CIED Enfeksiyonlarında Sistemin Çıkarılması?

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Bilkent, Ankara

ESC European Society of Cardiology

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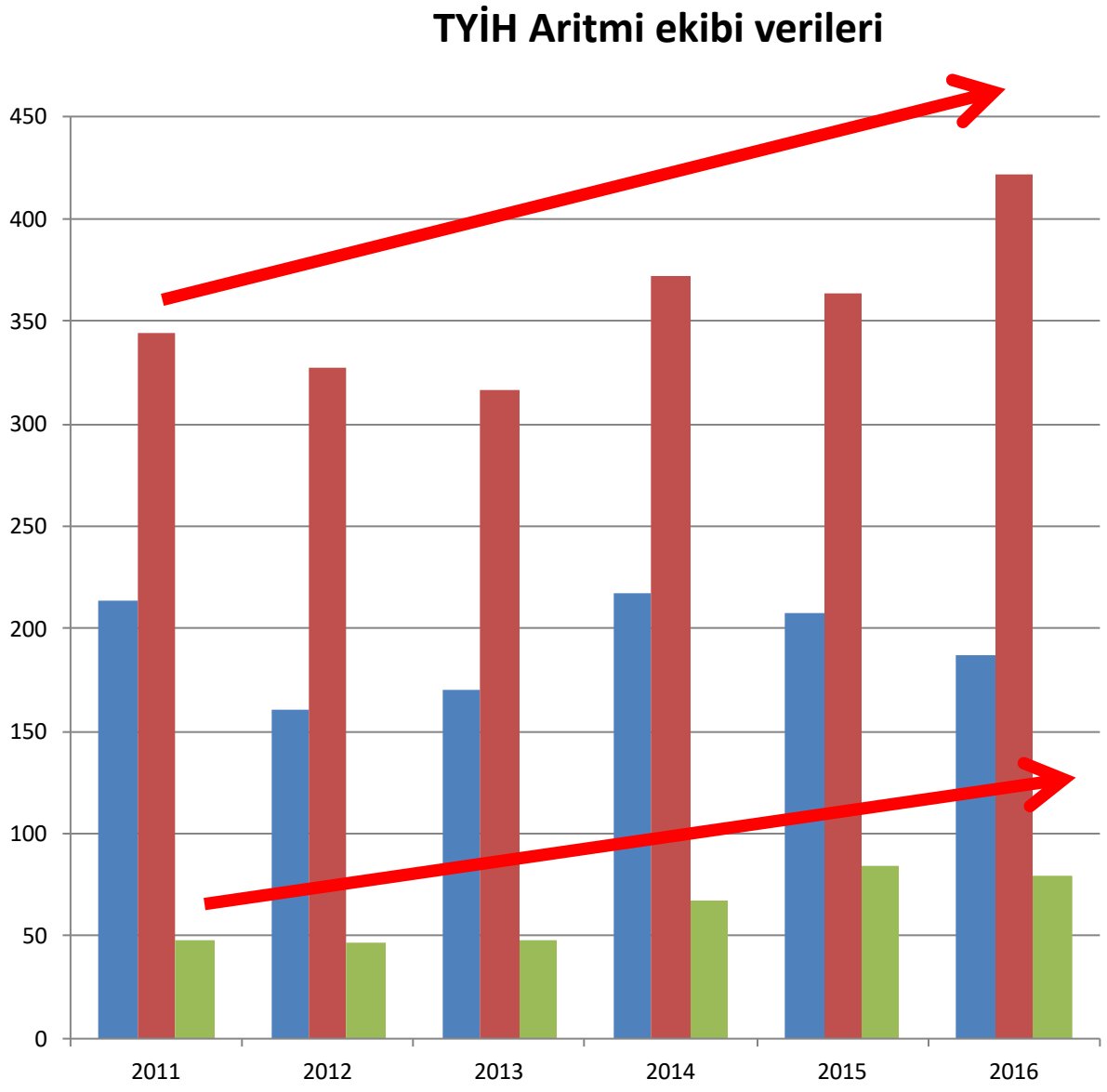
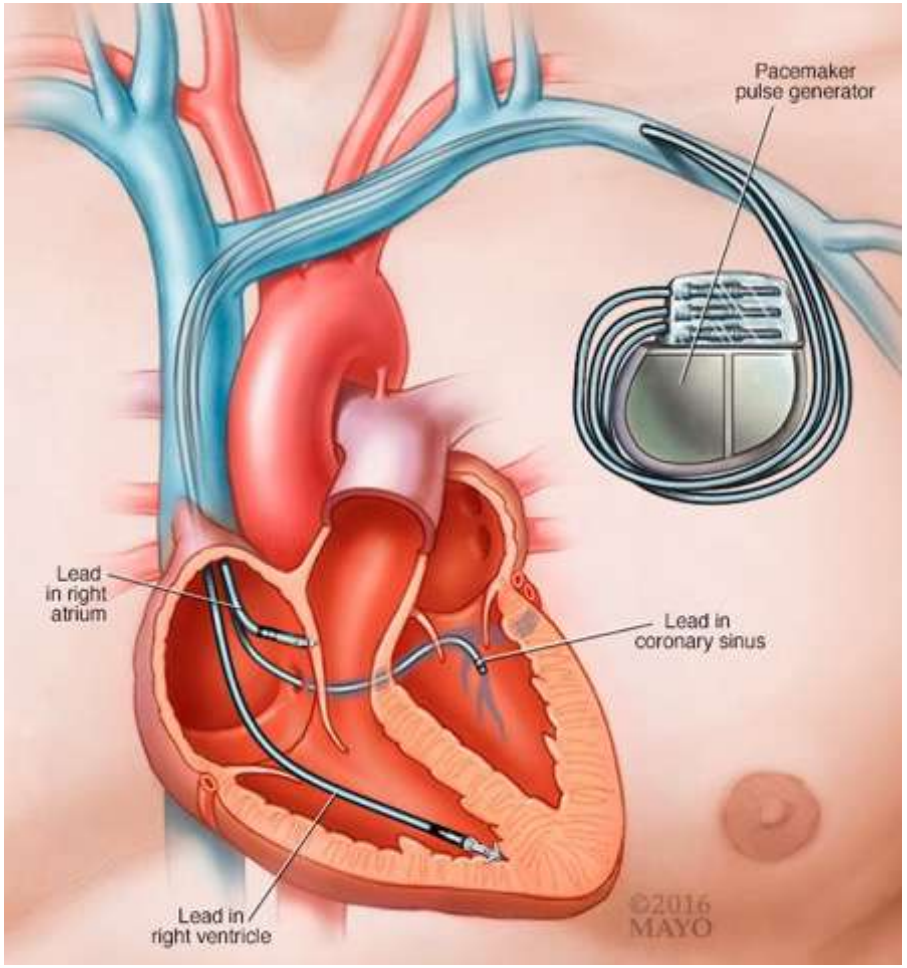
EHRA CONSENSUS STATEMENT

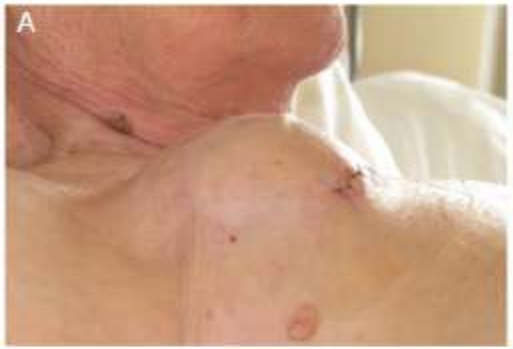
2018 EHRA expert consensus statement on lead extraction: recommendations on definitions, endpoints, research trial design, and data collection requirements for clinical scientific studies and registries: endorsed by APHRS/HRS/LAHRS

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



2019 yılı ilk 8 ay
Extraksiyon:
50 hasta
80 lead


Pacemaker
pulse generator
Lead
in right
atrium
Lead in
coronary sinus
Lead in
right ventricle
©2016
MAYO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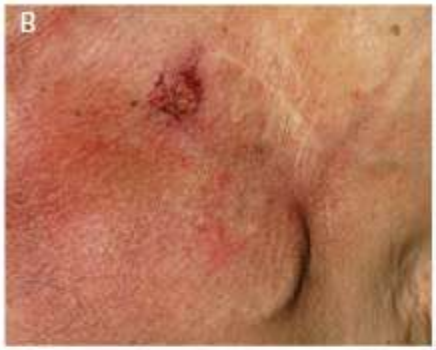
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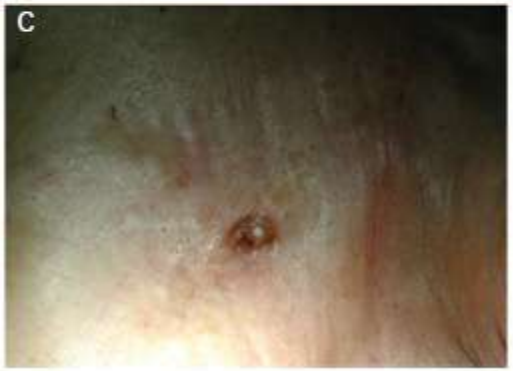
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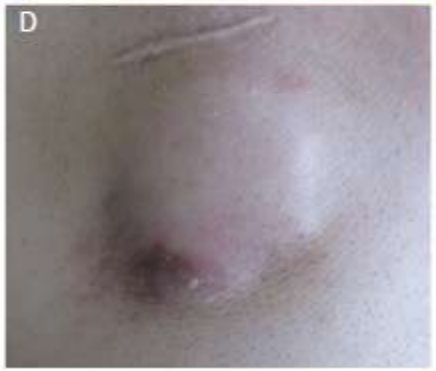
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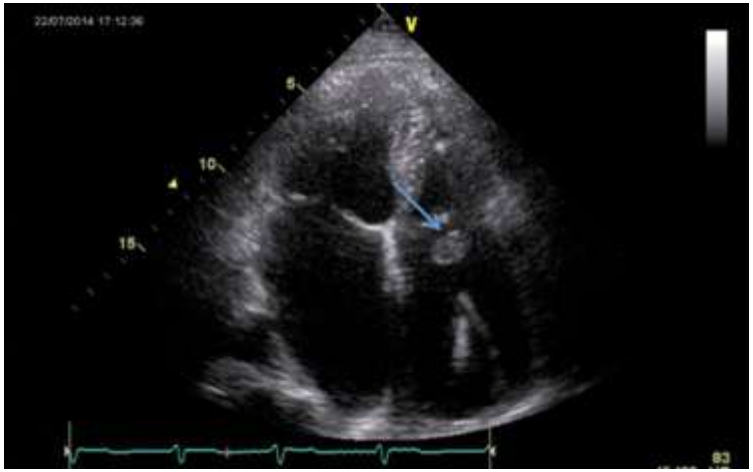
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CIED-related infection types

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	Local signs of pocket infection and positive blood cultures, without lead or valvular vegetation(s)
CIED-related endocarditis without pocket infection	Systemic	Bacteraemia and lead or valvular vegetation(s), without local signs of pocket infection
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	Bacteraemia without an alternative source

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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]

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]

18-Fluorodeoxyglucose (^{18}F-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 ^{18}F-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-hexamethypropylene 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]

