Welcome

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The Fundamentals of Cardiac Devices
Module 2
Objectives

After completing this introduction to Cardiac Devices, you will be able to:

• Identify the various cardiac device systems

• Identify the basic indications for implantation for each device

• Recognize each device type on a chest x-ray
Cardiac Devices

• Designed to:
  – Restore or maintain a rhythm and rate sufficient to meet metabolic needs
  – Provide diagnostic information about
    • Device operation
    • The patient
Cardiac Devices

• Pacemakers or Implantable Pulse Generators (IPG)
  – Provide a rate to support metabolic needs
  – Provide various diagnostics
  – Single and dual chamber
  – About 8-10 years longevity
  – Some of the newer pacemakers include therapies which pace-terminate AT/AF
Cardiac Devices

- Implantable Cardioverter Defibrillators (ICDs)
  - Restore sinus rhythm in the presence of tachycardia
    - Defibrillate
    - Cardiovert
    - Anti-Tachy Pace (ATP)
  - Provide a rate to support metabolic needs
    - Includes single or dual chamber pacing
  - Provide various diagnostics
  - About 6-9 years longevity
  - There are also devices designed to terminate AF via cardioversion/ATP in addition to standard ICD therapies

www.pacericd.com
Cardiac Devices

• Cardiac Resynchronization Therapy (CRT)
  – IPG with CRT, or an IPG + ICD with CRT
  – Restore ventricular synchrony
    • Uses a specially designed lead placed usually on the posterior-lateral wall of the LV via the Coronary Sinus circulation
    • LV epicardial lead placement is an option
    • Provides RV and LV synchronous pacing
  – May restore rhythms in presence of lethal tachycardia
    • CRT pacing +ICD (High-Power CRT)
  – Provides a rate to support metabolic needs
    • CRT pacing only (Low-Power CRT)
  – Provides various diagnostics
Cardiac Devices

• Implantable Loop Recorders (ILR)
  – Provides rate-based monitoring
    • Fast rates
    • Slow rates
  – Provides EGM during patient triggered events
Indications
Pacemakers

• The AHA and ACC have defined the indications for pacing by the underlying arrhythmia

• Very detailed, but to simplify:
  – Symptomatic bradycardia refractory to any treatment
  – Typical diagnoses:
    • Sinus Node Disease (SND), or Sick Sinus Syndrome
    • Complete Heart Block
    • Chronotropic Incompetence
    • Vaso-vagal syncope
    • Carotid sinus hypersensitivity
  – Usually excludes “low grade” blocks (Mobitz I and 1st degree)
Indications
Defibrillators

• Primary vs. Secondary Prevention for SCA
  – Primary
    • Patients who have experienced a previous SCA or ventricular arrhythmia
    • Studies such as AVID\textsuperscript{1}, CIDS\textsuperscript{2}, CASH\textsuperscript{3} support the use of ICDs in this population
  – Secondary
    • Patients who have not previously experienced SCA/VA, but are at risk
    • Studies, such as MADIT II\textsuperscript{4} and SCD-HeFT\textsuperscript{5}, have demonstrated the use of ICDs in these patients
Indications
Defibrillators (cont.)

Well defined by Heart Rhythm Society (HRS) and include:

• Cardiac Arrest
  – Due to VT or VF, not transient or reversible
  – Spontaneous sustained VT with structural heart disease

• Syncope of undetermined origin with:
  – Sustained VT or VF induced during EP

• Nonsustained VT with:
  – Coronary disease or prior MI and LV Dysfunction
  – Inducible VF or sustained VT (non-suppressible by antiarrhythmic drugs)

• Spontaneous sustained VT
  – Not amenable to other treatments
Indications
Defibrillators (cont.)

