ly Mobilization After emaker Implantation.

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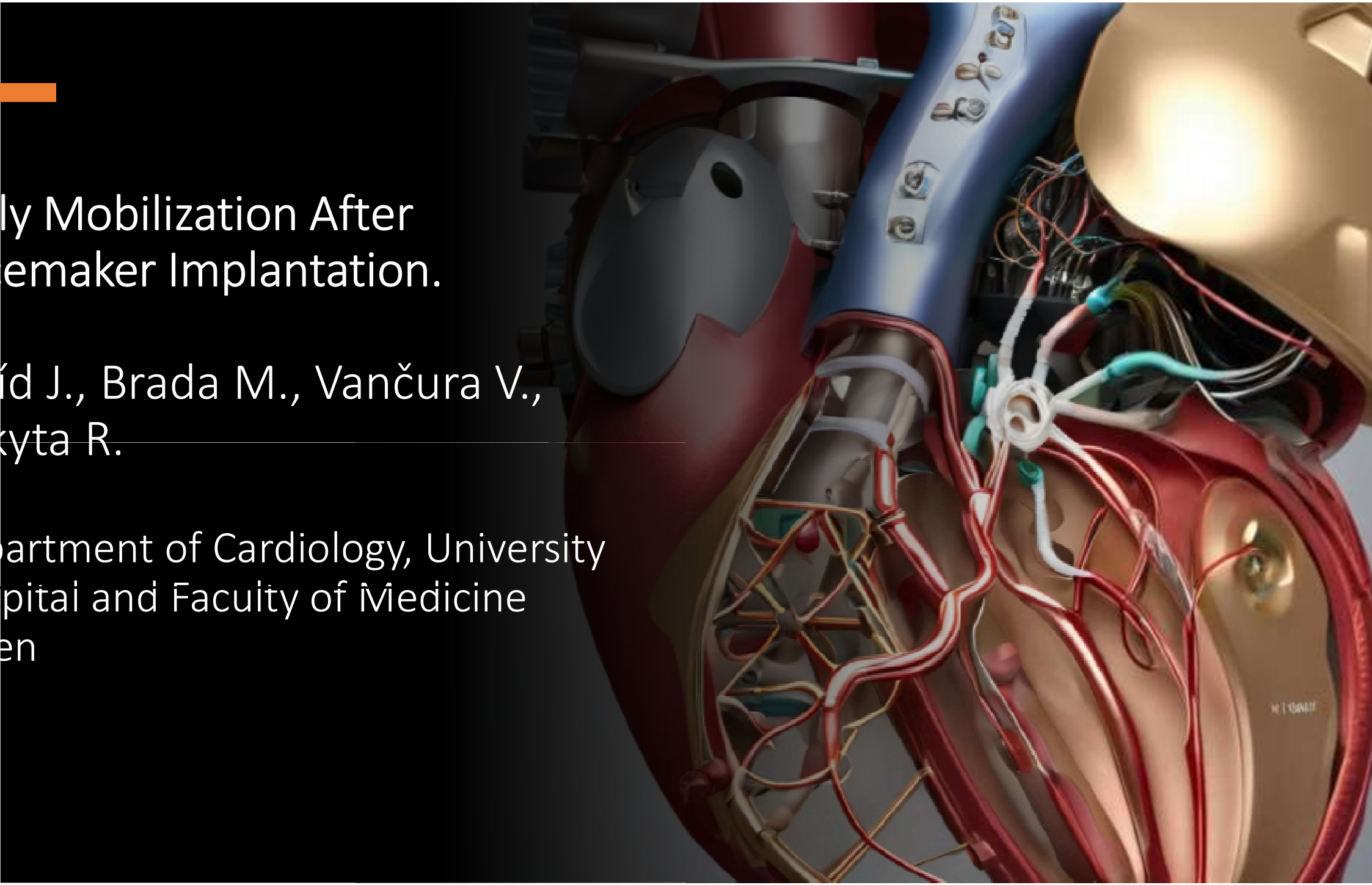