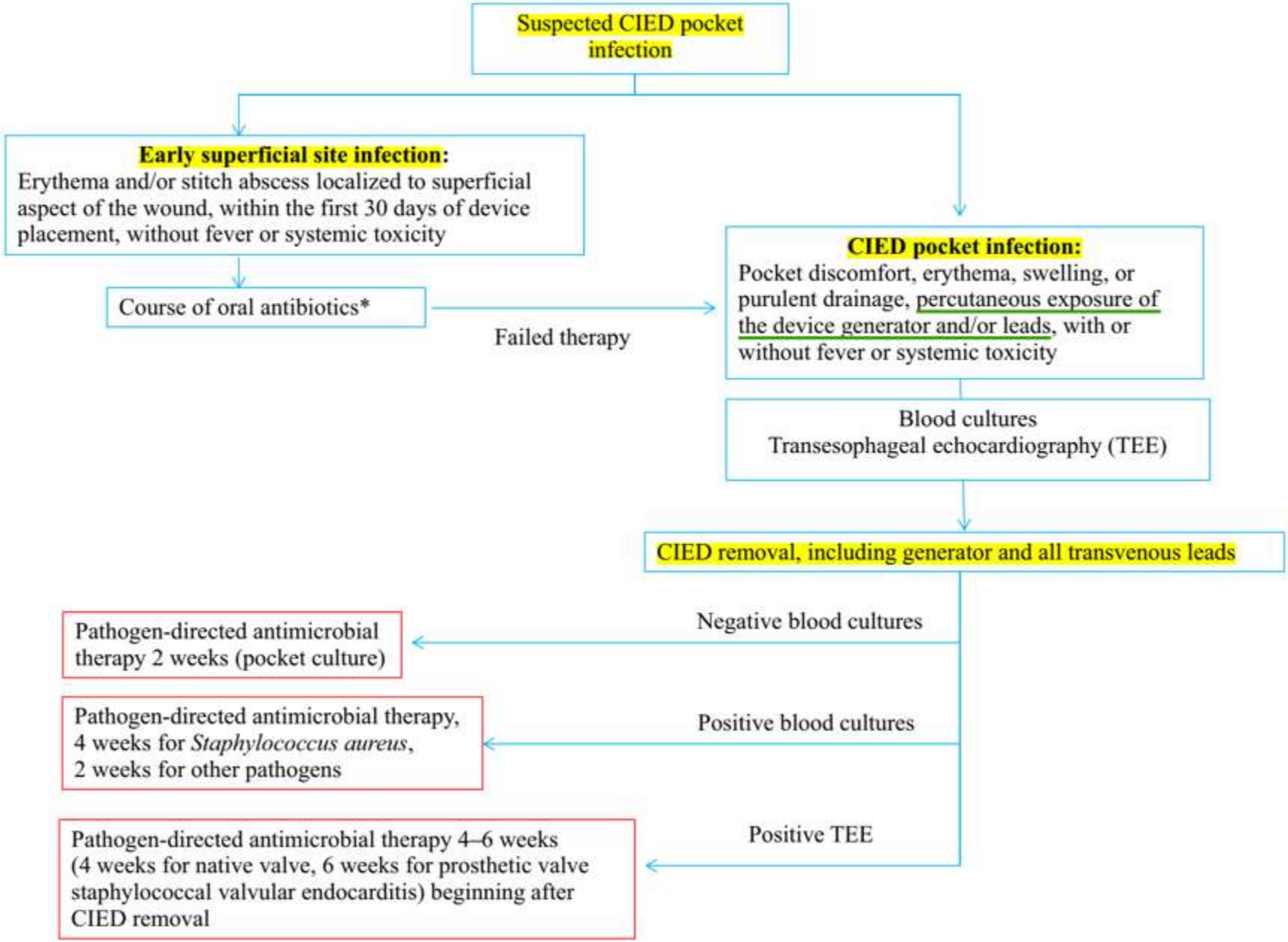
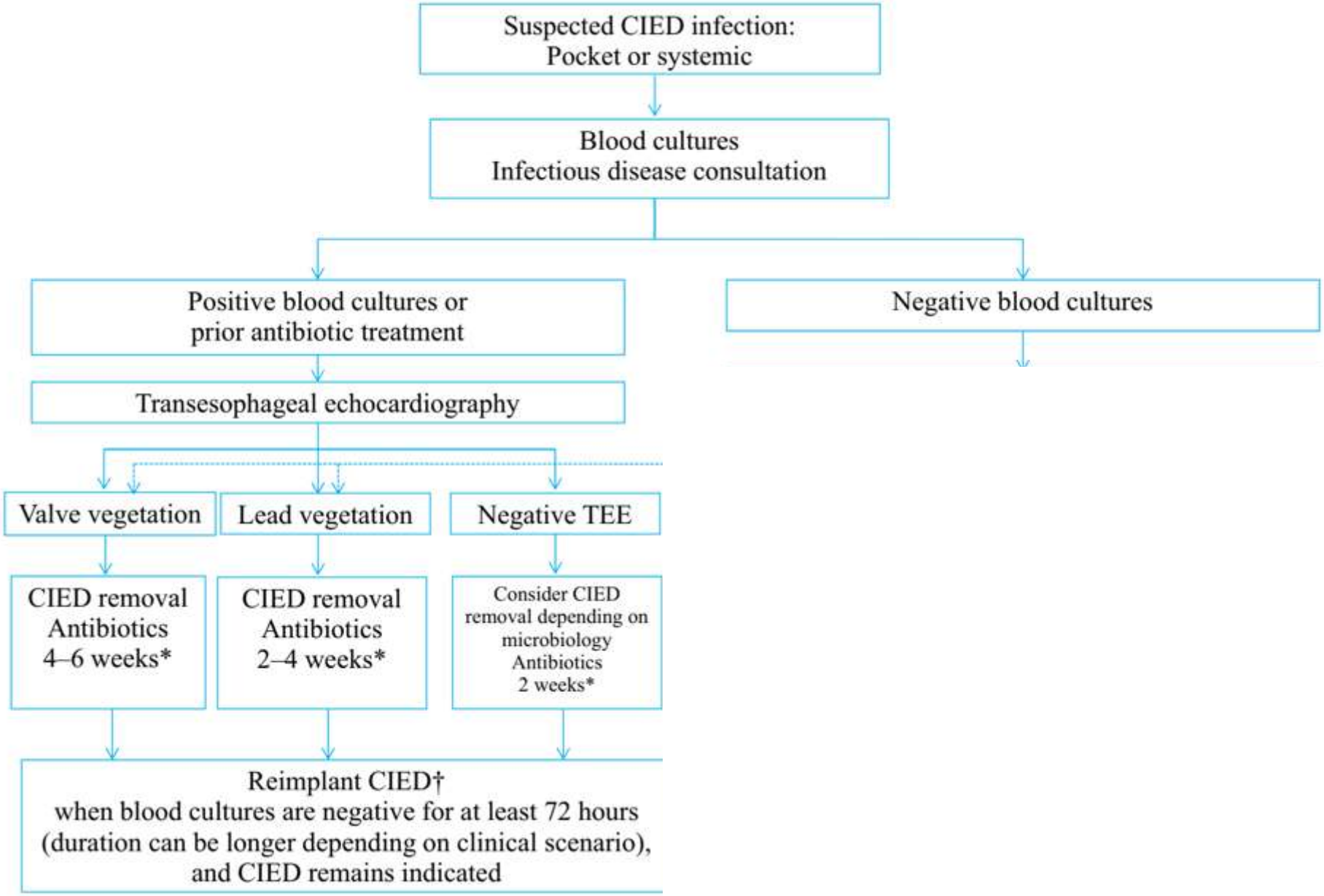
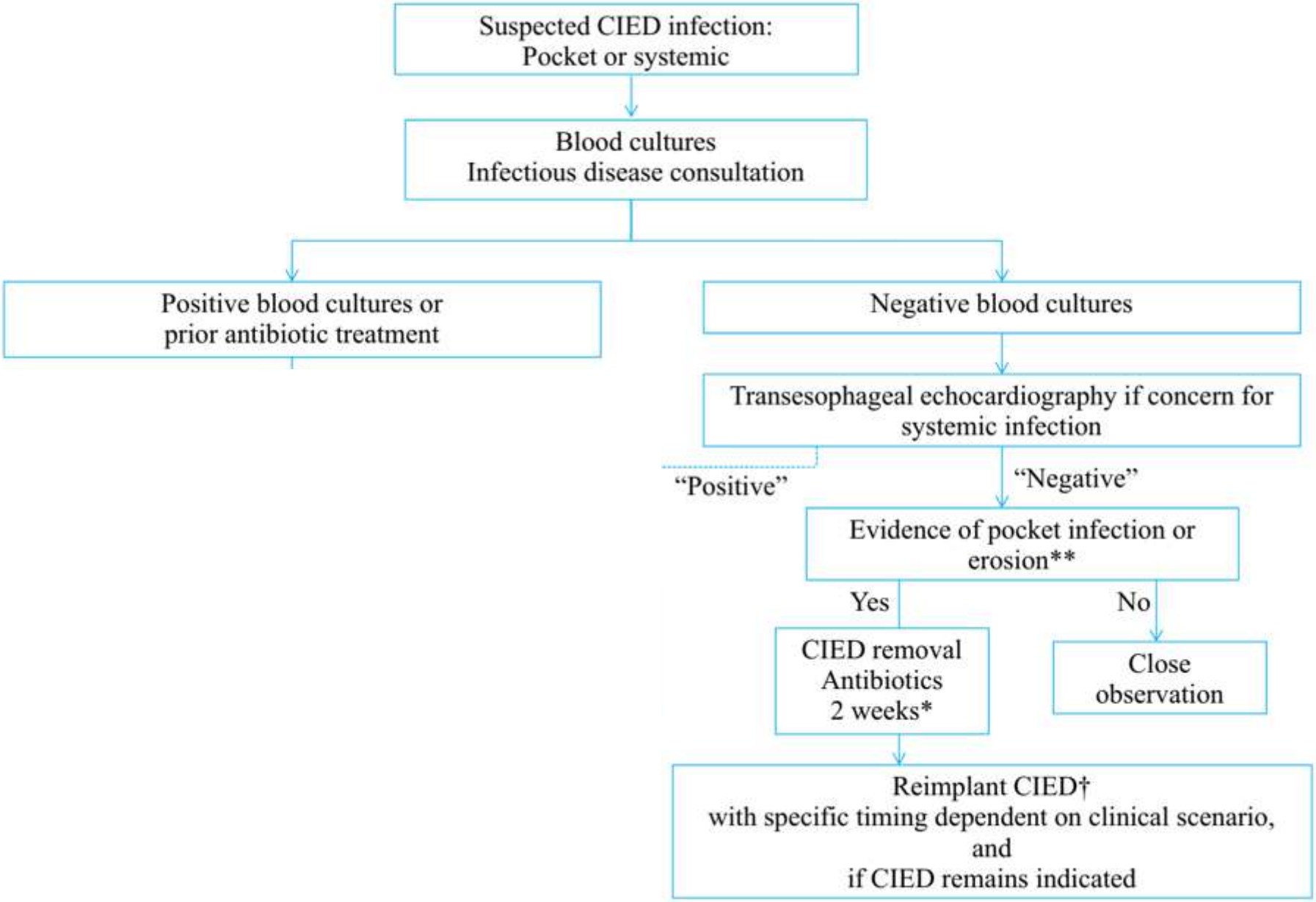


Figure 3 Management of suspected pocket infection. *See text for examples.


Suspected CIED infection:
Pocket or systemic
Blood cultures
Infectious disease consultation
Positive blood cultures or
prior antibiotic treatment
Negative blood cultures
Transesophageal echocardiography
Valve vegetation
Lead vegetation
Negative TEE
CIED removal
Antibiotics
4–6 weeks*
CIED removal
Antibiotics
2–4 weeks*
Consider CIED
removal depending on
microbiology
Antibiotics
2 weeks*
Reimplant CIED†
when blood cultures are negative for at least 72 hours
(duration can be longer depending on clinical scenario),
and CIED remains indicated


Suspected CIED infection:
Pocket or systemic
Blood cultures
Infectious disease consultation
Positive blood cultures or
prior antibiotic treatment
Negative blood cultures
Transesophageal echocardiography if concern for
systemic infection
"Positive"
"Negative"
Evidence of pocket infection or
erosion**
Yes
No
CIED removal
Antibiotics
2 weeks*
Close
observation
Reimplant CIED†
with specific timing dependent on clinical scenario,
and
if CIED remains indicated

I	B-NR	**Complete device and lead removal is recommended for all patients with definite CIED system infection.**	169–171

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

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

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.**	

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,

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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]