• ICD Class I Recommendation
  • Patients at least 40 days post-MI
    • LVEF ≤ 30 – 40%
    • NYHA class II or III
  • Non-ischemic patients
    • LVEF ≤ 30 – 35%
    • NYHA class II or III
  • Patients at risk of SCA due to genetic disorders
    • Long QT syndrome
    • Brugada syndrome
    • Hypertrophic cardiomyopathy (HCM)
    • Arrhythmogenic right ventricular dysplasia (ARVD)

Note: This list includes the current major indications for an ICD
Indications
Cardiac Resynchronization Therapy

• NYHA Class III or IV heart failure
• On optimal medical therapy
• QRS ≥ 120 ms wide
  – Or Echo evidence of ventricular dyssynchrony
• Ejection Fraction of ≤ 30%
• Who are candidates for an ICD with CRT, and who for an IPG with CRT?
  – Most get an ICD with CRT (also called “High-Power CRT”) because of the risk of SCD in patients with LV dysfunction
Indications
Loop Recorders

• Transient, infrequent but recurrent syncope
Recognizing Systems
Pacemakers

Dual Chamber Pacemaker

RA Lead in Appendage

RV Lead at the Apex
Recognizing Systems
ICD or High Power

Right Atrial Lead
Approximate position outlined

Right Ventricular Lead
With RV and SVC coils
Recognizing Systems
CRT Low-Power

Right Atrial Lead

Left Ventricular Lead
Placed on the surface of the LV via the Coronary Sinus

Right Ventricular Lead
Recognizing Systems
CRT High-Power

Right Atrial Lead

Left Ventricular Lead
Placed on the surface of the LV via the Coronary Sinus

Right Ventricular Lead
Note the 2 high voltage defib coils

Surface ECG leads
Pacing Therapy

• Senses underlying heart rate
  – Delivers low energy electrical pulses when rate falls below programmed limit

• Low energy pulses capture and depolarize the heart muscle causing it to contract
  – Dual Chamber IPGs provide A-V synchrony
ICD Pacing Therapy

• Atrium and Ventricle
  – Sensing
  – Pacing
• Ventricle
  – Antitachycardia pacing (ATP)
High-Voltage Therapy

Cardioversion and Defibrillation are delivered in biphasic waves

For example: First, from the SVC coil and the Can to the RV coil, and then reverse.

The device must detect – charge – confirm – and deliver the shock.

Fast, accurate detection, and fast charge times are critical
ICD Therapy

- The ICD lead is designed to carry both high voltage and pacing therapies
  - Brady
  - ATP
  - Cardioversion
  - Defibrillation
CRT Therapy

- Video of Dyssynchronous Heart
- Video of CRT in Action

By pacing from both the right and left ventricles, CRT may improve EF and reduce patient symptoms.
Implant Evolution

Pacemakers—Yesterday

• First Implants in early 1960s
• Single Chamber, non programmable
• About 2 year longevity
• About 200 cc
• Abdominal implants, sternotomy for epicardial leads
Implant Evolution

Pacemakers—Today

• Pectoral implants
• 6-7 F transvenous lead placement
  – Outpatient/overnight stay
• < 30 cc
• 8-10 years longevity
• Dual chamber, multi-programmable
• Advanced diagnostics and trending information
Implant Evolution

ICD Past: ~10-12 years ago ICDs

- Required major surgery
  - Abdominal implants
  - Median sternotomy to suture defib patches on heart
  - Length of hospital stay ≥ 1 week
- Nonprogrammable
- High-energy shock only
- Indicated for patients who survived cardiac arrest - twice
- 1 ½ year longevity
- 209 cc
- < 1,000 implants/year
Implant Evolution

ICDs Today

• Similar to a pacemaker implant
• Transvenous, single incision
  – Pectoral implant
  – Overnight stay
• Local anesthesia, conscious sedation
• Programmable therapy options
• Single, dual and triple chamber (CRT)
• Up to 9 years longevity
• About 35 cc
• > ~100,000 implants/year
Status Check

• Given the following patient
  – 67 YO male patient, had an anterior MI 2 years ago
  – EF 20%
  – History includes
    • Tobacco 2 packs/day
    • CAD
  – Medications
    • Vasopril (ACE Inhibitor)
    • Coreg (ARB)
    • Atenolol (Beta Blocker)
    • Hyperlipidemia
    • Lipitor (Statin)
    • Aldosterone (ADH)
  – C/O
    • Severe shortness of breath at rest, fatigue, unable to perform ADL, vertigo, rare syncope
Status Check

• Patient’s ECG:

What device system (if any) is the patient likely to get?

