



Arrhythmias & Heart Failure
New Insights & Technological Advances

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9th Congress Edition
Novotel PARIS Tour Eiffel



Management of Cardiac Implanted Electronic Devices Infections *Last Updates*

Dr Edouard Gitenay



Disclosure

Speaker name: Dr Edouard Gitenay

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I have the following potential conflicts of interest to report:

I do not have any potential conflict of interest



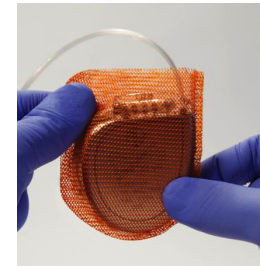
Novelties in the field of CIED infections :

❖ PREVENTION

❖ DIAGNOSIS

❖ TREATMENT

PREVENTION



Antibiotic prophylaxis

ESC guidelines Infective endocarditis 2015

E. Prophylaxis

| | | |
|---|------------|----------|
| 1. Routine antibiotic prophylaxis is recommended before device implantation | I | B |
| 2. Potential sources of sepsis should be eliminated ≥ 2 weeks before implantation of an intravascular/ cardiac foreign material, except in urgent procedures | IIa | C |

- Usually cefazolin 2g <1h before implantation (+/- 6g/24h after)
- **Consider vancomycine** (or daptomycine, teicoplanine) in case of documented SAMR or high incidence of SAMR

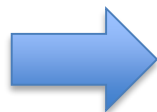
[Circ Arrhythm Electrophysiol.](#) 2009 Feb;2(1):29-34. doi: 10.1161/CIRCEP.108.795906. Epub 2009 Feb 10.

Efficacy of antibiotic prophylaxis before the implantation of pacemakers and cardioverter-defibrillators: results of a large, prospective, randomized, double-blinded, placebo-controlled trial.

[de Oliveira JC](#)¹, [Martinelli M](#), [Nishioka SA](#), [Varejão T](#), [Uipe D](#), [Pedrosa AA](#), [Costa R](#), [D'Avila A](#), [Danik SB](#).

DESIGN

- 1000 patients
- Randomized
- Double blind vs placebo
- Cefazolin 1g IV
- FU 6 months



Stopped by safety committee after 649 patients (26 months)

- **0,64% ATB grp**
- **3,28% Control grp**
(**p=0,016**)

2 predictors in multivariate analysis :

- **ATB**
- **hematoma**



The PADIT trial : *still to come !*

Canadian Journal of Cardiology 29 (2013) 652–658

Special Article

Randomized Cluster Crossover Trials for Reliable, Efficient, Comparative Effectiveness Testing: Design of the Prevention of Arrhythmia Device Infection Trial (PADIT)

Stuart J. Connolly, MD,^a Francois Philippon, MD,^b Yves Longtin, MD,^c Amparo Casanova, PhD,^a David H. Birnie, MD,^c Derek V. Exner, MD,^d Paul Dorian, MD,^e Ratika Prakash, MD,^f Marco Alings, MD,^g and Andrew D. Krahn, MD^h

- ✓ Multicentric (Canada/Europe)
- ✓ 10 000 patients
- ✓ High risk patients (≥ 2 proc./pocket, CRT)
- ✓ Center randomization and cross-over to the other group after 6 months / cluster design

PADIT

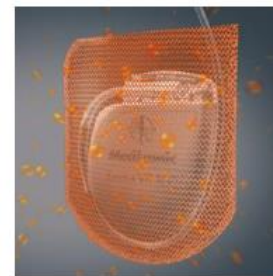
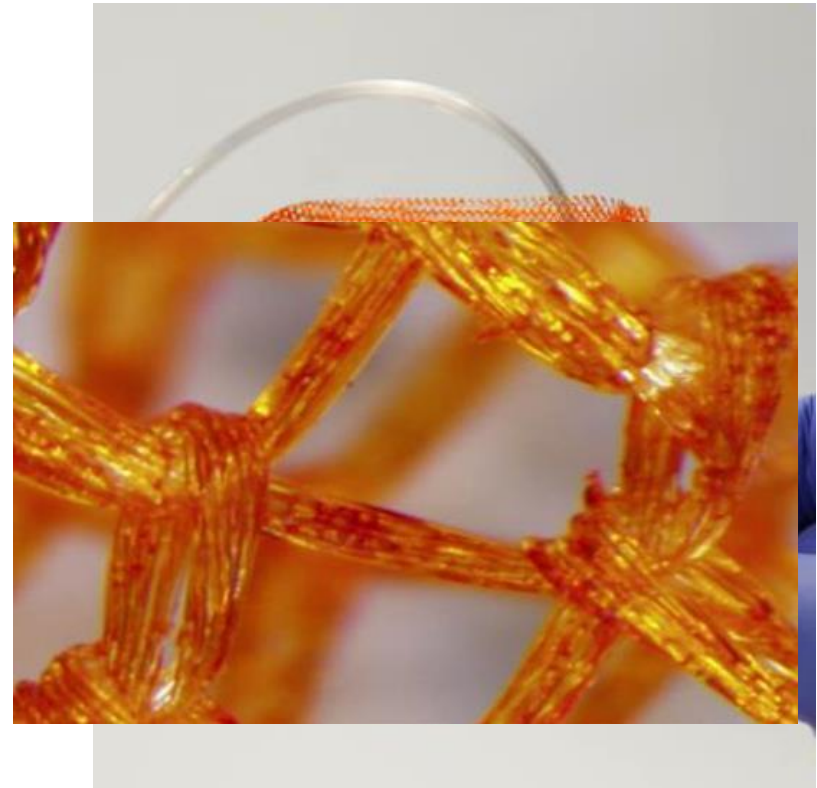
Conventional Antibiotic Therapy:

