the strain on the heart. The restriction in blood flow from the renal artery to the kidney can also result in the reduced capacity of the kidneys to remove the waste and fluids from the body (renal insufficiency). Renal artery stenosis may ultimately lead to kidney failure.



Healthy renal artery



Renal artery with plaque

DIAGNOSIS OF RENAL ARTERY DISEASE

A history of your symptoms and your risk factors (including overweight, smoking, high cholesterol and family history of peripheral artery disease) are important to your doctor to consider in making a diagnosis. Tests such as a renal artery duplex ultrasound scan, a CTA (computed tomography arteriography) scan, an MRA (magnetic resonance Angiogram) scan, blood tests, or a renal arteriogram (angiogram), can help your physician diagnose renal artery disease.

A DUPLEX ULTRASOUND SCAN

This is a non-invasive test that uses soundwaves to create an image of your renal arteries and can measure the speed at which blood is flowing through them.

A CTA SCAN

This is a type of scan that uses x-ray beams taken from different angles around your body to create pictures of cross-sections of your body. If contrast is injected into your veins at the time of the scan, then the arteries can also be seen. Computer techniques can make the pictures of your arteries similar to the pictures from a renal arteriogram, however, only involves an IV (intravenous) placed in the arm. The pictures of the arteries produced by this test is not as detailed as the renal arteriogram pictures, however is detailed enough for the diagnosis of many conditions and are better at generating three-dimensional images.

A MRA SCAN

The is a variant of an MRI (magnetic resonance imaging) that uses radio waves and a magnetic field to take pictures of blood vessels. Like CTA, MRA uses computer techniques to make the blood vessels more visible. Unlike CTA or the renal arteriogram, MRA does not use x-rays or any form of radiation. A contrast fluid is sometimes used but is different from the kind used for the renal arteriogram or CTA and does not have the potential side effects on the kidneys.

BLOOD TESTS

There are different blood tests that can be done to look for substances in the blood that are either produced by the kidneys or are increased when the kidneys are not functioning properly. Blood tests will require a needle puncture of the vein in your arm.

A RENAL ARTERIOGRAM (or angiogram)

Your doctor may perform a special x-ray test called an arteriogram or angiogram to look for narrowed or blocked renal arteries. This test is performed in the catheterization laboratory (cath lab), a room designed especially for this procedure. This test takes between 20 and 40 minutes.

During the procedure, your doctor and the cath lab staff will:

- ❑ Insert an intravenous (IV) small tube into your arm. This IV allows fluids and medications to be given to you.
- ❑ Place small sticky patches (electrodes) on your chest to monitor your heart rate and rhythm.
- ❑ Shave and wash the area where the catheter will be inserted (your groin or arm).
- ❑ Cover your body with sterile sheets.
- ❑ Give a mild sedative to help you relax.
- ❑ Use medication to numb the area that has been cleansed.
- ❑ Insert a hollow tube, into the artery in your groin or arm. Through this hollow tube, the doctor can move or advance guidewires and catheters to the arteries leading to your kidney.
- ❑ Inject a special x-ray dye called contrast through the tube to allow your doctor to see the arteries leading to your kidney on an x-ray monitor similar to a television screen. You may be able to look at the monitor during the procedure if you choose.
- ❑ After the doctor has finished the angiogram and no further treatment or procedures are to be done at this time, you will go to a recovery area for monitoring before returning to your hospital room or going home.

Four to six hours following the procedure, you will be asked to lie flat and not bend your leg or arm, depending on which approach your doctor used to insert the catheters. You may have a vascular closure device to seal the puncture site in your groin or arm. This device will allow you to get up and walk around sooner. Your hospital stay may range from one to three days.

TREATMENT FOR RENAL ARTERY DISEASE

Each year many patients with renal artery disease need treatment to increase the flow of blood to the kidneys. Treatment usually includes controlling the factors that are causing the disease process. While some of these risk factors are not controllable, many are. Risk factors for this condition that are not controllable include your gender, age, ethnicity and family history. Risk factors that can be modified or reduced include smoking, lack of regular exercise, eating a high-fat diet, obesity, uncontrolled diabetes or high blood pressure, stress or anger, and high cholesterol. It is important that patients make changes in each risk factor area in order to slow the progression of atherosclerosis. Also these lifestyle changes can increase the patient's chances of long-term success with any treatment that may be considered. Treatments for renal artery disease in addition to lifestyle changes include drug therapy, surgical procedures and balloon angioplasty or stenting. Ask your doctor to explain the risks and benefits of these options for your particular renal artery disease.

