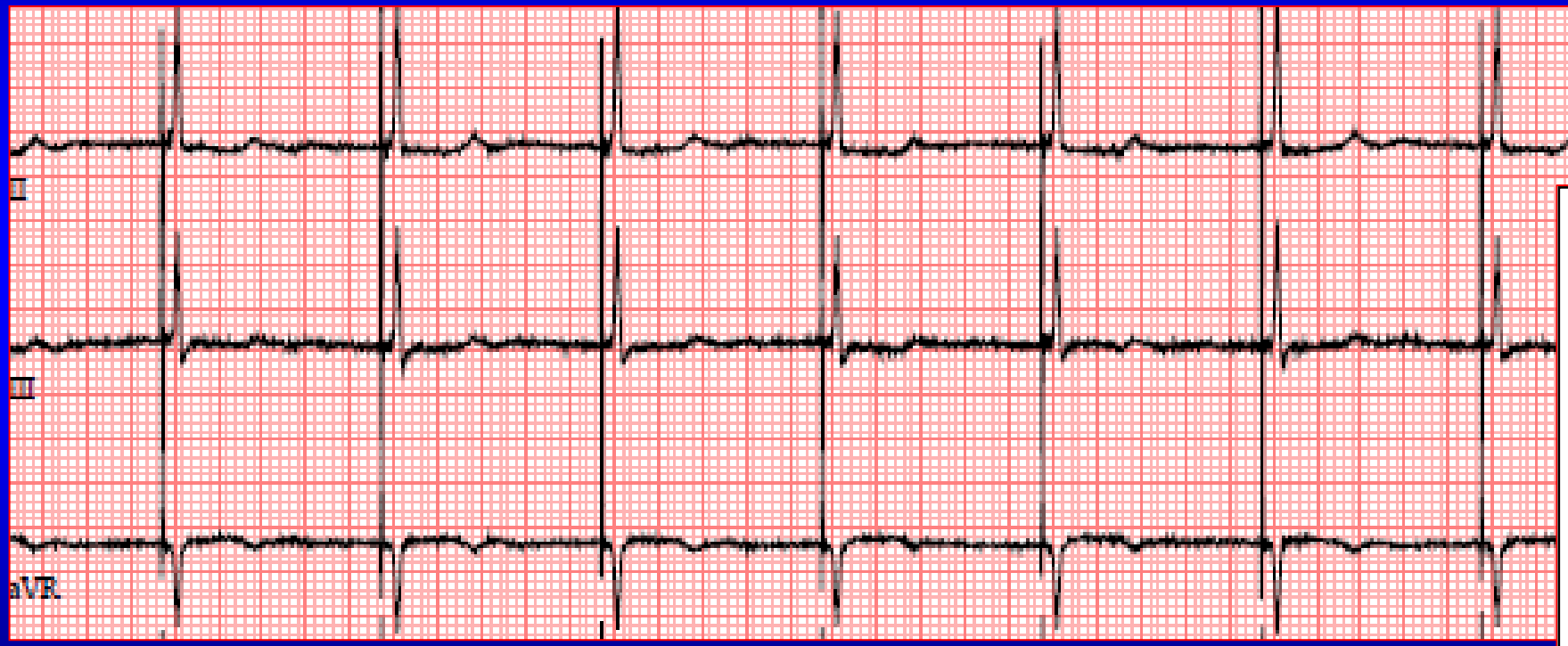
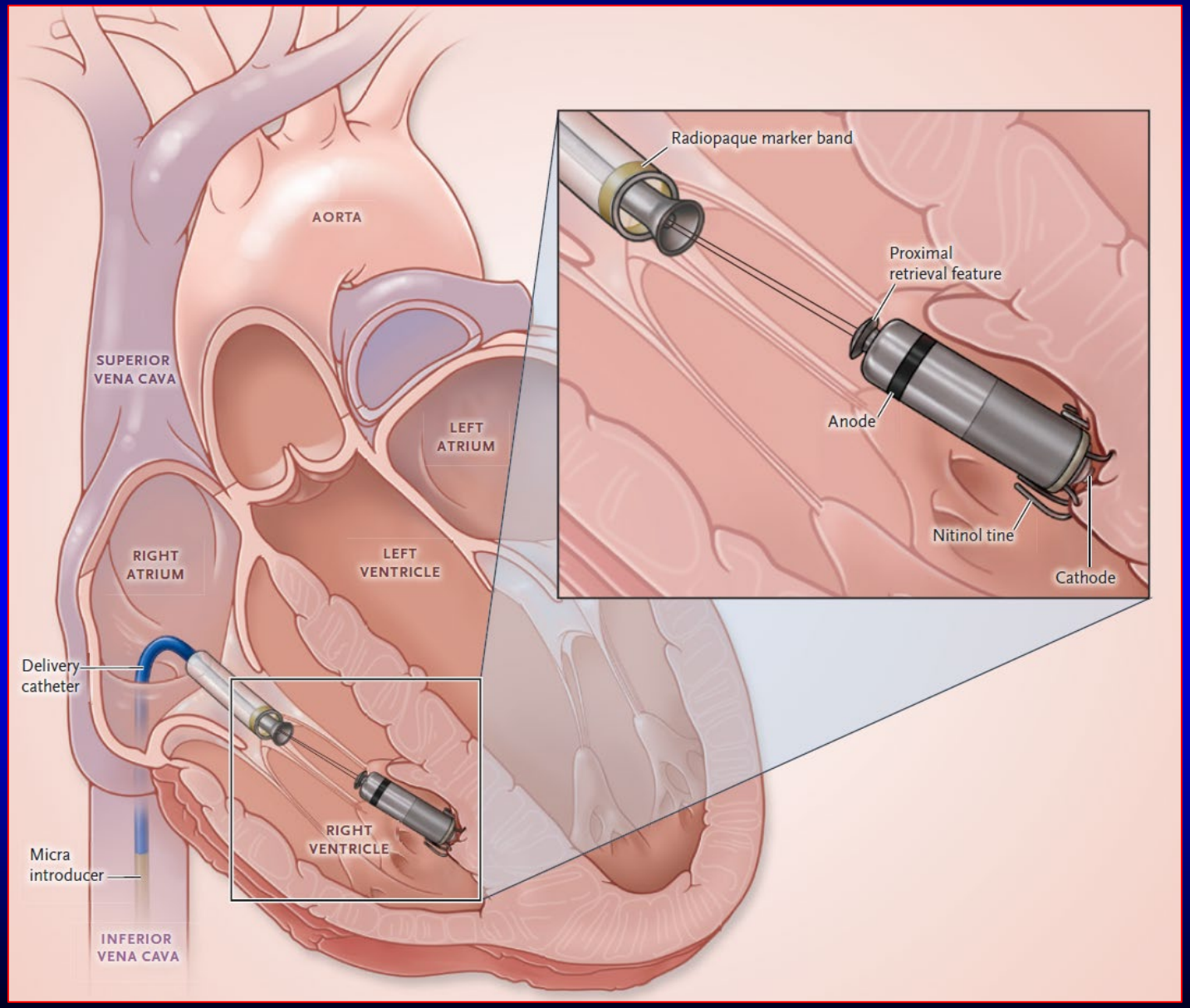
Was ist neu … in der Schrittmachertherapie



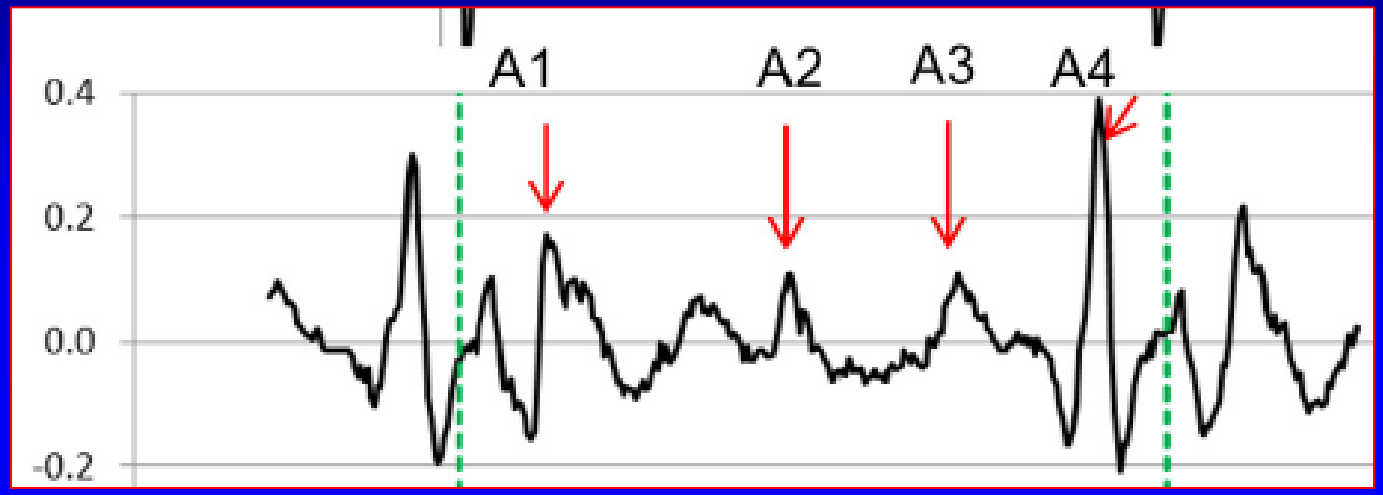
Carsten W. Israel
Ev. Klinikum Bethel, Bielefeld
Carsten.Israel@evkb.de

Leadless/Trans-Catheter Pacemaker



Reynolds, New Engl J Med 2015

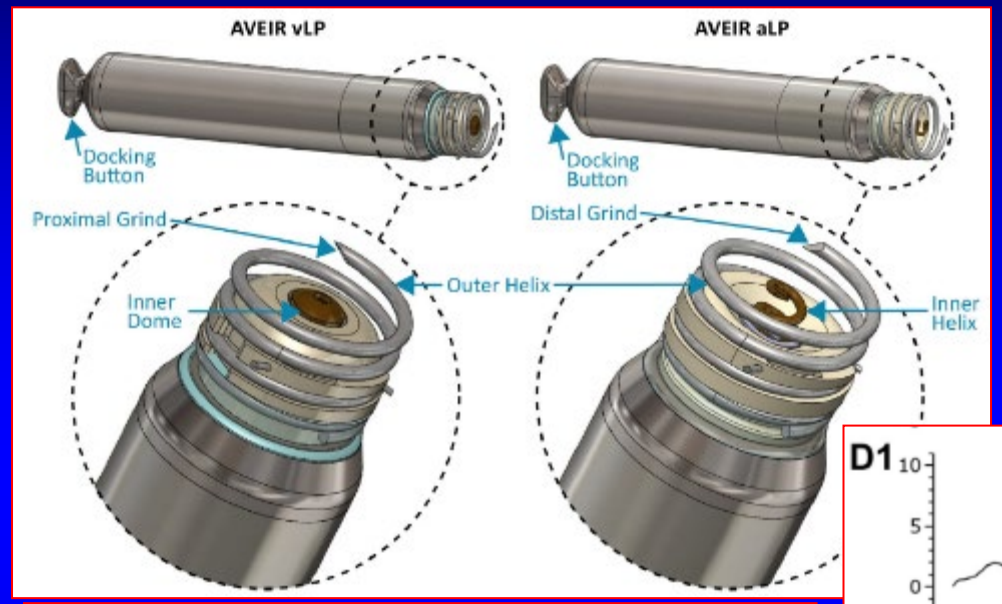
Leadless VDD-Schrittmacher

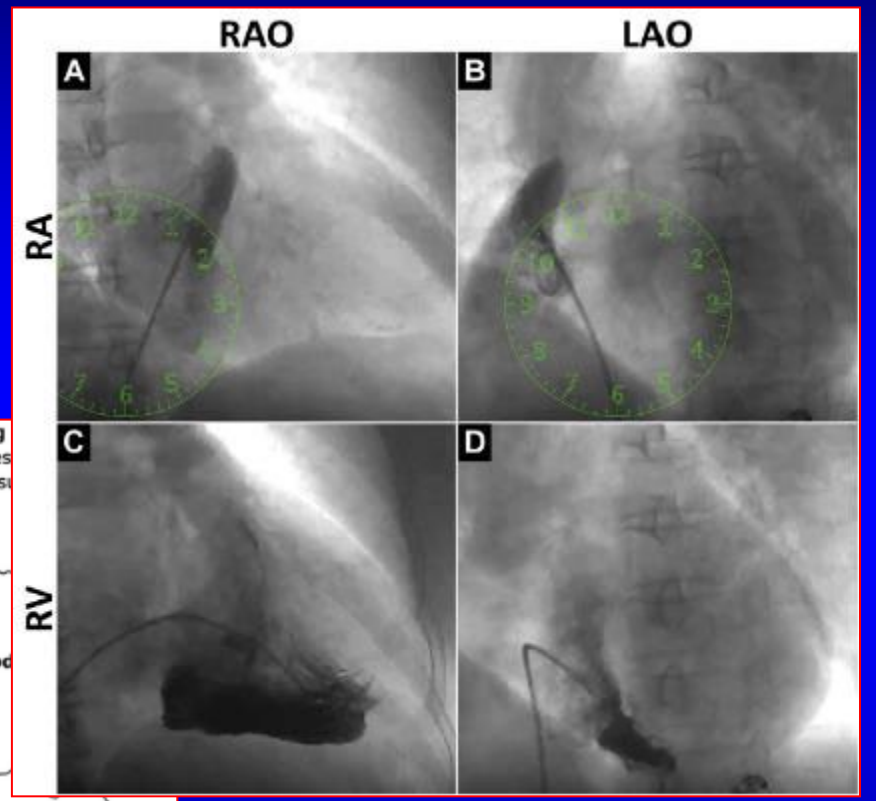


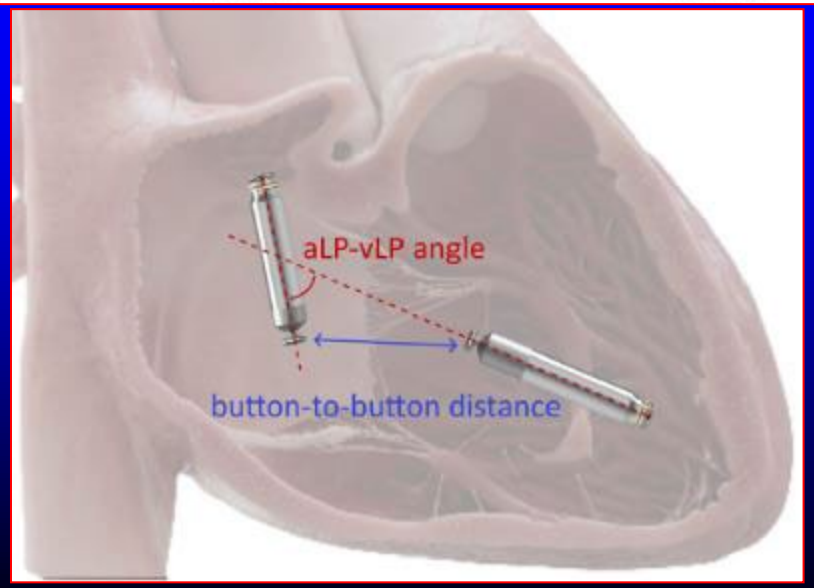
mitral/tricuspid valve closure (A1)
aortic/pulmonic valve closure (A2)
passive ventricular filling (A3)
atrial contraction (A4)