Click for Answer

High-Power CRT

Wide QRS, EF < 30% on max medical therapy and is S/P MI. = ↑ risk of SCD
Status Check

• Could this be the previous patient’s chest x-ray?
  – Is it CRT?
  – Is it High-Power?

Click for Answer

Yes, we see an RV lead with RV and SVC coils, an atrial pacing lead, and an LV pacing lead.
Status Check

• Consider the following patient
  – Elderly female patient
  – Medical history includes
    • Ex-smoker – quit 10 years ago
    • Mild exertional angina
      – Cardiac cath shows mild disease right coronary artery
    • 3 adult children
  – Medications
    • Nitroglycerine PRN
    • Aspirin 81 mg. 1/day
  – C/O
    • Fatigue, unable to perform normal activities
Status Check

• Patient’s stress test indicates:
  – Stopped after 4 minutes for fatigue
  – ECG immediately after stress test:

Likely a pacemaker, as the patient has chronotropic incompetence – her heart rate does not increase with exercise.
Basic Concepts—Electricity and Pacemakers
Module 3
Objectives

Upon completion you will be able to:

• Describe the relationship between voltage, current, and resistance

• Describe the clinical significance of alterations in voltage, current, and resistance
Characteristics of an electrical circuit: Including a pacemaker circuit

- Voltage
- Current
- Impedance
Voltage

• Voltage is the force, or “push,” that causes electrons to move through a circuit

• In a pacing system, voltage is:
  – Measured in volts (V)
  – Represented by the letter “V”
  – Provided by the pacemaker battery
  – Often referred to as amplitude or pulse amplitude
Current

• The flow of electrons in a completed circuit

• In a pacing system, current is:
  – Measured in milliamps (mA)
  – Represented by the letter “I”
  – Determined by the amount of electrons that move through a circuit
Impedance

• The opposition to current flow

• In a pacing system, impedance is:
  – Measured in ohms (Ω)
  – Represented by the letter “R”
  – The measurement of the sum of all resistance to the flow of current
Voltage, Current, and Impedance are Interdependent

• The interrelationship of the three components is analogous to the flow of water through a hose
  – Voltage represents the force with which . . .
  – Current (water) is delivered through . . .
  – A hose, where each component represents the total impedance:
    • The nozzle, representing the electrode
    • The tubing, representing the lead wire
Voltage, Current, and Impedance

Recap

• Voltage: The force moving the current (V)
  – In pacemakers it is a function of the battery chemistry

• Current: The actual continuing volume of flow of electricity (I)
  – This flow of electrons causes the myocardial cells to depolarize (to “beat”)

• Impedance: The sum of all resistance to current flow (R or $\Omega$ or sometimes Z)
  – Impedance is a function of the characteristics of the conductor (wire), the electrode (tip), and the myocardium
Voltage and Current Flow

Electrical Analogies

Water pressure in system is analogous to voltage – providing the force to move the current.

Spigot (voltage) turned up, lots of water flows (high current drain).

Spigot (voltage) turned low, little flow (low current drain).
Resistance and Current Flow
Electrical Analogies

• Normal resistance – friction caused by the hose and nozzle

• Low resistance – leaks in the hose reduce the resistance.

More water discharges, but is all of it going to the nozzle?

• High resistance – a knot results in low total current flow.
Ohm’s Law

- Describes the relationship between voltage, current, and resistance

\[ V = I \times R \]
\[ I = \frac{V}{R} \]
\[ R = \frac{V}{I} \]
Ohm’s law tells us:

1. If the impedance remains constant, and the voltage decreases, the current decreases

2. If the voltage is constant, and the impedance decreases, the current increases

So What?
Status Check

What happens to current if the voltage is reduced but the impedance is unchanged?

