DEUTSCHES HERZZENTRUM
DER CHARITÉ

Prof. Dr. Christoph Starck, FEHRA

Behandlung von systemischen Infektionen – Durchführung der perkutanen Aspiration

Hamburg, September 15th 2023

CHARITÉ

Rate of CIED infections…

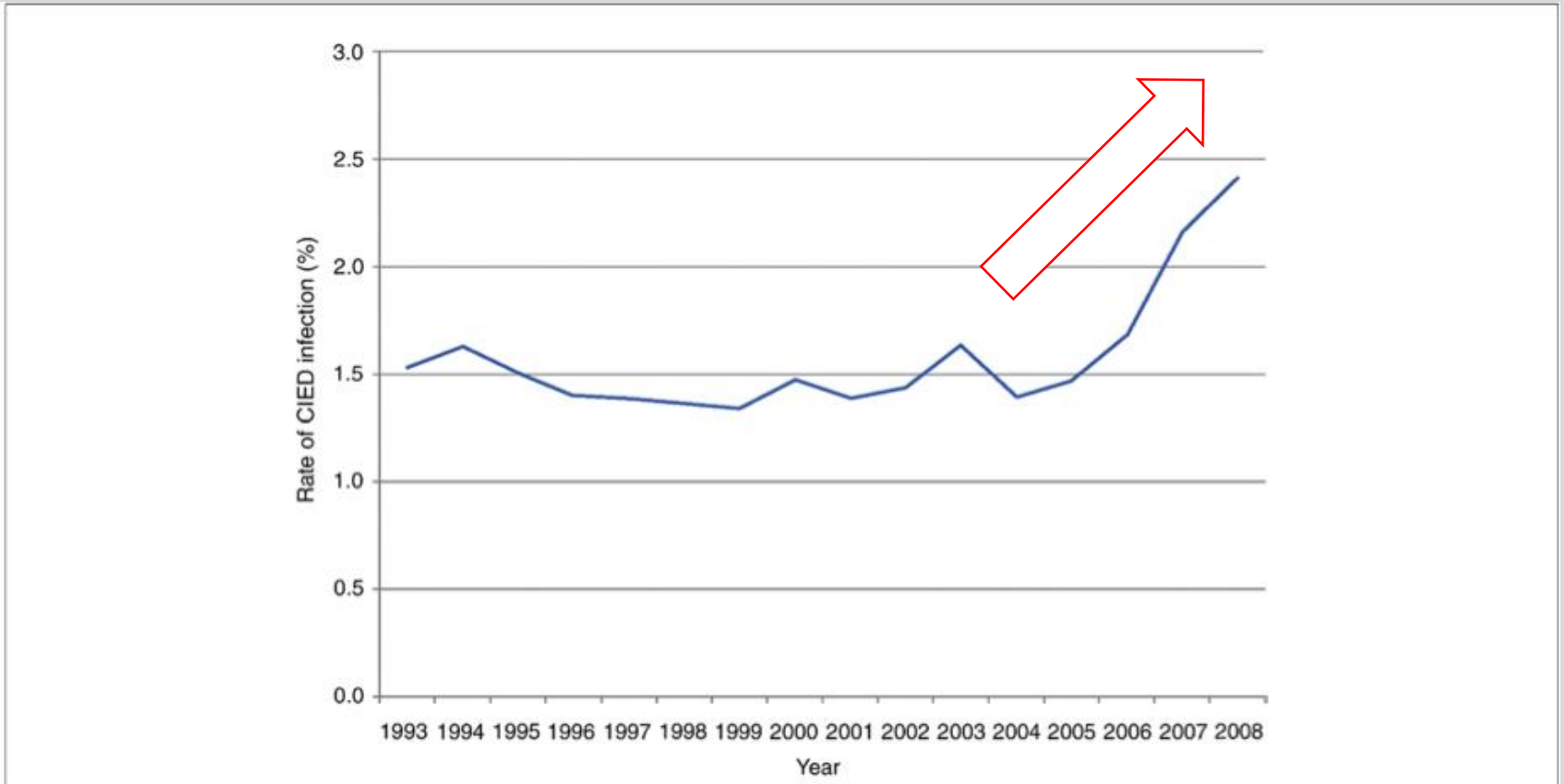


Figure 3 Rate of CIED Infection

Greenspon et al. JACC 2015

Costs of CIED infections…

ESC European Society of Cardiology
Europace (2018) 0, 1–7
doi:10.1093/europace/eux387

CLINICAL RESEARCH

Infections and associated costs following cardiovascular implantable electronic device implantations: a nationwide cohort study

Nicolas Clémenty[1]*, Phuong Lien Carion[2], Lucie de Léotoing[3], Ludovic Lamarsalle[3], Fanny Wilquin-Bequet[2], Benedict Brown[4], Koen J. P. Verhees[5], Jérôme Fernandes[6], and Jean-Claude Deharo[7]

Table 1 Infection rates

		CIED *de novo*		CIED replacement	
		36M infection rate	*P*-value (at 36M)	36M infection rate	*P*-value (at 36M)
Defibrillators	SCD + DCD	1.6%		2.9%	
	CRT-D	1.6%	0.93 (vs. SCD + DCD)	3.9%	0.36 (vs. SCD + DCD)
Pacemakers	SCP + DCP	0.5%		1.4%	
	CRT-P	1.0%	0.01 (vs. SCP + DCP)	1.3%	0.93 (vs. SCP + DCP)

CIED, cardiac implantable electronic device; CRT-D, cardiac resynchronization therapy-defibrillator; CRT-P, cardiac resynchronization therapy-pacemaker; DCD, double-chamber defibrillator; DCP, double-chamber pacemaker; SCD, single-chamber defibrillator; SCP, single-chamber pacemaker; 36M, 36 months.

Table 2 Infection associated costs

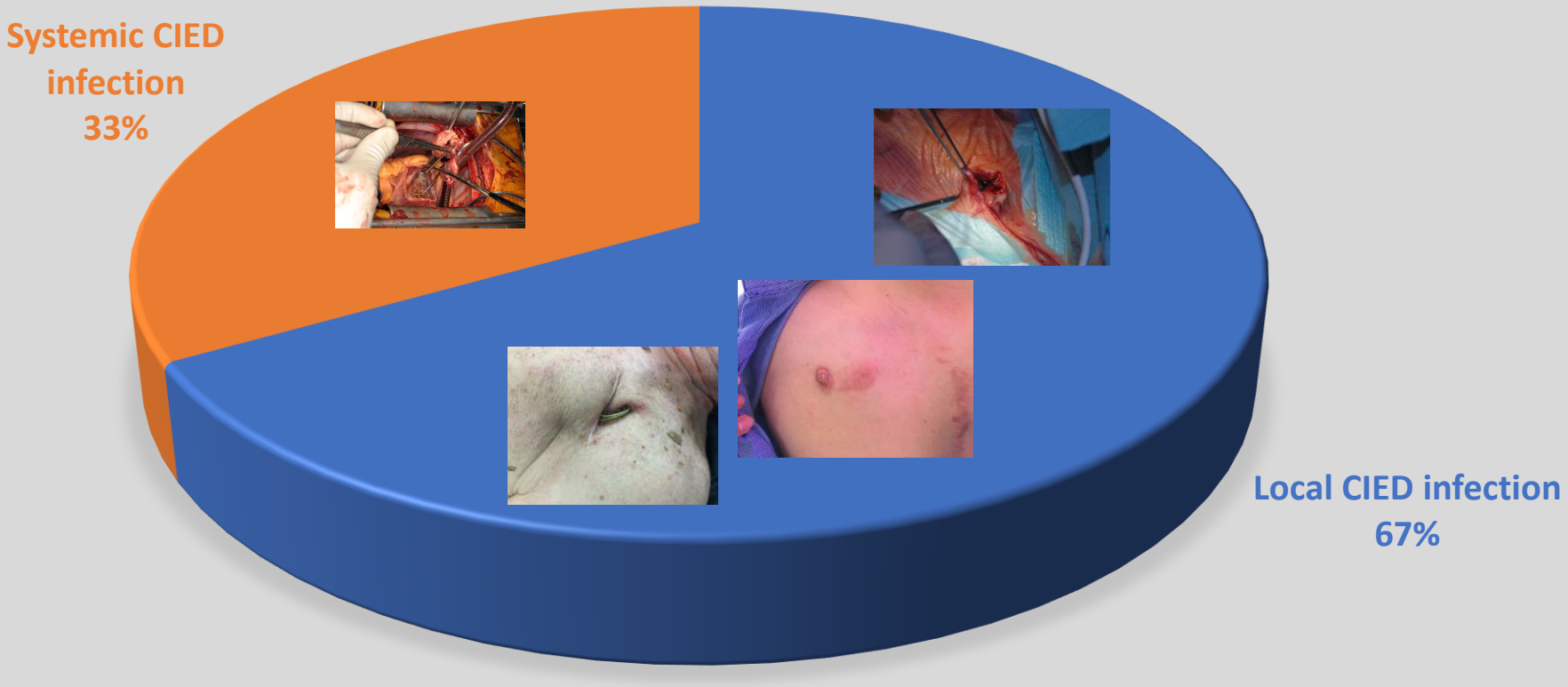
	24M infection *de novo*			24M infection replacement		
	n	Mean	SD	*n*	Mean	SD
Total	356	€23 234	€50 294	331	€20 623	€18 778
Type of CIED						
Defibrillator						
SCD + DCD						8611
CRT-D						0485
Pacemaker						
SCP + DCP						8029
CRT-P						0461

CIED, cardiac implantable
ber defibrillator; DCP, dou
ble-cham-

Mean costs

20.000,00 – 25.000,00 Euros

CIED infections – systemic vs. local



CIED infections – GOLDEN RULE of treatment

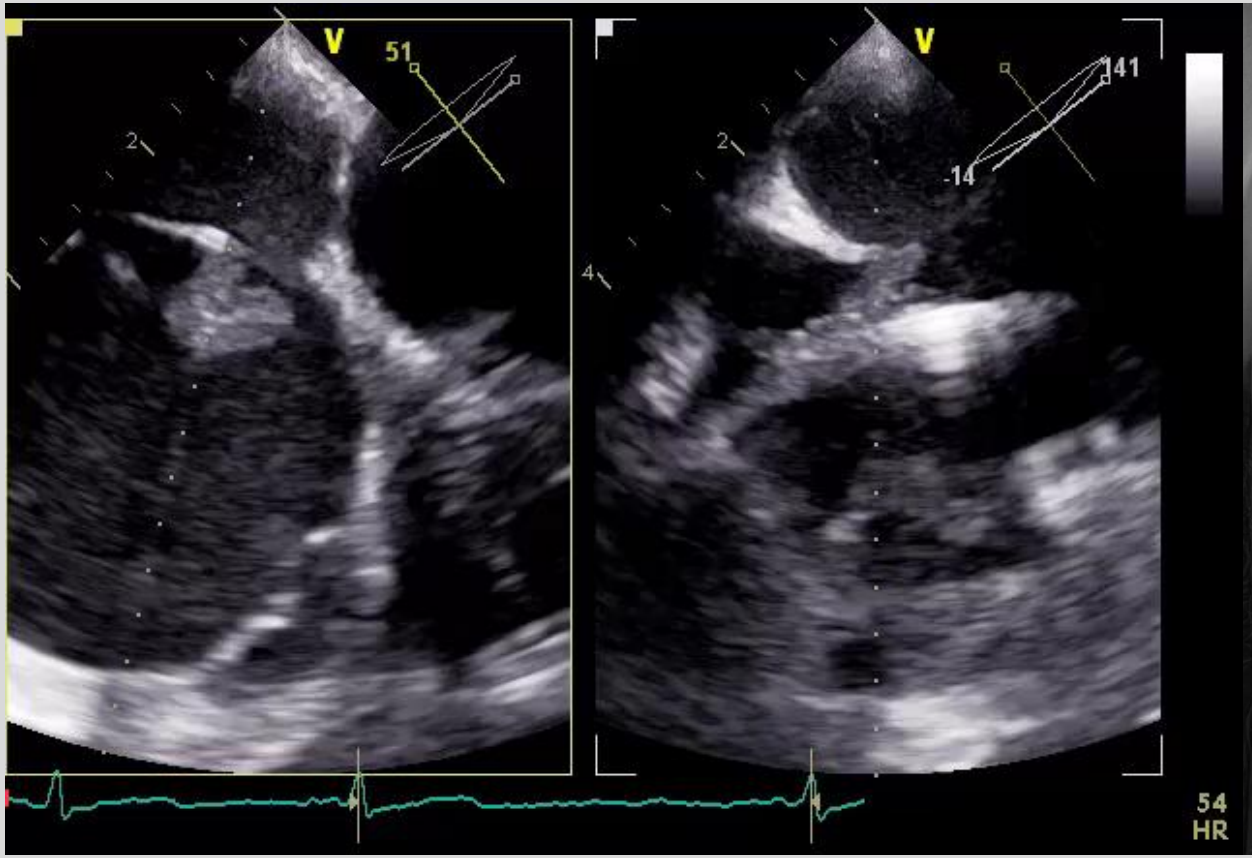
I	B-NR	Complete device and lead removal is recommended for all patients with definite CIED system infection.	169–171