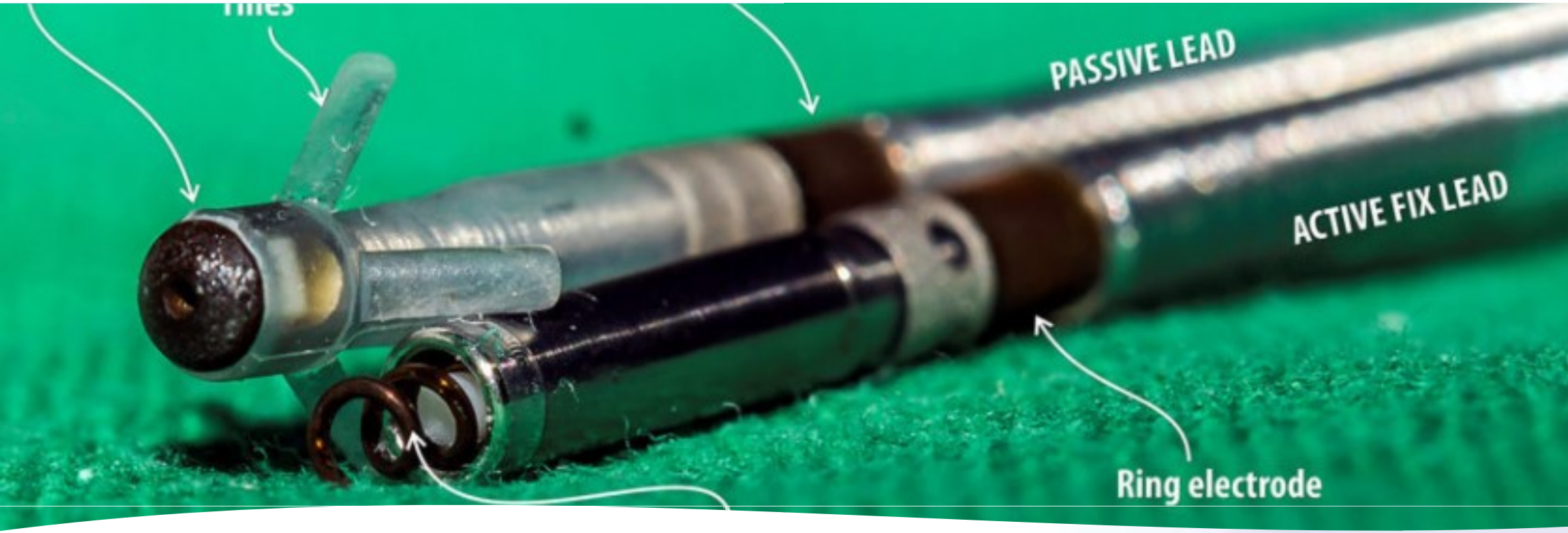
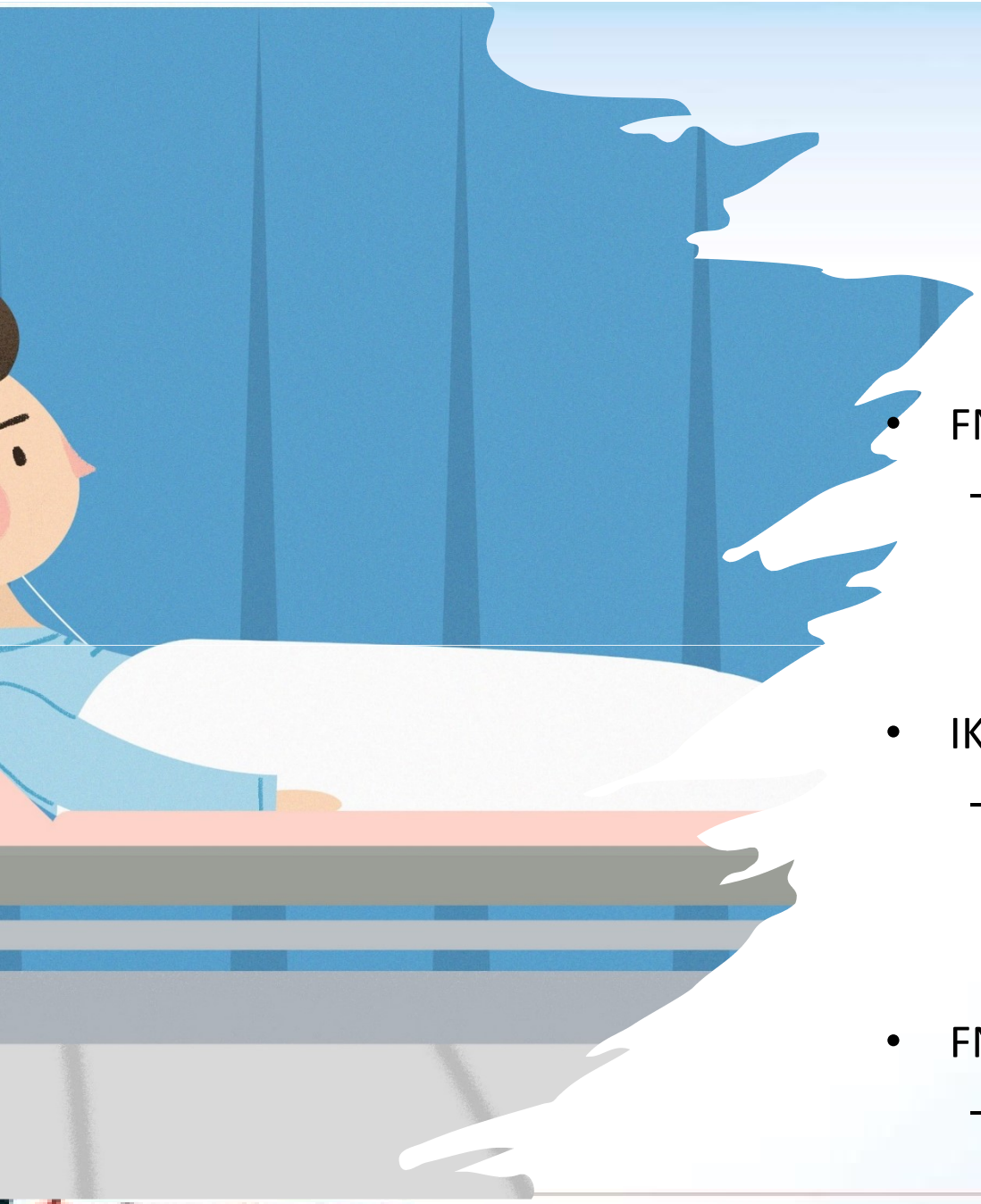