1. Preoperative intravenous antibiotics (single dose of Cefazolin 1-2 g iv 120-30 minutes prior to skin incision is recommended. In penicillin-allergic patients, Vancomycin 1g (500 mg for patients < 50 kg) given over 60-120 minutes 30-120 minutes prior to skin incision)

Incremental Antibiotic Therapy:

1. Preoperative intravenous antibiotics **CEFAZOLIN + VANCOMYCIN**
2. Intracavitary antibiotics (Antibacterial wash with bacitracin)
3. Postoperative antibiotics (oral antibiotics to last a total of 3 days after the procedure. Cefalexin (250-500 mg TID) is recommended, or Clindamycin 150-300 mg TID for penicillin allergic patients)

- TyrX[®] antibacterial envelope (Medtronic)
- Rifampicine and Minocycline eluted from 2 hours to >7days
- Complete absorption at 9 weeks



Envelope after implantation¹



Envelope at 4 weeks²

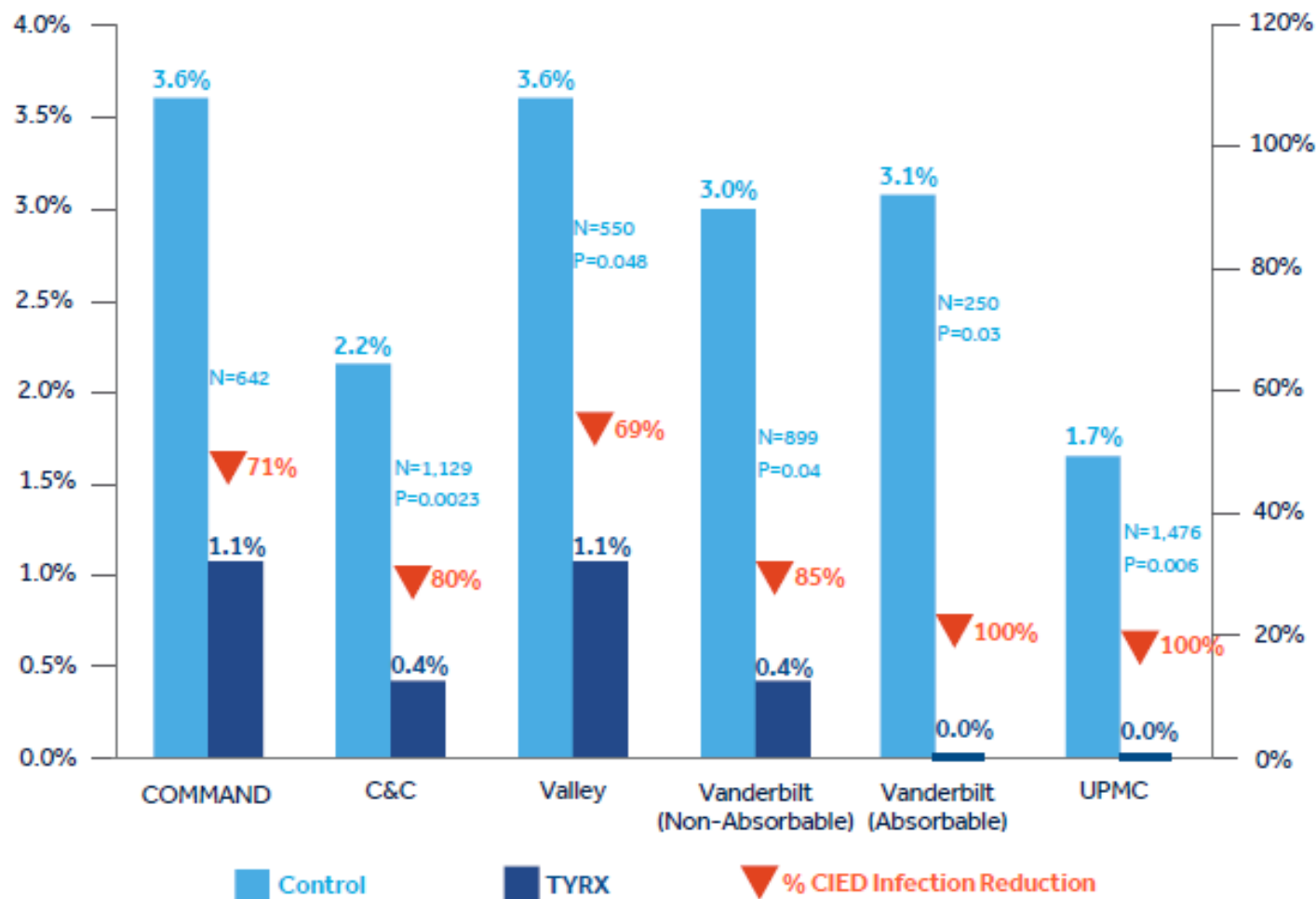


Envelope at ~9 weeks³

| PATHOGENS RESPONSIBLE FOR CIED INFECTIONS | SINGLE-AGENT THERAPY | | TYRX |
|---|----------------------|------------|--------------------------|
| | cefazolin | vancomycin | Minocycline and Rifampin |
| <i>Coagulase (-) Staphylococcus</i> (e.g., <i>S epidermidis</i>) | | | |
| Methicillin-sensitive <i>S aureus</i> (MSSA) | | | |
| Methicillin-resistant <i>S aureus</i> (MRSA) | | | |
| <i>E coli</i> | | | |
| <i>H influenzae</i> | | | |
| <i>M catarrhalis</i> | | | |
| <i>Corynebacterium jeikeium</i> | | | |

TYRX™ ANTIBACTERIAL ENVELOPES HELP PREVENT CIED INFECTIONS IN HIGH-RISK PATIENTS

70% - 100% REDUCTION IN CIED INFECTION



J Cardiovasc Electrophysiol. 2015 Jul;26(7):783-9. doi: 10.1111/jce.12684. Epub 2015 May 25.

