



Division and Chair of Cardiology
EP Laboratory
Spedali Civili – University of Brescia



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Lead extraction in patients with endocardial vegetations: when and how?

Advances in Cardiac Arrhythmias and Great Innovations in
Cardiology

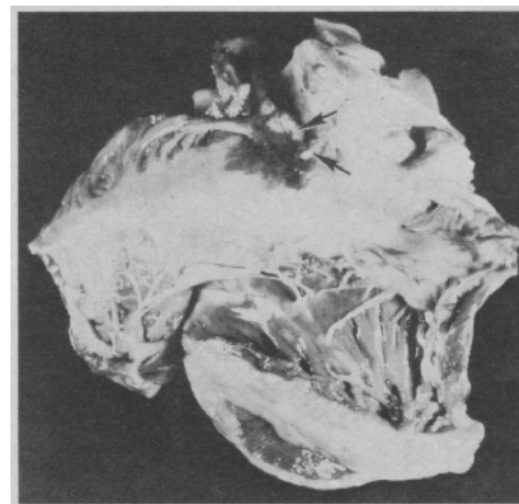
Turin October 23-25, 2014

Bacterial Endocarditis Associated With a Permanent Transvenous Cardiac Pacemaker

Ira S. Schwartz, MD, and Nafees Pervez, MD

To our knowledge, the first case of acute bacterial endocarditis in a patient with a permanent pervenous cardiac pacemaker occurred on the mural endocardium of the right atrium along the course of the pacemaker catheter. It is suggested that bacteremia, probably originating from a sacral decubitus ulcer, resulted in implantation of organisms on the damaged atrial endocardium with subsequent septic embolization.

JAMA, Nov 1, 1971 • Vol 218, No 5



1. Right side of heart showing endocarditis in right atrium beneath transe of superior vena cava. Bacterial vegetations are present

References

1. Spencer WJ, Miller HS Jr, Headley RN, et al: Initial experience with permanently implanted transvenous pacemakers. *Arch Intern Med* 122:291-297, 1968.
2. Wheelis RF, Cobb LA: Pathologic findings in perforation of the myocardium by a permanent endocardial electrode. *JAMA* 210:1278-1280, 1961.
3. Beregovich J, Fenig S: Complications with permanent transvenous pacemakers. *NY State J Med* 70:761-766, 1970.
4. Alegre JM, Yore R: Perforation of myocardium by pacemaker catheter. *JAMA* 212:481, 1970.
5. Prozan GB, Shipley RE, Madding GF, et al: Pulmonary thromboembolism in the presence of an endocardial pacing catheter. *JAMA* 206:1564-1565, 1968.
6. Robboy SJ, Hawthorne JW, Leinbach RC, et al: Autopsy findings with permanent pervenous pacemakers. *Circulation* 39:495-501, 1969.

It is reasonable to postulate that the areas of endocardium in contact with the pacemaker catheter, being subject to mechanical trauma, may serve as fertile soils for bacterial proliferation, ie, bacterial endocarditis.

BACKGROUND

- The **prevalence** of both permanent pacemakers (PPM) and implantable cardioverter defibrillators (ICD) utilizing transvenous leads is **increasing** as the population lives longer
- With the increased prevalence of these devices, physicians are faced with more patient **complications**, including PPM and ICD infections
- While this is an **unusual** complication with a reported **incidence of 0.2–16%¹** its associated **mortality** can reach 30–35%.²
- **Antimicrobial therapy** and **extraction** of the transvenous system is generally **required** for definitive treatment of lead-associated endocarditis or device infection.

