

İNFEKTİF ENDOKARDİT

VE DİĞER KARDİOVASKÜLER İNFEKSİYONLARDA
TARTIŞMALI KONULAR: MULTİDİSİPLİNER YAKLAŞIMLAR

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KLİMİK DERNEĞİ İNFEKTİF ENDOKARDİT VE DİĞER
KARDİOVASKÜLER İNFEKSİYONLAR ÇALIŞMA GRUBU

20-21 EYLÜL 2019



CIED Enfeksiyonlarında Sistemin Çıkarılması? Cerrahi mi? Perkütan mı?

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Ankara Şehir Hastanesi

Kardiyoloji Kliniği

Bilkent, Ankara



ESC

European Society
of Cardiology

Europace (2018) 00, 1–11

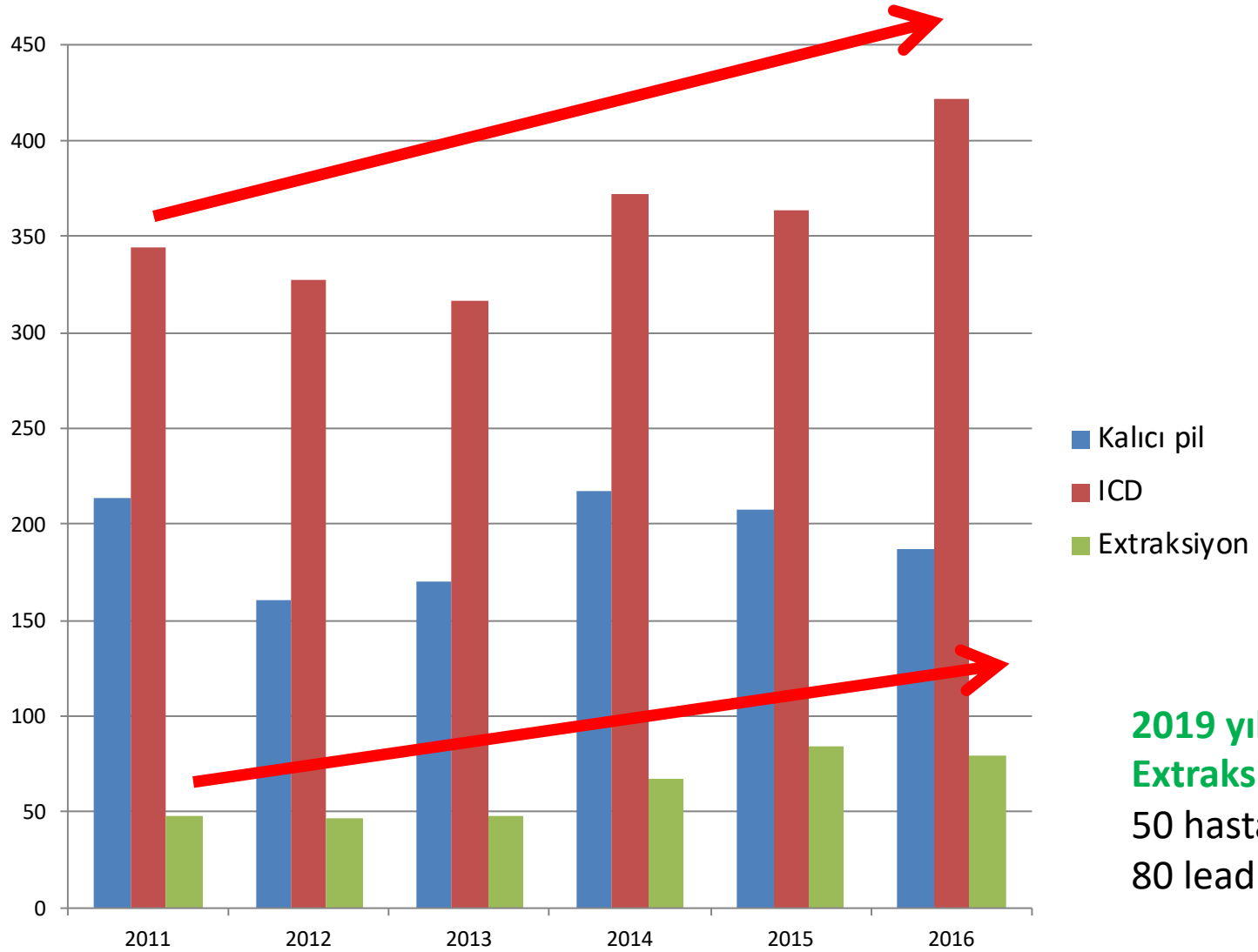
doi:10.1093/europace/euy050

EHRA CONSENSUS STATEMENT

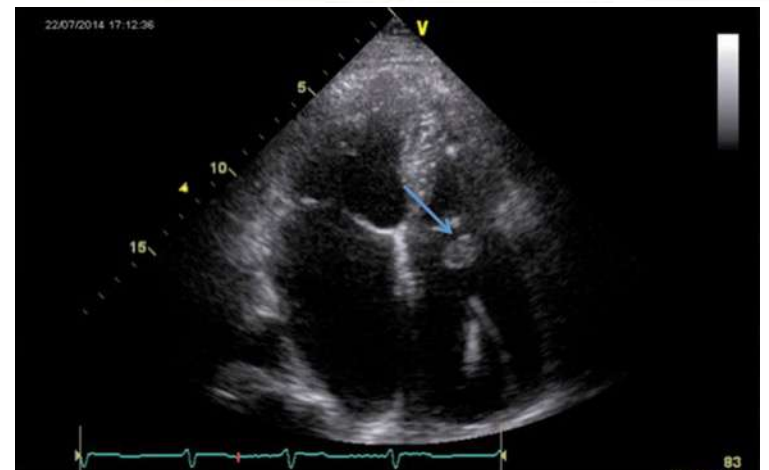
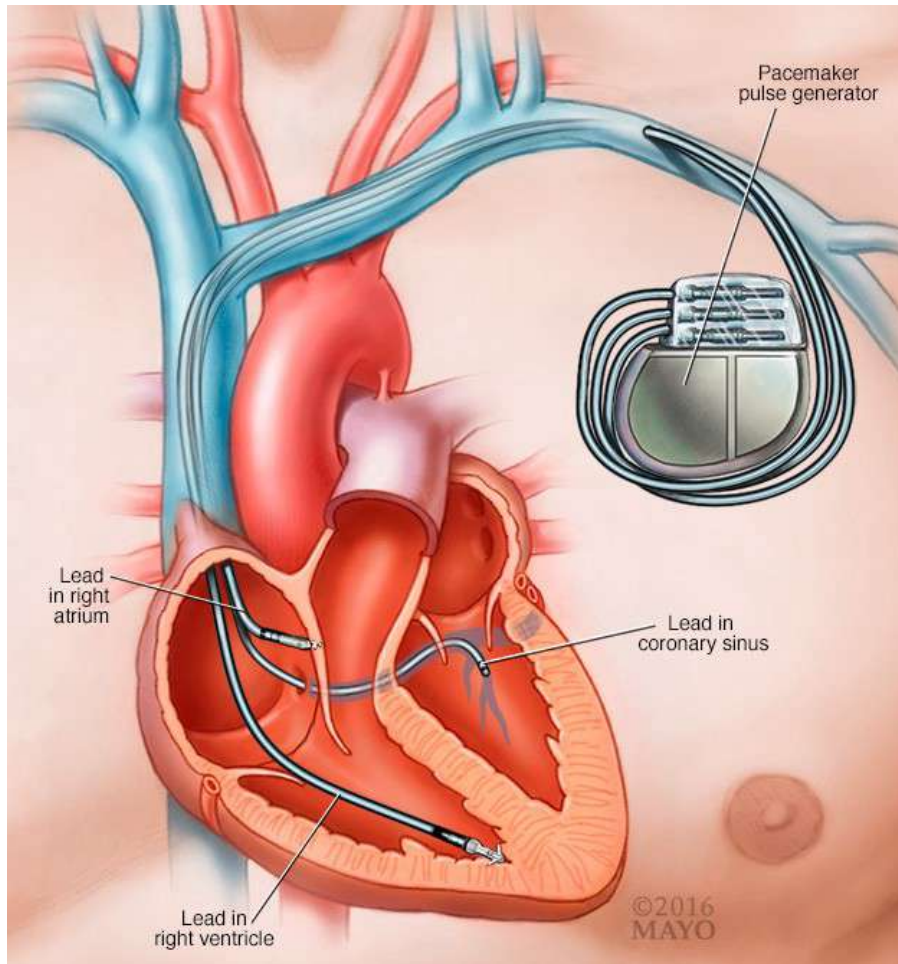
2018 EHRA expert consensus statement on lead extraction: recommendations on definitions, endpoints, research trial design, and data collection requirements for clinical scientific studies and registries: endorsed by APHRS/HRS/LAHRS

2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction 

TYİH Aritmi ekibi verileri



2019 yılı ilk 8 ay
Extraksiyon:
50 hasta
80 lead



CIED-related infection types

Clinical scenarios	Infection types	Definitions
Bacteraemia	Systemic	Positive blood cultures with or without systemic infection symptoms and signs
Pocket infection (open or closed) with bacteraemia	Systemic	<u>Local signs of pocket infection and positive blood cultures, without lead or valvular vegetation(s)</u>
CIED-related endocarditis without pocket infection	Systemic	<u>Bacteraemia and lead or valvular vegetation(s), without local signs of pocket infection</u>
Pocket infection with lead/valvular endocarditis	Systemic	Local signs of pocket infection and positive blood cultures and lead or valvular vegetation(s)
Occult bacteraemia with probable CIED infection	Systemic	<u>Bacteraemia without an alternative source</u>

2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction

COR	LOE	Recommendations
I	C-LD	If antibiotics are going to be prescribed, drawing at least two sets of blood cultures before starting antibiotic therapy is recommended for all patients with suspected CIED infection to improve the precision and minimize the duration of antibiotic therapy.
I	C-LD	Gram stain and culture of generator pocket tissue and the explanted lead(s) are recommended at the time of CIED removal to improve the precision and minimize the duration of antibiotic therapy.
I	B-NR	Preprocedural transesophageal echocardiography (TEE) is recommended for patients with suspected systemic CIED infection to evaluate the absence or size, character, and potential embolic risk of identified vegetations.
I	C-EO	Evaluation by physicians with specific expertise in CIED infection and lead extraction is recommended for patients with documented CIED infection.

