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Engaging Every Voice for Optimal Lead Management

Webinar Series

Pocket Management: Before, During, and After (Extended Q&A)

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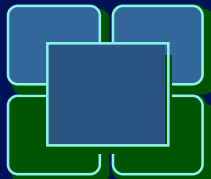
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Pocket Management: Before, During, and After



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Cleveland Clinic

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The Cleveland Clinic Foundation



Preoperative Pocket Management

- Predictable & Great Outcomes
 - Start before the incision
 - Risk assessment
 - Anticoagulants
 - Antibiotics
 - Skin preparation

Infection Analysis - REPLACE

- 1744 replacement or upgrade procedures
- Infections: 1.3%
- Hematoma increases infection
 - 22.7% vs 0.98%
- Higher infection rates:
 - Povidone-iodine (Betadine) prep
 - Low implantation volume
 - High Charlson Comorbidity Index

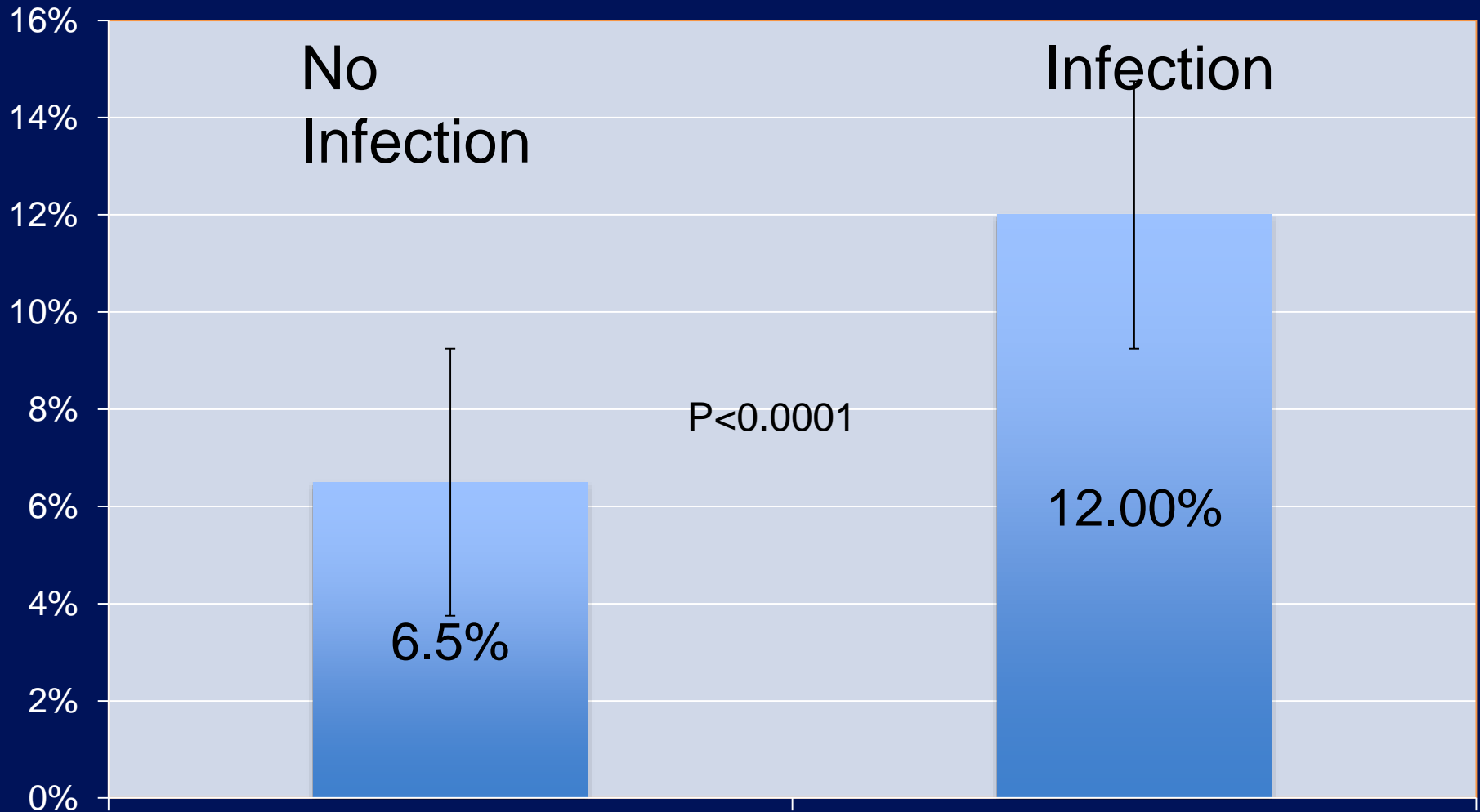
NCDR – Registry Infection Rates

	2006	2007	2008	2009	Exclusions	Totals
Patients	36,578	44,709	58,759	64,263	3400	200,909
Hospitals	1045	1140	1186	1191		1348
		Infection (N=3390)			P value	
Overall		3390 (1.7%)				
Number of Leads					<0.0001	
Single Chamber		450 (1.4%)				
Dual Chamber		1079 (1.5%)				
Biventricular		1860 (2.0%)				
Initial ICD implant?						
Generator Change		1084 (1.9%)			<0.0001	
First Device		2306 (1.6%)				

