Sudden Death Prevention: How You Can Help

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Disclosures

• Boston Scientific
  – Consultant, Research Support

• Medtronic
  – Consultant

• Glaxo Smithkline
  – Speakers’ Bureau
Today’s Agenda

• Definition of Sudden Cardiac Death (SCD)
• Magnitude of the problem in the U.S.
• Populations at risk for SCD
• What you can do to help prevent SCD
  – Before your patient is in the high-risk group
  – After high risk profile has been identified
Modern SCD Definition

(1) Witnessed cardiac arrest; (2) within 1 hour after the onset of acute symptoms; or (3) unexpected, un-witnessed death in a patient known to have been well within the previous 24 hours.

Note: The terms SCD (Sudden Cardiac Death) and SCA (Sudden Cardiac Arrest) are interchangeable.
Arrhythmic Cause of SCD

• US vital statistics mortality data for 1989-1998 estimated 719,456 cardiac deaths for 2000; with 63% (456,078) being defined as SCD.¹

• A large study recently completed with 121,701 women (Nurse’s Health Study) over a 20 year period estimated 88% of sudden cardiac deaths were due to arrhythmic causes.²

• Cardiac and non-cardiac events that cause SCD can be indistinguishable from ventricular arrhythmias.

Underlying Arrhythmias of Sudden Cardiac Arrest

- Monomorphic VT 62%
- Bradycardia 17%
- Polymorphic VT 13%
- Primary VF 8%

SCA Signs and MI Symptoms

SCA Signs:
• Sudden collapse and loss of consciousness
• Cessation of normal breathing
• Loss of pulse and blood pressure

MI Symptoms:
• Uncomfortable pressure, fullness, squeezing, or pain in the center of the chest lasting more than a few minutes
• Pain spreading to the shoulders, neck, or arms
• Chest discomfort with lightheadedness, fainting, sweating, nausea, or shortness of breath
• Atypical chest pain, stomach, or abdominal pain
• Nausea or dizziness
• Shortness of breath and difficulty breathing
• Unexplained anxiety, weakness, or fatigue
• Palpitations, cold sweat, or paleness

www.americanheart.org
This is what SUDDEN Cardiac Arrest looks like

Adapted from a slide by David Cannom
This is what SUDDEN Cardiac Arrest LOOKS like
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Sudden Cardiac Arrest (SCA)

• SCA claims an estimated 325,000-450,000 lives each year
  – 1,000 to 1,200 lives every day; 1 life every 80 seconds
• SCA accounts for half of all cardiac-related deaths
• 97% of people die from their first episode of SCA
• Over half of SCA victims have no prior symptoms
Leading Causes of Death in the U.S.

- Septicemia
- Nephritis
- Alzheimer's Disease
- Influenza/pneumonia
- Diabetes
- Accidents/injuries
- Chronic lower respiratory diseases
- Cerebrovascular disease
- Other cardiac causes
- Sudden cardiac arrest (SCA)
- All other causes
- All cancers

You must combine deaths from all cancers to outnumber the deaths from SCA each year.


Magnitude of SCA in the U.S.

SCA claims more lives each year than these other diseases combined:

- Stroke: 167,366
- Lung Cancer: 157,400
- Breast Cancer: 40,600
- AIDS: 42,156
- Total: 450,000

Magnitude of SCA in the U.S.

- 450,000 per year\(^1\)
- 1,200 per day
  - 1 every 80 seconds
  - One since I last mentioned this fact
- Coronary artery disease is present in 80-85% of patients who experience SCA.\(^2,3\)

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\(^3\) Cobb LA. *Circulation*. 1975;51(III):223.
Influence of Race on SCD Rates - Males

Age-adjusted death rates (per 100,000 US population) for sudden cardiac death among men aged 35 years and older by race in the US from 1989 to 1998.

Influence of Race on SCD Rates - Females

Age-adjusted death rates (per 100,000 US population) for sudden cardiac death among women aged 35 years and older by race in the US from 1989 to 1998.