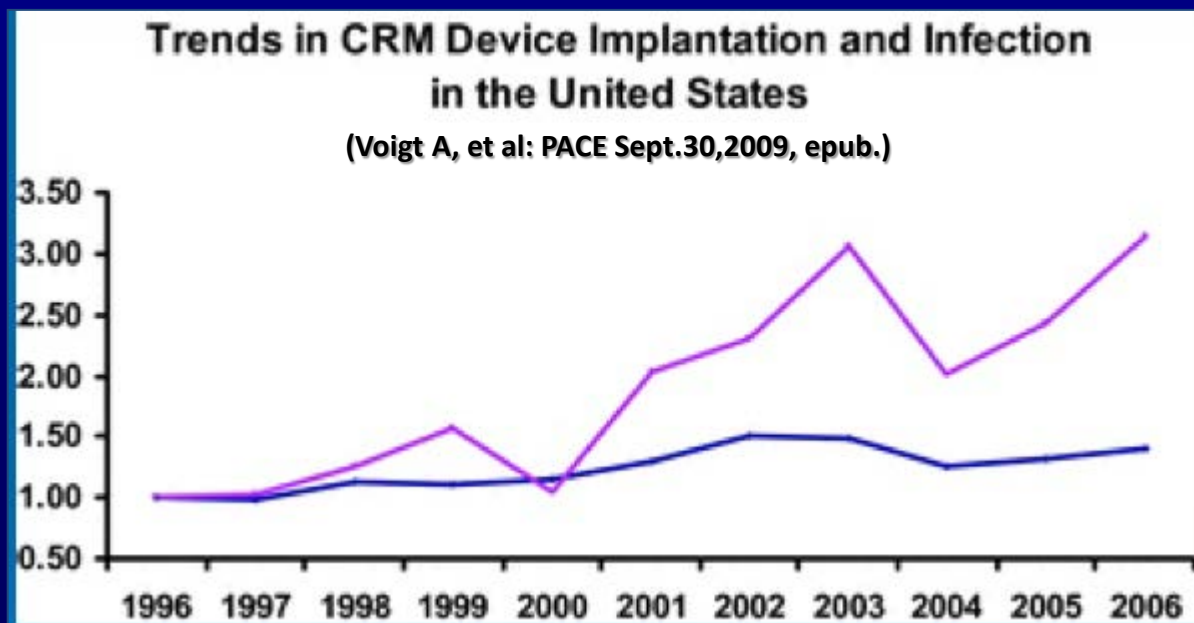
1-Wasson S et Coll, Echocardiography 2003;20:289–290.

2-Del Rio A, et Coll, Chest 2003; 124:1451–1459.

CIED INFECTIONS

Incidence ⁽¹⁾ :

- Medicare (USA) data : 1990-1999
 - Increasing use : + 42% ($P < 0.001$ for trend)
 - Increasing infections : + 124% ($P < 0.001$ for trend)



CIED INFECTIONS

- Reasons for disproportionate rise in CIED infections ?
 - Host related
 - Procedure related
 - Device related
 - Multifactorial

CLINICAL PRESENTATION

- Generator pocket infection
 - Most common
 - After implantation or manipulation
- Deeper infection
 - Leads
 - Endocarditis



Classification and definitions

Indications for echocardiography

Clinical suspicion of IE

Microbiological diagnosis

Modified Duke criteria for the diagnosis of IE (Adapted from Li & al)

MAJOR CRITERIA

Diagnosis of IE

Diagnosis of IE is definite
in the presence of

2 Major criteria

or

1 major and **3** minor criteria

or

5 minor criteria

Diagnosis of IE is possible
in the presence of

1 Major and **1** minor criteria

or

3 minor criteria

Blood culture

- Typical microorganism
Viridans streptococci
acquired

- Microorganism
At least 2
≥ 4 separate

- Single positive

Evidence

- Echocardiogram
- New valvular

- Predisposing

- Fever: ten

- Vascular

- Intracranial

- Immunologic

- Microbiologic

- evidence

Prosthetic
or
Intracardiac

Positive cultures

Clinical/echo
Suggest IE?

