Interventional Treatments: ACS, Mitral Regurgitation, Aortic Stenosis

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Interventional Treatments: ACS, Mitral Regurgitation, Aortic Stenosis Topics

• Describe the pathophysiology of ACS
• Identify symptoms and signs associated with ACS patient
• Describe pharmacotherapies used to treat the ACS patient
• Discuss 4 methods of treating ACS interventionally: PCI, Stent, Thrombectomy, Atherectomy
• Describe pathophysiology of Mitral Regurgitation (annular vs. leaflet)
• Discuss interventional methods of treatment for Mitral Regurgitation
• Describe pathophysiology of Aortic Stenosis
• Discuss interventional methods of treatment for Aortic Stenosis
Pathophysiology of Acute Coronary Syndrome
Acute coronary syndrome can be subdivided into two separate syndromes: Non S-T Elevated Myocardial Infarction (NSTE-ACS) and S-T Elevated Myocardial Infarction (STEMI).

- NSTE-ACS is identified as a patient with signs and symptoms associated with ACS, but without ST elevation on ECG (typically presenting with T-wave inversion or ST Depression).

- STEMI is identified as a patient with signs and symptoms associated with ACS and ST Elevation on ECG.

- Both forms of ACS are serious, and may lead to sudden cardiac death.

Pathophysiology of ACS
STEMI ECG
NSTE-ACS ECG
Pathophysiology of ACS

• ACS occurs when the lumen of the coronary artery is suddenly and significantly reduced / occluded, and vascular flow is not sufficient to meet oxygen demands of the heart
  
  • The most common cause is a rupture of an unstable/vulnerable plaque
  
  • Collagenases produced by inflammatory cells located within the plaque are released, triggering platelet aggregation
  
  • Microemboli are produced, which may trigger microvessel occlusion distally
  
  • As platelet aggregation continues, occlusive thrombus forms occluding vessel
Symptoms and Signs

• Symptoms:
  - Retrosternal Chest Discomfort (pressure/tightness) that does not alleviate with rest [unstable angina]
    - Alternate locations of discomfort: Shoulders, arm, neck, jaw, back between shoulder blades, consistent heartburn/GI discomfort
  - Light-headed / Dizziness / Syncope
  - Nausea and Vomiting
  - Diaphoretic
  - SOB

• Signs:
  - EKG Changes
    - ST elevation in associated leads (STEMI)
    - T-wave Inversion in associated leads (NSTE-ACS)
    - ST depression in associated leads (NSTE-ACS)
  - New onset BBB
  - Cardiac Arrhythmias
  - Cardiac Biomarkers
    - Troponin I and T
    - CK
    - CK-MB

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  - Diaphoretic
  - SOB
Stabilizing the ACS Patient

• Pharmacotherapy for ACS

  • Oxygen: When appropriate
    • O2 sat <90%. Avoid hyperoxemia and resultant increase in coronary resistance

  • Aspirin: 325 mg Chewable

  • Sublingual Nitroglycerine Tablet/Spray
    • Use with caution, only if patient is hemodynamically stable

  • Morphine
    • May be started if nitroglycerine therapy is not effective for STEMI, use with caution with NSTE-ACS
Stabilizing the ACS Patient

• Advanced Pharmacotherapies

  • Heparin (UFH, LMW)

  • Beta Blockers (metoprolol)
    • Decreases O2 demand by decreasing cardiac contractility and rate
    • Do not give if patient’s CO is compromised by low BP, Heart Failure, Cardiogenic Shock, or Bradycardia

  • ACE Inhibitors
    • Patients with EF <40%, Hypertensive, Diabetic, Stable Chronic Kidney Disease

  • High Dose Statin Therapy (pravastatin, atorvastatin)
    • Supposedly reduce inflammation collagenases, endothelial dysfunction, and thrombus formation in the acute setting
Is There a Role For Fibrinolytic Therapy in Today’s Environment of Primary Stenting?
Use of Fibrinolytic Therapy for ACS

• Considerations for Use:
  • 12 hours of onset of symptoms, STEMI or posterior MI, and PCI not available within 90 minutes of first medical contact
  • 12 hours of onset of symptoms, patient is being transferred to facility greater than 120 minutes away from first medical contact

• Medications:
  • rtPA, reteplase, tenecteplase
Interventional Procedures to Treat ACS

• Pre-Procedural Medication
  • Heparin (UFH, LMW)
    OR
  • Direct thrombin inhibitor
    Bivalirudin
  • ADP Inhibitors

• IIb/IIIa inhibitors:

• Antiarrhythmic (as necessary)
Why So Many Anticoagulants?