Health and Economic Outcomes Associated with Use of an Antimicrobial Envelope as a Standard of Care for Cardiac Implantable Electronic Device Implantation.

Sharif N¹, Eby E², Adelstein E¹, Jain S¹, Shalaby A³, Saba S¹, Wang NC¹, Schwartzman D¹.

- Retrospective analysis 1476 implantations (365 with envelope)
- Infection rates:
 - With TyrX 1,7%
 - Without 0% (p=0,006)

=> Seems efficient and cost effective for high risk patients

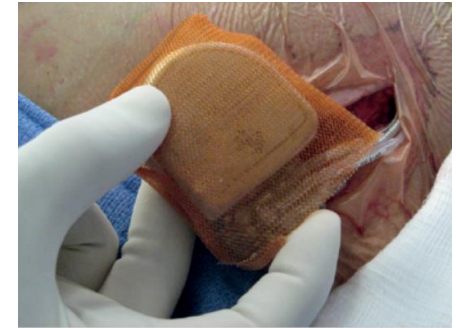
TABLE 4
Financial Implications of Use of AIGISRx as a Standard of Care

| | N | Infection Rate (N) | Infection Care Cost | Differential Cost* |
|----------------------------|-----|--------------------|---------------------|--------------------|
| All patients | 365 | 1.71% (6.20) | \$342,854 | \$23,863 |
| Preoperative risk score <3 | 179 | 1.03% (1.85) | \$101,708 | -\$54,729 |
| Preoperative risk score ≥3 | 186 | 2.45% (4.55) | \$250,115 | \$87,560 |
| Early reintervention | 12 | 6.67% (0.80) | \$43,941 | \$33,453 |

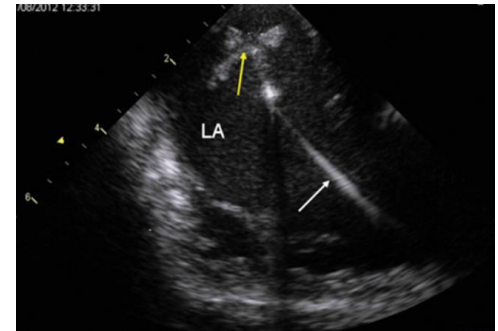
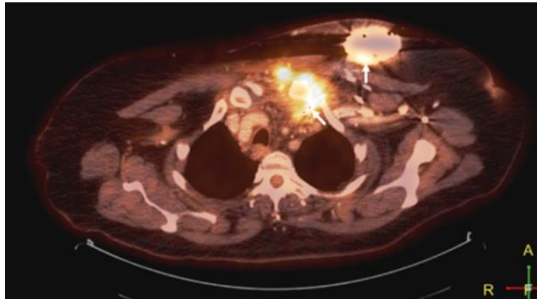
Hypothetical projection which assumes Yes-AIGISRx patients experienced the same infection rate as actually observed among No-AIGISRx patients.
*Differential cost = cost of infection care minus cost of AIGISRx as a standard of care.

Waiting for WRAP-IT results...

- Multicentric, randomized
- Single blind
- TyrX vs no envelope
- Population : « high risk » = CRT and previous pocket surgery
- FU 12 months

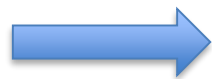


DIAGNOSIS



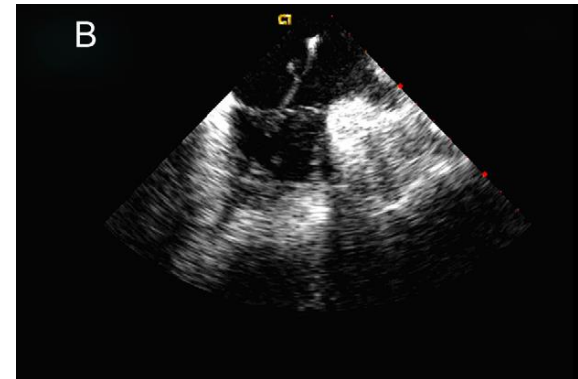
In most cases...

- Medical history
- Clinical examination
 - local signs of inflammation at the generator pocket (erythema, warmth, fluctuance) wound dehiscence or purulent drainage
- Positive blood cultures
- TEE



Lead to a reliable diagnosis

Intracardiac echocardiography (ICE) ?



Usefulness of intracardiac echocardiography for the diagnosis of cardiovascular implantable electronic device-related endocarditis.

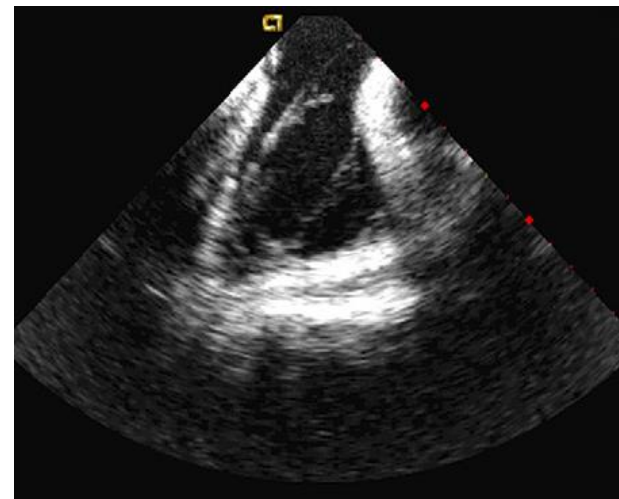
Narducci ML¹, Pelargonio G, Russo E, Marinaccio L, Di Monaco A, Perna F, Bencardino G, Casella M, Di Biase L, Santangeli P, Palmieri R, Lauria C, Al Mohani G, Di Clemente F, Tondo C, Pennestri F, Ierardi C, Rebuzzi AG, Crea F, Bellocci F, Natale A, Dello Russo A.