IIa	B-NR	TEE can be useful for patients with CIED pocket infection with and without positive blood cultures to evaluate the absence or size, character, and potential embolic risk of identified vegetations.	123
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Device pocket infection might or might not be accompanied by bloodstream infection. In one study, intravascular lead involvement was present in 88% of patients presenting with pocket infection despite lack of symptoms of systemic infection.¹²³

IIb	C-LD	Additional imaging may be considered to facilitate the diagnosis of CIED pocket or lead infection when it cannot be confirmed by other methods.	124–129
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18-Fluorodeoxyglucose (¹⁸F-FDG) positron emission tomography (PET)/computed tomography (CT) scanning might provide helpful evidence when diagnosis of CIED pocket or lead infection is doubtful.^{124–126} One study showed that PET/CT had a high sensitivity of 87% and a specificity of 100% for device pocket infection but a low sensitivity of 31% and a specificity of 62% for endocarditis.¹²⁷ In another single-center, prospective, controlled study of 86 patients, patients with suspected generator pocket infection requiring CIED extraction had significantly higher ¹⁸F-FDG activity (4.80 [3.18–7.05]) compared with those who did not have the infection (1.40 [0.88–1.73]) and compared with controls (1.10 [0.98–1.40]).¹²⁸ The diagnostic performance of ^{99m}Tc-hexamethylpropylene amine oxime–labeled autologous white blood cell (^{99m}Tc-HMPAO-WBC) scintigraphy had a sensitivity of 94% for both detection and localization of CIED-associated infection.¹²⁹

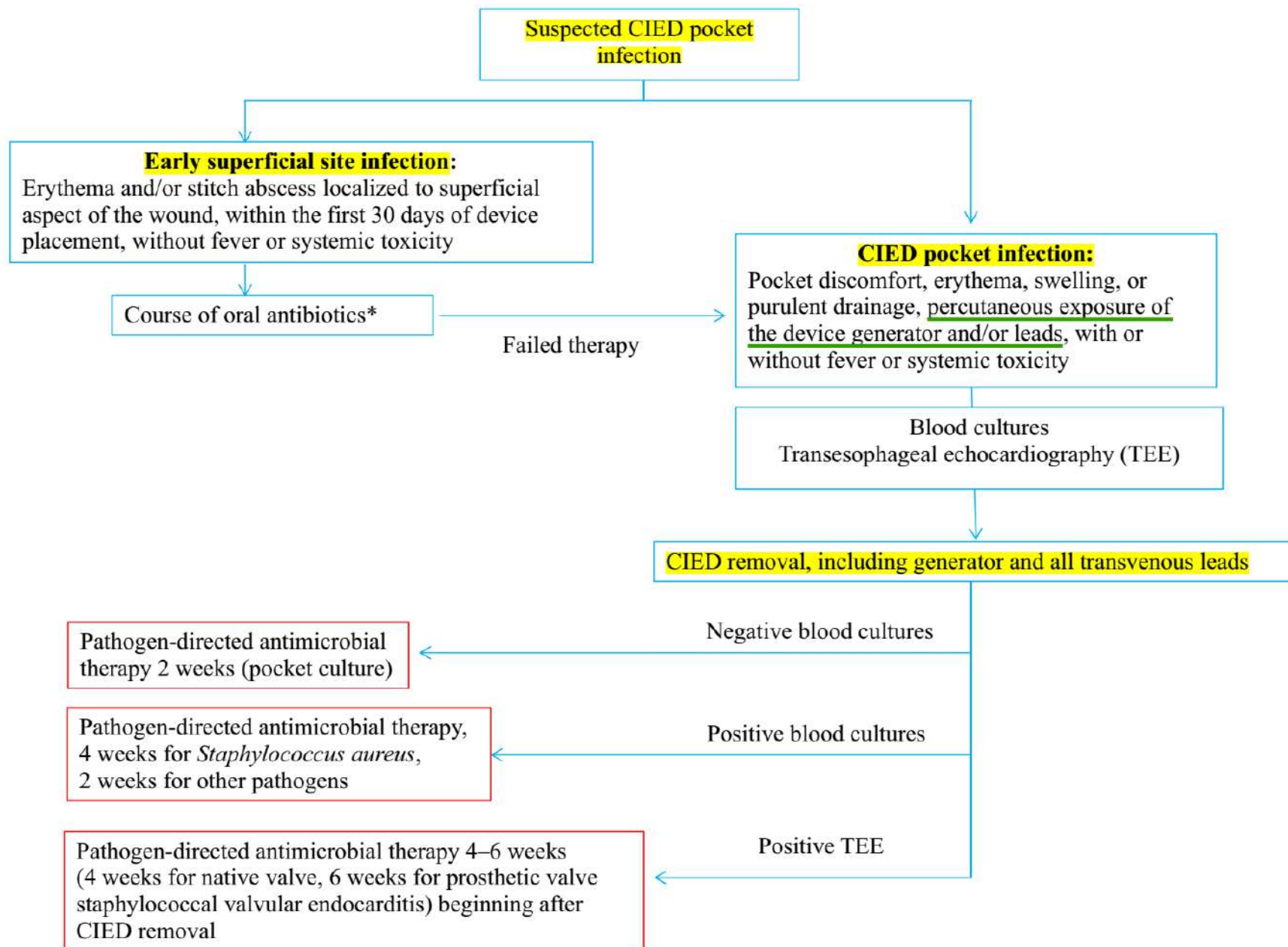
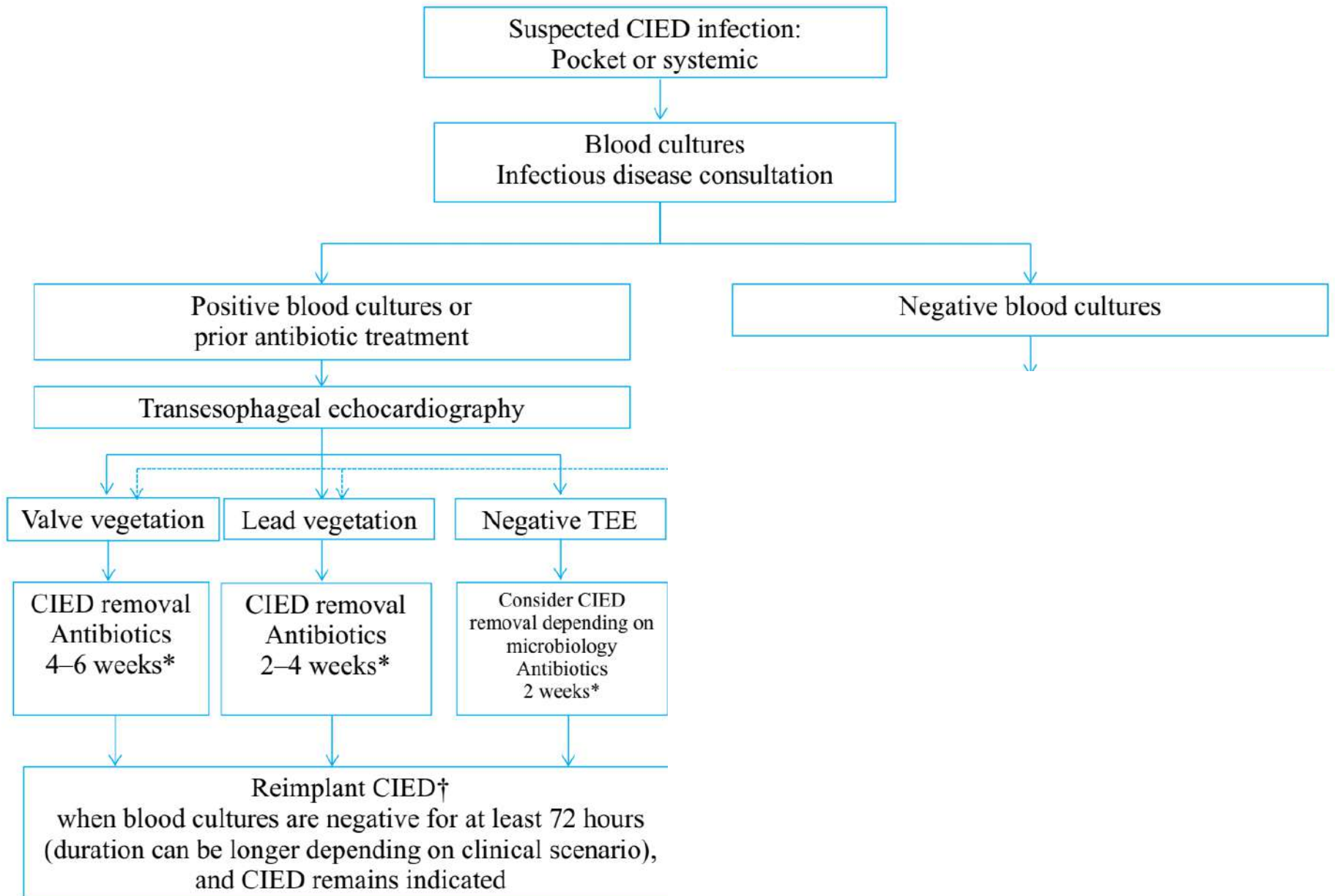
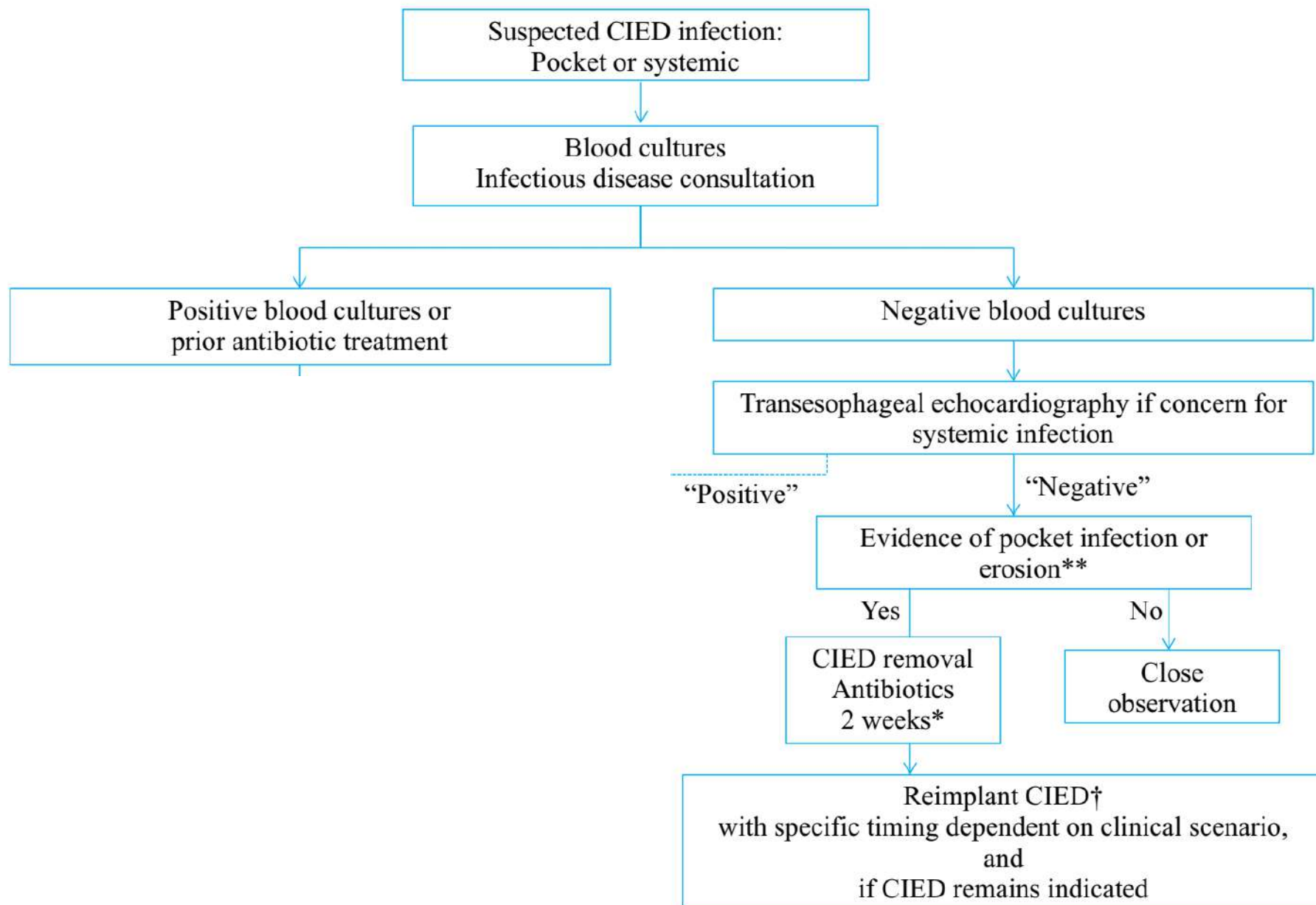