- Thienopyridines (e.g., clopidogrel) only block one pathway to platelet activation.
- Aspirin only blocks one pathway to platelet activation.
- Heparin & enoxaparin reduce thrombin generation to indirectly and partially block one pathway to platelet activation.
- Bivalirudin inactivates some thrombin molecules, indirectly and partially blocking one pathway to platelet activation.
- GP IIb-IIIa inhibitors displace fibrinogen existing thrombi and prevent further platelet cross-linking and thrombosis.
Percutaneous Balloon Angioplasty

• Procedure: Inserting a balloon tipped catheter into the coronary artery stenosis, and inflating to distribute plaque and increase lumen size

• Attention to vessel size and characteristics is a must when selecting balloon catheter

• Vessel lesion should be measured (length), and reference vessel measured (diameter) for proper balloon selection

• Compliance of balloon must also be considered (compliant / non-compliant / transitional)
Balloon Angioplasty Catheter Selection

• Over the Wire (OTW):
  • Tracks well over interventional wire, effective in tortuous vessels
  • Typically larger external diameter due to central wire lumen
  • Requires long wire
  • May increase x-ray exposure time

• Rapid Exchange (monorail, RX)
  • Single operator advancement
  • Use of shorter wires
  • Typically decreased x-ray exposure time
  • Smaller external diameter
  • Does not track as well, may cause catheter back-up when dottering

• Balloon Mounted
How Angioplasty Works (Physiologic Effect)

- Plaque Compression (Slight Effect)
- Plaque Fracture: Fractures in plaque structure allowing blood flow
- Intimal flaps and medial dissection
- Stretching of plaque-free wall segments (over extension)
- Stretching and minimal compression of media
Restenosis of Balloon Angioplasty

• 30-60% restenosis (usually occurring after first 6 months)

• Causes:
  • Elastic recoil of vessel
  • Negative vessel remodeling
  • Neointimal hyperplasia
  • Excessive matrix remodeling
Is There a Place for POBA in the World of Stenting?

- Bifurcated Lesions
- Small Vessel Disease
- Inability to Anticoagulate Effectively (prolonged anticoagulation)
- Cost
Advanced Balloon Therapy

- Plaque remodeling and redistribution

- Drug-Eluting Balloons (Paclitaxel eluting balloon)
Invasive ACS Therapy: Coronary Stenting
Percutaneous Coronary Stenting

• Procedure: Deployment of a support scaffolding designed to assist maintaining vessel patency after intravascular coronary repair

• Due to the poor performance and need for target lesion revascularization following angioplasty, it was hypothesized that inserting a malleable scaffolding into the vessel would increase therapy effect
Stent Classification

- There are many ways to classify coronary stents
  - Composition (metallic [stainless steel or cobalt-chromium], polymeric)
  - Configuration (coil, slotted tube, modular) (open or closed cell design)
  - Bioabsorption (inert/durable, biodegradable)
  - Bioactive (drug-eluting)
  - Implantation Method (balloon expanding, self expanding)

- Each factor of classification needs to be considered when selecting a stent device
Stent Sizing and Deployment

• Selecting proper size of stent is imperative in order to achieve the best therapeutic results

  • Stent diameter should be approximately 1.1 : 1 of the vessel’s distal reference site (longer lesions may require results comparison to proximal and distal reference points to facilitate proper tapering of vessel)

  • Overhang should be minimized to < 1 mm beyond the ends of the lesion to avoid trauma to healthy vessel segments

• All stents (including self expanding stents) should be post inflated with a high pressure, non-compliant balloon to ensure appropriate strut opposition into vessel wall

• IVUS imaging allows operator to achieve a better visualization of stent opposition post implantation
Drug Eluting Stent

• Purpose: Bare Metal Stents (BMS) were found to improve vascular patency and decrease the need for TLR; however, there is still high rates of in-stent restenosis due to neointimal hyperplasia. (20-40% within a 6 – 12 month period)

• In an attempt to correct this issue, a cytostatic or cytotoxic medication is bound to the stent surface by a biodegradable polymer.