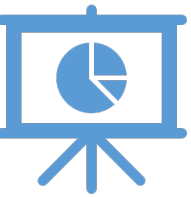
- There are not any recommendations (professional societies or corporate) specifying the duration of immobilization after CIED implantation.
- Time of immobilization is based on the historical concept from the time of implantation leads with passive fixation and varies in different hospitals.



Early mobilization after permanent pacemaker implantation

- FN Brno
  - After the procedure, the patient returns to his bed. the day of the implantation we recommend a more restful regime, the next days after the procedure a normal movement regime.
- IKEM
  - To reduce the risk of dislodgement of the lead, it is important to maintain bed rest, usually until the ne day, and then minimize movements of the upper li on the side where the pacemaker is implanted.
- FN Bulovka
  - The patient should spend the next 24 hours at rest hospital bed.

Early Mobilization After Pacemaker Implantation



Study design

rospective, randomized, single-enter study that enrolled patients ndergoing pacemaker implantation t our institution.

Inclusion criteria

(1) Minimum age of 18 years

(2) class I and II recommendations for pacing according to ESC guidelines

(3) mobile, cooperative patients

(4) signed informed consent for the study

Exclusion criteria

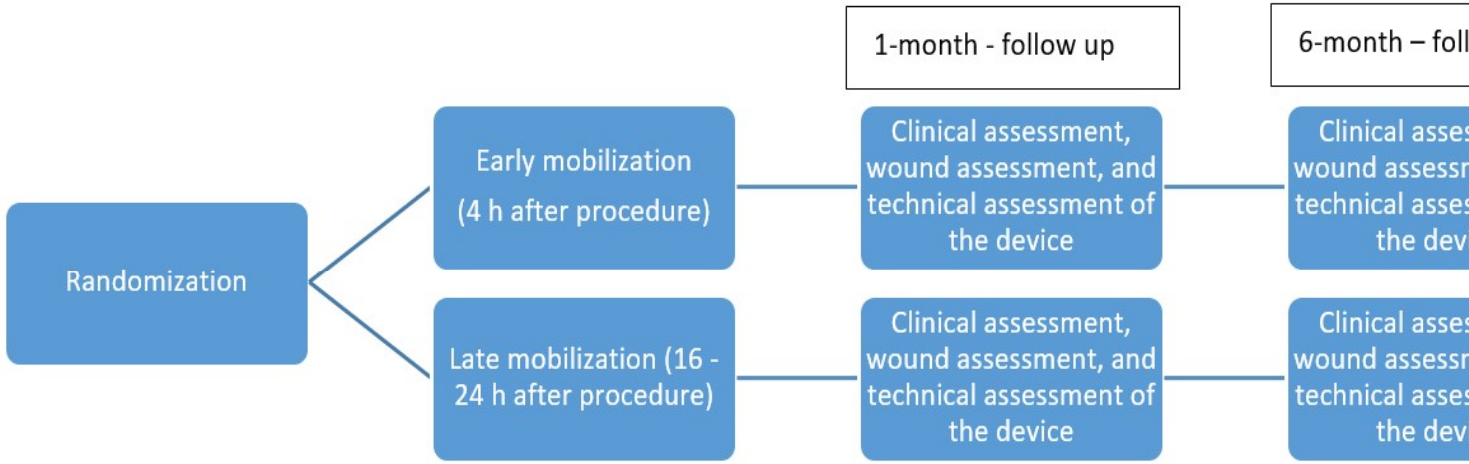
(1) implantation of CRT devices

(2) device upgrade or revision

(3) patients with the usual contraindications to permanent pacemaker implantation

(4) pregnancy.

Early Mobilization after emaker Implantation



Early Mobilization After Pacemaker Implantation

- The primary composite endpoint
  - Included the most commonly encountered complications associated with CIED implantation.
    - Hematoma, major bleeding (requiring intervention/revision, blood transfusion, or prolonged hospitalization)
    - Wound infection
    - Pneumothorax
    - Atrial lead dislodgement
    - Ventricular lead dislodgement
    - Other, extracardiac complications
- The secondary endpoint
  - compared the incidence of each complication listed as part of the primary composite endpoint and any changes in the technical parameters of the CIEDs.

Patients characteristics

	Total	Early mobilization		Late mobilization		p
		n	%	n	%	
Randomization short x long	200	100		100		
Age	74,89	74,85		74,94		
Male	121	61	50,4%	60	49,6%	
Female	79	39	49,4%	40	50,6%	
Indication						
Sick sinus syndrome	71	38	53,5%	33	46,5%	0.679
AV block	79	37	46,8%	42		0.6907
AF with bradycardia	50	25	50%	25	50%	
Type of device						
Single chamber pacemaker	50	25	50%	25	50%	
Dual chamber pacemaker	150	75	50%	75	50%	
Medication						
Warfarin	59	29	49,2%	30	50,8%	
Rivaroxaban	33	17	51,5%	16	48,5%	
Dabigatran	9	8	88,9%	1	11,1%	0.036
Apixaban	14	8	57,1%	6	42,9%	0.7835
Edoxabam	0	0	0%	0	0%	
Anopyrin	50	17	34%	33	66%	0.0567
Trombex	7	3	42,9%	4	57,1%	
Brilique	3	2	66,7%	1	33,3%	
Prasugrel	0	0	0%	0	0%	