Figure 3 Management of suspected pocket infection. *See text for examples.





I	B-NR	Complete device and lead removal is recommended for all patients with definite CIED system infection.	169–171
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Early diagnosis of CIED infection and performing lead extraction within 3 days of diagnosis is associated with lower in-hospital mortality.¹⁶⁹ A multivariate analysis found a 7-fold increase in 30-day mortality if the CIED was not removed. Although CIED removal resulted in fatal complications, the mortality associated with a delay in removal was even higher.¹⁷⁰ Therefore, CIED-associated infections are the strongest indication for complete CIED system removal and should not be delayed, regardless of the timing of the start of antimicrobial therapy^{1,171}

I	B-NR	Complete device and lead removal is recommended for all patients with valvular endocarditis without definite involvement of the lead(s) and/or device.	153,169
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I	B-NR	Complete device and lead removal is recommended for patients with persistent or recurrent bacteremia or fungemia, despite appropriate antibiotic therapy and no other identifiable source for relapse or continued infection.	153,165
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I	C-EO	Careful consideration of the implications of other implanted devices and hardware is recommended when deciding on the appropriateness of CIED removal and for planning treatment strategy and goals.	
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Patients who have received a CIED might have other implanted devices and hardware. For example, left ventricular assist device (LVAD) recipients often have a CIED in place (up to 87%). In a large series of 247 LVAD patients, 2.8% had CIED infection. Patients with an LVAD and CIED infection should undergo CIED removal to eliminate a potential source of microbial seeding and infection. Chronic suppressive antibiotic therapy is warranted in concomitant LVAD infection.¹⁷³

Approaches, tools and techniques

Type	Definitions
Approach	Defined according to vein used to remove the lead
Transvenous	Percutaneous (closed) lead removal performed through a central vein (subclavian, jugular, and femoral)
Superior approach	Lead removed above the diaphragm
Venous entry site	Lead removed using the implantation venous entry site (right or left subclavian, axillary, cephalic, and jugular vein)
Transjugular	Lead removed using the right internal jugular vein
Inferior approach	Lead removed below the diaphragm (right or left femoral vein)
Surgical	Surgical (open) lead removal. Includes standard sternotomy,

2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction

10.2.4. *Extraction Approach: Open Versus Percutaneous Extraction*

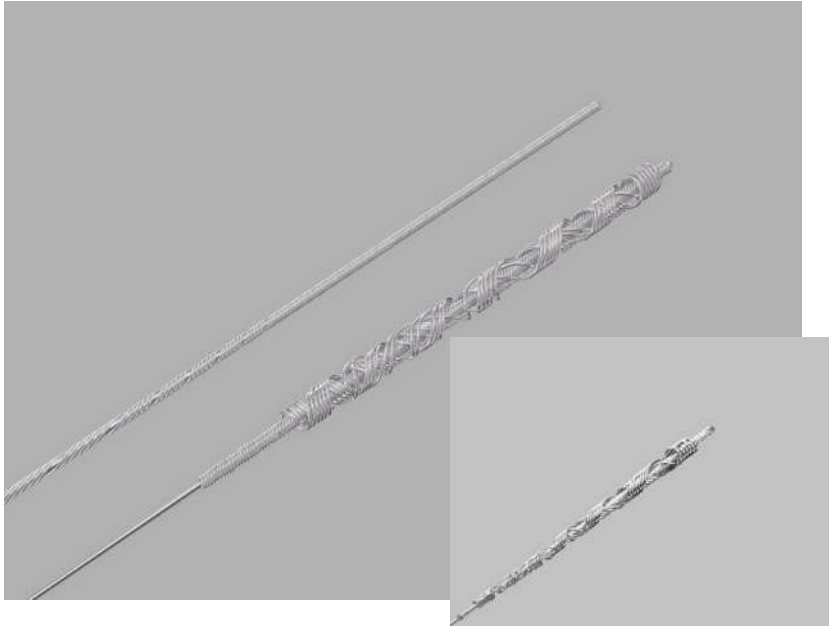
The percutaneous approach to lead extractions is generally preferred over open extractions because it is inherently less invasive and significantly reduces patient morbidity.^{1,178} Conversely, open extractions are generally favored in high-risk extractions to avoid potentially life-threatening complications that can be encountered during percutaneous extractions.¹ The challenge then becomes predicting which extractions are sufficiently high-risk to justify the inherent morbidities associated with open-heart surgery. In general, open extractions are considered when the patient has failed a prior extraction procedure, has another reason for cardiac surgery, or when cardiac imaging identifies large lead masses (vegetation or thrombus >2.5 cm).¹

