Disposable Miniature Pressure Sensor for Cardiologist Use

Xingwei Wang

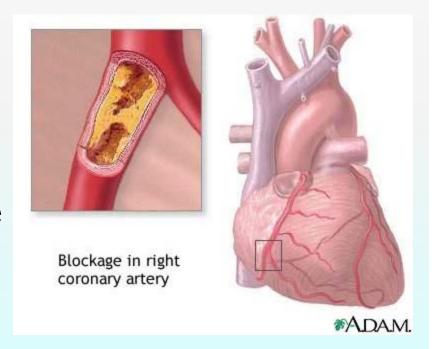
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Coronary Artery Disease

- Build up of plaque (fat and cholesterol)
- Arteries become narrowed and hardened
- Less blood flow to the heart muscle
- Heart muscle tissue can be damaged
- Atherosclerosis hardening of the arteries



Symptoms?

Angina (chest pain)

- Exercise or stress
- Arteries are too narrow
- Not enough blood and oxygen to meet the increased demand

Heart attack

- Artery becomes completely blocked
- Cutting off blood and oxygen to part of the heart
- Causing that tissue to die

Background

- Coronary artery disease (CAD)
 - « Kills ~ 871,000 people/year
 - Leading cause of death in US
 - 14 million US patients /year [1]
- Coronary angioplasty
 - ⋄ ~650,000 U.S. patients /year
 - More than 2 million /year worldwide
 - Nearly 3 million /year by 2010
 - Annual medical cost > 112 Billion

The 1st Balloon Angioplasty

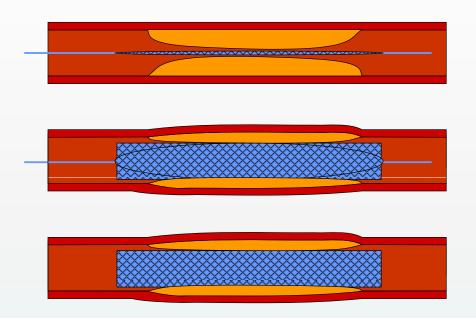
- Dr. AndreasGruentzig
- The first successful balloon angioplasty in the heart
- in (which year?)1977
- in (which country?)

Switzerland

- Launched a new medical subspecialty interventional cardiology
- Using catheters with a variety of devices on the tip, to treat heart problems without surgery.

What is Angioplasty?

- Surgery?
 - Non-surgical procedure
- Open blocked heart arteries
- Coronary: The arteries that supply the heart muscle with blood.



Interesting Latin Words:

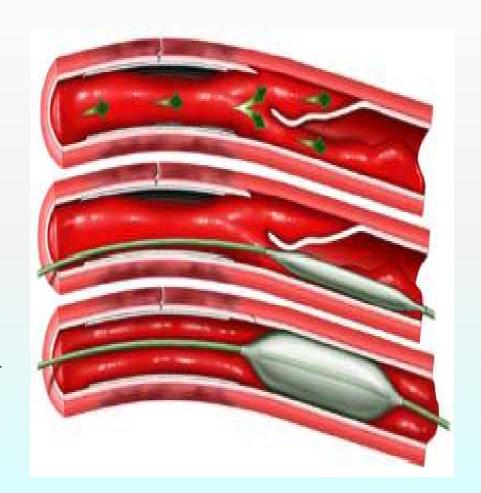
Coronory: crown

Angio: vessel

Plasty: repair

Balloon Angioplasty

- Guide a catheter with a small balloon tip to the narrowing
- Inflate the balloon
 - Compress the fatty matter into the artery wall
 - Stretch the artery open to increase blood flow to the heart



http://www.ehealthmd.com/library/angioplasty/AGO_types.html

Stent-a Small Metal Mesh Tube

- Inflate the balloon tip
- Expand the stent to the size of the artery to hold it open
- Relate and remove the balloon
- First coronary stent was approved in (which year?)

1993





Rotoblation

- Guide a special catheter with an acornshaped, diamond-coated tip
- The tip spins around at a high speed and grinds away the plaque
- The microscopic particles are washed safely away in your blood stream and filtered out by your liver and spleen
- Hard, calcified plaque

Atherectomy

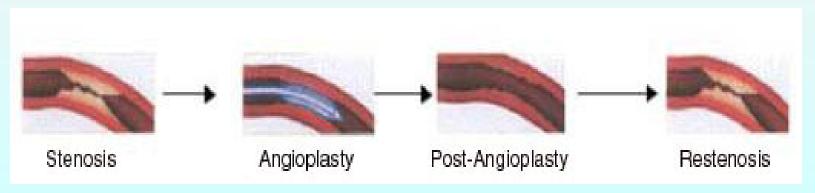
- Catheter has a hollow cylinder on the tip with an open window on one side and a balloon on the other
- Inflate the balloon
- Pushing the window against the fatty matter
- A blade (cutter) within the cylinder rotates and shaves off any fat that protruded into the window. (up to 1,200 revolutions per minute)
- The shavings are caught in a chamber within the catheter and removed.

