

# Periprocedural management and transvenous lead extraction of implantable cardiac devices

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- Summary

# General Data

- 1 million new devices implanted annually worldwide [1]
- Over 4.5 million active devices [1]
- 10,000-15,000 lead extraction procedures annually [2]
- The most common indication for extraction is device related infection (local or systemic)
- Extraction techniques: surgical or transvenous
- Multiple approaches to the transvenous technique: Laser sheaths, mechanical gun, snare devices, simple non-motorized dissection polypropylene sheaths, etc.
- Alternative variable venous approach

# General classification of implantable cardiac devices

Cardiac Pacemakers	Cardiac Defibrillator
Single-chamber pacemaker (active/passive lead, atrium/right ventricle)	Single-chamber defibrillator (right ventricular lead with single or dual coil)
Dual-chamber pacemaker (two active/passive leads atrium + right ventricle)	Dual-chamber defibrillator (right atrial lead + right ventricular lead with single or dual coil.
Triple pacemaker (three probes right atrium, right ventricle, coronary sinus or, rarely, transseptal endocardial left ventricle)	Triple chamber defibrillator (right atrium lead + right ventricle lead with single or dual coil, coronary sinus probe)
Leadless Pacemaker	S-ICD

# PhD thesis objectives

- Study of the efficiency and safety of the transvenous technique using simple rotary mechanical extraction sheaths with manual metal handle (Bon Giorni technique [3])
- The study of the reimplantation strategy in patients in whom the presence of the device is still necessary: pacemaker dependent patients, patients with SCD arrhythmic risk (primary or secondary prophylaxis) and patients "responders" or "super-responders" of cardiac resynchronization therapy CRT-P/ CRT-D.
- Study of infections (endocarditis) associated with intracardiac prostheses in the pediatric population

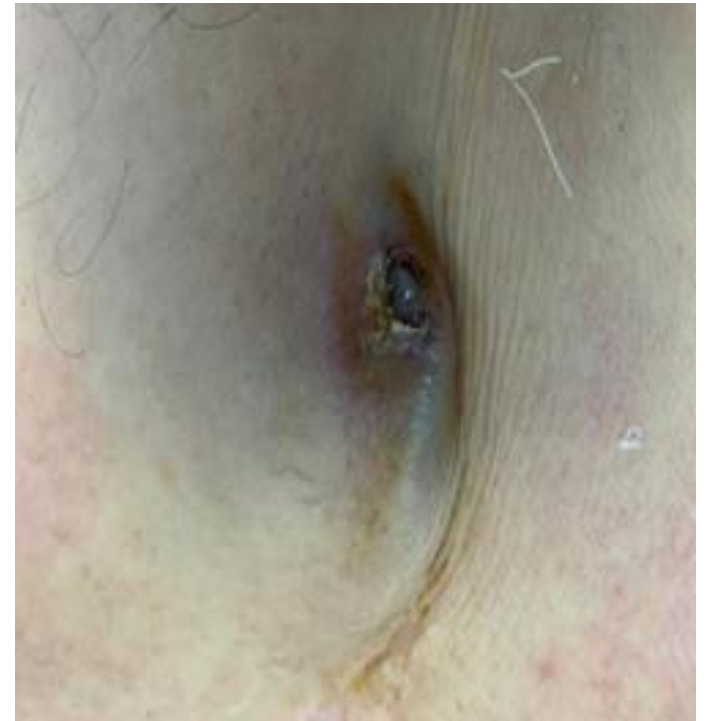
# Definitions

- Definition of extraction: minimally invasive interventional complete or partial removal of the device and its components for any cause, more than 1 year after implantation, OR:
- The need to use extraction dedicated materials (sheaths, snares, catheters, etc.) regardless of the time elapsed since the first implant
- Open cardiovascular surgical removal of the device and components in patients with increased interventional risk and/or transvenous failure.
- Major complications: cardiac avulsion, vascular lacerations, massive pericardial tamponade, and death
- Minor complications: pocket hematoma, pericardial effusion, pulmonary embolism..