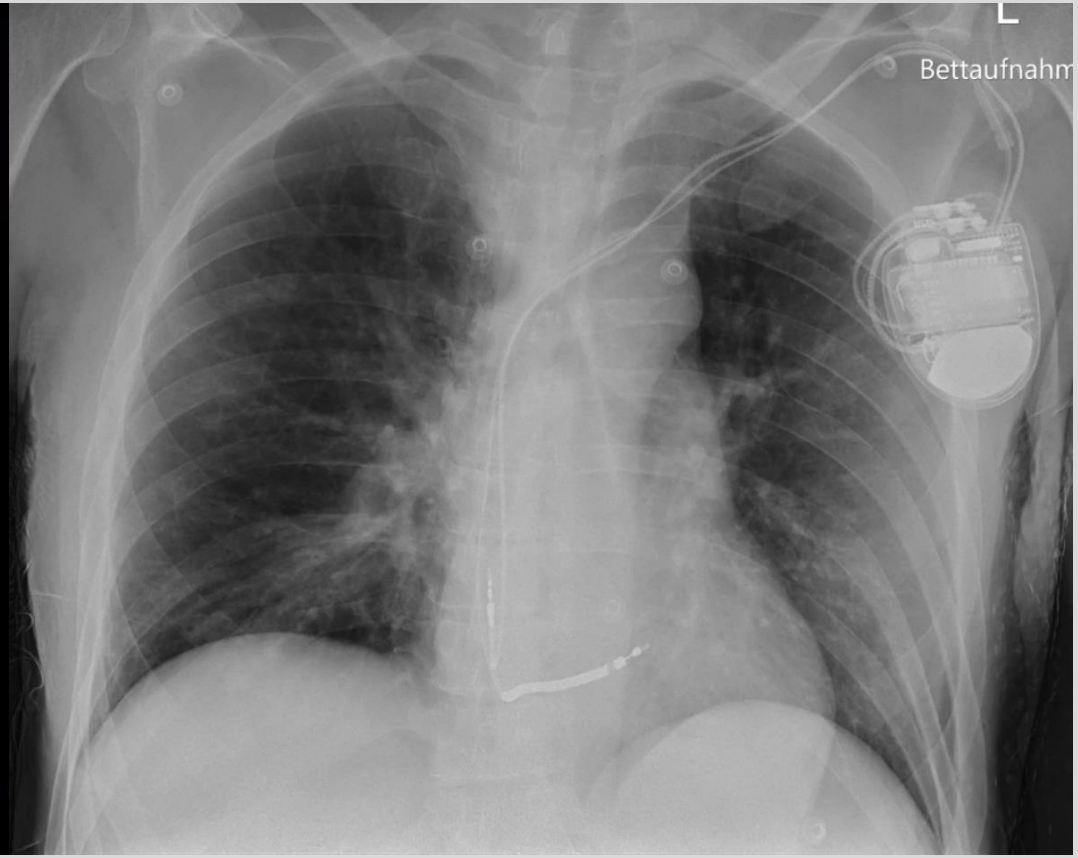
COMPLETE CIED REMOVAL

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

Kusumoto et al. Heart Rhythm 2017

The PROBLEM…



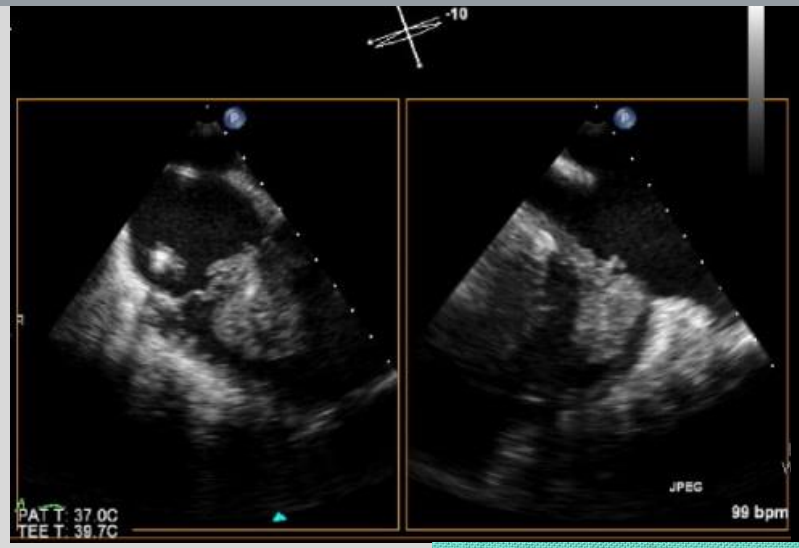


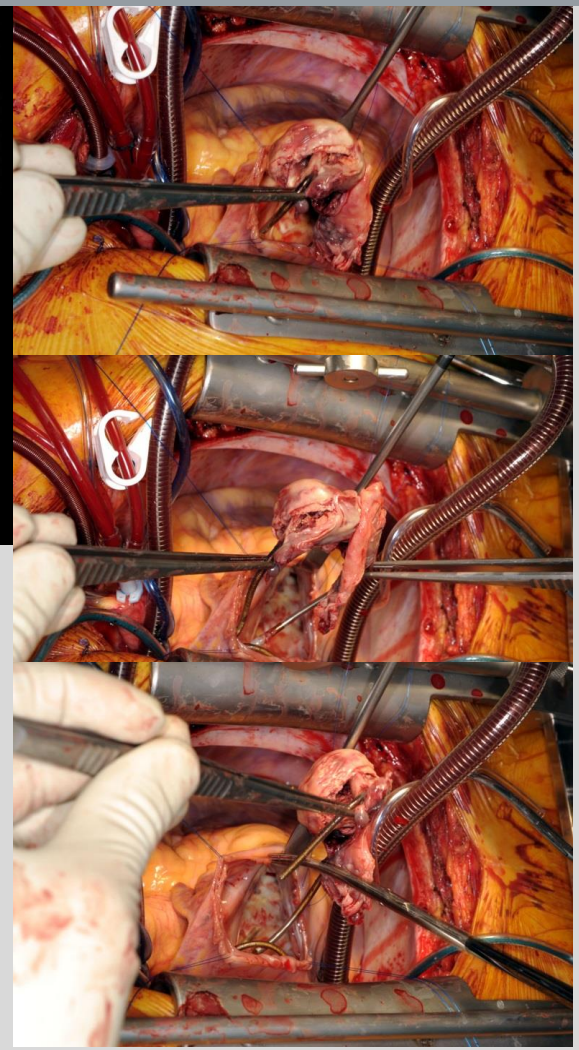
2015 ESC guidelines for the management of infective endocarditis

C. Mode of device removal			
1. Percutaneous extraction is recommended in most patients with CDRIE, even those with vegetations >10 mm	I	B	382, 391, 405
2. Surgical extraction should be considered if percutaneous extraction is incomplete or impossible or when there is associated severe destructive tricuspid IE	IIa	C	
3. Surgical extraction may be considered in patients with large vegetations (>20 mm)	IIb	C	

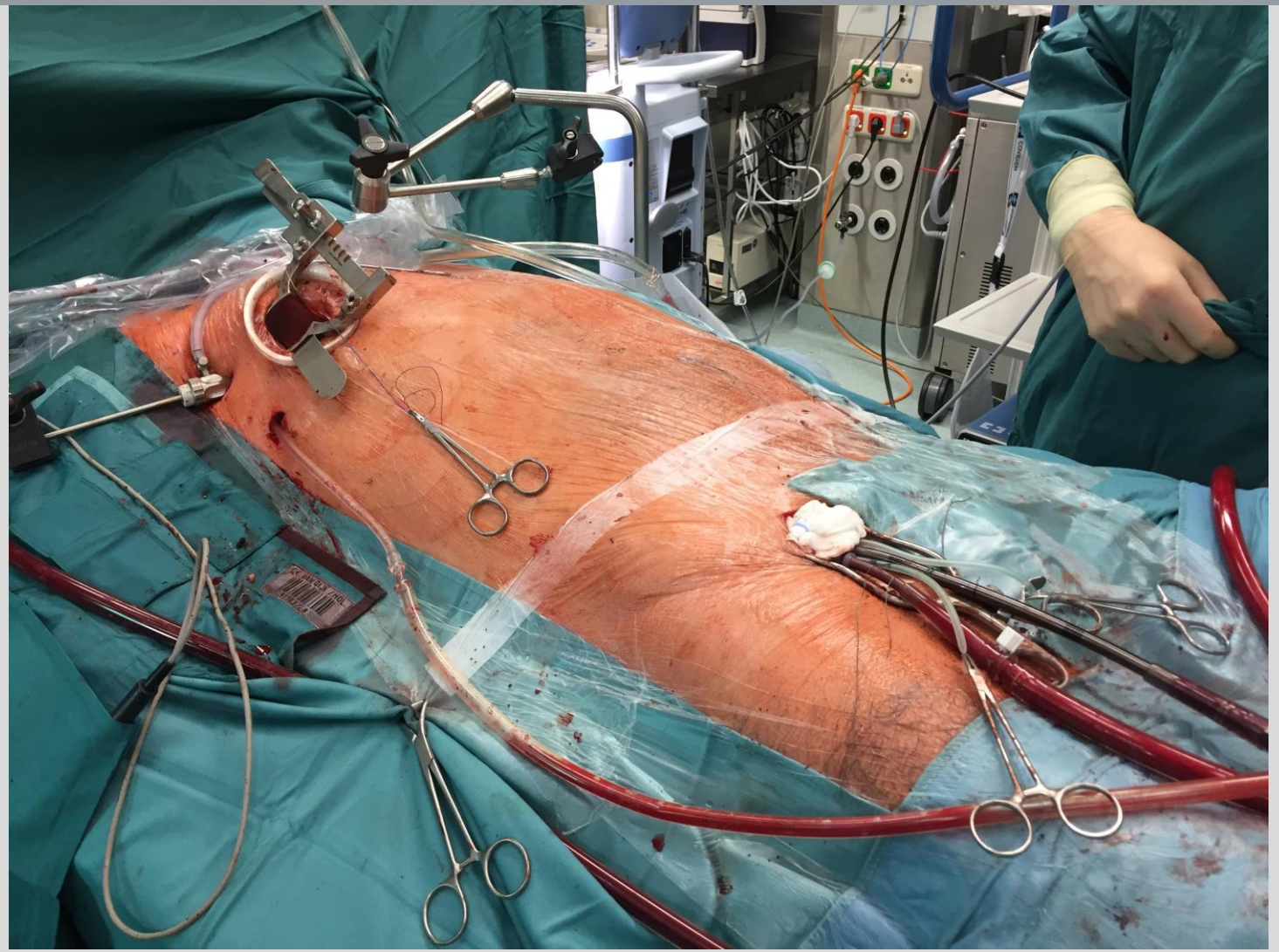
Habib et al. EHJ 2015

Large lead vegetations - OLD concept - surgical extraction

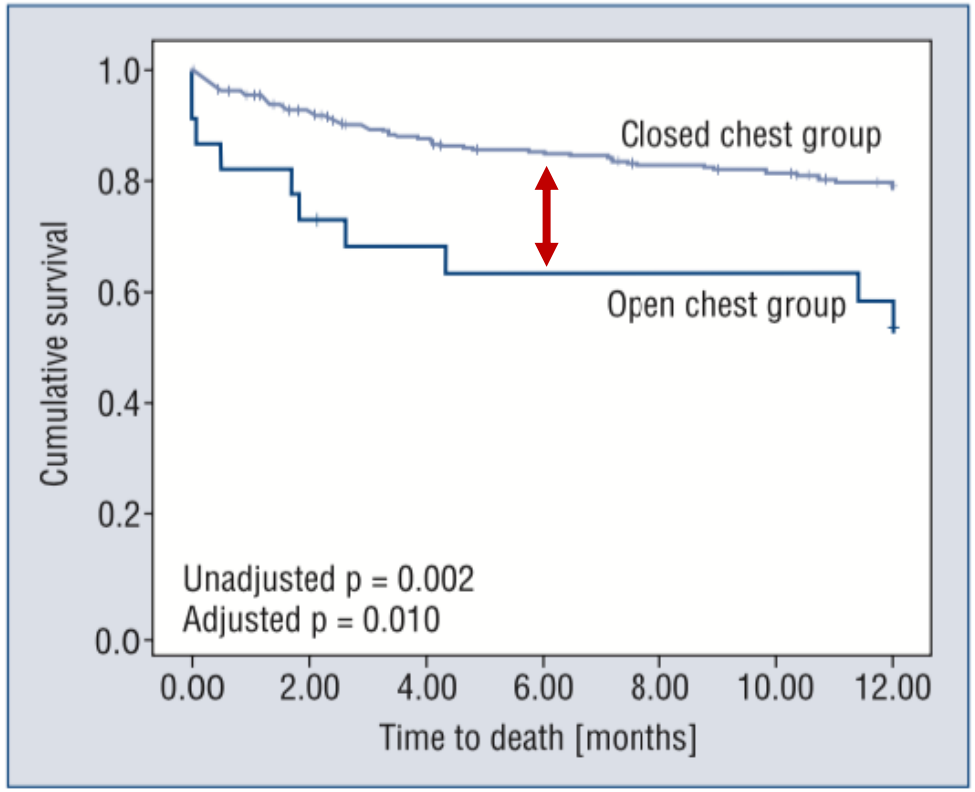




EVOLUTION - MIC Surgical Extraction



Surgical extraction is associated with higher mortality...