NCDR - Adverse events

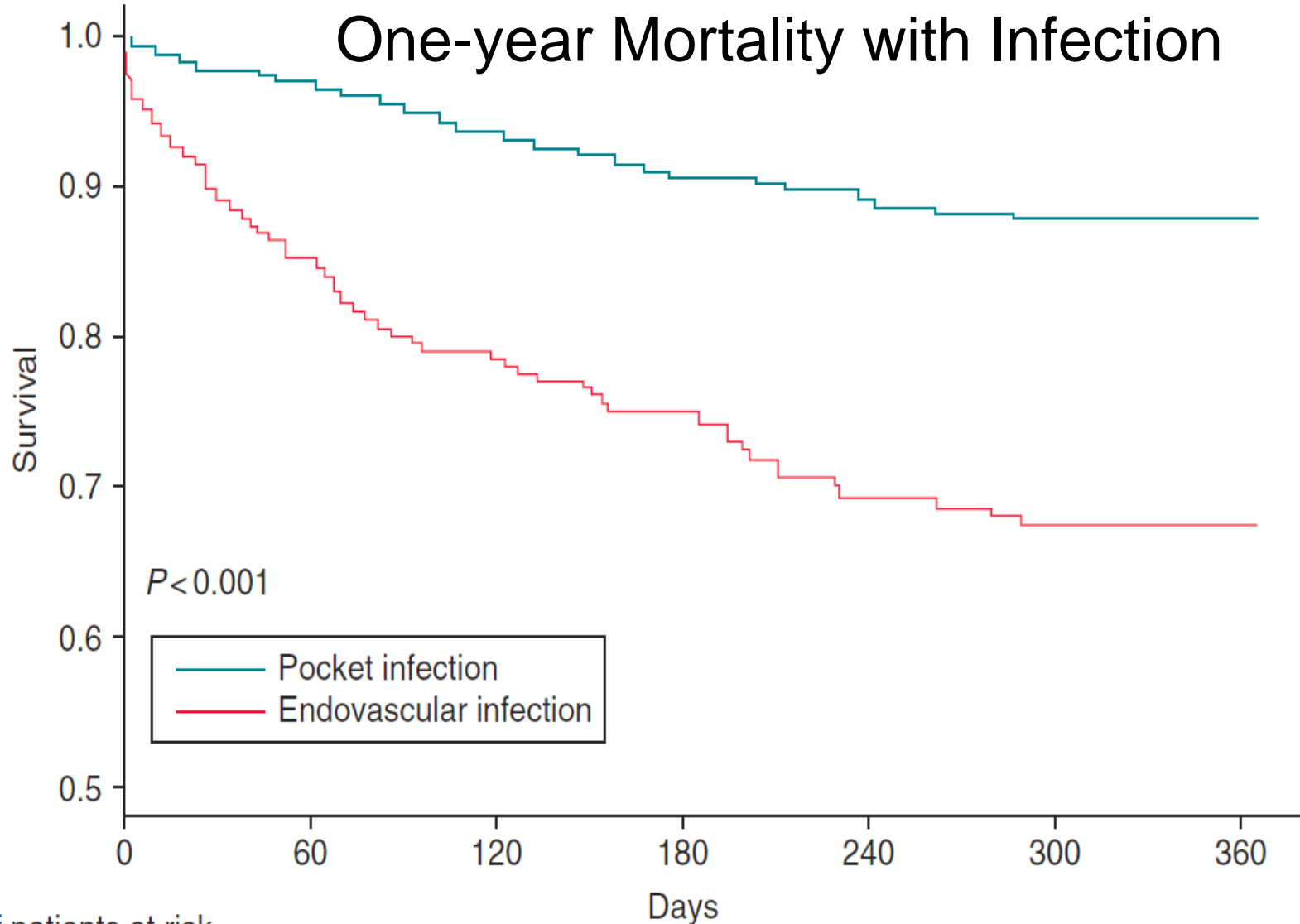
	No Infection (N=197,519)	Infection (N=3390)	P value
<i>Any</i>	3692 (1.9%)	182 (5.4%)	<0.0001
<i>Hematoma</i>	1828 (0.93%)	127 (3.75%)	<.0001
<i>Lead Dislodgement</i>	1884 (0.95%)	56 (1.65%)	<.0001
<i>Hemothorax</i>	173 (0.09%)	7 (0.21%)	0.02
Pneumothorax	954 (0.48%)	17 (0.50%)	0.88
Pericardial Tamponade	194 (0.10%)	3 (0.09%)	0.86
<i>AV Fistula</i>	7 (0.004%)	2 (0.06%)	<0.001

NCDR - 6-month Mortality



Prutkin JM et al. *Circulation*. 2014;130:1037-43.