• Start with:
  – Voltage = 5 V
  – Impedance = 500 Ω
  – Current = 10 mA

• Solve for Current (I):
  – I = V/R
  – I = 5 V ÷ 500 Ω = 0.010 Amps
  – Current is 10 mA

• Reduce the voltage to 2.5 V
  – Voltage = 5 V
  – Impedance = 500 Ω
  – Current = ?

• Is the current increased/decreased or unchanged?
  – I = V/R
  – V = 2.5 V ÷ 500 Ω = 0.005 Amps or 5 mA

• The current is reduced
Status Check

What happens to current if the impedance is reduced but the voltage is unchanged?

• Start with:
  – Voltage = 5 V
  – Impedance = 500 Ω
  – Current = 10 mA

• Solve for Current (I):
  – I = V/R
  – I = 5 V ÷ 500 Ω = 0.010 Amps
  – Current is 10 mA

• Reduce impedance to 250 Ω
  – Voltage = 5 V
  – Impedance = 250 Ω
  – Current = ?

• Is the current increased/decreased or unchanged?
  – I = V/R
  – V = 2.5 V ÷ 250 Ω = 0.02  Amps or 20 mA

• The current is increased
Other terms

• Cathode: A negatively charged electrode
  – For example, the electrode on the tip of a pacing lead

• Anode: A positively charged electrode
  – Examples:
    • The “ring” electrode on a bipolar lead
    • The IPG case on a unipolar system
  – More on this later (see: Pacemaker Basics)
Battery Basics
So where does the current come from?

• A battery produces electricity as a result of a chemical reaction. In its simplest form, a battery consists of:
  – A negative electrode (anode)
  – An electrolyte, (which conducts ions)
  – A separator, (also an ion conductor) and
  – A positive electrode (cathode)
Applying Electrical Concepts to Pacemakers
Module 4
Objectives

• Upon completion you will be able to:
  – Recognize a high impedance condition
  – Recognize a low impedance condition
  – Recognize capture threshold
  – Determine which sensitivity value is more (or less) sensitive
Electrical Information

• Why is this electrical information relevant?

• A pacemaker is implanted to:
  – Provide a heart rate to meet metabolic needs
    • In order to pace the heart, it must capture the myocardium
    • In order to pace the heart, it must know when to pace, i.e., it must be able to sense

• A pacemaker requires an intact electrical circuit
Ohm’s Law
Relevance to Pacemaker Patients

• High impedance conditions reduce battery current drain
  – Can increase pacemaker battery longevity
  – Why?
    • $R = \frac{V}{I}$ If “$R$” increases and “$V$” remains the same, then “$I$” must decrease

• Low impedance conditions increase battery current drain
  – Can decrease pacemaker battery longevity
  – Why?
    • $R = \frac{V}{I}$ If “$R$” decreases and “$V$” remains the same, then “$I$” must increase
The Effect of Lead Performance on Myocardial Capture

What would you expect to happen if a lead was partially fractured?

- Impedance (or Resistance) would rise
- Current would decrease and battery energy conserved

Could you guarantee that enough current (I) can flow through this fractured lead so that each time the pacemaker fired the myocardium would beat?
High Impedance Conditions
A Fractured Conductor

• A fractured wire can cause Impedance values to rise
  – Current flow from the battery may be too low to be effective

• Impedance values may exceed 3,000 Ω

Other reason for high impedance: Lead not seated properly in pacemaker header.
Lead Impedance Values Change as a Result of:

- Wire fractures
- Insulation breaks

Typically, normal impedance reading values range from 300 to 1,000 Ω

- Some leads are high impedance by design. These leads will normally show impedance reading values greater than 1,000 ohms
  - Medtronic High Impedance leads are:
    - CapSure® Z
    - CapSure® Z Novus
Low Impedance Conditions

• Insulation breaks expose the lead wire to the following
  – Body fluids, which have a low resistance, or
  – Another lead wire (in a bipolar lead)