Results – technical parameters

	EaM	LaM	EaM	LaM	EaM	LaM	p
	Discharge follow-up		1 - month follow-up		6 - month follow-up		Discharge FU/6M FU
A sensing (mV)	2,29	2,57	2,79	2,88	2,48	2,73	0,30
V sensing (mV)	11,59	11,97	13,87	13,11	12,92	12,17	0,70
A treshold (V)	0,52	0,52	0,55	0,53	0,61	0,55	1
V treshold (V)	0,68	0,62	0,76	0,79	0,76	0,82	0,29
A impedance (ohm)	410,09	413,71	410,11	408,43	390,69	390,97	0,94
V impedance (ohm)	752,53	758,66	686,80	690,48	651,29	637,21	0,91

- The technical parameters (sensing, threshold, and impedance) were stable over the course of the follow-up in b

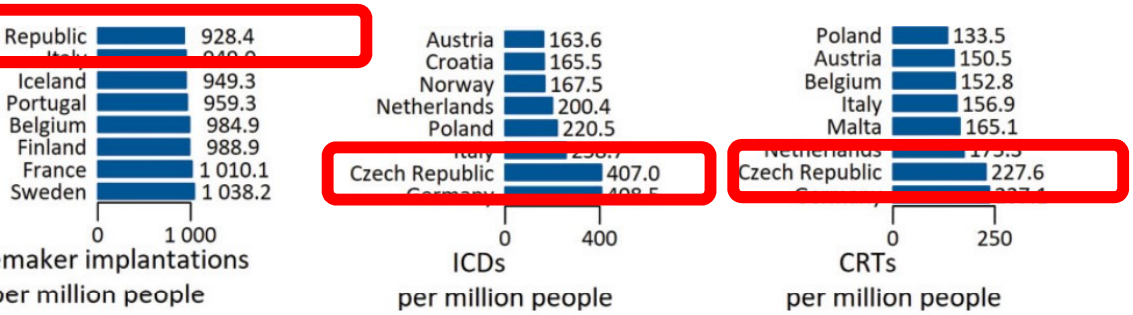
arms of our trial and no significant variation in the evolution of sensing, threshold, or impedance values was found.

Results – complications

	Total	Early mobilization		Late mobilization		p (Fisher exact test)
		n	%	n	%	
Primary composite endpoint	11	4	0	7	0	0.5378
Haematoma, major bleeding	0	0	0%	0	0%	NS
Pneumothorax	2	0	0%	2	100%	0.4957
Atrial lead dislodgement	4	2	50%	2	50%	NS
Ventricular lead dislodgement	0	0	0%	0	0%	NS
Wound infection	1	1	100%	0	0%	NS
Perforation	1	0	0%	1	100%	NS
Others complications	3	1	33%	2	66%	NS

- Other complications (Upper arm thrombosis, lead fracture, upgrade to ICD) - thrombosis and fracture in long arm of immobilization
- 6 deaths occurred before 6 month follow-up (Covid 2x, cancer 1x, sepsis 1x, heart failure 1x, unknown 1x)

Early Mobilization After Pacemaker Implantation



Achieving a larger number of events would require the involvement of most implant centres in the Czech Republic within one year.

Incidence of complications after CIED therapy	%
Lead-related reintervention[354,639,690,692,695,700,701] (including dislodgement, malposition, subclavian crush syndrome, etc.)	1.0–5.9
CIED-related infections, <12 months[354,639,641,645,685,695,702]	0.7–1.7
Superficial infection[354]	1.2
Pocket infections[354]	0.4
Systemic infections[354]	0.5
CIED-related infections, >12 months[702–709]	1.1–4.6
Pocket infections[702]	1.3
Systemic infections[702,705]	0.5–1.2
Pneumothorax[354,658,690,692,700,701,707]	0.5–2.2
Haemothorax[695]	0.1
Brachial plexus injury[695]	<0.1
Cardiac perforation[354,663,690,692,695]	0.3–0.7
Coronary sinus dissection/perforation[710,288]	0.7–2.1
Revision due to pain/discomfort[354,690]	0.1–0.4
Diaphragmatic stimulation requiring reintervention[711,712,665,713]	0.5–5
Haematoma[354,639,650,652,654,690,700,714,715]	2.1–5.3
Tricuspid regurgitation[716–718]	5–15
Pacemaker syndrome[146,701,719]	1–20
Generator/lead problem[354,639,690]	0.1–1.5
Deep venous thrombosis (acute or chronic)[354,720,721]	0.1–2.6
Any complication[354,639,690,692,695,707,722,723]	5–15
Mortality (<30 days)[354,694]	0.8–1.4

CIED = cardiovascular implantable electronic device.