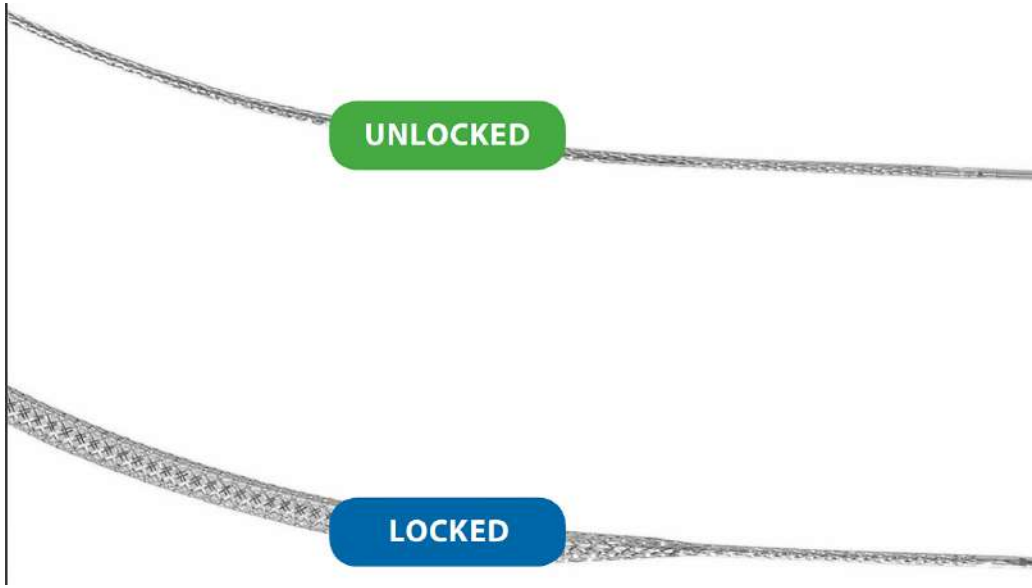
Lead ekstraksiyonu

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

Kilitleme stileleri

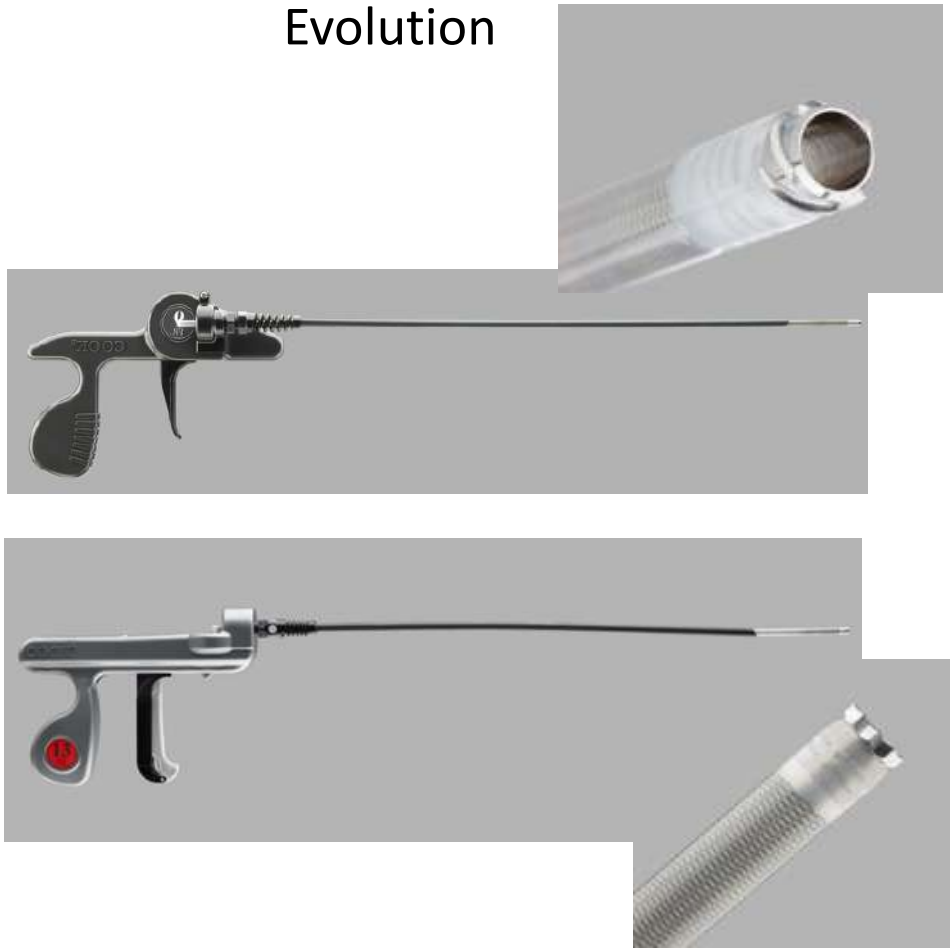
Liberator Device)

LLD (Lead Locking



Rotasyonel mekanik cihazlar

Evolution



TightRail

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PACE WILEY

DEVICES

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

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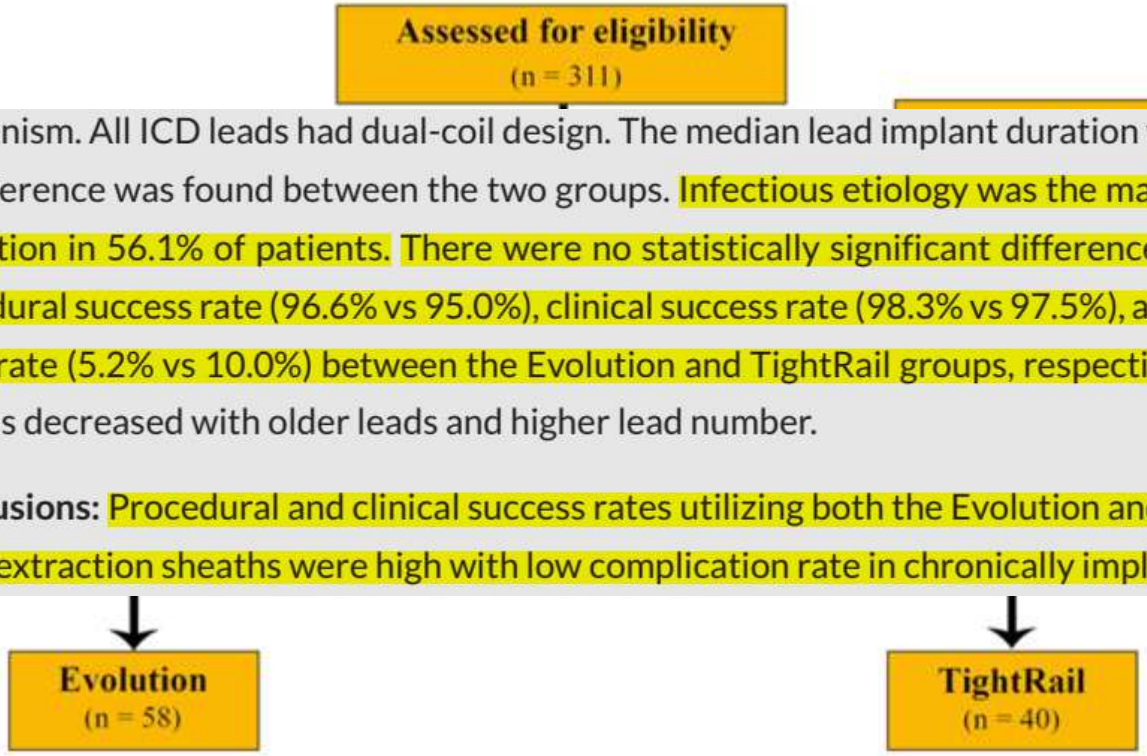
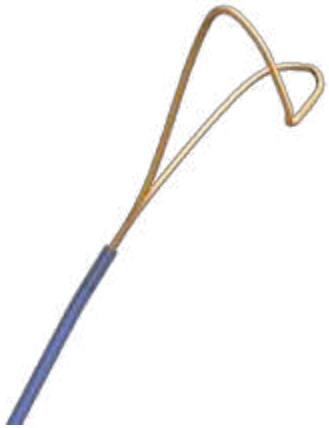
mechanism. All ICD leads had dual-coil design. The median lead implant duration was 4 years, and no difference was found between the two groups. Infectious etiology was the main indication for extraction in 56.1% of patients. There were no statistically significant differences regarding the procedural 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.