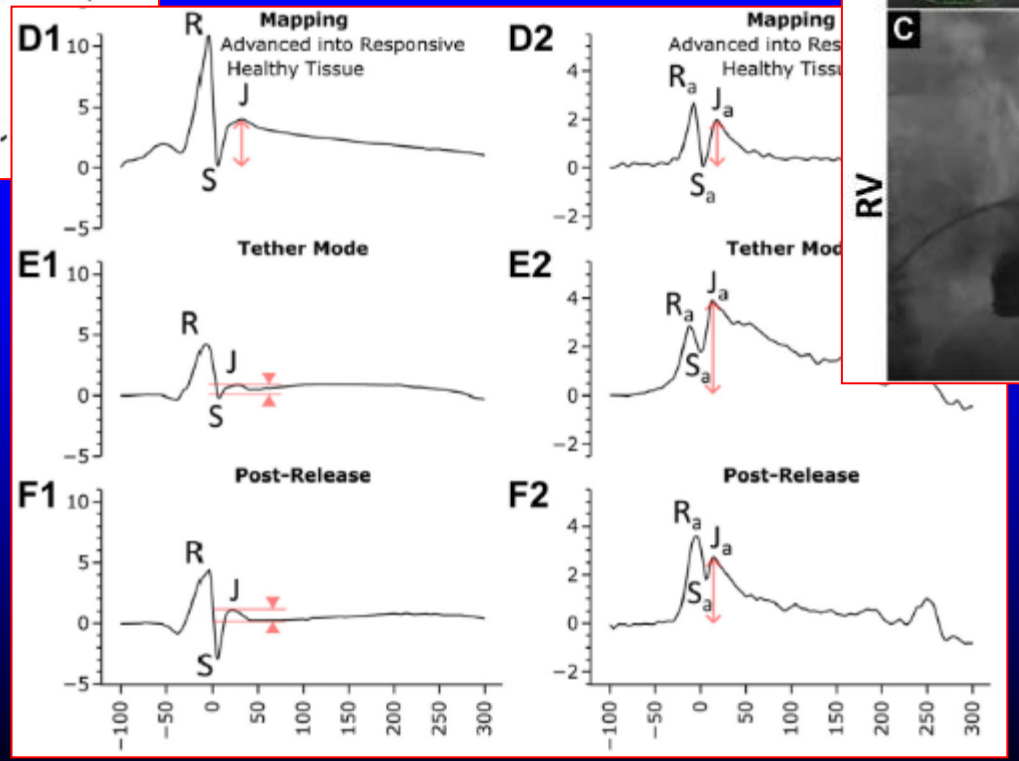
Chinitz, Heart Rhythm 2018;15:1363-71

Leadless DDDR (AAIR)-Schrittmacher



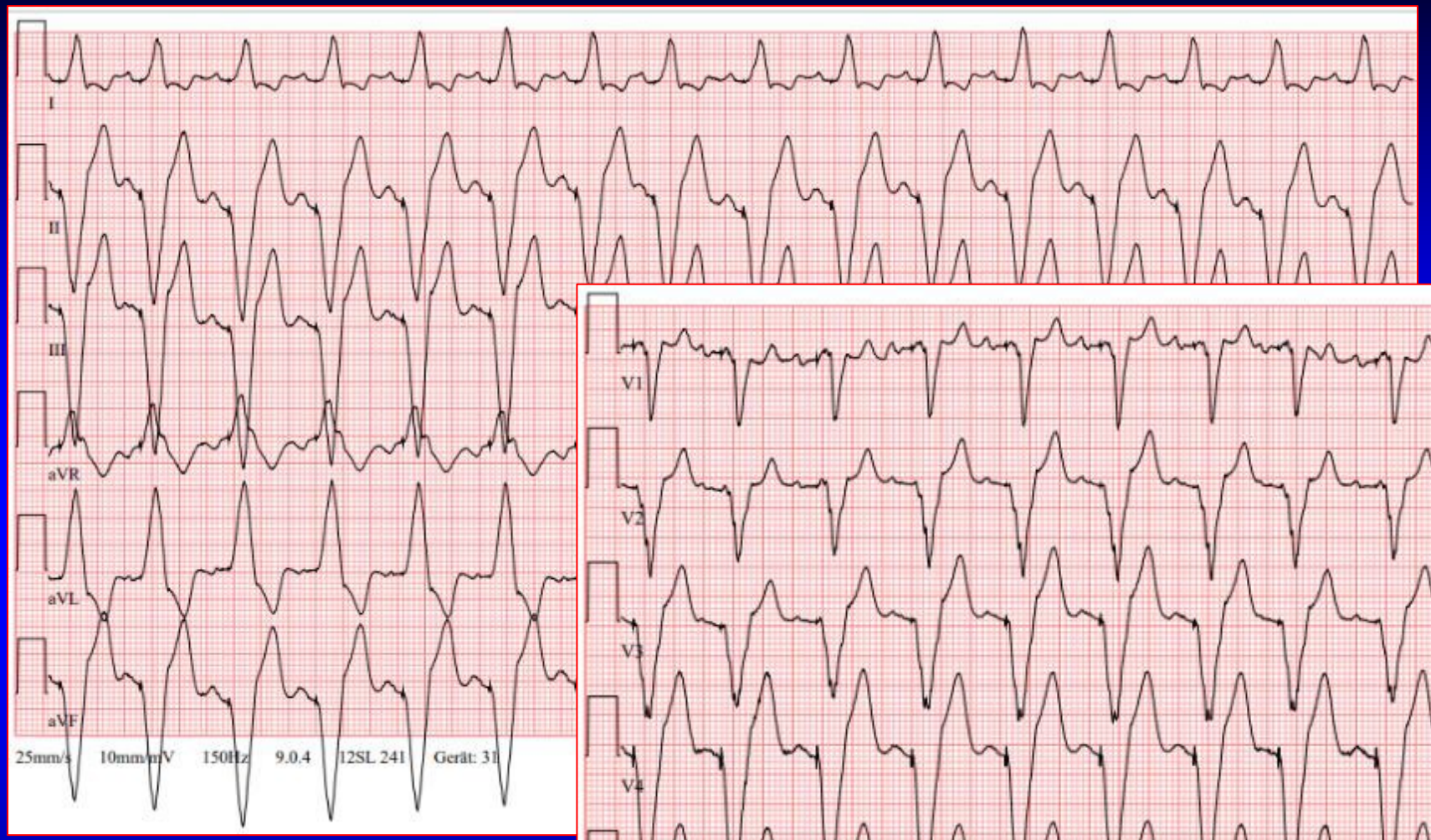






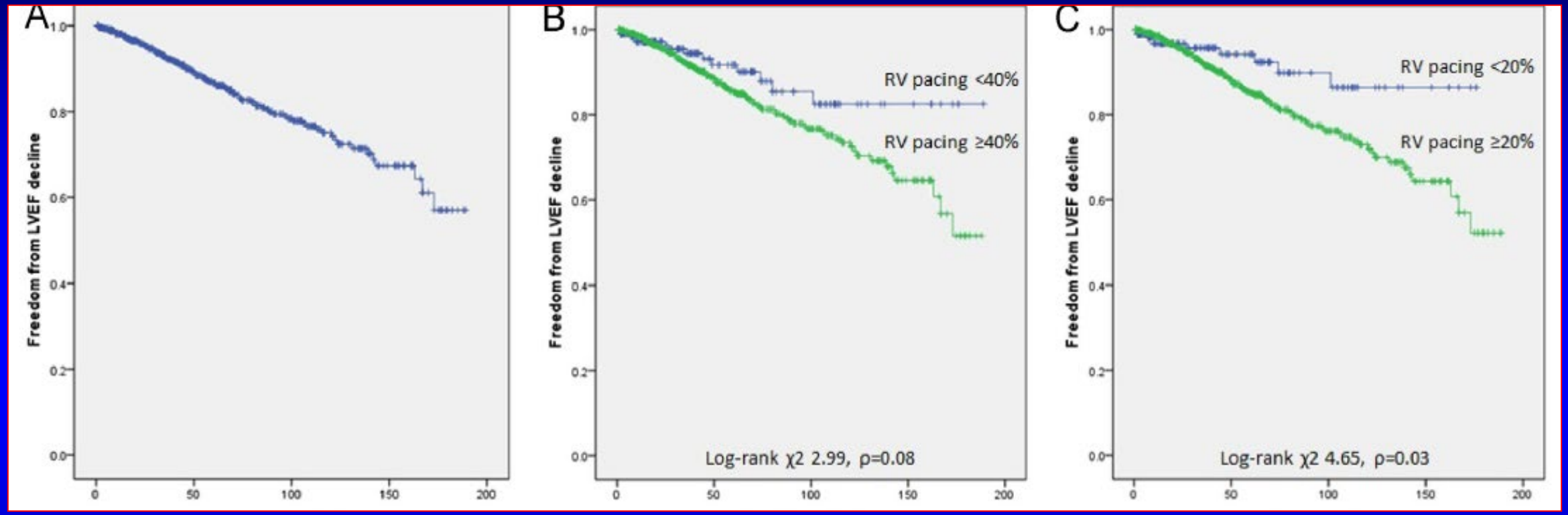
Neuzil,
Heart Rhythm 2024;
21:2552–2562

Bethel



Problem gelöst?

Pacing-induced Cardiomyopathy (PICM)

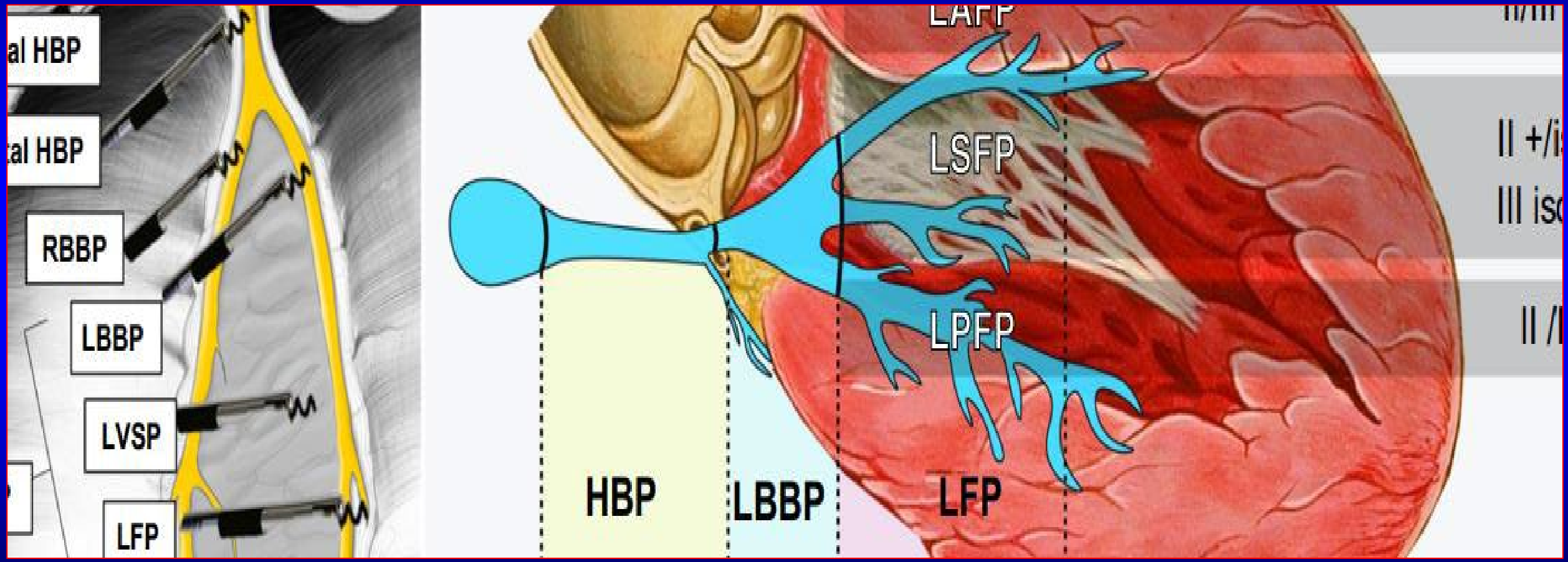


- Häufigkeit bis zu 3-5%/Jahr, v. a.
  - ⇨ RV-Stimulation >20%
  - ⇨ vorbestehende Herzerkrankung (Hypertonie, KHK)
  - ⇨ leicht-/mittelgradig reduzierte LVEF (40-50%)
  - ⇨ RV-apikales Pacing

Kiehl, Heart Rhythm 2016;13:2272-8

Bethel

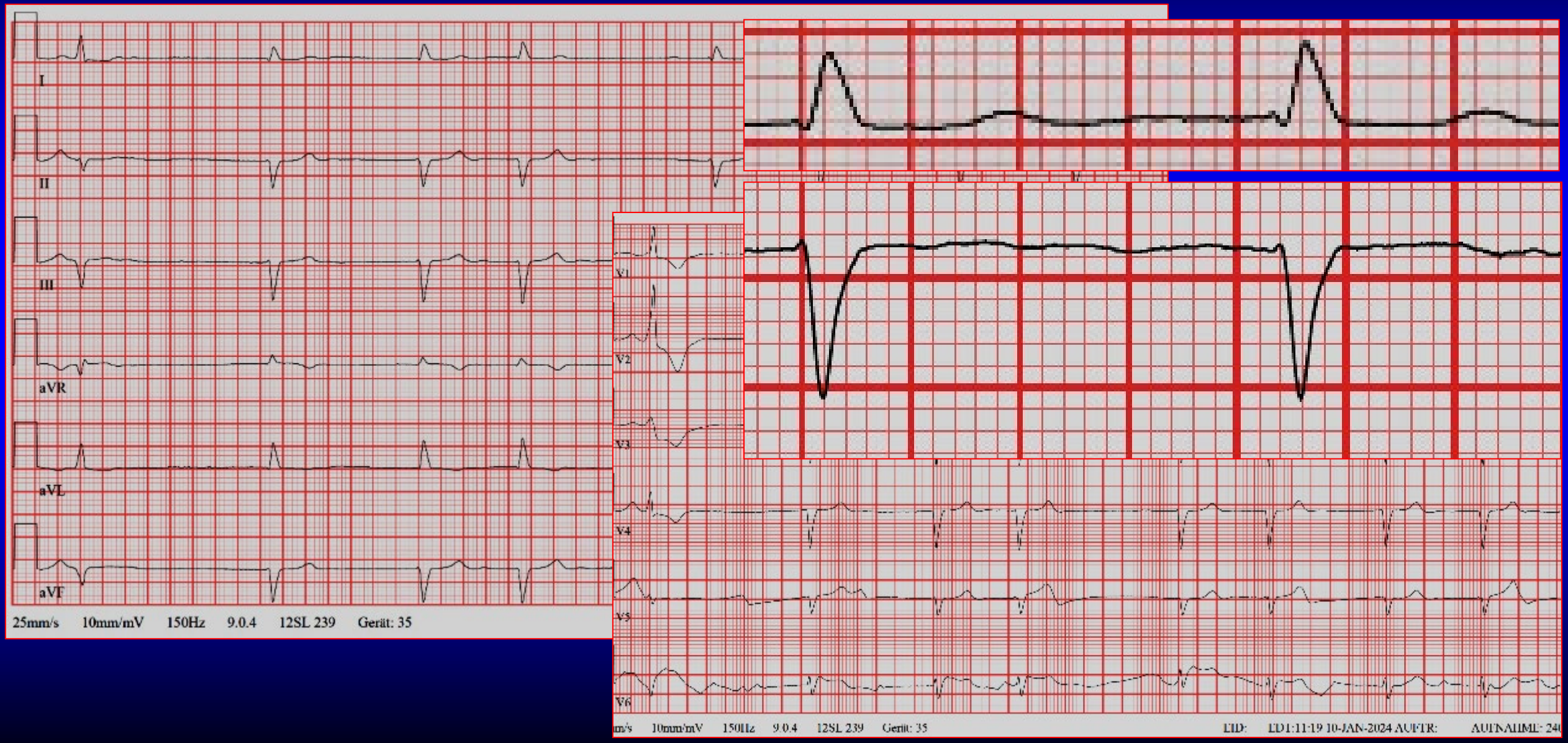
Conduction System Pacing



Burri, Europace 2023;25:1208-36

Bethel

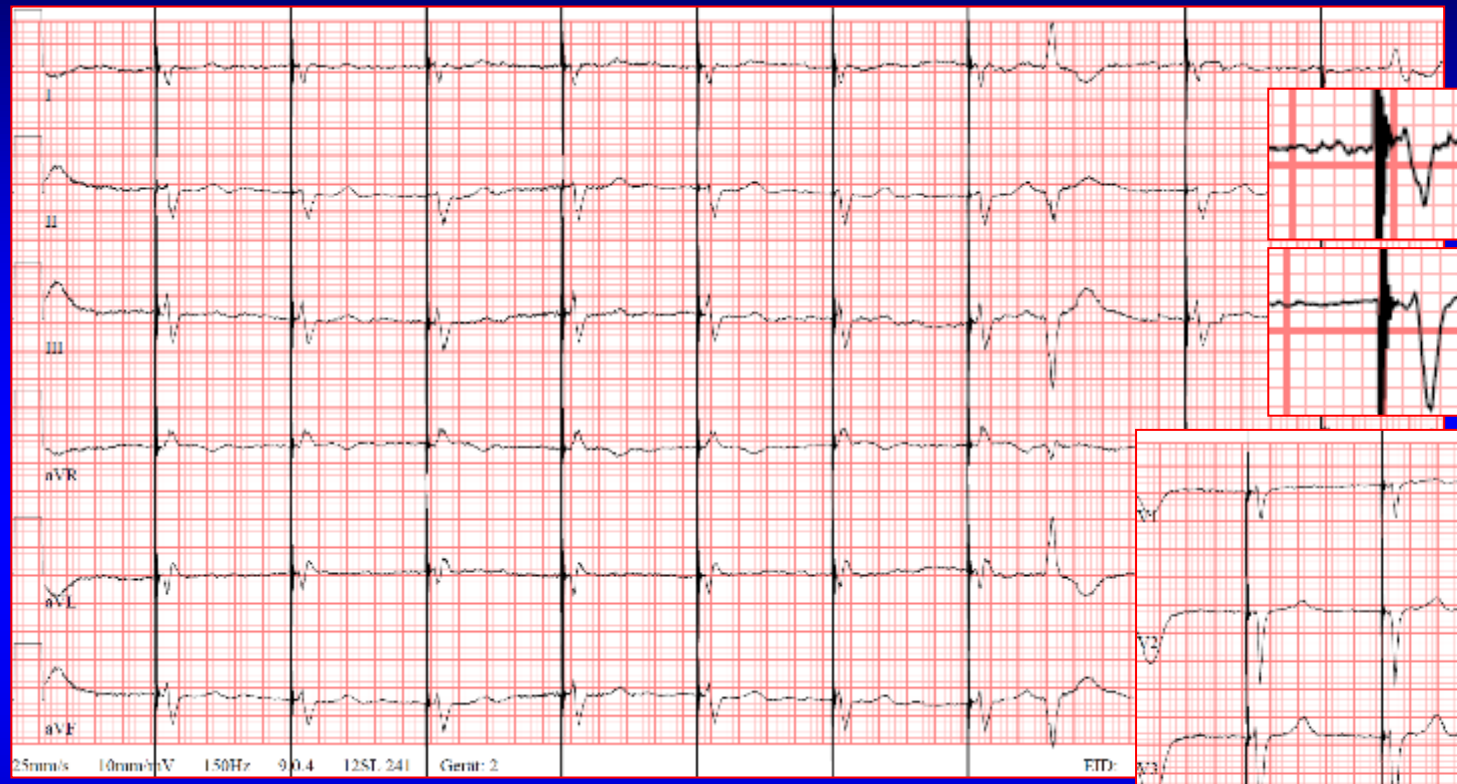
Patientin mit Vorhofflimmern und AV-Block III°