SCD Rates for Males and Females

Incidence of SCD by Age Among Males and Females

% Cardiac Deaths that are SCD by Age Group Among Females

Proportion of cardiac deaths (with information on timing) that were SCDs according to 10-year age groups

SCA Resuscitation Success vs. Time

*Non-linear

Chance of success reduced 7-10% each minute

After cardiac arrest, you need help within 5 minutes. The ambulance usually takes 9.

For the best chance of survival, a shock should be delivered within five minutes. But most sudden cardiac arrests happen at home, where help often doesn’t arrive in time. Designed a defibrillator for the home that can be used by people just like you. Now you can help save a life in about the time it takes to read this ad. It just makes sense.
SCA Survival is Variable

- Toronto: 5%
- Seattle: 13-26%
- Airline: 24-40%
- Las Vegas casino: 53%

Estimated 80% of SCA occurs at home.
Even in the best EMS/early defibrillation programs it is difficult to achieve high survival rates due to many SCA events not being witnessed and the difficulty of reaching victims within 6-8 minutes.

- 40% SCAs not witnessed or occur in sleep¹
- 80% SCAs occur at home¹
- 5% estimated SCA out-of-hospital survival²;³

“Medic One's...average response time in the county is a little more than 18 minutes”
– *The Bellingham Herald, Sunday Sept 6, 2009*

This from one of the premier EMS/paramedic systems in the country
SCA Chain of Survival

1. Early Access
2. Early CPR
3. Early Defibrillation
4. Early Advance Care
5. Evaluate Need for ICD

www.americanheart.org The Links in the Chain of Survival
Adapted by Medtronic, Inc. to include refer to EP.
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Incidence of SCD in Specific Populations and Annual SCD Numbers

GROUP

General population
Patients with high coronary-risk profile
Patients with previous coronary event
Patients with ejection fraction < 35%, heart failure
Patients with previous out-of-hospital cardiac arrest
Patients with previous myocardial infarction, low ejection fraction, and vent. tachycardia

Incidence of Sudden Death (% of group)

Clinical SCD Risk Factors

• Reduced left ventricular ejection fraction
• Coronary heart disease, prior MI
• Dilated cardiomyopathy and heart failure symptoms
  – Due to coronary artery disease (ischemic)
  – In the absence of coronary artery disease (nonischemic)
• Inducible VT by Electrophysiologic Study (EPS)
• Resuscitation from prior VT/VF event
• Family History of SCD
• Genetic Disorders: HCM, LQTS, ARVD, Brugada Syndrome
• Other Risk Factors
Clinical SCD Risk Factors

Reduced Left Ventricular Ejection Fraction
Reduced left ventricular ejection fraction (LVEF) remains the single most important risk factor for overall mortality and sudden cardiac death.

Role of Ventricular Ectopy and LV Dysfunction in SCD Risk – GISSI-2 Trial

Maggioni AP. Circulation. 1993;87:312-322.
Relation of LVEF to Risk of SCA

LVEF

% Sudden Cardiac Deaths

Note: 56.5% of all SCA victims had an LVEF > 30%

Clinical SCD Risk Factors

Coronary Heart Disease, Prior MI
Coronary Heart Disease and its consequences account for the majority of sudden cardiac deaths in Western cultures.

- Coronary Heart Disease: 80%
- Nonischemic Cardiomyopathy: 15%
- Other*: 5%

*ion-channel abnormalities, valvular or congenital heart disease, other causes


People who’ve had a MI (“heart attack”) have a sudden death rate that’s 4-6 times that of the general population.
Post-MI and LV Dysfunction

- Post-MI patients who also have LV dysfunction (≤40%) are at an increased risk of SCD.*
- Analysis of mortality rates in the control groups of clinical studies in post-MI patients with LV dysfunction show the overall mortality to be ~20-30% at 2 years, with ~50% of this due to SCD.*
- Symptomatic HF confers a 20-25% risk of premature death in the first 2.5 yrs after diagnosis; ≈50% of these premature deaths are SCD¹,²
- Thus, post-MI patients with LV dysfunction have mortality rates from SCD that are similar to a HF population.

