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OCTOBER 7 – 8, 2016

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SESSION TITLE: **Practical Update on Cardiac Implantable Electronic Devices (CIEDs)**

SESSION DAY/TIME: Saturday, October 8, 5:15pm-6:00pm

Cardiac Implantable Electronic Devices

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Disclosures: Research grants Biosense Webster Inc., St Jude Medical Inc.

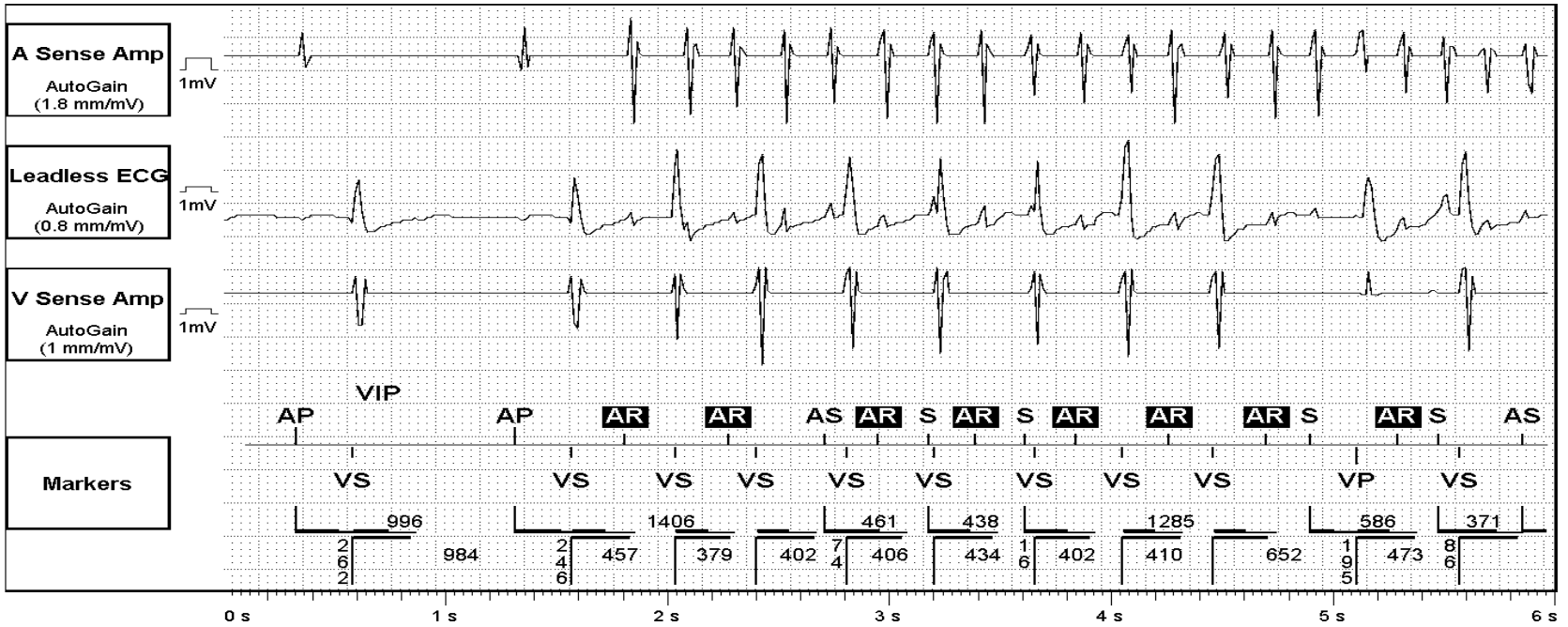
Case Study 1

- A 75 year old lady with hypertension and diabetes who underwent a dual chamber pacemaker implant for sinus node disease sends in a remote transmission of her pacemaker interrogation. She is asymptomatic. Relevant traces are shown:

1: A Sense Amp AutoGain (1.8 mm/mV)
2: Leadless ECG AutoGain (0.8 mm/mV)
3: V Sense Amp AutoGain (1.0 mm/mV)

4: Markers

Sweep Speed: 25 mm/s



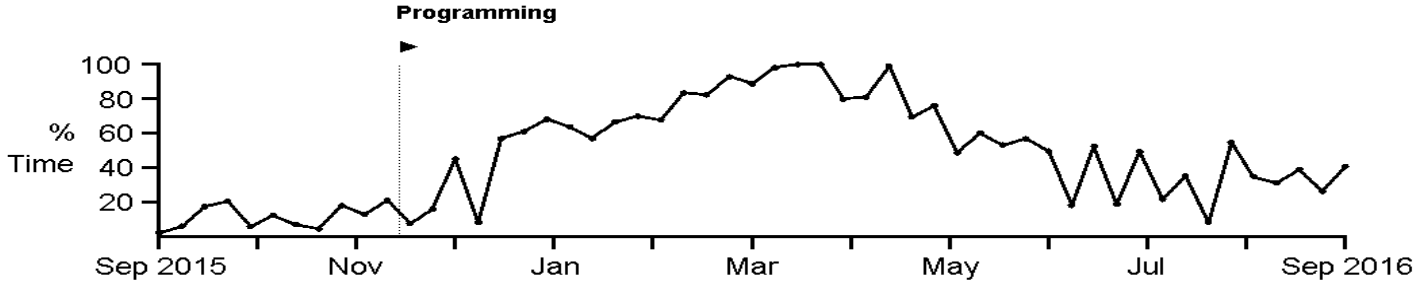
AT/AF Burden **34%**

Total AT/AF Burden 36%

Since May 19, 2015

(5m 26d sampled in AT/AF)