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et al. European Society of Cardiology: cardiovascular disease statistics 2021.

et al.; 2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

› Journal of Interventional Cardiac Electrophysiology › Article

tcomes of an expedited same-
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d: 09 January 2024

Cite this article

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ethods

observational, restrospective, multicentre study

owing CIED implantation at three centers between 2015 and 2021. Patients were divided into same-day discharge (SDD) and delay
harge (DD) cohorts. Adverse event data were obtained from electronic medical records.

mary outcomes were complications including electrode failure requiring revision, pneumothorax, hemothorax, electrode dislodgem
ctrode perforation with tamponade, and death within 30 days of the procedure. Results were compared between the two cohorts
χ2 test.

sults

otal of 4543 CIED implantation procedures: with 1557 patients (34%) included in the SDD cohort.

% had a permanent pacemaker implanted (89% 2 lead system), 31% ICD, 20.6% CRT-P or CRT-D

ents with SDD were relatively younger, more often male, and had fewer comorbidities than patients with DD.

mean time to postoperative chest X-ray was 2.6 h. SDD had lower complication rates (1.3% vs 2.1%, p = 0.0487) and acute care uti
r discharge (9.6% vs 14.0%, p < 0.0001). There was no difference in infection rates at 90 days between cohorts.

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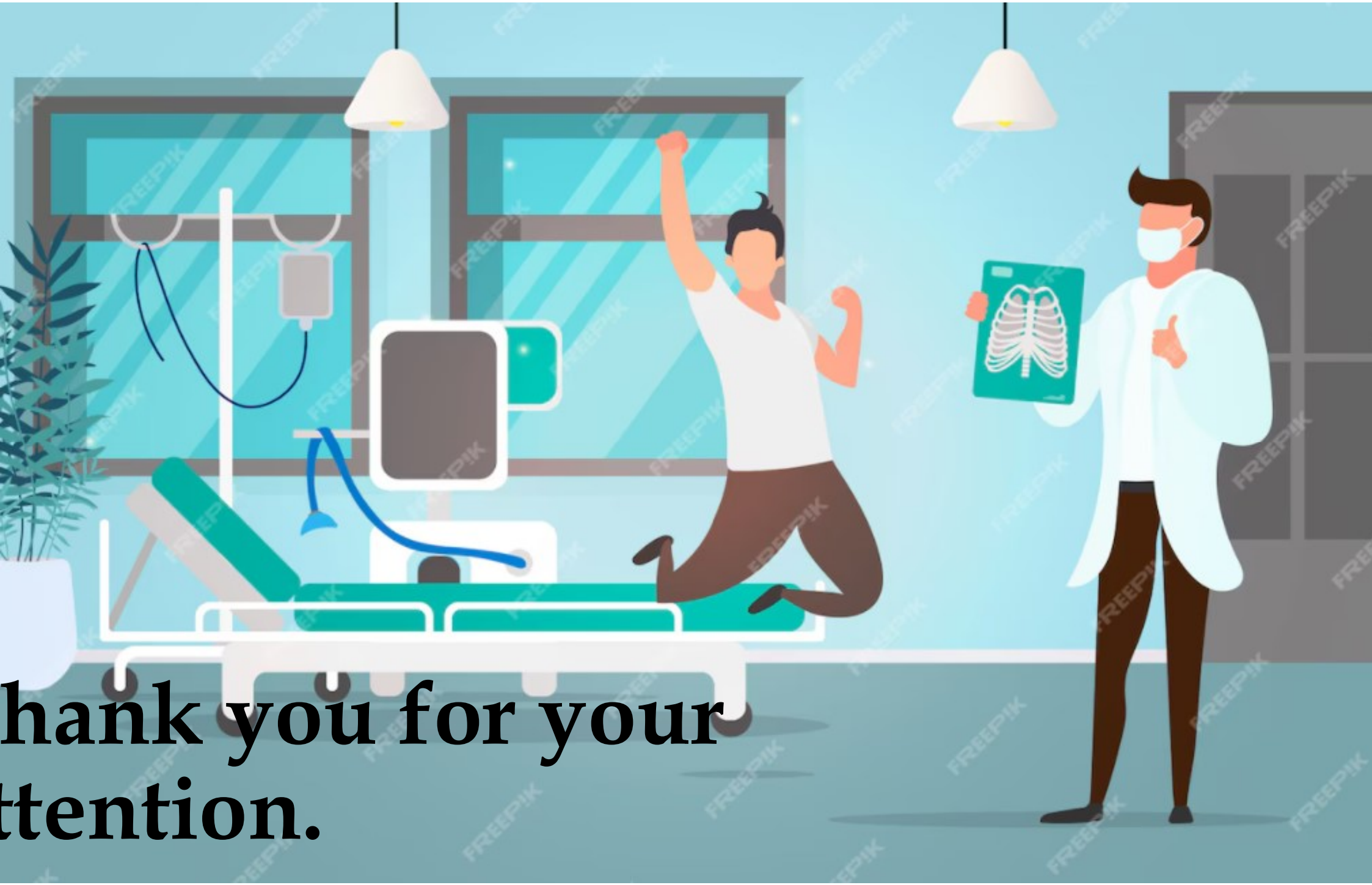
Observed 30-day complications among all patients undergo-
D implantation