- 162 patients undergoing lead extraction (with or without evidence for infection)
- TEE + ICE before extraction

⇒ **ICE : more sensitivity**

Issues :

- Cost
- Feasibility out of extraction setup ?



Nuclear imaging

18F-fluorodeoxyglucose
positron emission
tomography/
computed tomography
(18F-FDG PET/CT)



Radiolabelled white blood
cell single-photon emission
computed
tomography/computed
tomography (WBC
SPECT/CT)

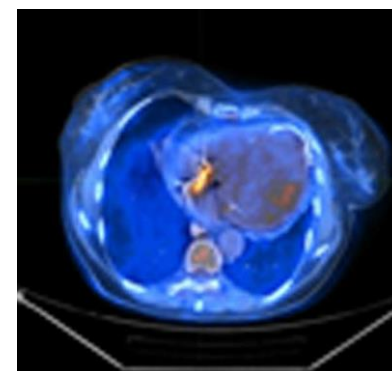
FDG

Advantages

- ¹⁸F-FDG PET/CT
- Excellent spatial resolution
- Short acquisition time
- High sensitivity for the detection of hypermetabolic activity
- Detection of peripheral events
- Detection of other sources of fever or bacteremia in patients with CIED
- Detection of CIED infection and PVE in cases of a negative TEE

Limitations

- Moderate radiation exposure (8-30 mSv depending on the study performed)
- Not available in several centers
- Physiological uptake of ¹⁸F-FDG in the myocardium might prevent adequate detection of cardiac infection
- Recent surgery may demonstrate residual inflammatory changes without evidence of infection
- Possible uptakes can be found in active thrombi, cardiac tumours or metastasis, and foreign body reactions
- Possible false-negative test in patients with small vegetations or prolonged antibiotic therapy
- Less useful for infectious brain embolisms because of high glucose metabolism in the brain



Role of radionuclide imaging for diagnosis of device and prosthetic valve infections

JF Sarrazin et al, WJC
 2016

WBC

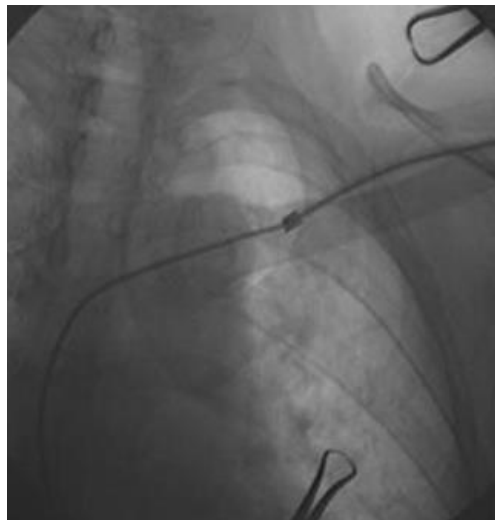
WBC SPECT/CT

- High specificity for the presence of active infection

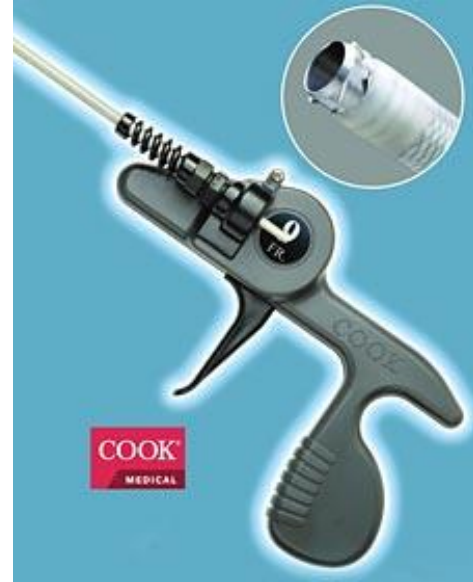
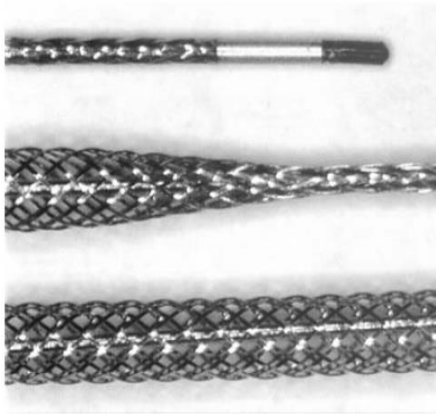
Time-consuming

- It involves blood products handling
- Cases of false-negative study seen with Candida and Enterococcus infection