No

Yes

If initial TEE is

Reassess patient &
consider alternative diag

Adapted from Li Js et al., *Clin Infect Dis.* 200;30:633-638

www.escardio.org/guidelines

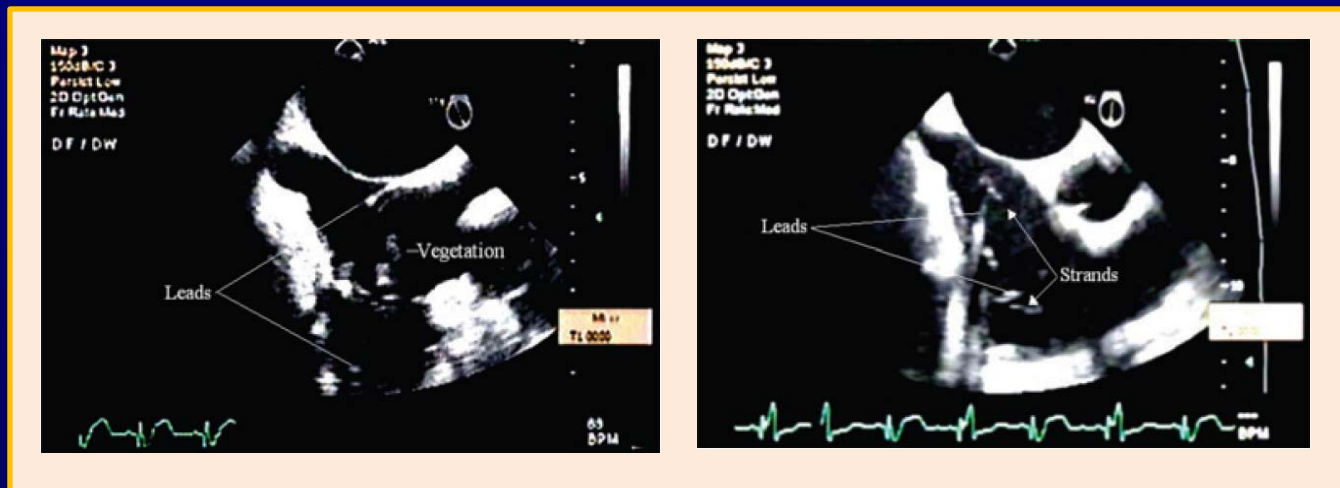
European Heart Journal (2009) 30:2369-2413

Incidence and Significance of Pacemaker and Implantable Cardioverter-Defibrillator Lead Masses Discovered during Transesophageal Echocardiography

BRIAN C. DOWNEY, M.D., WHITNEY E. JUSELIUS, M.D., NATESA G. PANDIAN, M.D.,
N. A. MARK ESTES, III, M.D., and MARK S. LINK, M.D.

From the Department of Medicine, Division of Cardiology, Tufts Medical Center, Boston, Massachusetts

Single center, retrospective study of **consecutive patients** (n =162) with PPM and ICD devices undergoing echo-**TEE** to determine the **prevalence of lead-associated masses**, as well as their **predictive** value in **diagnosing** pacemaker **endocarditis** or device **infection**.



	+TEE (26)	+TEE with + Device Infection	Vegetation	Strand	Both
Atrial fibrillation	4/68 (6%)	0/4 (0%)	0	4	0
Endocarditis	12/40 (8%)	7/12 (58%)	8	5	1
Valvular disease	2/25	0/2	0	2	0
Source of systemic embolus	3/14 (33%)	1/3 (0%)	2	1	0
LVAD	3/9	0/3	2	2	1
Other	2/21 (10%)	0/2 (0%)	1	1	0

- Lead-associated masses were found in 14% of patients.
- In 72% of patients, the mass did not prove to be secondary to infectious causes

Conclusion:

The masses attached to a device lead should be *interpreted* in the overall *clinical context* and, in the absence of concomitant evidence of endocarditis, *should not mandate device and lead removal.*

Lead vegetations in patients with local and systemic cardiac device infections: prevalence, risk factors, and therapeutic effects

Pier Giorgio Golzio*, Anna Laura Fanelli, Melissa Vinci, Elisa Pelissero, Mara Morello, Walter Grosso Marra, and Fiorenzo Gaita

136 pts infective indications:

- 39.2% chronic draining sinus
- 20.9% pocket infections
- 28.8% systemic infections/sepsis.

Lead vegetation prevalence on Echo TEE was 40.4%:

- 62.2% in systemic infection
- 21.9 in local infection
- 36.4% chronic draining sinus

TEE should be mandatory in all patients undergoing LE for infective indications.

BACKGROUND

- Two techniques can be used:
 - **surgical removal** : by thoracotomy and extracorporeal circulation
 - **percutaneous removal** : by traction or intravascular extraction techniques.
- the perceived **risk of embolic events** in the presence of large (10 mm) vegetations has been considered a relative **contraindication to transvenous removal** ¹⁻²
- Surgical **removal** of pacemaker leads has been **suggested** in this situation to **avoid** occurrence of **pulmonary embolization**.