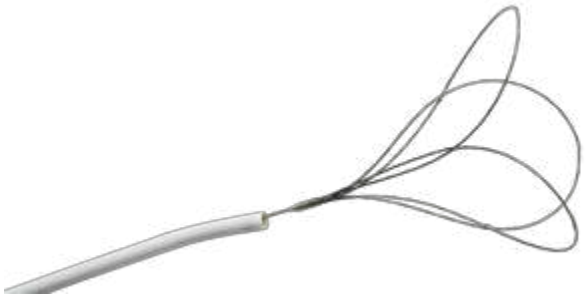


Snare ve Biyoptom

Tekli kement

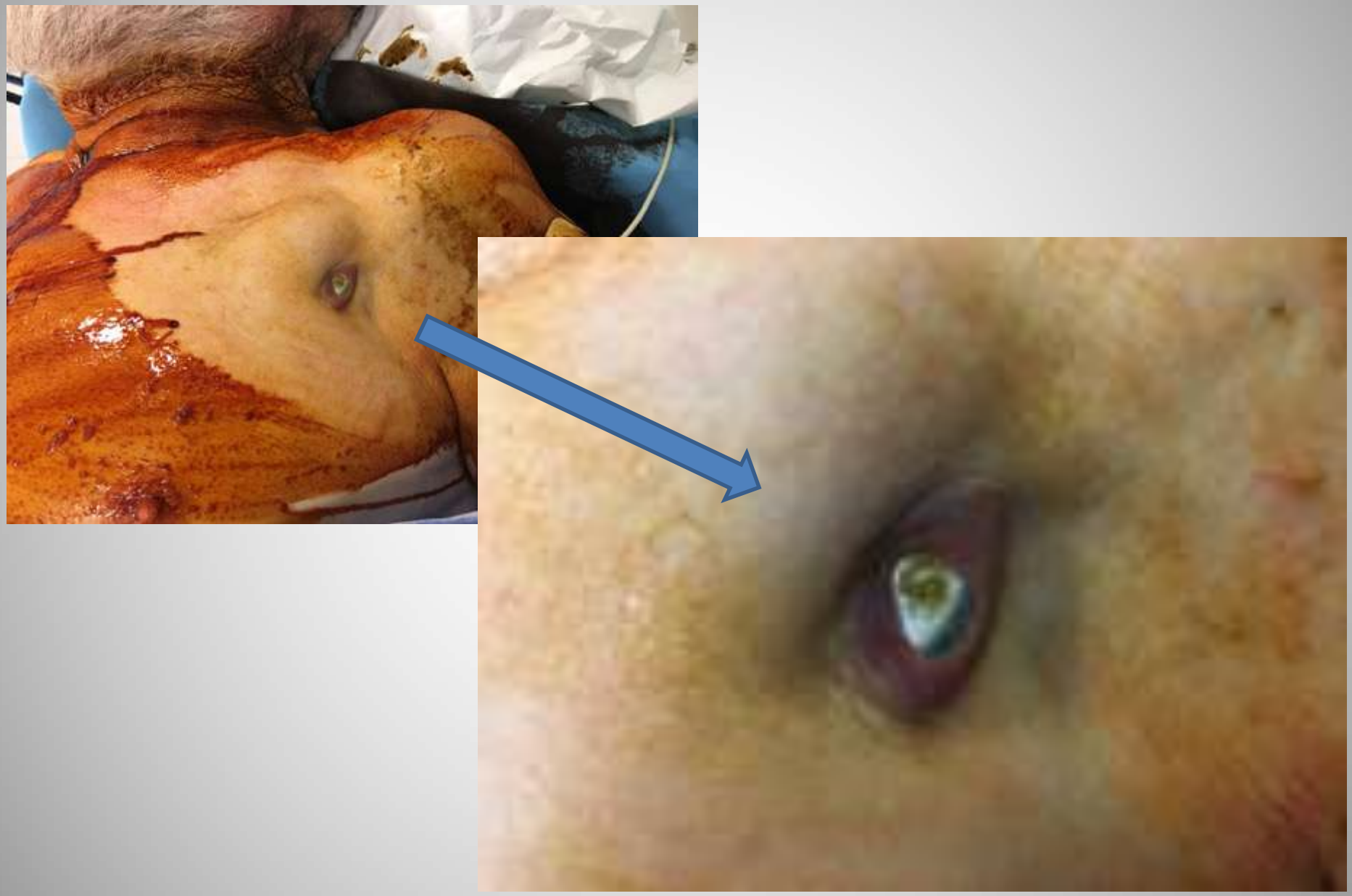


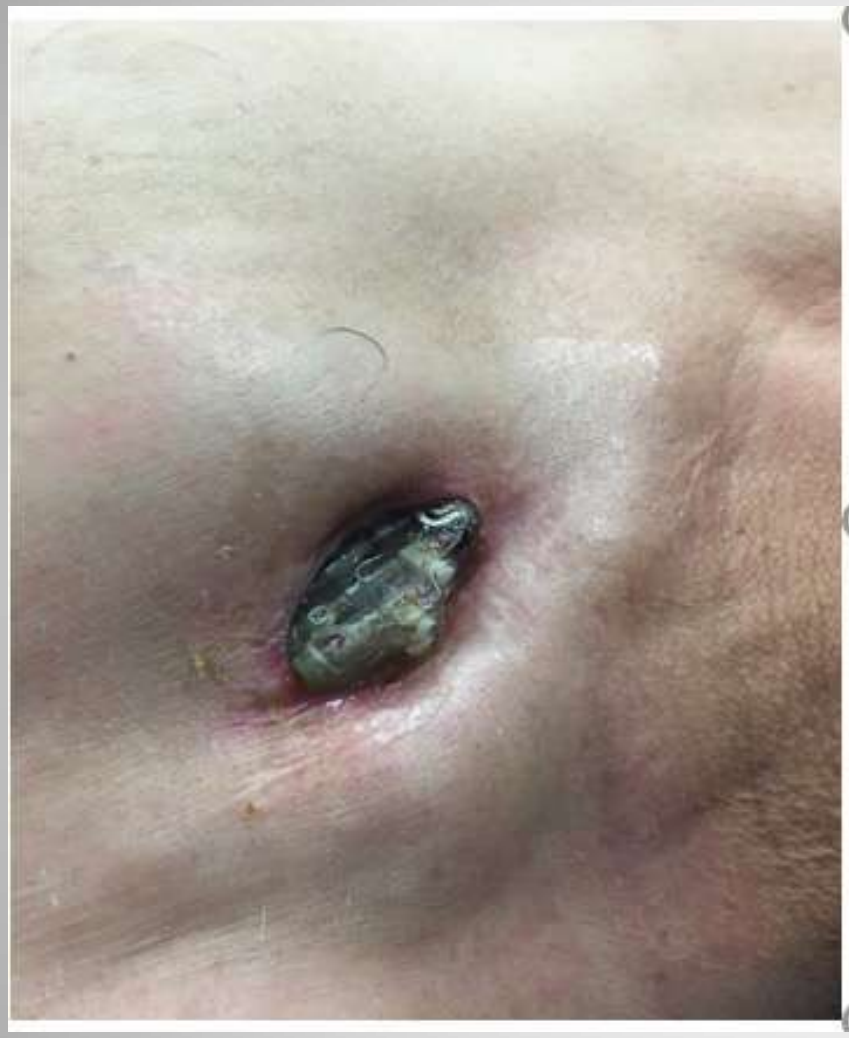
Çoklu kement

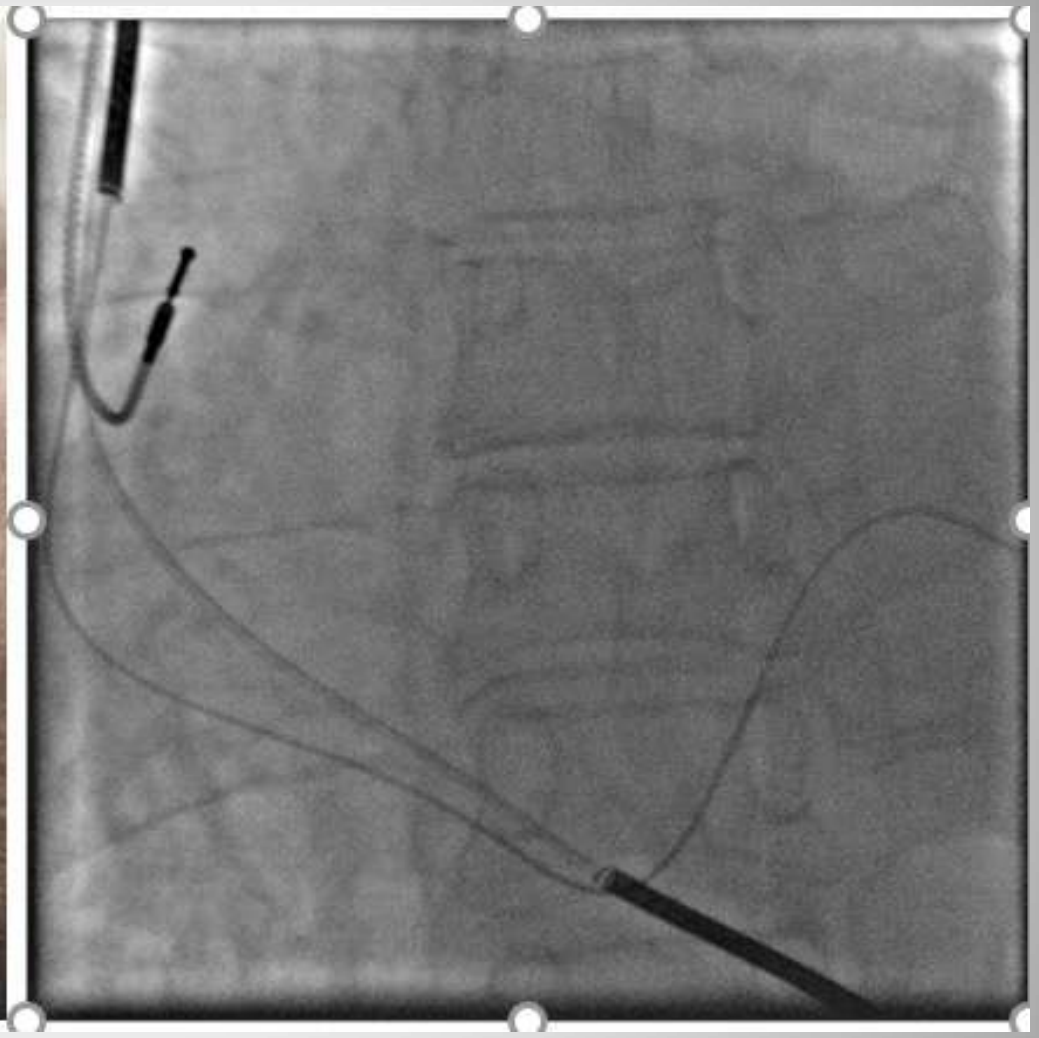


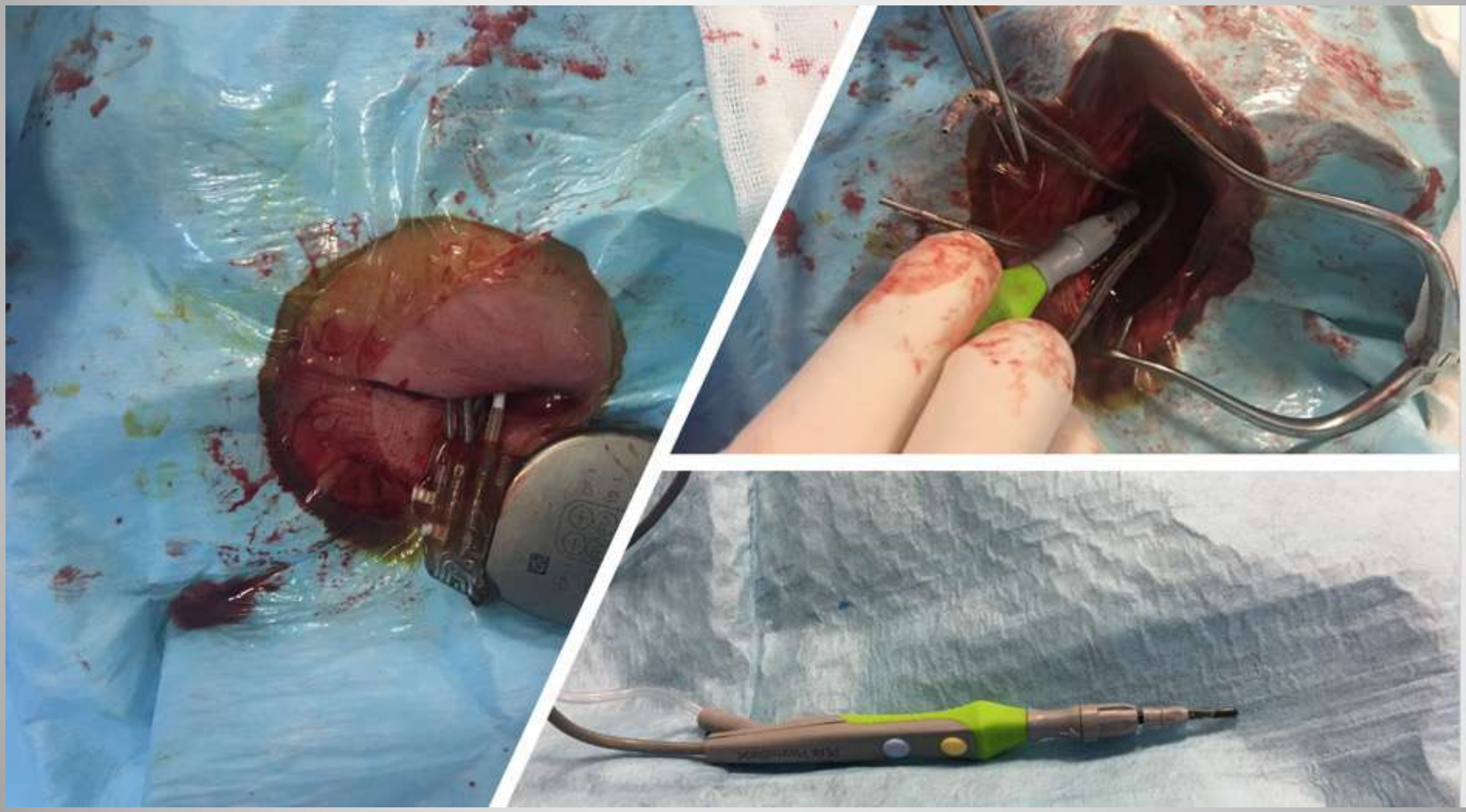
Needle’s Eye Snare

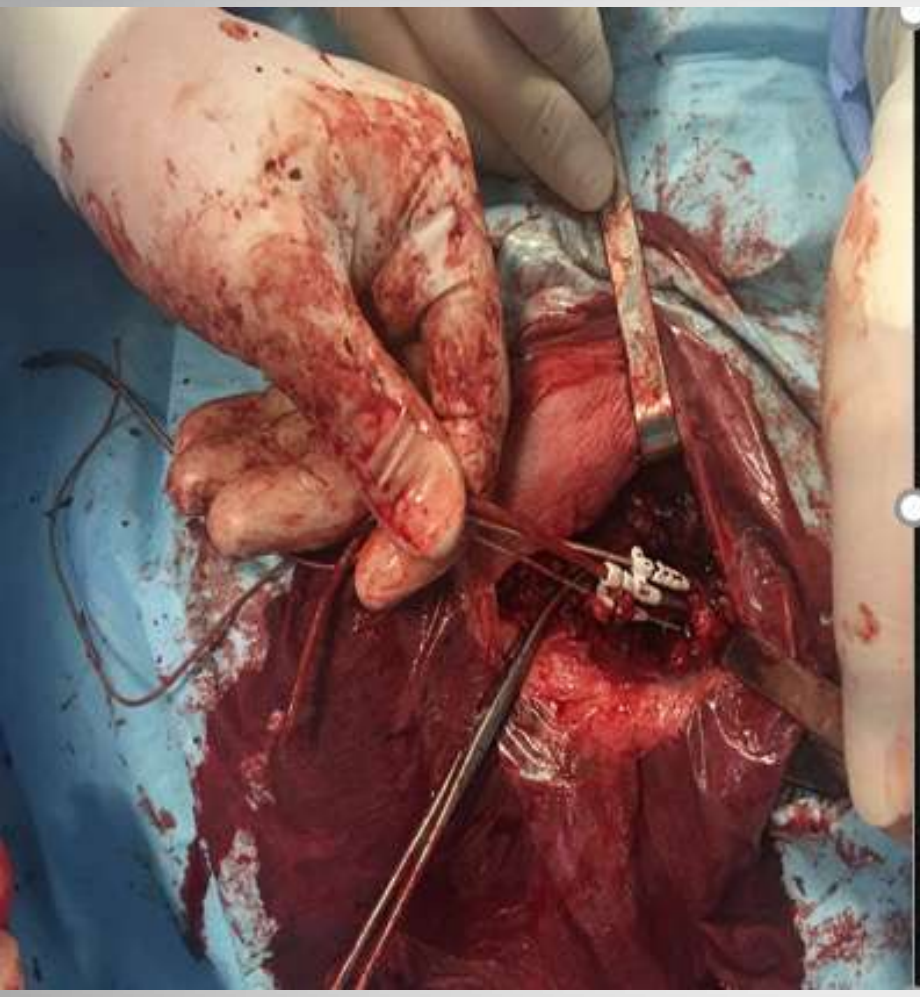