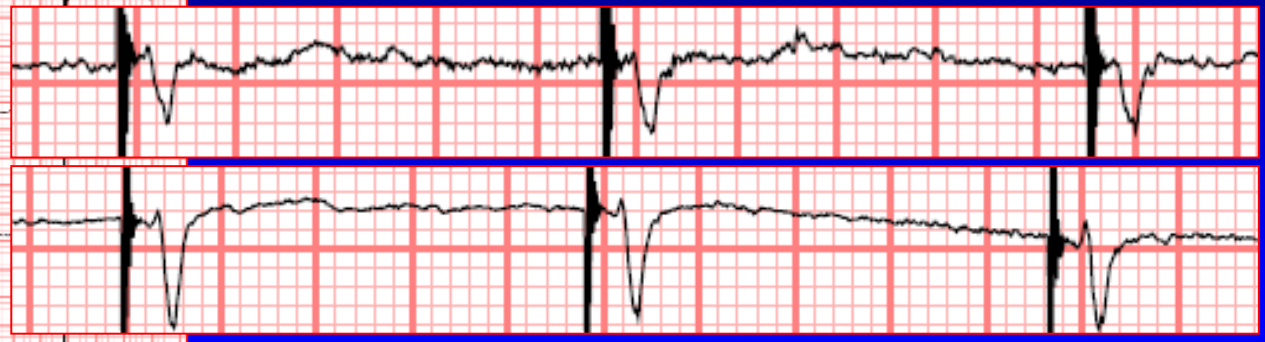


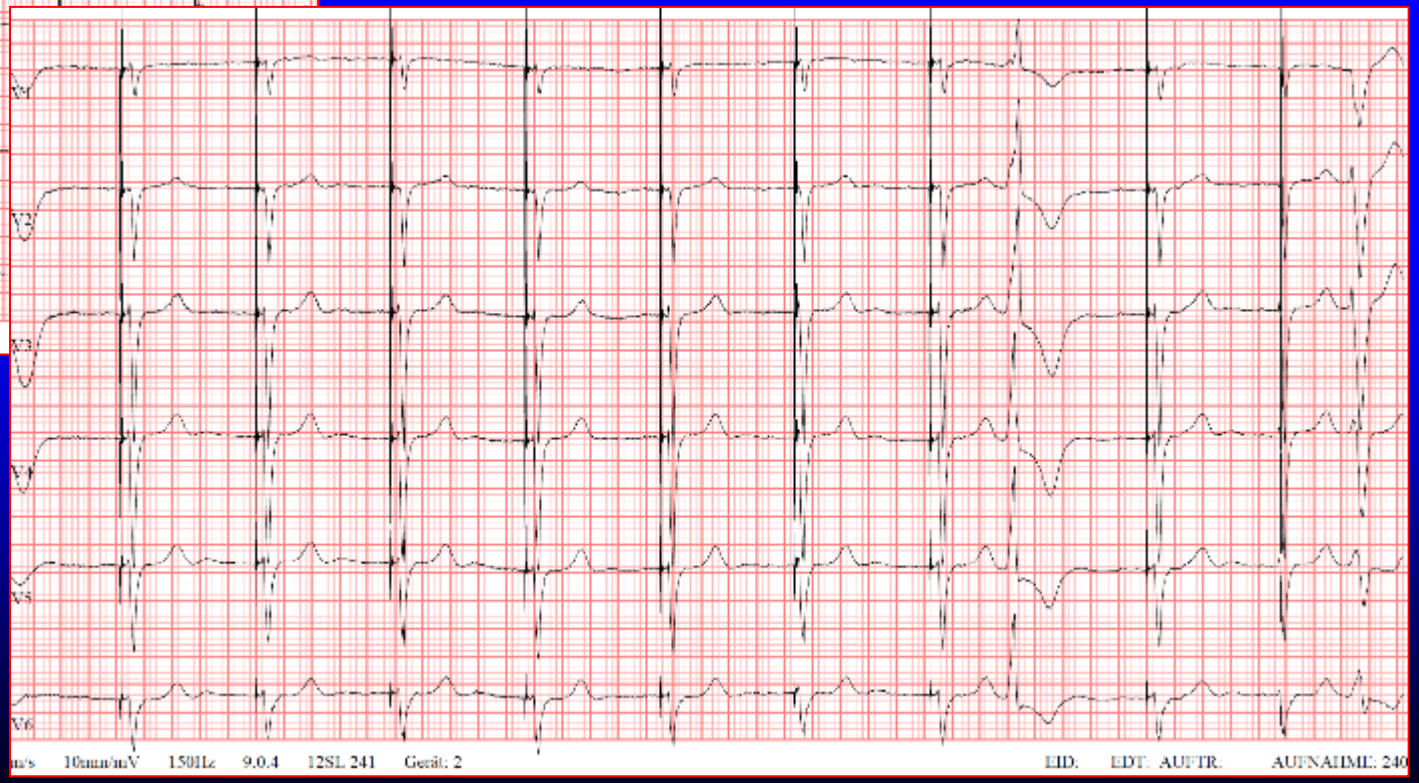
His-Bündel-Stimulation bei TriClip®

Bethel

Selektive His-Bündel-Stimulation

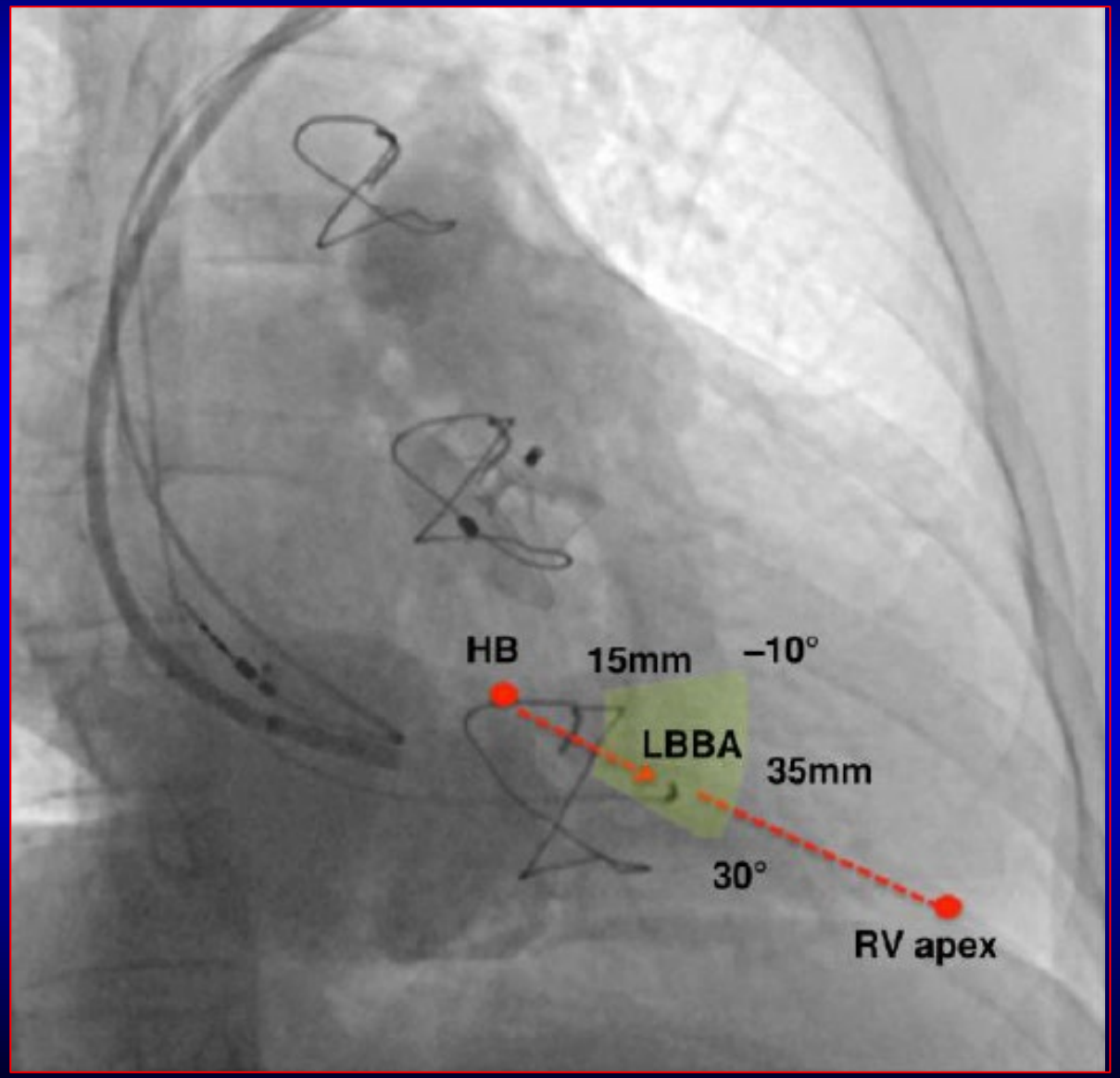


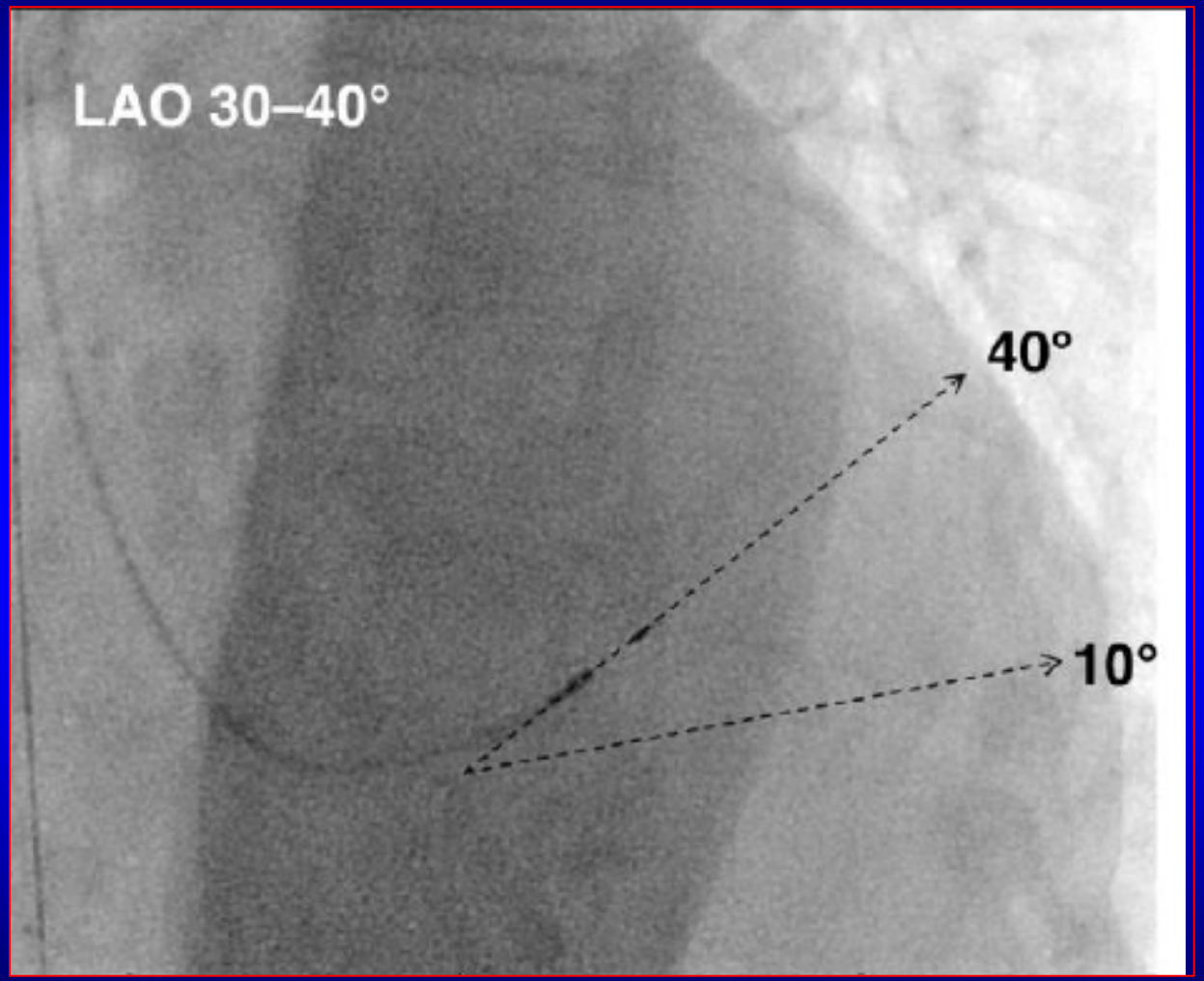




Bethel

Left Bundle Branch (Area) Pacing





Burri, Europace 2023;25:1237-48

Linksschenkel-Pacing nach „failed CRT“

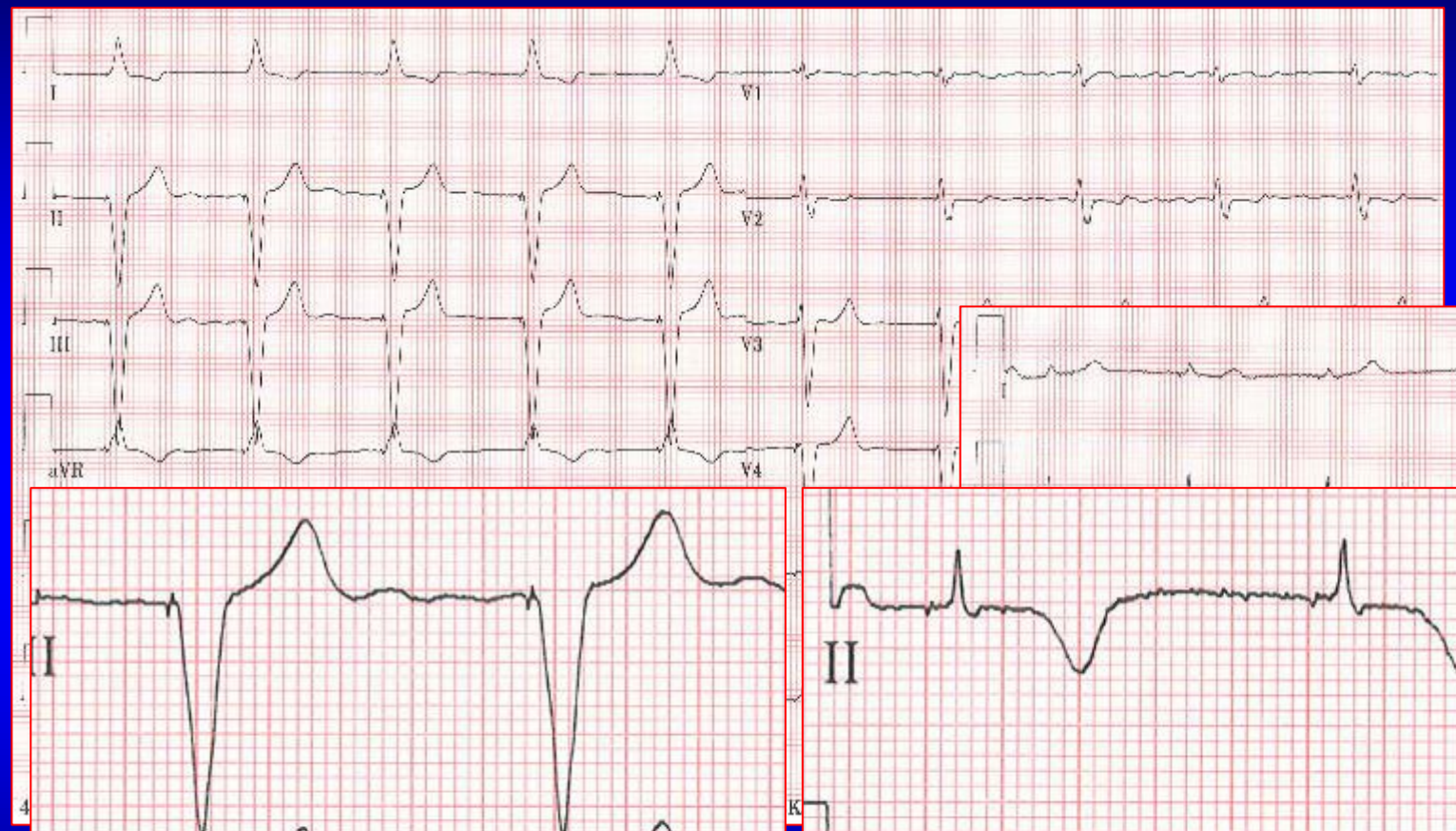
LAO 40°

Left Bundle Branch (Area) Pacing

Mein größter Interessenskonflikt

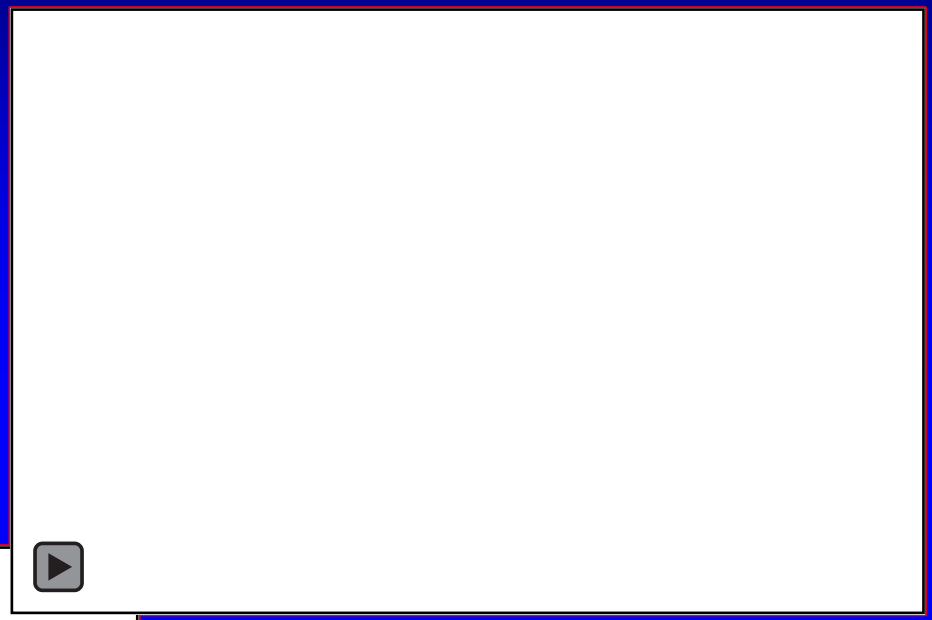
Einkammer-ICD, AV-Knotenablation

Upgrade auf His-Bündel-Pacing



Strain-Imaging: RV- versus HB-Pacing

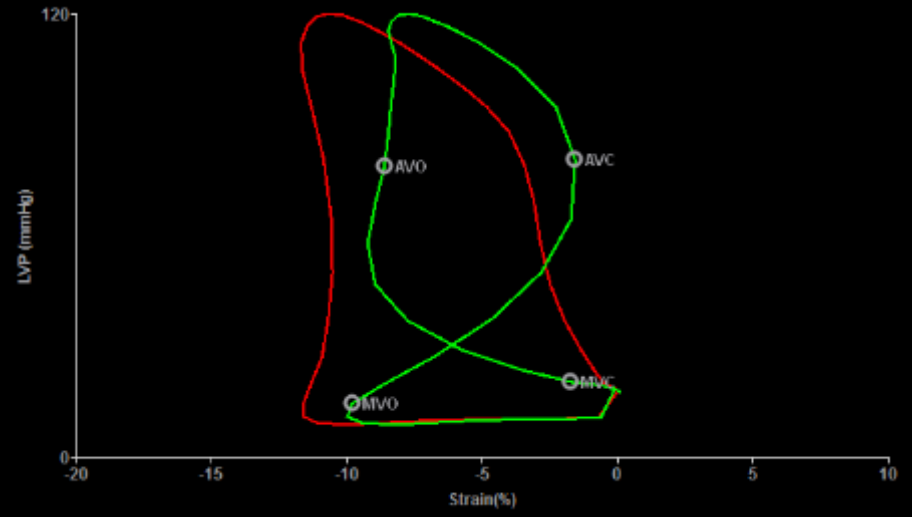
intrinsisch

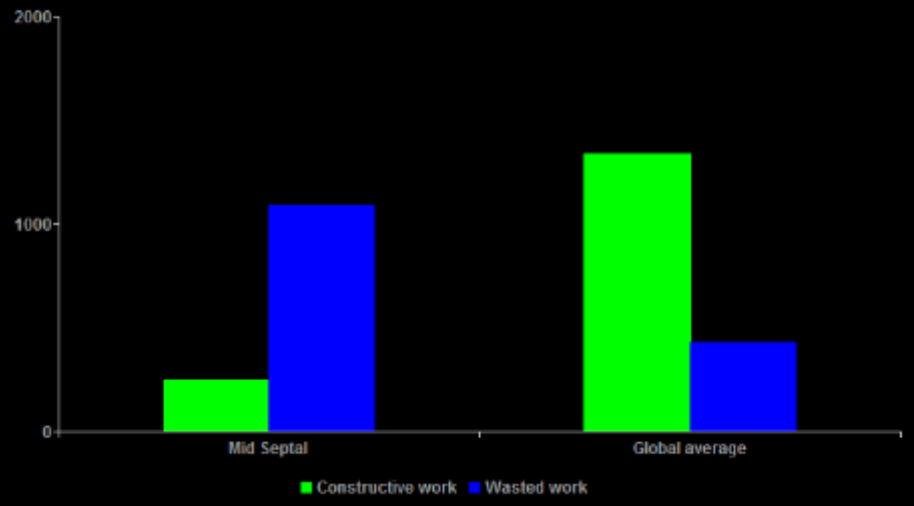


Rechtsventrikuläres Pacing

Nicht-selektives His-Pacing

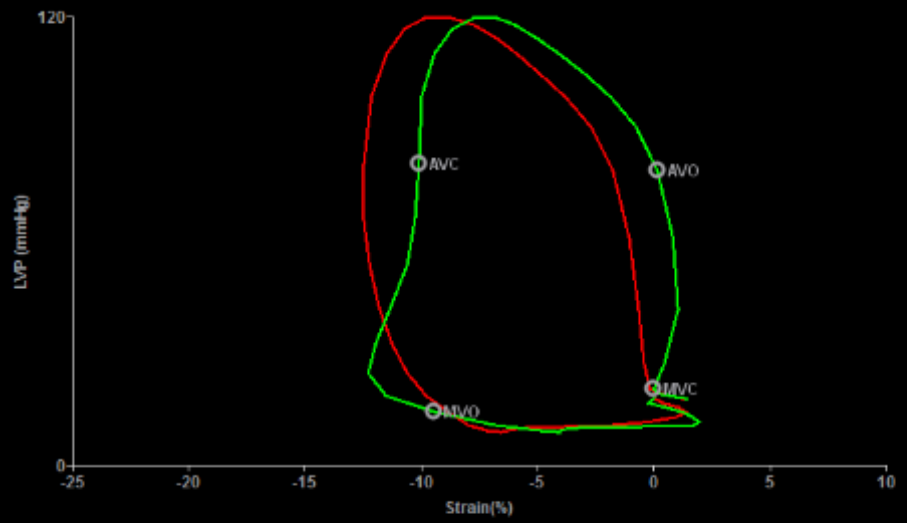
Global Work Efficiency: RV-Pacing

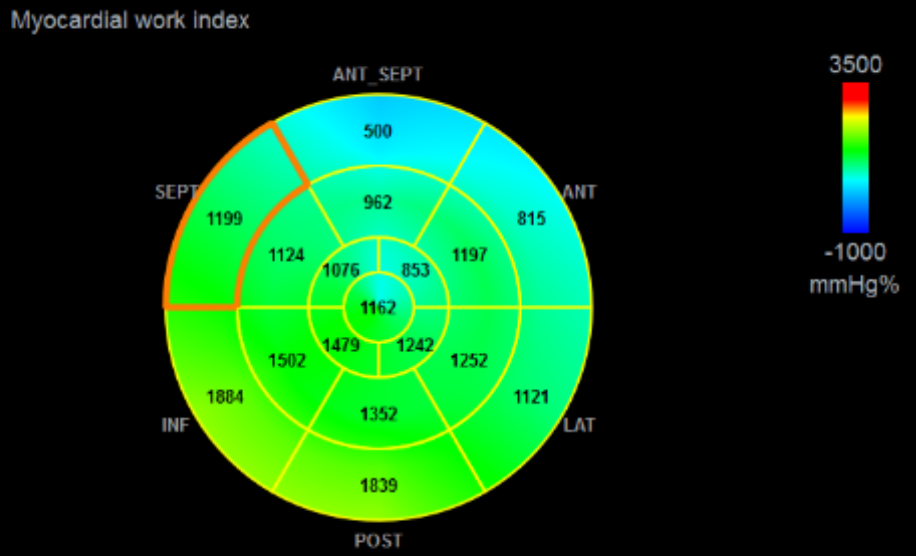


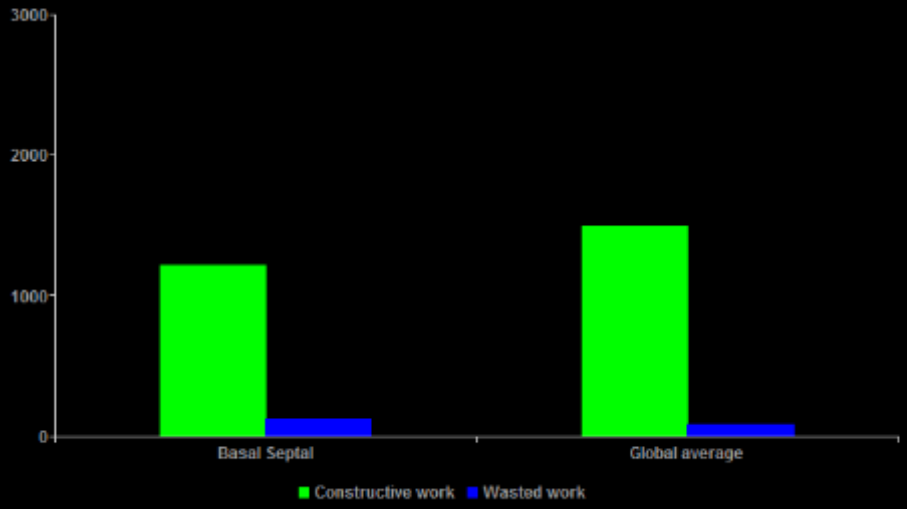


GLS:	-11 %
GWI:	942 mmHg%
GCW:	1333 mmHg%
GWW:	426 mmHg%
GWE:	73 %
BP:	120/80 mmHg

Global Work Efficiency: HB-Pacing

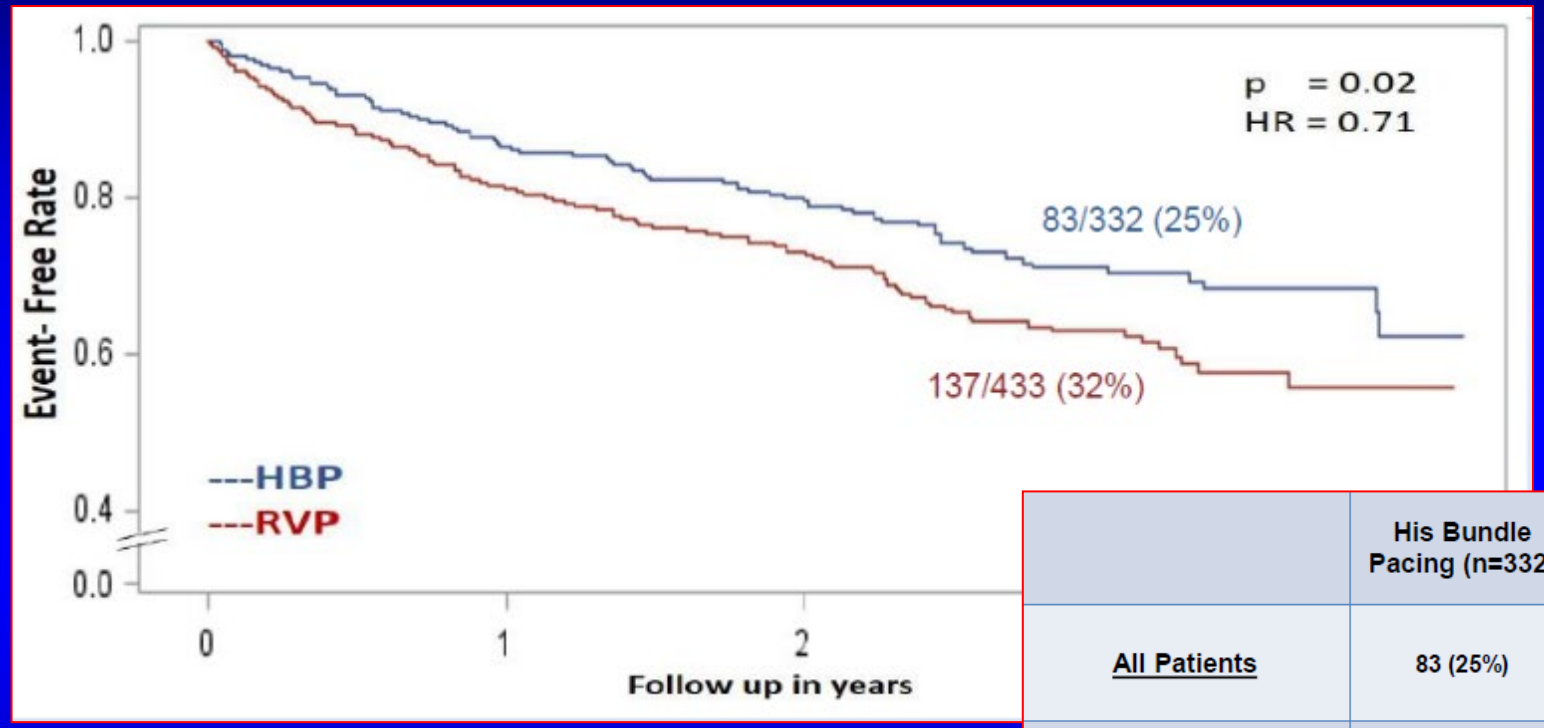






GLS: -12 %
GWI: 1207 mmHg%
GCW: 1493 mmHg%
GWW: 84 mmHg%
GWE: 94 %
BP: 120/80 mmHg

Primärer Endpunkt (Tod, HFH, CRT)



	His Bundle Pacing (n=332)	RV Pacing (n=433)		HR	CI	p-value
All Patients	83 (25%)	137 (31.6%)		0.71*	0.53-0.94	0.02