Since Jun 17, 2016



Week	D:H:M:S	%	Week	D:H:M:S	%	Week	D:H:M:S	%
Sep 22, 2015	0:04:20:28	2.6	Jan 26, 2016	4:11:24:46	64	May 31, 2016	4:05:13:28	60
Sep 29, 2015	0:10:22:10	6.2	Feb 2, 2016	3:23:51:40	57	Jun 7, 2016	3:17:36:04	53
Oct 6, 2015	1:05:35:40	18	Feb 9, 2016	4:16:20:14	67	Jun 14, 2016	3:23:34:52	57
Oct 13, 2015	1:10:52:54	21	Feb 16, 2016	4:21:45:16	70	Jun 21, 2016	3:11:35:32	50
Oct 20, 2015	0:10:00:58	6.0	Feb 23, 2016	4:18:07:02	68	Jun 28, 2016	1:06:42:12	18
Oct 27, 2015	0:21:02:24	13	Mar 1, 2016	5:20:13:32	83	Jul 5, 2016	3:16:29:28	53
Nov 3, 2015	0:12:17:22	7.3	Mar 8, 2016	5:18:40:14	83	Jul 12, 2016	1:07:55:32	19
Nov 10, 2015	0:07:40:44	4.6	Mar 15, 2016	6:12:03:16	93	Jul 19, 2016	3:11:07:38	49
Nov 17, 2015	1:06:14:50	18	Mar 22, 2016	6:05:05:02	89	Jul 26, 2016	1:12:45:26	22
Nov 24, 2015	0:22:03:08	13	Mar 29, 2016	6:20:52:32	98	Aug 2, 2016	2:11:20:52	35
Dec 1, 2015	1:11:30:52	21	Apr 5, 2016	7:00:00:00	100	Aug 9, 2016	0:14:21:36	8.5
Dec 8, 2015	0:12:55:40	7.7	Apr 12, 2016	7:00:00:00	100	Aug 16, 2016	3:20:06:00	55
Dec 15, 2015	1:03:03:32	16	Apr 19, 2016	5:14:16:02	80	Aug 23, 2016	2:10:53:18	35
Dec 22, 2015	3:03:48:06	45	Apr 26, 2016	5:16:10:48	81	Aug 30, 2016	2:04:48:04	31
Dec 29, 2015	0:14:08:10	8.4	May 3, 2016	6:22:38:30	>99	Sep 6, 2016	2:17:47:58	39
Jan 5, 2016	3:23:46:50	57	May 10, 2016	4:20:56:50	70	Sep 13, 2016	1:20:22:06	26
Jan 12, 2016	4:06:36:26	61	May 17, 2016	5:08:11:30	76	Sep 19, 2016	2:07:39:42	41
Jan 19, 2016	4:18:28:56	68	May 24, 2016	3:09:59:56	49			

Based in the information provided, what is most important next step?

1. Begin flecainide 100 mg bid
2. Start amiodarone
3. Begin oral anticoagulation
4. No immediate intervention is necessary