Lead ekstraksiyonu

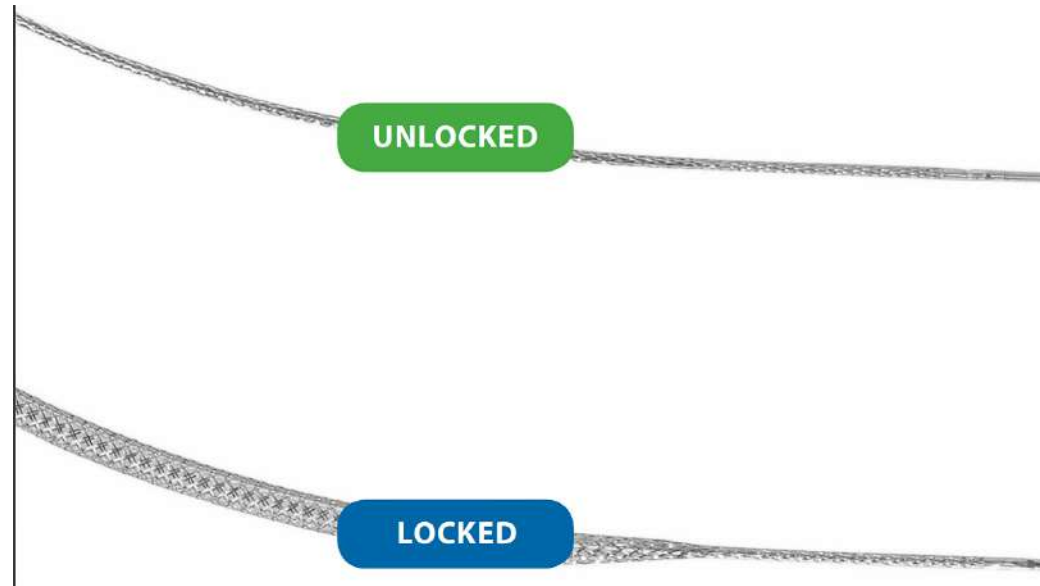
- Kilitleme stileleri
- Rotasyonel mekanik cihazlar
- Snare ve Biyoptom
- Lazer cihazlar
- Elektrocerrahi cihazlar (RF)

Kilitleme stileleri

Liberator
Device)

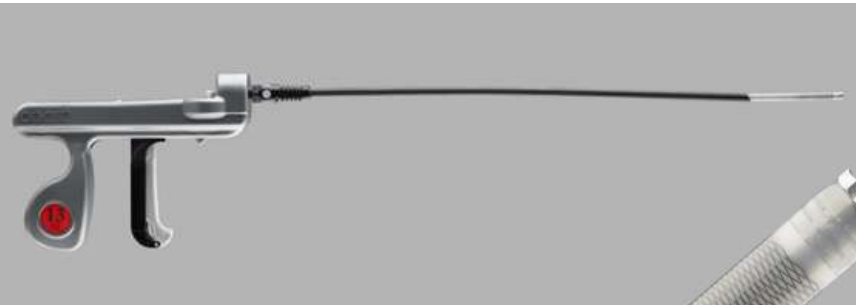


LLD (Lead Locking



Rotasyonel mekanik cihazlar

Evolution



TightRail



Comparison of two types of rotational mechanical dilatator sheath: Evolution[®] and TightRail[™]

Serkan Cay MD  | Ozcan Ozeke MD  | Firat Ozcan MD | Serkan Topaloglu MD |
Dursun Aras MD

Assessed for eligibility

(n = 311)

mechanism. All ICD leads had dual-coil design. The median lead implant duration was 4 years, and no difference was found between the two groups. Infectious etiology was the main indication for extraction in 56.1% of patients. There were no statistically significant differences regarding the procedural success rate (96.6% vs 95.0%), clinical success rate (98.3% vs 97.5%), and total adverse event rate (5.2% vs 10.0%) between the Evolution and TightRail groups, respectively. Procedural success decreased with older leads and higher lead number.

Conclusions: Procedural and clinical success rates utilizing both the Evolution and TightRail rotational extraction sheaths were high with low complication rate in chronically implanted leads.

Evolution
(n = 58)

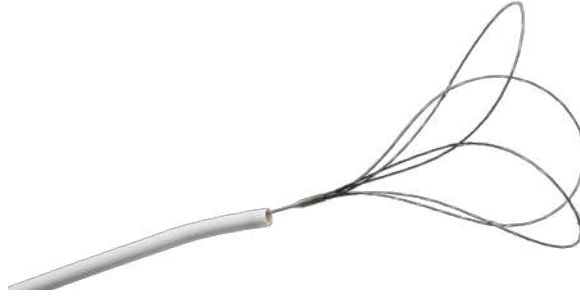
TightRail
(n = 40)