	His Bundle Pacing (n=194)	RV Pacing (n=278)		HR	CI	p-value
Patients with VP >20%	49 (25.3%)	99 (35.6%)		0.65*	0.46-0.93	0.02
	His Bundle Pacing (n=125)	RV Pacing (n=152)		HR	CI	p-value
Patients with VP <20%	27 (22%)	36 (23.7%)		0.78	0.47-1.30	0.34

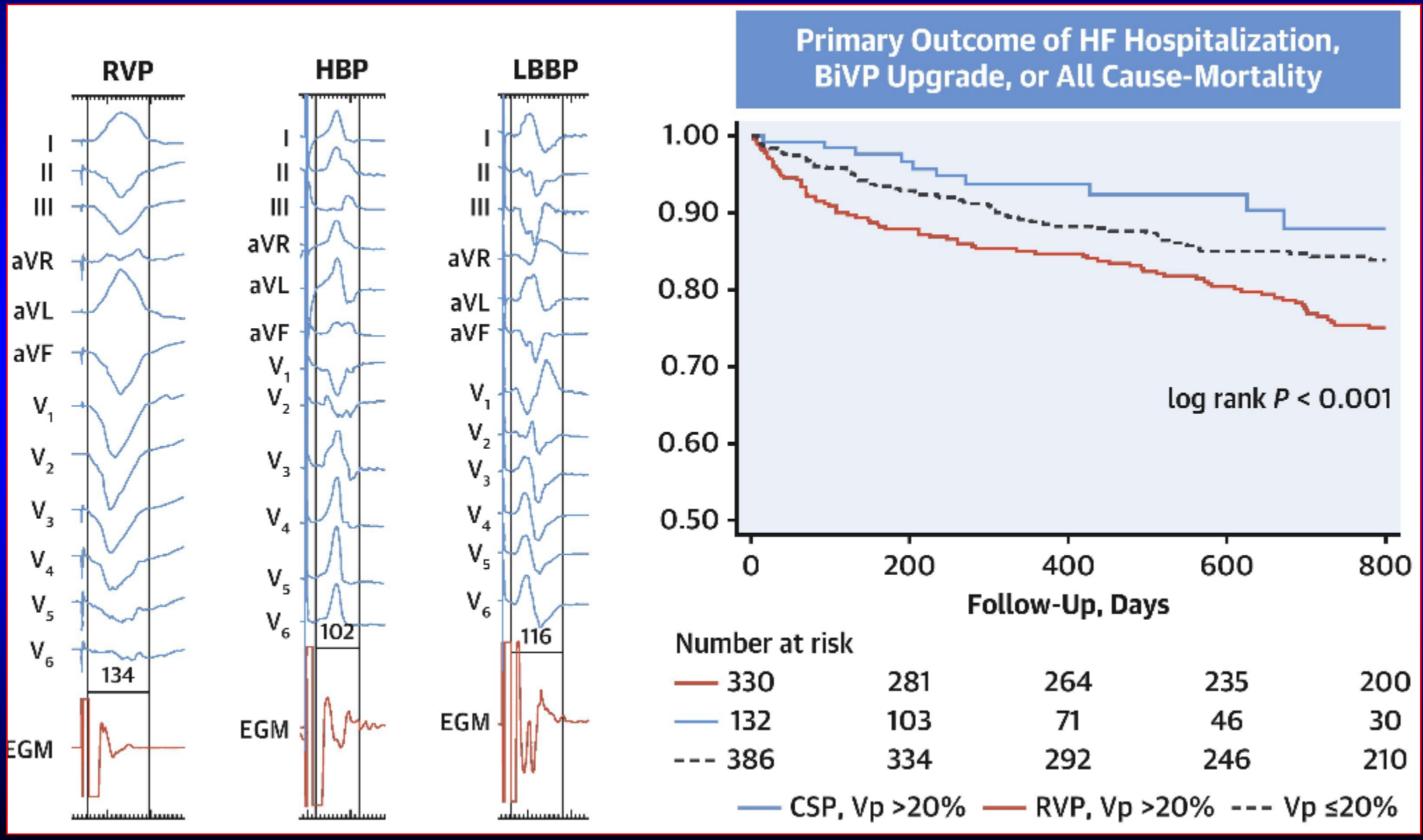
Bethel

His Bundle Pacing

In patients treated with HBP, device programming tailored to specific requirements of His bundle pacing is recommended.	I	C
In CRT candidates in whom coronary sinus lead implantation is unsuccessful, HBP should be considered as a treatment option along with other techniques such as surgical epicardial lead.	IIa	B
In patients treated with HBP, implantation of a right ventricular lead used as "backup" for pacing should be considered in specific situations (e.g. pacemaker-dependency, high-grade AVB, infra-nodal block, high pacing threshold, planned AVJ ablation), or for sensing in case of issues with detection (e.g. risk of ventricular undersensing or oversensing of atrial/His potentials).	IIa	C
HBP with a ventricular backup lead may be considered in patients in whom a "pace-and-ablate" strategy for rapidly conducted supraventricular arrhythmia is indicated, particularly when intrinsic QRS is narrow.	IIb	C
HBP may be considered as an alternative to right ventricular pacing in patients with AVB and LVEF >40%, who are anticipated to have >20% ventricular pacing.	IIb	C