Cutting Balloon

- Catheter has a special balloon tip with small blades
- Inflate the balloon
- Small blades score the plaque
- Balloon compresses the fatty matter into the artery wall.
- Laser angioplasty uses laser energy to destroy plaque

Restenosis

- Gradual re-narrowing of the artery
- Blood clots at or near the site of the treatment.
- Anti-clotting drugs
- Coronary stents coated with anti-clotting drugs



Why restenosis?

 Walls of the artery may recoil to their original position (hours after angioplasty)

- Angioplasty create tiny cracks in the plaque -> Causes injury to the artery wall
- Body attempts to heal itself
 - Platelets accumulate causes blood clots
 - Thrombin causes cells of artery to multiply and form new tissues

Angioplasty VS. Bypass Surgery

- Open up the narrowed vessel
- 1-2 days hospital stay
- Local anesthesia
- Chest not opened
- No heart-lung machine
- Death rate ~0.1%
- Successful in 98% patients
- Major complications: 1.5%
- Emergency bypass surgery: 0.1%
- Restenosis redo the angioplasty next few months

- Create a different blood vessel
- ♦ 1-2 weeks
- General anesthesia
- Open chest
- Needs; risk of stroke
- ♦ 1% to 2%
- Severe plaques
- Many narrowings in arteries
 - -> higher risk
- Weakly pumping heart

Angioplasty V.S. Medication

	Angioplasty	Medication
Rate of deaths, heart attacks and strokes	20%	19.5%
Hospitalization rate for heart attacks and worsening chest pain	12.4%	11.8%
Hospitalization rate for heart attacks alone	13.2%	12.3%
Pain free after 5 years	74%	72%
Initial Cost	~ \$8,000	~ \$2,700

Riskier and no more beneficial than medication

Drug therapy could account for as much as \$1 billion a year in medical savings (\$5,000 * 200,000 patients ~ \$1,000,000,000)

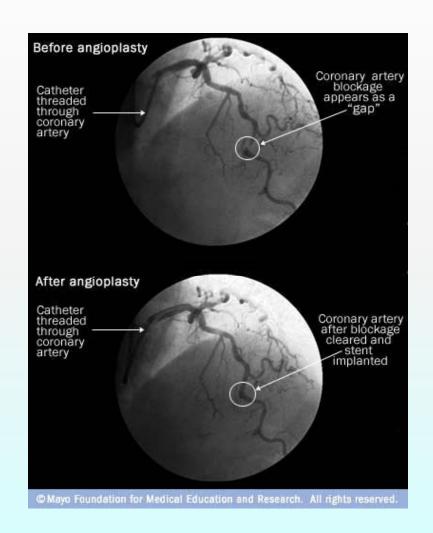
Source: The New England Journal of Medicine, March 2007 (2,287 patients)

Comments from Doctors

- * "In low-risk patients with stable coronary artery disease, aggressive lipid-lowering therapy is at least as effective as angioplasty and usual care in reducing the incidence of ischemic events." [4]
- * "In this small pilot study, intensive medical therapy and PTCA were comparable at suppressing ischemia in stable patients after AMI. ..Corroboration of these preliminary findings in a larger cardiac-event trial is warranted." [5]

Who Needs Angioplasty?

- How many blockage
- Where is the blockage
- Extent of the blockage
- Evaluate the last angioplasty
- Assess blood flow

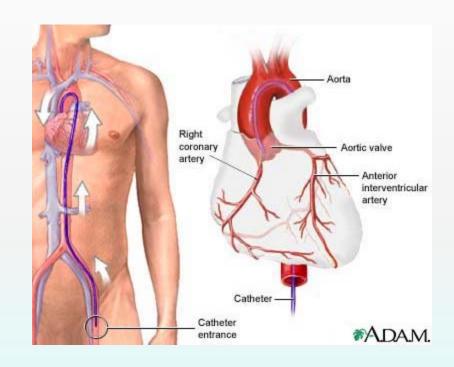


Coronary angiogram (cardiac catheterization)

- Thread a catheter through the blood vessels to the heart
- Inject a special contrast dye that shows up on x-rays into the arteries
- Take X-ray images
- Look for narrowed areas in the arteries
- Determine how severe the narrowings are

How to do Angiogram?

- Numb: local anesthesia
- Insert a sheath (a thin plastic tube) into an artery from groin or arm
- Pass a catheter through the sheath and guide up the blood vessel to the arteries surrounding the heart.



http://www.mayoclinic.com/health/coronary-angiography/HB00048

How to do Angiogram (2)?