Device-detected AF

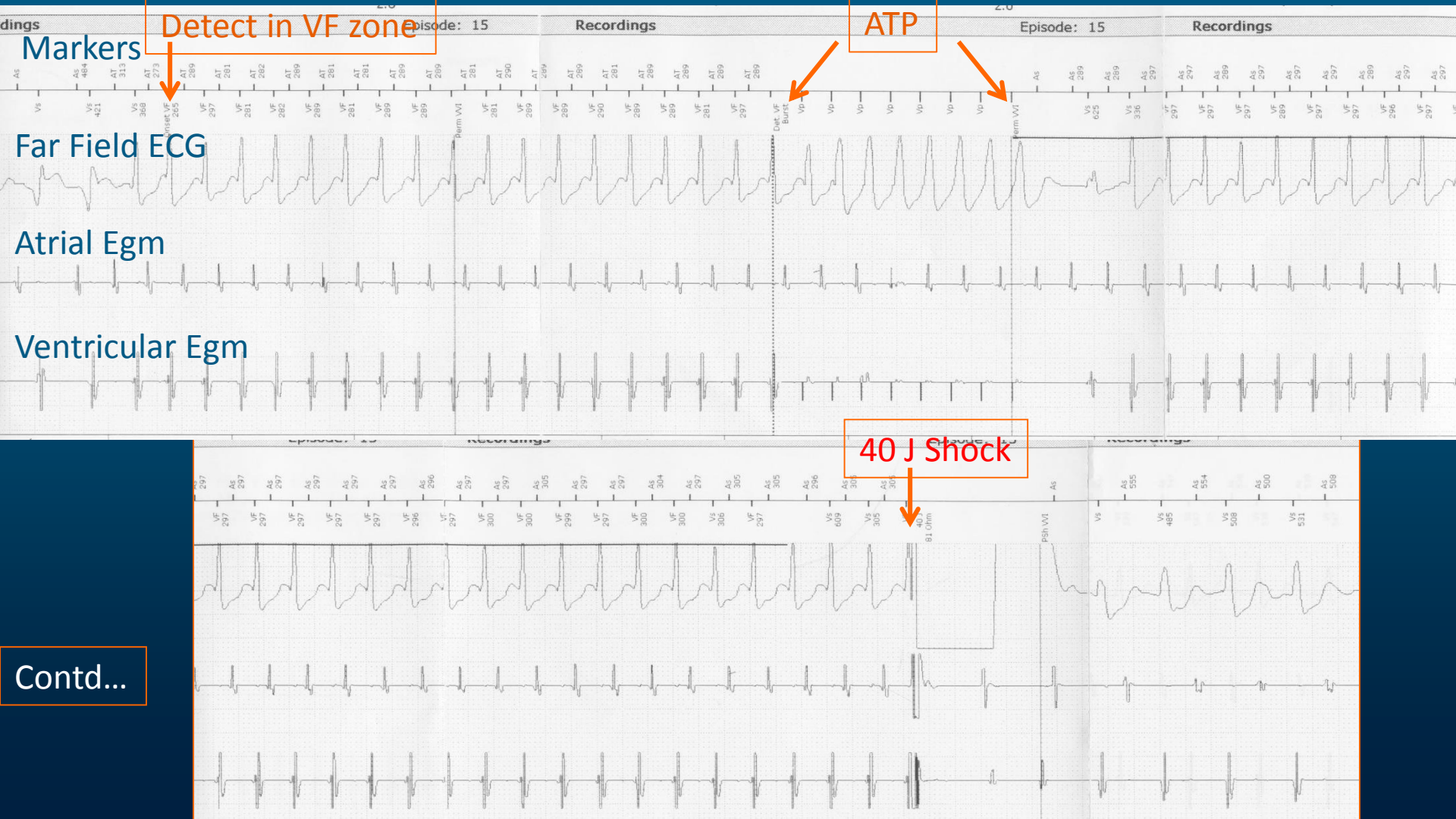
- Confirm true AF and not spurious detections of far field electrograms or noise
- No clear AF burden that defines a risk
- CHA_2DS_2-VASc score is the probably the best determinant of stroke risk

Chen-Scarabelli C. et al. JACC 2015; 65: 281

Case Study 2

- A 55 year old male with prior inferior myocardial infarction and depressed LV function (LVEF 30%) had a dual chamber ICD implant for primary prevention 5 years ago. Following strenuous exercise, he received multiple ICD shocks (he counts 10). He felt slightly flushed before the shocks.
- In the emergency room, he is placed on telemetry that shows sinus rhythm with heart rate of 90bpm. An ECG shows sinus rhythm with no evidence for acute MI. Troponins are mildly elevated.

- Which of the following is most important next step in his management?
  1. Begin lidocaine infusion
  2. Interrogation of the ICD with a programmer
  3. Intravenous esmolol
  4. Begin oral amiodarone


Detect in VF zone
ATP
Markers
Far Field ECG
Atrial Egm
Ventricular Egm
40 J Shock
Contd…

Causes of Multiple ICD shocks

- Recurrent VT/VF
- Atrial fibrillation or tachycardia
- ICD lead malfunction with lead conductor coil fracture or insulation break
- Abnormal sensing of intrinsic T waves
- Sinus tachycardia with low ICD rate cut off

