

Thoracoscopic left ventricular lead implantation



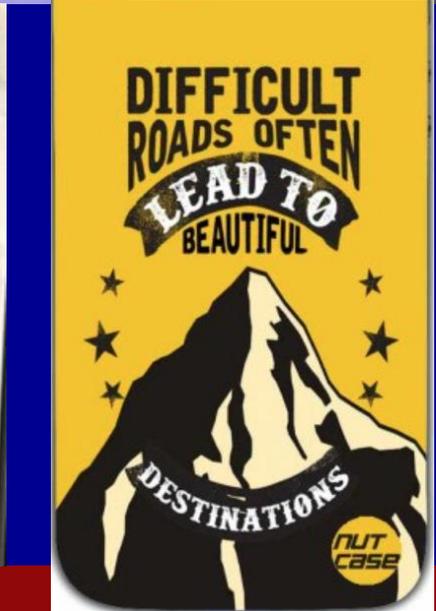
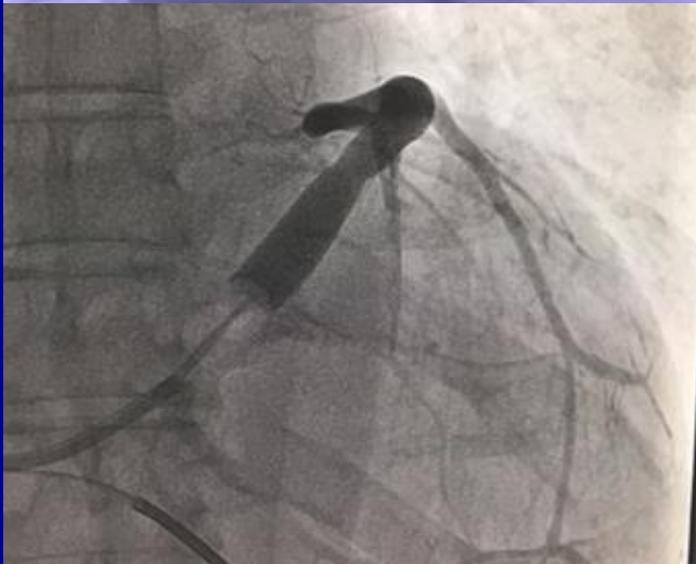
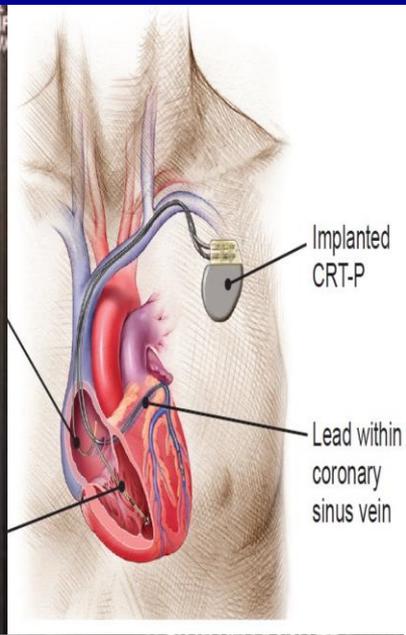
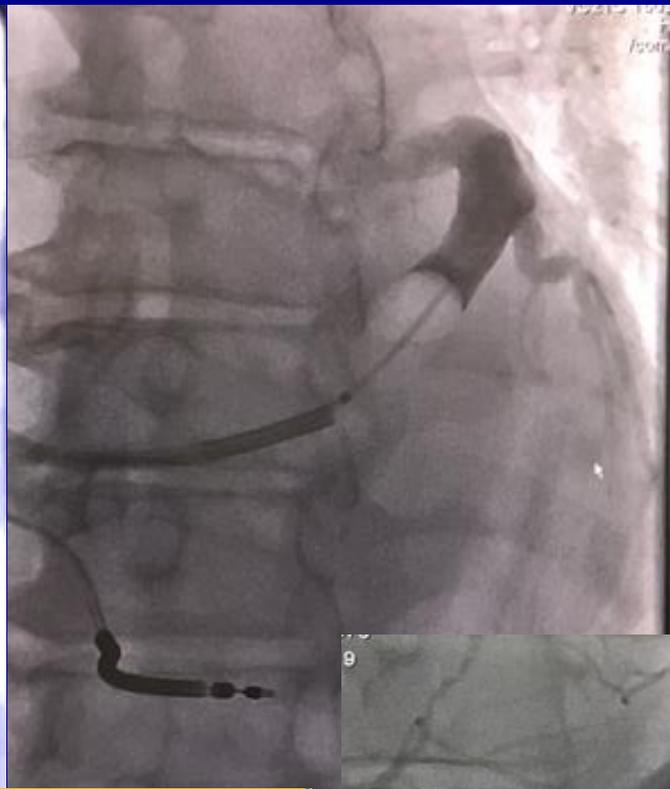
Budano Carlo, MD

Cardiologia Universitaria

Città della Salute e della Scienza di Torino

Dipartimento Cardiovascolare





CRT procedural success rate

Implantation of cardiac resynchronization therapy systems in the CARE-HF trial: procedural success rate and safety

D. Gras¹, D. Böcker², M. Lunati³, H.J.J. Wellens⁴, M. Calvert⁵, N. Freemantle⁵, R. Gervais⁶, L. Kappenberger⁷, L. Tavazzi⁸, E. Erdmann⁹, J.G.F. Cleland¹⁰, and J.-C. Daubert^{6*} on behalf of The CARE-HF Study Steering Committee and Investigators

Table 1 Numbers (%) of successful CRT system implantations at the first, second, and third attempt in each study group

<u>Attempt no</u>	Treatment group (<i>n</i> = 404 attempts)	Control group (<i>n</i> = 65 attempts)
1	<u>349 (86.3)</u>	58 (89.2)
2	36 (8.9)	2 (3.1)
3	5 (1.2)	0
Total	390 (96.4)	60 (92.3)

up to 8–10% of patients undergoing CRT device implantation failure

Why failure ?

**WHY
NOT**

Table 2 Causes of failures of CRT system implantation or activation at the time of first implant

Cause	<i>n</i>
Intolerance of procedure due to	2
Dyspnea	4
Claustrophobia	1
Fatigue	1
Septic shock during the procedure	1
Ventricular fibrillation	1
Unsuccessful pulse generator implantation	1
Unsuccessful left ventricular lead implantation	49
due to:	
<u>Inaccessible coronary sinus</u>	21
No accessible target vein	6
<u>Stable lead position unachievable</u>	16
Unacceptable stimulation threshold	4
Phrenic nerve stimulation	2
Dissection of	
Coronary sinus	1
Cardiac vein	1
Chest wall perforation	1
Contrast myography	1
Patient discharged and rescheduled because	1
of unavailable implant facilities	
Adverse reaction to medication	1
Vein thrombosis	1

CRT procedural success and SAFETY rate

FOCUS ISSUE: CARDIAC RESYNCHRONIZATION THERAPY

Safety of Transvenous Cardiac Resynchronization System Implantation in Patients With Chronic Heart Failure

Combined Results of Over 2,000 Patients From a Multicenter Study Program

Angel R. León, MD,* William T. Abraham, MD,†‡ Anne B. Curtis, MD,§ James P. Daubert, MD,|| Westby G. Fisher, MD,†¶ John Gurley, MD,† David L. Hayes, MD,# Randy Lieberman, MD,** Susan Petersen-Stejskal, BS,†† Kevin Wheelan, MD,‡‡ for the MIRACLE Study Program

Atlanta, Georgia; Lexington, Kentucky; Columbus, Ohio; Gainesville, Florida; Rochester, New York; Evanston, Illinois; Rochester, Minnesota; Minneapolis, Minnesota; and Dallas, Texas

2005

Parameters	MIRACLE n = 571	MIRACLE ICD n = 1,085	InSync III n = 422	Total n = 2,078
Age, yrs (mean ± SD)	64 ± 11	66 ± 11	66 ± 11	66 ± 11
Gender, % male	68	78	58	72
Ethnicity, % Caucasian	90	NA	86	88
NYHA, % functional class III	90	61	92	75
QRS, ms (mean ± SD)	166 ± 21	166 ± 23	164 ± 22	166 ± 22
LV ejection fraction, %	22 ± 6	21 ± 7	21 ± 7	22 ± 7
LVEDD, mm (mean ± SD)	69 ± 10	70 ± 10	69 ± 10	70 ± 10
HF etiology, % ischemic	55	64	47	58
Diuretic use, %	94	91	92	92
ACE-I or ARB use, %	92	92	90	92
Beta-blocker use, %	55	64	69	63

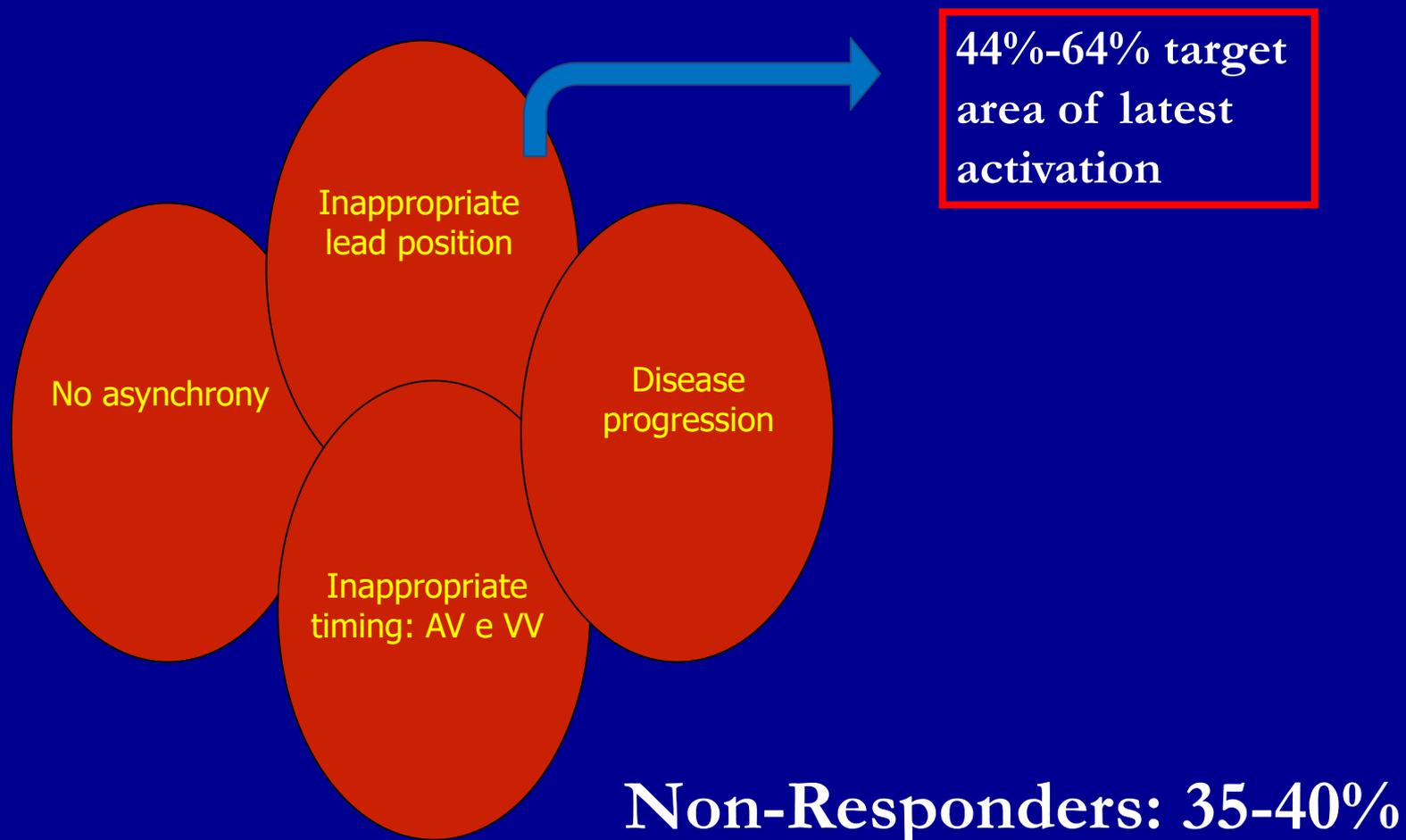
Perioperative Complications From CRT Device Implantation