Snare ve Biyoptom

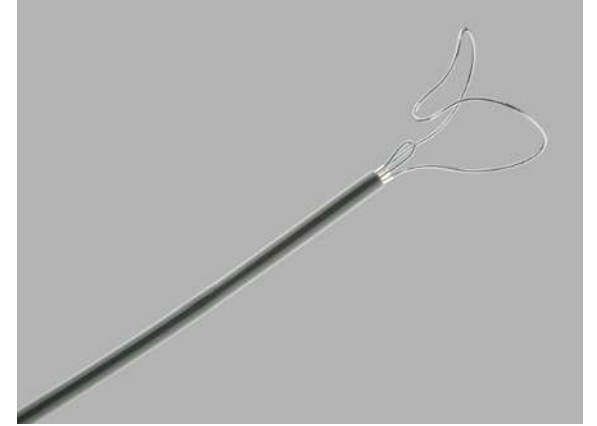
Tekli kement



Çoklu kement

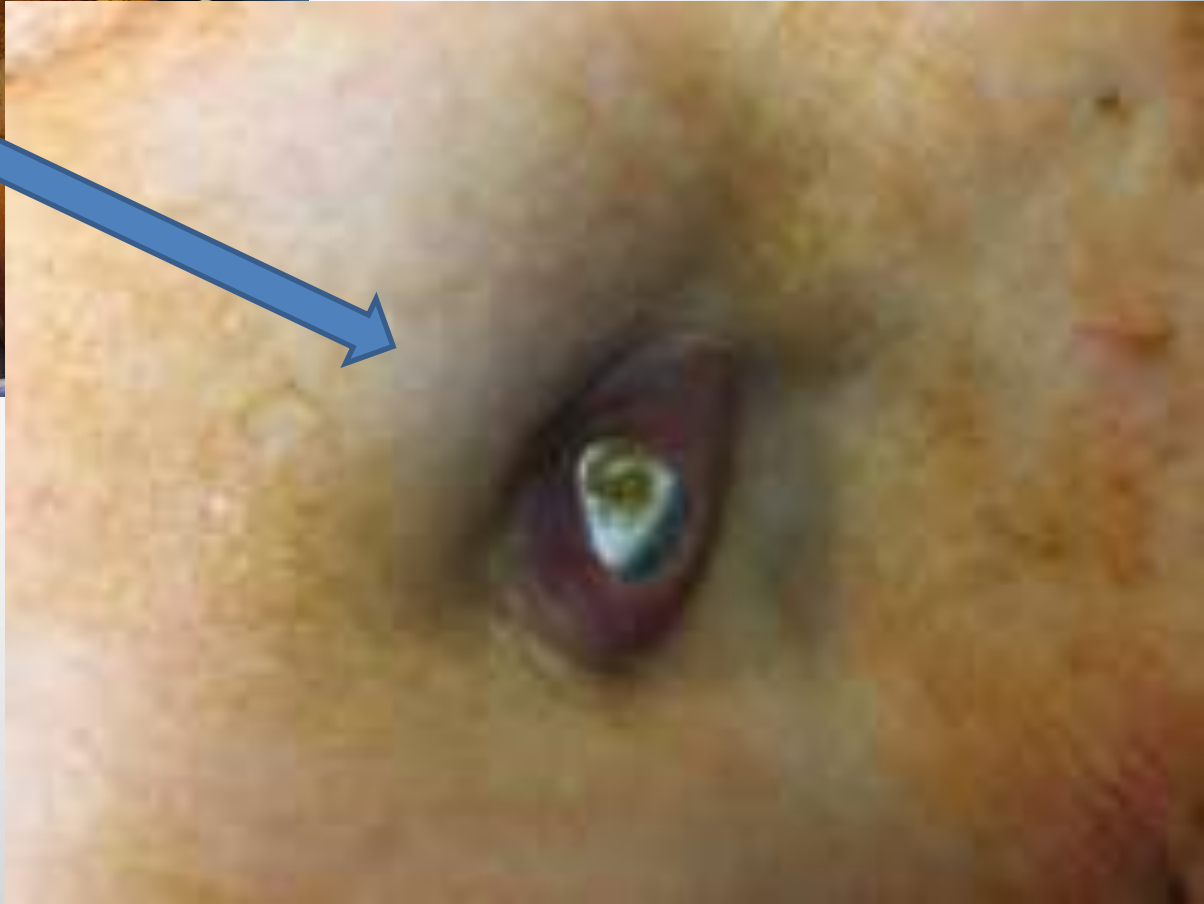


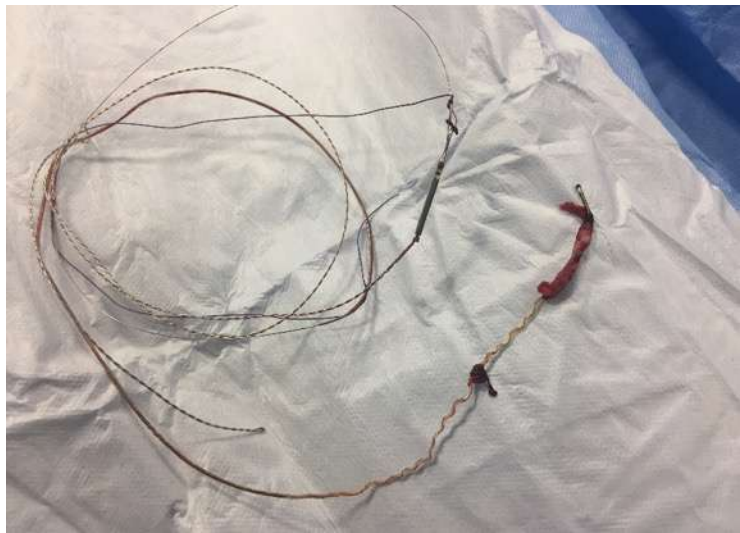
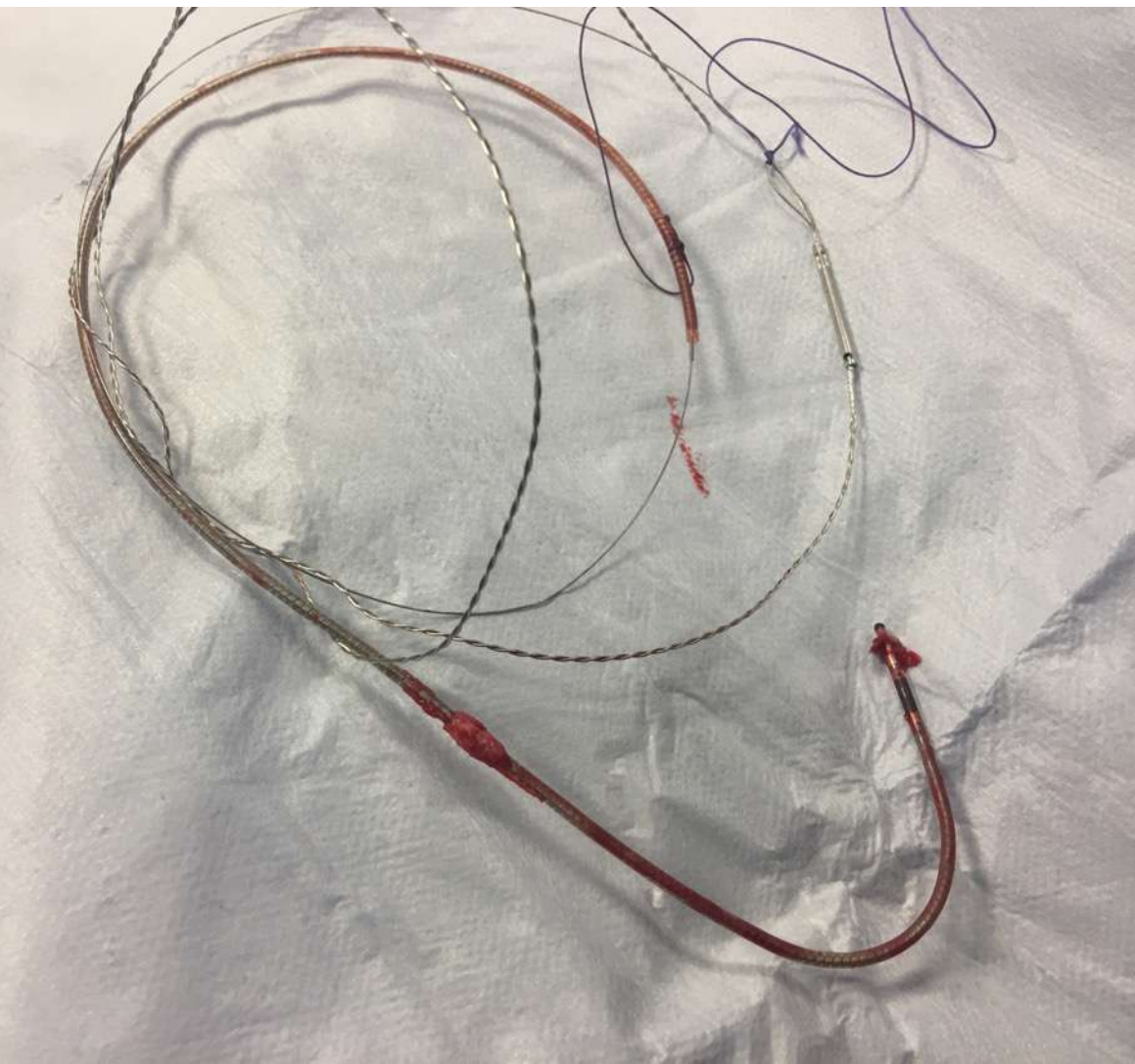
Needle's Eye Snare



Biyoptom







İşlem öncesi

(Hikaye, Fizik muayene, EKG, Tele, Cihaz kontrolü, Lab. Hastanın bilgilendirilmesi)



Risk değerlendirmesine göre yer seçimi

(Lead yaşı, çeşidi, sayısı, Hasta yaşı, morbidite varlığı, kırılganlık,...)



Hibrit Oda (>1 yıl lead yaşı)

Elektrofizyoloji Lab. (<1 yıl lead yaşı)



Gerekli antimikrobiyal koşulların sağlanarak hastanın hazırlanması

(Çeneden dize kadar boyama, cerrahi örtüler, foley sonda, arteriyel basınç ve oksijenizasyon ölçümü)



Anestezi ve analjeninin sağlanması

(Propofol, fentanil, midazolam, gerekirse genel anestezi)



Cep açılması ve implant vene kadar tüm sistemin explore edilmesi

(Jeneratör, leadler, sleeve, dikişler ve varsa enfeksiyöz dokular)



Basit traksiyon

(Serbestleşen leadlere basit stileler yerleştirilerek çekme)



İlk ekstraksiyon

(Lead makasıyla kesilen leadin kilitleme stilesi kullanılarak manüel çekilmesi)



İkinci Ekstraksiyon

(Kilitleme stilesi olan leadin mekanik sheath kullanılarak çekilmesi)



Diğer venöz yollardan Ekstraksiyon

(İmplant venden çekilemeyen, deforme olan leadlerin ya da parçaların snare, biyoptom gibi malzemelerin kullanılmasıyla çekilmesi)



İşlem sonu

(Venöz ve arteriyel yolların hemostazının sağlanarak, cebin primer olarak kapatılması)

Incidence and Predictors of Perioperative Complications With Transvenous Lead Extractions

Real-World Experience With National Cardiovascular Data Registry

Major Perioperative Complications*

Circ Arrhythm Electrophysiol. 2018;11:e004768. DOI: 10.1161/CIRCEP.116.004768

Type	Total (%: Complication Rate: Entire Cohort 11 304 Extraction Procedures)	High-Voltage Lead Extraction Procedure (%: Complication Rate in 8362 Extraction Procedures)	Pacing Lead Extraction Procedure (%: Complication Rate in 2942 Extraction Procedures)
Any complication	258 (2.3%)	200 (2.4%)	58 (1.9%)
Cardiac arrest	62 (0.5%)	51 (0.60%)	11 (0.37%)

CONCLUSIONS: The rate of major complications and mortality with transvenous lead extraction is similar in the real-world outcomes to that reported in recent single-center studies from high-volume centers. There is significant risk of urgent cardiac surgery, which carries a high mortality, and planning for appropriate cardiothoracic surgery backup is imperative.

Pericardial tamponade	55 (0.48%)	48 (0.57%)	7 (0.24%)
Pneumothorax	47 (0.4%)	33 (0.39%)	14 (0.47%)
Urgent cardiac surgery	41 (0.36%)	38 (0.45%)	3 (0.10%)
Death	98 (0.86%)	79 (0.94%)	19 (0.65%)

Lead Ekstraksiyon Komplikasyon ve Mortalite Riskini Artıran Faktörler

Table 4 Factors associated with extraction procedure complications and longer-term mortality

Factor	Associated risk
Age	1.05-fold ↑ mortality ²³⁸
Female sex	<u>4.5-fold ↑ risk of major complications</u> ²³⁹
Low body mass index (<25 kg/m ²)	1.8-fold ↑ risk of 30-day mortality ⁶² ↑ no. of procedure-related complications ²¹²
History of cerebrovascular accident	2-fold ↑ risk of major complications ⁶²
Severe LV dysfunction	2-fold ↑ risk of major complications ⁶²
Advanced HF	1.3- to 8.5-fold ↑ risk of 30-day mortality ⁶² 3-fold ↑ 1-year mortality ²⁴⁰
Renal dysfunction	<u>ESRD: 4.8-fold ↑ risk of 30-day mortality</u> ⁶² Cr ≥2.0: ↑ in-hospital mortality ²¹⁰ and 2-fold ↑ risk of 1-year mortality ²⁴⁰
Diabetes mellitus	↑ in-hospital mortality ²¹² 1.71-fold ↑ mortality ²³⁸
Platelet count	Low platelet count: 1.7-fold ↑ risk of major complications ⁶²

Coagulopathy	<u>Elevated INR: 2.7-fold ↑ risk of major complications and 1.3-fold ↑ risk of 30-day mortality</u> ⁶²
	Anticoagulant use: 1.8-fold ↑ 1-year mortality ²⁴⁰
Anemia	3.3-fold ↑ risk of 30-day mortality ⁶²
Number of leads extracted	<u>3.5-fold ↑ risk of any complication</u> ²⁴¹ 1.6-fold ↑ long-term mortality ²⁴²
Presence of dual-coil ICD	2.7-fold ↑ risk of 30-day mortality ⁶²
<u>Extraction for infection</u>	<u>2.7- to 30-fold ↑ risk of 30-day mortality</u> ^{62,241} 5- to 9.7-fold ↑ 1-year mortality ^{62,242} CRP >72 mg/L associated with ↑ 30-day mortality ²⁴³ 3.52-fold ↑ mortality ²³⁸
<u>Operator experience</u>	<u>2.6-fold ↑ no. of procedure-related complications</u> ²⁴⁴
Prior open heart surgery	↓ risk of major complications ²⁴¹

Percutaneous Lead Extraction in Infection of Cardiac Implantable Electronic Devices: a Systematic Review

Braz J Cardiovasc Surg 2018;33(2):194-202

Table 3. Characteristics of selected studies in relation to device extraction and in-hospital and long-term mortality.