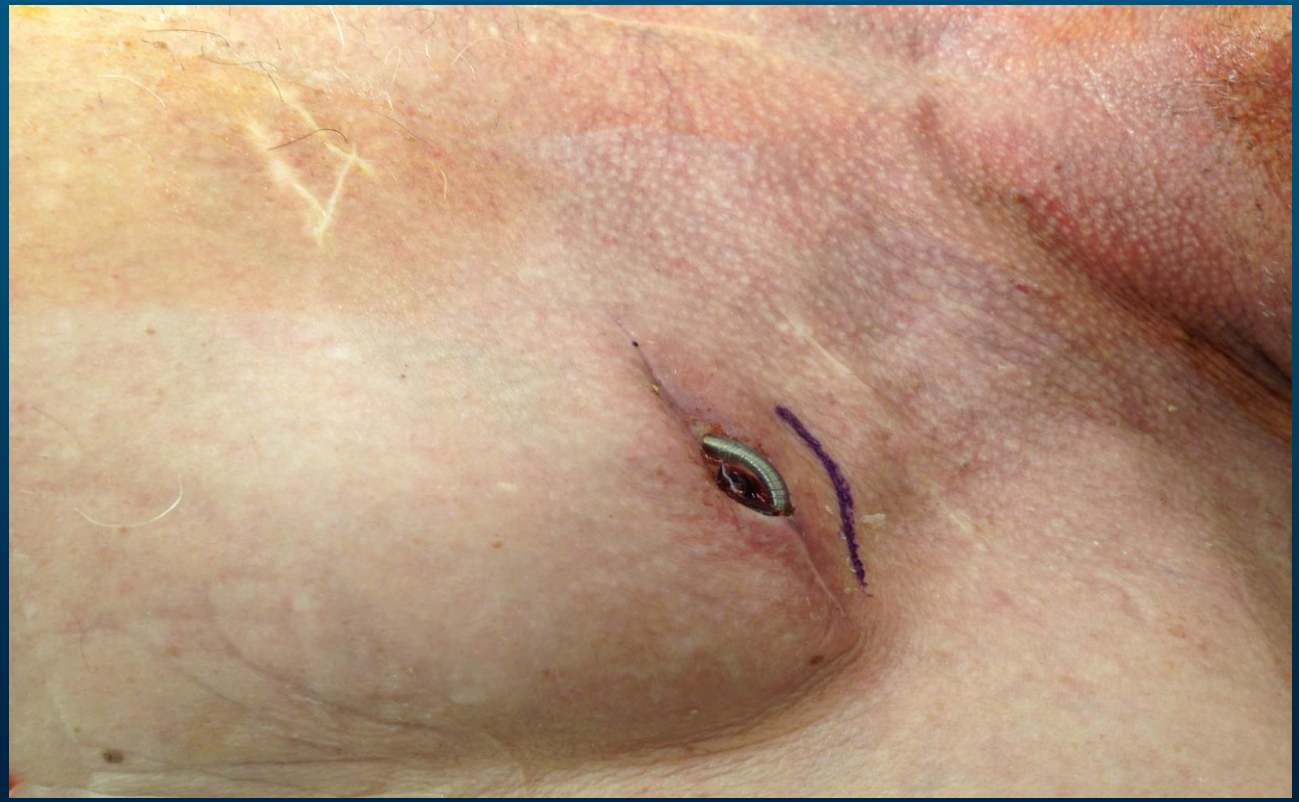
Management of Electrical Storm

- Sedation
- Determine rhythm and if inappropriate, apply magnet over device to deactivate
- If VT/VF:
    - Antiarrhythmic including beta blockers
    - Correct electrolytes
    - Rule out myocardial ischemia
    - May need general anesthesia
    - Consider catheter ablation if VT storm or PVC mediated VF

Case Study 3

A 70 year old male with prior CABG and ischemic CM (LVEF 30%) had a single chamber ICD implant for primary prevention 8 years ago. He received one shock two years after implant for rapid VT that was successfully terminated. He was commenced on sotalol with no further shocks. Two weeks ago, he had a generator replacement for battery depletion of the ICD. He returns to the clinic today for wound check:

Wound dehiscence with exposure of Lead

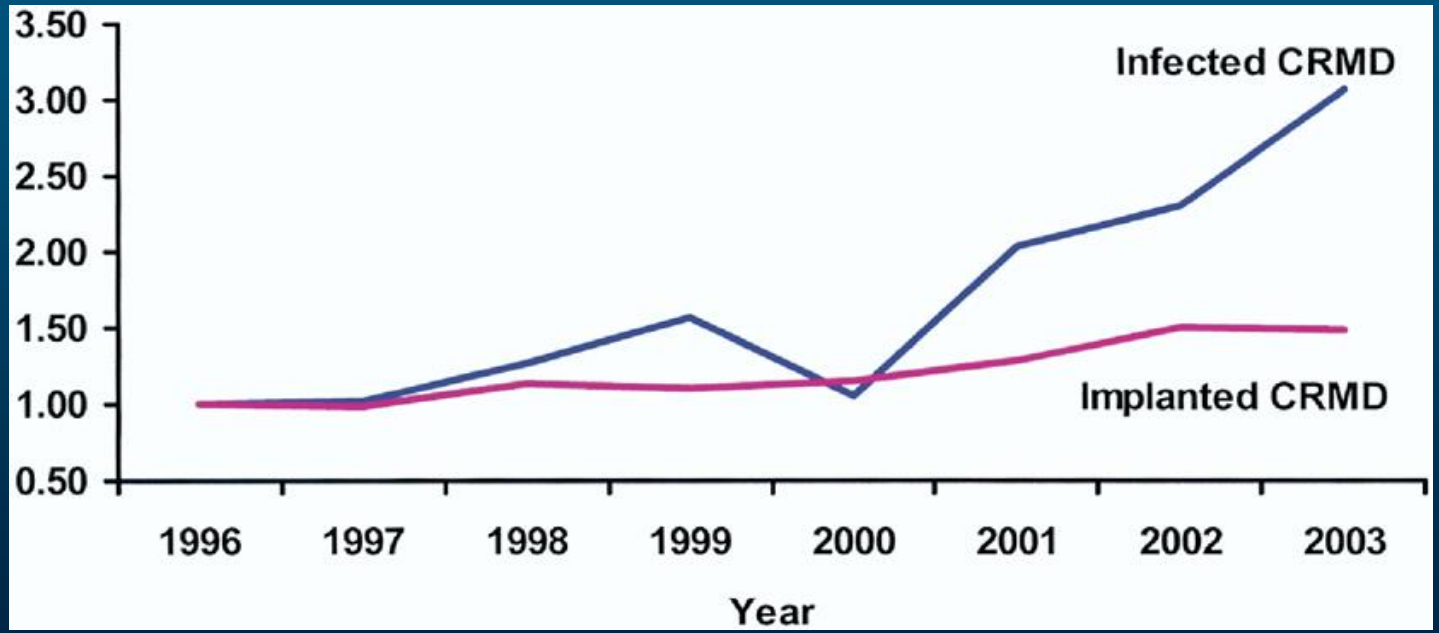


Case Study 1 – contd…

Which of the following should be your recommendation at this stage?