Glikson, Eur Heart J 2021;42:3427-520

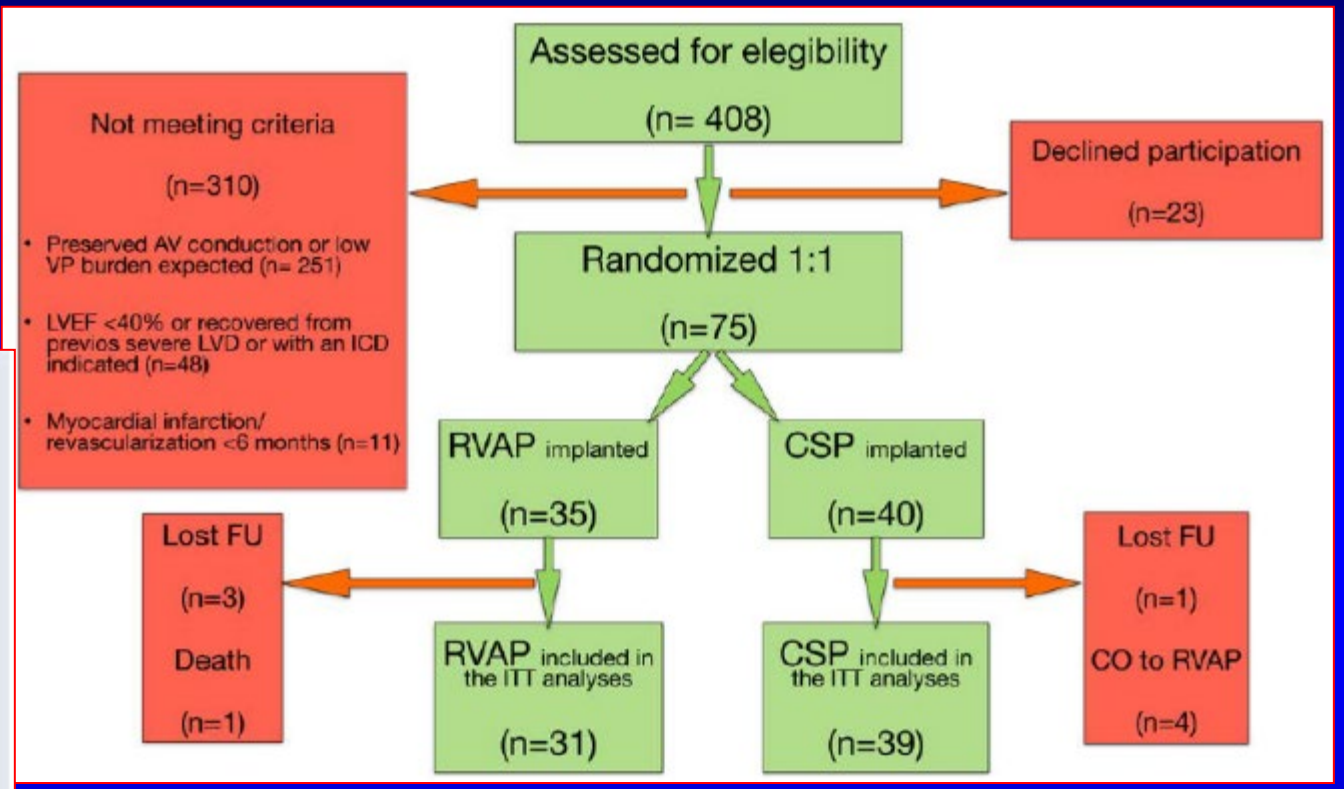
CSP versus RV Pacing

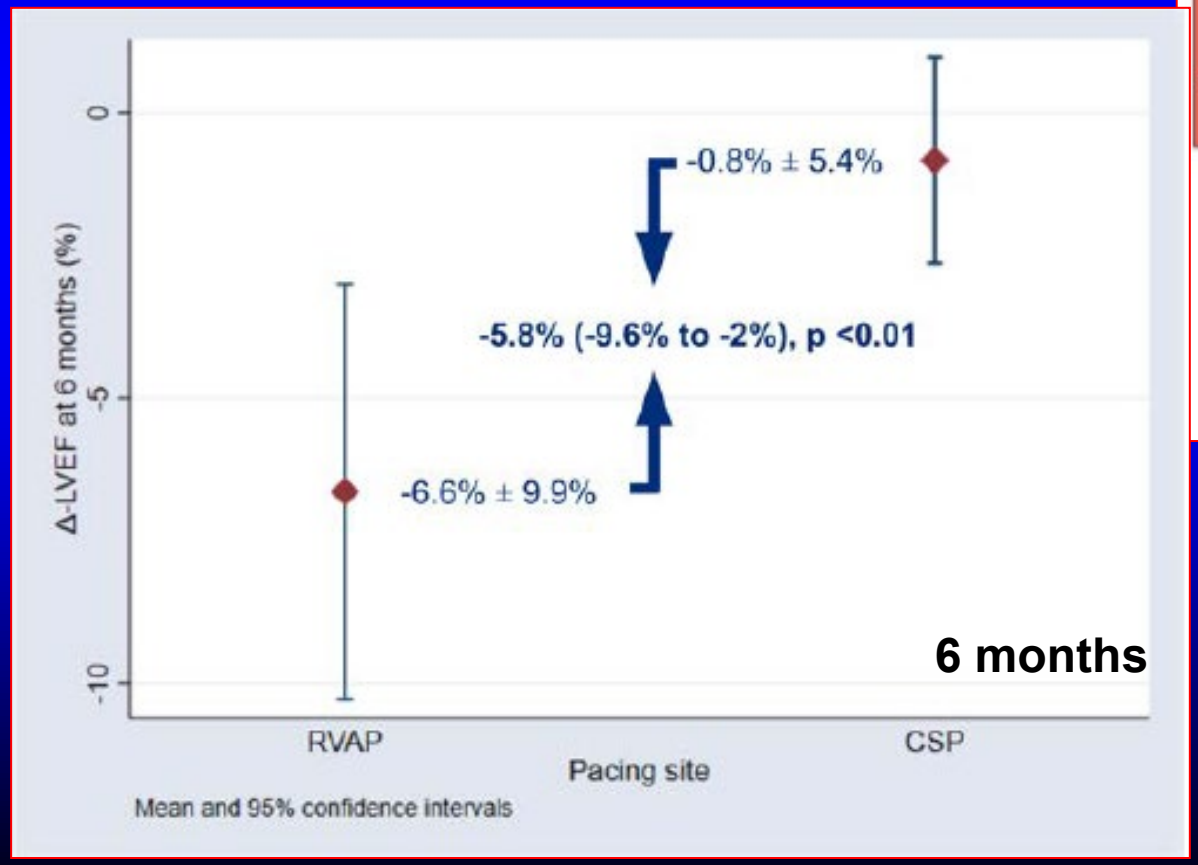


Tan, JACC EP 2023; 9:992-1001

CSP bei normaler LVEF?

Consecutive pts with high-degree AV block and preserved/mildly reduced LVEF (>40%)





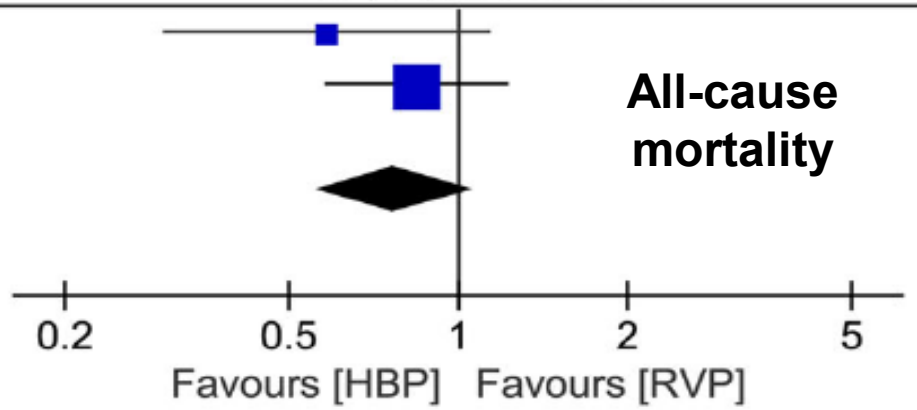
Gonzalez-Matos, Circ AE 2024; 17:e012473

Bethel

Metaanalyse: HBP versus RVP

or Subgroup	HBP Events	HBP Total	RVP Events	RVP Total	Weight	Odds Ratio M-H, Fixed, 95% CI
raman 2018	19	75	36	98	27.2%	0.58 [0.30, 1.13]
rahman 2018	57	304	93	433	72.8%	0.84 [0.58, 1.22]
(95% CI)		379		531	100.0%	0.77 [0.56, 1.07]
events	76		129			

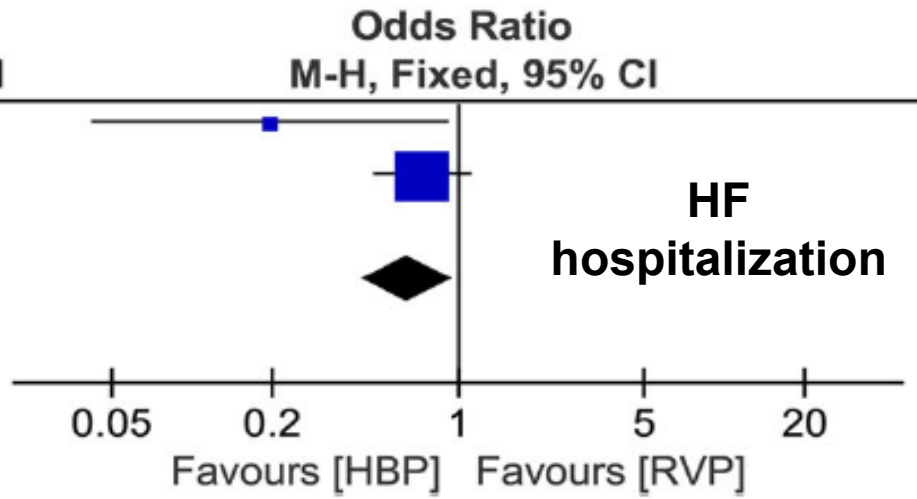
ogeneity: Chi² = 0.90, df = 1 (P = 0.34); I² = 0%
or overall effect: Z = 1.57 (P = 0.12)



All-cause mortality

or Subgroup	HBP Events	HBP Total	RVP Events	RVP Total	Weight	Odds Ratio M-H, Fixed, 95% CI
raman 2018	2	75	12	98	15.7%	0.20 [0.04, 0.91]
rahman 2018	41	304	76	433	84.3%	0.73 [0.49, 1.11]
(95% CI)		379		531	100.0%	0.65 [0.44, 0.96]
events	43		88			

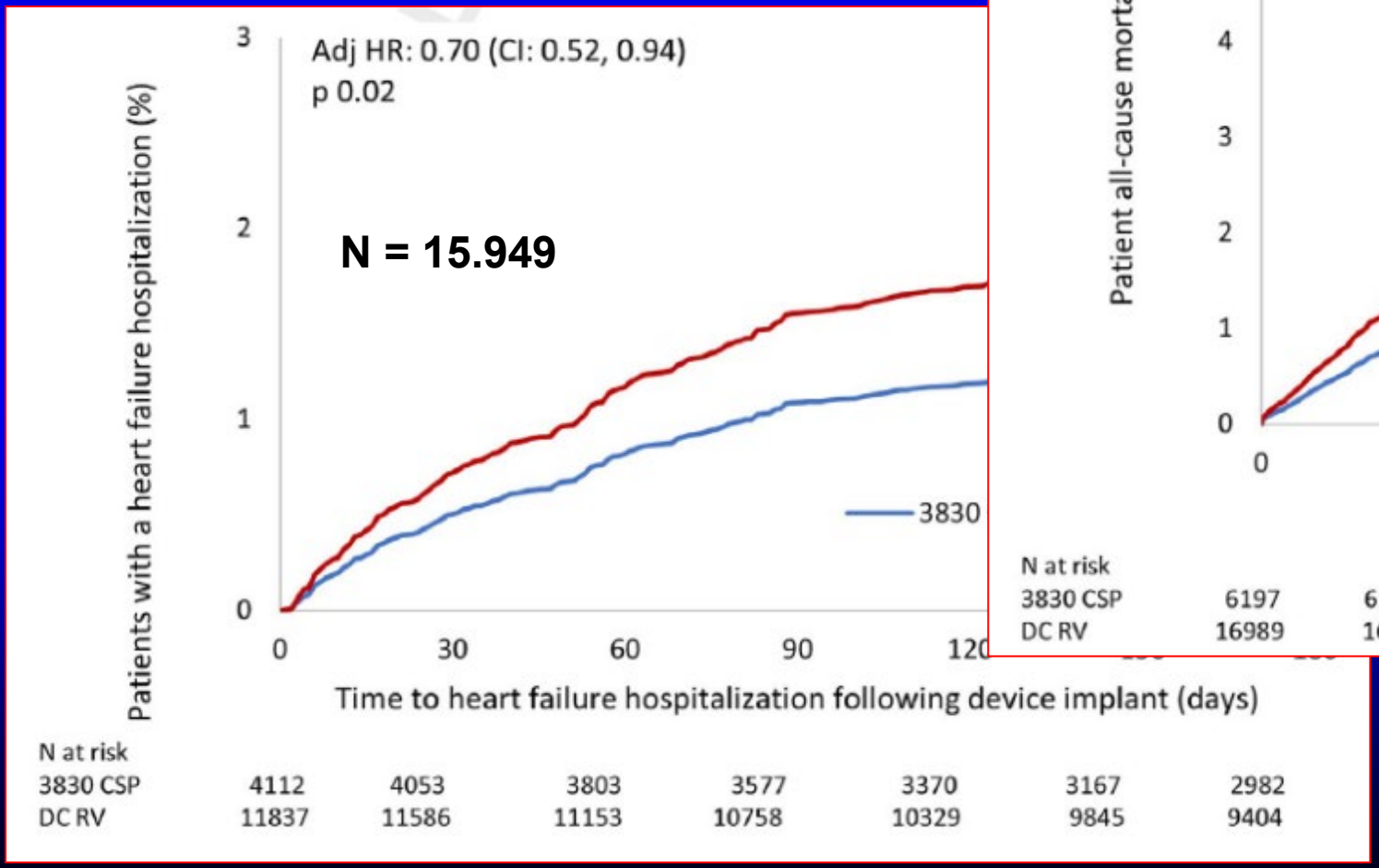
ogeneity: Chi² = 2.68, df = 1 (P = 0.10); I² = 63%
or overall effect: Z = 2.17 (P = 0.03)

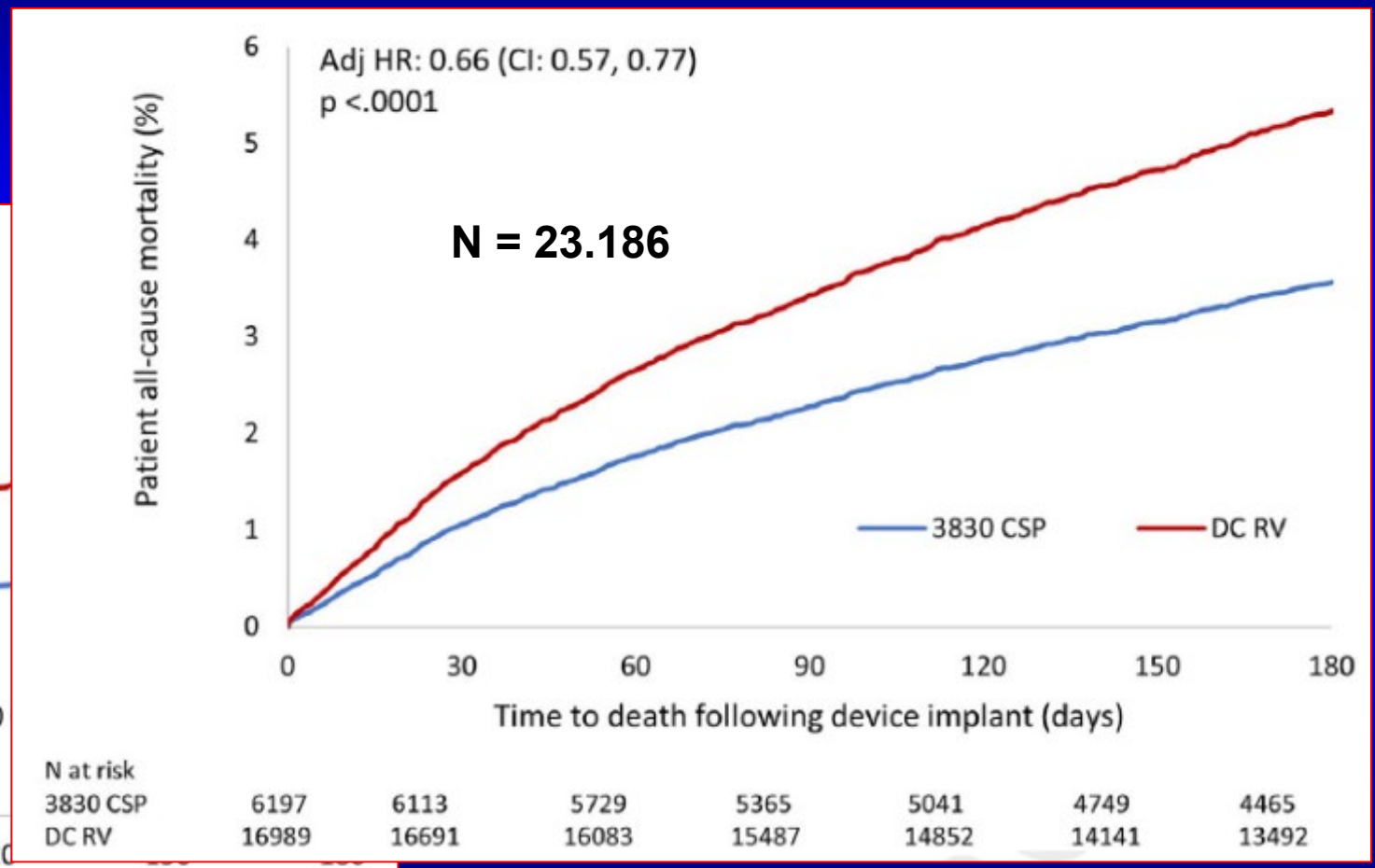


HF hospitalization

Conduction System Pacing versus RV-Pacing

MEDICARE-Datenbank





Vijayaraman, Heart Rhythm 2024 (in press)

Bethel

CSP: Ongoing Studies CSP versus RVP

TABLE 4 Ongoing or Planned Clinical Trials for Conduction System for Bradyarrhythmias

Name NCT Status	Treatments	Size	Population	Primary Endpoint	Other Endpoints	Follow-up (mo)	Country
LEFT Bundle Pacing vs Standard Right Ventricular Pacing for Heart Failure NCT05015660 Recruiting	LBBP vs RVP	100	LVEF ≥50%, high-degree AVB with anticipated RVP >90%	LVESVi, implant success, feasibility	CV death, HFH, death, LVEF, NT-proBNP, AF progression, TR, MR, lead parameters, QoL, safety	24	Canada
PHYSPAVB NCT05214365 Recruiting	His/LBBP vs RVP	200	LVEF >50%, AV block	PICM	LVESV, septal flash, AF, HFH, NYHA 6MWT, NT-proBNP, QoL, safety	12	Spain
LEAP NCT04595487 Recruiting	LVSP vs RVP	470	LVEF >35%, second or third AVB, or atrial arrhythmia with slow VR, expected VP >20%	Combined death, HFH, and LVEF	Death, HFH, combined death and HFH, AF, LVEF, QoL, Safety, QALY, CEA, BIA	12	Netherlands
PROTECT-SYNC NCT05585411 Not recruiting	LBBP vs RVP	450	Bradyarrhythmia with anticipated RVP >40%	Composite, HFH, and upgrade to CRT	Death, CV death, HFH, implant success, safety, LVEF, AF, cardiopulmonary exercise parameters	24	South Korea
LEAP-Block NCT04730921 Recruiting	LBBP vs RVP	458	LVEF ≥50%, AVB patients with anticipated RVP > 40%	Composite death, HFH, and upgrade to CRT	Death and HFH, and upgrade to CRT, echo parameters, implant success, safety, device parameters, atrial arrhythmias	24	China
OptimPacing NCT04624763 Recruiting	LBBP vs RVP	683	LVEF >35%, NYHA I-III, second or third AV block or persistent or permanent AF with VR < 50 beats/min	Combined death, HFH, and PICM	Echo parameters, NT-proBNP, NYHA 6MWT, QoL, safety	36	China
PROTECT HF	CSP vs RVP	2,600	LVEF >35%, high burden of VP	Cardiovascular death, HFH, QOL, upgrade		48	UK, world