Author	Patients (number)	Method of extraction of intracardiac devices	Complications related to extraction (%)	Mortality during hospitalization (%)	Follow-up time (months)	Long-term mortality (%)
Greenspon et al. ^[16]	129	Percutaneous: 112 Surgery: 17	Majors: 4.6 Minors: -	10.8	6	14.5
Rickard et al. ^[14]	151	Percutaneous: 151 Surgery:	-	6.6	24	-
Ipek et al. ^[20]	34	Percutaneous: 28 Surgery: 5	Majors: 2.9 Minors: 14.7	8.8	-	-
Pichlmaier et al. ^[23]	178	Percutaneous: 144	Majors: 2.2	3.9	Average of 55	18.5

The main indications for surgical removal were the failure of transvenous extraction, large vegetations, vascular trauma in percutaneous extraction, the need for epicardial leads, concomitant valve involvement, abscesses, and tricuspid valve stenosis^[16,20,25].

Goya et al. ^[22]	183	Percutaneous: 183 Surgery: 4	Majors: 2.7 Minors: 3.8	2.2	-	-
Deharo et al. ^[13]	197	Percutaneous: 189 Surgery: 13	Majors: 1.0 Minors: 12.2	4.1	Average of 25	1 year: 14.3 5 years: 25.4

Total	3354	Percutaneous: 3081 Surgery: 238				
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Total	3354	Percutaneous: 3081 Surgery: 238	-	-	-	-
Mean	209.6	-	Majors: 2.9 Minors: 8.4	5.4	24	-

Explantation of Implantable Defibrillator Leads Using Open Heart Surgery or Percutaneous Techniques

(Ann Thorac Surg 2008;85:50–5)

Cerrahi: 21 hasta,
Perkütan 53 hasta

Table 2. Results of Explantation

ECC (Group A)

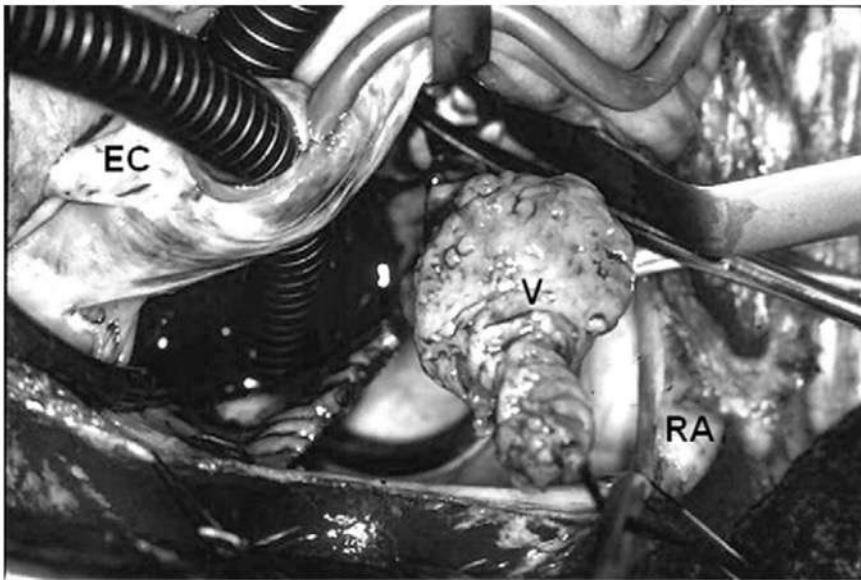


Fig 4. Intraoperative view into the right atrium (RA) with a large vegetation surrounding an implantable cardioverter defibrillator lead. (EC = extracorporeal circulation access; V = infective vegetation.)

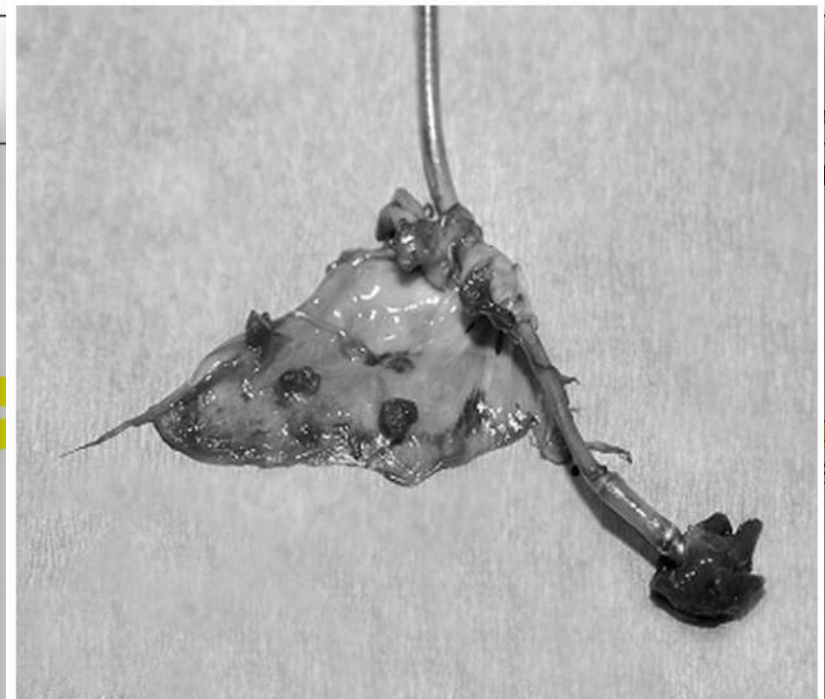


Fig 3. Picture of a transvenously extracted implantable cardioverter defibrillator lead with an attached tricuspid valve leaflet. Notice the myocardial tissue at the tip of the implantable cardioverter defibrillator lead.

Percutaneous Pacemaker and Implantable Cardioverter-Defibrillator Lead Extraction in 100 Patients With Intracardiac Vegetations Defined by Transesophageal Echocardiogram

(J Am Coll Cardiol 2010;55:886–94)

CIED enfeksiyonları **tedavi edilmez ise mortalite %66,**

sistemin çıkarılması ve antibiyotik ile **tedavi edilir ise %18**

Cihaz enfeksiyonlarında **endokardit sıklığı %10 (bazı serilerde %20-25)**

984 hastada 1850 lead çıkarılmış,

✓ 480 hasta **(%49)** sistemik ya da lokal enfeksiyon endikasyonu ile.

✓ 100 hastada TEE'de intrakardiyak vejetasyon var (%10)