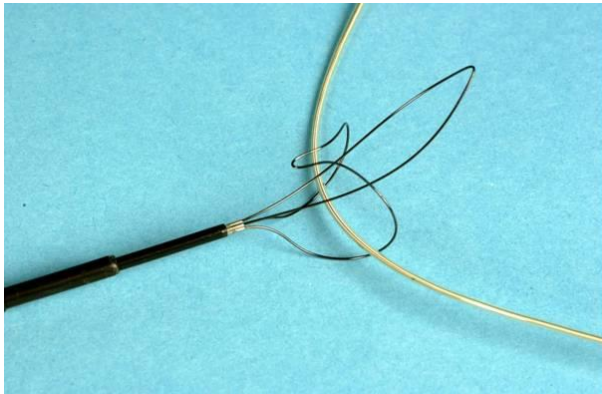
TREATMENT

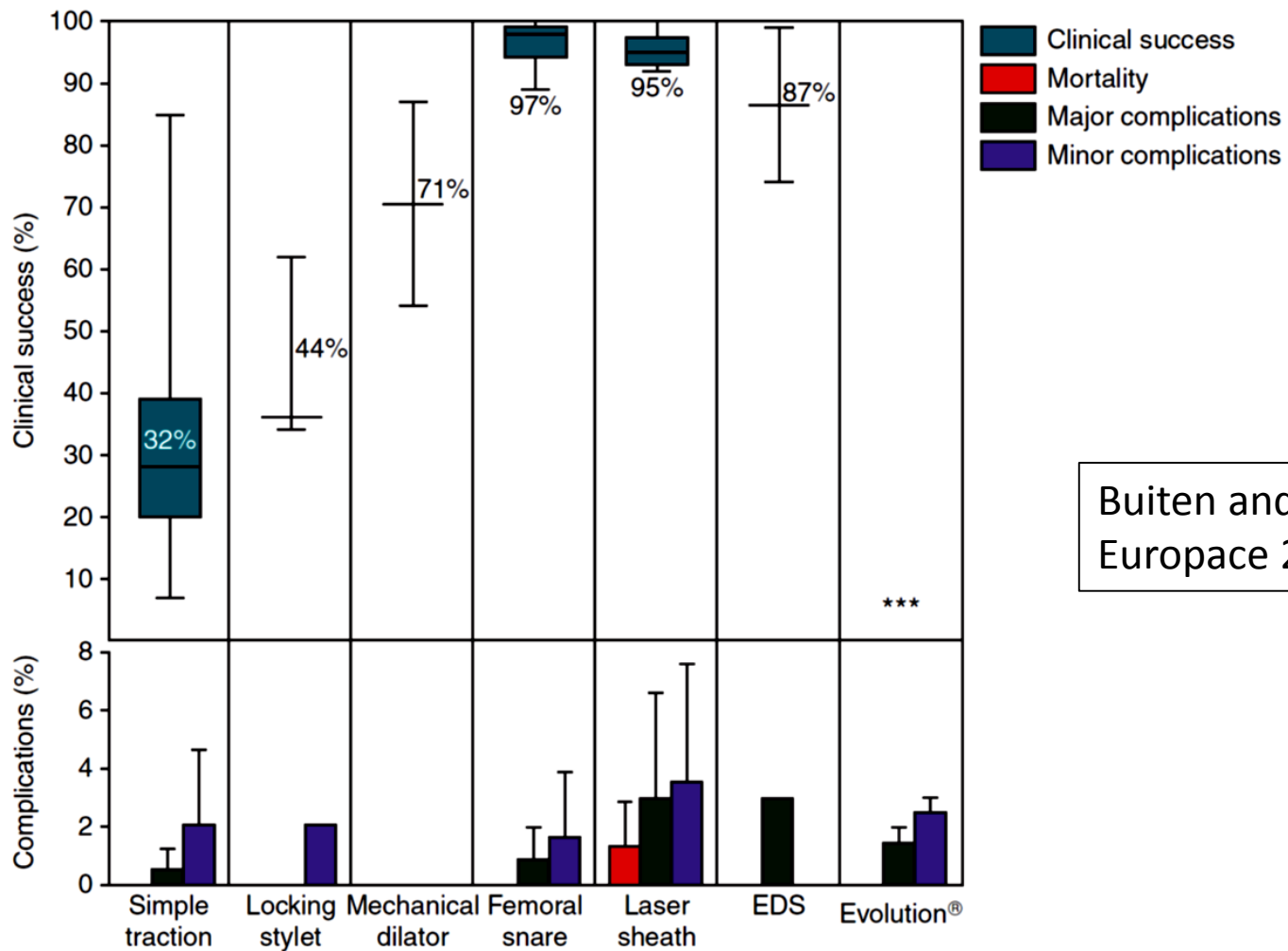


Toolbox...