Biyoptom

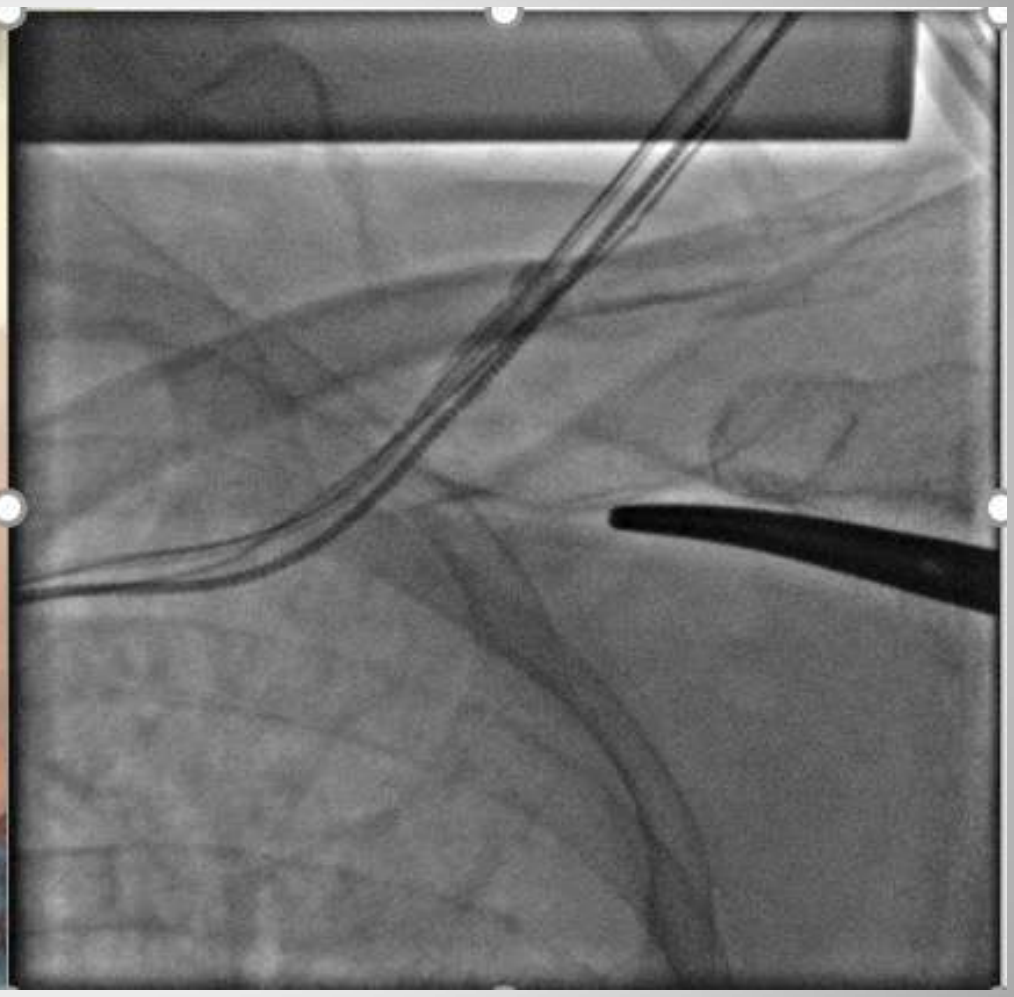


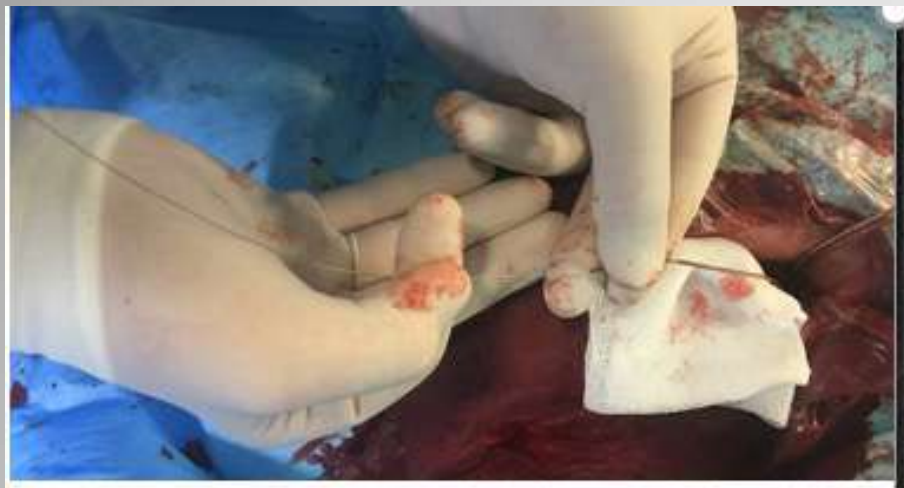


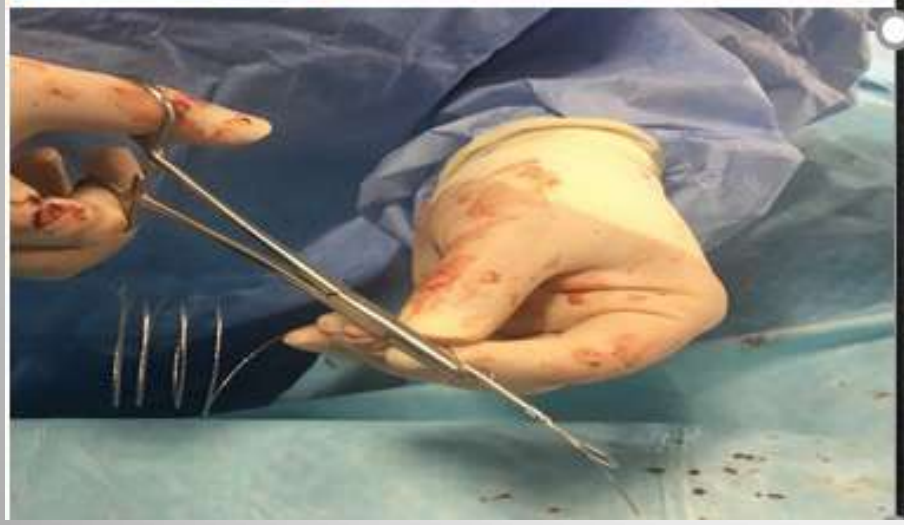


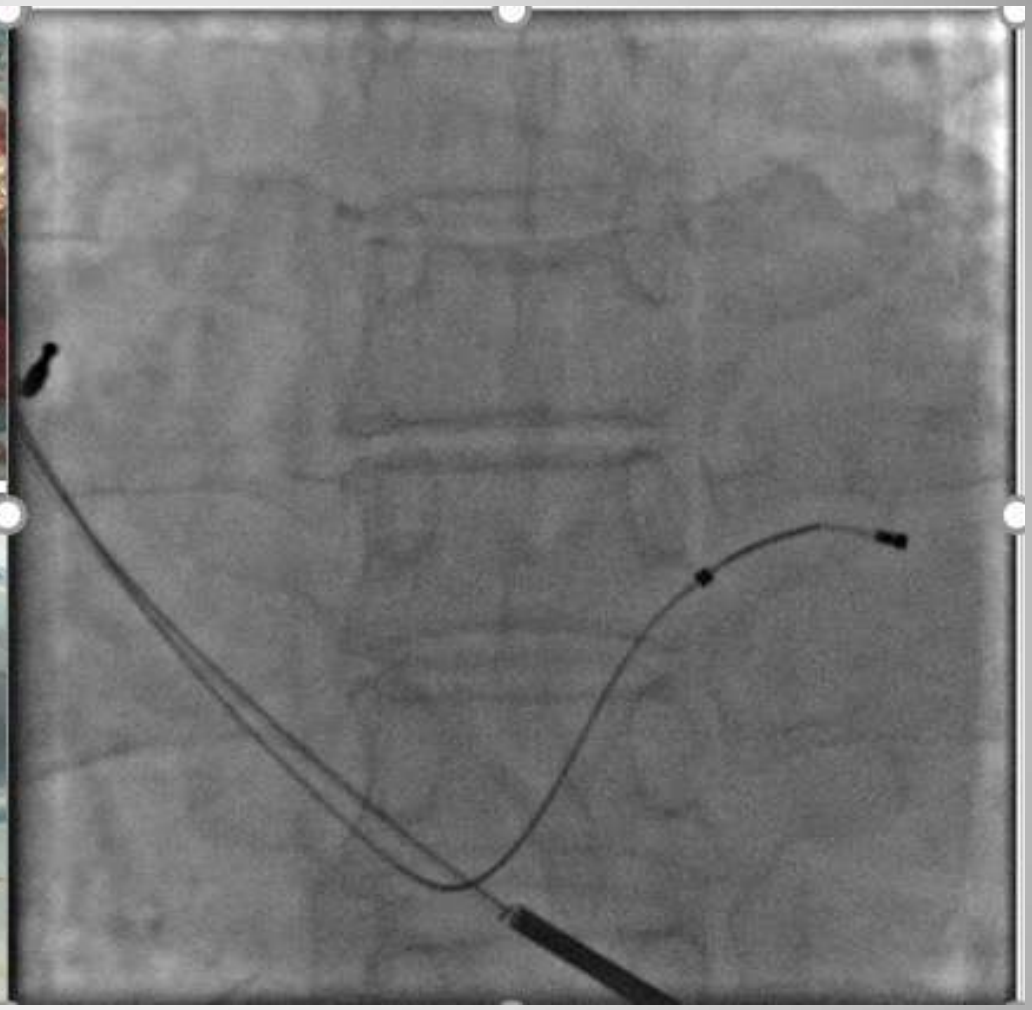


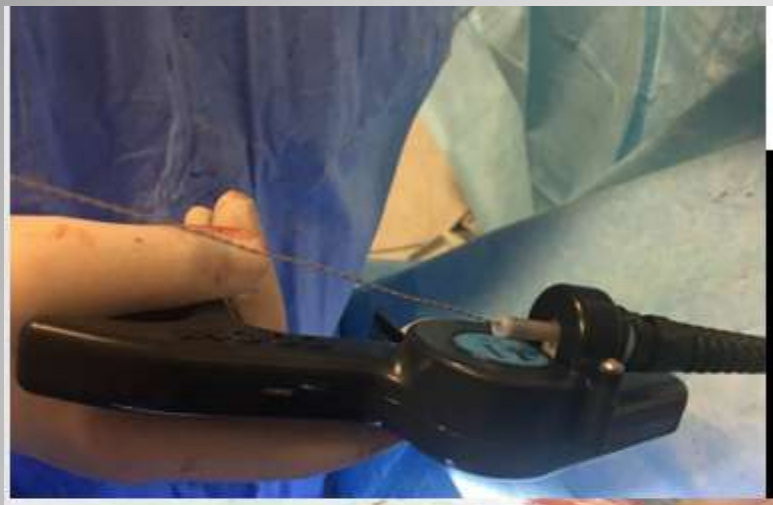


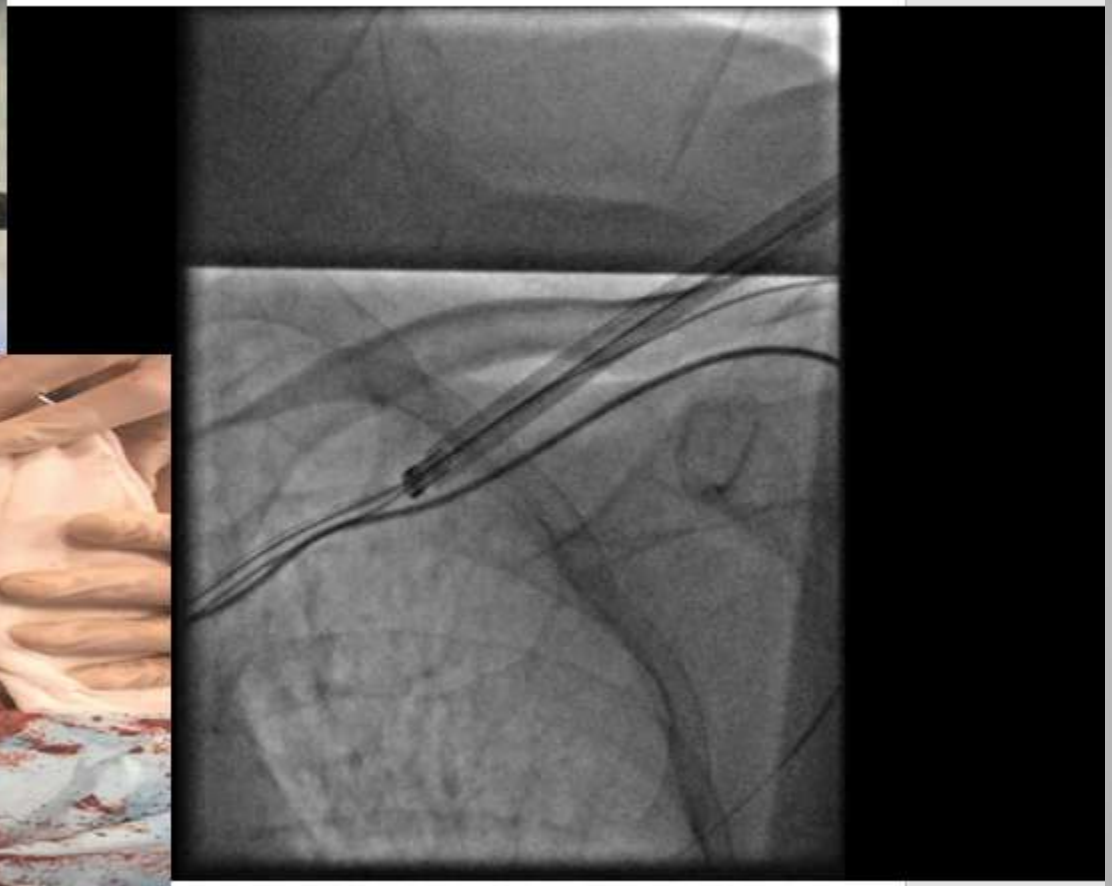


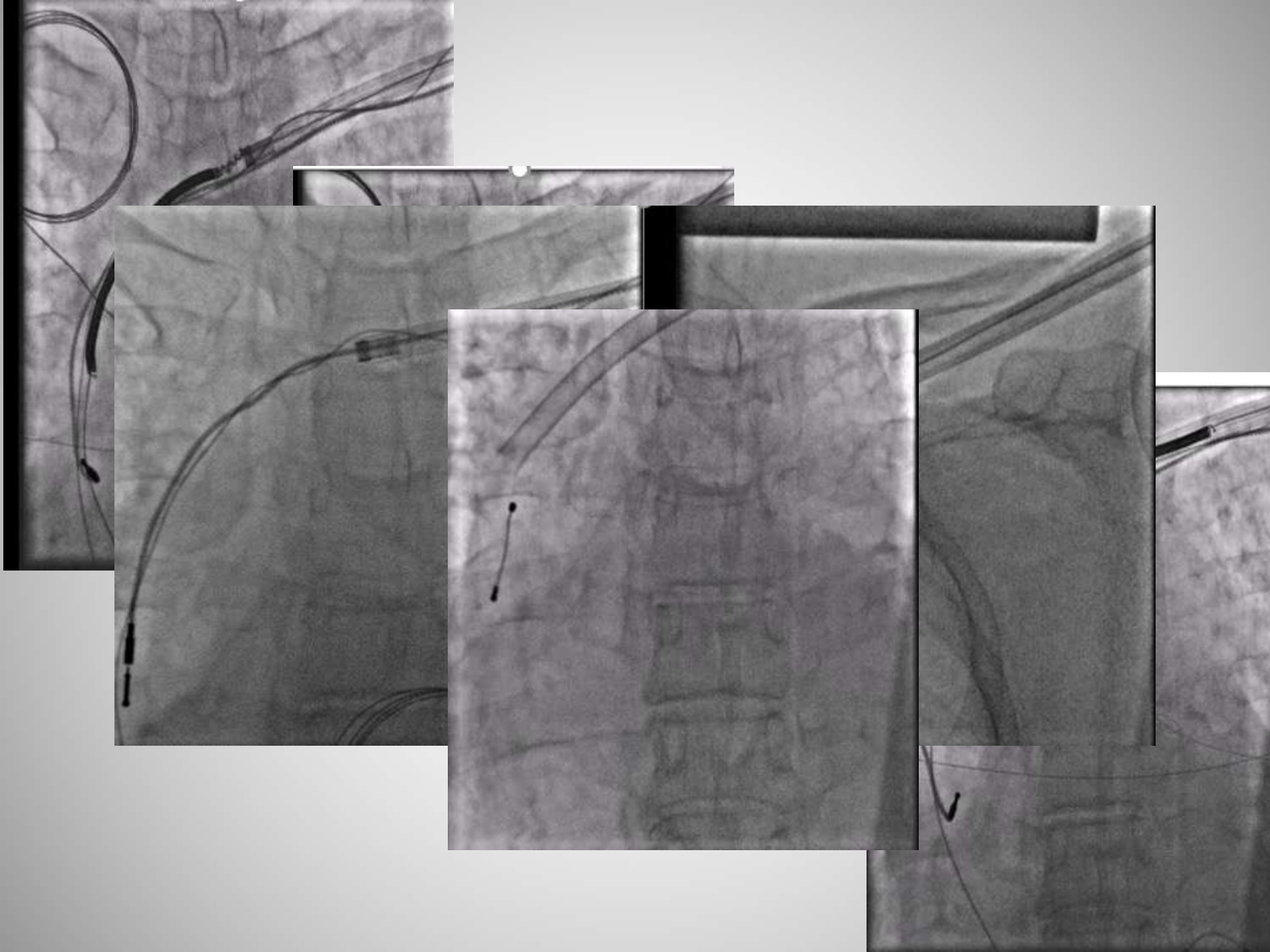