1. Wound culture, begin antibiotics, dress the wound and continue to observe
2. Removal of generator, cap the lead and re-implant new system on the left
3. Reopen the wound, debride, wash with antibiotics and re-suture the wound
4. Remove the ICD generator and lead and re-implant on the left

CIED (Cardiac Implantable Electronic Devices) Implants and Infection between 1996 and 2003 Normalized to 1996



Voigt A. et al. J Am Coll Cardiol 2006; 48: 590

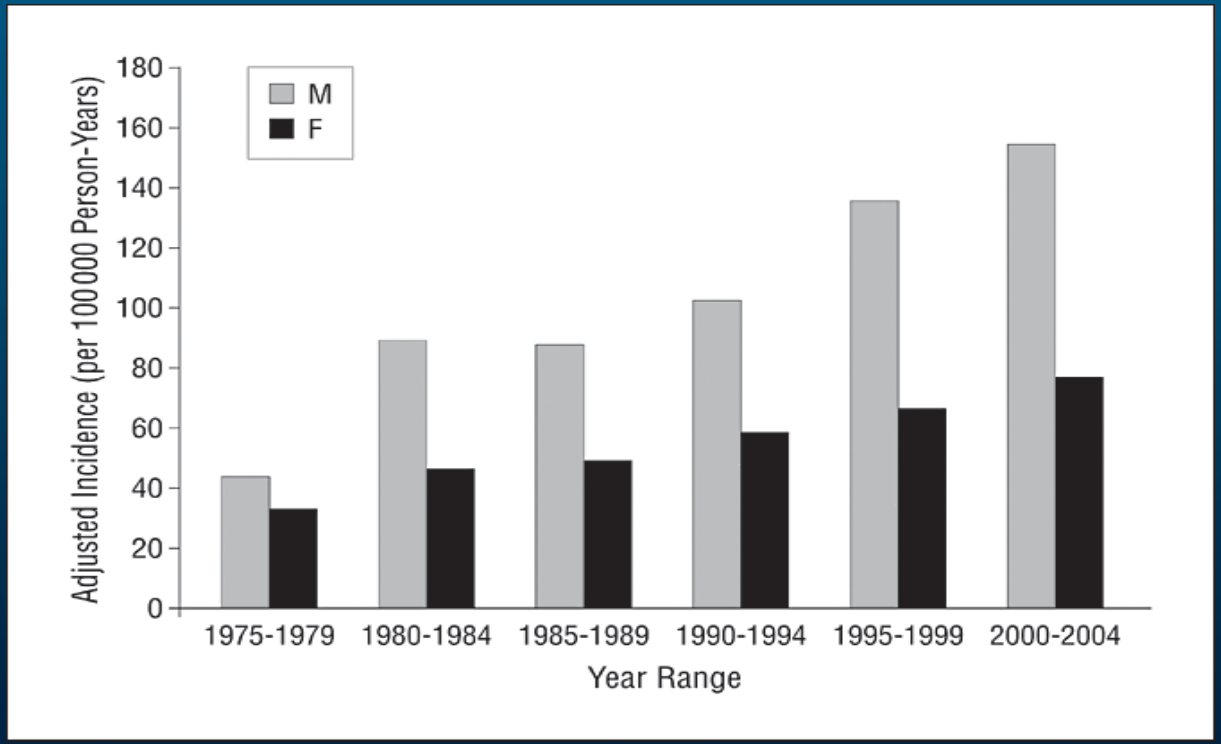
Population Based Study Olmsted County 1975-2004 . *Uslan DZ, et al. Arch Intern Med 2007; 167: 669*

Incidence of CIED infections per 1000 device years of follow up:

<u>Total:</u>
1.9 (95% CI, 1.1-3.1)

<u>Pocket infection:</u>
1.37 (CI, 0.62-3.05)

<u>Blood Stream Infection:</u>
1.14 (CI, 0.47-2.74)



Why Increasing Rate of Infections?