# Lead extraction indications

- Pocket infections
- Systemic infection: sepsis with no obvious starting point other than the implanted cardiac device – with or without pocket infection
- Infective endocarditis with or without positive blood cultures.
- Venous occlusion
- Lead failure/abandoned leads

# Examples of pocket infection



# Patient-dependent risk factors for device infection

Device infection occurs in 1-1.3% of all implanted devices, risk factors include:

- Diabetes
- Renal disease
- COPD
- Heart failure Use of corticotherapy
- History of device infection
- Malignancy
- Anticoagulant therapy



# Risk factors for procedure-dependent device infection

- Post-operative hematoma
- Lead dislodgmente and early reintervention to reposition the leads.
- Re-intervention to change generator or device upgrade
- Lack of pre-procedural antibioprophylaxis
- Temporary pacing
- Prolonged duration of the procedure

# First study

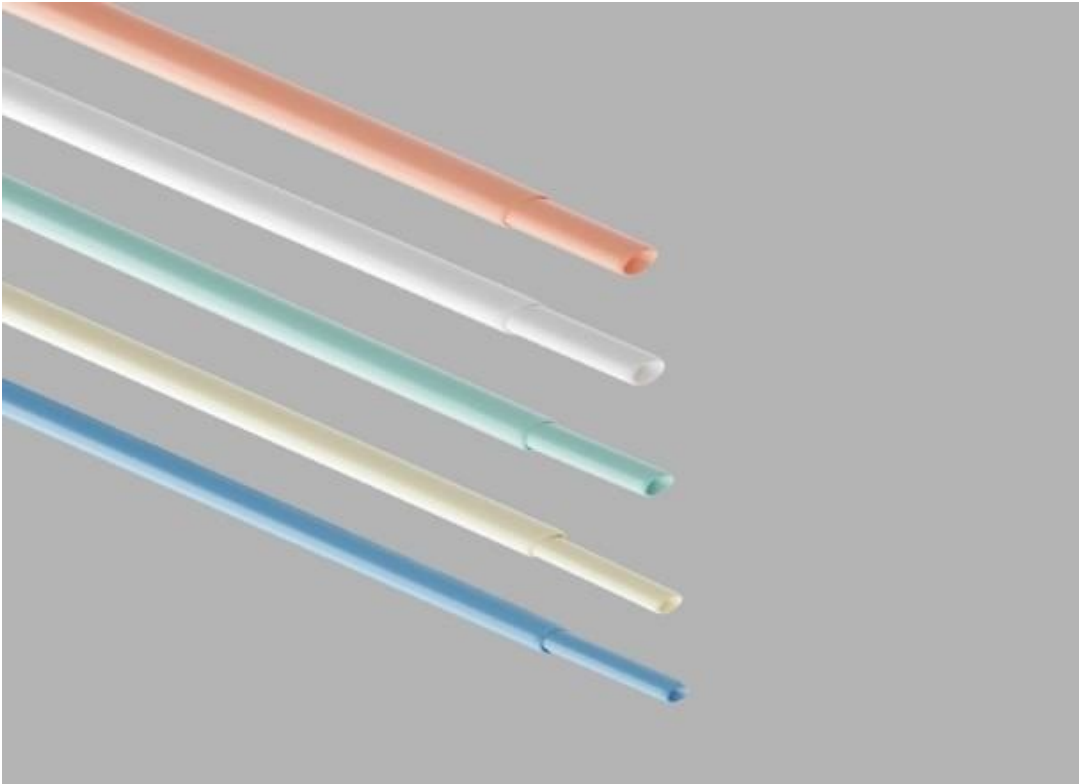
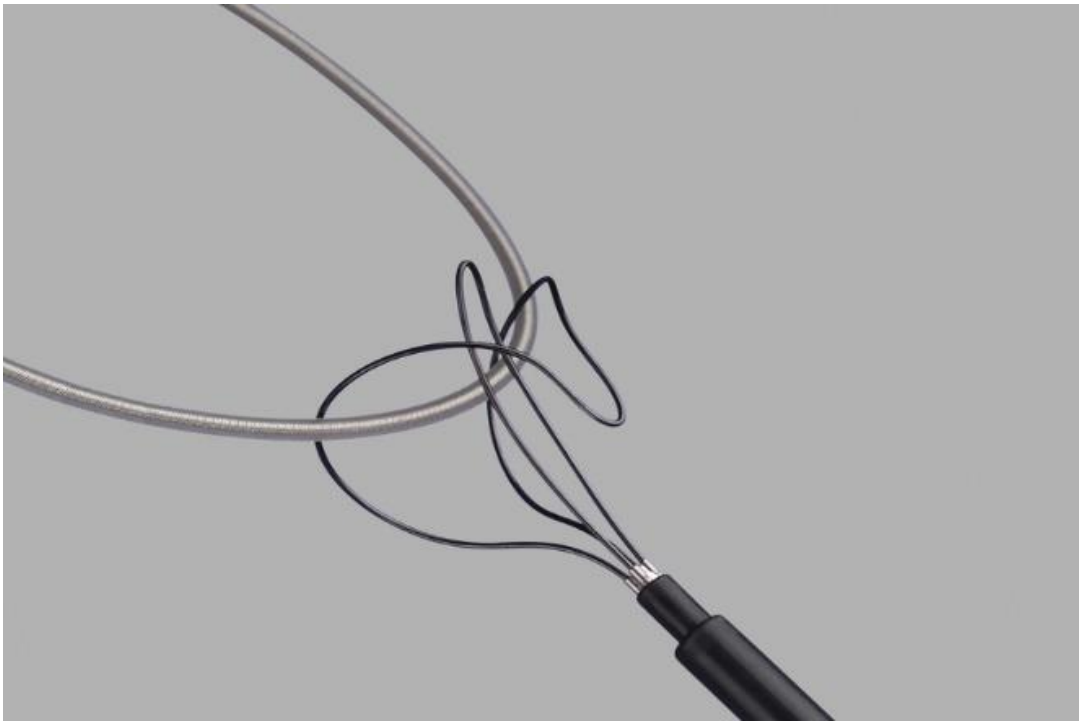
- 88 patients enrolled in the study, between October 2018 and July 2022.
- Cardiovascular imaging: TTE, TOE, PET/CT
- Blood work: inflammatory tests and multiple sets of blood cultures
- Empiric or targeted antibiotic therapy
- Angiography room with surgical support on request
- Temporary back-up pacing, BP monitoring, pericardiocentesis kit, continuous EKG
- Local anesthesia with Xylin 1% in most cases, IV sedation in 3 cases
- Femoral sheath for venous back-up access
- Two operators: maine + second.