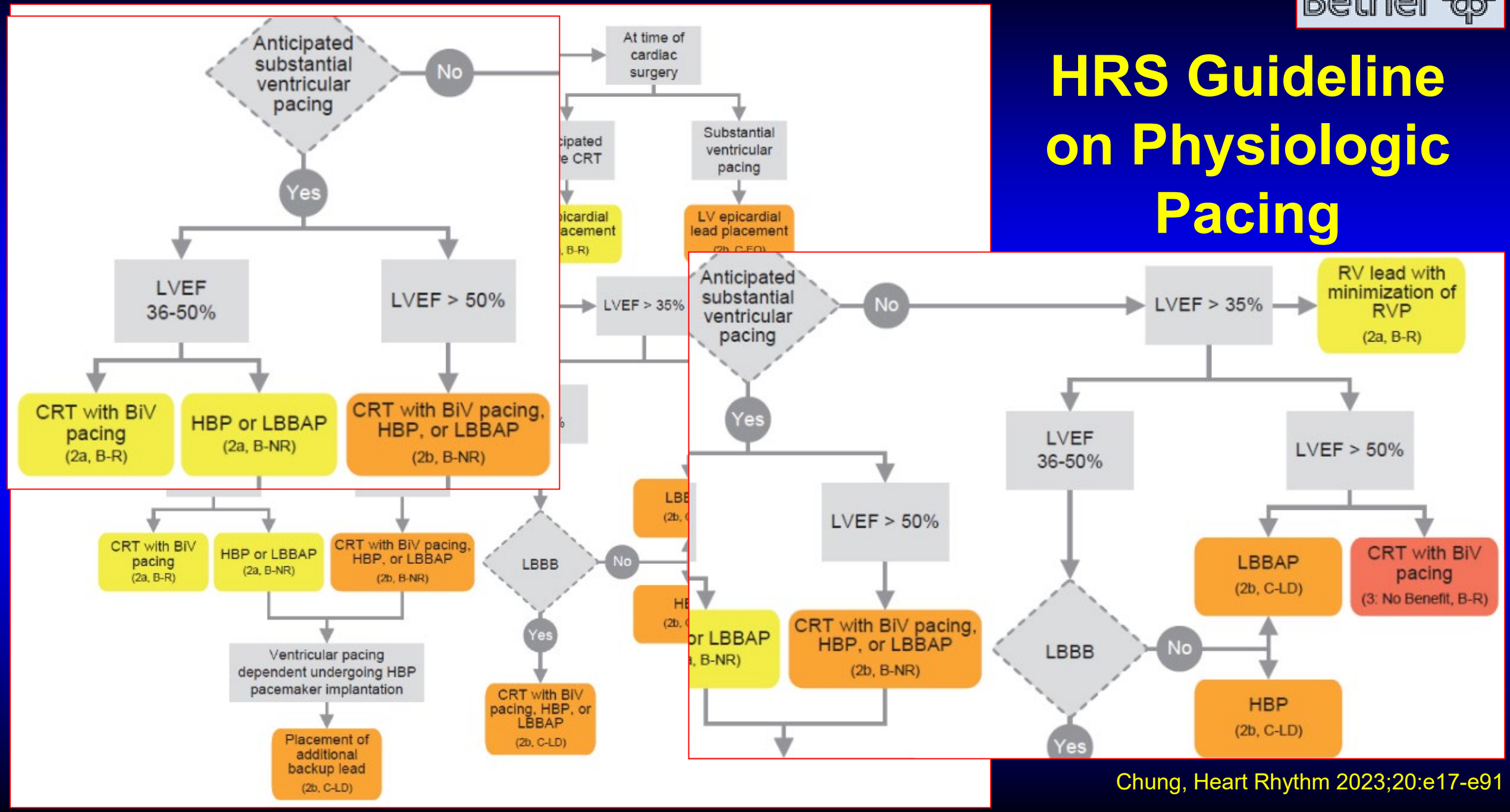
Vijayaraman, JACC Clin Electrophysiol 2023;9:2358-87

2023 HRS/APHRS/LAHRS guideline on cardiac physiologic pacing for the avoidance and mitigation of heart failure

Mina K. Chung, MD, FHRS (Chair),[1,*] Kristen K. Patton, MD, FHRS (HRS Vice-Chair),[2,*] Chu-Pak Lau, MD, FHRS, CCDS (APHRS Vice-Chair),[#,3] Alexander R. J. Dal Forno, MD (LAHRS Vice-Chair),[††,4] Sana M. Al-Khatib, MD, MHS, FHRS, CCDS,[5,*] Vanita Arora, MBBS, MD, FHRS,[6,*] Ulrika Maria Birgersdotter-Green, MD, FHRS,[7,*] Yong-Mei Cha, MD, FHRS, FACC,[8,*] Eugene H. Chung, MD, MPH, FHRS,[9,*] Edmond M. Cronin, MB BCh BAO, FHRS,[10,*] Anne B. Curtis, MD, FHRS,[11,*] Iwona Cygankiewicz, MD, PhD,[12,†] Gopi Dandamudi, MBA, MD, FHRS,[13,*] Anne M. Dubin, MD, FHRS, CEPS-P,[14,‡] Douglas P. Ensch, AEET,[1,§] Taya V. Glotzer, MD, FHRS, FACC,[15,*] Michael R. Gold, MD, PhD, FHRS,[16,*] Zachary D. Goldberger, MD, MS, FHRS, CCDS,[17,*] Rakesh Gopinathannair, MD, MA, FHRS,[18,*] Eiran Z. Gorodeski, MD, MPH,[19,¶] Alejandra Gutierrez, MD,[20,*] Juan C. Guzman, MD, MSc,[21,*] Weijian Huang, MD, FHRS,[22,#] Peter B. Imrey, PhD,[1,23,*] Julia H. Indik, MD, PhD, FHRS,[24,*] Saima Karim, DO, FHRS,[25,**] Peter P. Karpawich, MD, MS, FHRS,[26,‡] Yaariv Khaykin, MD, FHRS,[27,*] Erich L. Kiehl, MD, MS,[28,*] Jordana Kron, MD, FHRS,[29,*] Valentina Kutyifa, MD, PhD, FHRS,[30,*] Mark S. Link, MD, FHRS,[31,*] Joseph E. Marine, MD, MBA, FHRS,[32,*] Wilfried Mullens, MD, PhD,[33,*] Seung-Jung Park, MD, PhD,[34,#] Ratika Parkash, MD, MS, FHRS,[35,*] Manuel F. Patete, MD,[36,††] Rajeev Kumar Pathak, MBBS, PhD, FHRS,[37,#] Carlos A. Perona, MD,[38,††] John Rickard, MD, MPH,[1,*] Mark H. Schoenfeld, MD, CCDS, FHRS, FACC, FAHA,[39,*] Swee-Chong Seow, MD, FHRS,[40,#] Win-Kuang Shen, MD, FHRS,[41,*] Morio Shoda, MD, PhD,[42,#] Jagmeet P. Singh, MD, PhD, FHRS,[43,*] David J. Slotwiner, MD, FHRS, FACC,[44,*] Arun Raghav M. Sridhar, MBBS, MPH,[2,*] Uma N. Srivatsa, MBBS, MS, FHRS,[45,*] Eric C. Stecker, MD, MPH, FHRS, FACC,[46,‡‡] Tanyanan Tanawuttiwat, MD, MPH, FHRS,[47,*] W. H. Wilson Tang, MD, FHFSA,[1,¶] Carlos Andres Tapias, MD,[48,††] Cynthia M. Tracy, MD,[49,*] Gaurav A. Upadhyay, MD, FHRS, FACC,[50,*] Niraj Varma, MA, MD, PhD, FRCP,[1,*] Kevin Vernooy, MD, PhD, FESC, FEHRA,[51,*] Pugazhendhi Vijayaraman, MD, FHRS,[52,*] Sarah Ann Worsnick, PAC, FHRS, CEPS, CCDS,[52,*] Wojciech Zareba, MD, PhD,[30,†] Emily P. Zeitler, MD, MHS, FHRS[53,*]

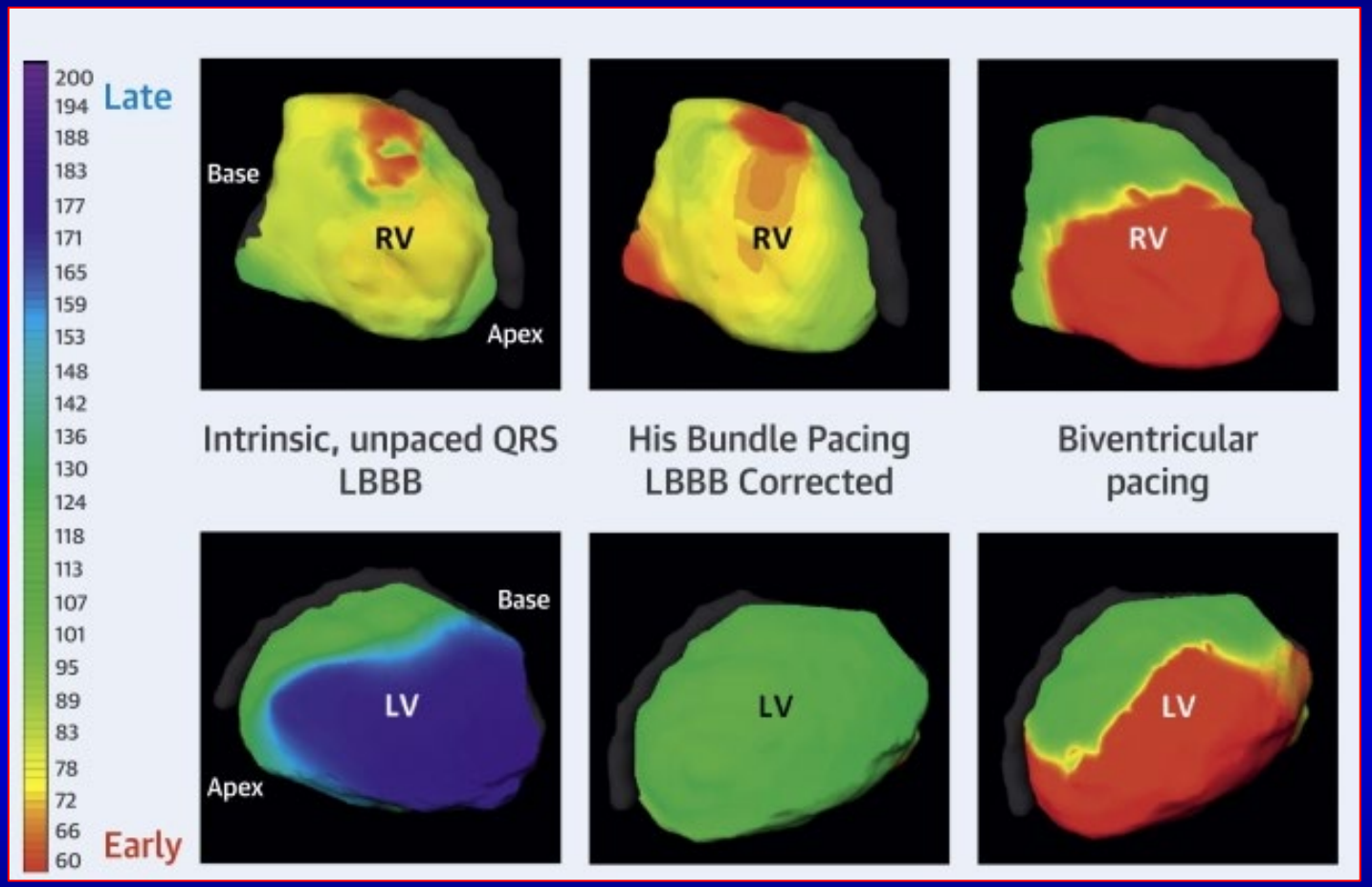
Bethel

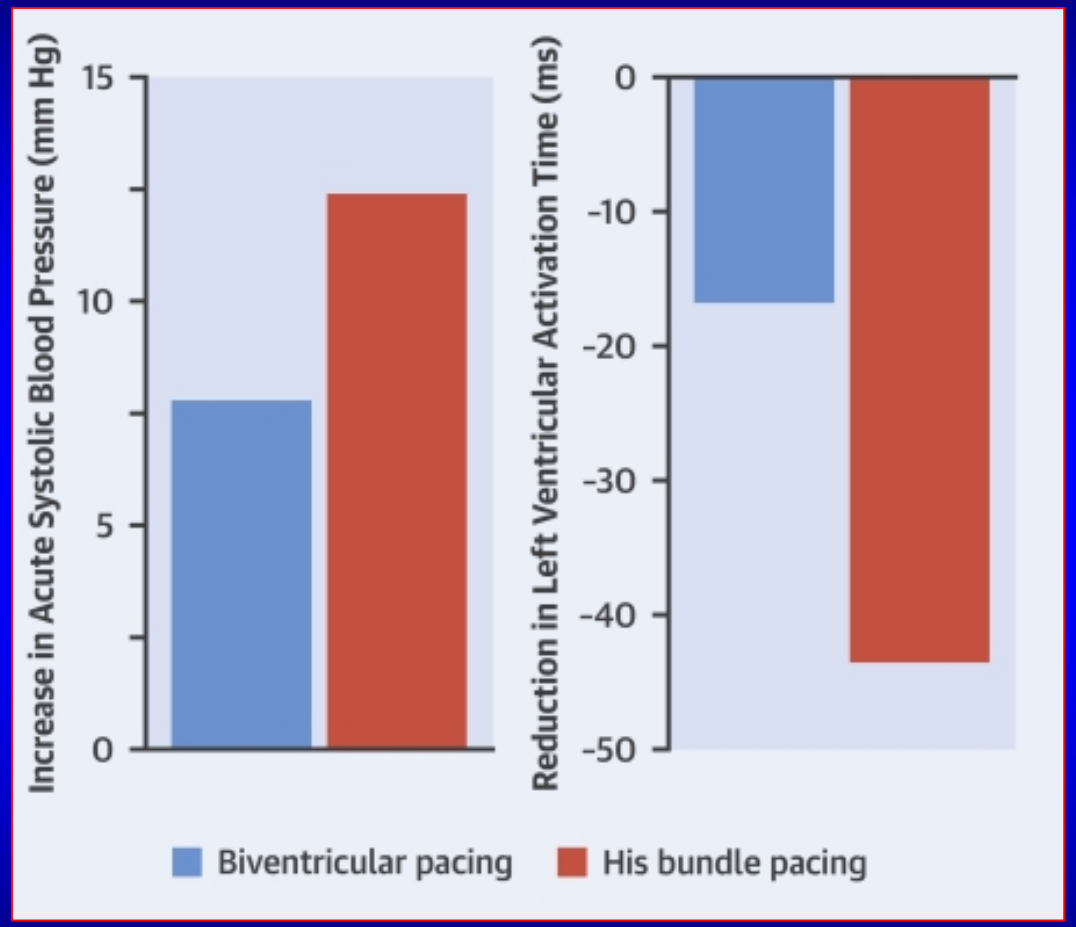
HRS Guideline on Physiologic Pacing



Chung, Heart Rhythm 2023;20:e17-e91

Randomisierte Studien His-Bündel-Pacing vs. CRT

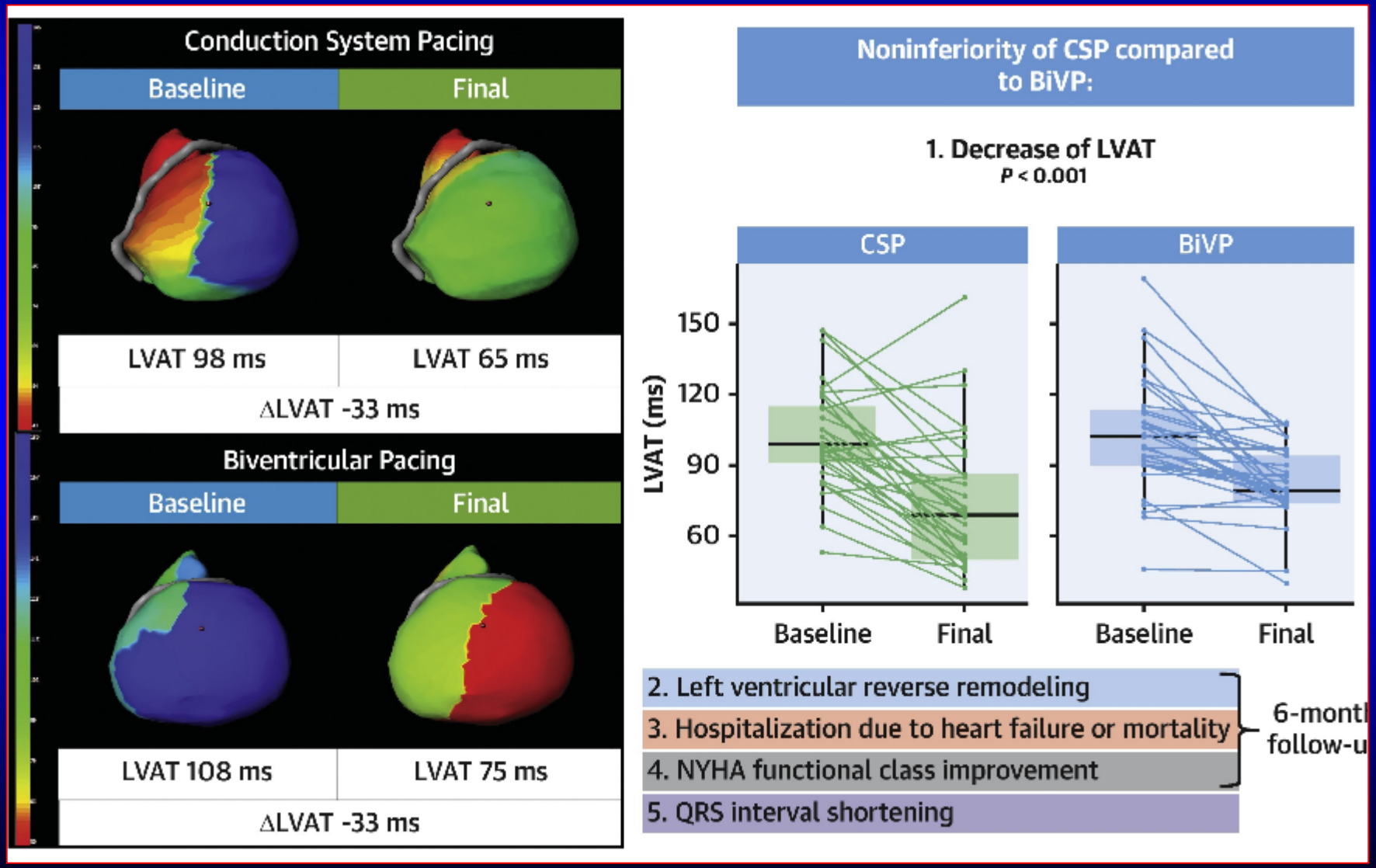




- QRS kürzer unter HBP
- LVAT besser unter HBP
- Hämodynamische Reaktion besser unter HBP