Lead Model(s) Used/Primary Lead Recommended (% Used)	MIRACLE 2,187/2,188 (97.5%)	M-ICD Randomized 2,187/2,188/4,189 (48.5%)	M-ICD General 2,187/2,188/4,193 (90.4%)	InSync III 2,187/2,188/4,193 (88.9%)	Total
Event Description†	Patients/ Events	Patients/ Events	Patients/ Events	Patients/ Events	Patients (% of Attempts)
Leads total	32/35	67/73	28/29	10/10	137 (6.6%)
LV lead subtotal	19/21	54/55	22/22	5/5	100 (4.8%)
Lead dislodgement	7/7	19/19	10/10	2/2	
Elevated pacing thresholds/failure to/loss of capture	4/4	14/15	2/2		
Muscle stimulation-diaphragm	1/1	9/9	6/6	1/1	
Cardiac/cardiac vein/CS perforation or dissection	4/4	9/9	2/2	1/1	
Arrhythmias (AF/VT/VF/junctional)		1/1			
Other	5/5	2/2	3/3	1/1	
Implant tools total	4/4	16/17	3/3	8/8	31 (1.5%)
Cardiac/cardiac vein/CS perforation or dissection	2/2	10/10	3/3	7/7	
Hemo/pneumothorax		1/1			
Arrhythmias (AF/VT/VF/junctional)		1/1		1/1	
Heart block	1/1	1/1			
Other	1/1	3/4			
System-related total	1/1	10/12	1/1		12 (0.6%)
Procedure-related total	19/22	49/57	33/38	20/23	121 (5.8%)
Pocket pain/seroma/hematoma/shoulder pain/discomfort		17/20	9/9	2/2	
Hypotension	3/3	6/6	7/7		
Heart block	11/11			3/3	
Arrhythmias (AF/VT/VF/junctional)	4/4	1/1	3/3	3/3	
Heart failure decompensation		5/5	2/2	1/1	
Hemo/pneumothorax	1/1	2/2	1/1	3/3	
Cardiac/cardiac vein/CS perforation or dissection			1/1		
Thrombosis		2/2			
Other	3/3	19/21	15/15	11/11	

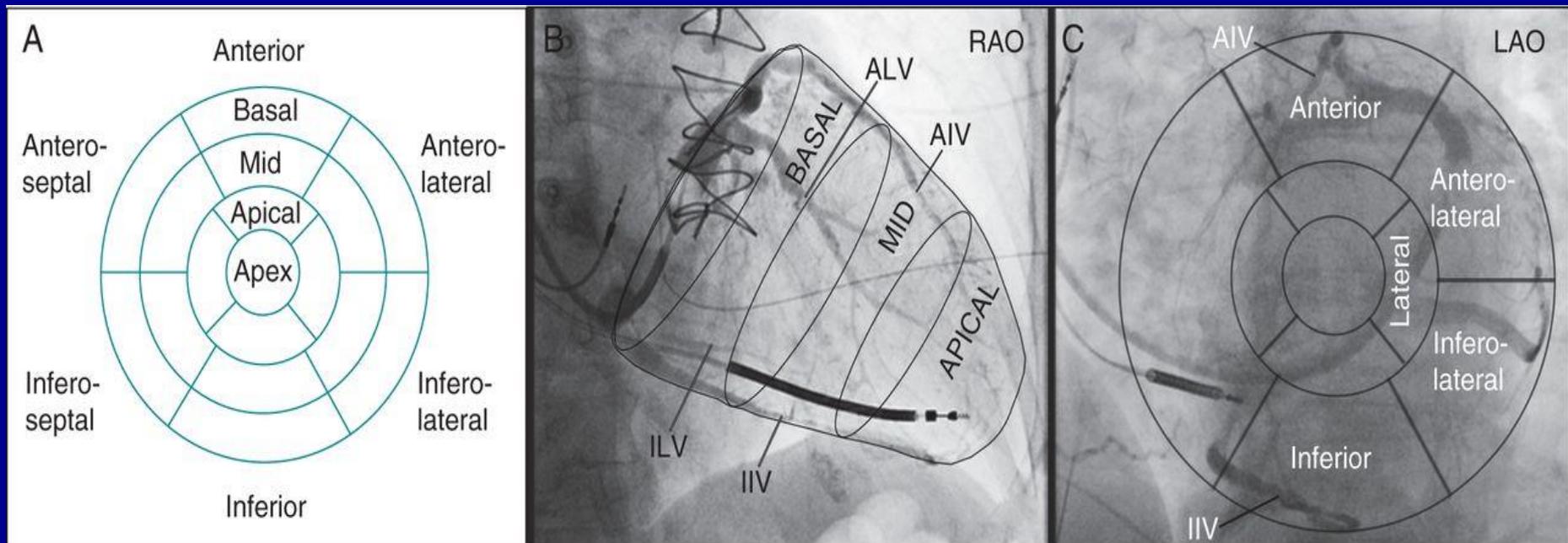
Postoperative Complications From CRT Device Implantation

Successfully Implanted Patients	MIRACLE 528	M-ICD Randomized 570	M-ICD General 408	Insync III 397	Total 1,903
Event Description†	Patients/ Events	Patients/ Events	Patients/ Events	Patients/ Events	Patients (% Attempts)
Leads total	45/54	49/53	35/43	22/24	151 (7.9%)
LV lead subtotal	39/45	42/44	32/36	16/18	129 (6.8%)
<u>Lead dislodgement</u>	20/22	29/30	21/23	13/14	
Muscle stimulation-diaphragm	9/9	6/6	6/6	2/2	
Elevated pacing thresholds/failure to/loss of capture	12/12	5/5	6/6	2/2	
Cardiac/cardiac vein/CS perforation or dissection		1/1			
Hypotension	1/1				
Arrhythmias (VT/VF/AF/PMT)			1/1		
Other	1/1	2/2			
System-related total	13/13	11/11	1/1	9/9	34 (1.8%)
Pocket/system infection	7/7	3/3		2/2	
Thrombosis				4/4	
Arrhythmias (VT/VF/AF/PMT)	2/2	2/2			
Pocket pain/seroma/hematoma/shoulder pain/discomfort			1/1	1/1	
Muscle stimulation-diaphragm		1/1			
Other	4/4	5/5			
Procedure-related total	6/6	13/13	12/12	4/4	35 (1.8%)
Pocket pain/seroma/hematoma/shoulder pain/discomfort		4/4	5/5	1/1	
Pocket/system infection		6/6	2/2	1/1	
Thrombosis	2/2		1/1		
Hypotension	1/1				
Hemo/pneumothorax		1/1			
Other	3/3	2/2	4/4	2/2	

Reason CRT Non-Response



Angiographic classification of the latest activated region and final LV lead position.