One-year Mortality with Infection

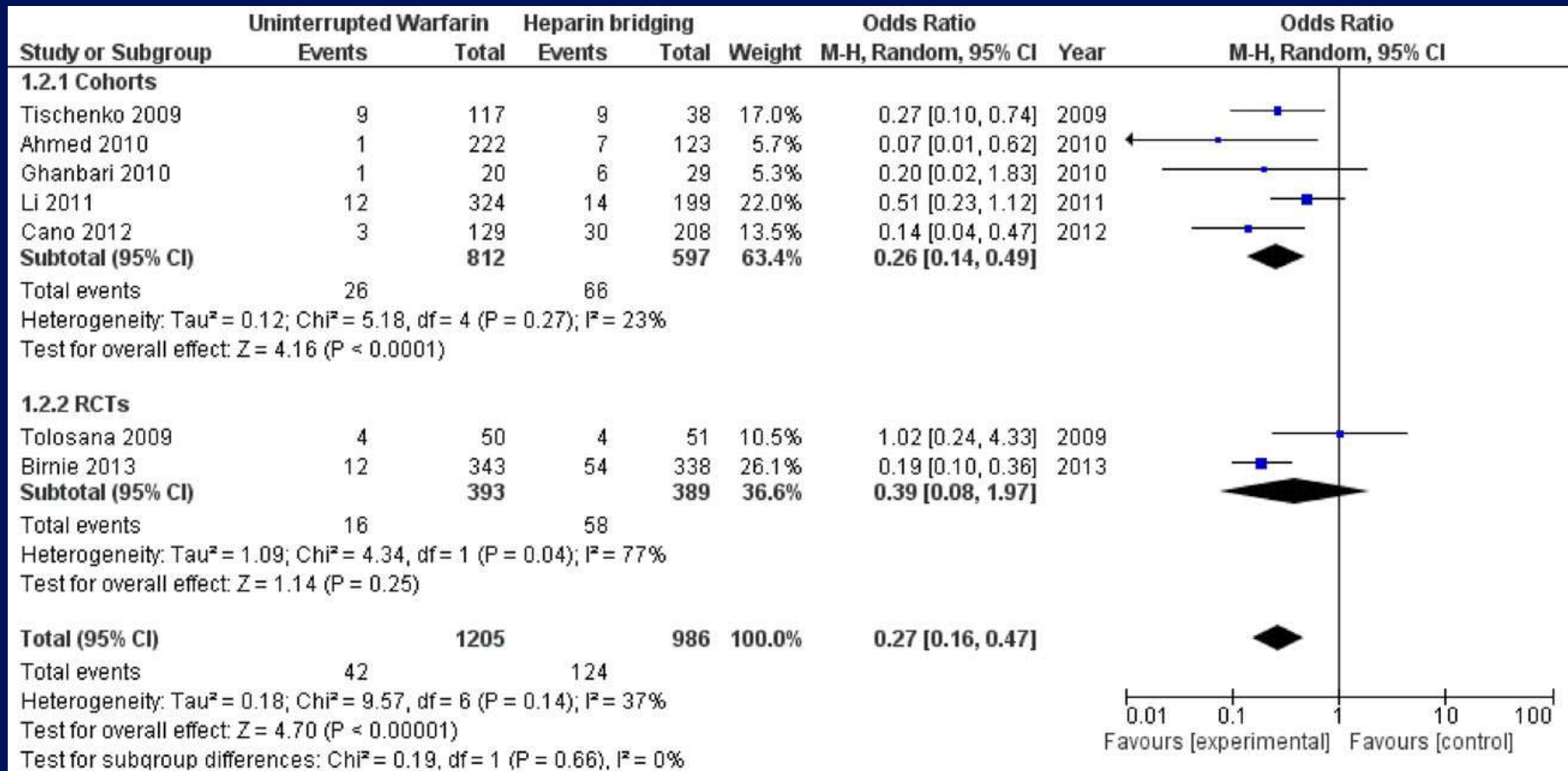


Number of patients at risk

	0	60	120	180	240	300	360
Pocket	289	270	258	245	238	232	230
Endovascular	213	175	159	149	137	132	130

Pre-implantation Anticoagulation Management

- Uninterrupted warfarin vs heparin bridging



Novel Oral Anticoagulants

- Hematoma risk in small observational studies
 - Uninterrupted Dabigatran: 2% – 3 %
 - Uninterrupted Rivaroxaban: 5%
 - Comparable to Warfarin
- Ongoing clinical trial
- BRUISE-CONTROL 2