Cardiac implantable electronic device lead extraction in patients with underlying infection using open thoracotomy or percutaneous techniques

(Cardiol J 2015; 22, 1: 68–74)

Table 2. Mortality and non-lethal complication rates for the two study groups.

Adverse events	Open thoracotomy	Percutaneous techniques	P
Deaths after 30 days	4/24 (17%)	15/329 (5%)	0.036
Deaths after 6 months	8/24 (33%)	45/329 (14%)	0.020
Deaths after 1 year	10/24 (42%)	61/329 (19%)	0.012
Non-lethal complications during procedure	0/24 (0.0%)	6/329 (2.0%)	0.99
Non-lethal complications 30 days post procedure	2/24 (8%)	22/329 (7%)	0.31
Hospital length of stay [days]	23 ± 15	12 ± 9	< 0.001

...& longer hospital stay

JUST DO IT – „naked“ transvenous lead extraction…

Long-term survival in CIED infections

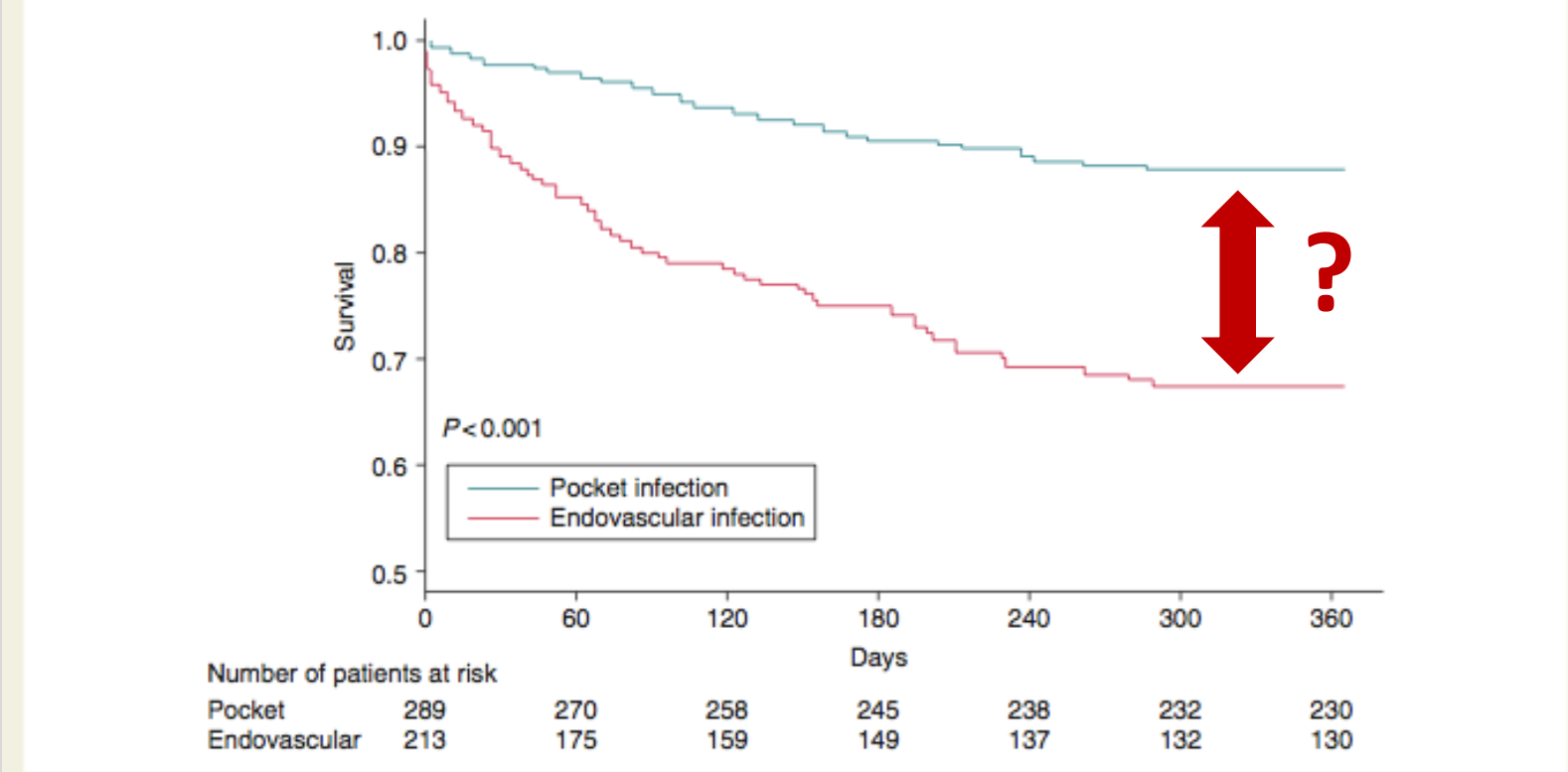


Figure 1 Kaplan–Meier survival curves over 1 year among patients with pocket infection (blue line) and endovascular infection (EVI) (red line) following CIED removal.

Tarakji et al. Europace 2014

Large lead vegetations in CIED infections

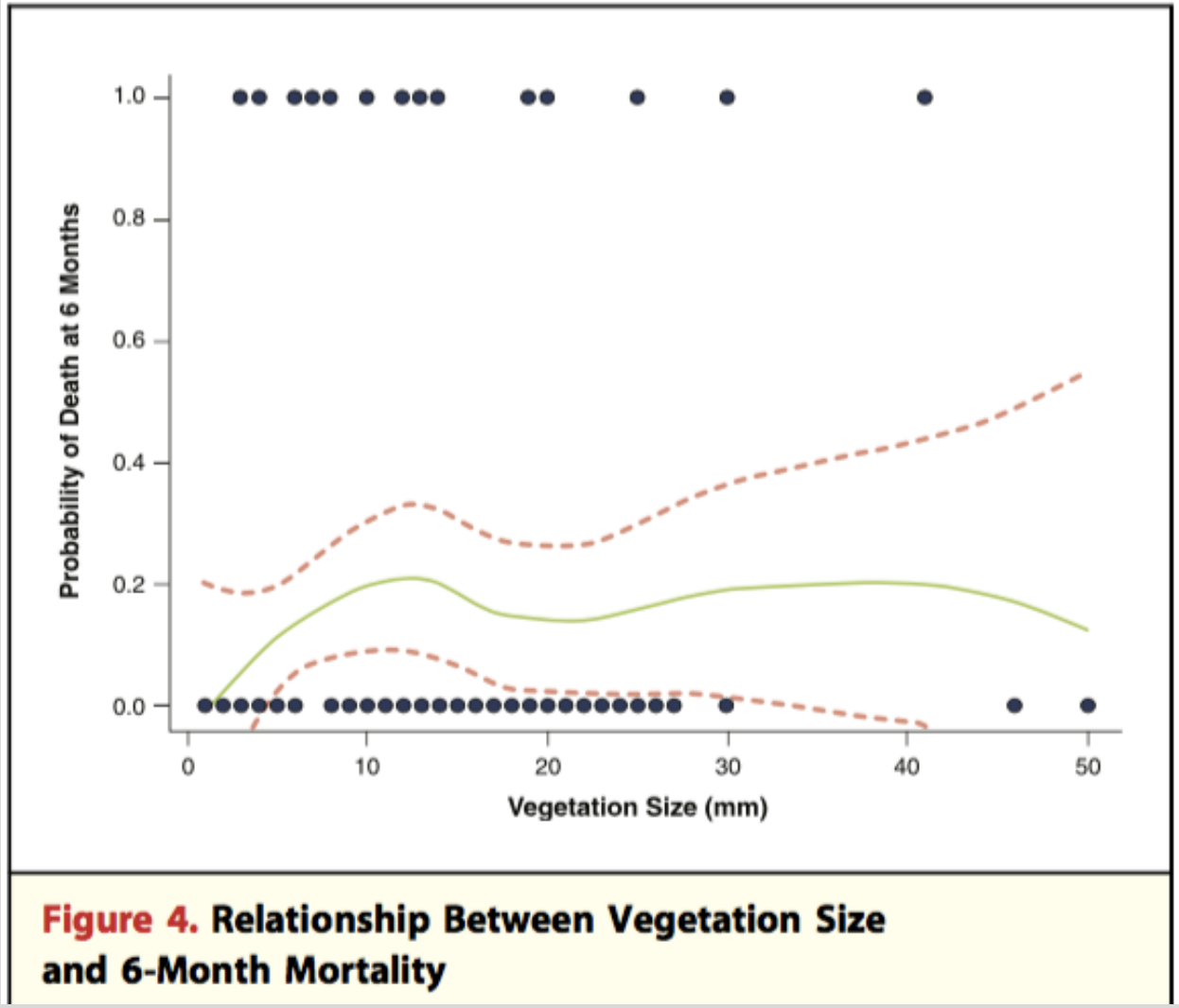


Figure 4. Relationship Between Vegetation Size and 6-Month Mortality

Influence of Vegetation Size on the Clinical Presentation and Outcome of Lead-Associated Endocarditis

Results From the MEDIC Registry

JACC: CARDIOVASCULAR IMAGING, VOL. 7, NO. 6, 2014
JUNE 2014:541–9

Larger vegetations = higher mortality @ 6 months

Lead vegetation size

Lead-related infective endocarditis: factors influencing the formation of large vegetations

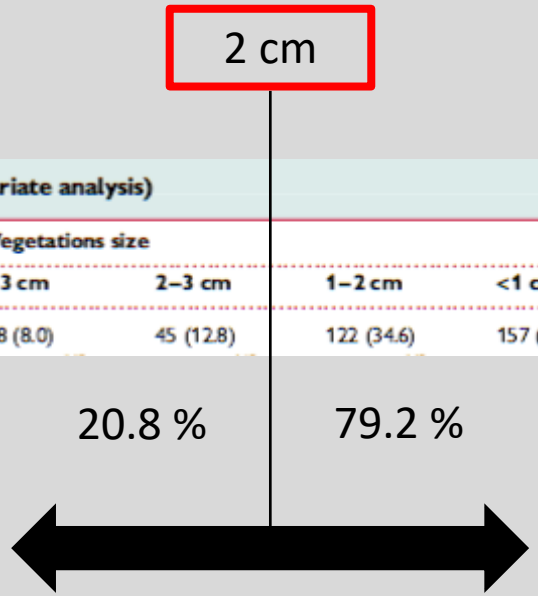
Anna Polewczyk[1,2*], Wojciech Jacheć[3], Andrzej Tomaszewski[4], Wojciech Brzozowski[4], Marek Czajkowski[5], Aneta Maria Polewczyk[6], Marianna Janion[1,2], and Andrzej Kutarski[4]

[1]Department of Medicine and Health Sciences Kielce, The Jan Kochanowski University, Kielce, Poland; [2]Second Department of Cardiology, Swietokrzyskie Cardiology Center, Grunwaldzka St. 45, 25-736 Kielce, Poland; [3]Second Department of Cardiology, Silesian Medical University, Zabrze, Poland; [4]Department of Cardiology, Medical University, Lublin, Poland; [5]Department of Cardiac Surgery, Medical University, Lublin, Poland; and [6]First Department of Pediatrics, District Hospital, Kielce, Poland