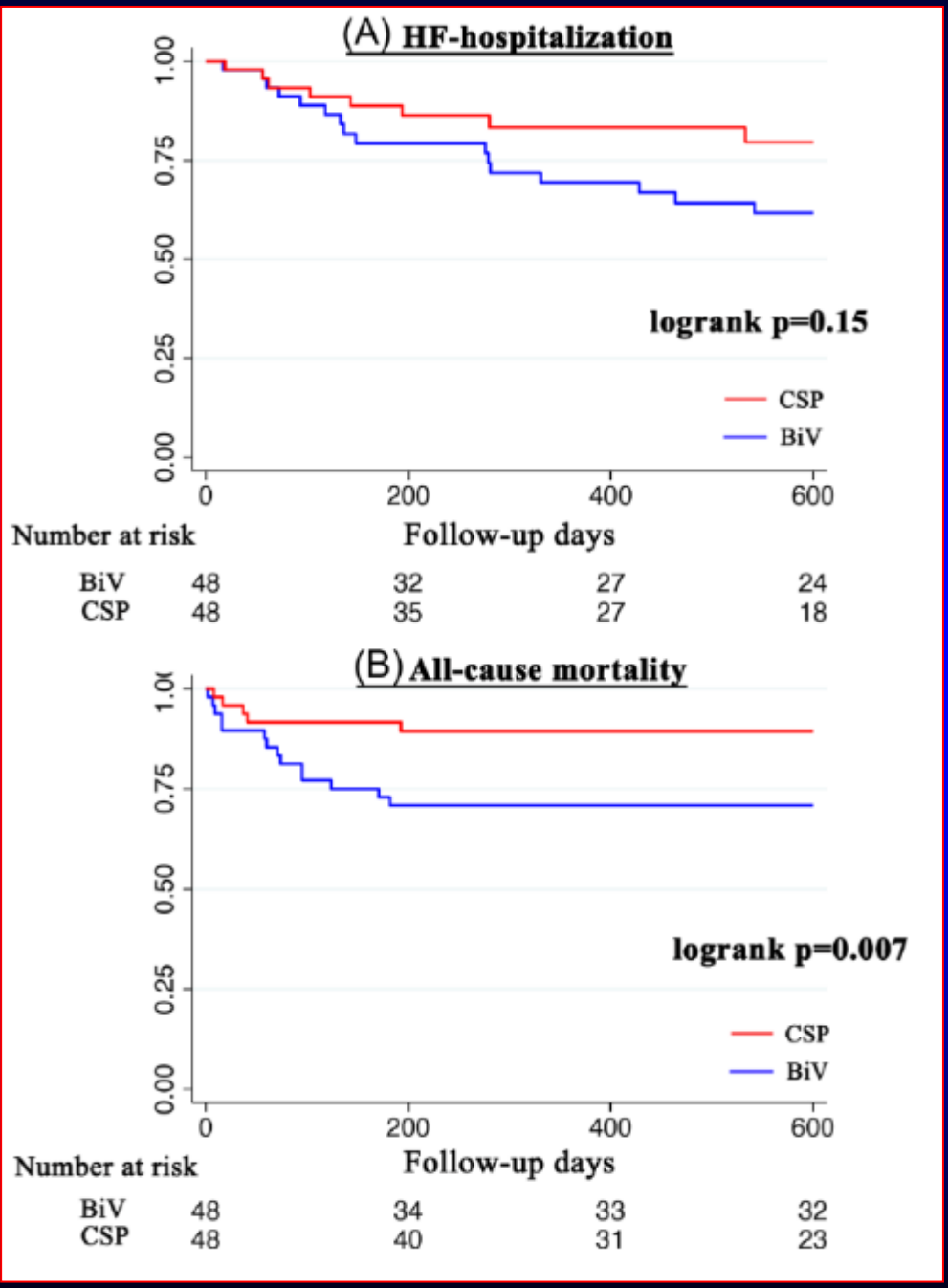
Arnold, J Am Coll Cardiol 2018;72:3112-22

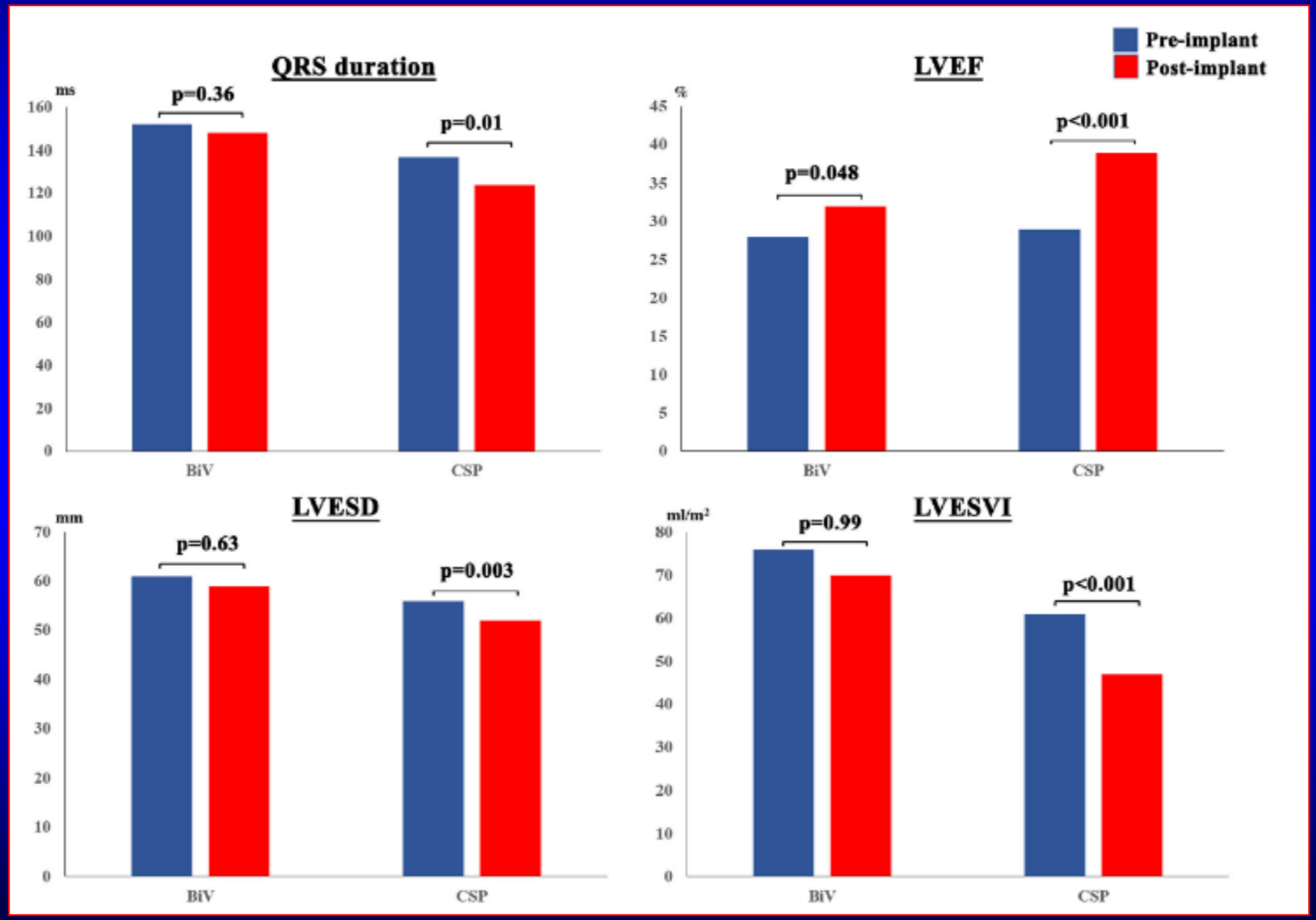
LVAT in LBBB: CSP versus CRT



Pujol-Lopez, J Am Coll Cardiol EP 2022;8:1431-45

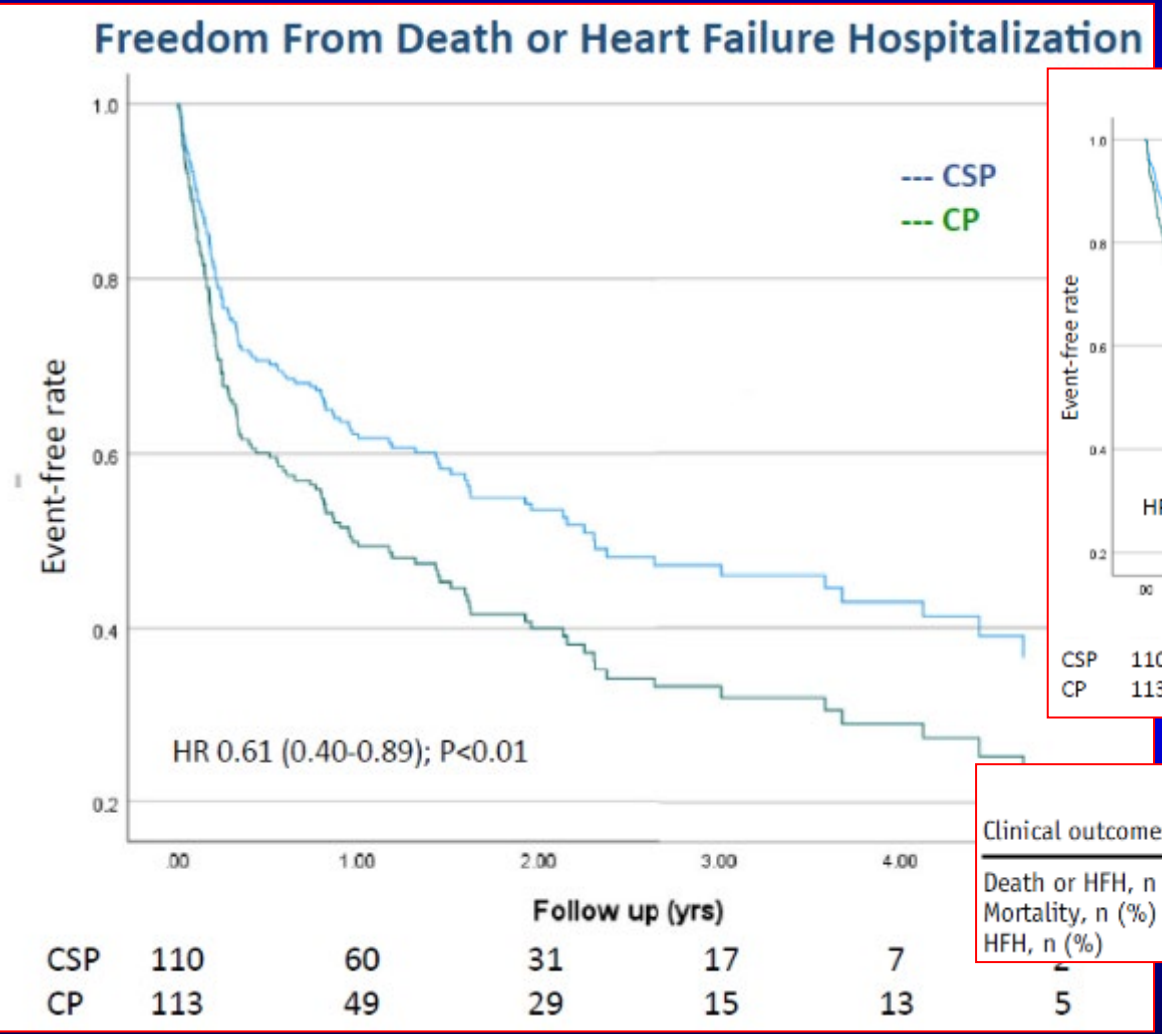
CSP versus BiV (Non-LBBB)

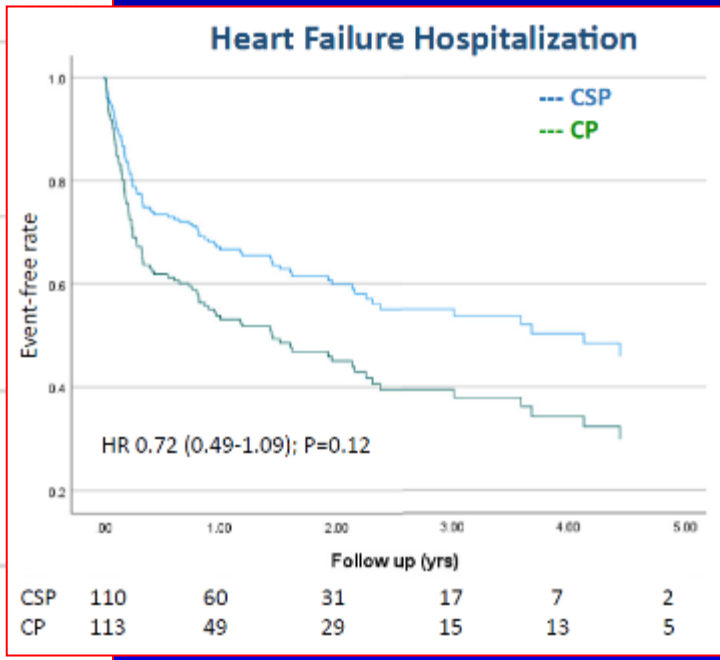


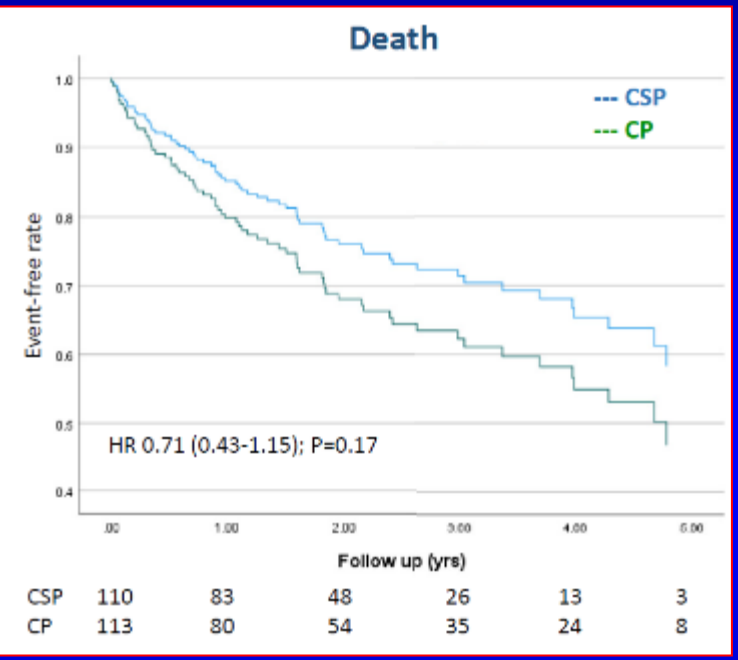


Tan, J Cardiovasc Electrophysiol 2023;34:976-83

„Pace & Ablate“: CSP versus Biventricular Pacing





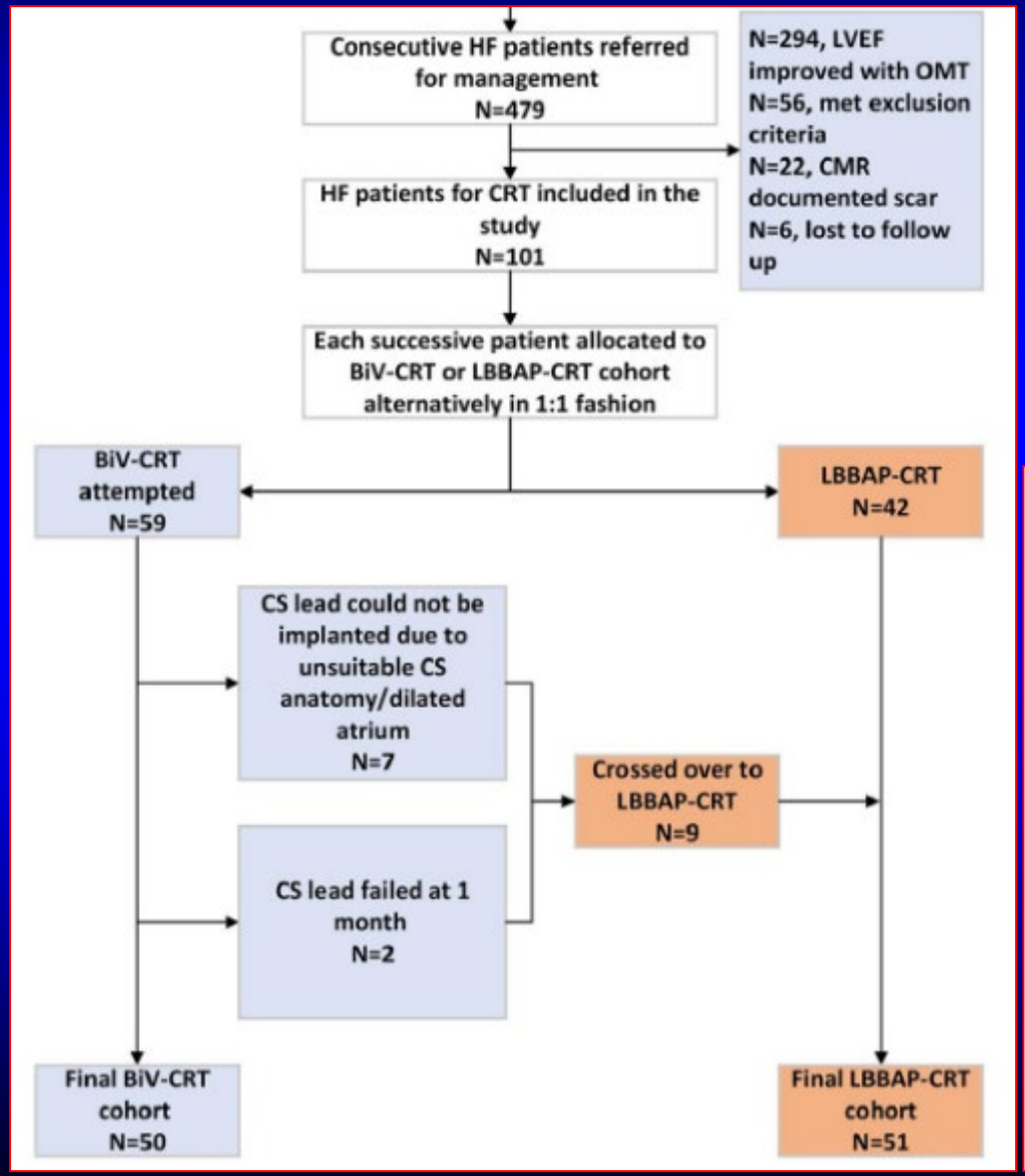


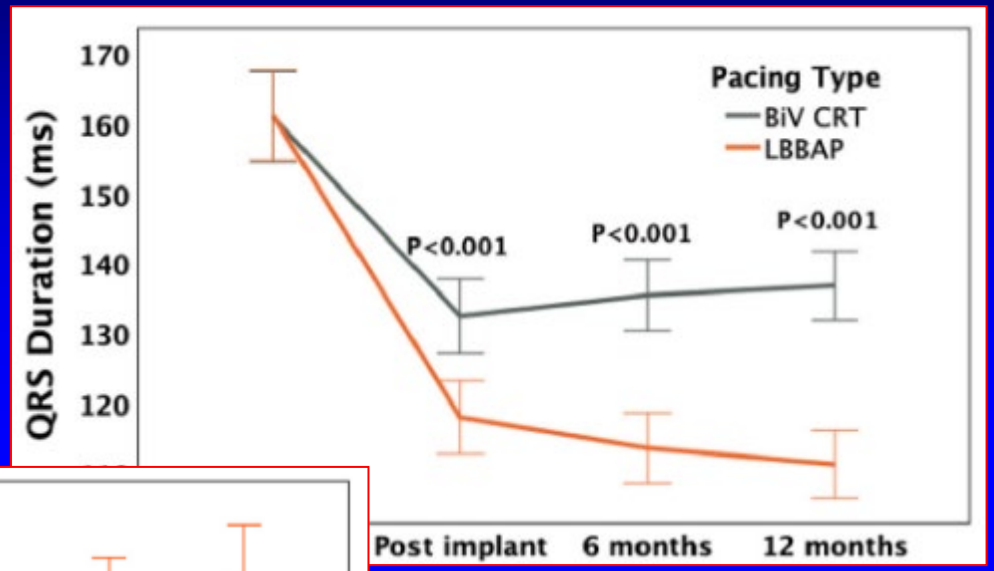
					Univariate			Multivariate		
Clinical outcomes	Total	CSP	CP	*P* value	HR	95% CI	*P* value	HR	95% CI	*P* value
Death or HFH, n (%)	123 (55%)	53 (48%)	70 (62%)	.04	0.68	0.48–0.98	.04	0.61	0.42–0.89	<.01
Mortality, n (%)	69 (31%)	27 (25%)	42 (37%)	.04	0.71	0.43–1.15	.168			
HFH, n (%)	99 (44%)	43 (39%)	56 (50%)	.03	0.64	0.42–0.95	.03	0.72	0.49–1.09	.12