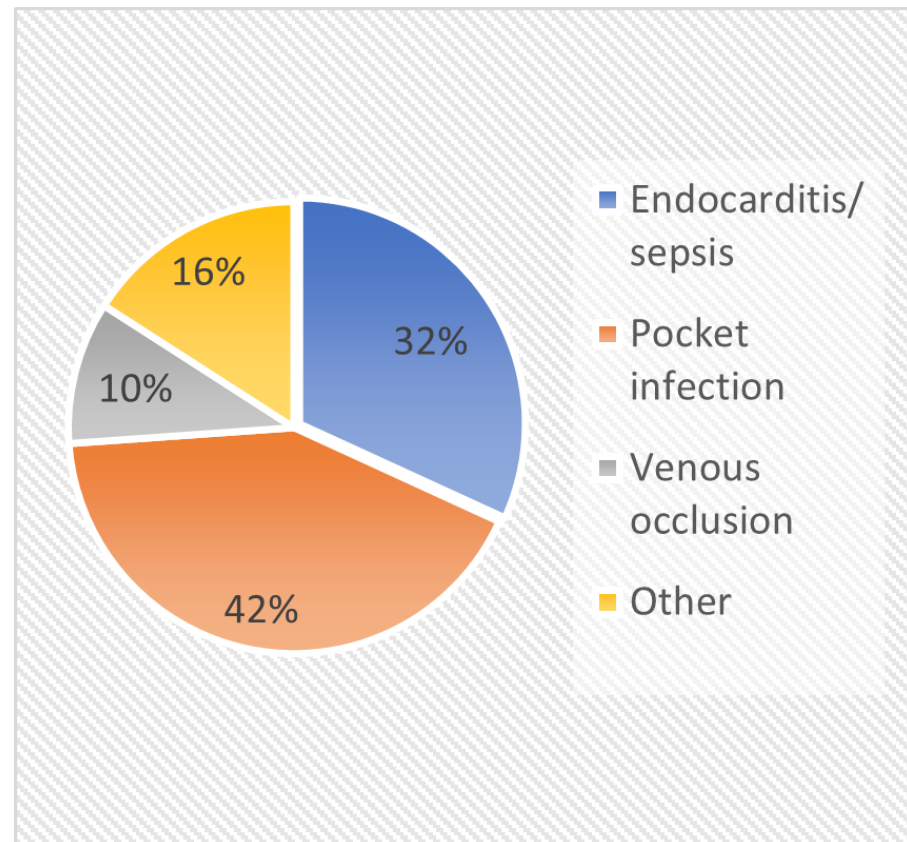
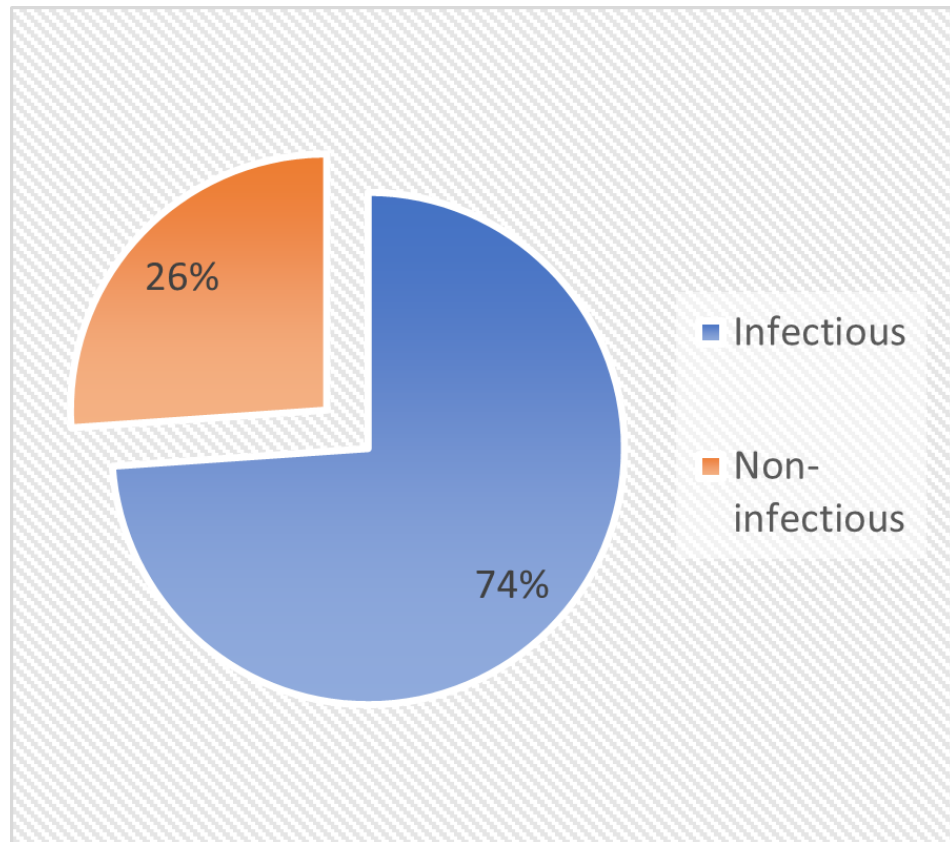
# Materials used for TLE