  • This medication is absorbed by the intimal tissue, slowing down the smooth muscle proliferation

  • Unfortunately, the delay in the smooth muscle proliferation may increase the time it takes for the coronary stent to be fully covered by vessel tissue, increasing the need for prolonged anticoagulation.
DES Stent Devices and Pharmacotherapy

• There are two BASIC classes of cytostatic medications that are used on DES stents
  • Rapamycin Analogues (the “-limus” family), and Paclitaxel

• Evorilimus
• Zotarolimus
• Paclitaxel
The New Era of Stenting?
**Biaabsorbable DES**

• New stent theory suggests that, if given enough time, vascular recoil could be prevented by “training” the vessel to maintain size
  • This is hard to accomplish with balloon angioplasty (though was attempted prior to stent therapy by utilizing perfusion balloons)

• Clinical evaluation and FDA approved the first Bioabsorbable DES stent device:
  • Balloon expandable, polymeric (PLLA) scaffolding coated with evorilimus which will completely absorb over a period of time [absorption of stent noted at approximately 2 years, full reabsorption in approximately 3 – 3.5 years]

• Benefits: return of normal arterial vessel function, allows for repeat intervention if necessary (but is it better?)
Invasive ACS Therapy: Thrombectomy

Aspiration
Catheters

Rheolytic
Thrombectomy
Devices
Thrombectomy in ACS

• Since the cause of ACS is the sudden formation of intravascular thrombus, an appropriate course of action was to consider removal of the vascular thrombus prior to initiating coronary angioplasty and stent therapy

  • Suggested algorithm for device selection indicated aspiration thrombectomy for moderate thrombus burden, and rheolytic therapy for high thrombus burden

• Recent studies (TASTE and TOTAL) have brought course of action into question

  • No significant difference in end-point components when comparing thrombectomy + PCI to PCI alone

  • Slight stroke risk increase in thrombectomy patients

• There may still be patient populations that can benefit from thrombectomy therapy during ACS.
Invasive ACS Therapy: Atherectomy
Percutaneous Transluminal
Rotational Atherectomy

Laser Coronary
Angioplasty System

Direction
Atherectomy
Vascular Atherectomy
Rotational Atherectomy

• Distal tip of the rotational atherectomy catheter is a nickel-coated brass burr that is attached to a drive shaft

  • While cutting plaque, RPM need to be above 5,000 RPM to avoid large particle debridement

  • Rotaglide solution is often added to the system to act as a lubricant to the drive shaft (egg based)

• During therapy, the burr cuts the plaque into small pieces that will be reabsorbed in the body

  • Multiple burrs are utilized, becoming progressively larger, to avoid large particle debridement which could embolize
Rotational Atherectomy

• Indications:
  • Calcified Plaques
  • Non-dilatatable lesions
  • Concentric plaques
  • NOT suggested for ACS
  • NOT suggested for lesions with angiographic evidence of thrombus
  • NOT for excessively angulated lesions

• Complications of this therapy:
  • Device can be difficult to deliver due to the equipment
  • No Reflow or Slow Reflow phenomenon is often encountered
  • Bradyarrhythmias may be triggered when atherectomy is performed on the dominant artery due to release of tissue release of adenosine
    • Prophylactic pacing therapy should be considered
Excimer Laser Coronary Angioplasty (ELCA)

• Procedure:
  • ELCA produces plaque ablation by vaporizing tissue, breaking down of molecules, and ejecting small debris from the plaque site
  
  • These effects are produced by a high energy light that is passed through a catheter via fiber-optic cables
  
  • The catheter is connected to a large light source generator system, and must be calibrated outside the body prior to angioplasty therapy
Excimer Laser Coronary Angioplasty

**Indications:**
- Concentric and Eccentric Lesions
- Calcified lesions
- Ostial Lesions
- ACS
- Non-dilatable lesions
- Not suggested for lesions near large bifurcations
- NOT for excessively angulated lesions