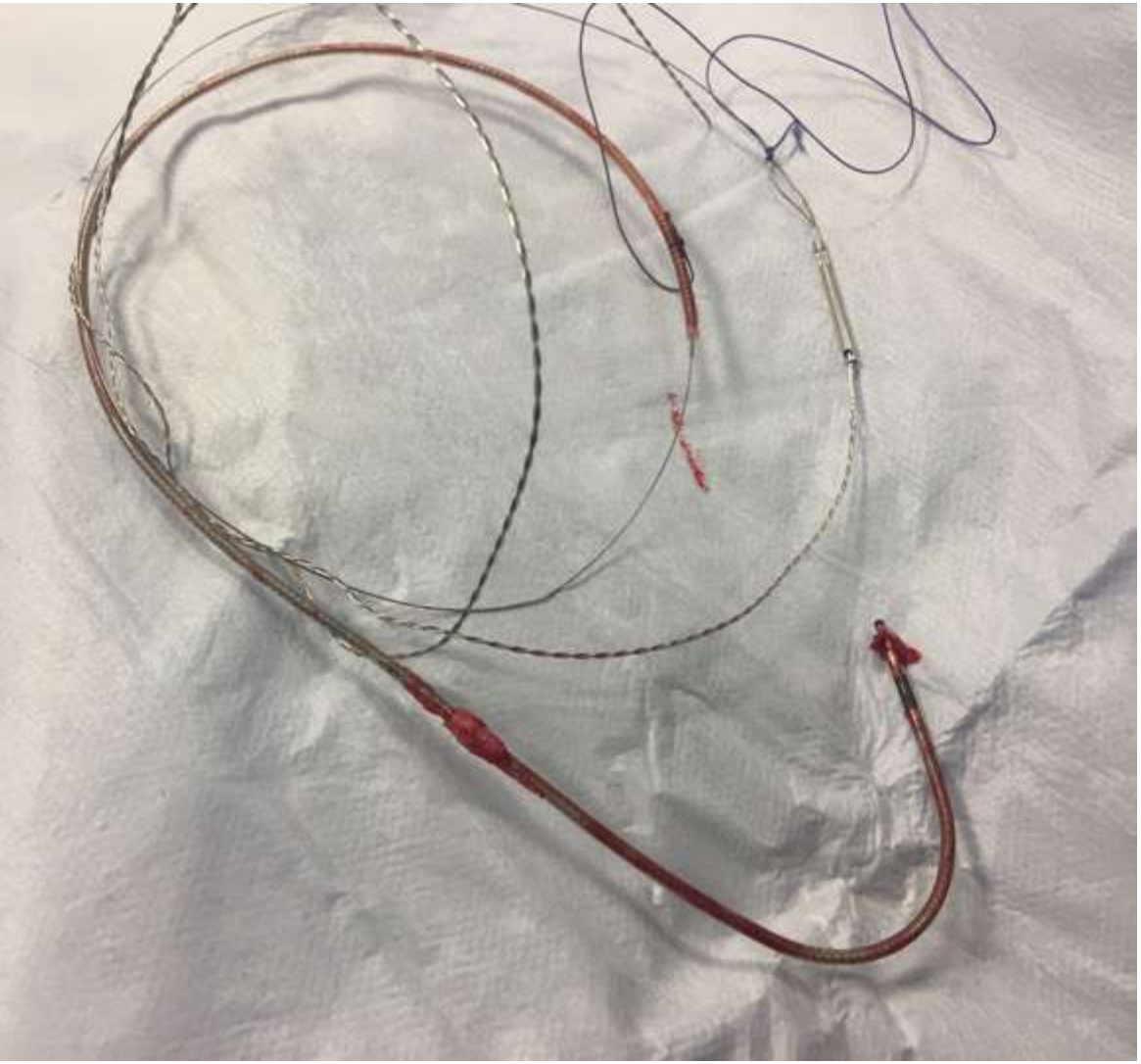


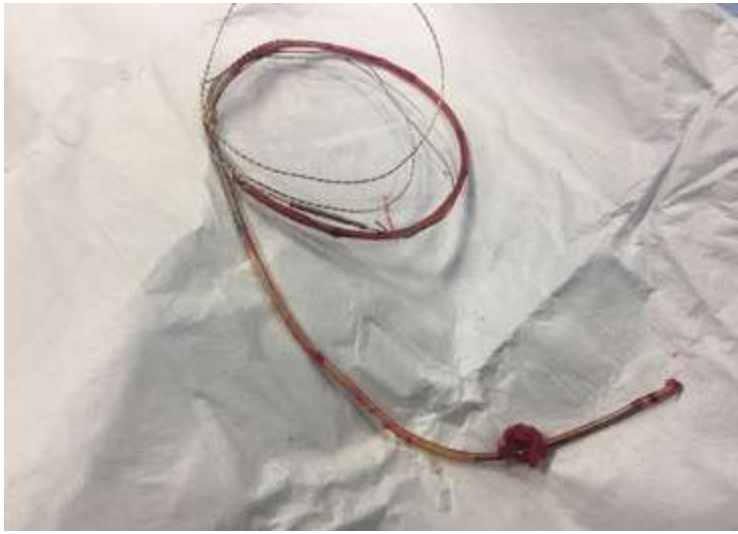


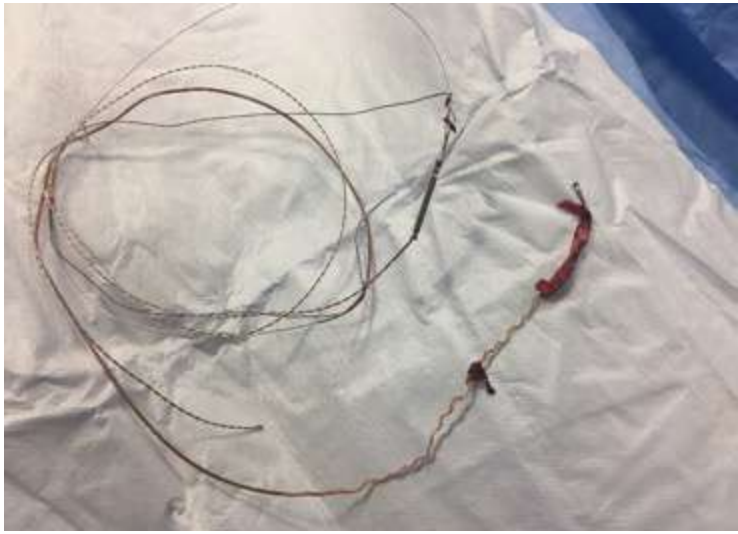












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Modified snare removal of a retained lead

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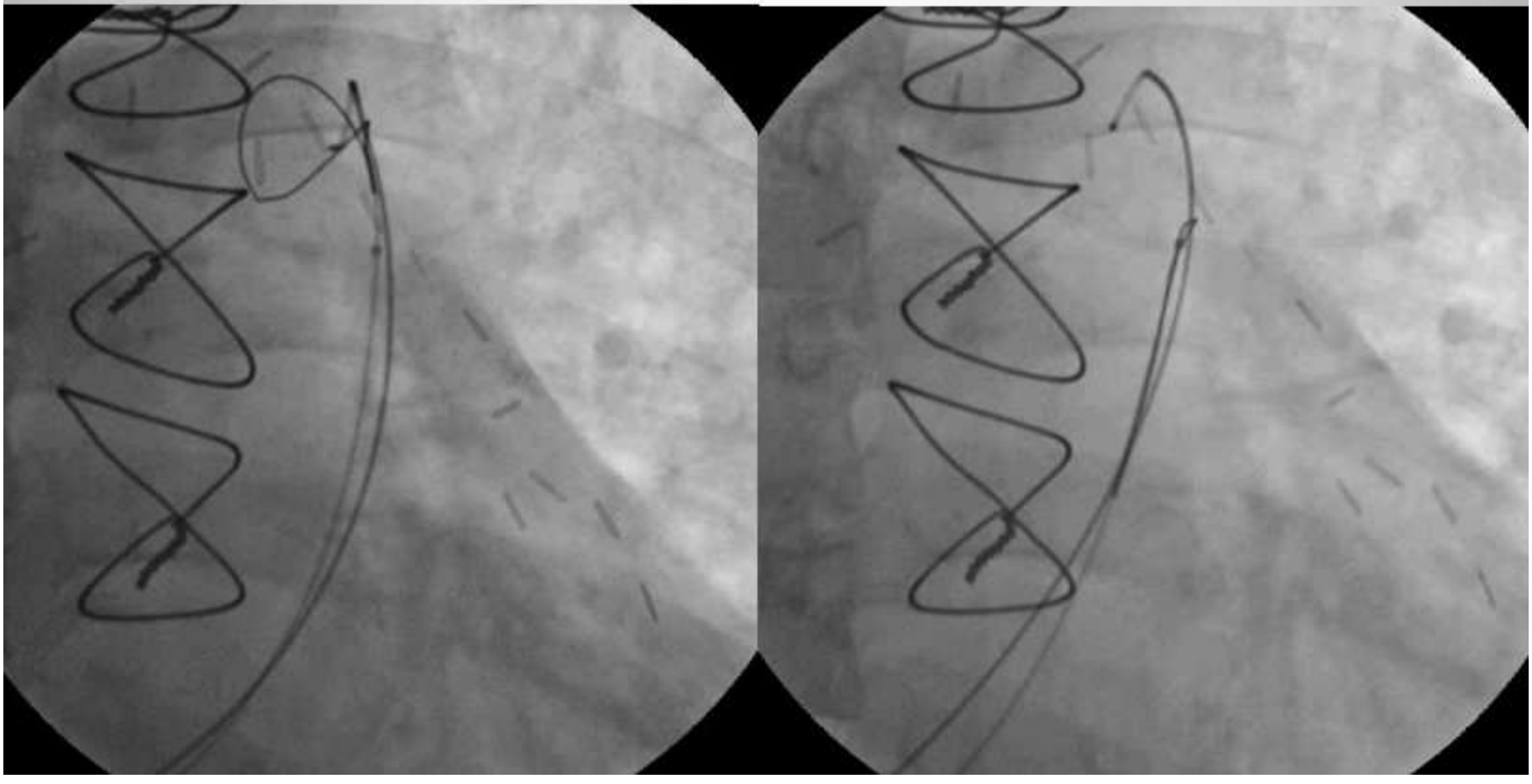