cation type	Total	SDD	DDD
orax	1	0	1
slodgement	62	17	45
thorax	14	0	14
rforation with effusion	6	3	3

- Most lead dislodgements were detected during the pre-discharge inspection of the device.
- The same-day, two-hour discharge protocol is safe and effective with l rates of complications, infections, a postoperative acute care utilization

Conclusion

- Our trial presents compelling evidence that early mobilization after CIED implantation is safe and effective.
- The absence of significant differences in periprocedural complications between the EaM and LaM arms supports the feasibility of early discharge, which could lead to substantial healthcare savings and improved patient experiences.
- Our findings advocate for a reconsideration of current post-implantation care protocols and promote early mobilization as the new standard of care.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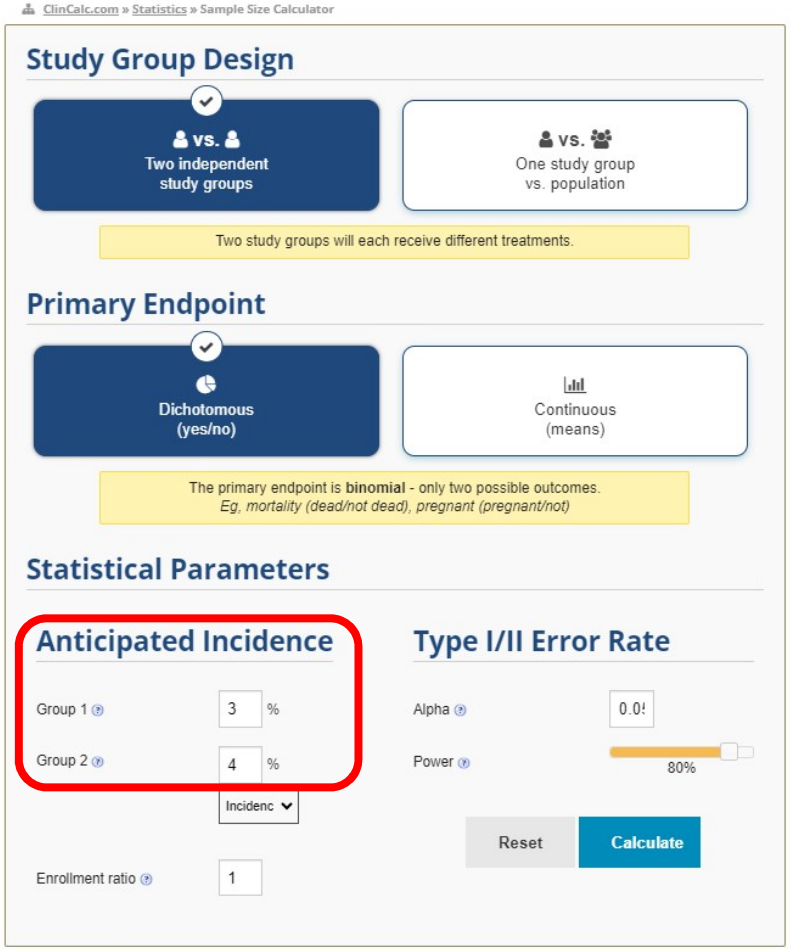
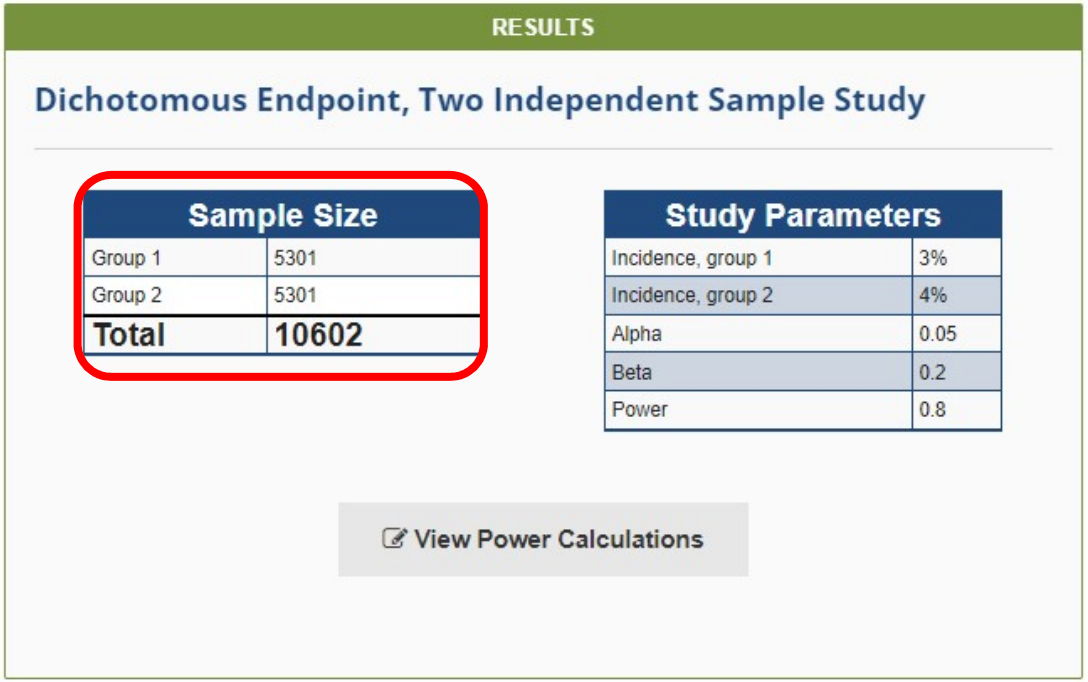
Early Mobilization After Pacemaker Implantation

Sample Size Calculator

Determines the minimum number of subjects for adequate study power





Early Mobilization After Pacemaker Implantation

Sample Size Calculator

Determines the minimum number of subjects for adequate study power

ClinCalc.com » Statistics » Sample Size Calculator

Study Group Design

- **vs.** Two independent study groups
- vs. One study group vs. population

Two study groups will each receive different treatments.

Primary Endpoint

- **Dichotomous (yes/no)**
- Continuous (means)

The primary endpoint is **binomial** - only two possible outcomes.
Eg, mortality (dead/not dead), pregnant (pregnant/not)

Statistical Parameters

Anticipated Incidence

Group 1: 3 %

Group 2: 5 %

Incidenc

Enrollment ratio: 1

Type I/II Error Rate

Alpha: 0.05

Power: 80%

Reset | Calculate

RESULTS

Dichotomous Endpoint, Two Independent Sample Study

Sample Size	
Group 1	1506
Group 2	1506
Total	**3012**

Study Parameters	
Incidence, group 1	3%
Incidence, group 2	5%
Alpha	0.05
Beta	0.2
Power	0.8

View Power Calculations