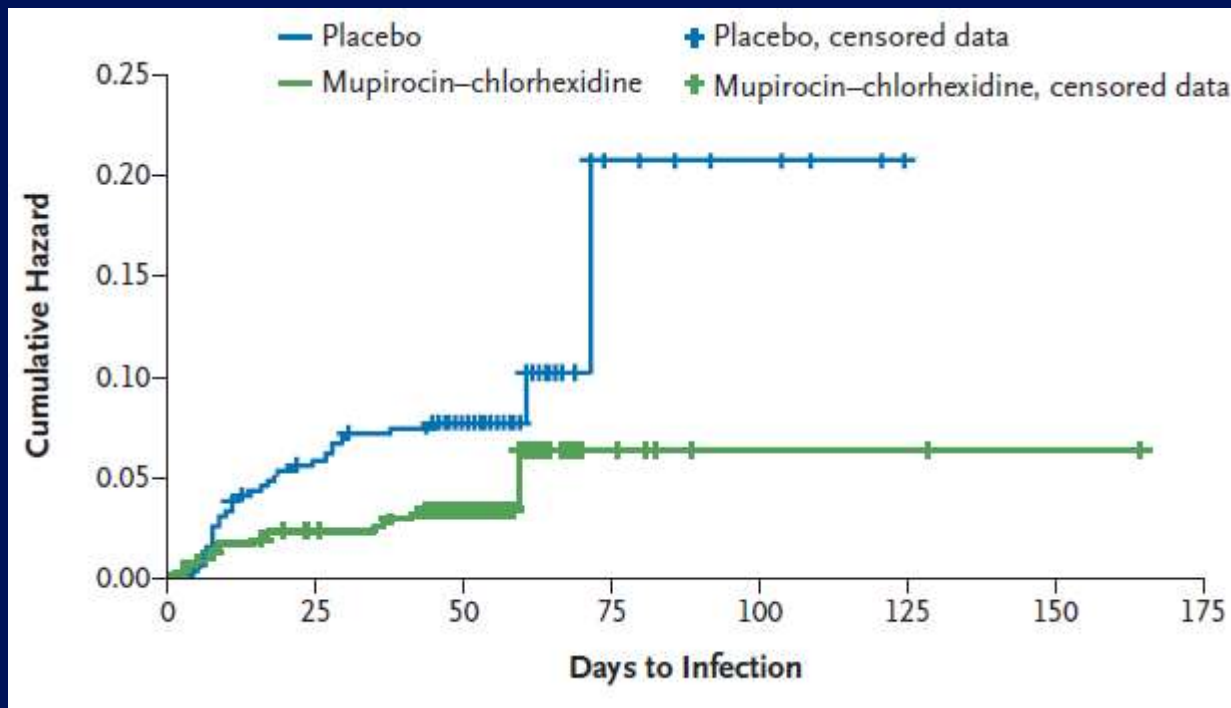
Kosiuk J et al. *Circ J*. 2014;78:2402-7.

Kosiuk J et al. *Europace*. 2014;16:1028-32.

Jennings JM et al. *J Cardiovasc Electrophysiol*. 2013;24:1125-9.

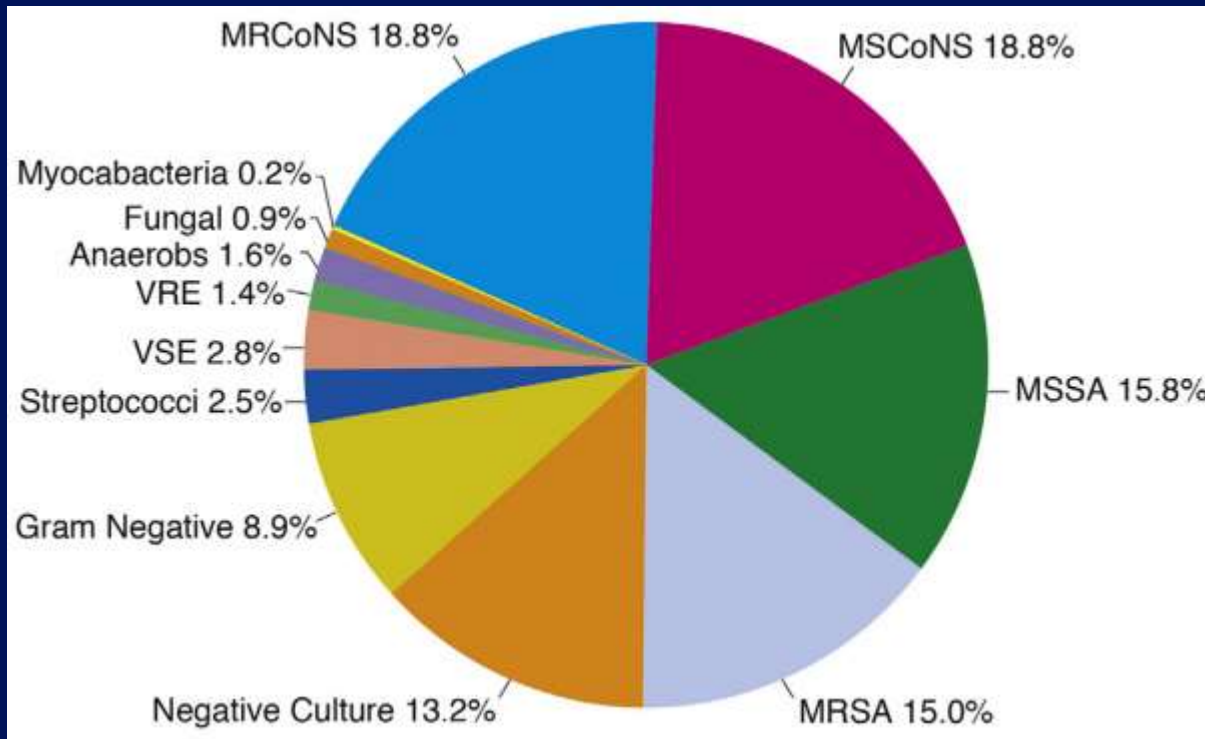
Pre-implantation Nasal Mupirocin and Chlorhexidine Bath