SLS™ II
Laser Sheath

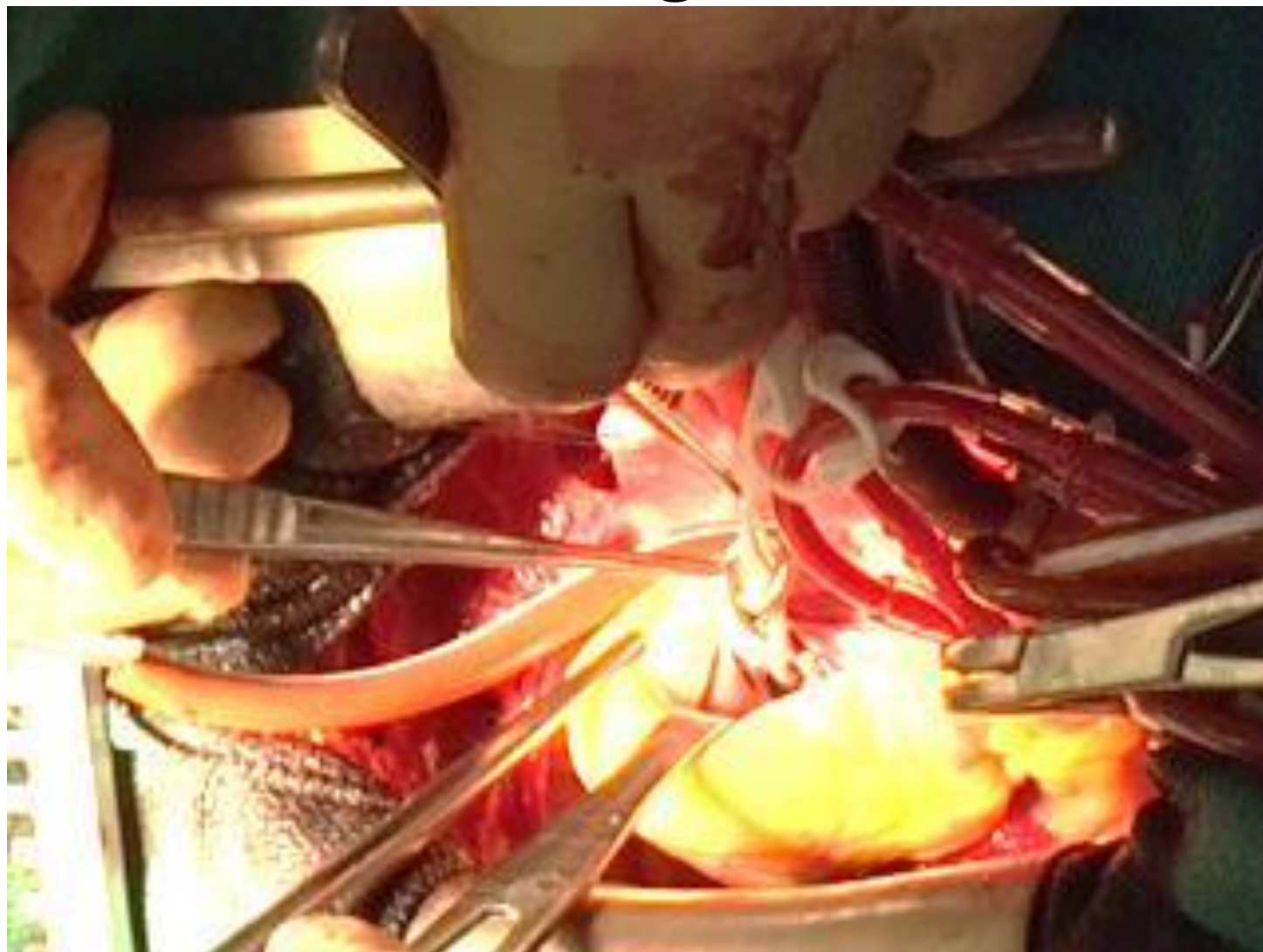




Buiten and al,
Europace 2015

Figure 2 Clinical outcomes of different extraction methods. Clinical success rate is reported per lead and complication rate is reported per patient. The percentages represent the mean success rate. EDS, Electrosurgical dissection sheath. ***Clinical success or complication rates were not reported for this extraction method.

Sometimes the surgeon has to do it...