1 -Klug D et al. Circulation 1997;95:2098–107.

2-Robbins MJ et al. Influence of vegetation.Am J Med 1986;80:165–71.

Management and Outcome of Permanent Pacemaker and Implantable Cardioverter-Defibrillator Infections

Muhammad R. Sohail, MD,* Daniel Z. Uslan, MD,* Akbar H. Khan, MD,‡ Paul A. Friedman, MD,† David L. Hayes, MD,† Walter R. Wilson, MD,* James M. Steckelberg, MD,* Sarah Stoner, MS,§ Larry M. Baddour, MD*

Rochester, Minnesota

Retrospective review 189 pts with CDI (138 PPM, 51 ICD): 90 % percutaneous / 10 % surgical

Clinical presentation	
Pocket infection	99 (52%)
Pocket infection with bacteremia	32 (17%)
Device-related endocarditis	44 (23%)
Bacteremia without localizing signs at pocket	21 (11%)
Generator or lead erosion	10 (5%)

- The diameter of vegetations ranged from 0.3 to 7.0 cm.

Result

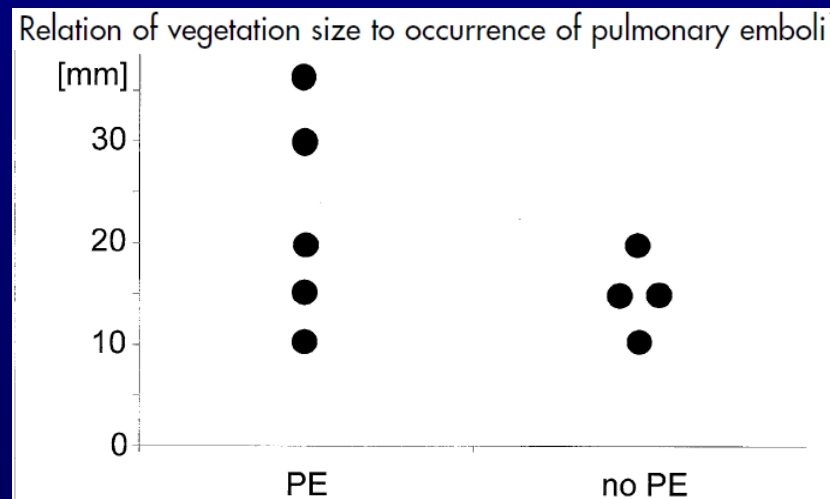
- No clinical manifestations of pulmonary embolism as a complication of percutaneous lead extraction
- Lead removal by cardiectomy has been advocated to prevent symptomatic pulmonary embolism but, as shown in the current case series, this approach can be complicated by serious adverse events. (5 pts suffered massive hemorrhages postoperatively, and 1 died)

Endocardial pacemaker or defibrillator leads with infected vegetations: A single-center experience and consequences of transvenous extraction

Hans K. Meier-Ewert, MD, Mary-Ellen Gray, PAC, and Roy M. John, MD, PhD *Burlington, Mass*

38 pts :

- Vegetations were detected in 9 patients (range 10 - 38 mm)
- 5 of 9 patients (55%) had evidence of pulmonary embolism.(Spiral TC/Scintigraphy)
- no difference in hospitalization or survival between those with or without pulmonary embolism



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

0.2-4 cm

Patients, n	984
Leads extracted, n	1,838
Patients infected, n (% of all patients)	480 (49)
Infected leads, n (% of all leads)	1,000 (54)
Infected patients with vegetation, n	100
Percent of total patients	10
Percent of infected patients	21
Infected leads from patients with vegetation, n	215
Percent extracted leads	12
Percent infected leads	22

- 2 pts : embolization of vegetation material, >2 cm before extraction).
- 1 pt had presumptive embolization of a vegetation measuring 1.2 cm after extraction

- Post-operative 30-day mortality was 10% (no deaths related directly to the procedure)

Conclusions :

percutaneous lead extraction techniques is safety in patients with intracardiac vegetations

Transvenous Pacemaker Lead Removal Is Safe and Effective Even in Large Vegetations: An Analysis of 53 Cases of Pacemaker Lead Endocarditis

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Transvenous lead extraction (T.L.E) : 30 pts (successful 96.7%).