**Complications:**
- Significant dissection due to laser-induced vapor bubble in blood stream.
  - Intracoronary saline infusion during therapy decreases this risk
- Randomized trials have not shown an advantage of laser assisted angioplasty compared to primary angioplasty and stent therapy
  - ELCA therapy should be considered as a plaque debulking technique in coronary intervention rather than a primary therapy
TRANSCATHETER THERAPY FOR MITRAL VALVE REGURGITATION
Mitral Valve Regurgitation / Insufficiency

- Failure of the mitral valve to align and seal properly, allowing for retrograde flow through the valve into the left atrium

- Causes of mitral valve regurgitation/insufficiency can be grouped into one of four categories
  1. Leaflet Abnormalities
  2. Enlarged Mitral Annulus
  3. Papillary Muscle Dysfunction
  4. Dysfunction of Chordae Tendineae

- Repair of the regurgitant mitral valve has historically been relegated to surgical procedures; however, invasive catheter procedures are being developed to treat specific causes.
Mitral Valve Clip (Mitraclip)

• Purpose: Mechanical coaptation of the anterior and posterior leaflets in order to decrease leaflet movement (and reguritant area) during ventricular Systole.

• Indications: Indicated for the reduction of significant, symptomatic mitral regurgitation (MR ≥ 3+) due to abnormality of the mitral valve leaflets, chordae tendinae, or papillary muscles [degenerative MR] in patients who have been determined to be non-surgical candidates

• Patient Eligibility:
  1. Degenerative Mitral Valve Regurgitation (DMR)
  2. Significant (+3) Mitral Valve Regurgitation
  3. Symptomatic (NYHA Class III or IV)
  4. Non-Surgical Candidate for Mitral Valve Repair / Replacement
  5. Absence of comorbidities that would limit the benefit of Mitraclip therapy

• Preferred Anatomical Characteristics for Mitraclip Therapy:
  1. Regurgitant jet is noncommissural
  2. Mitral Valve Area > 4.0 cm²
  3. Minimal Calcification, especially at the clip deployment site (center of the anterior and posterior cusps commissure)
  4. No leaflet Cleft at deployment site
  5. Minimal flail
  6. LV EF >20%
Mitral Valve Clip (Mitraclip)

- **Device Goal:**
  - Transcatheter deployment of a metallic clip that will provide mechanical coaptation of the anterior and posterior mitral valve leaflets; reducing the orifice surface area and reducing regurgitant volume
Mitral Valve Clip (Mitraclip)

**Procedure:**
- Perform right heart catheterization to evaluate regurgitant physiology
- Transeptal technique via femoral vein
- Advance clip device through transeptal guiding catheter or sheath
- Hand controls allow very specific tip positioning in order to align device with leaflets (TEE or TTE ultrasound should be used for positioning and regurgitant jet analysis)
- Place catheter at point of mid regurgitant jet
- Advance device and open clip
- Pull device back, ensuring both leaflets are secured
- Deploy clip, assess regurgitant jet and right heart pressures
Mitraclip Device
Coronary Sinus Annuloplasty Devices
Transcatheter Treatments for Aortic Stenosis
Balloon Aortic Valvuloplasty

• Purpose: Dilation of a stenotic aortic valve with a percutaneous balloon.

  • Originally performed on children and young adults to increase valve area associated with congenital, non-calcific, congenital valve stenosis (acceptable effectiveness)
  • This therapy was later applied to patients with acquired calcific aortic valve stenosis following pediatric success

• Outcomes:

  • Pediatric Outcomes: 50% of patients treated for non-calcific congenital disease have no need of further intervention at 38 month follow up
  • Acquired Calcified Disease: Majority of patients have anatomical and symptomatic restenosis between 6 and 18 months post procedure
Indications for Balloon Aortic Valvuloplasty in Adults

- Severe aortic stenosis associated with cardiogenic shock (stabilize for surgery)
- Bridge to aortic valve surgery (especially in patients at increased surgical risk due to significant CHG)
- Poor surgical candidate
- Rheumatic aortic stenosis
- Congenital aortic stenosis
- Predilatation prior to transcatheter aortic valve stenosis
Selection of Aortic Valvuloplasty Balloon

- Aortic annulus diameter measurement from echocardiography improves balloon size selection

- Most adults can be treated with a 20 or 22 mm diameter x 4 – 6 cm length balloon
  - Balloon to annulus diameter should be as close to 1:1 as possible