- *S. aureus* nasal colonization
- Nasal Mupirocin BID & Chlorhexidine bath X 5 days
- *S. aureus* infection RR 0.42 (0.23–0.75)



Pre-operative Antibiotic

- Choice of Antibiotic
- Microbiology of CIED infection
- Local incidence of MRSA?



Hussein AA et al. *JACC Clin Electrophysiol.* 2016; online@
<http://electrophysiology.onlinejacc.org/article.aspx?articleid=2511384#tab1>

Pre-operative Antibiotic

- Current Recommendations
 - Cephalosporin (Cefazolin) – within 60 min
 - In Cephalosporin allergy
 - Clindamycin – within 60 min
 - Vancomycin – within 90 – 120 min
- Cleveland Clinic
 - Vancomycin
- PADIT Trial >12,500 patients, 28 sites
 - Single preop antibiotic
 - Dual preop antibiotic, irrigation, postop antibiotic

Skin Preparation

- Clip don't shave
- Alcohol vs Iodine prep
- Let dry
- Plastic skin drape

Preoperative Pocket Management

- Predictable & Great Outcomes
 - Start before the incision
 - Risk assessment
 - Anticoagulants
 - Antibiotics
 - Skin preparation

Pocket Infection

Management after Extraction

Saumya Sharma, MD

Assistant Professor – University of Texas Houston

McGovern School of Medicine

Considerations

- Peri-procedural techniques
- Wound management
- Antibiotic therapy
- Re-implantation of new device

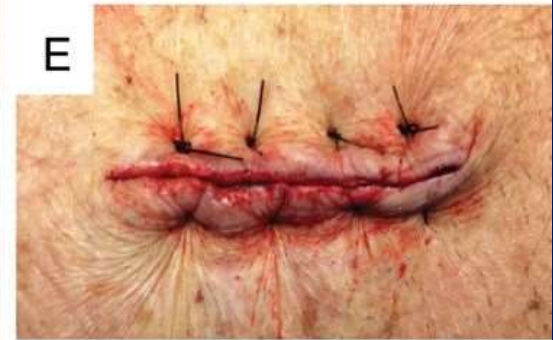
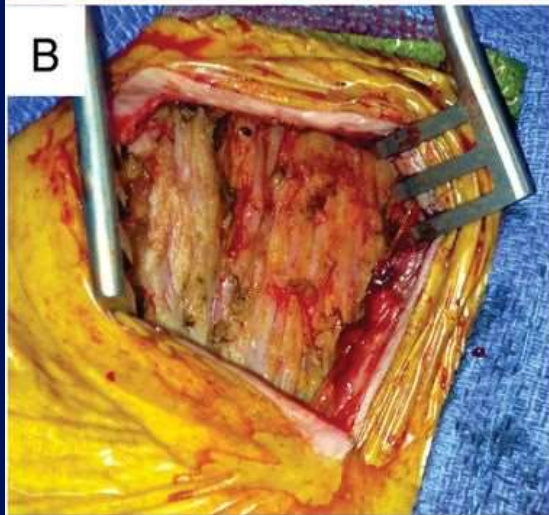
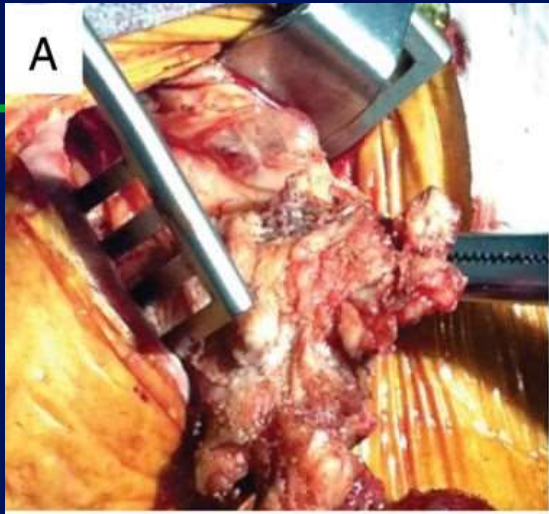
Peri-procedural