Surgical lead extraction(S.L.E.): 23 pts (large vegetations with the risk of obstructing a main stem of the pulmonary artery)

	T.L.E	S.L.E	p
Pulm.Embolism	14.8 %	14.3 %	0.68
Vegetation size	1.78 ±0.6 cm	2.24± 1 cm	< 0,001
Perioperative mortality	0 %	5.7 %	

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

Transvenous Extraction of Pacemaker Leads in Infective Endocarditis With Vegetations >20 mm: Our Experience

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percutaneous removal of CIEDs in patients with IE with large vegetations.

Aim:

- *in-hospital* morbidity and mortality related to percutaneous removal of vegetations ≥ 20 mm.
- 8 cases with a follow-up period of 20 months.
- We removed 100% of leads in the study population.

Conclusions:

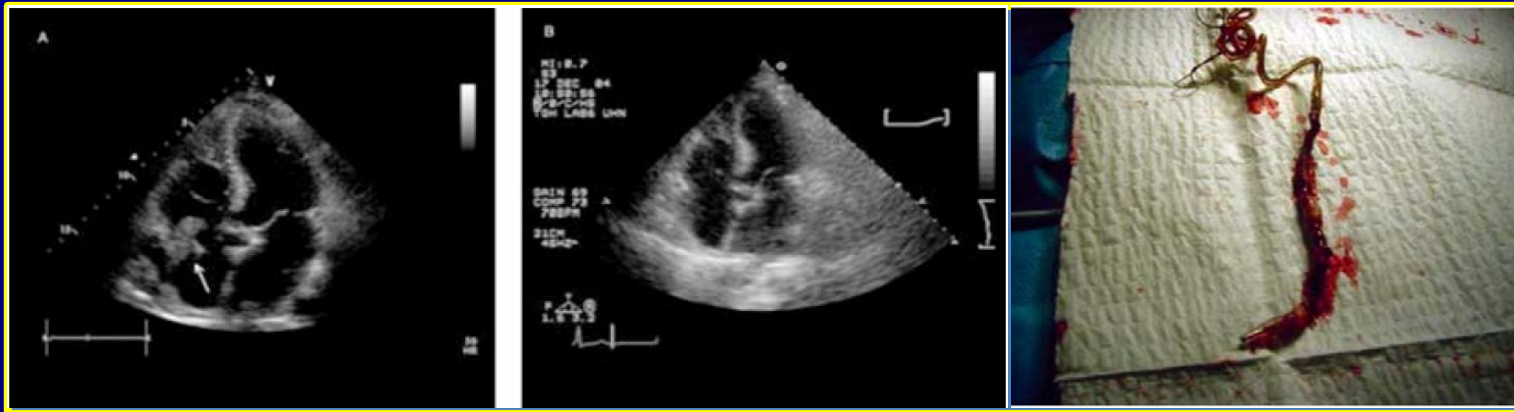
- *Transvenous extraction of pacing leads with larger vegetations is a feasible technique.*
- *There was a tendency toward symptomatic pulmonary embolism in patients with vegetations larger than 20 mm;*
- **morbidity and mortality were not influenced**

Successful Laser-Assisted Removal of an Infected ICD Lead with a Large Vegetation

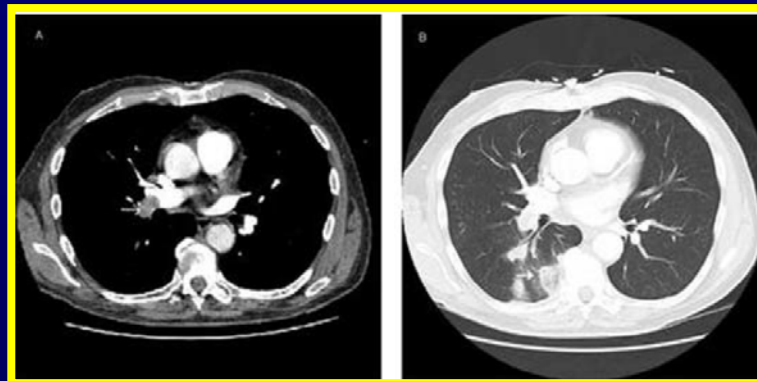
RAJNEESH CALTON,* DOULAS CAMERON,* ROBERT J. CUSIMANO,† NAEEM MERCHANT,‡ and VIJAY CHAUHAN*