- Bipolar electrocautery
  - Surgical kit
  - Surgical threads of various sizes
  - Polypropylene sheaths of various sizes
  - Manual metal handle
  - Needle Eye snare device.
  - Drain pipes
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# Materials



# Indications



## INDICATIONS FOR REMOVAL

	=N	%
<b><u>Infection-related indication</u></b>	<b>65</b>	<b>74%</b>
<b>Endocarditis</b>	28	31.8%
<b>Pocket infection</b>	37	42%
<b><u>Non-infectious indications</u></b>	<b>23</b>	<b>26%</b>
<b>Venous occlusion</b>	9	10.2%
<b>Abandoned or dysfunctional leads</b>	14	15.9%

# Caracteristicile Pacientilor

Patient age, years, mean (standard deviation)	66.16 (16.00)
Time since first implant, years, mean (standard deviation)	6.92 (4.47) 0.477

Left ventricular EF, %, mean (standard deviation)	43.8% (14.06)
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Creatinine, mg/dL, mean (standard deviation)	1.00 (0.46)
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Number of patients	Frecvență = n	Procent%
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Number of patients	88	100
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Sex, male	59	67.0%
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## Comorbidities

HTN	55	65.5%
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Ischemic Cardiomyopathy	21	25%
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Diabetes	23	27.4%
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Renal failure	13	14.7%
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Dyslipidemia	10	11.9%
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Atrial fibrillation	36	42.9%
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Anemia	52	63.4%
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## Extracted device type

Device type	Frequency (n)	Percentage (%)
VVI	12	13.6%
DDD	32	36.4%
CRT-P	7	8.0%
SC-ICD	15	17.0%
DC-ICD	7	8.0%
CRT-D	15	17.0%
Total	88	100.0%



# Lead characteristics

<b>Lead type</b>		
<b>Lead age (average, years)</b>	6.92 ± 4.47 (1-26)	
<b>&gt;5 years (leads, =n)</b>	46	52.8%
<b>&gt;10 years (leads, =n)</b>	14	15.8%
<b>Probes extracted per procedure (=n)</b>		
<b>Average</b>	2 (1-4)	
<b>1</b>	31	38.2%
<b>2</b>	34	42%
<b>3</b>	14	17.3%
<b>4</b>	2	2.5%
<b>Types of leads extracted</b>	Frecvență = n	Procent%
<b>RA/RV pacing</b>	102	68
<b>ICD S-C</b>	25	16.6
<b>ICD D-C</b>	7	4.6
<b>CS pace</b>	16	10.6
<b>Fixation type</b>		
<b>Active fixation</b>	139	92.6
<b>Passive fixation</b>	11	7.3



# Results

- 93% complete extraction – no residual material
  - 94% partial extraction but achieving the clinical objective of the procedure
  - Simple traction effective in only 11.5% of cases
  - The snare device was used in 9 patients
  - Alternative jugular approach for dissection in 3 patients
  - 1 case of femoral approach snare for an intravascular lead
  - 1 failure
  - Success rates similar to those in the literature, including high-volume centers.
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# Complications

- No intraprocedural deaths
  - No major complications
  - 6.8% had minor complications: 3 cases of ventricular arrhythmias or conduction disturbances, two cases of post-procedural local hematoma, and 1 case of spontaneously resolved pericardial effusion.
  - 3.4% mortality at 30 days: 1 case of refractory sepsis (albeit with procedural success), 1 case of refractory acute failure, 1 sudden death on the second post-procedural day.
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# First study conclusions:

- The transvenous extraction technique with non-motorized sheaths is safe and effective
- Requires experienced operator with training in a reference center.
- On-site surgical support is preferred.
- The diagnosis of systemic infections is complex and requires interdisciplinary collaboration and careful correlation of data.
- Early referral plays an important role in curing the device infection

# Studiul II

- All patients undergoing extraction were re-evaluated for re-implantation

3 strategies were proposed:

1. Patients with an infectious indication and pacemaker dependent:

with pocket infection - contralateral reimplantation within the same hospitalization, but only after post-extraction antibiotic therapy

*\*Until reimplantation, patients were temporarily stimulated with a permanent catheter through the jugular vein and an externally fixed generator.*

2. Infectious and pacemaker non-dependent patients:

with pocket infection – remote contralateral reimplantation (minimum 2 weeks of waiting + antibiotic therapy). The ipsilateral reimplantation was possible in case of a waiting period of >6 months after the healing of the infection

with systemic infection - waiting 90 days + normalization of ultrasound (vegetation) and two negative blood cultures