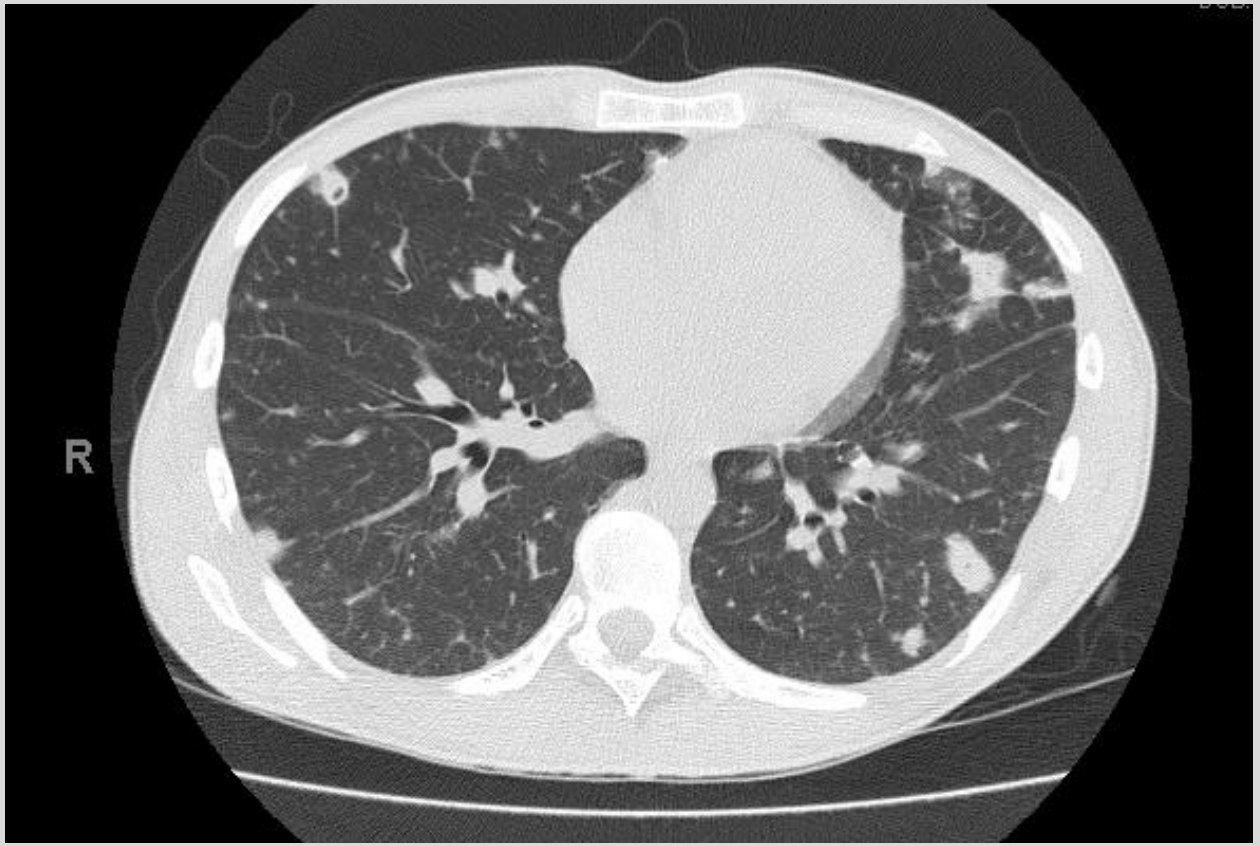
Table I Risk factors for developing ILVs including the giant, large, modest-sized, and small ones (univariate analysis)

Variable	Vegetations		Significant coefficient	Odds ratio [95%CI], *P*-value	Vegetations size			
	Absence	Presence			>3 cm	2–3 cm	1–2 cm	<1 cm
Number of patients (%)	148 (29.6)	352 (71.4)			28 (8.0)	45 (12.8)	122 (34.6)	157 (44.6)

Europace
doi:10.1093/europace/euw121



Septic pulmonary embolization after transvenous extraction...



...as potential cause for high longterm mortality...!

VEGECTOMY – a NEW-OLD Concept !

Some centers define any size of vegetations, even far less than 10 mm, as an indication for cardiopulmonary bypass, because of the risk of spreading septic emboli and a possible underestimation by echocardiography [4].

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

Daniele Camboni, MD,* Christian G. Wollmann, MD,* Andreas Löher, MD, Rainer Gradaus, MD, Hans Heinrich Scheld, MD, and Christof Schmid, MD

Departments of Thoracic and Cardiovascular Surgery, and Cardiology and Angiology, University Hospital, Muenster, Germany

(Ann Thorac Surg 2008;85:50–5)

SEPTIC EMBOLISM

CIED - LEAD MANAGEMENT

Risk Factors for Repeat Infection and Mortality After Extraction of Infected Cardiovascular Implantable Electronic Devices

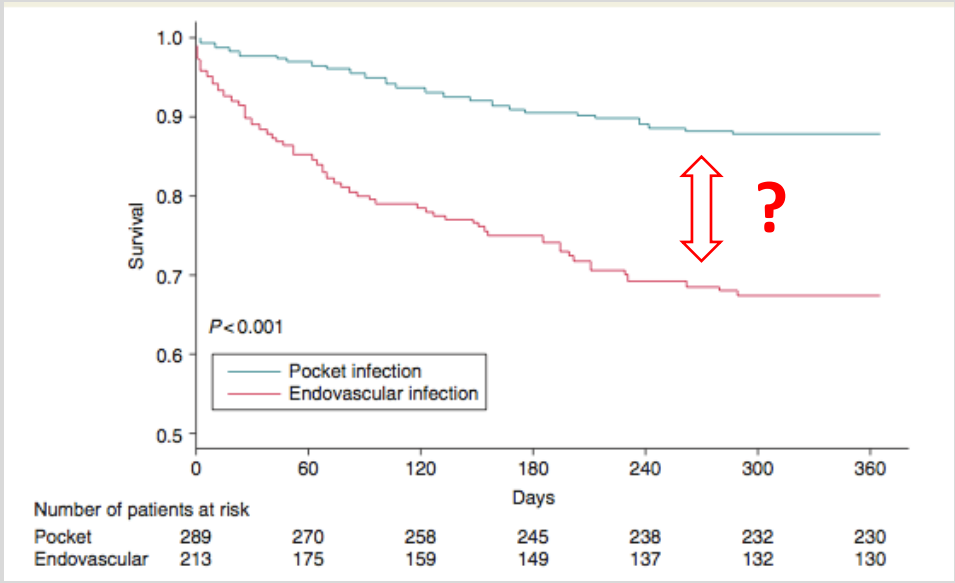
Ryohsuke Narui, MD, PhD, Ikutaro Nakajima, MD, PhD, Caleb Norton, MD, Benjamin B. Holmes, MD, Zachary T. Yoneda, MD, Neil Phillips, MD, Andrew Schaffer, BA, Alex Tinianow, BA, Asad A. Aboud, MD, William G. Stevenson, MD, Travis D. Richardson, MD, Christopher R. Ellis, MD, George H. Crossley III, MD, Jay A. Montgomery, MD

Multivariable Predictors of Mortality

	HR	95% CI	*P* Value
Chronic kidney disease	1.694	1.178 - 2.437	0.004
Congestive heart failure	1.479	1.001 - 2.187	0.049
Staphylococcus aureus infection	1.419	1.003 - 2.007	0.048
Septic embolism	2.674	1.546 - 4.624	<0.001
Major procedural complication	8.245	3.874 - 17.550	<0.001

(J Am Coll Cardiol EP 2021;7:1182-1192)

SEPTIC EMBOLISATION



Tarakji et al. Europace 2014

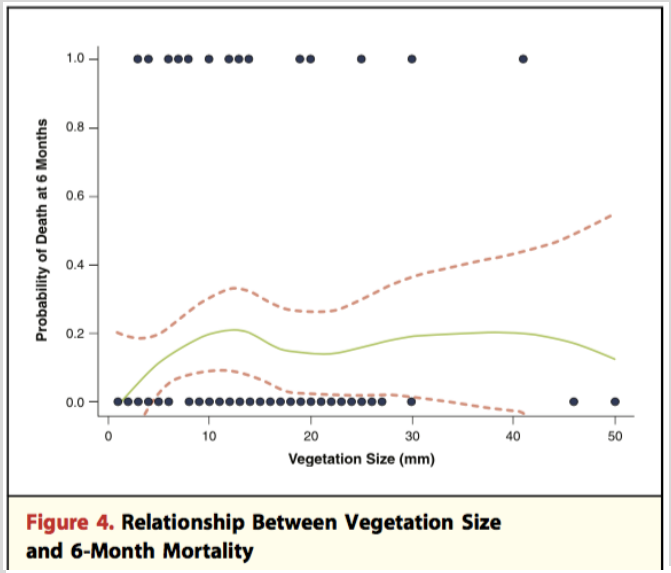


Figure 4. Relationship Between Vegetation Size and 6-Month Mortality

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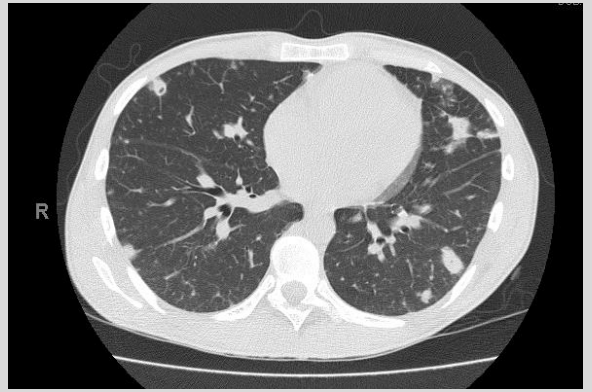
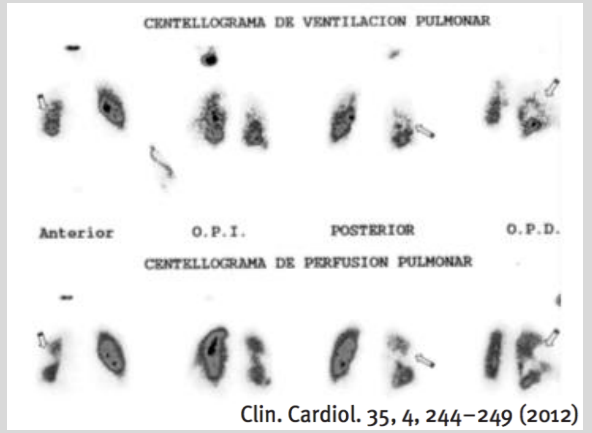
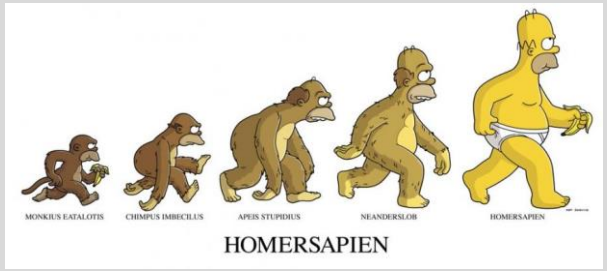
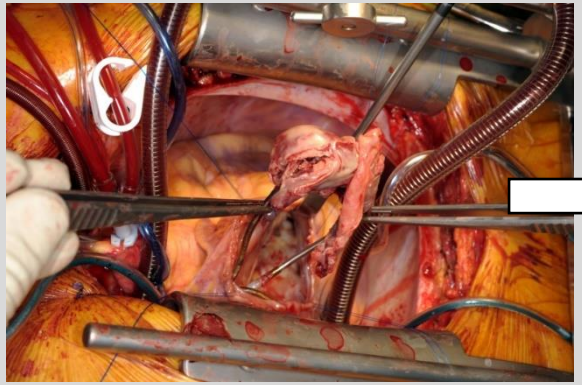