From the *Division of Cardiology, †Division of Cardiothoracic Surgery, and ‡Department of Medical Imaging, University Health Network, Toronto, Canada

ICD lead with vegetation greater than 41×12.5 mm (512 mm²)



The resulting pulmonary embolus produced a 33×20 mm pulmonary infarction without hemodynamic or respiratory compromise



Risk Factors for Mortality in Patients With Cardiac Device-Related Infection

Timir S. Baman, MD; Sanjaya K. Gupta, MD; Javier A. Valle, MD; Elina Yamada, MD, FACC, FASE

- 210 patients with CDI -observational and retrospective analysis
- Prognostic significance of key **clinical** and **echo** variables at high-risk for mortality

Table 1. Unadjusted Hazard Ratios for 6-Month Mortality Associated With Age, Sex, and Treatment Group

	Total (n=210)	Survived (n=173)	Died (n=37)	HR	95% CI	P Value
Age, y	63±17	61±17	71±11	1.04	1.01–1.06	≤0.01
Male gender	138 (66)	112 (65)	26 (70)	1.56	2.91–3.45	0.28
Treatment option						
Medical management	23 (11)	15 (9)	8 (22)	1.00	...	(reference)
Percutaneous device removal	170 (81)	142 (82)	28 (76)	0.44	0.20–0.96	0.04
Cardiac surgical removal	17 (8)	16 (9)	1 (3)	0.15	0.02–1.19	0.07

Values are n (%) or mean±SD.

percutaneous removal was found to be significantly associated with better survival

Table 2. Adjusted Hazard Ratios for 6-Month Mortality Associated With Patient Characteristics and Controlling for Age, Sex, and Treatment Group

	Total (n=210)	Survived (n=173)	Died (n=37)	HR	95% CI	P Value
Type of device						
Pacemaker	126 (60)	103 (60)	23 (62)	1.00		(reference)
ICD	69 (33)	59 (34)	10 (27)	0.93	0.47–2.41	0.88
Biventricular PM/ICD	15 (7)	10 (6)	5 (14)	1.53	0.56–5.44	0.47
Previous device upgrade/replacement	38 (18)	34 (20)	4 (11)	1.37	0.48–3.94	0.56
Clinical variables						
Diabetes	57 (27)	45 (26)	12 (32)	1.59	0.78–3.22	0.20
Coronary artery disease	110 (52)	83 (48)	27 (73)	2.12	1.10–5.00	0.07
CABG	51 (24)	42 (24)	9 (24)	0.81	0.37–1.74	0.58
Hypertension	137 (65)	106 (61)	31 (84)	2.20	0.90–5.36	0.08
Abnormal creatinine >1.5 mg/dl	99 (47)	70 (40)	29 (78)	3.99	1.71–9.30	≤0.01
Positive blood culture	108 (51)	77 (45)	31 (84)	6.05	2.30–15.97	≤0.01
Positive device culture	147 (70)	120 (69)	27 (73)	1.52	0.62–3.75	0.37
Echocardiographic variables						
Lead vegetation visualized	48 (23)	37 (21)	11 (30)	1.47	0.69–3.15	0.32
Lead vegetation size						
Absent/not obtained	168 (80)	139 (81)	29 (78)	1.00	...	(reference)
1–10 mm	10 (5)	9 (5)	1 (3)	0.84	0.11–6.21	0.86
11–20 mm	19 (9)	13 (8)	6 (16)	2.05	0.81–5.23	0.13
≥21 mm	13 (6)	11 (6)	2 (5)	1.03	0.23–4.73	0.97