• Insulation break that exposes a conductor causes the following
  – Impedance values to fall
  – Current to drain through the insulation break into the body, or into the other wire
  – Potential for loss of capture
  – More rapid battery depletion

Current will follow the path of LEAST resistance
Capture Threshold

• The minimum electrical stimulus needed to consistently capture the heart outside of the heart’s own refractory period

Ventricular pacemaker 60 ppm
Effect of Lead Design on Capture

• Lead maturation
  – Fibrotic “capsule” develops around the electrode following lead implantation
  – May gradually raise threshold
  – Usually no measurable effect on impedance
Steroid Eluting Leads

• Steroid eluting leads reduce the inflammatory process
  – Exhibit little to no acute stimulation threshold peaking
  – Leads maintain low chronic thresholds
Effect of Steroid on Stimulation Thresholds

Pulse Width = 0.5 msec

Implant Time (Weeks)

Volts

Smooth Metal Electrode

Textured Metal Electrode

Steroid-Eluting Electrode

Myocardial Capture

• Capture is a function of:
  – Amplitude—the strength of the impulse expressed in volts
    • The amplitude of the impulse must be large enough to cause depolarization (i.e., to “capture” the heart)
    • The amplitude of the impulse must be sufficient to provide an appropriate pacing safety margin
  – Pulse width—the duration of the current flow expressed in milliseconds
    • The pulse width must be long enough for depolarization to disperse to the surrounding tissue
Comparison
5.0 Volt Amplitude at Different Pulse Widths

Amplitude
5.0 V

0.5 ms

0.25 ms

1.0 ms
The Strength-Duration Curve

- The strength-duration curve illustrates the relationship of amplitude and pulse width
  - Any combination of pulse width and voltage, on or above the curve, will result in capture
Clinical Utility of the Strength-Duration Curve

• By accurately determining capture threshold, we can assure adequate safety margins because:
  
  – Thresholds may differ in acute or chronic pacing systems
  – Thresholds fluctuate slightly daily
  – Thresholds can change due to metabolic conditions or medications
Programming Outputs

• Primary goal: Ensure patient safety and appropriate device performance

• Secondary goal: Extend the service life of the battery

  – Typically program amplitude to < 2.5 V, but always maintain adequate safety margins
    • A common output value might be 2.0 V at 0.4 ms

  – Amplitude values greater than the cell capacity of the pacemaker battery (usually about 2.8 V) require a voltage multiplier, resulting in markedly decreased battery longevity
Pacemaker Sensing

- Refers to the ability of the pacemaker to “see” signals
  - Expressed in millivolts (mV)
- The millivolts (mV) refers to the size of the signal the pacemaker is able to “see”

![Diagram showing 0.5 mV and 2.0 mV signals]
Sensitivity
The Value Programmed into the IPG

- 5.0 mV
- 2.5 mV
- 1.25 mV

Time
Sensitivity
The Value Programmed into the IPG

At this value the pacemaker will not see the 3.0 mV signal
Sensitivity
The Value Programmed into the IPG

At this value, the pacemaker can see both the 3.0 mV and the 1.30 mV signal. So, is “more sensitive” better, because the pacemaker sees smaller signals?

1.25 mV Sensitivity

But what about this?

Time

5.0 mV

2.5 mV

1.25 mV
Sensing Amplifiers/Filters

- Accurate sensing requires that extraneous signals are filtered out
  - Because whatever a pacemaker senses is by definition a P- or an R-wave
  - Sensing amplifiers use filters that allow appropriate sensing of P- and R-waves, and reject inappropriate signals

- Unwanted signals most commonly sensed are:
  - T-waves (which the pacemaker defines as an R-wave)
  - Far-field events (R-waves sensed by the atrial channel, which the pacemaker thinks are P-waves)
  - Skeletal muscle myopotentials (e.g., from the pectoral muscle, which the pacemaker may think are either P- or R-waves)
  - Signals from the pacemaker (e.g., a ventricular pacing spike sensed on the atrial channel “crosstalk”)
Sensing Accuracy