* References in slide notes.

¹ Bardy G. The Sudden Cardiac Death-Heart Failure Trial (SCD-HeFT) in Woosley RL, Singh S, Arrhythmia Treatment and Therapy, Copyright 2000 by Marcel Dekker, Inc., pp. 323-342.

² Sweeney, MO. PACE 2001;24:871-888.
Myocardial Infarction

- Prior myocardial infarctions are identified in as many as 50-75% of SCA victims.\textsuperscript{1-3}

- Therapeutic innovations in the last decade* have improved initial survival in patients with reduced ejection fraction and may have altered the epidemiology of post-MI risk.

\textsuperscript{2} Lombardi G. JAMA. 1994;271:678-683.
\textsuperscript{3} Bigger JT. Circulation. 1984;69:250-258.

*including early and aggressive revascularization and effective pharmacologic therapy
VF in Acute MI - Survival Results

GISSI-2 Trial

% Surviving

Reference Group
Early PVF
Late PVF
Nonprimary VF

Log-Rank Test
P<0.0001

Days

Time Dependence of Mortality Risk Post-MI

Prediction of Sudden Cardiac Death After Myocardial Infarction in the Beta-Blocking Era¹

- 700 post-MI patients; ~95% on beta-blockers 2 years after discharge.
- The epidemiologic pattern of SCD was different from that reported in previous studies.

Arrhythmia events did not concentrate early after the index event; most occurred >18 months post-MI.

Relation of Time from MI to ICD Benefit in the MADIT-II Trial

Time Dependence of Mortality Risk Post-MI

Maastricht Circulatory Arrest Registry¹:
- In 224 SCA victims, only 4% were due to an acute MI.
- The median time from MI to SCA was 9 years in 92 patients (41% of total).

¹Gorgels PMA. *European Heart Journal*. 2003;24:1204-1209.
MUSTT\textsuperscript{1} and MADIT-II\textsuperscript{2,3}
Arrhythmic Death Results in Study Control Arms

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|c|}
\hline
Year & MUSTT & MADIT-II & \hline
1 Year & 10\% & 6\% & \hline
2 Years & 18\% & 14\% & \hline
3 Years & 21\% & 20\% & \hline
5 Years & & & 32\% \textsuperscript{3} \textsuperscript{3} \textsuperscript{3} \hline
\end{tabular}
\caption{
\textsuperscript{3}Moss AJ. Presented before ACC 51st Annual Scientific Sessions, Late Breaking Clinical Trials, March 19, 2002.
}
\end{table}
Take Home Points

• If your patient has had a prior MI:
  – Survival of the MI doesn’t = low SCA risk
  – The lower the EF, the higher the SCA risk
  – Survival long term **DOESN’T** = low SCA risk
    • SCA risk in post-MI patients continues to increase with time
    • Take Action!
Clinical SCD Risk Factors

Dilated Cardiomyopathy and Heart Failure
In people diagnosed with Heart Failure, sudden cardiac death occurs at 6-9 times the rate of the general population.

Heart Failure & Sudden Cardiac Death

Heart Failure predicts increased sudden death and overall mortality during a 38-year follow-up of subjects in the Framingham Heart Study.

Severity of Heart Failure and Modes of Death

NYHA Class II  n = 103

- CHF: 64%
- Other: 24%
- Sudden Death: 12%

NYHA Class III  n = 103

- CHF: 59%
- Other: 15%
- Sudden Death: 26%

NYHA Class IV  n = 27

- CHF: 56%
- Other: 33%
- Sudden Death: 11%

SCD Rates in CHF Patients with LV Dysfunction

Total Mortality ~15-40%; SCD accounts for ~50% of the total deaths

References in slide notes.
SCD in Heart Failure

Despite improvements in medical therapy, symptomatic HF still confers a 20-25% risk of premature death in the first 2.5 years after diagnosis.¹,²

≈ 50% of these premature deaths are SCD

¹ Bardy G. The Sudden Cardiac Death-Heart Failure Trial (SCD-HeFT) in Woosley RL, Singh S, Arrhythmia Treatment and Therapy, Copyright 2000 by Marcel Dekker, Inc. 323-342.