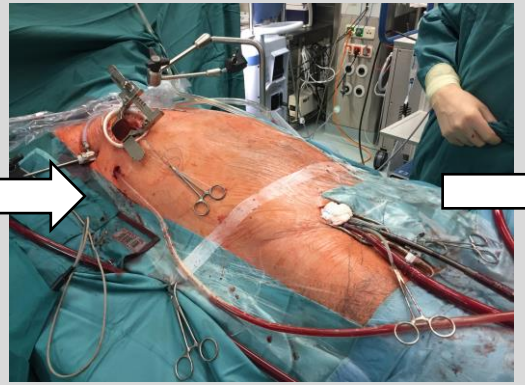


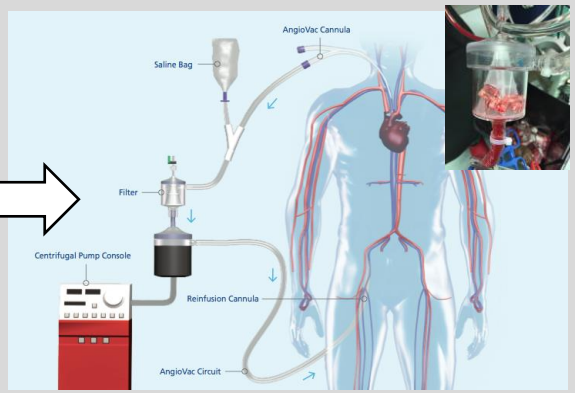
Clin. Cardiol. 35, 4, 244–249 (2012)

Systemic CIED infection with large lead vegetations

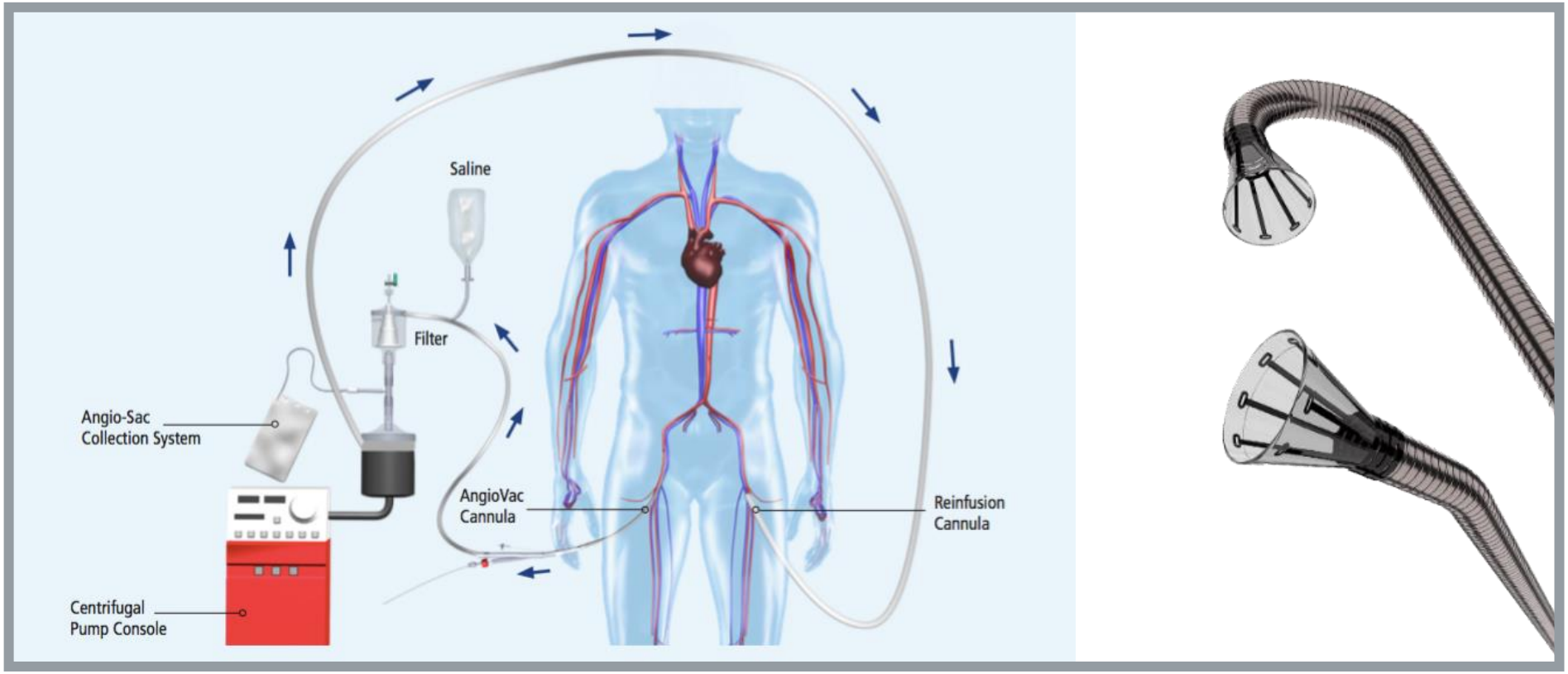








Percutaneous aspiration using the ANGIOVAC system



Veno-venous extracorporeal circulation with in-line filter

Systemic CIED infection with large lead vegetations

2020 EHRA International consensus document – CIED infection

ESC European Society of Cardiology
Europace (2020) 22, 515–516
doi:10.1093/europace/euz246

EHRA CONSENSUS PAPER

European Heart Rhythm Association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections—endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), the Latin American Heart Rhythm Society (LAHRS), International Society for Cardiovascular Infectious Diseases (ISCVID) and the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS)

Carina Blomström-Lundqvist (Chair)[1]*, Vassil Traykov (Co-Chair)[2], Paola Anna Erba[3], Haran Burri[4], Jens Cosedis Nielsen[5], Maria Grazia Bongiorni[6], Jeanne Poole (HRS representative)[7], Giuseppe Boriani[8], Roberto Costa (LAHRS representative)[9], Jean-Claude Deharo[10], Laurence M. Epstein (HRS representative)[11], Laszlo Saghy[12], Ulrika Snygg-Martin (ESCMID and ISCVID representative)[13], Christoph Starck (EACTS representative)[14], Carlo Tascini (ESCMID representative)[15], and Neil Strathmore (APHRS representative)[16]

Table 8 Recommendations for device and lead removal

Consensus statement	Statement class	Scientific evidence coding	References
In patients with definite CIED infection (systemic and local), complete device removal is recommended (including abandoned leads, epicardial leads, and lead fragments)		O	81,102,104
After diagnosis of CIED infection, the device removal procedure should be performed without unnecessary delay (ideally within 3 days)		O	104
The recommended technique for device system removal is percutaneous, transvenous extraction technique. Epicardial leads require surgical removal		O	105
In patients with systemic infection and lead vegetations of approximately >20 mm, percutaneous aspiration of vegetations prior to and during transvenous lead extraction or alternatively surgical extraction may be considered		O	105–107

Transcatheter aspiration of large pacemaker and implantable cardioverter-defibrillator lead vegetations facilitating safe transvenous lead extraction

Christoph T. Starck [1,2,3*†], Raymond H.M. Schaerf[4,5*†], Alexander Breitenstein [6], Sasan Najibi[4], John Conrad[4], Joseph Berendt[4], Fardad Esmailian[5], Jürgen Eulert-Grehn [1,2], Thomas Dreizler[1], and Volkmar Falk [1,2,7]

67.3 % staphylococci

3.07 cm

Mean vegetation size

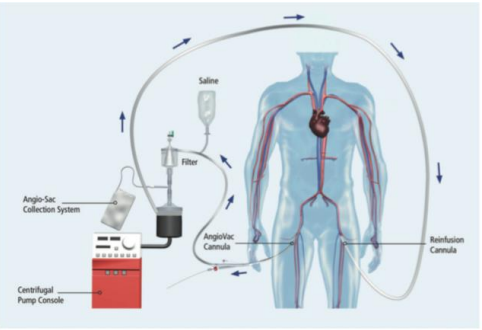


Table I Baseline characteristics

Number of patients	101
Mean age (years)	68.2 (30–92)
Gender	
Male	71 (70.3%)
Female	30 (29.7%)
Diabetes mellitus	29 (28.7%)
Chronic kidney disease	41 (40.6%)
Bacteria	
Methicillin-sensible *Staphylococcus aureus*	22 (21.7%)
Methicillin-resistant *Staphylococcus aureus*	9 (8.9%)
Staphylococcus epidermidis	25 (24.8%)
Other *Staphylococcus*	12 (11.9%)
Enterococcus faecium	4 (4.0%)
Escherichia coli	1 (1.0%)
Streptococcus	9 (8.9%)
Other bacteria	12 (11.9%)
Culture negative	7 (6.9%)

Number of targeted leads	247
Mean lead implant duration (months)	81.7 (1–254)
Number of targeted leads per patient	2.4 ± 1.2
Lead characteristics	
Pacemaker leads	170 (68.8%)
ICD leads (single vs. dual coil)	77 (31.2%)
	(28 vs. 49)
Active fixation	180 (72.9%)
Passive fixation	67 (27.1%)
Right atrial leads	80 (32.4%)
Right ventricular leads	132 (53.4%)
Left ventricular leads	35 (14.2%)
Mean lead vegetation size (mm) (preoperative TOE)	30.7 ± 13.5

Starck & Schaerf et al. Europace 2020

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94.0% complete procedural success

3.0% major complications

3.0% 30-day mortality

Table 2 Procedural data and outcomes

Configuration extracorporeal circuit	
Veno-venous	101 (100%)
Femoro-femoral	98 (97.0%)
Right internal jugular-femoral	3 (3.0%)
Mean heparin dose per patient (IU)	17 296 (3000–40 000)
Mean intraoperative ACT (s)	379.8 (172–917)
Mean extracorporeal circuit perfusion time (min)	30.2 ± 18.3
Outcome percutaneous aspiration procedure	
Complete procedural success	95 (94.0%)
Partial success	5 (5.0%)
Failure	1 (1.0%)
Major complications (device related)	3 (3.0%)
Extraction devices	
No extraction tools used	38 (15.4%)
Locking stylet	158 (64.0%)
Compression coil	149 (60.3%)
Polypropylene extraction sheath	3 (1.2%)
Powered rotational extraction sheath	140 (56.7%)
Evolution RL (Cook Medical, USA)	139 (56.3%)
Tightrail (Spectranetics, USA)	1 (0.4%)
Laser sheath (Spectranetics, USA)	14 (5.7%)
Femoral/internal jugular snare	13 (5.3%)
Outcome TLE procedure	
Complete procedural success (leads)	245 (99.2%)
Clinical success (leads)	247 (100%)
TLE related major complications (patients)	2 (2.0%) (2 TLE related high grade TR)
Mortality	
30-day mortality	3 (3.0%)

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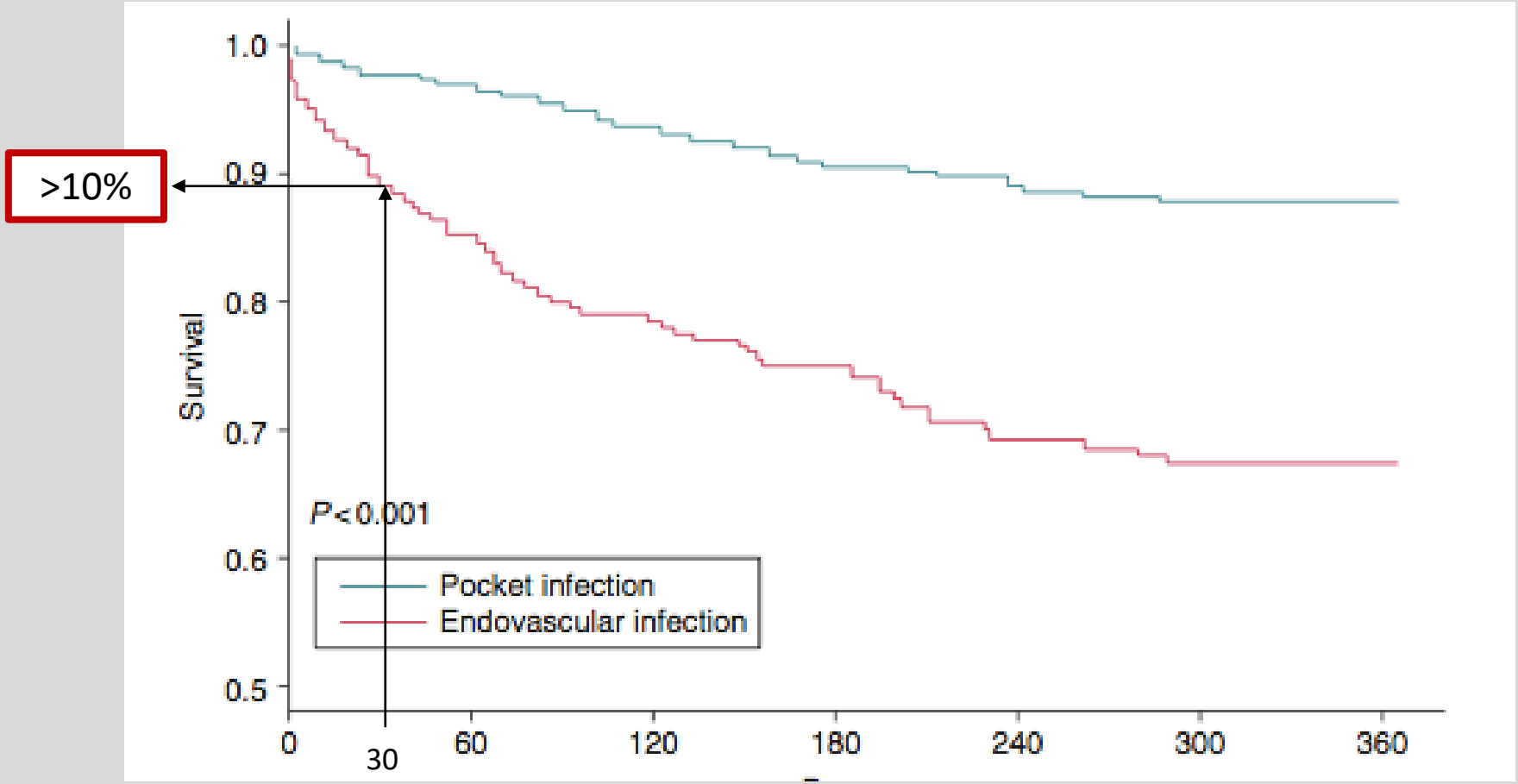
30-day survival in CIED infections