• Affected by:
  – Pacemaker circuit (lead) integrity
    • Insulation break
    • Wire fracture
  – The characteristics of the electrode
  – Electrode placement within the heart
  – The sensing amplifiers of the pacemaker
  – Lead polarity (unipolar vs. bipolar)
  – The electrophysiological properties of the myocardium
  – EMI – Electromagnetic Interference
Lead Conductor Coil Integrity
Affect on Sensing

• Undersensing occurs when the cardiac signal is unable to get back to the pacemaker
  – Intrinsic signals cannot cross the wire fracture

• Oversensing occurs when the severed ends of the wire intermittently make contact
  – Creates signals interpreted by the pacemaker as P- or R-waves
Lead Insulation Integrity Affect on Sensing

• Undersensing occurs when inner and outer conductor coils are in continuous contact
  – Signals from intrinsic beats are reduced at the sense amplifier, and amplitude no longer meets the programmed sensing value

• Oversensing occurs when inner and outer conductor coils make intermittent contact
  – Signals are incorrectly interpreted as P- or R-waves
Unipolar Pacemaker

- Where is the sensing circuit?

Lead tip to can
This can produce a large potential difference (signal) because the cathode and anode are far apart.
Bipolar Pacemaker

- Where is the sensing circuit?

  **Click for Answer**

Lead tip to ring on the lead
This usually produces a smaller potential difference due to the short inter-electrode distance
- But, electrical signals from outside the heart (such as myopotentials) are less likely to be sensed
By now we should be familiar with the surface ECG and its relationship to cardiac conduction. But, how does this relate to pacemaker sensing?
The wave of depolarization produced by normal conduction creates a gradient across the cathode and anode. This changing polarity creates the signal.

Once this signal exceeds the programmed sensitivity – it is sensed by the device.
A PVC occurs, which is conducted abnormally. Since the vector relative to the lead has changed, what effect might this have on sensing?

In this case, the wave of depolarization strikes the anode and cathode almost simultaneously. This will create a smaller gradient and thus, a smaller signal.
Putting It All Together

• Appropriate output programming can improve device longevity
  – But, do not compromise patient safety!

• Lead design can improve device longevity via
  – Steroid eluting leads
    • Can help keep chronic pacing thresholds low by reducing inflammation and scarring
  – High Impedance leads
    • Medtronic CapSure Z and Medtronic CapSure Z Novus
    • Designed so electrode $\Omega$ is high, but $V$ low so current ($I$) is low as well, reducing battery drain

• Control of manufacturing
  – Batteries, circuit boards, capacitors, etc., specific to needs, can lead to improved efficiencies and lowered static current drain
  – Highly reliable lead design
Putting It All Together

• Pacemaker Longevity is:
  – A function of programmed parameters (rate, output, % time pacing)
  – A function of useful battery capacity
  – A function of
    • Static current drain
    • Circuit efficiency
    • Output Impedance

• The lower the programmed sensitivity the MORE sensitive the device
  – Lead integrity also affects sensing
Status Check

- Determine the threshold amplitude

Capture threshold = lowest value with consistent capture

This is at 1.25 V
Status Check

• Which of these pacemakers is more sensitive?

Pacemaker A is able to “see” signals as small as 0.5 mV. Thus, it is more sensitive.
Status Check

• A pacemaker lead must flex and move as the heart beats. On average, how many times does a heart beat in 1 year?

Click for Answer

35 MILLION times. It is not a simple task to design a lead that is small, reliable, and lasts a lifetime.
Status Check

Do you notice anything on this x-ray?

Lead Fracture:
• High Impedance
• Possible failure to capture myocardium
Status Check
What would you expect?

- Which value is out of range?
- What could have caused this?

Pacemaker Interrogation Report

Mode: DDDR
Lower: Rate 60 ppm
UTR: 130 ppm
USR: 130 ppm
Atrial Lead Impedance: 475 Ohms
Ventricular Lead Impedance: 195 Ohms

Click for Answer
Insulation failure
Thank You