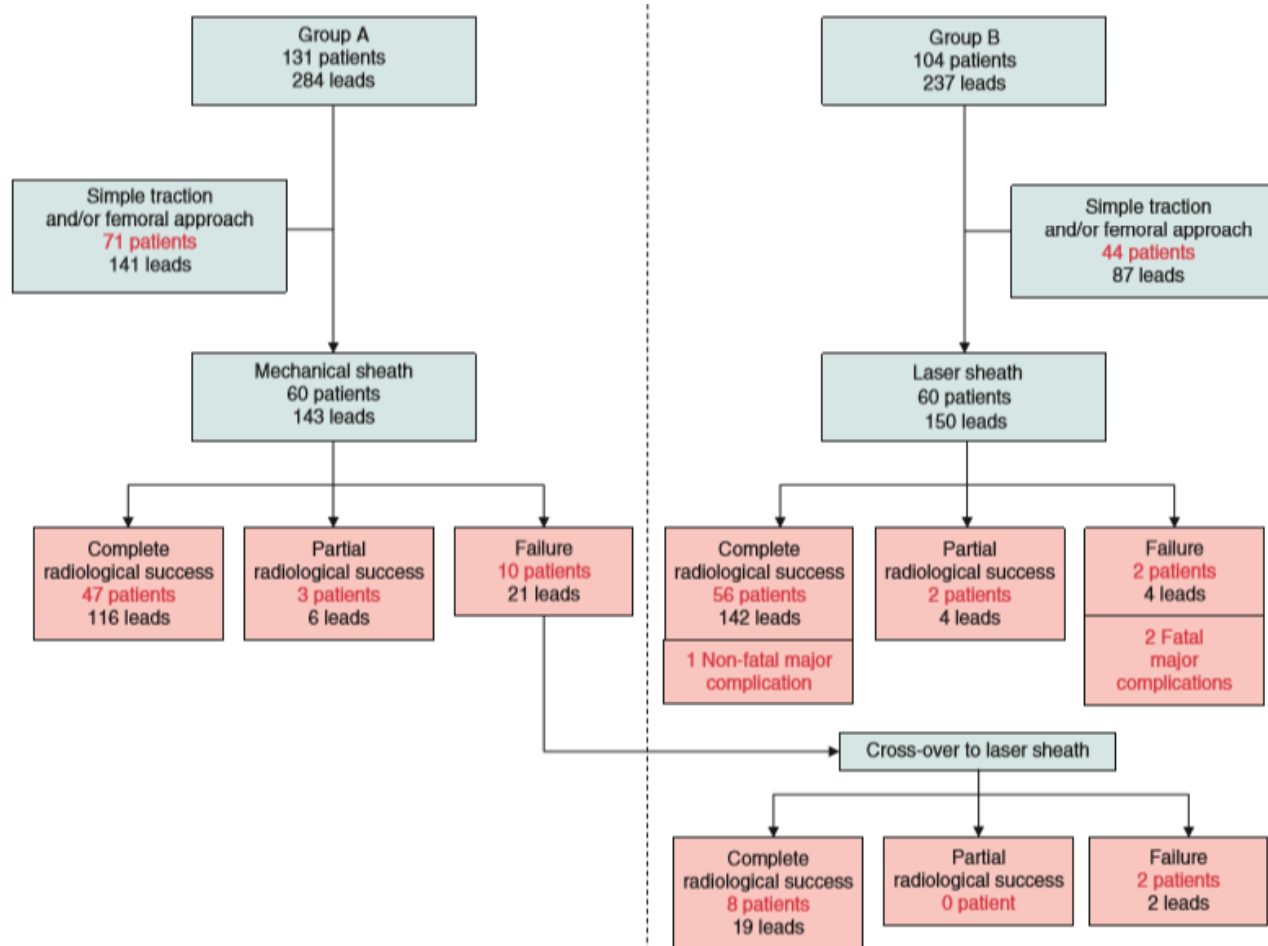


Quebec Case

Europace. 2016 Oct 12. pii: euw254. [Epub ahead of print]

Outcomes and costs associated with two different lead-extraction approaches: a single-centre study.

Gaubert M¹, Giorgi R², Franceschi F¹, Koutbi-Franceschi L¹, Gitenay E¹, Maille B¹, Deharo JC³.



| | Polypropylene sheath (n = 60 patients, 143 leads) | Laser sheath (n = 60 patients, 150 leads) | P-value |
|---|--|--|------------------|
| Radiological success^a | | | <0.001 |
| Complete | 116 (81.1) | 142 (94.7) | |
| Incomplete | 6 (4.2) | 4 (2.7) | |
| Failure | 21 (14.7) | 4 (2.7) | |
| Clinical success^b | 50 (83.3) | 58 (96.7) | 0.01 |
| Procedural characteristics^b | | | |
| Total duration (min) | 96.8 ± 58.5 | 87.3 ± 39.2 | 0.34 |
| Lead-extraction duration (min) | 31.6 ± 23.0 | 23.0 ± 26.6 | 0.28 |
| Fluoroscopy time (min) | 15.4 ± 13.5 | 10.9 ± 14.9 | 0.11 |
| Radiation exposure (mGy²) | 2.0 ± 1.7 | 1.1 ± 1.0 | 0.03 |
| Cost of the materials used^b (€) | 2332 ± 1256 | 3712 ± 1166 | <0.001 |

Predictors and outcomes of lead extraction requiring a bailout femoral approach: Data from 2 high-volume centers.

El-Chami MF¹, Merchant F², Waheed A³, Khattak F³, El-Khalil J⁴, Patel A⁵, Saveqh MN⁶, Desai Y⁶, Leon AR², Saba S⁷.

| Characteristic | Femoral (n = 50) | Superior (n = 1030) | P |
|---|------------------|---------------------|-------|
| Age (y) | 60.5 ± 17.8 | 62.4 ± 16.5 | .438 |
| Sex: male | 39 (78.0) | 685 (66.5) | .122 |
| Height (cm) | 175.0 ± 11.3 | 172.5 ± 13.0 | .209 |
| Weight (kg) | 86.2 ± 26.2 | 89.4 ± 44.8 | .641 |
| Left ventricular ejection fraction (%) | 38.0 ± 17.5 | 38.2 ± 16.5 | .927 |
| Coronary artery disease | 16 (32.0) | 463 (45.0) | .081 |
| Chronic kidney disease | 17 (34.0) | 235 (22.8) | .085 |
| Hypertension | 37 (74.0) | 707 (68.6) | .532 |
| Diabetes mellitus | 21 (42.0) | 309 (30.0) | .084 |
| No. of leads extracted per procedure | 2.0 ± 1.0 | 1.7 ± 0.9 | .003 |
| ICD leads extracted per procedure | 0.69 ± 0.5 | 0.79 ± 0.5 | .142 |
| Dwell time of the oldest extracted lead (y) | 9.5 ± 6.0 | 5.7 ± 4.3 | <.001 |
| Indication for extraction | | | |
| Infection | 36 (72.0) | 383 (37.2) | <.001 |
| Lead failure | 12 (24.0) | 467 (45.3) | .003 |
| Upgrade | 1 (2.0) | 78 (7.6) | .171 |
| Other | 1 (2.0) | 66 (6.4) | .361 |

Bridge OCCLUSION balloon



[Europace](#). 2010 Mar;12(3):395-401. doi: 10.1093/europace/eup375. Epub 2009 Nov 27.

Deaths and cardiovascular injuries due to device-assisted implantable cardioverter-defibrillator and pacemaker lead extraction.