DRUG THERAPY

Drugs work to dilate/expand the arteries, increasing the flow of blood to your kidneys. If your symptoms include significant high blood pressure, medications may be prescribed to lower the blood pressure. If patients do not respond to drug therapy, there are a variety of procedures that can be done to restore adequate blood flow through the renal arteries.

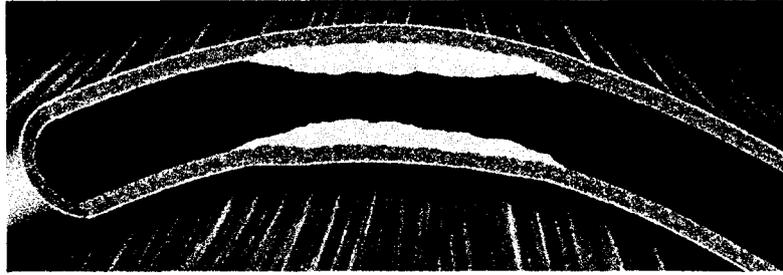
SURGICAL PROCEDURES TO TREAT RENAL ARTERY DISEASE

There are two types of surgical procedures that can be performed to treat renal artery disease - renal artery endarterectomy or renal artery bypass.

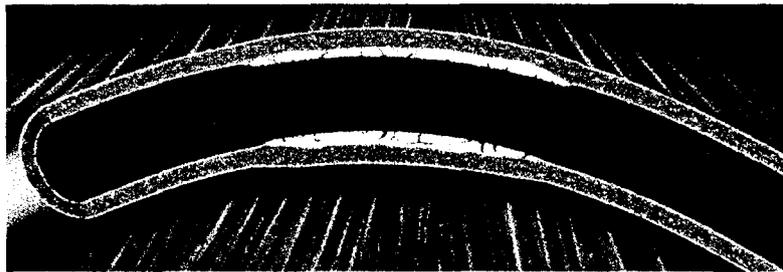
Renal artery endarterectomy is a surgical procedure in which the surgeon exposes the renal artery through an incision and the plaque is physically removed. This is a major surgical procedure and patients maybe hospitalized for at least a week. Renal artery bypass, is essentially the same procedure as the renal artery endarterectomy except that a bypass is made around the blocked artery rather than removing the plaque from the artery. In this procedure, a healthy segment of vein or artery from another part of the body is used to create a bypass (or detour) for blood to flow around the clogged area. Again this is a major surgical procedure and patients maybe hospitalized for at least a week.

BALLOON ANGIOPLASTY (PTA)

The procedure to perform balloon angioplasty or PTA (percutaneous transluminal angioplasty) is very similar to the renal arteriogram procedure. With PTA, a catheter with a small balloon on it is moved to the area of plaque buildup in the renal artery. The balloon is inflated to push the plaque against the artery wall to create a larger opening in the artery. This improves the blood flow through the artery (opens the artery lumen). The balloon is then deflated and the catheter withdrawn from the body.



Before PTA - artery is narrowed by plaque



After PTA - artery lumen is opened (enlarged)

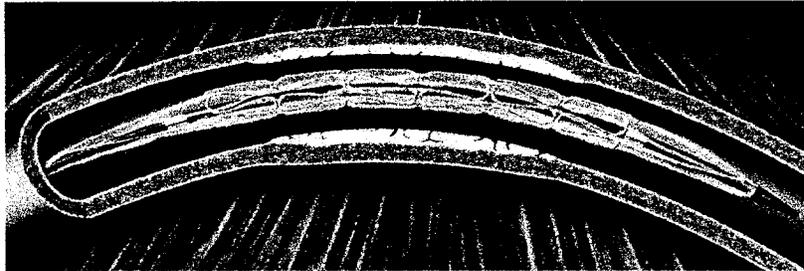
In some cases, the result of PTA alone does not provide sufficient blood flow through the arteries. In this circumstance, a stent (an expandable wire-mesh tube) can be inserted to keep the artery from re-closing (restenosis).

CONTRAINDICATIONS FOR STENT PLACEMENT

Your doctor will determine if you may benefit from the placement of a renal stent. There may be patients who are not good candidates for this procedure because they cannot or should not take the platelet inhibitors (antiplatelet) and/or anticoagulation therapy that may be needed or they have renal artery disease in a location that prevents complete inflation of an angioplasty balloon. Your doctor will discuss these risks with you before the procedure.