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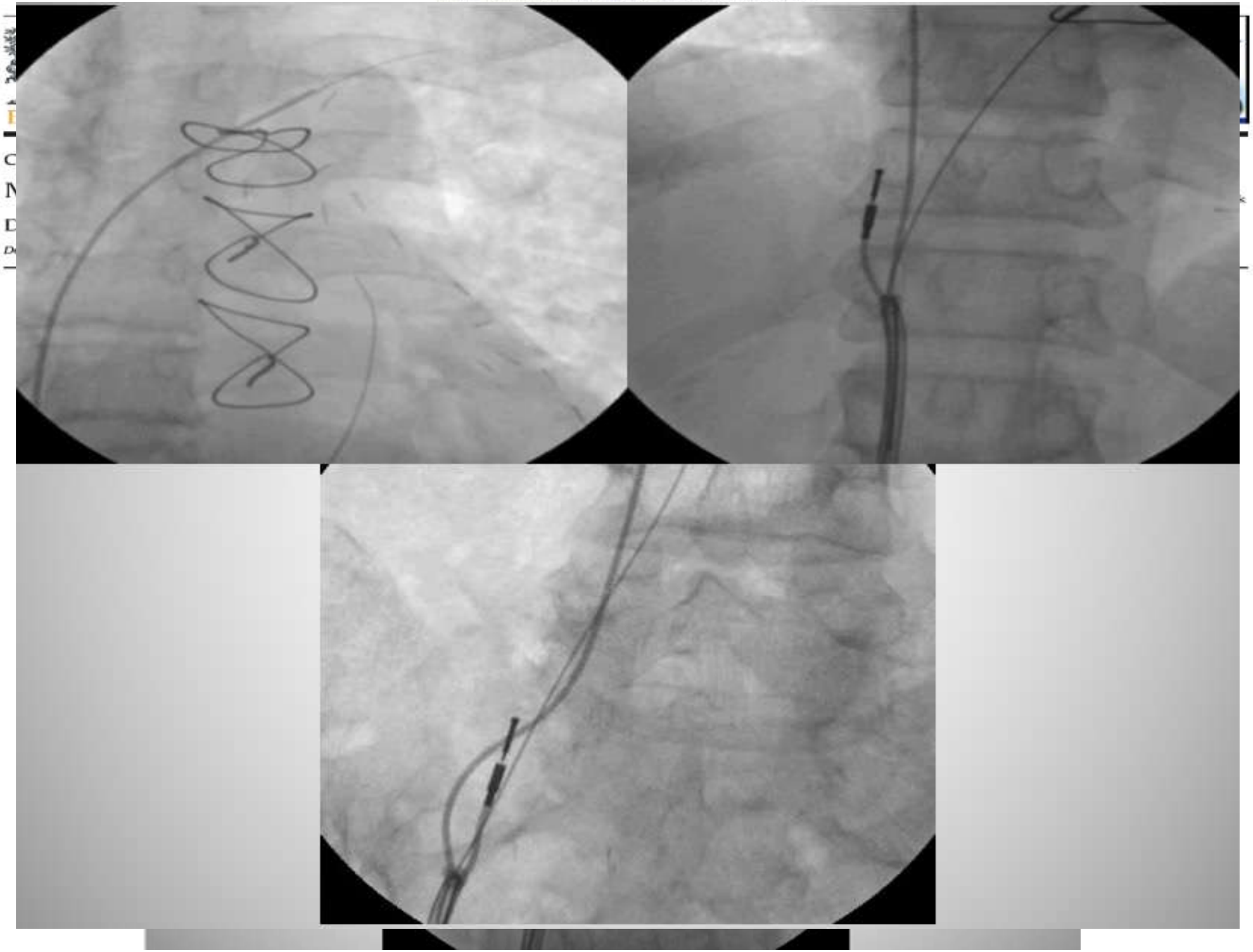
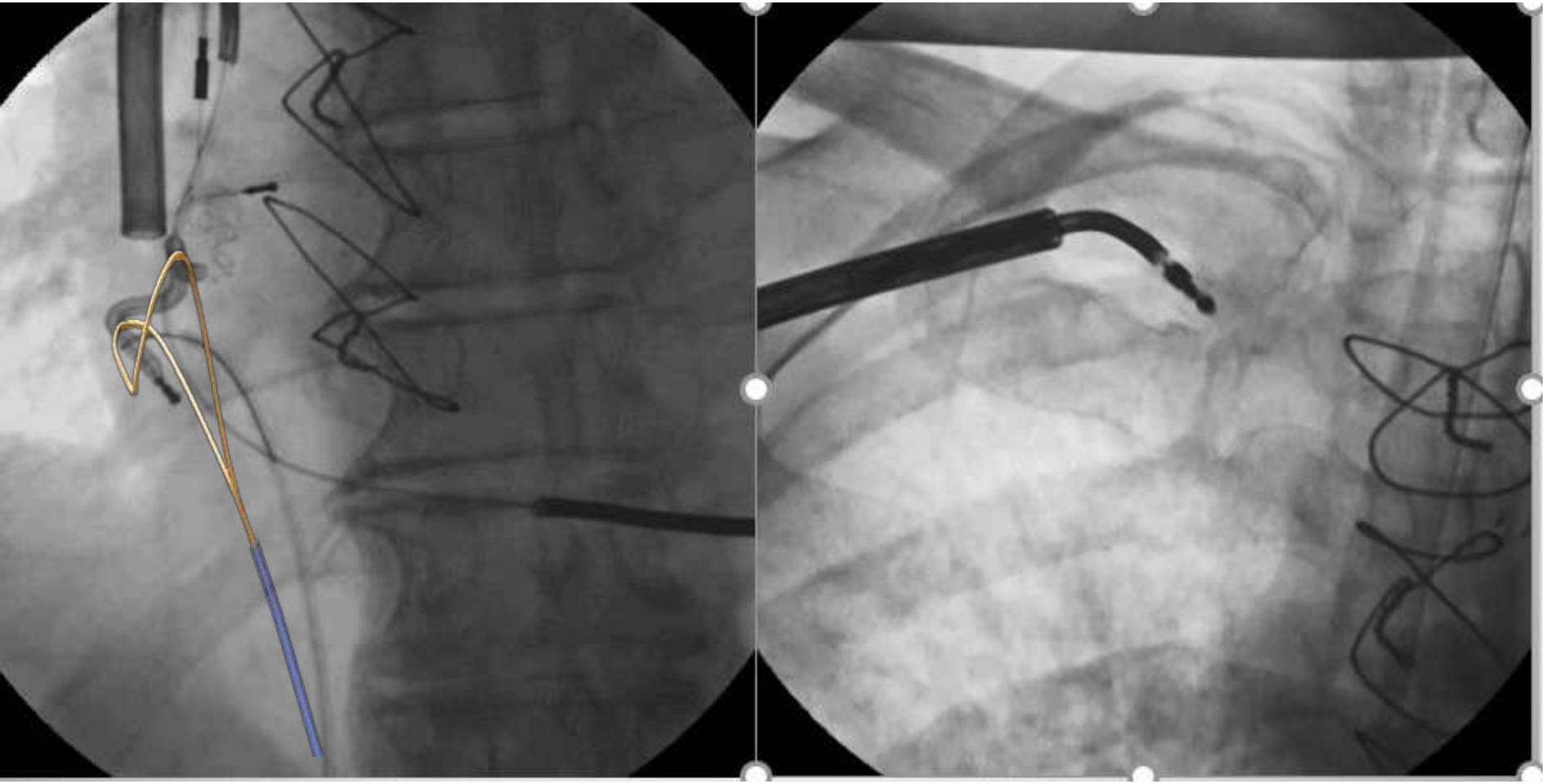
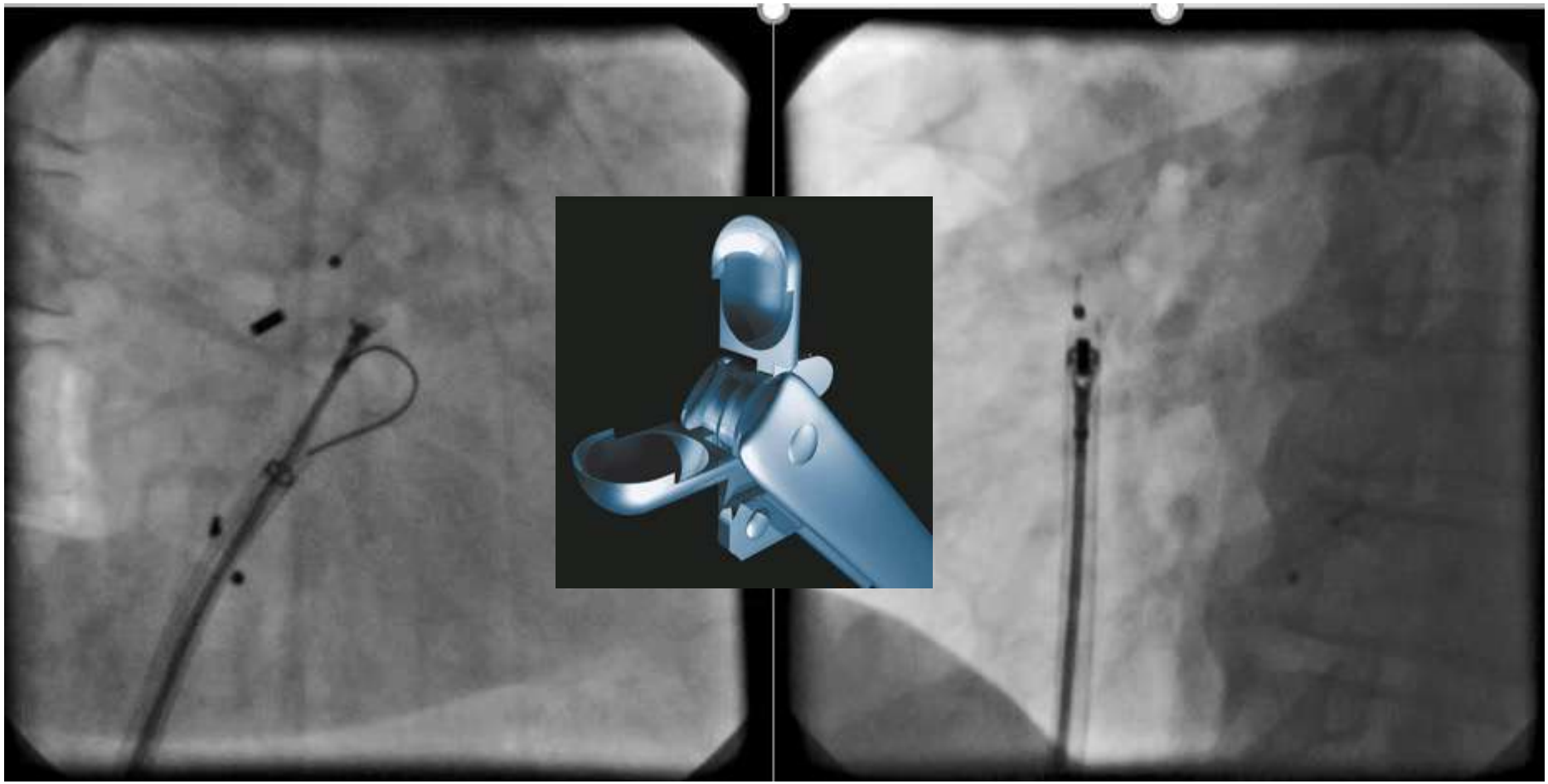






İşlem öncesi

(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 yerleştirerek çekme)

İlk extraksiyon

(Lead makasıyla kesilen leadin kilitleme stilesi kullanılarak manüel çekilmesi)

İkinci Extraksiyon

(Kilitleme stilesi olan leadin mekanik sheath kullanılarak çekilmesi)

Diğer venöz yollardan Exraksiyon

(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

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

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.

Major Perioperative Complications*

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%)
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	4.5-fold ↑ risk of major complications[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	ESRD: 4.8-fold ↑ risk of 30-day mortality[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	Elevated INR: 2.7-fold ↑ risk of major complications and 1.3-fold ↑ risk of 30-day mortality[62] Anticoagulant use: 1.8-fold ↑ 1-year mortality[240]
Anemia	3.3-fold ↑ risk of 30-day mortality[62]
Number of leads extracted	3.5-fold ↑ risk of any complication[241] 1.6-fold ↑ long-term mortality[242]
Presence of dual-coil ICD	2.7-fold ↑ risk of 30-day mortality[62]
Extraction for infection	2.7- to 30-fold ↑ risk of 30-day mortality[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]
Operator experience	2.6-fold ↑ no. of procedure-related complications[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.[25]	178	Percutaneous: 144	Majors: 2.2	3.9	Average of 55	18.5
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:
Total	3354	Percutaneous: 3081 Surgery: 238	-	-	-	-
Mean	209.6	-	Majors: 2.9 Minors: 8.4	5.4	24	-

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].

Total	3354	Percutaneous: 3081 Surgery: 238

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)**

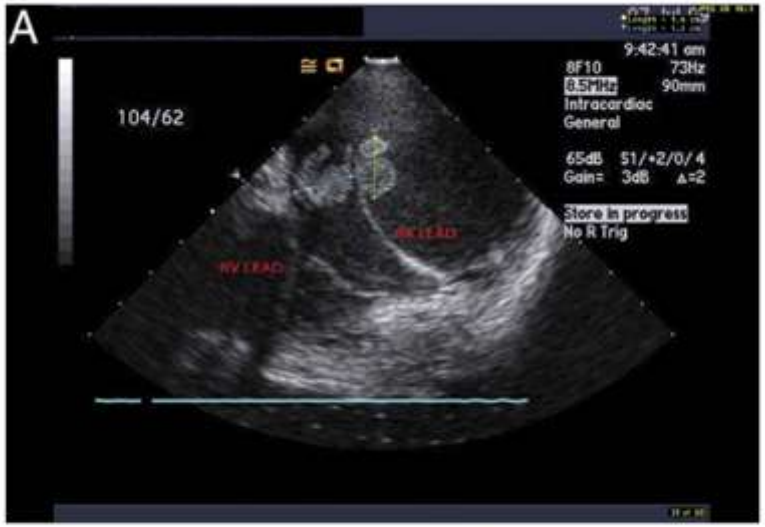
984 hastada 1850 lead çıkarılmış,

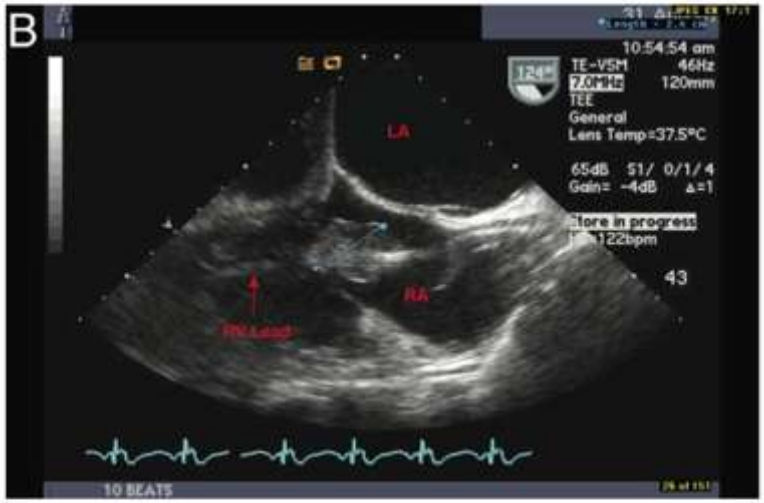
- ✓ 480 hasta **(%49) sistemik ya da lokal enfeksiyon endikasyonu ile.**
- ✓ **100 hastada TEE'de intrakardiyak vejetasyon var (%10)**

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.