- **Pocket debridement**
 - Complete capsulectomy
 - Tissue/Fluid/Device culture and sensitivity
 - Adequate hemostasis (avoid hematoma)
 - Pocket irrigation (e.g. Pulse Lavage/Pulse Irrigator)
- **Wound Closure**
 - Secondary intention when infection compromises incision/skin
 - Close with interrupted sutures and Jackson-Pratt drain for pocket abscess
- **Temporary Pacing**
 - Temporary externalized pacing systems (utilizing an active fixation lead through the internal jugular or subclavian vein connected to sterilized generator)



Wound Management

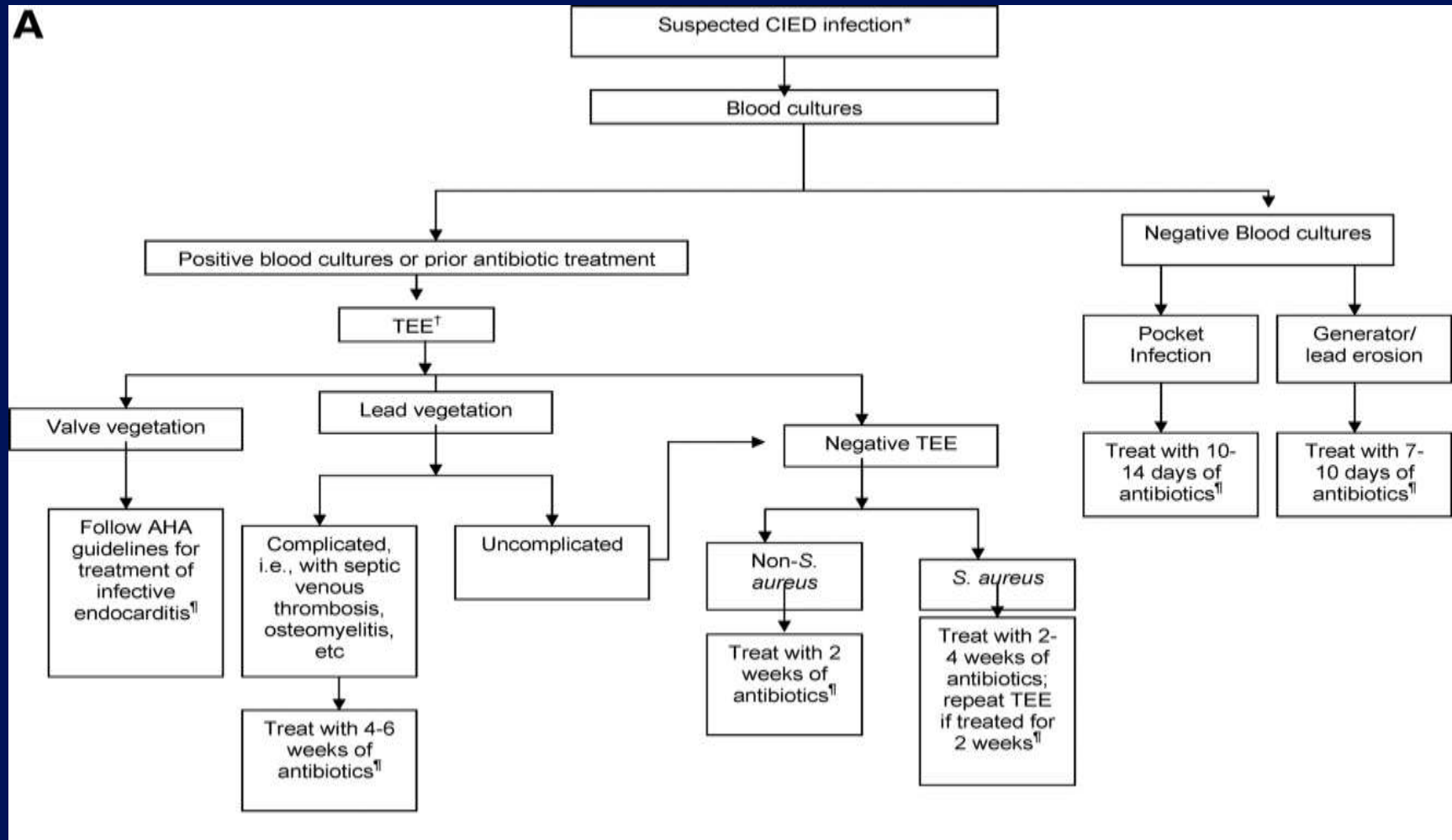
- **Vacuum-Assisted Closure therapy (e.g. Wound–Vac)**
 - Granulo-foam occlusive dressing with portable suction (125 mmHg) applied
 - Dressing changed every 72 hours
 - Promotes angiogenesis, cell division, local growth factors
 - Delayed closure 3-6 days later
 - Patient can be discharged with Wound–Vac and home health
- **Wet to Dry Dressing**
 - Wound healing very slow
- **Interrupted sutures with Jackson-Pratt drain**
 - Only when skin/incision is not involved with infection
 - Patient can be discharged with drain to be removed as outpatient