- Use of CIEDs in older patients
- Multiple comorbidities eg. Dialysis
- Complex implant procedures (CRT devices)
- Expanding implant centers with smaller volumes

Risk Factors for CIED Infections

Host Related:

- Renal failure (Odds Ratio: 4.8)
- Congestive heart failure
- Diabetes Mellitus
- Anticoagulation therapy with warfarin
- Long term corticosteroid use (OR: 13.9)
- Malignancy
- Fever within 24 hours prior to procedure (OR: 5.83)
- Male sex and younger age at implant

Bloom H, et al. Pacing and Clin Electrophysiol 2006; 29: 142
Sohail MR, et al. Clin Infect Dis 2007; 45: 166
Klug D, et al. Circulation 2007; 116: 1349
Johansen JB, et al. Eur Heart J 2010; 32:991

Risk Factors for CIED Infections

Klug et al, Circulation 2007; 116: 1349; de Oliveira, et al, Circ Arrhythmia Electrophysiol 2009; 2: 29
Uslan D, et al. REPLACE Registry Analysis. PACE 2012; 35:81

Device Related:

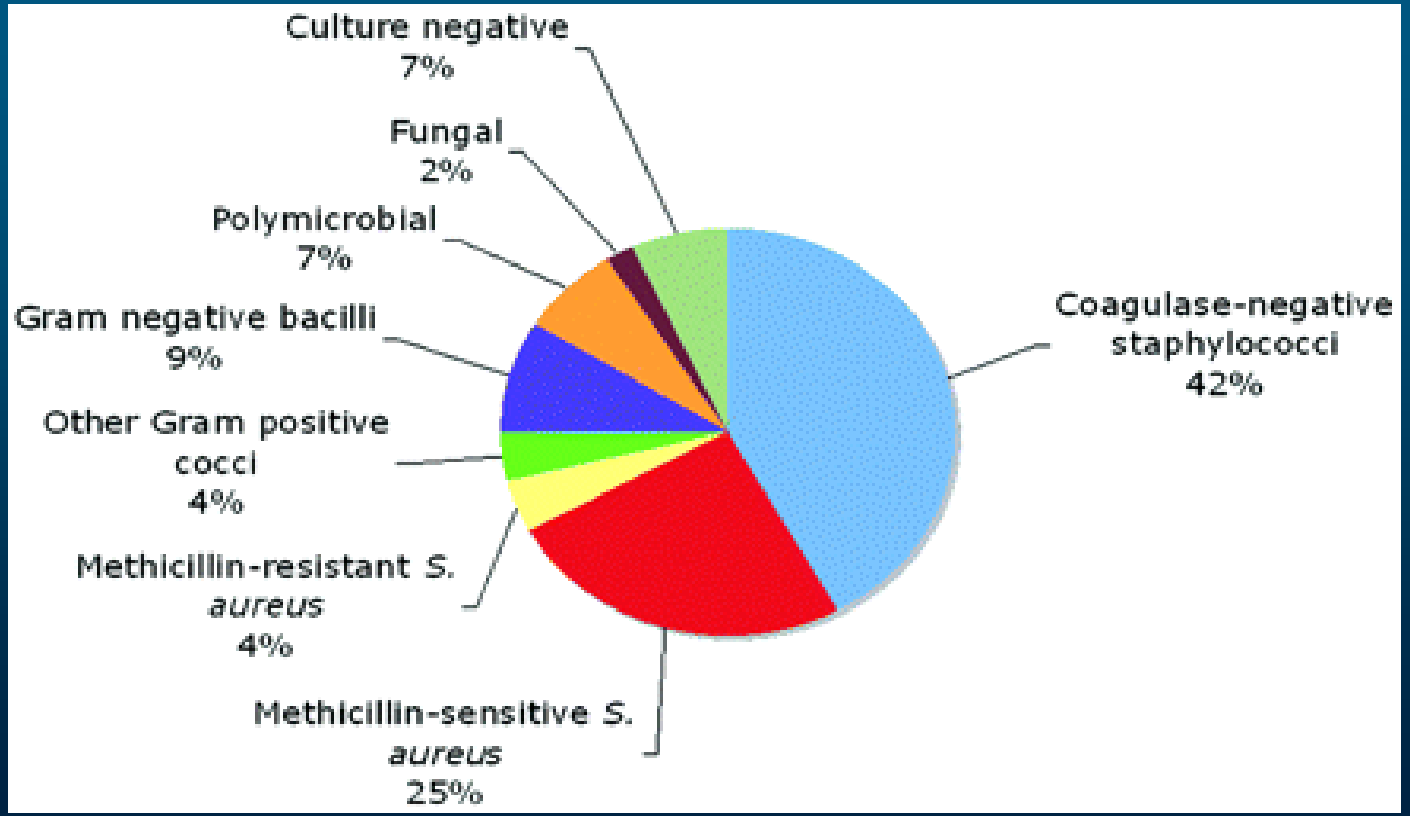
- ICDs > pacemakers
- Greater complexity (? CRT systems)
- Abdominal implants for ICD
- Prior device revisions

Procedural:

- Non use of antibiotic prophylaxis
- Operator experience (Lowest rate of implants versus highest rate OR: 2.47)
- Post op hematoma
- Early re-intervention (OR: 15)
- Use of temporary pacing pre-implant (OR: 2.46)