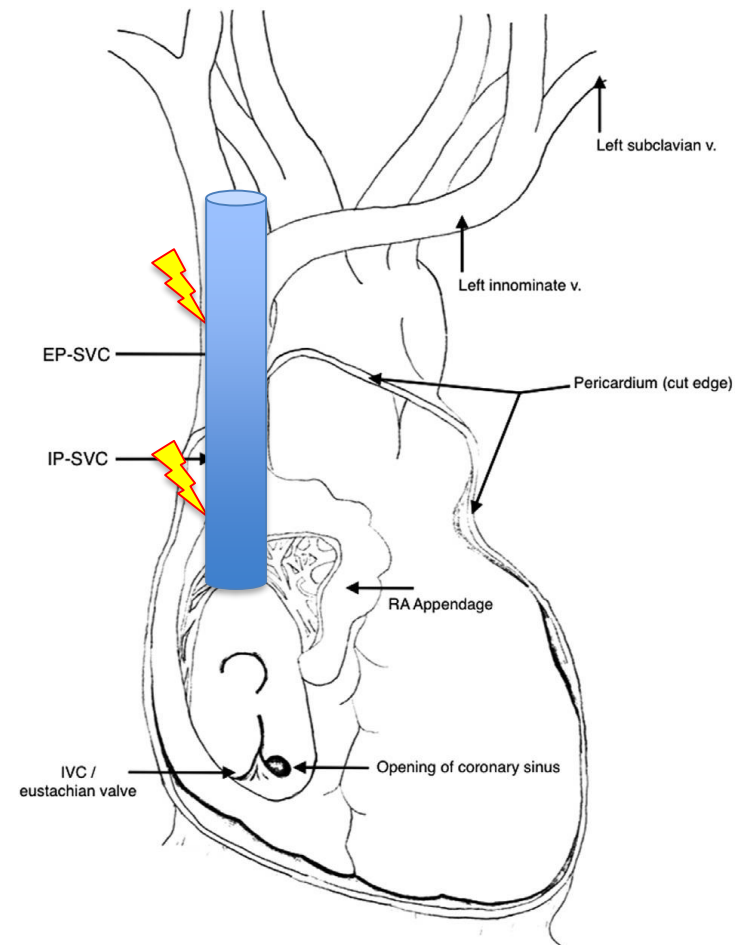
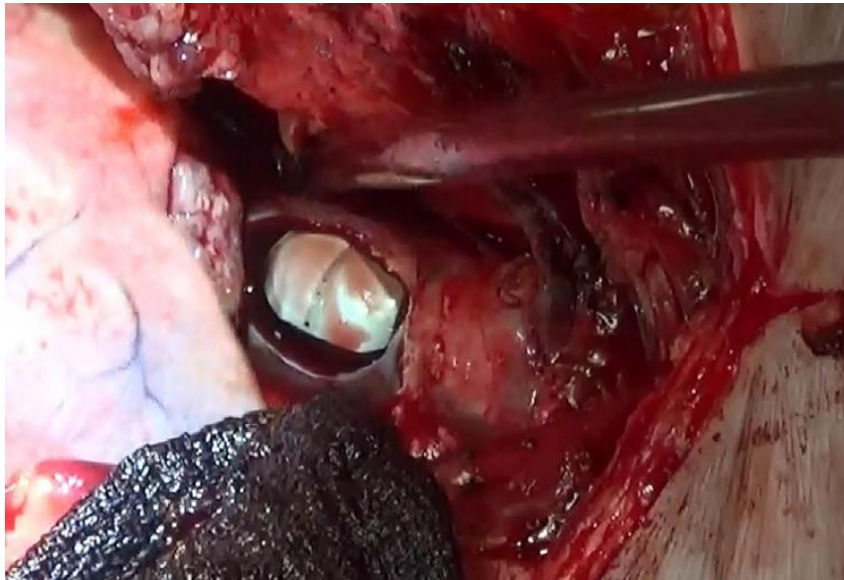
[Hauser RG](#)¹, [Katsiyiannis WT](#), [Gornick CC](#), [Almquist AK](#), [Kallinen LM](#).

- *FDA registries : death or major injuries related to lead extraction between 1995 and 2008*
- 57 deaths – 48 CV injuries
- Devices implicated : laser, mechanical, teflon, electro-surgical
- ⇒ **All but 3 cases were vascular or cardiac tears** (1 pulmonar embolism, 2 unspecified events)
- 62 emergency surgical repair
- ⇒ 35 patients (56%) survived

Heart Rhythm. 2016 Nov;13(11):2215-2220. doi: 10.1016/j.hrthm.2016.06.028. Epub 2016 Jun 23.

Percutaneous occlusion balloon as a bridge to surgery in a swine model of superior vena cava perforation.

Clancy JF¹, Carrillo RG², Sotak R³, Ram R³, Ryu RK⁴, Kennergren C⁵.



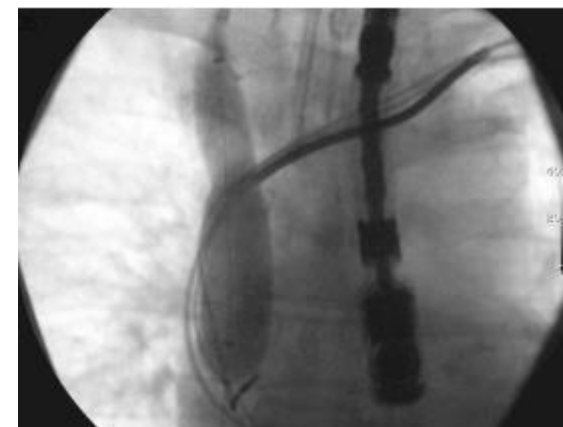
Heart Rhythm. 2016 Dec 15. pii: S1547-5271(16)31222-X. doi: 10.1016/j.hrthm.2016.12.028. [Epub ahead of print]

Balloon-assisted rescue of four consecutive patients with vascular lacerations inflicted during lead extraction.

Boyle TA¹, Wilkoff BL², Pace J³, Saleem M⁴, Jones S⁵, Carrillo R⁶.

Report of the 4 first cases

- Stiff guidewire from femoral vein to IJV before extraction under fluoro guidance
- Deployment time : 30sec > 2min
- Vascular repair without CP bypass
- 4 patients survived



Conclusion

- ❖ There's a lot of clinical research in the field of CIED infections

- ❖ Growing data about :
 - ❖ preventive interventions (antibiotics, antimicrobial pocket)
 - ❖ Diagnostic tests (nuclear imaging+++)

- ❖ Still not part of guidelines

Thanks for your attention !