56 hastada lead üzerinde , 35 hastada kapak üzerinde

Vejetasyon büyüklüğü 0.2- 4 cm, ortalama 1.6 cm

**Bütün hastalarda EPS lab'da perkütan yolla lead çıkarılmış,
Cerrahi hiçbir hastada gerekmemiş.**

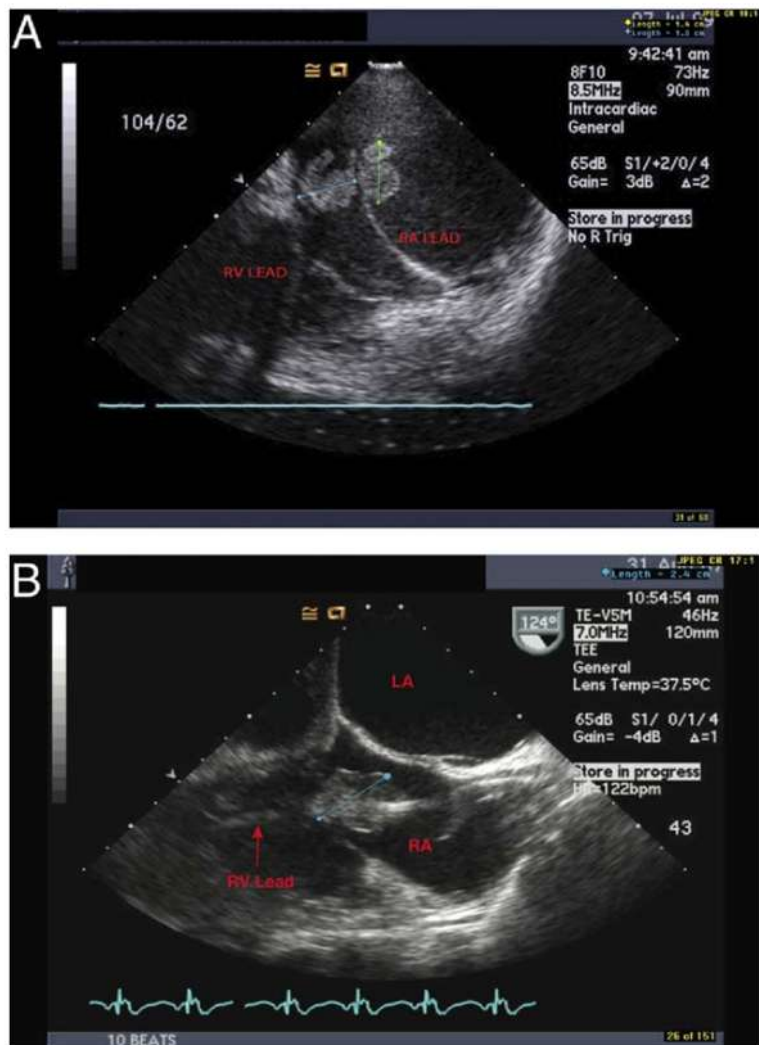
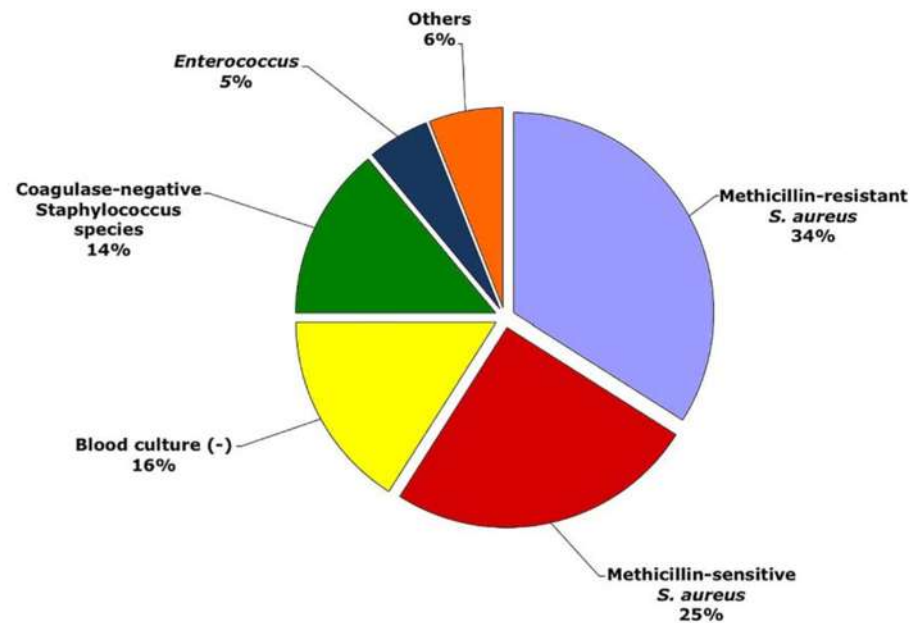


Figure 2 ICE and TEE of Lead Vegetation

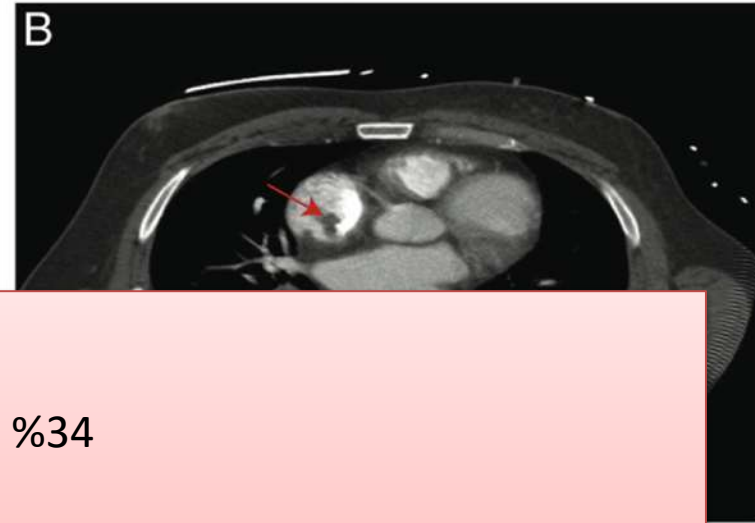
(A) Intracardiac echocardiogram (ICE) shows vegetations attached to both right ventricle (RV) and right atrium (RA) leads. **(B)** Transesophageal echocardiogram (TEE) of lead vegetation attached to the RV lead as it crosses the tricuspid valve. The approximate diameter is 2.4 cm. LA = left atrium.



54 hastaya hospitalizasyon sırasında yeni cihaz takılm

46 hastaya indeks hospitalizasyonda cihaz takılmamış

- 18 hasta devam eden sistemik enfeksiyon neden
 - **18 hastada tekrar cihaz takılma endikasyonu olm**
 - 39 hasta stabil şekilde taburcu edilmiş,
 - 7 hasta hospitalizasyon sırasında ölmüş.
-
- Ortalama 15 aylık takipte mortalite %27 (19 hasta),
 - 30 günlük mortalite %10,
 - Hospitalizasyon süresince 10 hasta ölmüş,
 - **En sık ölüm nedeni persistan sepsisemi (%59)**



Pulmoner embolism;

- Ventilasyon-perfüzyon sintigrafisi ile bir çalışmada %34
 - Başka bir çalışmada %55
 - Pulmoner emboli olmayanlara göre hospitalizasyon süresi aynı ve mortalitye yok.
-
- Bu çalışmada 3 p. emboli var: 2 hastada vejetasyon >2 cm, bir hastada 1.2 cm
 - 3 hastada tam iyileşmiş ve taburcu olmuş.

Table 2		Post-Operative 30-Day Mortality		
Patient #	Vegetation Size (cm)	Death After Explant (days)	Brief Clinical Summary	
1	1.0	5	Device reimplanted but severe <i>Enterococcus</i> sepsis persisted with subsequent VDRF, ARF, and MOSF	
2	2.9	21	Developed diffuse purulent lymphadenopathy and bilateral pneumonia; MSSA sepsis with septic emboli found at autopsy	
3	NA	18	Fever, hypotension, and MRSA sepsis	
4	NA	15	Treated for sepsis; post-extraction transesophageal echocardiogram revealed persistent mitral valve vegetation and right atrial mass. Transferred to skilled nursing facility 8 days later; died 1 week later of presumed septicemia	
5	1.8	5	Initial device extraction without incident, new device reimplanted 4 days later; found unresponsive 1 day later; echocardiogram negative for tamponade; ACLS initiated for PEA code was unsuccessful	
6	3.0	0	Transferred from outside facility on multiple pressors from septic arthritis that seeded device; was coagulopathic, which was reversed before extraction; worsening hypotension after procedure despite pressors; ACLS initiated but unsuccessful	
7	2.2	14	MSSA sepsis with multiorgan failure; VDRF; ARF developed requiring HD; pseudomembranous colitis on multiple vasopressors; withdrawal of care	
8	NA	12	Encephalopathic after procedure with hepatic failure; ARF requiring HD; hypotensive requiring multiple vasopressors; withdrawal of care	
9	1.4	10	Had prosthetic valve endocarditis with perivalvular dehiscence; overwhelming sepsis developed with multiorgan failure, ARF requiring dialysis, atrial fibrillation, VDRF; withdrawal of care	
10	1.5	20	Discharged from hospital with LifeVest; reportedly found unconscious at home and pronounced dead on arrival at hospital	

ACLS = advanced cardiac life support; ARF = acute renal failure; HD = hemodialysis; MOSF = multiorgan system failure; MRSA = methicillin-resistant *Staphylococcus aureus*; MSSA = methicillin-sensitive *Staphylococcus aureus*; NA = not applicable; PEA = pulseless electrical activity; VDRF = ventilator-dependent respiratory failure.

Cerrahi lead çıkarmada morbidite ve mortalite yüksek,

Cerrahi mortalite %12.5-%40

Direkt karşılaştırmalı çalışma yok.

Table 3 Literature Review of Surgical and Percutaneous Lead Extraction Mortality

First Author, Year (Ref. #)	n	Extraction Approach*	Post-Operative Mortality, % (n)	Major Complications†	Comments
Brodman, 1992 (18)	11	Surgical	9% (1)	NA	Death related to sepsis
Frame, 1993 (10)	13	Surgical	15% (2)	NA	Deaths related to sepsis
Klug, 1996 (14)	12‡	Surgical	16.6% (2)	NA	Deaths related to sepsis; post-operative mortality 7.6%; 30% septic embolization
	38‡	Percutaneous			
Cacoub, 1998 (28)	29‡	Surgical	12.4% (4)	NA	Post-operative period defined as <8 days; IE proven by histology; overall mortality 24%
	4‡	Percutaneous			
Byrd, 1999 (33)	2,338	Percutaneous	0.4%	1.6%	U.S. lead extraction database
Victor, 1999 (15)	9‡	Surgical	11% (1)	NA	Deaths related to sepsis and heart failure; 12 patients had vegetations >1 cm
	14‡	Percutaneous	21% (3)		
Byrd, 2002 (44)	1,684	Percutaneous	0.8% (13)	1.9%	Total laser experience in U.S. (1995–99)
del Rio, 2003 (29)	5‡	Surgical	40% (2)	40%	12.5% “surgical” mortality includes surgical and percutaneous approaches
	25‡	Percutaneous	4% (1)	8%	
Meier-Ewert, 2003 (30)	9‡	Percutaneous	11% (1)	NA	Death from sepsis; 55% septic emboli
Massoure, 2007 (35)	20‡	Surgical	5.3% (3)	NA	90% with IE; mean vegetation size 1.3 cm; deaths related to sepsis
	37‡	Percutaneous			
Sohail, 2007 (31)	19	Surgical	5.3% (1)	26%	7 deaths during IH, only 2 procedure related; 5 deaths (11%) due to sepsis in 23% with IE
	166	Percutaneous	0.6% (1)	12%	
Camboni, 2008 (45)	21	Surgical	9.5% (2)	14%	Long-term survival between groups similar (p = 0.11)
	53	Percutaneous	0%	6%	
Jones, 2008 (34)	485	Percutaneous	0%	0.4%	Limited data on 85 patients with IE

CIED İnfeksiyonu risk faktörleri

Table 3 Risk factors for cardiovascular implantable electronic device infection^{154–166}

Patient-related factors	Procedure-related factors	Microbe-related factors
Age	<u>Pocket reintervention (generator change, upgrade, lead or pocket revision)</u>	Highly virulent microbes (eg, staphylococci)
Chronic kidney disease	Pocket hematoma	
Hemodialysis	Longer procedure duration	
Diabetes mellitus	<u>Inexperienced operator</u>	
Heart failure	ICD (compared with PM)	
Chronic obstructive pulmonary disease	<u>Lack of use of prophylactic antibiotics</u>	
Preprocedure fever		
Malignancy		
Skin disorder		
Immunosuppressive drug		
Prior CIED infection		
Anticoagulation		

Prevention of Arrhythmia Device Infection Trial

The PADIT Trial

(J Am Coll Cardiol 2018;72:3098-109)

BACKGROUND

procedural device infections, pre-organisms, which are common

OBJECTIVE

infection.