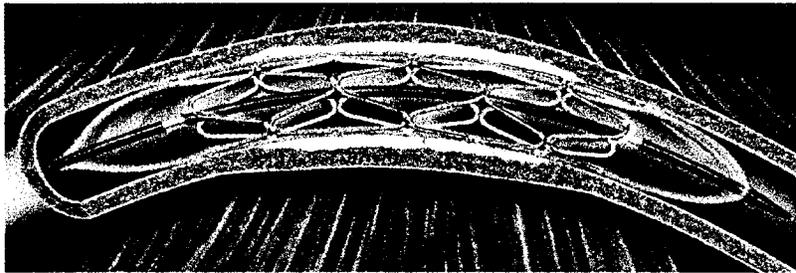
STENTING THE RENAL ARTERY

Your doctor may recommend placing a stent in the diseased area to help keep the artery open that is threatening to become, or is already, blocked due to the build up of plaque. The stent is a mesh-like tubular metal scaffold placed on a specially designed balloon catheter and then delivered to the diseased area in the same fashion as the PTA balloon catheter.



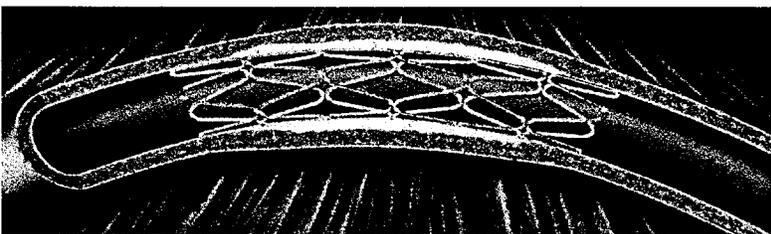
Stent mounted on a balloon catheter inside the artery

The balloon is inflated to expand the stent and flatten the plaque against the artery wall. The stent acts like a scaffold to hold the vessel open so that adequate blood flow can be maintained.

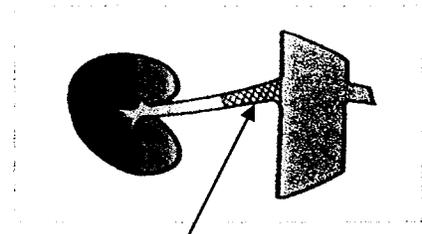


Stent with balloon inflated inside the artery

Once the stent is fully expanded, the balloon is deflated and the catheter is removed. The stent stays in place permanently. It may be necessary to place more than one stent in the artery.



Balloon deflated and catheter withdrawn, stent implanted inside the artery



Location of stent in renal artery

Once the stent is in place, the inside lining of the artery will grow over the stent in about 8 weeks.

THE MEDTRONIC AVE RENAL STENT

Medtronic AVE renal stents are both flexible and strong. Each stent is carefully polished for a smooth surface. They are made of medical-grade stainless steel and shaped to allow them to pass easily through your arteries on a specially designed balloon catheter. The renal stent is a mesh-like tubular metal scaffolding implanted in a renal artery that is threatening to become, or is already, blocked due to the build up of plaque. The stent acts like a scaffold to hold the vessel open so that adequate blood flow can be maintained. The stent is mounted over a deflated balloon, which is attached to a thin flexible tube (a balloon catheter). The tube helps deliver the stent to the diseased area of a coronary artery

AFTER YOUR STENT PROCEDURE

You may need to take drugs before and after stent placement. Aspirin and "platelet inhibitors" are the most commonly prescribed. Their purpose is to prevent blood clots (*thrombus*).

While taking these medications, you may need to have periodic blood tests. Your doctor or nurse will give you instructions about your medications before you leave the hospital.

It is very important that you take all of your medications until your doctor tells you to stop them.

Four to six hours following the procedure, you will be asked to lie flat and not bend your leg or arm, depending on which approach your doctor used to insert the catheters. You may have a vascular closure device to seal the puncture site in your groin or arm. This device will allow you to get up and walk around sooner. Your hospital stay may range from one to three days.

POTENTIAL ADVERSE EVENTS FROM YOUR STENTING PROCEDURE

Adverse events are unexpected incidents that **MAY** happen with the use of medical devices. These may occur during or after placement of a renal stent in your body.