Microbiology of CIED Infections

Nagpal A, et al. Circ Arrhythmia Electrophysiol 2012; 5: 433

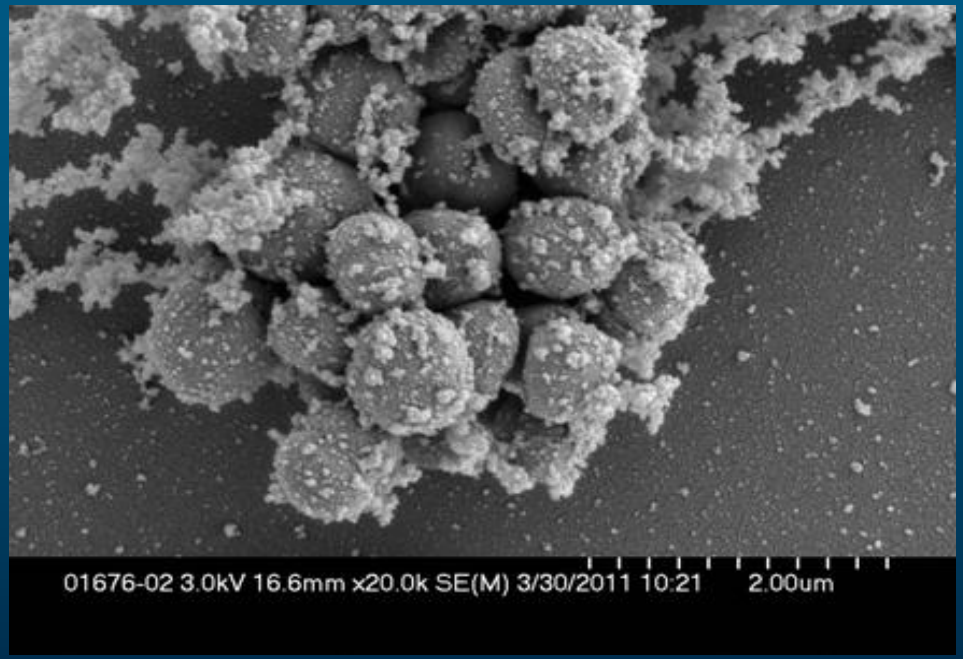


Pathology of CIED Infections

Adherence of bacterial organisms (S. aureus, epidermidis) to PVC, polyethylene, polyurethane, silicon etc. results in a biofilm

Biofilm defined as a surface associated community of 1 or more microbial community attached to surface and encased in extracellular matrix

Resistant to antibiotic and host defenses



Electron Micrograph of a biofilm due to coagulase negative staph. (Mayo Clinic, MN)

Outcome of CIED Infections

Publication	n	Patients	Treatment	Outcome
del Rio, et al 2003	31	PPM or ICD endocarditis	CT – 7 →	100% relapse, 1 death
			Removal 24 →	1 relapse; 3 deaths
Rundstrom et al 2004	38 (44)	PPM Endocarditis	CT -16 →	19% infection free
			Removal 28 →	64% infection free
Sohali et al 2007	189	CIED infection	3 removed after CT	
			Removal 183	3.7% in-hospital mortality
				95% infection free at 6 mo.
Sohali et al 2008	44	PPM or ICD endocarditis	Removal in 43	14% in-hospital mortality

CT = conservative therapy, CIED = cardiac implantable electronic device

Prevention of CIED Infection: At Implantation

- Preop control of blood sugar in diabetics
- Pre-operative antibiotics

  Cefazolin 1-2 g 1 hour prior or vancomycin 90-120 min
- Preoperative antiseptic skin preparation

  Chlorhexidine-alcohol superior to povidone iodine*
- Absolute sterile technique; OR environment with required airflow
- Consider retro-pectoral pocket in thin or malnourished patients

*Darouiche RO, et al. N Engl J Med 2010; 362: 18

Prevention of Infection in CIED Post Implant

Hematoma

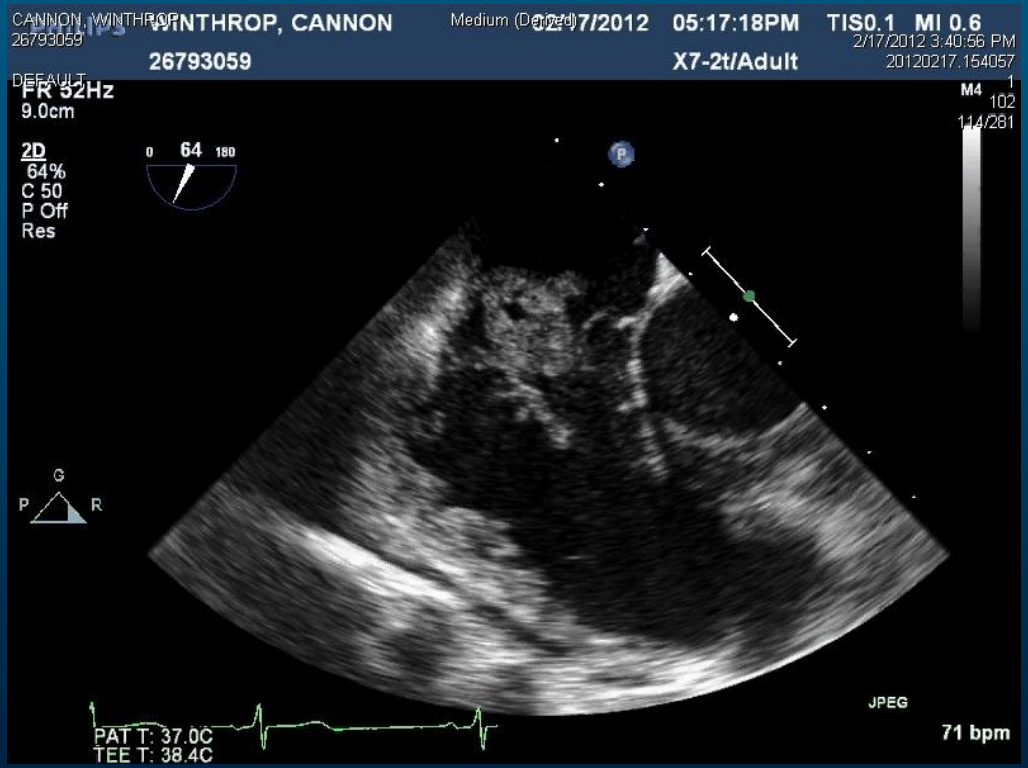
- Avoid needle aspiration
- Reopen to drain only if painful or increased tension on skin