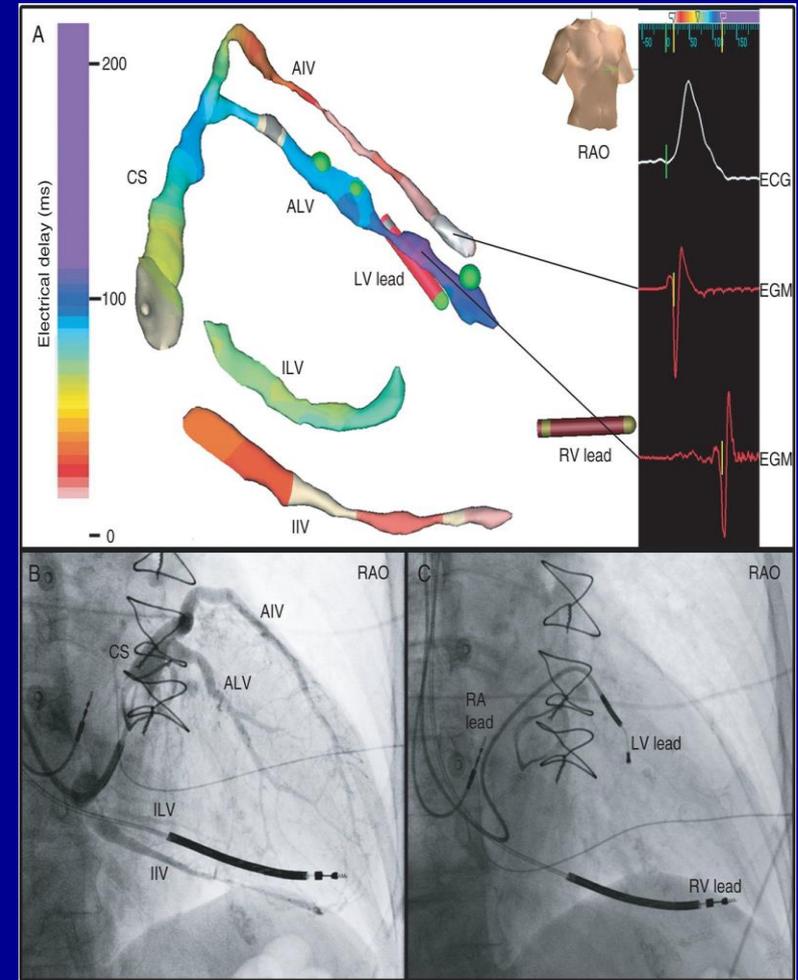
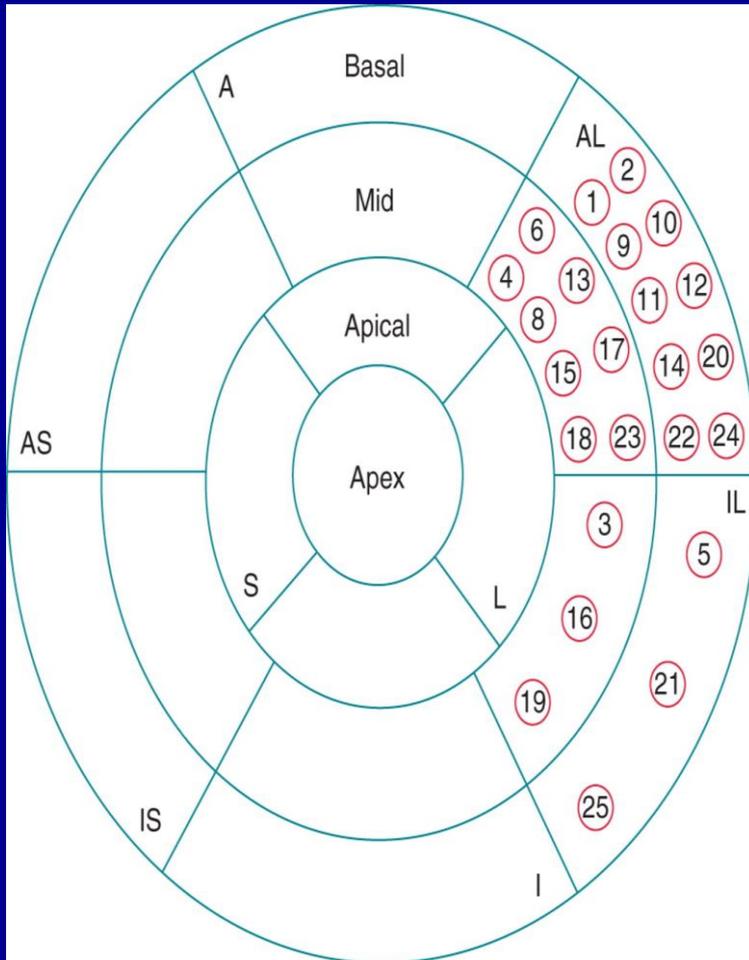
Masih Mafi Rad et al. *Europace* 2015;17:84-93

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Europace

European Pacing, Arrhythmias and Cardiac Electrophysiology

Distribution of the latest activated region.



Masih Mafi Rad et al. Europace 2015;17:84-93

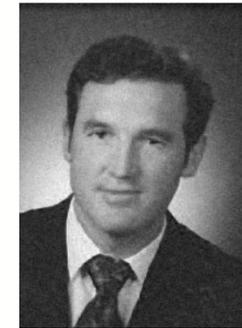


Epicardial Lead Implantation Techniques for Biventricular Pacing via Left Lateral Mini-Thoracotomy, Video-Assisted Thoracoscopy, and Robotic Approach

(#2003-4883)

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Dr. Mair



This report describes 3 epicardial lead placement techniques

	Mini-Thoracotomy (n = 16)	Implantation Tool (n = 31)	Robotic System (n = 33)
Male sex, n	9	23	23
Age, y	60.2 ± 9	64 ± 13	66.8 ± 15
NYHA class	3.1 ± 0.6	3.5 ± 0.6	3.2 ± 0.7
Ejection fraction, %	20 ± 7	19 ± 9	25 ± 11
Prior CABG, n	3	9	15
Pulmonary disease, n	3	3	7
Chronic renal insufficiency, n	4	13	4
QRS duration, ms	169 ± 21	ND	172 ± 21
Ischemic cardiomyopathy, n	4	13	10
Previous failed coronary sinus lead, n	11	31	10

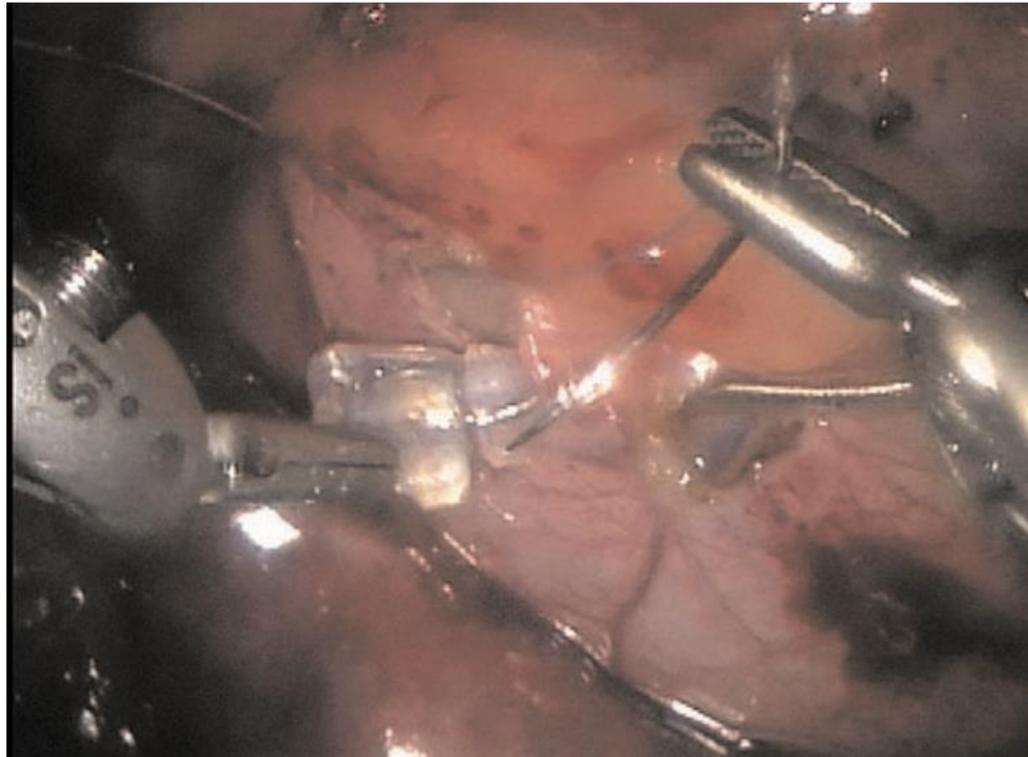
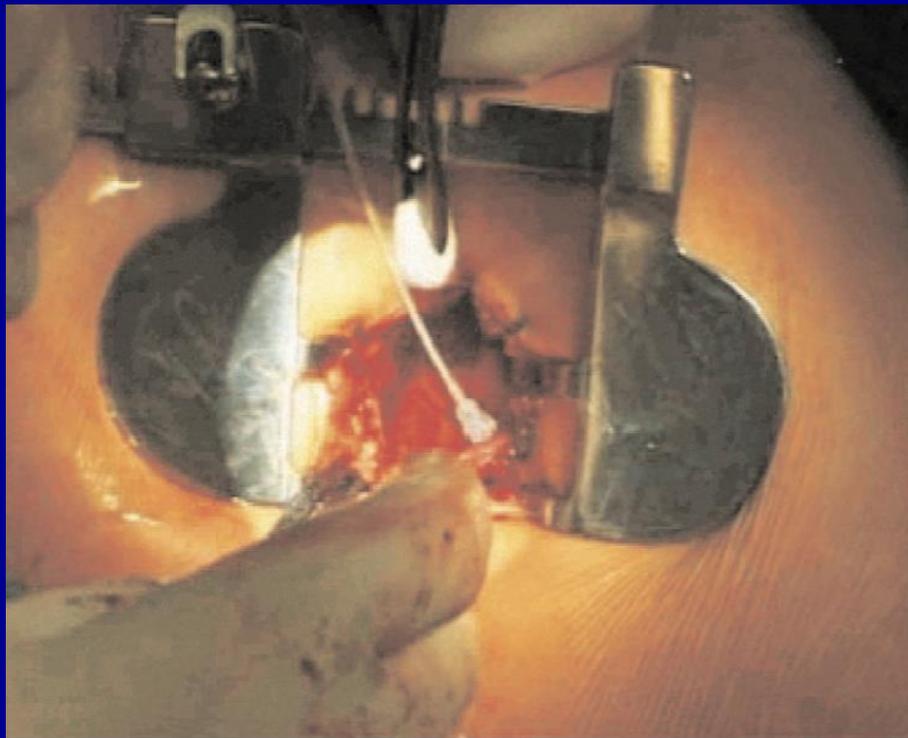


Figure 3. da Vinci robotic system, thoracoscopic view. The “shark fin” lead (modified Medtronic Model 4965) is held with the left robotic tool (SI) at the fin mounted on the lead tip and kept in contact with the lateral wall during the stitching of the electrode.

1) Robotically enhanced telemanipulation system



2) Left lateral mini-thoracotomy

- The connector of the lead was **submuscularly tunneled** to the device pocket and the pacemaker.
- **5-cm left lateral, midaxillary mini-thoracotomy at the site of the fourth intercostal space,**
- **The pericardium was opened anterior**
- Unipolar epicardial steroid lead (CapSure Epi Model 4965; Medtronic, Minneapolis, MN, USA) was attached to the target area and **secured with 2 polypropylene sutures** (Prolene 5-0 or 6-0).

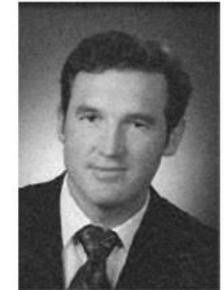


Figure 2. The Medtronic Model 10626 Epicardial Lead Implant Tool with a mounted epicardial screw-in lead (Medtronic Model 5071) is inserted in the chest through a working port (thoracoscopic view).