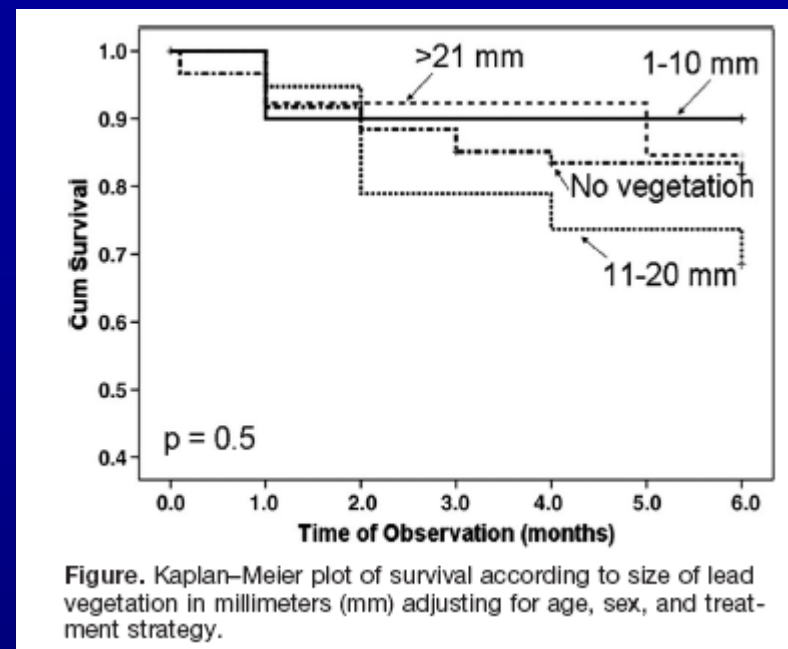
Table 2. Adjusted Hazard Ratios for 6-Month Mortality Associated With Patient Characteristics and Controlling for Age, Sex, and Treatment Group

	Total (n=210)	Survived (n=173)	Died (n=37)	HR	95% CI	P Value
Lead vegetation mobility						
Absent/not obtained	169 (80)	139 (80)	30 (81)	1.00	...	(reference)
Low	16 (8)	12 (7)	4 (11)	1.65	0.56–4.83	0.36
Moderate	13 (6)	12 (7)	1 (3)	0.37	0.05–2.74	0.33
Severe	12 (6)	9 (5)	3 (8)	2.04	0.54–7.67	0.29
Left ventricular dysfunction						
Normal	93 (44)	79 (46)	14 (38)	1.00	...	(reference)
Mild	14 (7)	13 (8)	1 (3)	0.43	0.06–3.33	0.42
Moderate	22 (10)	17 (10)	5 (14)	1.33	0.47–3.77	0.59
Severe	42 (20)	30 (17)	12 (32)	1.68	0.75–3.74	0.21
Abnormal right ventricular function	35 (17)	22 (13)	13 (35)	4.22	1.91–9.29	≤0.01
Moderate to severe tricuspid regurgitation	20 (10)	9 (5)	11 (30)	5.93	2.73–12.89	≤0.01
Right ventricular systolic pressure (RVSP)						
RVSP not obtained	69 (33)	60 (35)	9 (24)	1.00	...	(reference)
10–39 mm Hg	52 (25)	46 (27)	6 (16)	0.74	0.26–2.09	0.57
40–59 mm Hg	35 (17)	23 (13)	12 (32)	2.19	0.88–5.44	0.09
≥60 mm Hg	15 (7)	9 (5)	6 (16)	4.40	1.48–13.02	0.01
Aortic stenosis	7 (3)	5 (3)	2 (5)	0.86	0.45–1.63	0.63
Aortic insufficiency	9 (4)	7 (4)	2 (5)	1.07	0.56–2.02	0.85
Moderate to severe mitral regurgitation	31 (15)	19 (11)	12 (32)	1.61	1.12–2.31	≤0.01
Prosthetic valve						
Aortic	9 (4)	7 (4)	2 (5)	1.21	0.12–7.02	0.81
Mitral	6 (3)	5 (3)	1 (3)	1.08	0.09–13.36	0.94
Clinical events						
Pulmonary embolism	9 (4)	5 (3)	4 (11)	3.76	1.25–11.30	0.02
Systemic embolization	23 (11)	10 (6)	13 (35)	9.02	3.95–20.57	≤0.01