- Smaller patients, or patients that are more frail in health, may be treated with an 18 mm balloon diameter in some cases (echocardiography should be consulted if this is a consideration)
Aortic Valvuloplasty Inflation

• Prior to inflation, rapid ventricular pacing should be initiated at a rate between 180 and 220 bpm (reducing ventricular ejection and helping maintain the valvuloplasty balloon in the proper position)

• Connect a 20 – 50 ml syringe with diluted contrast, and a second 10 cc syringe filled with diluted contrast, on to a three-way stopcock

• Inflate the balloon RAPIDLY with the 20-50 ml syringe, and look for the “waist” in the balloon to give way. If the syringe is completely emptied, turn stopcock and inject the volume in the 10 cc syringe until waist is release. (15-20 second inflations)

• Two or more inflations may be necessary to achieve acceptable results. If single balloon technique is not successful, a dual balloon technique may be attempted

• After therapy, reinsert pigtail catheter and measure aortic valve area. Goal is to obtain an Aortic valve area of at least 1 cm2
Aortic Valvuloplasty
Transcatheter Aortic Valve Replacement

• Indications
  • AVR is recommended for patients with severe high-gradient AS who have symptoms by history or on exercise testing

  • AVR is suggested in symptomatic patients with low-flow/low-gradient severe AS with reduced left ventricular ejection fraction with a low-dose dobutamine stress study that shows an aortic velocity ≥4.0 m/s with a valve area ≤1.0 cm² at any dobutamine dose.

  • AVR is suggested in symptomatic patients who have low-flow/low-gradient severe AS who are normotensive and have an LVEF ≥50 percent if clinical, hemodynamic, and anatomic data support valve obstruction as the most likely cause of symptoms.

  • For symptomatic patients with severe AS and an intermediate to high surgical risk, clinical studies suggest that either TAVR or SAVR is an option. The decision should be made by a Heart Valve Team with consideration of patient-specific factors.

  • For symptomatic patients with severe AS, a prohibitive surgical risk, and a predicted post-TAVR survival >12 months.
Transcatheter Aortic Valve Replacement

• Exclusions
  • Bicuspid, unicuspid, or noncalcified aortic valve
  • Native aortic annulus size as measured by computed tomography is <18 mm (for a native valve), <17mm (for a surgical valve), or >the largest annulus size for which a TAVR device is available
  • Severe native aortic regurgitation (>3+) is generally an exclusion criterion when TAVR is performed to treat native aortic valve disease
  • TAVR is not recommended for patients with comorbidities that would preclude an expected benefit from correction of AS
Qualifications to Begin a TAVR Program

The heart team must include:

- **Cardiovascular surgeon with:**
  - ≥ 100 career AVRs including 10 high-risk patients; or
  - ≥ 25 AVRs in one year; or ≥ 50 AVRs in 2 years; and which include at least 20 AVRs in the last year prior to TAVR initiation

- **Interventional cardiologist with:**
  - Professional experience with 100 structural heart disease procedures lifetime; or; 30 left-sided structural procedures per year of which 60% should be balloon aortic valvuloplasty (BAV). Atrial septal defect and patent foramen ovale closure are not considered left-sided procedures

- **Additional members of the heart team**
  - Such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers

- **Device-specific training as required by the manufacturer.**
TAVR Devices

A
CoreValve  Evolut R

B
SAPIEN  SAPIEN XT  SAPIEN 3
Valve Sizing

• Sizing of the aortic annulus is one of the most important factors in preparing for the procedure

• Although TEE has been used, CT results seem to provide more accurate data.

• Proper valve prosthesis size should be 10-20% larger than measured aortic annulus diameter
Transcatheter Aortic Valve Replacement Procedure

• The TAVR procedure includes all the steps outlined for BAV noted earlier.

• TEE ultrasound should be available to assist with valve placement and post deployment assessment.

• Device is prepped according to manufacturer instructions, inserted through vascular access, and advanced across valve.

• Rapid ventricular pacing is again performed (same parameters as BAV)
  
  • Once aortic pressure drops below 50 mmHg, valve is deployed.

• Evaluate Aortic Gradient and Paravalvular leak.
Discussion:

• Questions / Comments / Quemments

• Obligatory Family Photo
Reference


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