- The first port, a 15-mm soft port (primary working port), was placed in the **sixth intercostal space at the midaxillary line.**
- The second port, a 5-mm rigid port (“grasping port”), was placed at the **sixth intercostal space inferolateral to the left mammilla.**
- The third port, a 5-mm rigid port (for the endoscope), was placed at the **fourth intercostal space in an anterior-axillary line.**

3) video-assisted thoracoscopy approach using a lead implantation tool

	Mini- Thoracotomy	Implantation Tool	Robotic System
Lead dislodgment or exit block, n	1	1	1
Nonresponder, n	1	1	0
Conversion to thoracotomy, n	—	1	5
Implantation-related major adverse events, n	0	0	0
Implantation-related minor adverse events, n	3	4	3
Postoperative intubation >24 h, n	2	3	1
Early mortality, n	1	1	1
Number of patients who experienced adverse events	4	5	6



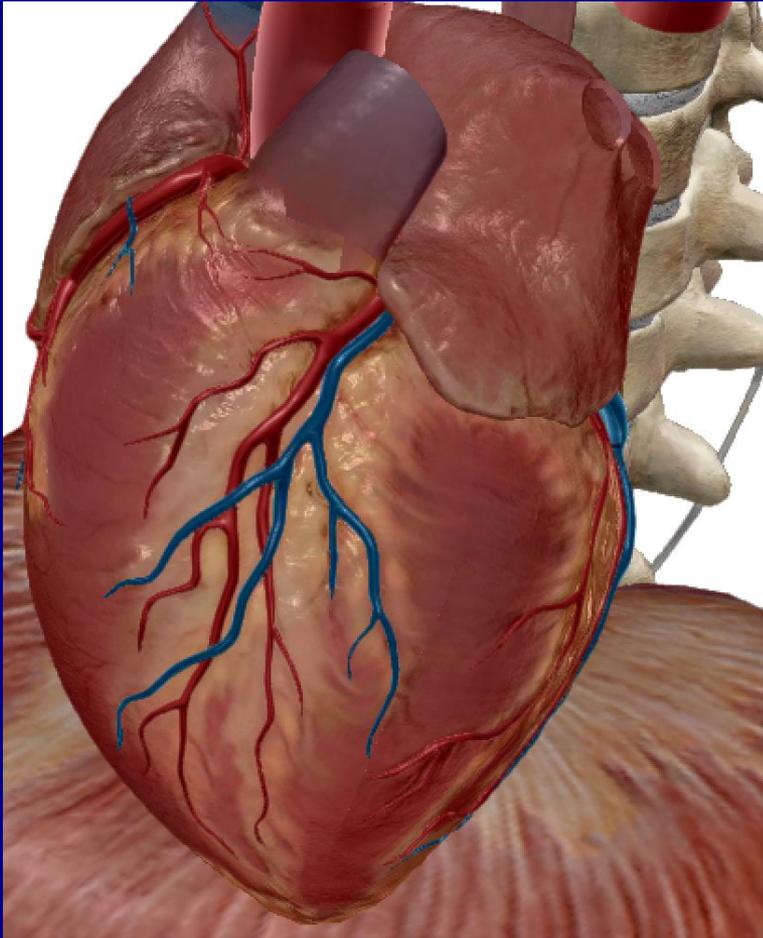
Dr. Mair



CONCLUSION

Epicardial lead implantation for BiV pacing is feasible with all 3 surgical techniques. Each method allows optimal lead implantation under direct vision and therefore reduces the incidence of nonresponders due to anatomical or technical reasons. We suggest the mini-thoracotomy as an appropriate solution to a suboptimal or time-consuming transvenous left ventricular lead placement. Thoracoscopic approaches with further improvements in the leads and implantation devices are at least equivalent or possibly better treatment options than the coronary sinus approach for BiV pacing.

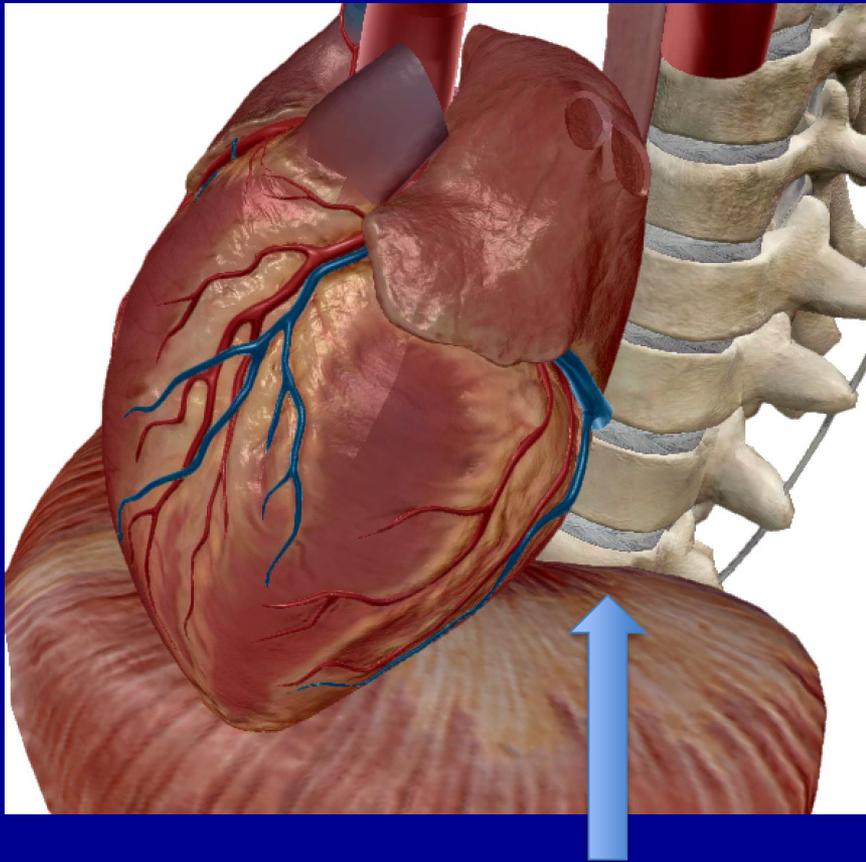
Which is the difference ?



**APPROCCIO in
MINITORACOTOMIA**

**APPROCCIO ANTERIORE
- ANTERO-LATERALE**

Which is the difference ?



**APPROCCIO in
TORACOSCOPICO**

**APPROCCIO
POSTERIORE
POSTERO-LATERALE**

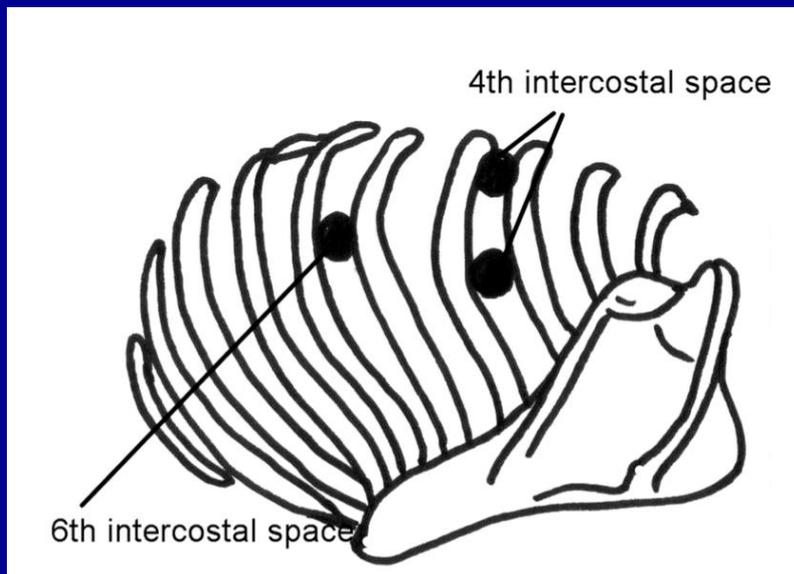
Video-Assisted Thoracoscopic Implantation of the Left Ventricular Pacing Lead for Cardiac Resynchronization Therapy

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(PACE 2008; 31:812–818)

17 pazienti a Leicester, UK



Thoracoscopic Epicardial Lead Implantation as an Alternative to Failed Endovascular Insertion for Cardiac Pacing and Resynchronization Therapy

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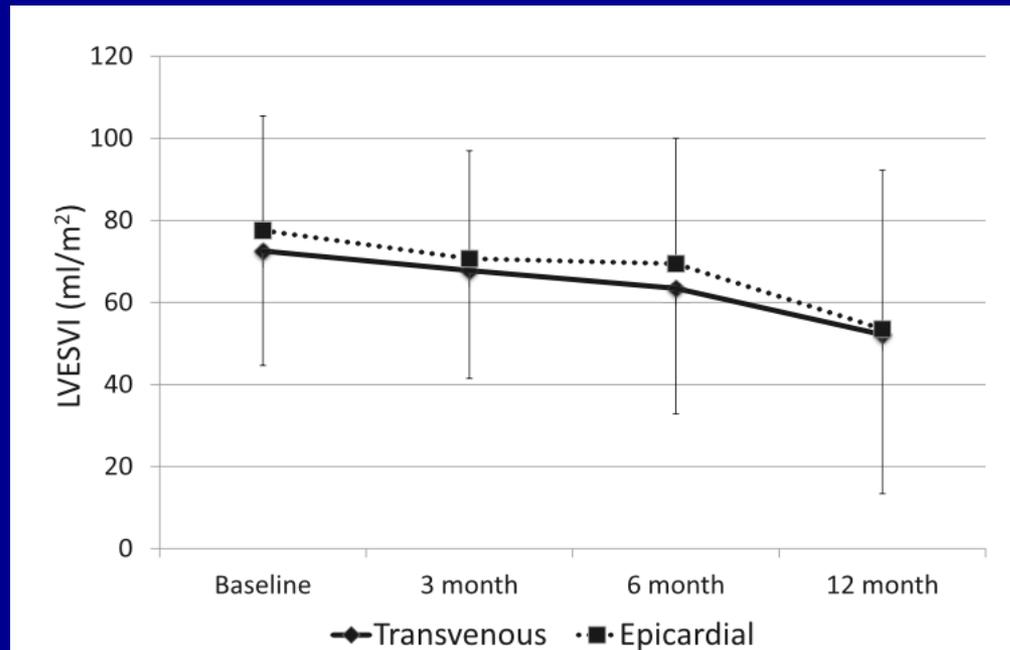
11 pazienti a Tel Aviv, Israel

TABLE 1. Reasons for Percutaneous Left Ventricular Lead Implantation Failure

Reason	No. Patients
Anatomical cardiac venous anomaly	5
Phrenic/diaphragmatic stimulation	1
Dislodgement	2
Perforation or dissection	1
Failure to cannulate the coronary sinus	2