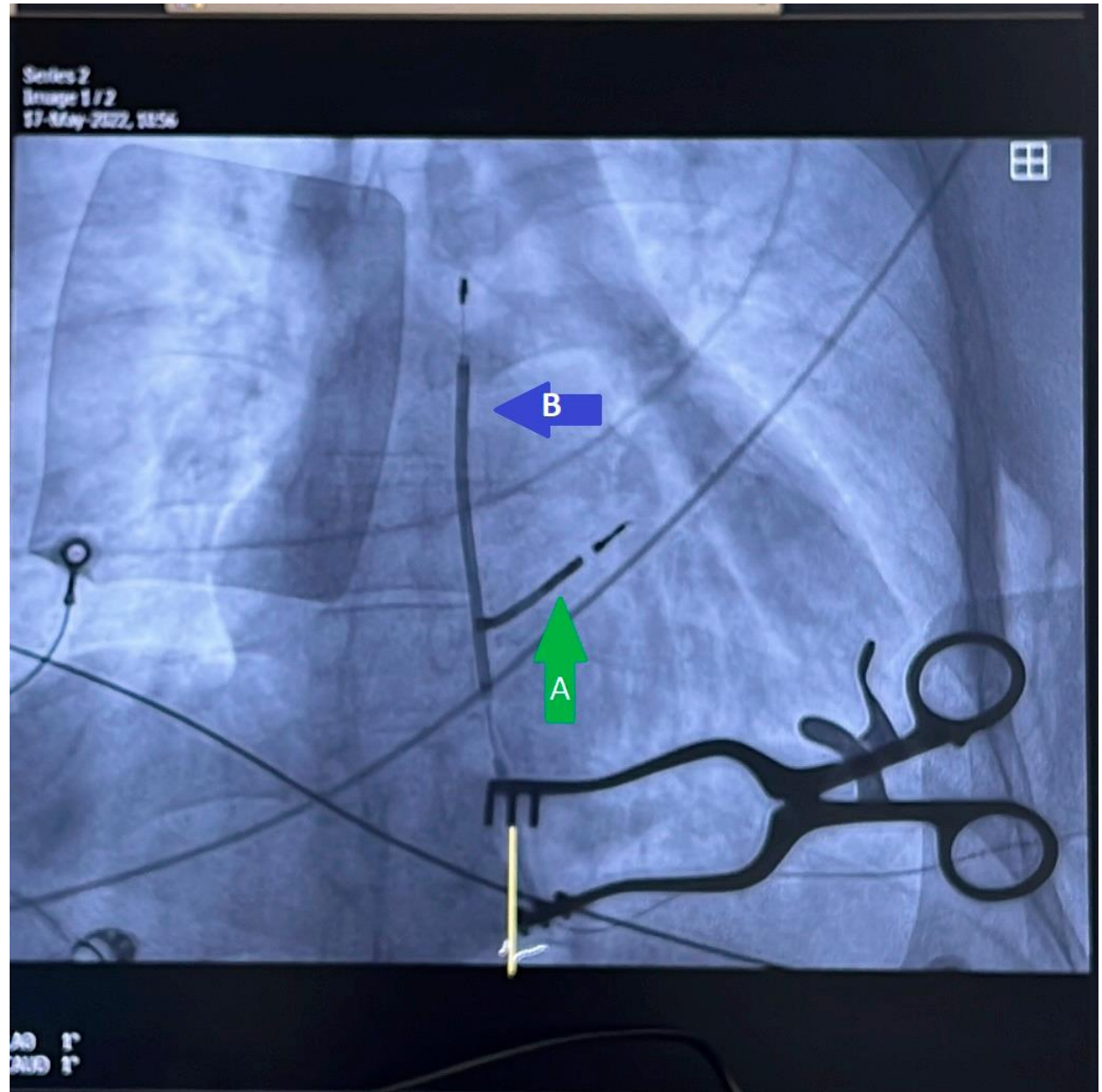
3. Patients with non-infectious indication for extraction:

Ipsilateral reimplantation synchronous with the extraction procedure

# Results

- 76% of patients still had an indication for the extracted device
- Of these, 3 patients refused reimplantation, and 86.5% were reimplanted.
- Reimplant site:
  - Contralateral implant: 58.6%
  - Ipsilateral implant: 38%
  - S-ICD: 2 patients.
- Time of reimplant:
  - 34.4% were reimplanted during the extraction procedure.
  - 24% were reimplanted during the same admission for extraction, but not during extraction.
  - 41.3% were discharged and reimplanted later.

# Reimplant S- ICD



# Concluzii studiul II

- ZERO reinfection rate 1 year after reimplantation using the proposed strategy
- Most patients still have an indication for an implantable cardiac device
- There are no consensus documents regarding the reimplantation strategy
- The best approach is a personalized one, depending on the indication for the extraction and the associated comorbidities.