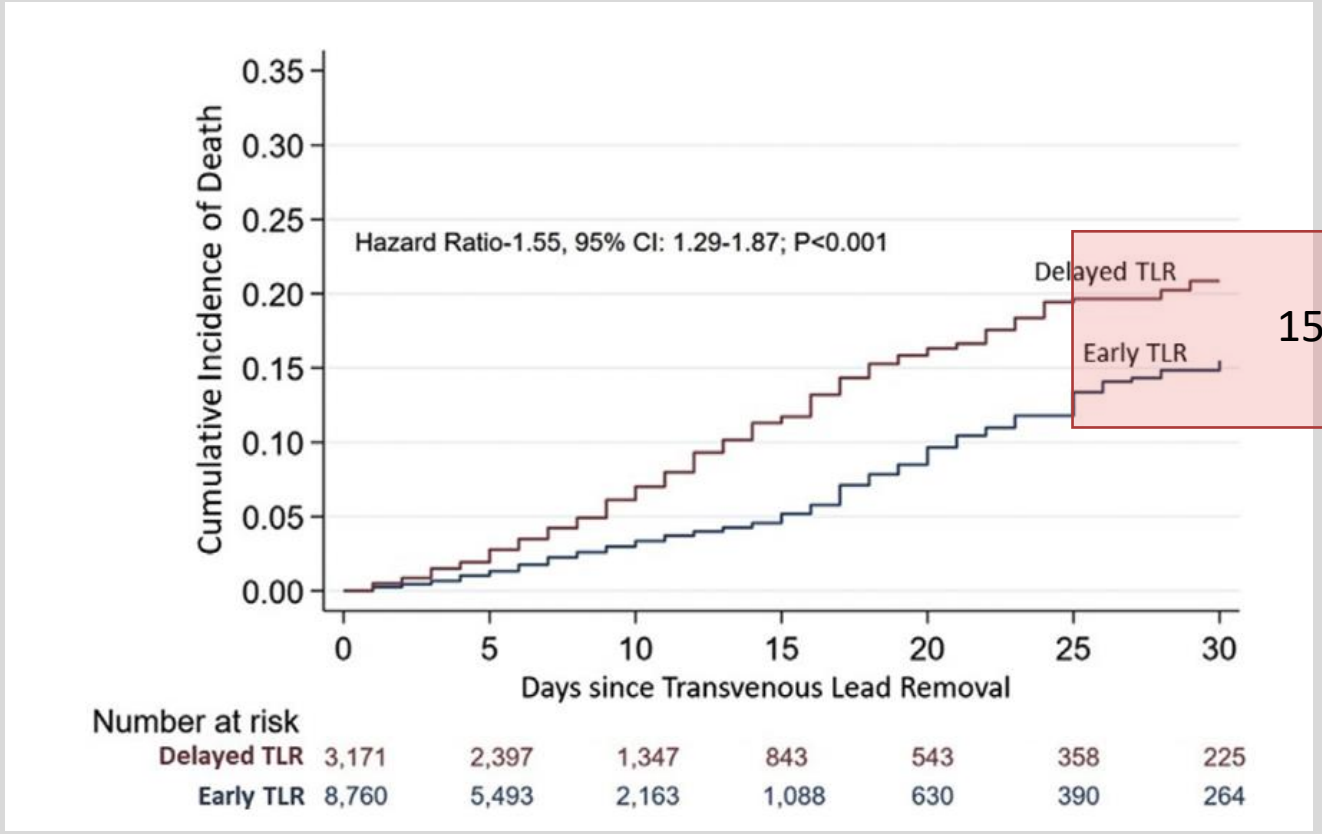


Tarakji et al. Europace 2014

30-day survival in CIED infections

Impact of timing of transvenous lead removal on outcomes in infected cardiac implantable electronic devices

Justin Z. Lee, MD,[*1] Monil Majmundar, MD,[†‡1] Ashish Kumar, MD,[‡§] Samarthkumar Thakkar, MD,[‖] Harsh P. Patel, MD,[¶] Dan Sorajja, MD, FHRS,[*] Arturo M. Valverde, MD, FHRS,[*] Ankur Kalra, MD,[‡#] Yong-Mei Cha, MD, FHRS,[**] Siva K. Mulpuru, MD, FHRS,[**] Samuel J. Asirvatham, MD, FHRS,[**] Christopher V. Desimone, MD, PhD, FHRS,[**] Abhishek J. Deshmukh, MBBS, FHRS[**]



15-20%

(Heart Rhythm 2022;19:768–775)

PAS – effect on survival

Figure 2. Kaplan Meier curve for the complete cohort stratified whether treated with PAS (vegetations >10mm)- or without PAS (vegetations <10mm). Below, a table with the patients at risk according to the time intervals of the Kaplan Meier curve.

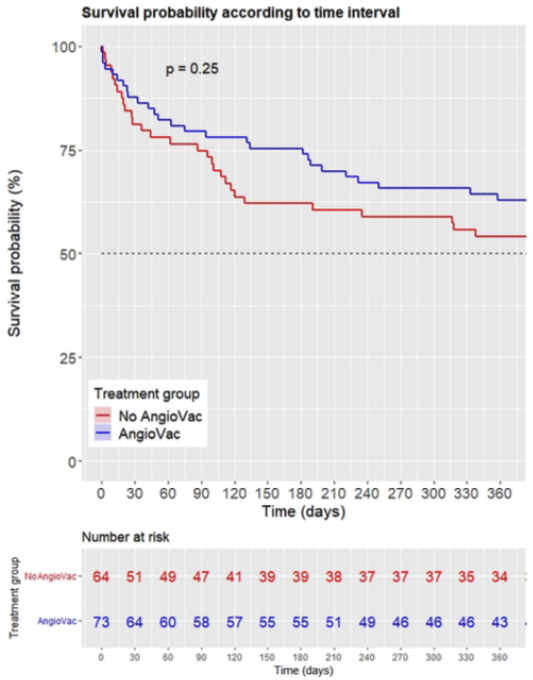
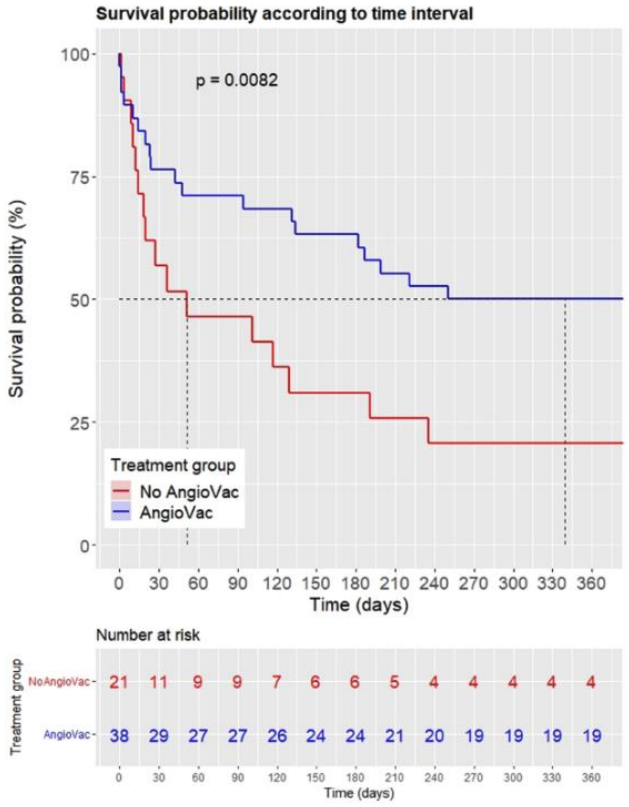


Figure 3. Kaplan Meier curve for the patients with acute sepsis at the time of intervention stratified whether treated with PAS (vegetations >10mm)- or without PAS (vegetations <10mm). Below, a table with the patients at risk according to the time intervals of the Kaplan Meier curve.



	Total cohort
Procedure characteristics: PAS (n=72)	
Aspiration cannula in right common femoral vein	65 (90.3%)
Aspiration cannula in right common jugular vein	6 (85.7%)
Heparin Bolus (IU)	12639 (±11520)
ACT after bolus (sec)	311 (±95)
Radiation (cGy*cm²)	2786 (±2848)
Procedure characteristics: TLE (n=137)	
Number of leads	277
Number of leads/patient	2,02 (±0,9)
Lead dwell time	74,4 (±60,7)
PM leads	183 (66%)
ICD leads	94 (33,9%)
Single coil leads	63 (22,7%)
Dual coil leads	31 (11,2%)
CRT-/Sinus coronarius leads	36 (13%)
RA leads	84 (30,3%)
RV leads	157 (56,7%)
Active fixation	190 (68,6%)
Passive fixation	83 (30%)
Left implantation side	104 (37,5%)
Right implantation side	35 (12,6%)
Received epicardial PM lead	22 (16%)
Received semi-permanent PM lead	7 (5,1%)

Heck & Starck et al. 2023 submitted & under review

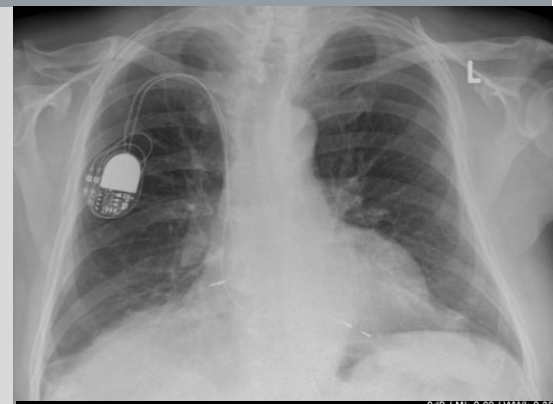
CASE-VIDEO

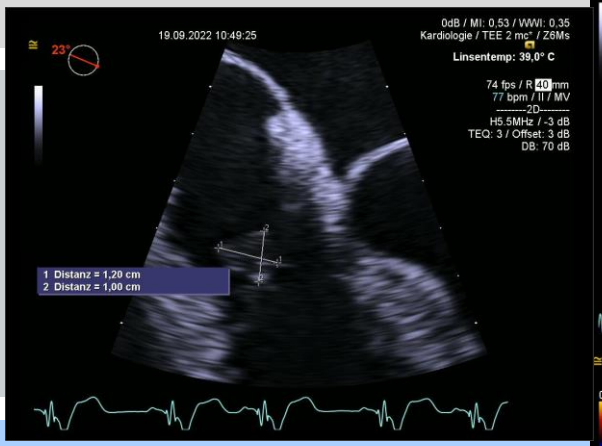
Patient history

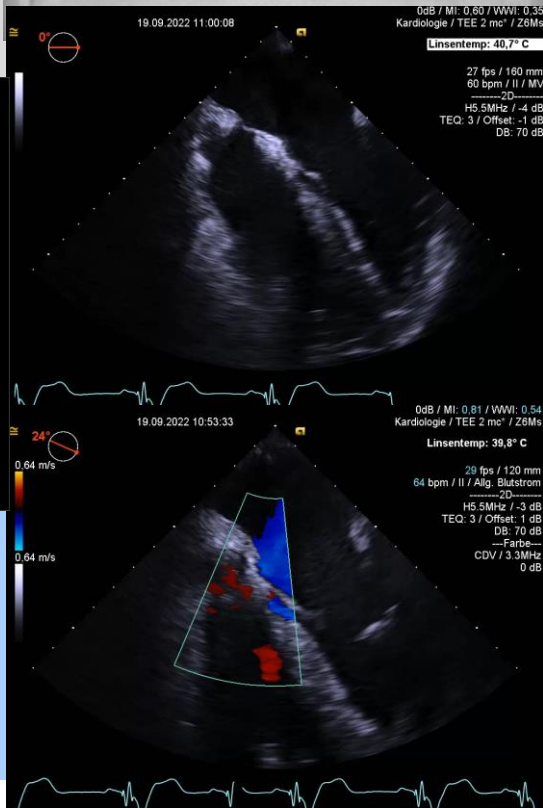
HISTORY

- 86 yo male patient
- St.p. dual chamber pacemaker implantation RIGHT side due to third degree AV-block - 7 YEARS ago
- 100% pacemaker dependent
- Chronic renal failure
- Diabetes with diabetic foot syndrom