Comparison of Endovascular Versus Epicardial Lead Placement for Resynchronization Therapy

Naga V. Garikipati, MD, MPH^a, Suneet Mittal, MD^{b,c}, Farooq Chaudhry, MD^d, Dan L. Musat, MD^{b,c}, Tina Sichrovsky, MD^{b,c}, Mark Preminger, MD^{b,c}, Aysha Arshad, MD^{b,c}, and Jonathan S. Steinberg, MD^{b,c,*}



Comparison of Endovascular Versus Epicardial Lead Placement for Resynchronization Therapy

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Cardiac resynchronization therapy (CRT) has been shown to improve survival and symptoms in patients with severe left ventricular (LV) dysfunction, congestive heart failure, and prolonged QRS duration. LV lead placement is achieved by placing the lead in the coronary sinus, an endovascular approach, or by a minimally invasive robotic-assisted thoracoscopic epicardial approach. There are no data directly comparing the 2 methods. Patients eligible for CRT were randomized to the endovascular and epicardial arms. Coronary sinus lead placement was achieved using the standard technique, and epicardial leads were placed using a minimally invasive robotic-assisted thoracoscopic approach. The primary end point was a decrease in LV end-systolic volume index at 6 months. The secondary end points included 30-day mortality rate, measures of clinical improvement, 1-year electrical lead performance, and 1-year survival rate. The relative improvement of LV end-systolic volume index from baseline to 6 months was similar between the arms (28.8% for the transvenous [n = 12] vs 30.5% for the epicardial (n = 9) arm, p = 0.93). There were no significant differences in the secondary end points between the 2 groups. In conclusion, there were no differences in echocardiographic and clinical outcomes comparing a conventional endovascular approach versus robotic-assisted surgical epicardial LV lead placement for CRT in patients with heart failure. Surgical approaches are still a viable alternative when a transvenous procedure has failed or is not technically feasible. © 2014 Elsevier Inc. All rights reserved. (Am J Cardiol 2014;113:840–844)

Minimally invasive thoracoscopic technique for cardiac resynchronization therapy

Andrea Droghetti^{a,*}, Maria Caterina Bottoli^a, Mark Ragusa^b, Patrizia Pepi^c, Michele Giovanardi^a, Albino Reggiani^c, Daniela Pozzetti^c, Maurizio Malacrida^d, Alessandra Colombo^d and Giovanni Muriana^a

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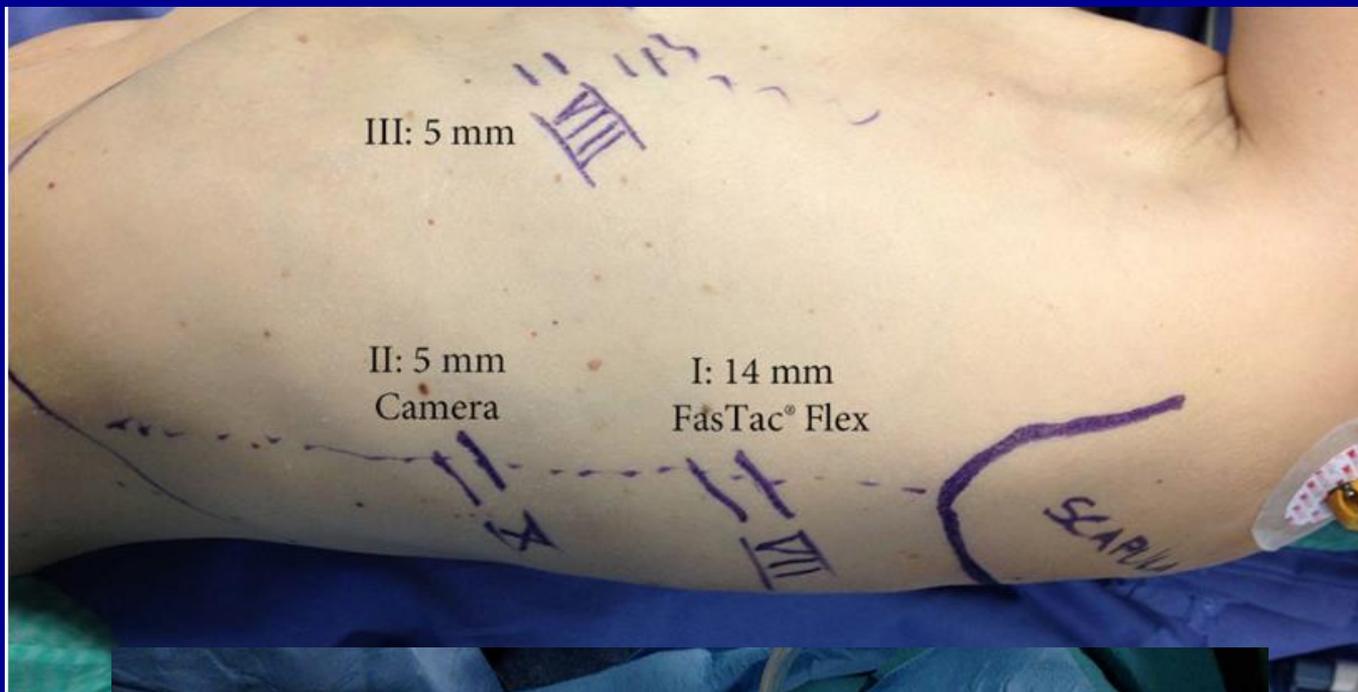
^dBoston Scientific, Milan, Italy



MULTIMEDIA MANUAL OF
CARDIO-THORACIC
SURGERY

Operating room

All 91 patients were provided standard monitoring with external defibrillator pads in place. The procedure was performed under general anaesthesia with oro-tracheal intubation using a double-lumen tube and right-sided ventilation. The patient was placed in the right lateral decubitus position with both arms anteriorly extended (Fig. 1).



A. Droghetti,
CardioThoracic
2015

Minimally invasive thoracoscopic technique for cardiac resynchronization therapy

Andrea Droghetti^{a,*}, Maria Caterina Bottoli^a, Mark Ragusa^b, Patrizia Pepi^c, Michele Giovanardi^a, Albino Reggiani^c, Daniela Pozzetti^c, Maurizio Malacrida^d, Alessandra Colombo^d and Giovanni Muriana^a

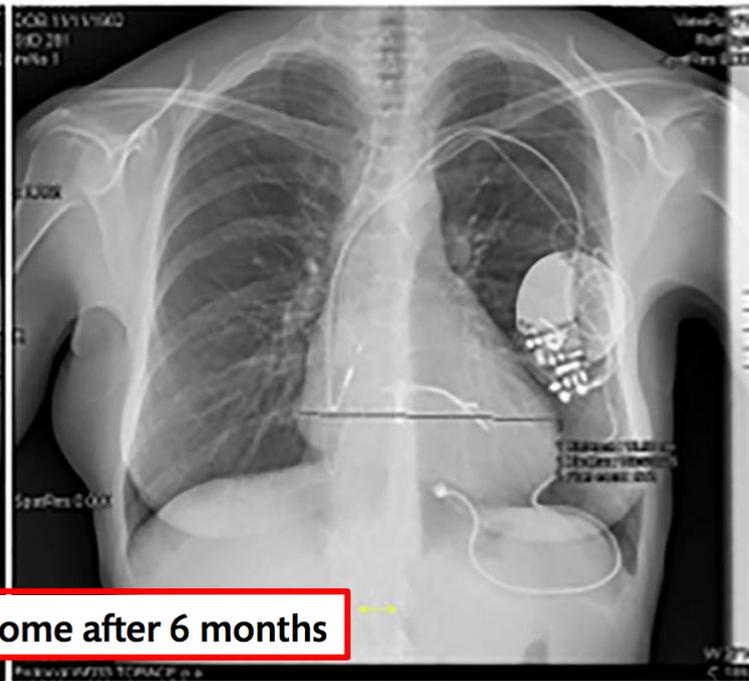
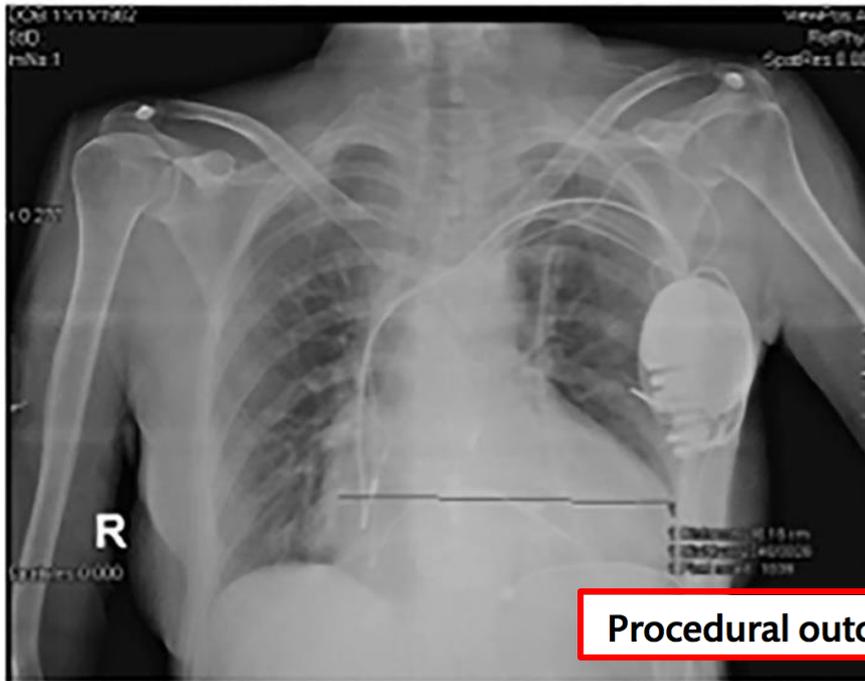
Table 2: Outcome after epicardial LV lead placement

Data	Pre-surgery	6 months	P-value
LV ejection fraction (%)	24 ± 6	43 ± 11	0.031
LV end-diastolic volume (ml)	251 ± 103	132 ± 26	0.013
QRS duration (ms)	169 ± 25	128 ± 19	0.030
Data	Surgery	1 year	P-value
LV capture threshold (V/0.5 ms)	1.04 ± 0.5	1.06 ± 0.5	0.5

A. Droghetti et al. / Multimedia Manual of Cardio-Thoracic Surgery, 2015
Andrea Droghetti – Thoracic Surgery Division – ASST Mantova-Cremona - Italy

Pre-CRT

After 6 months



Procedural outcome after 6 months

Heart Ø: 16.16 cm

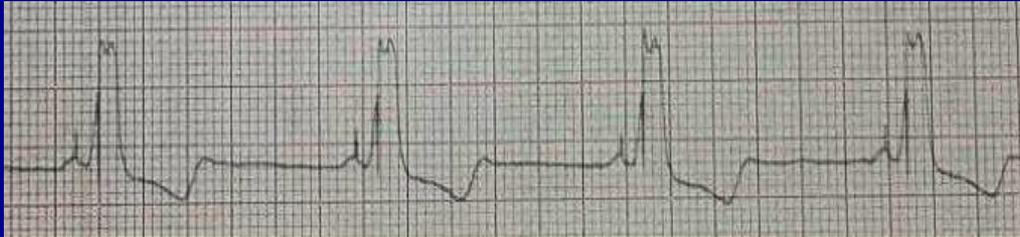
Heart Ø: 13.9 cm

Eighty-two (90%) patients reported an improvement in NYHA function class from the median preoperative class III to postoperative class II. The mean QRS duration was reduced from 169 ms preoperatively to 128 ms after 6 months. Pacing thresholds and impedances for the epicardial LV lead were 1.06 V/0.5 ms and $338 \pm 59 \Omega$, respectively, at median follow-up of 790 days (range 6–72 months). LVEF improved from an average of 24–43% (Table 2 and Fig. 7).