Adverse events may include, listed in alphabetical order:

- Abnormal connection (fistula) between an artery and vein
- Allergy or reaction to medication, stent material or contrast (x-ray dye)
- Bruising or bleeding into body tissue at the catheter insertion site
- Closure of the renal artery
- Death
- Decreased blood flow (ischemia) to the legs
- Embolization (air, pieces of devices or fragments of clots or plaque float downstream and block the renal artery or kidney)
- Emergency peripheral artery bypass surgery
- Excessive bleeding requiring transfusion

- ❑ Heart attack
- ❑ High or low blood pressure
- ❑ Infection or pain at catheter insertion site
- ❑ Irregular heartbeats
- ❑ Poor or no blood flow to the bowel or kidney causing tissue death (necrosis)
- ❑ Reduced kidney function or kidney failure
- ❑ Restenosis (re-narrowing) of a stented segment
- ❑ Rupture of the abdominal lining (peritoneum) or of a neighboring organ
- ❑ Rupture or tearing of the artery
- ❑ Spasm of the artery
- ❑ Stent blockage or closure
- ❑ Stent movement during placement
- ❑ Stroke or seizure
- ❑ Weakening of an artery wall (pseudoaneurysm or false aneurysm)

GOING HOME FROM THE HOSPITAL AFTER YOUR STENT PROCEDURE

After you leave the hospital, your family doctor and your Cardiologist/Radiologist will monitor your progress. **If you have any pain, discomfort or bleeding from your puncture site, call your doctor immediately.**

Doctor address: _____

Doctor Phone Number: _____

If your doctor is unavailable, call 911 to take you to the nearest hospital emergency room.

If your doctor orders a scan by magnetic resonance imaging (MRI), this can be performed 8 weeks after your stent implant.

DEFINITIONS

- **Anticoagulation therapy** – The use of medications to delay or prevent the blood from forming clots.
- **Atherosclerosis** - The process of fatty deposits and/or calcium build-up (plaque) on the inside of the coronary arteries.
- **Balloon Angioplasty (PTA)** - The opening of a narrowed or blocked artery with specially designed balloon catheters. The term PTA means Percutaneous (through the skin) Transluminal (through the lumen) Angioplasty.
- **Catheter** – A tube that can be passed through the blood vessels.
- **Contrast (x-ray dye)** - A liquid that is injected into the blood stream that is visible with x-rays and used to view the renal arteries during a renal angiogram.
- **CTA (Computed Tomography Arteriography)** – A test that uses x-ray beams and computer techniques to produce three-dimensional images of the inside of your body.
- **Duplex Ultrasound Scan** – A test that uses soundwaves to obtain images of the inside of your body.
- **Hypertension (high blood pressure)** – A condition where the blood pressure is considered higher than normal.
- **IV (intravenous)** – A tube or needle is placed through the skin into a vein to deliver fluids or medications directly into the blood.
- **Medical grade stainless steel** - A special type of stainless steel used for making medical products that are placed (implanted) in the body.
- **MRA (Magnetic Resonance Angiogram)** - A test that uses radio waves and a magnetic field to obtain images of the inside of your body. Similar to MRI.
- **MRI (Magnetic Resonance Imaging)** - A test that uses magnetic waves to obtain images of the inside of your body.
- **Renal arteriogram (or angiogram)** - A procedure in which contrast is injected into the renal arteries to diagnose a narrowing or blockage of the artery.
- **Renal arteries** - The blood vessels that bring blood to the Kidney.
- **Renal artery bypass** – The surgical procedure to create an alternative route for blood to flow around an obstruction or blockage of the renal artery.
- **Renal artery endarterectomy** – The surgical removal of the diseased lining of the renal artery.
- **Renal (Kidney) failure** – The complete failure of the kidney to perform its essential functions.
- **Renal insufficiency** – The reduced capacity of the kidney to perform its functions.
- **Platelet inhibitors** – Medications to prevent blood cells called platelets from sticking together and blocking the artery.
- **Restenosis** - The recurrence of a narrowing or blockage in an artery after treatment.
- **Thrombus** - Blood clot.
- **Vascular closure devices** - Used to seal or close the artery puncture after angiogram or angioplasty. Made from either collagen plugs (special fiber that seals the puncture site) or internal sutures (stitches).
- **X-ray dye** – See Contrast definition

Patient Implant Card (Product Information on one side, Medtronic AVE address on the other side) – is on the back cover of the Patient Guide

Renal Stent Implant Card	
Product Code (s)	Lot Number (s)
_____	_____
_____	_____
_____	_____

Or affix product identification label (s) here



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