Post Operative Antibiotics

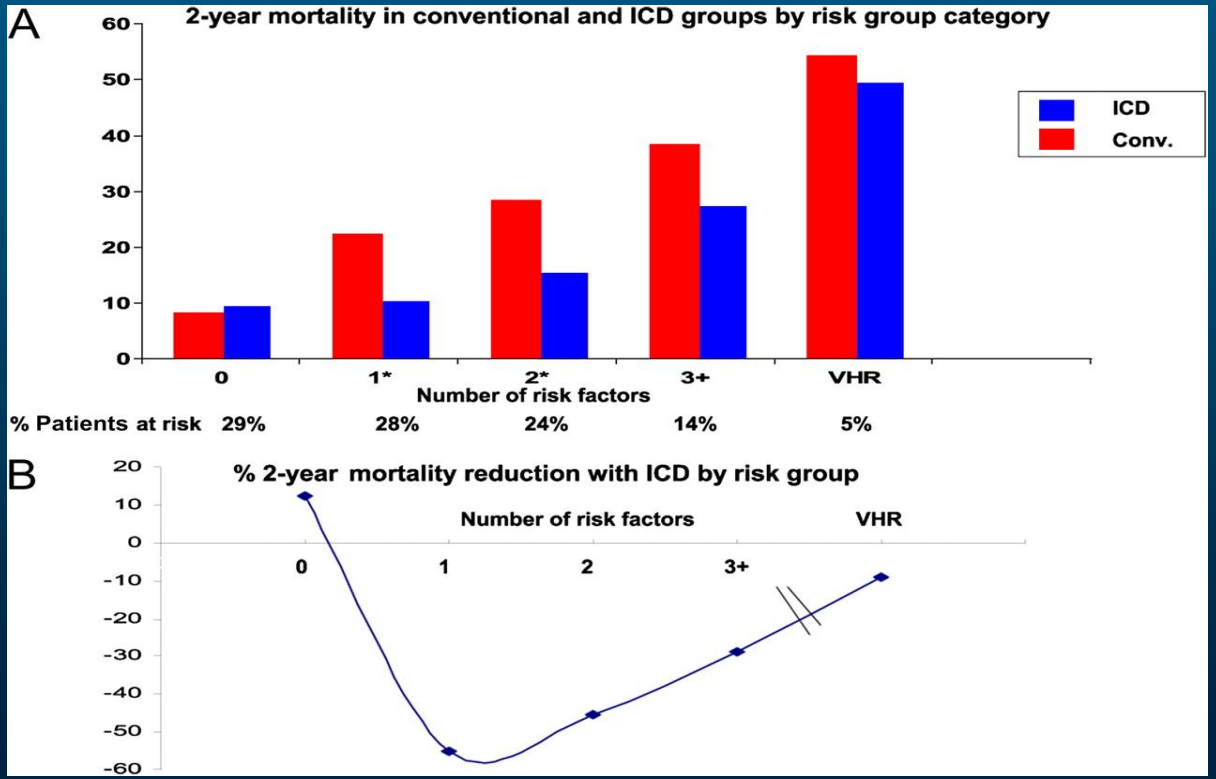
- No evidence to support post op antibiotics
- Not recommended to prevent C-Diff, adverse events and drug resistance

No indication for antibiotic prophylaxis for invasive procedure in CIED patients

81 y.o male with CAD and ICD with Failure to Thrive and Low Grade Fevers over 3 months:



(A) Two year Kaplan-Meier mortality rates in the implantable cardioverter-defibrillator (ICD) and conventional (Conv.) therapy groups of the MADIT II study based on the number of risk factors and for patients with severe kidney disease, considered very high risk (VHR); and (B) the corresponding 2 year mortality rate reduction with an ICD, by risk score and in VHR patients. *p<0.05 for the comparison between the conventional therapy and ICD groups.



Summary

- Remote monitoring of implanted devices are increasingly used for diagnosis. In high risk patients, detection of AF should be a consideration for anticoagulation

- Management of Electrical storm with recurrent ICD shocks should include:
  - Sedation
  - Arrhythmia diagnosis
  - Deactivation of ICD (magnet) if inappropriate shocks

- CIED Infections:
  - Prevention is critical
  - Removal of entire infected system is required in most cases