² Sweeney MO. PACE. 2001;24:871-888.
Clinical SCD Risk Factors

Resuscitation from Prior VT/VF Event
Arrhythmic Death Results in VT/VF Patients: AVID Results in Non-ICD Study Arm

AVID Study – Survival by Arrhythmia Type

Cumulative Survival (%) vs. Years

- Unexplained syncope
- Non-syncope/VT w/symptoms
- VF
- Transient correctable VT/VF
- Asymptomatic VT
- VT w/syncope

P = 0.007

Clinical SCD Risk Factors

Genetic Disorders
Genetic Disorders

- **LQTS** patients who experience syncope or a SCA event while taking beta-blockers are at highest risk of SCD. These patients usually have no evidence of structural heart disease or LV dysfunction.\(^1,2\)

- **HCM** is the most common cause of death in young people. The magnitude of left ventricular hypertrophy is directly correlated to the risk of SCD. Young patients with extreme hypertrophy and few or no symptoms are at substantial long-term risk of SCD.\(^3,4\)

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Cumulative Probability of LQTS – Related Death With Beta-Blockers

Wall Thickness and Sudden Death in HCM

Populations at Risk for SCD

• Reduced left ventricular ejection fraction
• Coronary heart disease, prior MI
• Dilated cardiomyopathy and heart failure symptoms
  – Due to coronary artery disease (ischemic)
  – In the absence of coronary artery disease (nonischemic)
• Inducible VT by Electrophysiologic Study (EPS)
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• Family History of SCD
• Genetic Disorders: HCM, LQTS, ARVD, Brugada Syndrome
• Other Risk Factors
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Let’s Focus on the People Above the Line!

GROUP

- General population
- Patients with high coronary-risk profile
- Patients with previous coronary event
- Patients with ejection fraction < 35%, heart failure
- Patients with previous out-of-hospital cardiac arrest
- Patients with previous myocardial infarction, low ejection fraction, and ventricular tachycardia

Incidence of Sudden Death (% of group)

No. of Sudden Deaths Per Year

Cardiovascular Disease

• Hypertension
  • 140/90
    – 58,000,000 Americans affected
    – 45,000,000 with “pre-hypertension” (>115/75)
• Coronary Heart Disease
  – Myocardial Infarction (heart attack) 7,200,000
  – Angina (chest pain) 6,500,000
• Heart Failure
  – Over 5,000,000 affected
• Stroke
  – 5,500,000 affected

Schwartz, Gary L; Sheps, Sheldon G, Cardiovascular Medicine, Ill Hypertension, ACP Medicine Online, Dale DC; Federman DD, Eds. WebMD, Inc., New York, 2000
Cardiovascular Disease: CVD

1 in 3 adults has some form of CVD
Cardiovascular Mortality
No.1 Killer in the United States

- In 2003, CVD was underlying or contributing cause of death in 1,408,000
  - By comparison, ALL cancers combined caused 554,643 deaths

- 37.3% of all deaths, or one of every 2.7

- 2,500 Americans die every day of CVD, an average of one death every 35 seconds
Cardiovascular Mortality
No.1 Killer in the United States

• 152,000 CVD deaths in patients under age of 65

• In 2002, 32% of CVD deaths occurred “prematurely” (before age 75, the average life expectancy)
CVD Risk Factors

• Tobacco use
• Hypertension
• Abnormal Cholesterol
  – High LDL
  – Low HDL
• Diabetes Mellitus
• Family History – CVD at an early age
Diabetes as a Risk Equivalent for CHD