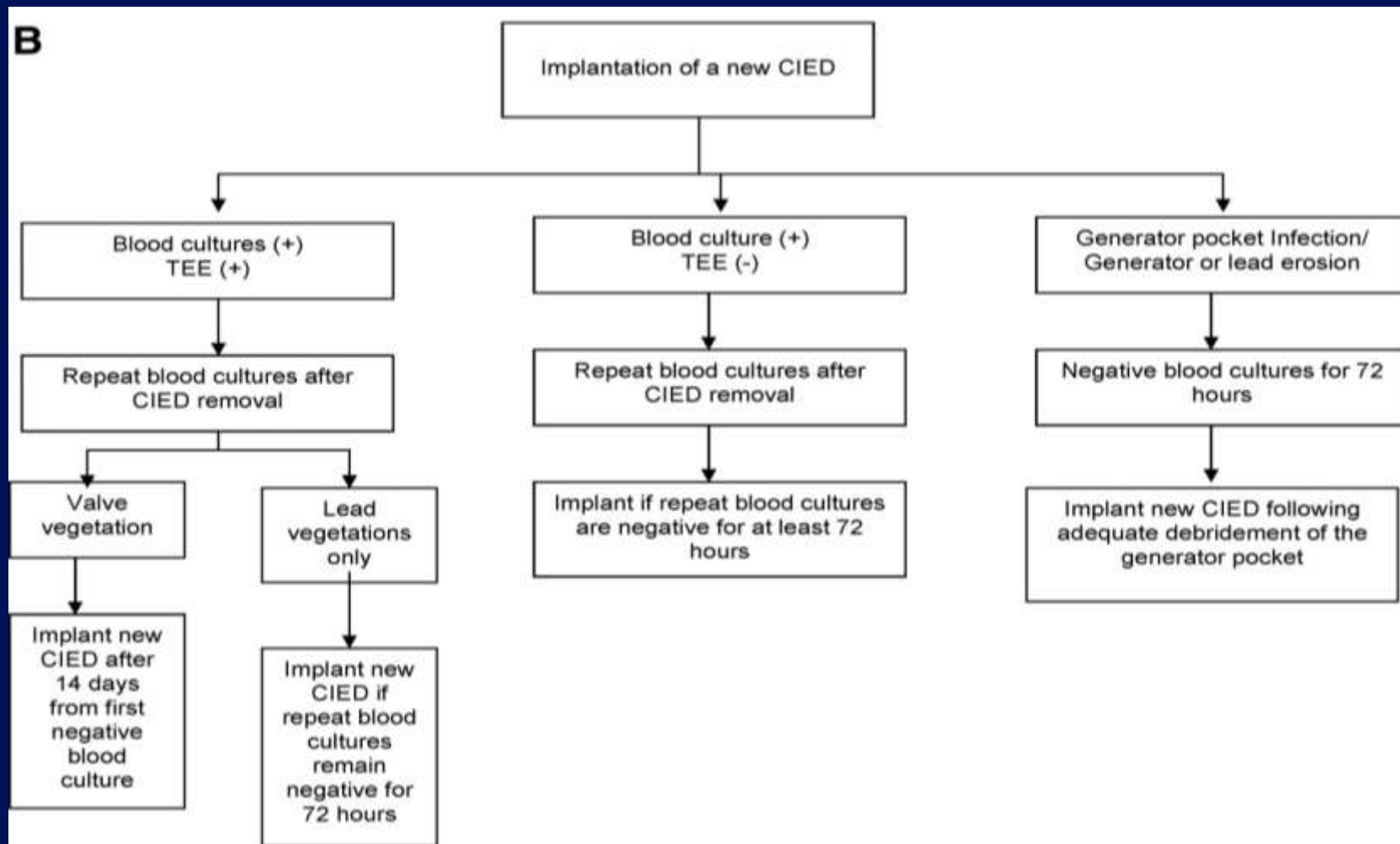
Antibiotic Therapy

- Two sets of Blood Cultures at initial evaluation prior to antibiotic initiation
- Gram stain/culture of pocket tissue/fluid and device/lead is essential
- Isolated pocket infection without positive blood cultures then 10 to 14 days of antibiotics
- For lead/device erosion then 7 to 10 days of antibiotics
- Pocket infection with positive blood cultures but negative TEE
 - Non-Staph Aureus: 2 weeks of antibiotics
 - Staph Aureus: 4 weeks of antibiotics