Table 4. Predictors of Pulmonary Embolism (Logistic Regression Analysis)*

	Pulmonary Embolism (n=9)	No Pulmonary Embolism (n=201)	OR	95% CI	P Value
Lead vegetation size					
0–10 mm	6 (67)	172 (86)	1.00	...	(reference)
>10 mm	3 (33)	29 (14)	0.88	0.14–5.42	0.89
Lead vegetation mobility					
Absent to low	6 (67)	179 (89)	1.00	...	(reference)
Moderate to severe	3 (33)	22 (11)	2.38	0.45–12.48	0.31

*All final models controlled for age, sex, and treatment group as well as other variables listed in the table.



- Neither lead vegetation size or mobility was found to correlate with an increased risk for pulmonary embolism
- Lead vegetation size was not significantly associated with decreased 6-month survival

Brescia experience (2003 - 6/2014)

Patients (n°)	1033
Mean age population (ys)	68,4 ± 13
Leads (n°)	2128
Mean age leads (mth)	120,6 ± 124
Sex	M 76% F 24%

	Percentage(%)
PM	46
ICD	30
CRT	22
SINGLE CHAMBER	24
DOUBLE CHAMBER	51
TRIPLE CHAMBER	22

Extraction Techniques

- Simple traction
- Simple traction through lead locking device (LLD)
- Mechanical Sheaths
- Powered Sheath
 - *Laser*
- Superior approach (jugular and subclavian veins)
- Femoral approach
- Hybrid approach

Extraction technique	Percentage(%)
Manual	38,9
Mechanical	2,1
Femoral	5
Laser	49,7
Hybrid	4,3

Results

Success	Percentage (%)
Complete	96.2
Partial	3,0
Faliure	0,8

Complications

Complications	Percentage (%)
No complications	93.4
VT	2
Hypotension	0.6
Premature pericardial effusion	0.3
Deferred pericardial effusion	0.3
Exitus	0.09

Indications

- Infection : 60%
 - Local
 - Systemic/sepsis
- Malfunction : 28 %
- Other : 12 %

Subgroup analysis : infection group (all pts underwent transesophageal echo):

- Lead vegetation : 35 %
- No lead vegetation : 65 %



Extraction technique	Percentage(%)
Manual	50
Mechanical	15
Femoral	5
Laser	22
Hybrid	8

Subgroup analysis : infection group

Patients (n°)	619
Mean age population (ys)	74,4 ± 9
Leads (n°)	1237
Mean age leads (mth)	110 ± 84
Sex	M 68% F 32%

Lead vegetation group 34,8%

Ø average(mm)	%
< 10	72
10-20	23
>20	5

Success	Percentage (%)
Complete	99
Partial	0.5
Faliure	0.5

Patients symptomatic during or within 12 hours of
the procedure for :

- Hypotension
- Fever
- Shaking chills

7 %

Pulmonary TC

Ø average (mm)	P.E (n. pts)	CLINICAL SIGNIF
< 10	2	NO
10-20	6	NO
>20	3	NO

Therapeutic approach

- Identification of the infecting organism with cultures
- Pre-procedure transesophageal echocardiography
- Pre-procedure management of **antibiotics** to suppress bacteremia or to reduce the size of vegetations for **at least 2 weeks**
- Extraction of all pacing system using **all percutaneous extraction tools** and techniques
- Post-lead extraction/ transvenous pacing, antibiotics, medical treatment of progressive heart failure and overwhelming sepsis, plus subsequent reimplantation of new, usually transvenous, implanted pulse generator–lead systems when appropriate.

Conclusions

- The data on device infections confirm that there is no statistical **difference** in lead vegetation **size** between patients with and without pulmonary embolism.

Conclusion

- With larger vegetations (> 2 cm), data is limited regarding the appropriateness of a transvenous versus a thoracic surgical approach but experience suggests that the leads can still be removed using intravascular techniques with an acceptably low complication rate and can be done without precipitating a clinically apparent pulmonary embolism.
- Until additional data are available, decisions regarding percutaneous versus surgical removal of leads with vegetations larger than 2 cm in diameter should be individualized and based on a patient's clinical parameters and the extractor's evaluation.