CHD = coronary heart disease; DM = diabetes mellitus; MI = myocardial infarction, fatal and non-fatal.
Other SCD Risk Factors
(Besides low EF, CHD and prior MI, Dilated CM/HF, prior arrest, genetic syndromes)

- Age
- Race
- Gender
- Activity
- Hypertension
- Left Ventricular Hypertrophy
- Intraventricular Conduction Block
- Inducible VT
- Elevated Serum Cholesterol
- Glucose Intolerance
- Decreased Vital Capacity
- Smoking
- Relative Weight
- Heart Rate

Intervene Early

• Focus on risk factors for both CVD & SCD
  – Hypertension
  – Glucose Intolerance/Diabetes
  – Smoking
  – Dyslipidemia

• Established CVD
  – Determine if in high risk group

• Family History of SCD – Refer to specialist
Build Community Awareness

• Sudden Cardiac Arrest Awareness Month
  October 1, 2008 – PITTSBURGH – Congress has declared October “National Sudden Cardiac Arrest Awareness Month” in an effort to raise awareness about the nation’s leading cause of death. The resolution “calls upon the people of the U.S. to observe this month with appropriate programs and activities.”

• Automatic External Defibrillators (AEDs)

• Citizen training for bystander CPR

• When appropriate: Refer for ICD therapy
Online Resources

SCA 360° Resource Center
Your online destination for information and education on Sudden Cardiac Arrest (SCA).

SCA 360° provides a single, trusted resource for the most comprehensive and relevant information and education on Sudden Cardiac Arrest. Led by the most respected professionals and drawing from top experts, publications and other leading sources, SCA 360° helps cardiac arrhythmia professionals improve patient outcomes.

Learning Center
Expand your clinical knowledge with an array of CME and non-CME educational resources. Learn about the recently released clinical documents on Catheter Ablation of Ventricular Arrhythmias, Lead Performance, and Lead Extraction, view multimedia webcasts from a variety of Heart Rhythm Society programs including our webinar on the 2009 New Cardiac Device Monitoring Codes, explore online case studies, and convenient Pocket Guides, journal articles.

New Additions to the SCA Resource Center
Check out the newest activities and information available in the SCA Resource Center.

- Interview with Kenneth A. Ellenbogen, MD, FHRs and Robert G. Hauser, MD, FHRs, CCDS on the importance of the...
Online Resources
What to Do When Your Patient is in a High Risk Group:

GROUP

General population

Patients with high coronary-risk profile

Patients with previous coronary event

Patients with ejection fraction < 35%, heart failure

Patients with previous out-of-hospital cardiac arrest

Patients with previous myocardial infarction, low ejection fraction, and vent. tachycardia

Incidence of Sudden Death (% of group)

No. of Sudden Deaths Per Year

PROPHYLACTIC IMPLANTATION OF A DEFIBRILLATOR IN PATIENTS WITH MYOCARDIAL INFARCTION AND REDUCED EJECTION FRACTION

ARTHUR J. MOSS, M.D., WOJCIECH ZAREBA, M.D., PH.D., W. JACKSON HALL, PH.D., HELMUT KLEIN, M.D., DAVID J. WILBER, M.D., DAVID S. CANNOM, M.D., JAMES P. DAUBERT, M.D., STEVEN L. HIGGINS, M.D., MARY W. BROWN, M.S., AND MARK L. ANDREWS, B.B.S., FOR THE MULTICENTER AUTOMATIC DEFIBRILLATOR IMPLANTATION TRIAL II INVESTIGATORS*
MADIT II

- 1232 patients enrolled
- Prior MI (at least a month ago)
- EF $\leq$ 30%
- 1$^{st}$ study with no arrhythmia marker
- ICD vs conventional MI/CHF treatment
- No surgical deaths
- Trial stopped early…
MADIT II: Survival Results

31% Less mortality on top of best medical therapy with ICDs

Number Needed to Rx: 17

Probability of Survival

P = 0.007

Year

0 1 2 3 4
MADIT II: 8 Year Follow-Up

- 37% less mortality on top of best medical therapy with ICDs

Number Needed to Rx 6

Dr. Ilan Goldenberg, oral presentation, Heart Rhythm Society 2009
What About Patients with Nonischemic Cardiomyopathy?