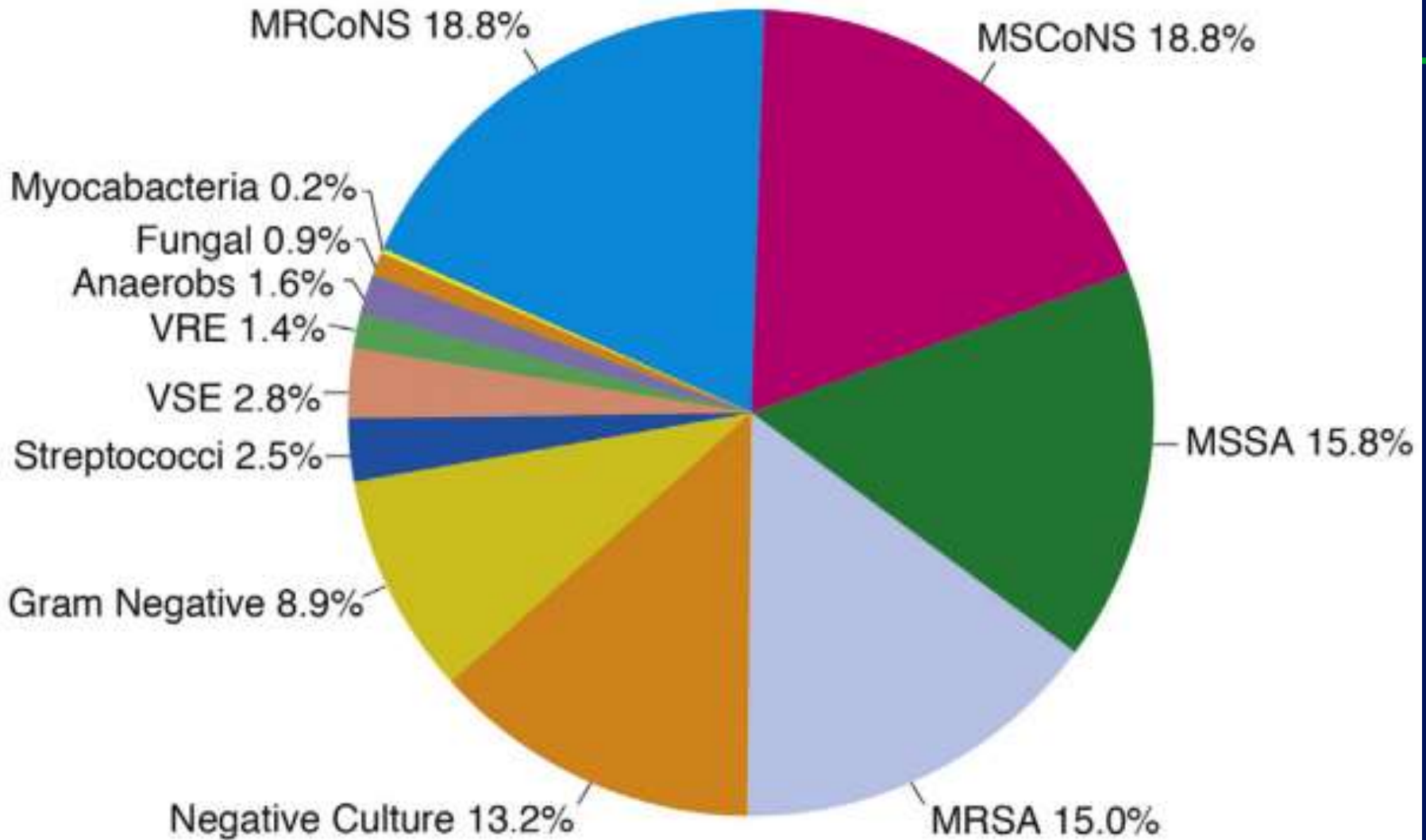
Approach to management of adults with CIED infection



Approach to infection management of adults with new CIED



Microbiology of PPM/ICD infections



Antibiotic Therapy

- Because Staph Aureus is the most common organism – Empiric Vancomycin therapy can be started after cultures are obtained until microbiology results are known
- For patients with positive blood cultures – 2 weeks of IV antibiotics
 - Home antibiotics with PIC line
- Infectious disease consultation in setting of positive blood cultures or unusual organism in pocket culture
- For isolated pocket infections with negative blood cultures, switch to oral antibiotics can be made when microbiology results are known
- Duration of antibiotics are counted from day of device explantation

Re-implantation

- Assessment of need for device
 - 30% of patients will not need reimplantation
 - Resolution/Change of underlying condition or inappropriate indication
- Postpone implantation until infection cleared or 72 hours after negative blood culture
- Pacemaker-dependent patients will require temporary externalized pacing systems through IJ or subclavian vein
- Re-implant in patients who are pacemaker dependent after 72 hours of negative blood cultures
- Re-implantation should be on contralateral side

Re-implantation

- If contralateral implantation is not possible, then transvenous lead can be tunneled to abdominal pocket site or epicardial pacing systems can be used
- *Ipsilateral implantation is discouraged*, but can be done if the site has completely healed and if the pocket is formed at a distance from and/or in a different plane (i.e. sub-pectoral)
- Temporary external wearable defibrillator systems (i.e. Life-vest) can be used in patients who need “bridge” therapy while awaiting re-implantation
- Subcutaneous ICD represents an alternative implant strategy in patients with vascular access issues and without pacing indications
 - Our center has performed combined epicardial pacing and S-ICD implantation successfully (n=3)

Thank You

References

1. Sohail MR et al. *J Am Coll Cardiol.* 2007;49:1851-9.
2. Baddour LM et al. *Circulation.* 2010;121:458-77.
3. Mulpuru SK et al. *Circulation.* 2013;128:1031-8.

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