EUROSCORE II: 31.54%







CURRENT PROBLEM

- Tricuspid valve endocarditis with moderate regurgitation
- MSSA sepsis
- Acute on chronic renal failure

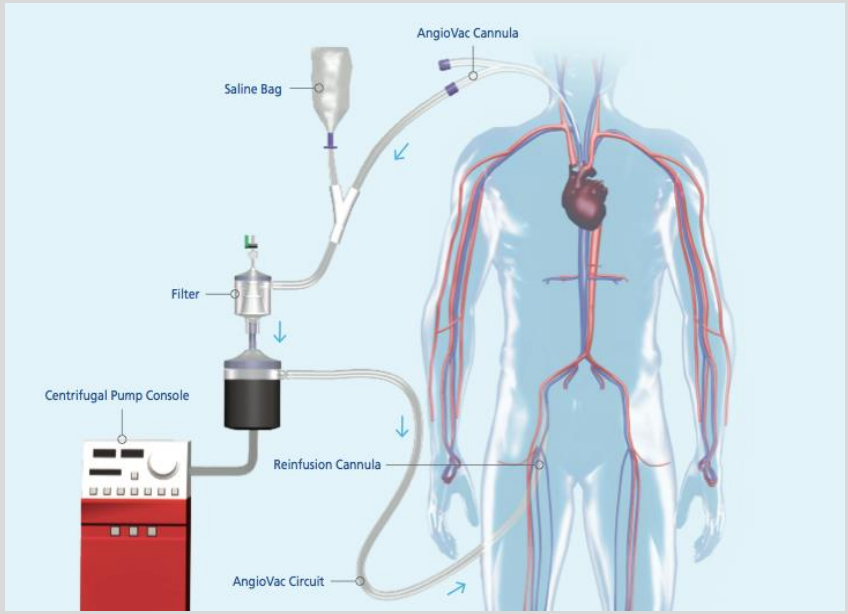
PLAN

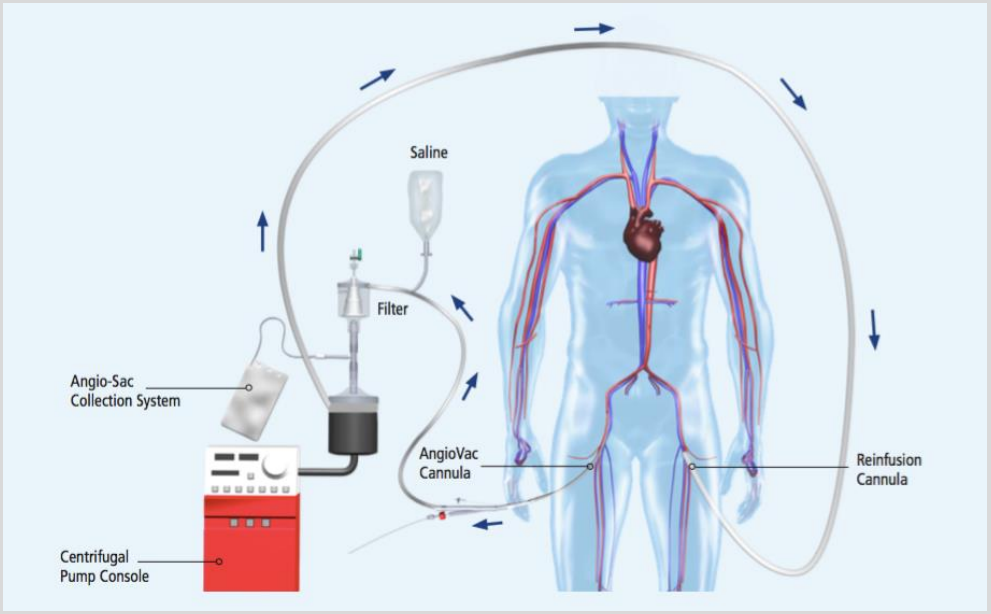
1. Percutaneous aspiration of TV vegetation
2. Dual chamber pacemaker explant
3. Implantation epicardial pacemaker

Percutaneous aspiration of tricuspid valve vegetations in endocarditis

Christoph Starck and Julius Kaemmel - German Heart Center Berlin

Percutaneous aspiration using the ANGIOVAC system





IJ – FEM – Configuration:

Right IJ vein: AngioVac Cannula (Aspiration)

Femoral vein: Reinfusion Cannula

FEM – FEM – Configuration:

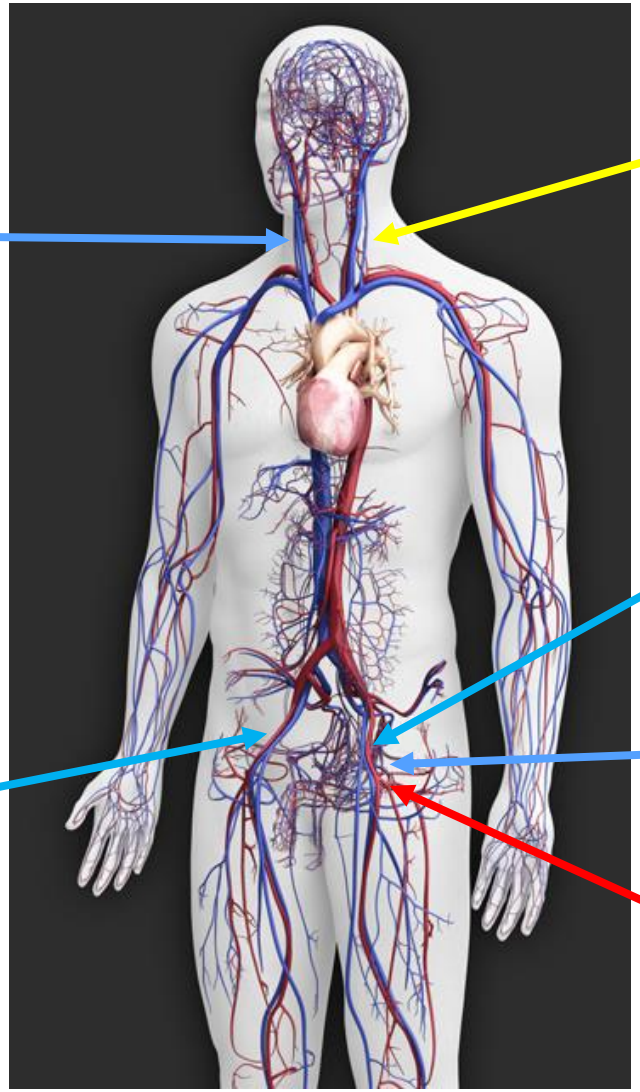
RIGHT femoral vein: AngioVac Cannula (Aspiration)

LEFT femoral vein: Reinfusion Cannula

Strategic Case Planning (Angiovac FEM-FEM configuration)

Right IJ-V (working port or alternate ANGIOVAC access):
6-8F sheath
(venography, snare, Cleaner, etc.)
OR exchange to
26F Gore Dry Seal sheath
(Alternate ANGIOVAC cannula access)

Right FEM-V:
26F Gore Dry Seal sheath
(ANGIOVAC cannula access)



Left IJ-V:
Central venous line + 9F sheath
(Anesthesia)

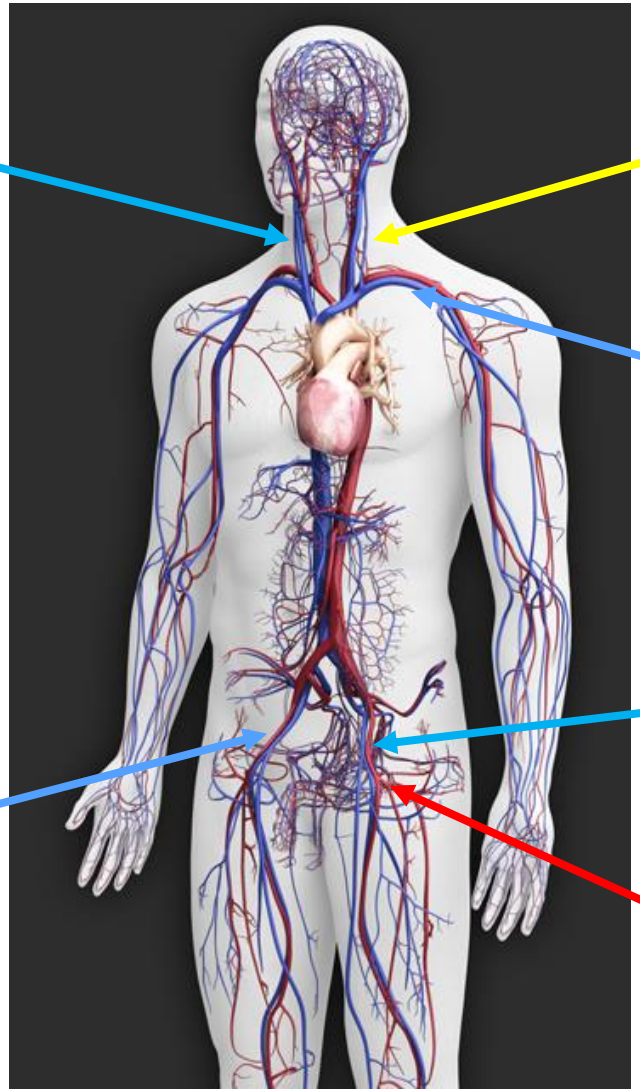
Left FEM-V:
16-18F Reinfusion cannula
(ANGIOVAC Reinfusion)

Left FEM-V (working port):
6-8F sheath
(Snares, Cleaner, etc.)