Postoperative complications included 2 cases of transient renal failure not requiring dialysis, 1 case of heart failure, 3 cases of pocket infection and 1 case of sepsis requiring the removal of all electrodes. There was no perioperative death.

Indication: Non-Responders ???

CASE REPORT 2003 Woman 52 years: Basal QRS:220 ms, EF 28%, LVEDV 273 ml



2003-2014 TRANSVENOUS CRT: QRS: 200 ms, EF 48%, LVEDV 170 ml



2014 CRT MALFUNCTION FOR LEAD FRACTURE EF 38% (AFTER 6 MONTHS)

2015 VIDEOTHORACOSCOPIC EPICARDIAL LEAD QRS:120 ms, EF 48% LVEDV 120 ml



2017 after 3 years Epicardial Lead QRS 120 ms, EF 62% LVEDV 103 ml

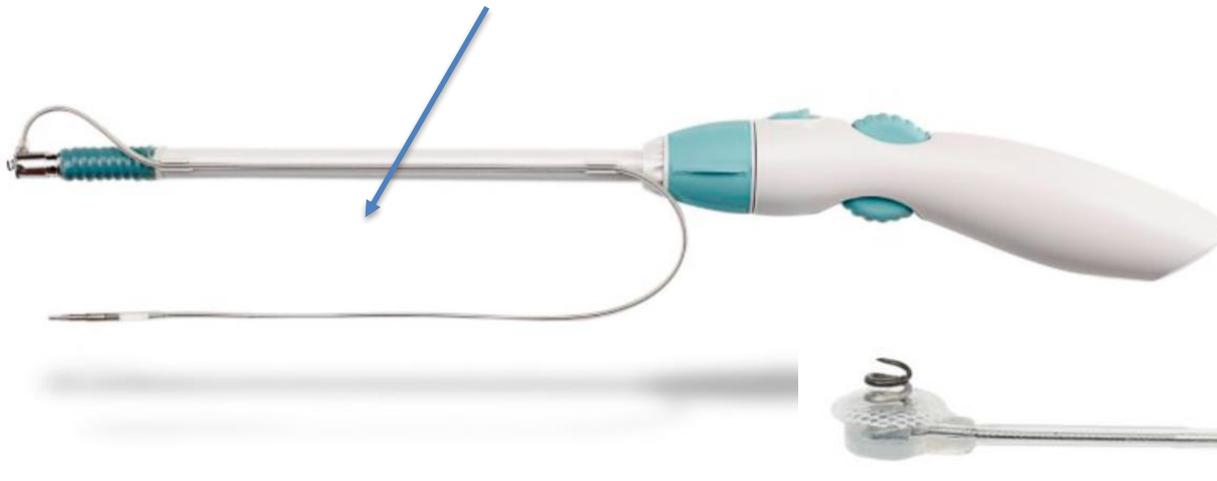




- ✓ Camera
- ✓ FasTac Flex
- ✓ Epicardial electrocatheter



FasTac™ Flex Steerable Lead Implant Tool



REMOTE DISTAL DEFLECTION CAPABILITIES

REMOTE LEAD ROTATION FOR INSERTION OF THE HELIX IN THE MYOCARDIUM

REMOTE LEAD RELEASE AND REGRASOING CAPABILITIES

Città della Salute e della Scienza di Torino Presidio Molinette

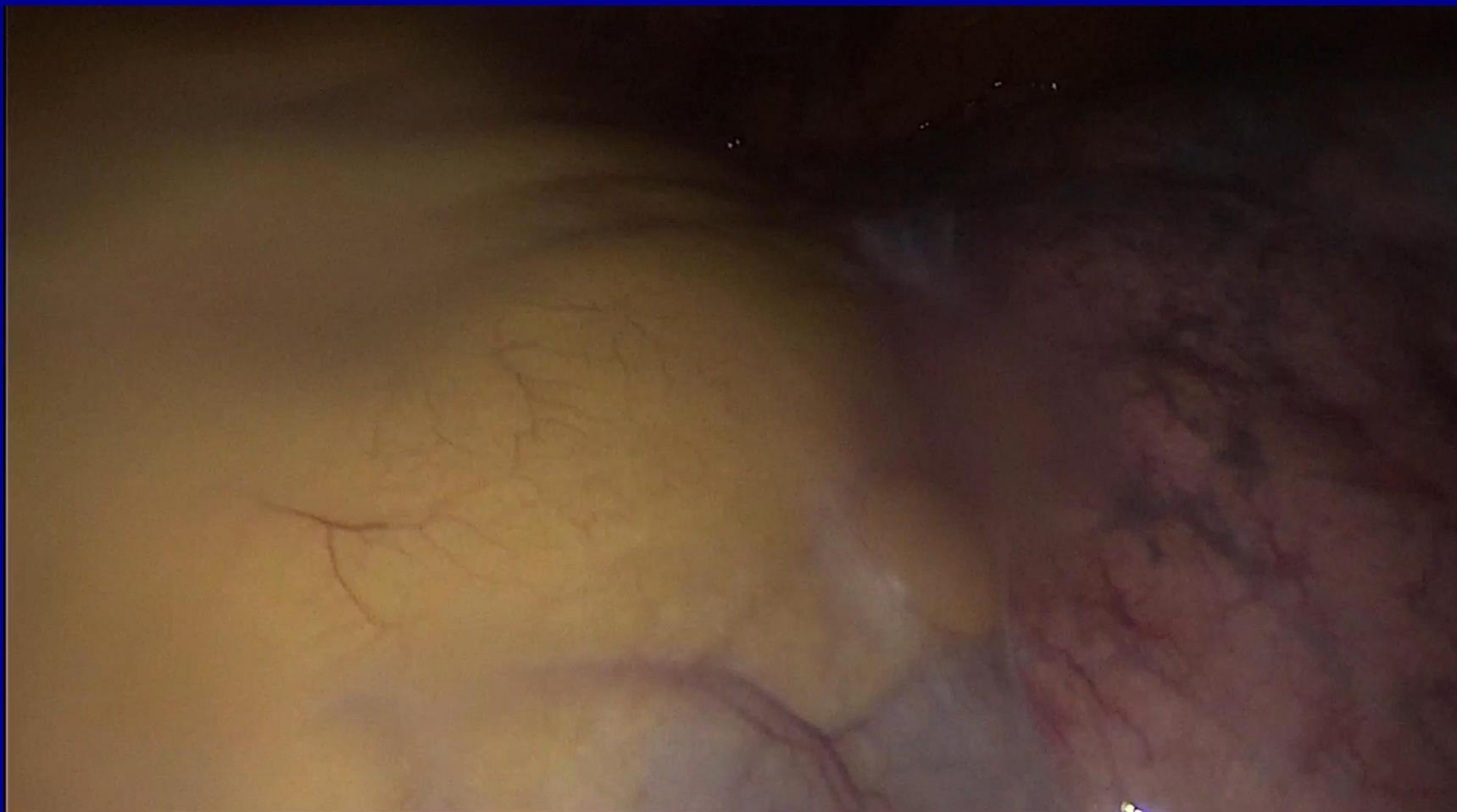
Referto operatorio

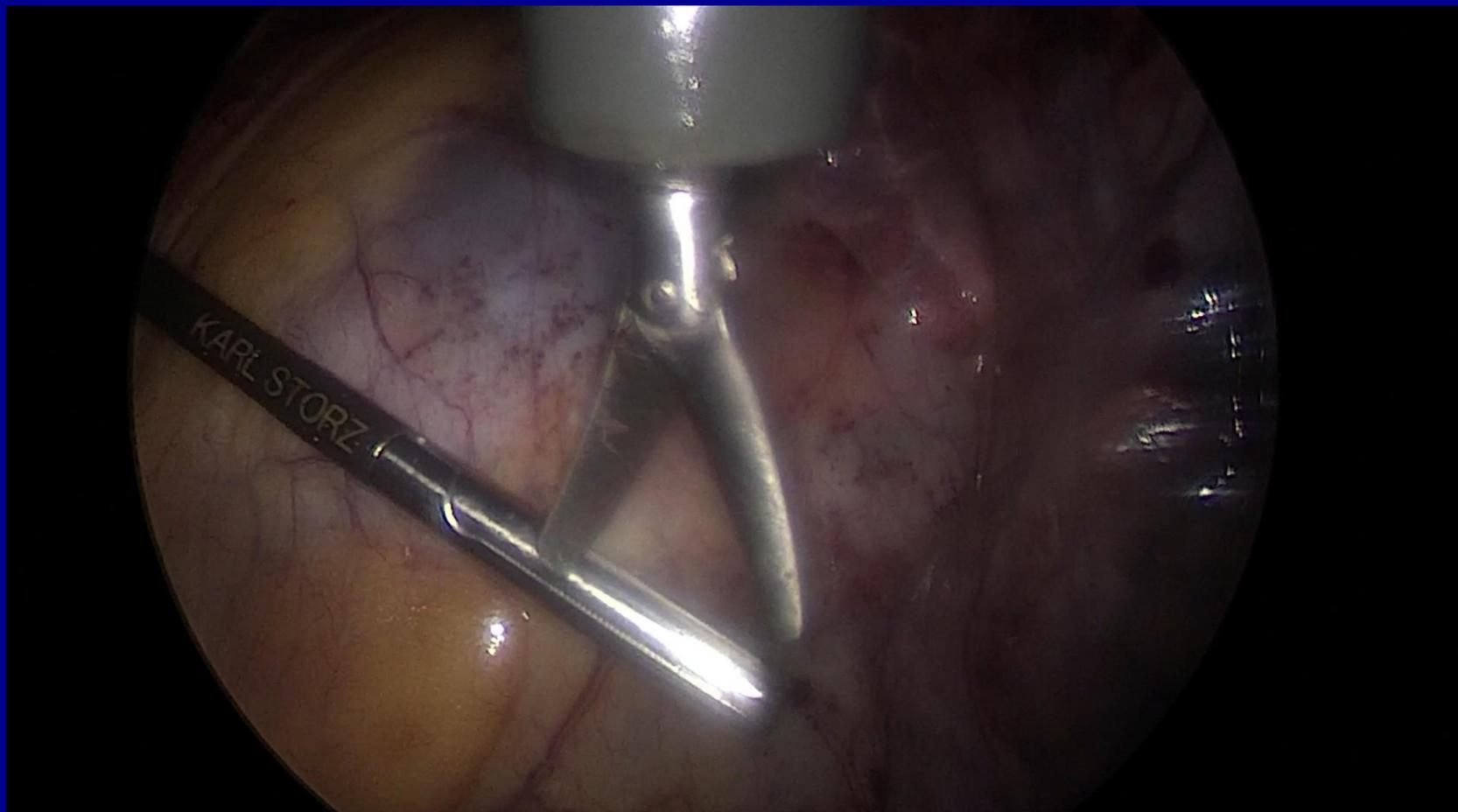