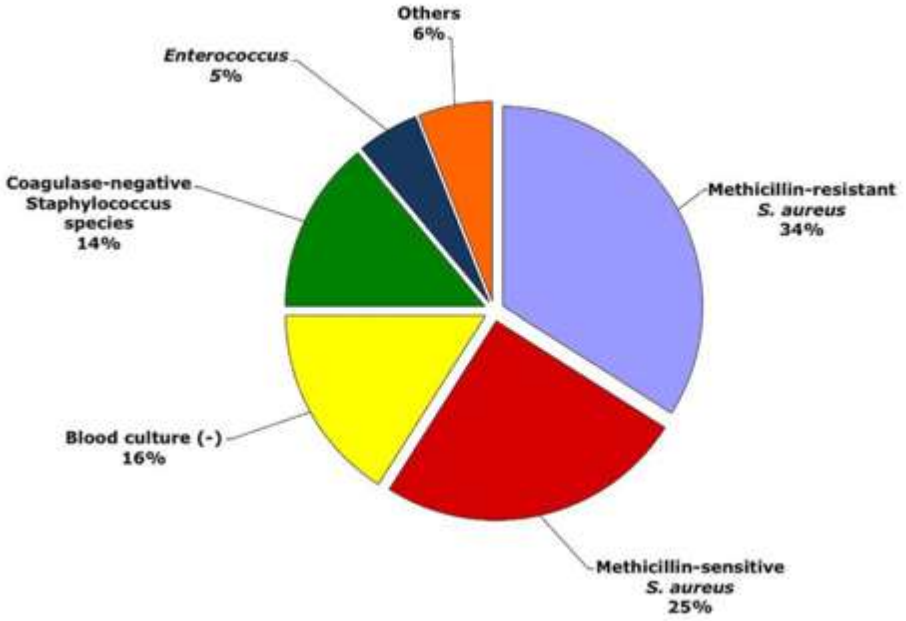


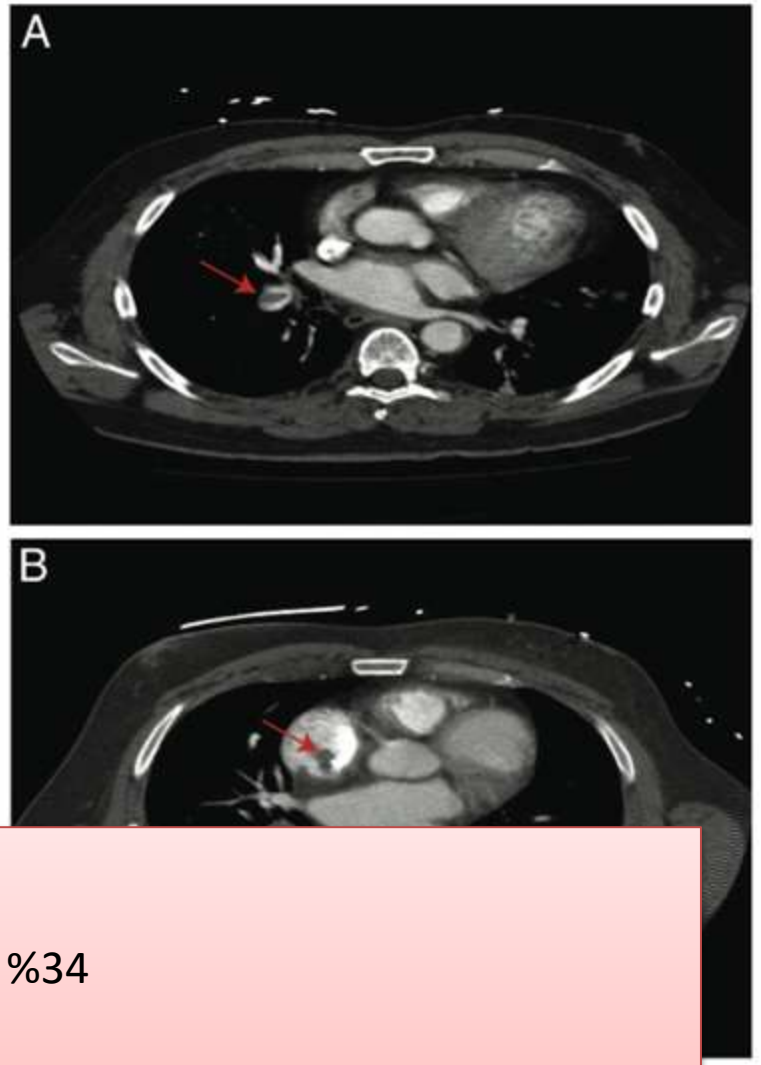
Figure 2 **ICE and TEE of Lead Vegetation**

(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 septisemi (%59)**



Pulmoner embolism;

- Ventilasyon-perfüzyon sintigrafisi ile bir çalışmada %34
- Başka bir çalışmada %55
- Pulmoner emboli olmayanlara göre hospitalizasyon süresi aynı ve mortaliite yok.

- Bu çalışmada 3 p. emboli var: 2 hastada vejetasyon >2 cm, bir hastada 1.2 cm
- 3 hastada tam iyileşmiş ve taburcu olmuş.

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	Pocket reintervention (generator change, upgrade, lead or pocket revision)	Highly virulent microbes (eg, staphylococci)
Chronic kidney disease	Pocket hematoma	
Hemodialysis	Longer procedure duration	
Diabetes mellitus	Inexperienced operator	
Heart failure	ICD (compared with PM)	
Chronic obstructive pulmonary disease	Lack of use of prophylactic antibiotics	
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)

BACKGRO

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OBJECTIVE

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METHODS

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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

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

This article was published on March 17, 2019, at NEJM.org.

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

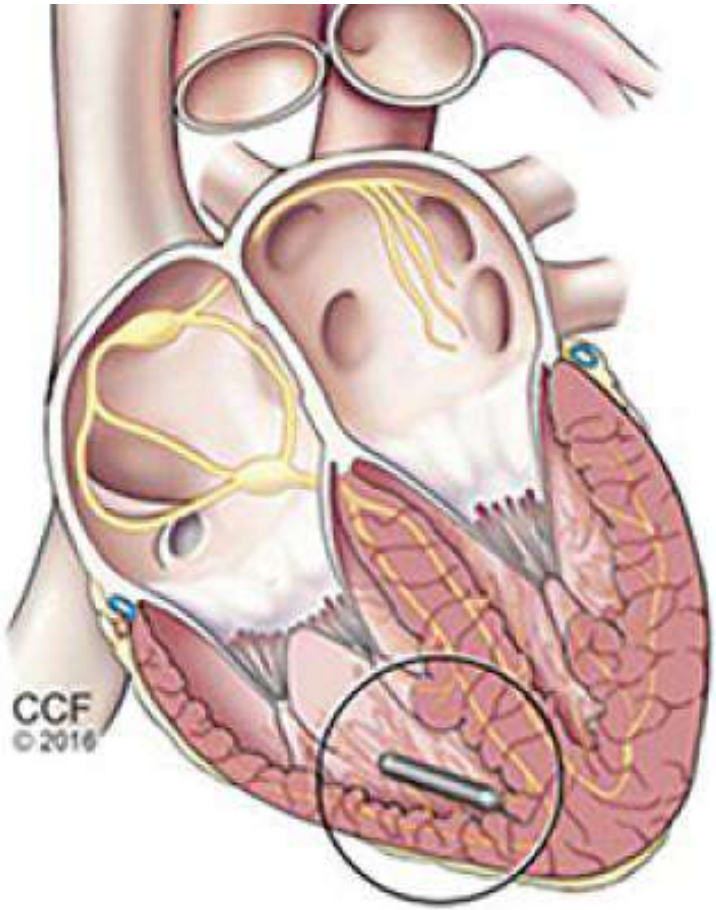
95% CI 0.36-0.98, P=0.04

Trial published in

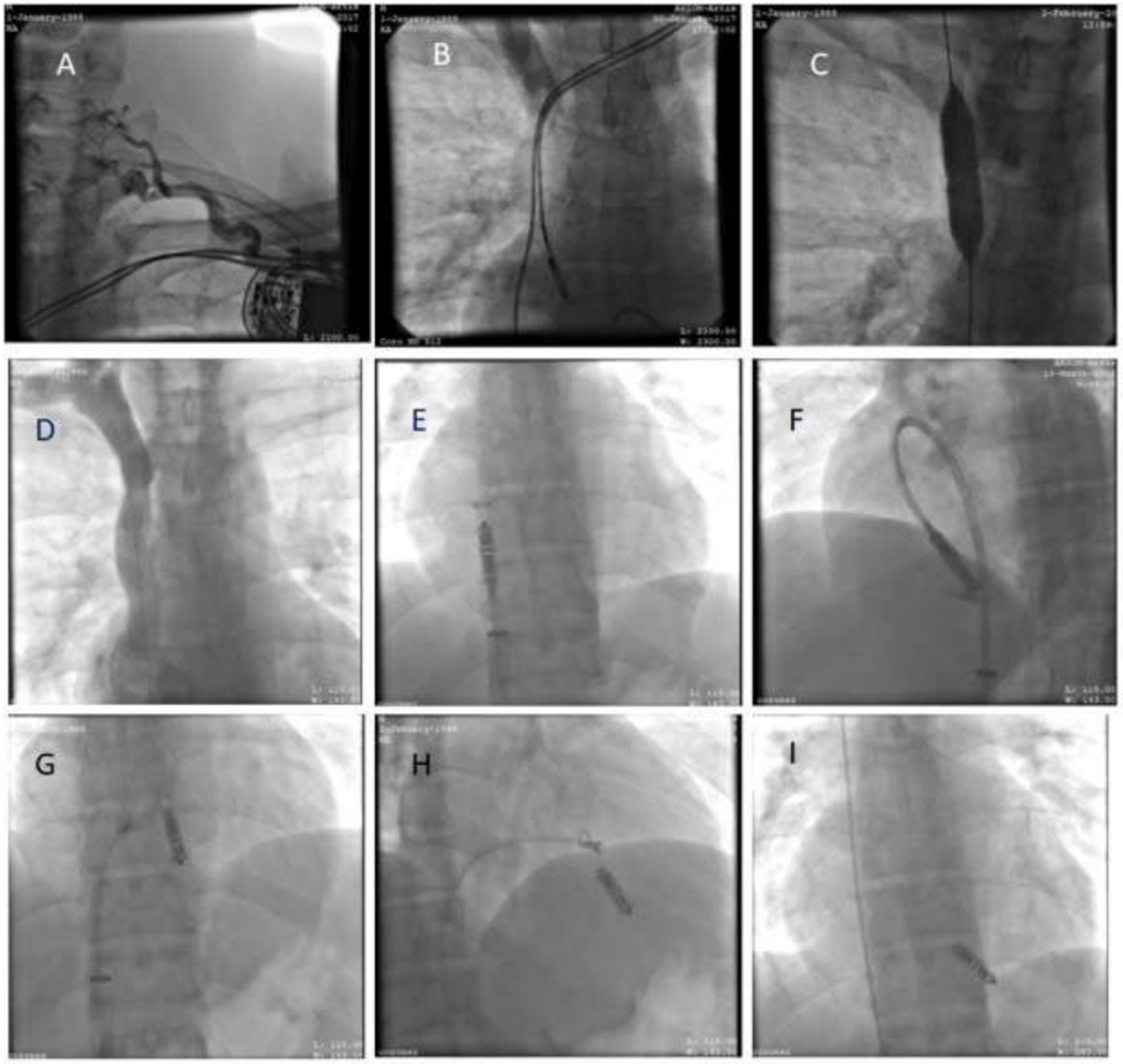
The NEW ENGLAND JOURNAL of MEDICINE

DOI: 10.1056/NEJMoa1901111

Leadless pacemaker



Leadless pacemaker



D. Aras ve ark.

Türkiye Yüksek İhtisas Hastanesi Aritmi Ekibi arşivinden., 2016

S-ICD: Subkutan ICD