- Inject a small amount of contrast material through the catheter
- Photograph as it moves through the heart's chambers, valves, and major vessels
- Tell whether the coronary arteries are narrowed and/or whether the heart valves are working correctly

Problems of Angiogram

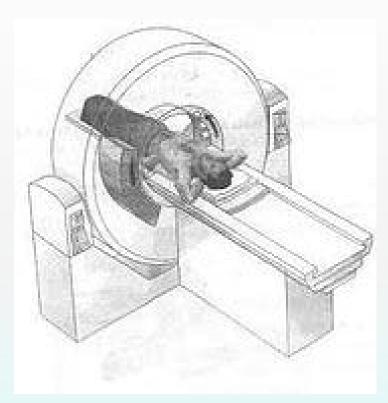
- Potential risks -> stroke; heart attacks
- Allergic to the iodine dyes
- Kidney damage
- Infection
- Trauma to the catheterized arteries
- Radiation exposure from the X-rays

X-Ray

- Body is made up of various substances with differing densities
- Denser substances (e.g. calcium rich bones) absorb X-ray photons -> film unexposed ->translucent blue
- Lower-density tissues (e.g. fat, skin, organs) -> black part of the film
- Reveal the internal structure of the body on film

Computerized Tomography (CT)

- An X-ray source rotates around the object
- X-ray sensors are positioned on the opposite side of the circle from the X-ray source
- large series of 2D X-ray images
- 3D image inside of an object



Greek words:
Tomography tomos
(slice) and graphein (to write).

Problems of Cardiac CT Angiography

- Heart is effectively imaged more than once
 ->a relatively high radiation exposure around 12 mSv
- ♦ A chest X-ray: ~0.02 to 0.2 mSv
- Natural background radiation exposure:
 ~0.01 mSv/day
- 100-600 chest X-rays or over 3 years worth of natural background radiation

Angiogram -> ??

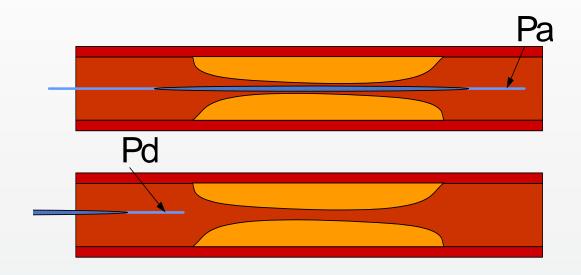
Angiogram

- Not always clear to decide which narrowing is the culprit lesion
- May underestimate or overestimate narrowing

??

- Account collateral flow
- Functional evaluation

Fractional Flow Reserve (FFR)



FFR= Pd/Pa ✓ Pd = pressure behind (distal to) a stenosis ✓ Pa = pressure before the stenosis

Abnormal?

- Maximal flow down a vessel in the presence of a stenosis compared to the maximal flow in the hypothetical absence of the stenosis
- No absolute cut-off point
- Cut-off point: 0.75-0.80

Radi's hydrophilic PressureWire® Certus

http://www.radi.se/home.aspx?n=10&m= 6&s=8&r=1

Can These Procedures Cure Coronary Artery Disease?

- Operation: 1.5-2.5 hours
- Preparation and recovery: several hours
- Several weeks for arteries heal (stent)
- Rarely used: Rotoblation; atherectomy; cutting ballon.
- Cure coronary artery disease?
 - ✓ Will not cure.
 - ✓ Lifestyle factors: smoking and diet
 - ✓ An exercise program

References

- § [1] http://www.redwoodeditor.com/content/SCAI/scai/
- [2] Tonino PA, De Bruyne B, Pijls NH, et al (January 2009). "Fractional flow reserve versus angiography for guiding percutaneous coronary intervention". N. Engl. J. Med. 360 (3): 213–24. doi:10.1056/NEJMoa0807611. PMID 19144937.
- [3] Cohen D. J., Carrozza J. P., Baim D. S., Ricciardi M. J., Davidson C. J., Bloom J. M., Pitt B., Waters D., Brown W. V., (Dec 9, 1999), "Aggressive Lipid-Lowering Therapy Compared with Angioplasty in Stable Coronary Artery Disease"

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References

[4] Habib A. Dakik, MD; Neal S. Kleiman, MD; John A. Farmer, MD; Zuo-Xiang He, MD; Juliet A. Wendt, MD; Craig M. Pratt, MD; Mario S. Verani, MD; John J. Mahmarian, MD, (Circulation. 1998;98:2017-2023.) © 1998 American Heart Association, Inc. "Intensive Medical Therapy Versus Coronary Angioplasty for Suppression of Myocardial Ischemia in Survivors of Acute Myocardial Infarction - A Prospective, Randomized Pilot Study", Presented in part at the 46th Scientific Sessions of the American College of Cardiology, Anaheim, Calif, March 17, 1997 and published in abstract form (J Am Coll Cardiol. 1997;29(suppl A):53A.