Left FEM-A:
5F sheath
(Emergency arterial access for ECC-support) - *OPTIONAL*

Strategic Case Planning (Angiovac RIJ-FEM configuration)

Right IJ-V:
26F Gore Dry Seal sheath
(ANGIOVAC cannula access)



Left IJ-V:
Central venous line + 9F sheath
(Anesthesia)

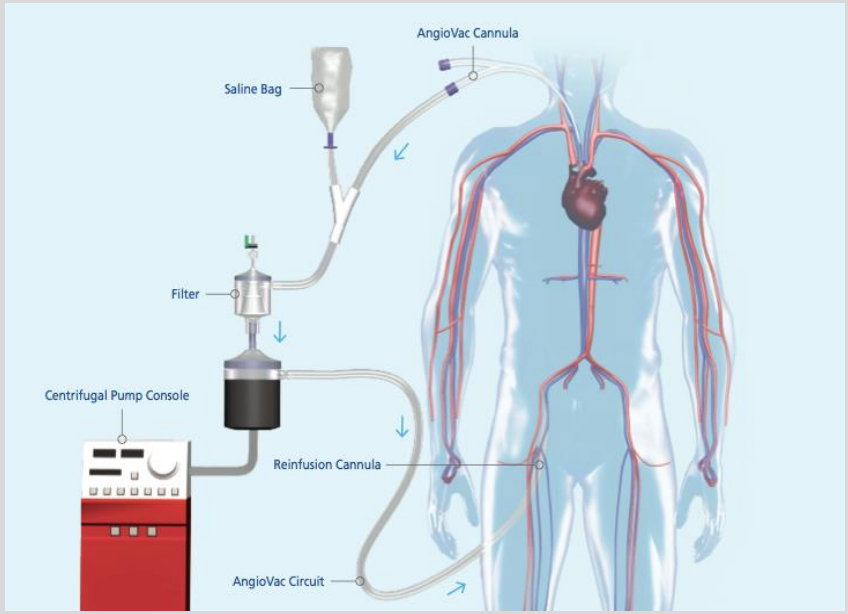
Left SCL-V (working port):
Long 8-10F sheath + snare
(e.g. IVC filter removal)

Right FEM-V (working port or alternate ANGIOVAC access):
6-8F sheath
(venography, snares, Cleaner, etc.)
OR
26F Gore Dry Seal sheath
(Alternate ANGIOVAC cannula access)

Left FEM-V:
16-18F Reinfusion cannula
(ANGIOVAC Reinfusion cannula)

Left FEM-A:
5F sheath
(Emergency arterial access for ECC-support) - *OPTIONAL*

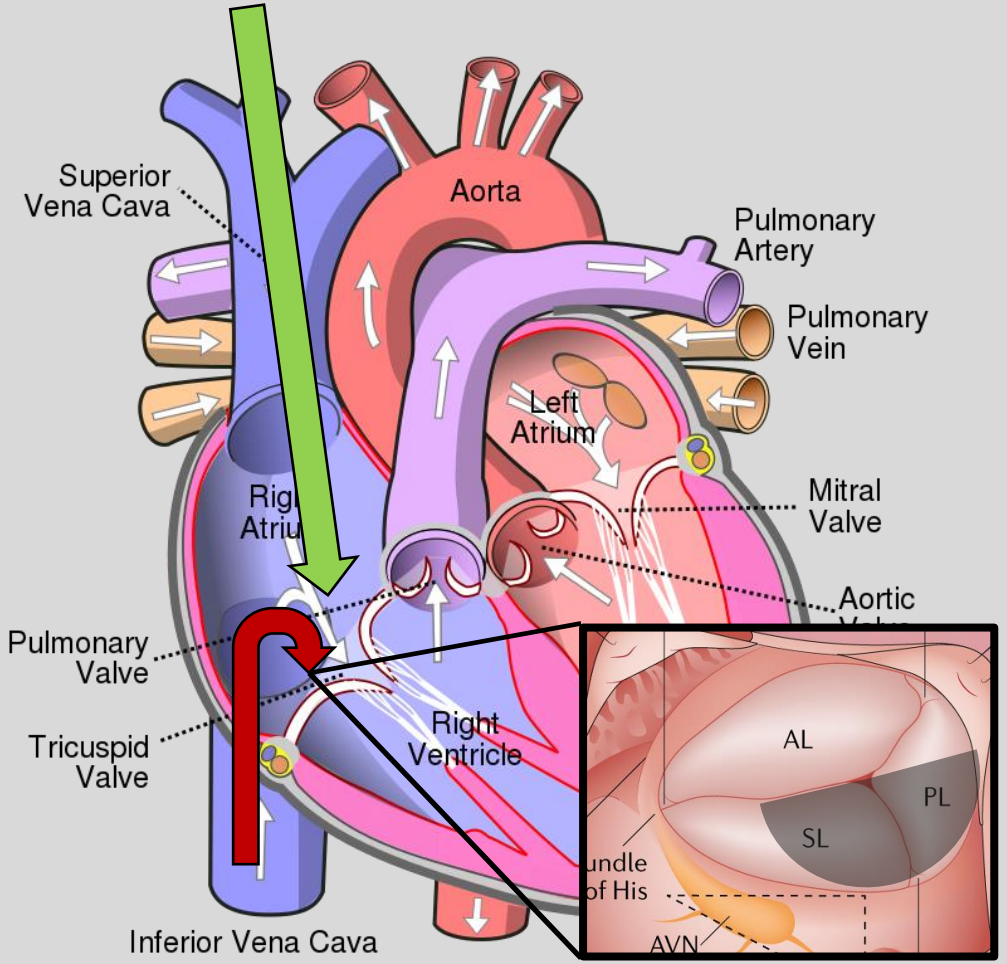
TV-Vegetations - Percutaneous aspiration using the ANGIOVAC system



IJ – FEM – Configuration:

Right IJ vein: AngioVac Cannula (Aspiration)

Femoral vein: Reinfusion Cannula



Angiovac in tricuspid valve endocarditis

Original Manuscripts

Clinical Efficacy of Percutaneous Vegetectomy in Tricuspid and Right-Heart Indwelling Device Infective Endocarditis

Angiology
2022, Vol. 0(0) 1–8

DOI: 10.1177/00033197221121009
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Joshua Scantland, MD[1], Justin Hendrix, MD[2], Adam Schmitz, MD[2], Thomas Casciani, MD[1], and Sabah Butty, MD[1]

Metrics measured	Tricuspid IE (N = 24)	Indwelling-device vegetation (N = 8)	All Groups (N = 32)	*P*-Value
Age (years)	34.8 ±10.7	54.8 ± 15.5	41.5 ± 16.5	.002
Length of hospital stay (days)	28.8 ± 16.2	27.1 ± 22.1	28.0 ± 17.4	.86
Duration of bacteremia (days)	10.1 ± 9.4	7.50 ± 3.4	8.80 ± 8.6	.386
Smoking (yes)	75.0% (n = 18)	62.5% (n = 5)	71.9% (n = 23)	.405
IV drug use (yes)	91.7% (n = 22)	12.5% (n = 1)	71.9% (n = 23)	.567
Sepsis (Yes)	62.5% (n = 15)	75.0% (n = 6)	65.6% (n = 21)	.175
Vegetation size by greatest dimension (cm)	2.4 ± 0.8	1.75 ± 0.7	2.3 ± 0.8	.041
Fluoroscopy time (min)	8.6 ± 7.2	17.4 ± 8.2	11.0 ± 8.4	.028
Procedure time (min)	101.5 ± 36.9	125.4 ± 43.8	107.7 ± 40.2	.221
Percentage of debulking (%)	86.1 ± 12.2	78.4 ± 30.3	83.6 ± 19.1	.433
≥ 70% debulked	21 (87.5%)	8 (100%)	29 (90.6%)	.532
≥ 90% debulked	5 (20.8%)	3 (37.5%)	8 (25.0%)	.455
Histological confirmation of IE	83.3% (n = 20)	87.5% (n = 7)	84.4% (n = 27)	.492
Minor duke criteria utilized	16.7% (n = 4)	12.5% (n = 1)	15.6 % (n = 5)	N/A
Subsequent surgical tricuspid valve repair (yes)	20.8% (n = 5)	N/A	15.6% (n = 5)	N/A

Angiovac in tricuspid valve endocarditis

Original Manuscripts

Clinical Efficacy of Percutaneous Vegetectomy in Tricuspid and Right-Heart Indwelling Device Infective Endocarditis

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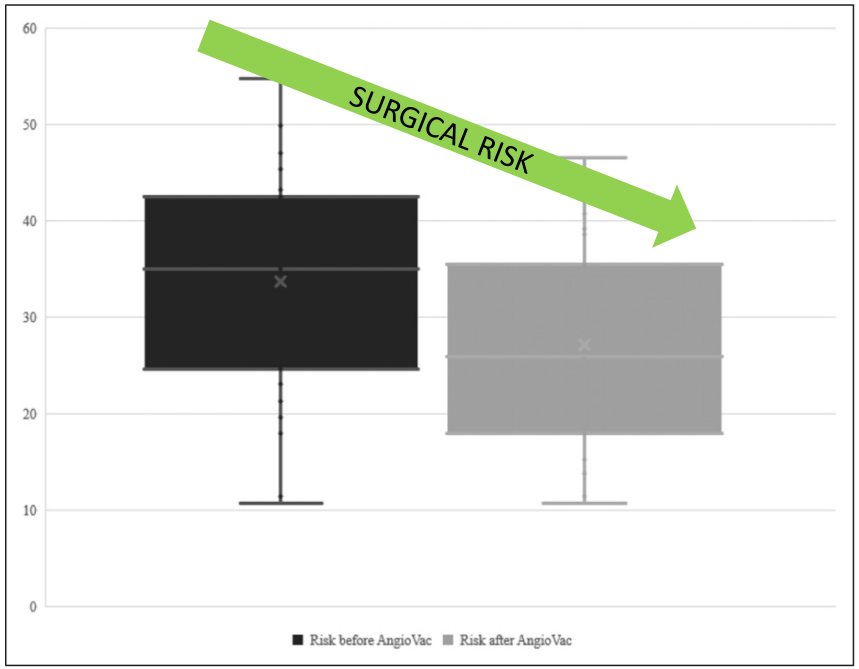
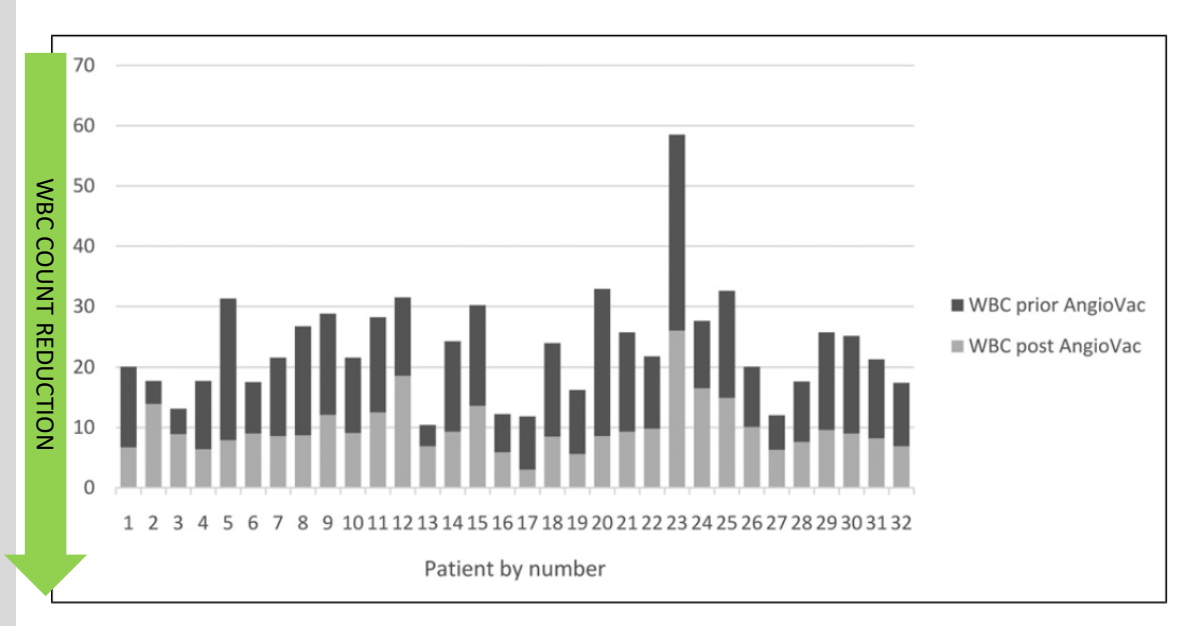




Angiovac in tricuspid valve endocarditis

1

Patient @ high risk for surgery

or

Patient inoperable

2

Concept of **debulking**

Reduction of bacterial load

3

Subsequent

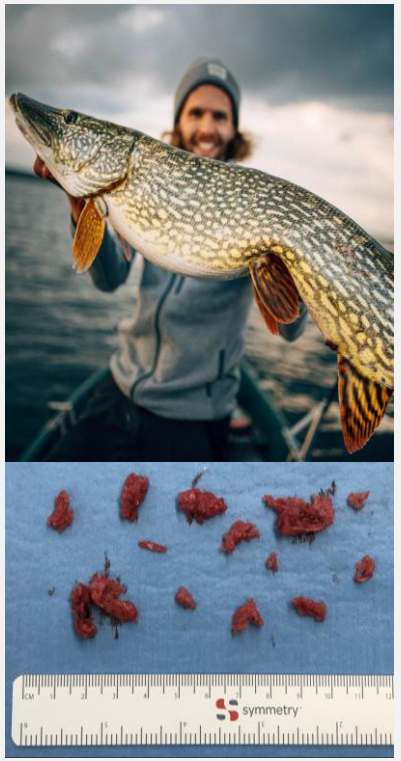
TV surgery?

TAKE HOME MESSAGES

- CIED infection + **large vegetations** → **PALV** + TLE + ABX
  - → avoid open extraction with sternotomy/thoracotomy
  - → safe & effective

- **Percutaneous aspiration of lead vegetations (PALV):**
  - *Concept of septic embolisation & infection control*
  - *Retrospective data suggests survival benefit versus „naked TLE“*
  - *Is the survival benefit real? - RCT needed →* ***REMOVE-IT***

ANGIOVAC vs FISHING



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DER CHARITÉ

Thank you.

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