METHODS

during which electronic device incremental treatment post-procedure group, analysis

PADIT Intervention

Conventional

Pre-operative antibiotic therapy:
Single pre-op iv antibiotic dose of Cefazolin*

Incremental

Pre-operative antibiotic therapy:
Single pre-op iv antibiotic dose of Cefazolin **AND** Vancomycin**

PLUS

Incremental intra-operative and post-operative ab therapy:

1. Intraoperative bacitracin pocket wash
2. 2 Days post operative oral cephalosporin***

RESULTS Device procedures were performed in 28 centers in 19,603 patients, of whom 12,842 were high risk. Infection occurred in 99 patients (1.03%) receiving conventional treatment, and in 78 (0.78%) receiving incremental treatment (odds ratio: 0.77; 95% confidence interval: 0.56 to 1.05; $p = 0.10$). In high-risk patients, hospitalization for infection occurred in 77 patients (1.23%) receiving conventional antibiotics and in 66 (1.01%) receiving incremental antibiotics (odds ratio: 0.82; 95% confidence interval: 0.59 to 1.15; $p = 0.26$). Subgroup analysis did not identify relevant patient or site characteristics with significant benefit from incremental therapy.

CONCLUSIONS The cluster crossover design efficiently tested clinical effectiveness of incremental antibiotics to reduce device infection. Device infection rates were low. The observed difference in infection rates was not statistically significant. (Prevention of Arrhythmia Device Infection Trial [PADIT Pilot] [PADIT]; [NCT01002911](#))

Antibacterial Envelope to Prevent Cardiac Implantable Device Infection

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DOI: 10.1056/NEJMoa1901111

WRAP-IT

RCT, 6983 pts



Multifilament knitted mesh coated with absorbable polymer mixed with **minocycline** and **rifampin**

Elutes antibiotics for a minimum of **7 days**
Fully **absorbed** in ~ **9 weeks**

Primary end point (infection resulting in system extraction or revision, long-term antibiotic therapy with infection recurrence, or death, within 12 months of procedure):
25 pts in envelope group, 42 in control

HR 0.6

95% CI 0.36-0.98, P=0.04

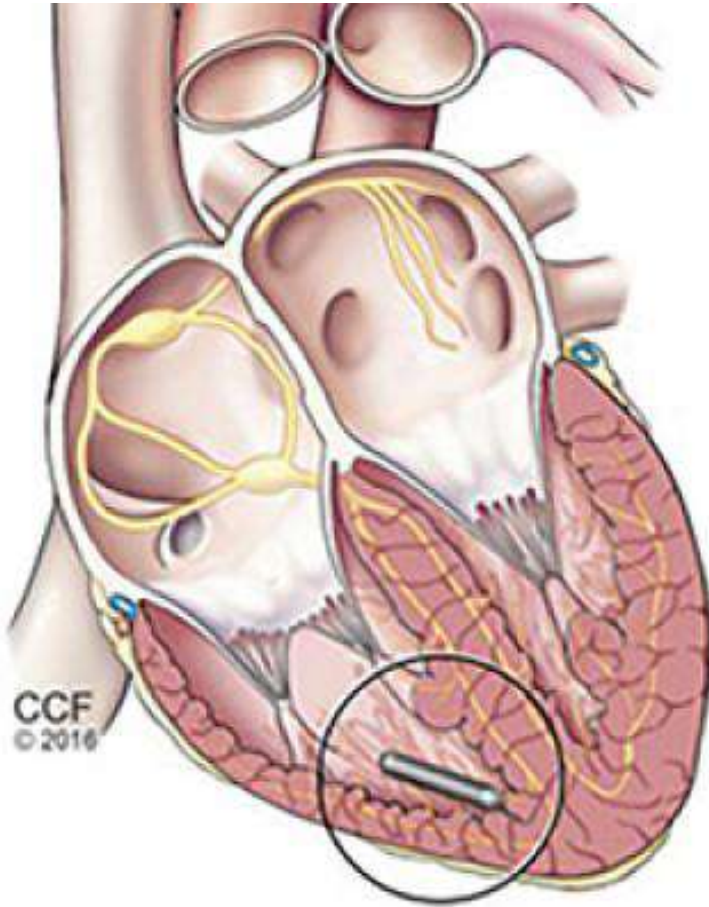
Trial published in



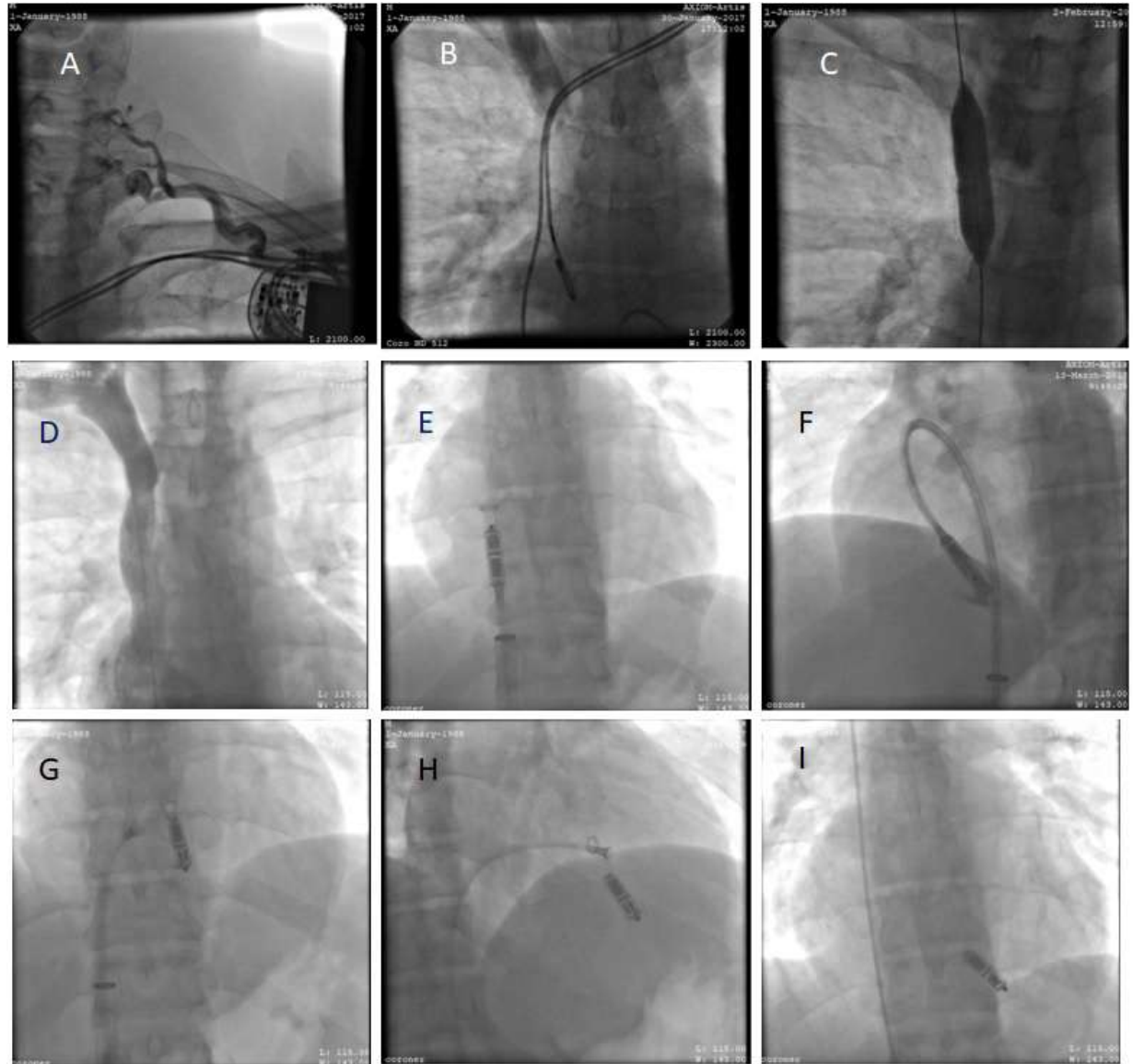
The NEW ENGLAND
JOURNAL of MEDICINE

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Leadless pacemaker



Leadless pacemaker



D. Aras ve ark.

Türkiye Yüksek İhtisas
Hastanesi Aritmi Ekibi
arşivinden., 2016

S-ICD: Subkutan ICD