CMP ipocinetica a coronarie sane, pregresso intervento di sostituzione aorta ascendente con protesi in dacron 32 post dissecazione aortica Stanford A nel 2001. Portatore di ICD bicamerale Biotronik in prevenzione primaria dopo tentativo infruttuoso di posizionamento di CRT-D il 2/9/2016. Dispositivo Inventra 7 HF-T già in sede. Severa riduzione della funzione sistolica globale FE 20%. All'ECG BBS completo. NYHA II-III

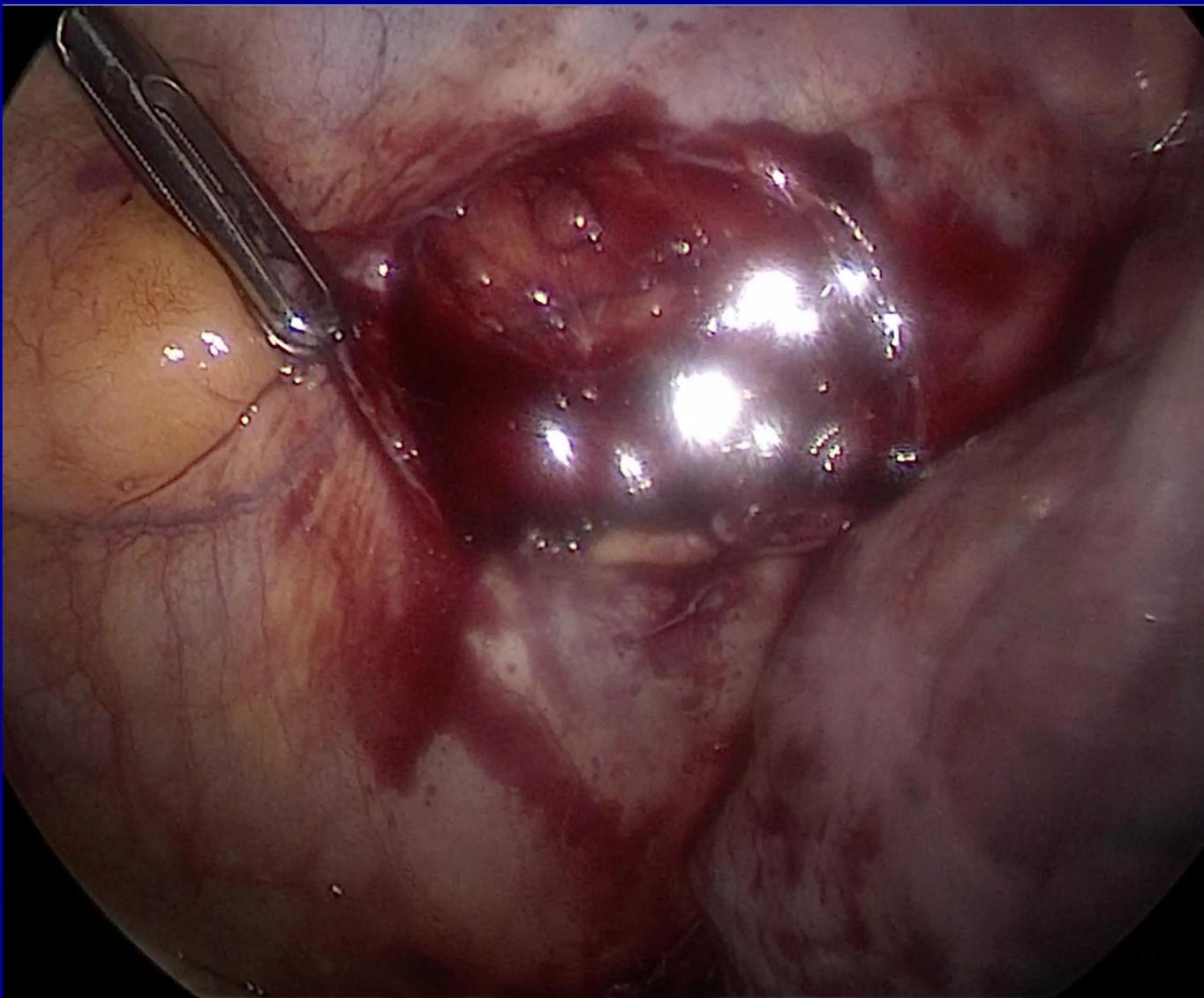
Previa intubazione selettiva DLT destra, decubito laterale destro.

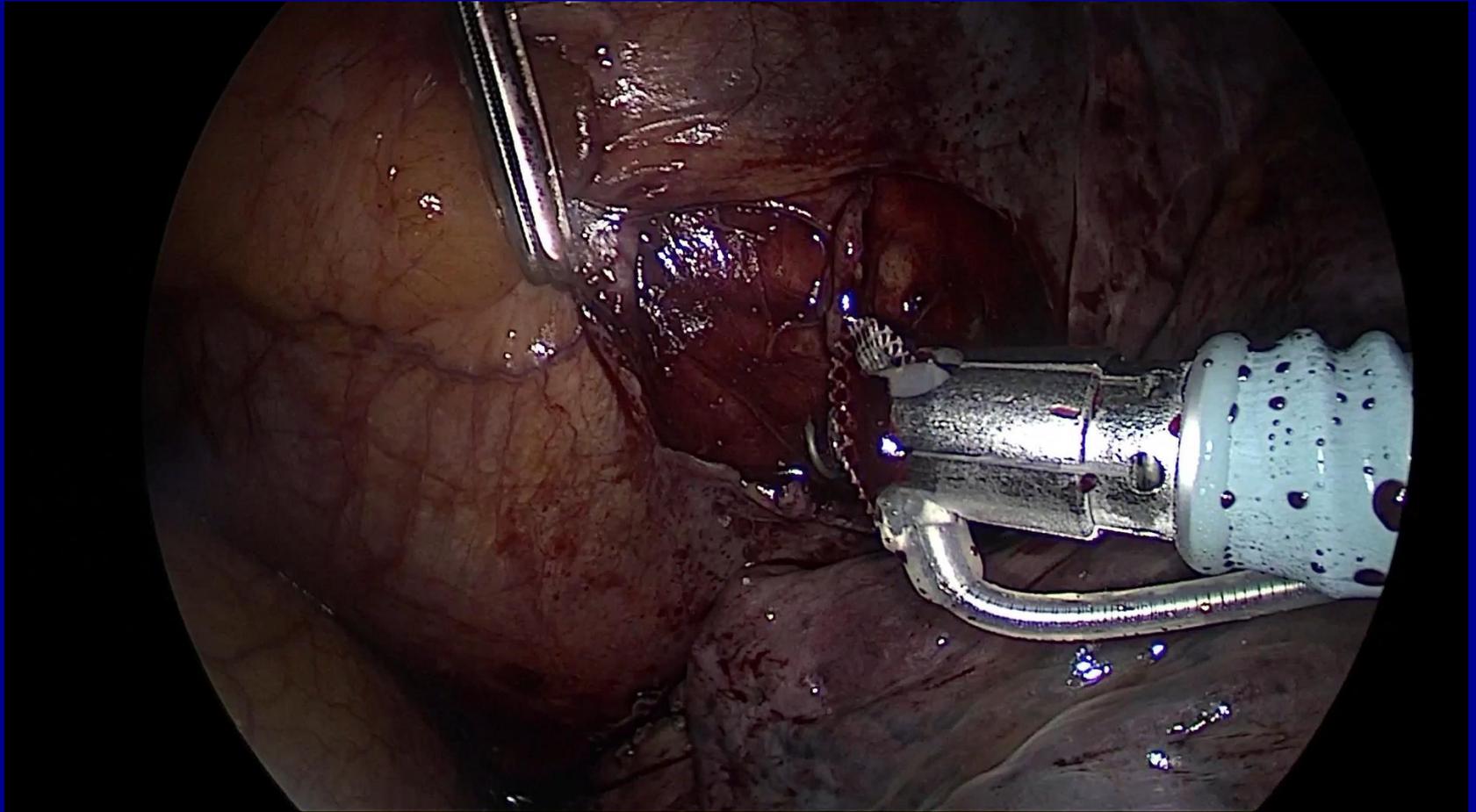
Inserimento del toracoscopio in ascellare posteriore sinistra in VII spazio intercostale. creazione di altre due porte: ascellare posteriore X spazio intercostale e anteriore VII sp.intercostale. Si sposta l'ottica nella porta inferiore e si insuffla CO2. Lisi di aderenze tra polmone e parete toracica. Si crea finestra pericardica posteriore: si reperisce sul miocardio punto idoneo a prevalenza muscolare e lì si inserisce, sotto controllo elettrofisiologico, l'elettrodo epicardico che viene quindi esteriorizzato attraverso la porta anteriore. Controllo emostasi/aerostasi. Un drenaggio h 24. Sutura delle pleurotomie.