SCD-HeFT trial

2521 Pts
NYHA II-III Heart Failure
LVEF≤35% (mean 25%)
ischemic and non ischemic

optimal drug Rx
placebo

optimal drug Rx
amiodarone

optimal drug Rx
ICD (VVI)
Amiodarone or an Implantable Cardioverter–Defibrillator for Congestive Heart Failure

SCD-HeFT Results

EF ≤ 35% and NYHA 2-3

Median Followup = 45.5 months

23% mortality reduction with prophylactic ICD

Current ICD Indications

- **Class I.**
  - 1 ICD therapy is indicated in patients who are survivors of cardiac arrest due to ventricular fibrillation or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes. *(Level of Evidence: A)* (4,133–138)
  - 2 ICD therapy is indicated in patients with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable. *(Level of Evidence: B)* (4,133–138)
  - 3 ICD therapy is indicated in patients with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or ventricular fibrillation induced at electrophysiological study. *(Level of Evidence: B)* (4,136)
  - 4 ICD therapy is indicated in patients with LVEF less than 35% due to prior myocardial infarction who are at least 40 days post--myocardial infarction and are in NYHA functional Class II or III. *(Level of Evidence: A)* (4,139)
  - 5 ICD therapy is indicated in patients with nonischemic dilated cardiomyopathy who have an LVEF less than or equal to 35% and who are in NYHA functional Class II or III. *(Level of Evidence: B)* (4,139–141)
  - 6 ICD therapy is indicated in patients with LV dysfunction due to prior myocardial infarction who are at least 40 days post--myocardial infarction, have an LVEF less than 30%, and are in NYHA functional Class I. *(Level of Evidence: A)* (4,132)
  - 7 ICD therapy is indicated in patients with nonsustained VT due to prior myocardial infarction, LVEF less than 40%, and inducible ventricular fibrillation or sustained VT at electrophysiological study. *(Level of Evidence: B)* (4,131,142)

- The remainder of ICD indications can be found via the following ACC online link:

  - http://content.onlinejacc.org/cgi/content/full/j.jacc.2008.02.033
Our Report Card: Preventing Sudden Death

- Observational study: October 2007
  - 13,034 patients admitted to US hospitals
  - Heart Failure, LVEF ≤ 30%, alive at D/C
  - ICD in place or plan for ICD

Study Results

• Of 13,034 Eligible Patients:
  – 4615 had ICD therapy at discharge (35.4%)
    • 2474 with prior ICD
    • 1614 new ICDs
    • 527 planned ICDs
  – Odds ratios for ICD use varied by sex & race when compared to white men
    • OR for black men = 0.73
    • White women = 0.62
    • Black women = 0.56
Study Results

35.4% SAD

ICD Therapy
No ICD Therapy
Conclusions

• Sudden cardiac arrest is a major public health problem (450,000 SCA/year). Only 5% of people survive.

• The majority of sudden deaths are caused by ventricular arrhythmias.

• The incidence of SCD is highest in males and blacks.

• Some early defibrillation programs have demonstrated significant improvements in survival rates, but the overall survival rates are still low.
Conclusions

- The highest clinical risk factors for SCD include:
  - Low left ventricular ejection fraction
  - Coronary artery disease, prior MI
  - Dilated cardiomyopathy and heart failure symptoms
    - Due to coronary artery disease (ischemic)
    - In the absence of coronary artery disease (nonischemic)
  - Resuscitation from prior VT/VF event
  - Genetic Disorders: HCM, LQTS, ARVD, Brugada Syndrome

- Any combination of these factors increases the risk of SCD
Conclusions

• Defibrillator Therapy
  – Proven Efficacy
    • Far superior to drugs or inaction
  – Excellent long term device safety/reliability
  – Standard of Care
What We Want for Our Patients: A Better Outcome