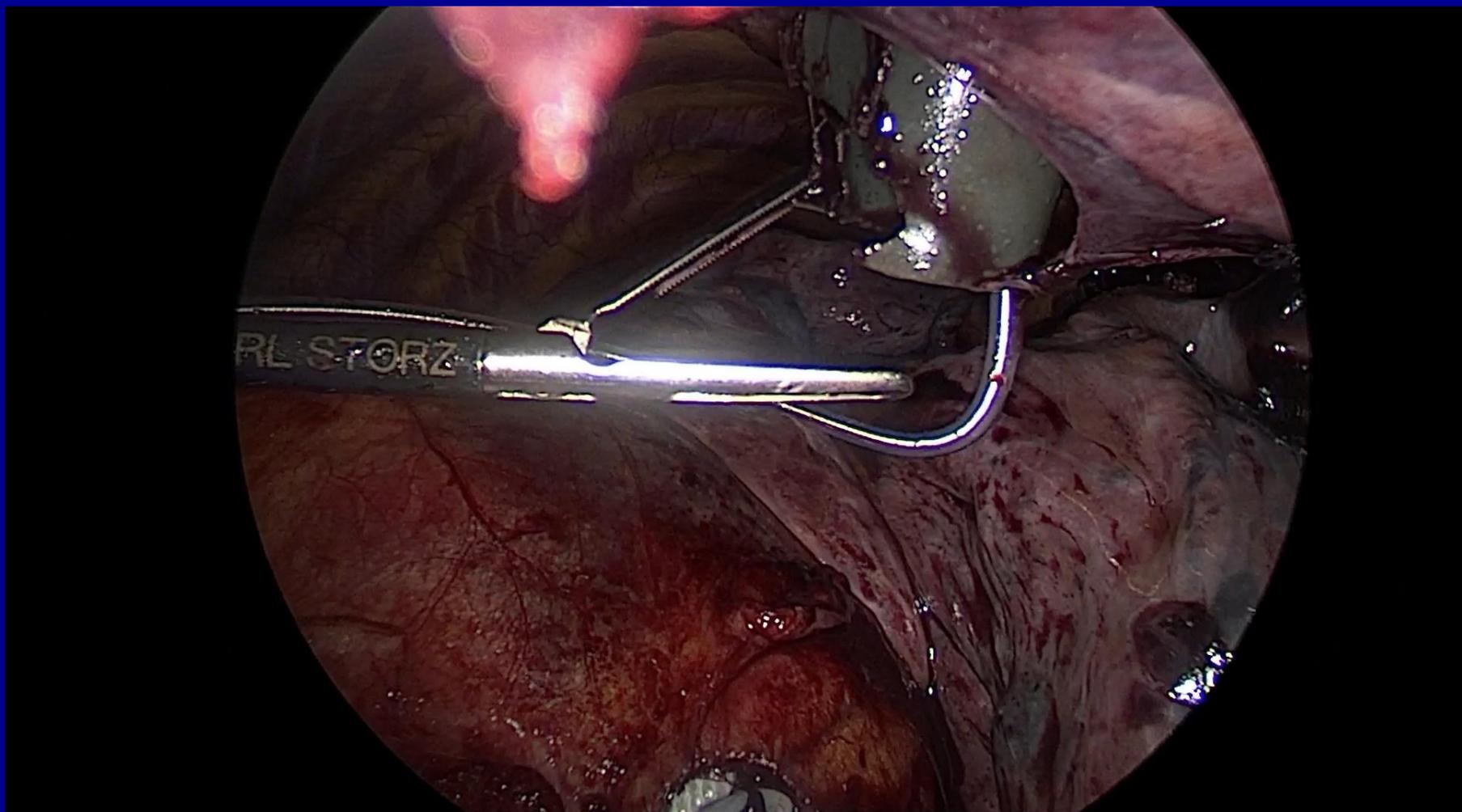
Si procede a incisione sottoclaveare sinistra. Tunnellizzazione dell'elettrodo epicardico al generatore CRT-D Biotronik Inventra 7 HF-T già in sede nella tasca pre-esistente. Controllo parametri con evidenza di soglia di stimolazione 0,9 V x 1 ms. Collegamento a generatore Biotronik. Introduzione del generatore nella tasca. Chiusura a strati riassorbibili (non necessità rimozione punti).





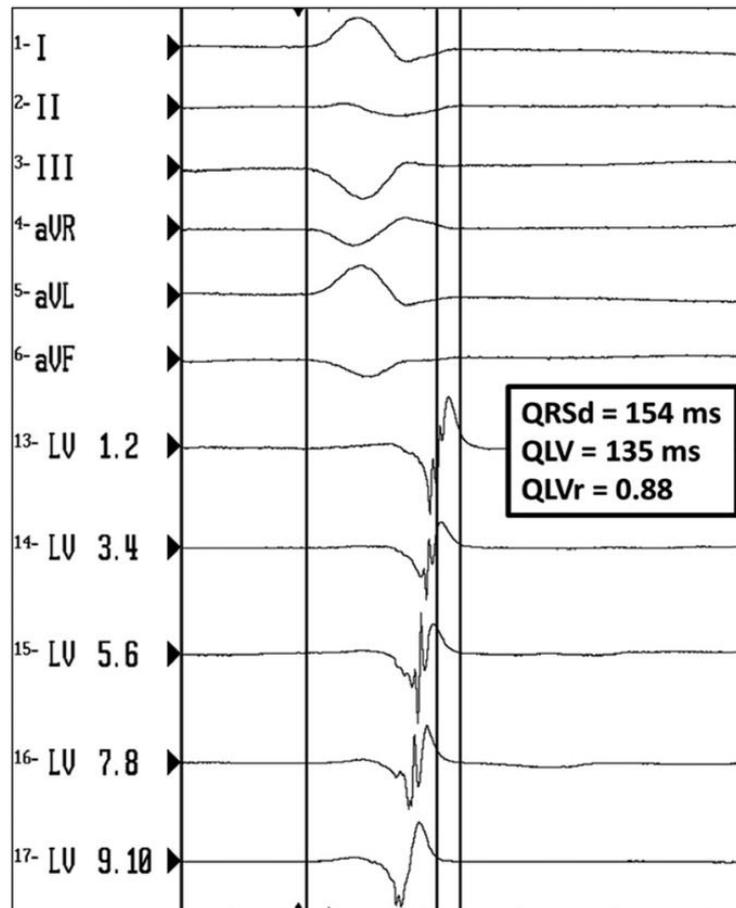




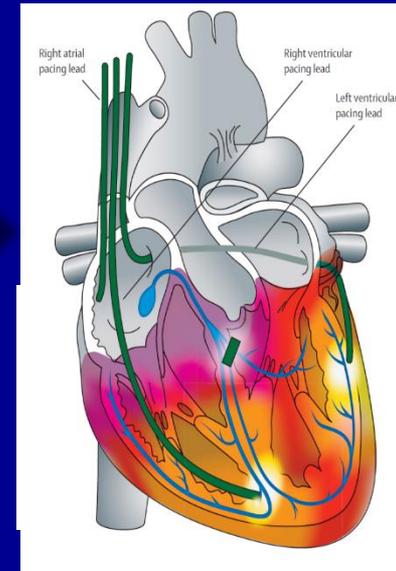
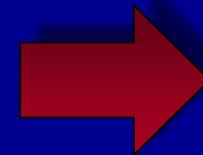
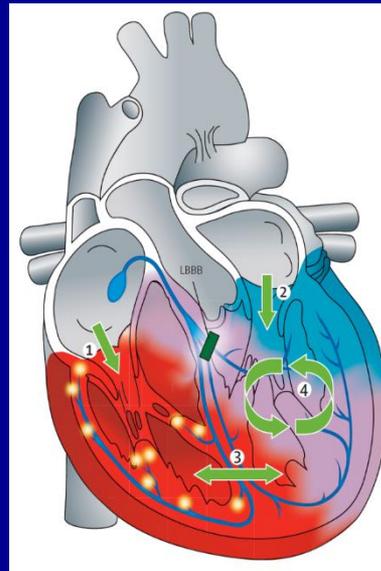
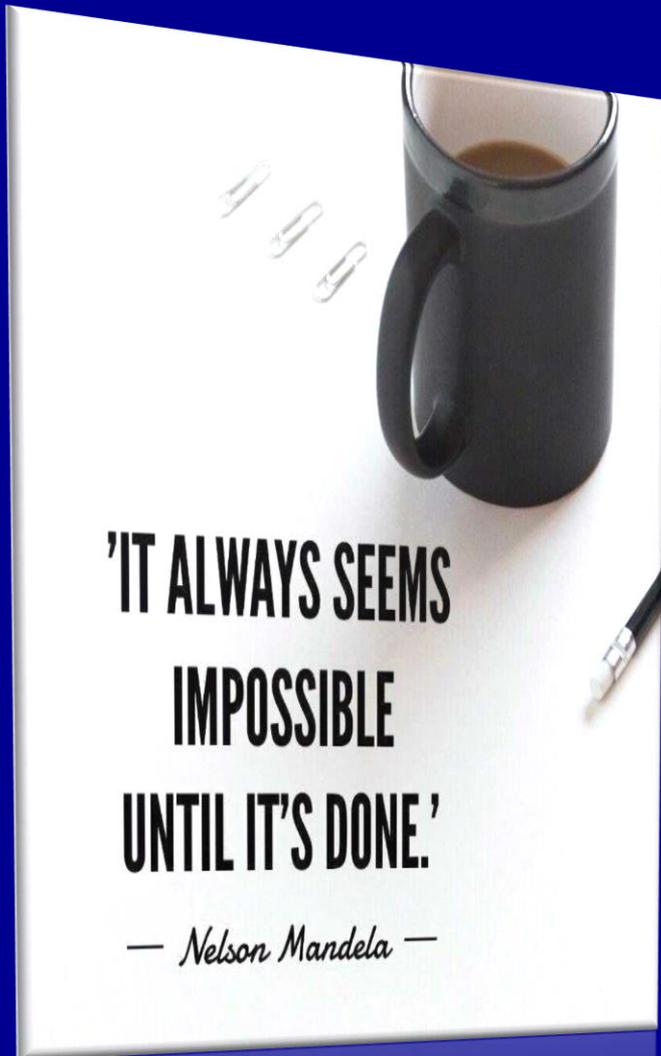


High-Density Epicardial Activation Mapping to Optimize the Site for Video-Thoracoscopic Left Ventricular Lead Implant

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Minimally invasive Cardiac Resynchronization Therapy





Grazie