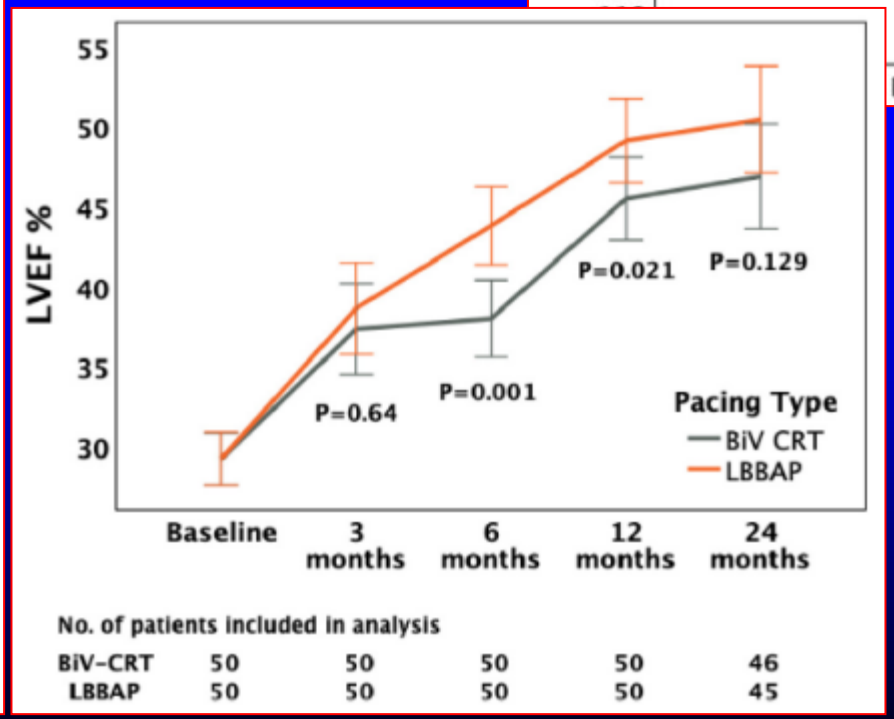
Biventrikulär = „conventional pacing“ (CP)

Vijayaraman, Heart Rhythm O² 2022;;3:368-76

Select Site Cohort Study

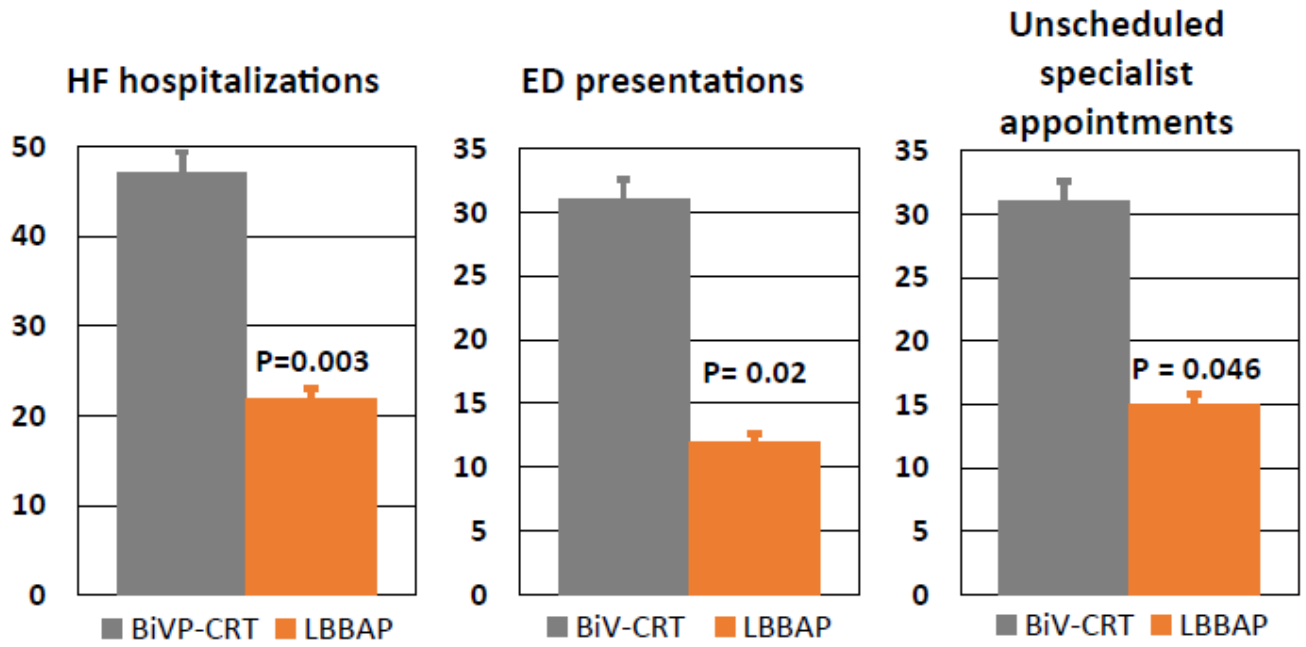






Shroff,
Heart Rhythm 2024;
21:893–900

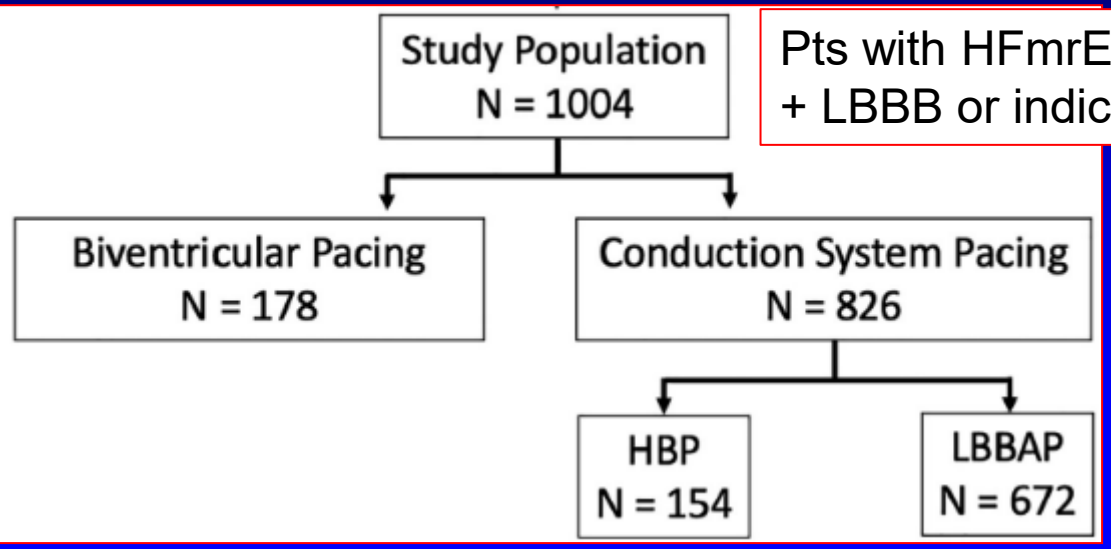
Select Site Cohort Study



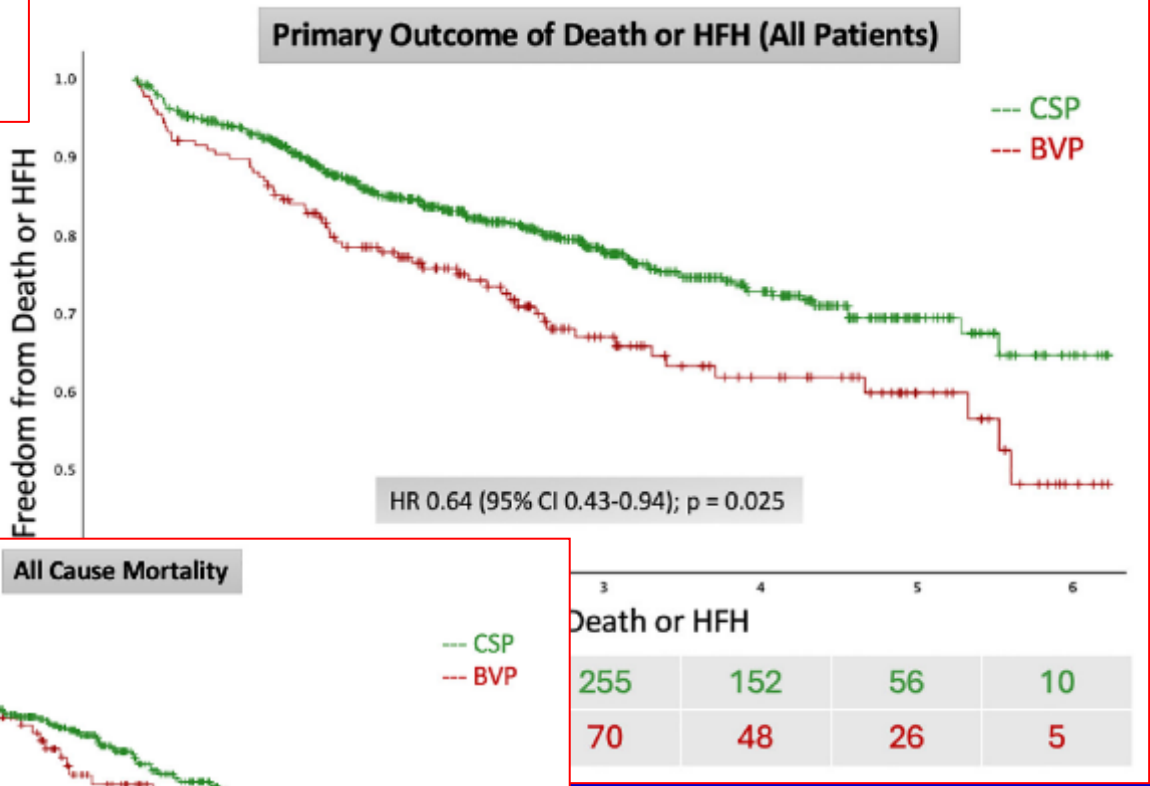
Parameter	BiV-CRT	LBBAP-CRT	*P*
Functional status			
NYHA class at 12 mo	1.66 ± 0.69	1.37 ± 0.63	.031
Improvement by ≥2 NYHA class at 12 mo	18 (36)	26 (51)	.129
METs at final follow-up	6.4 ± 2.7	6.7 ± 2.3	.613
Health care utilization			
No. of HF hospitalizations	47	22	.003
Incidence of HF hospitalizations	31.3/100 person-years Rate ratio: 1.8	17.25/100 person-years	.019
Unscheduled specialist appointments	20.7/100 person-years Rate ratio: 1.9	11/100 person-years	.046
ED presentations	20.7/100 person-years Rate ratio: 2.2	9.4/100 person-years	.02

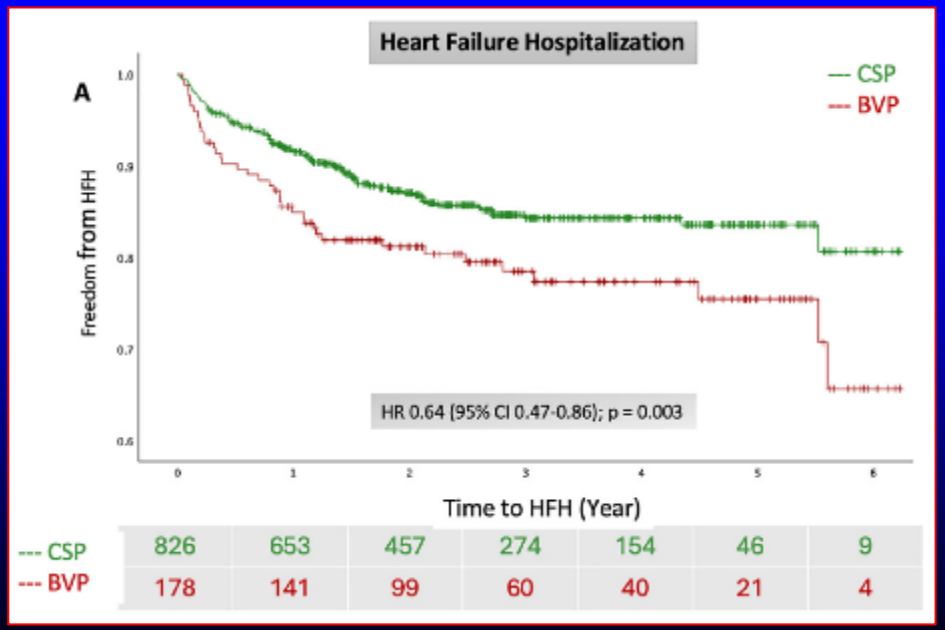
Shroff, Heart Rhythm 2024;21:893–900

CSP vs. BiV in HFmrEF: I-CLAS



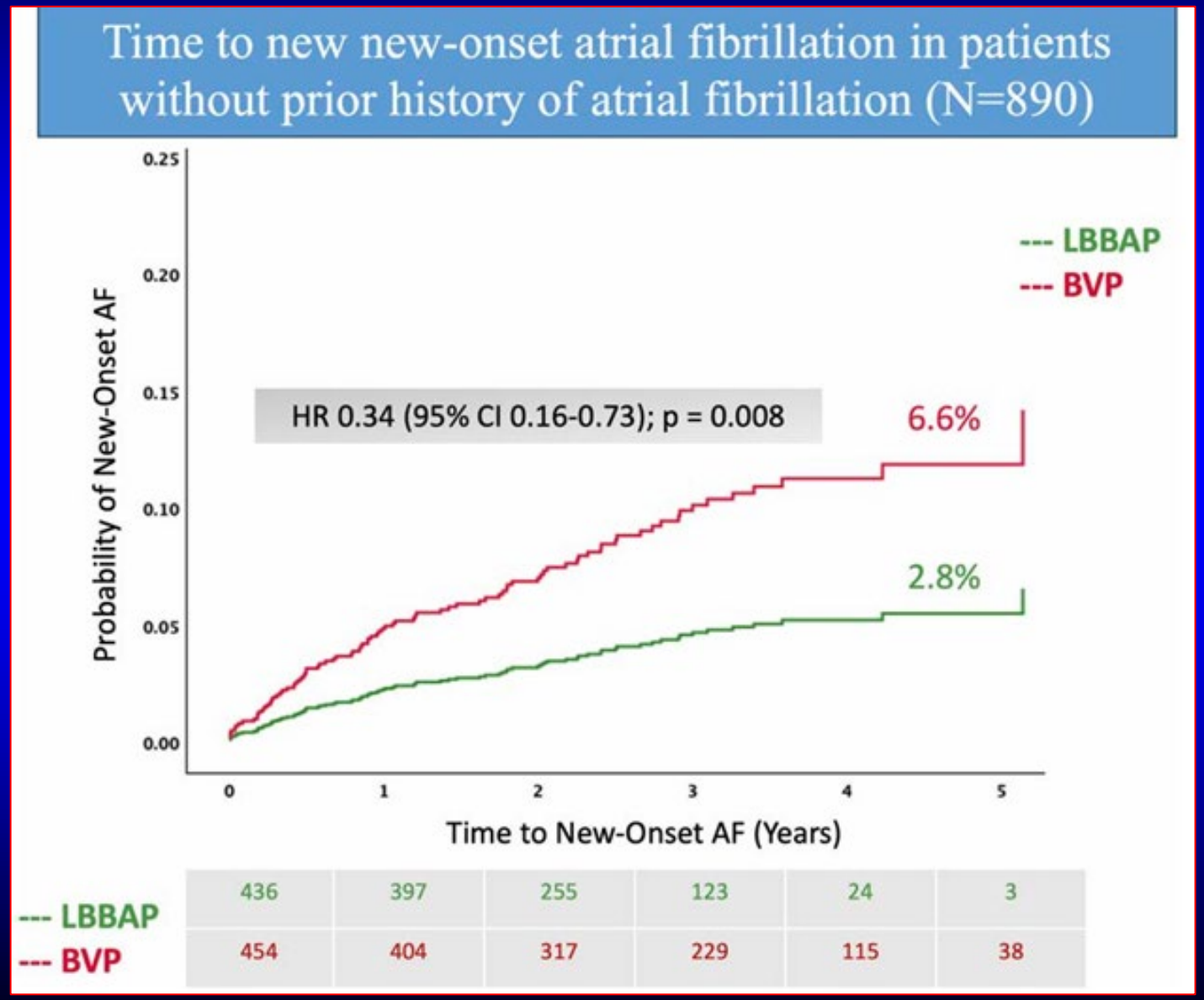
Pts with HFmrEF(36-50%)
+ LBBB or indication for VP





Vijayaraman,
Heart Rhythm 2024 (in press)

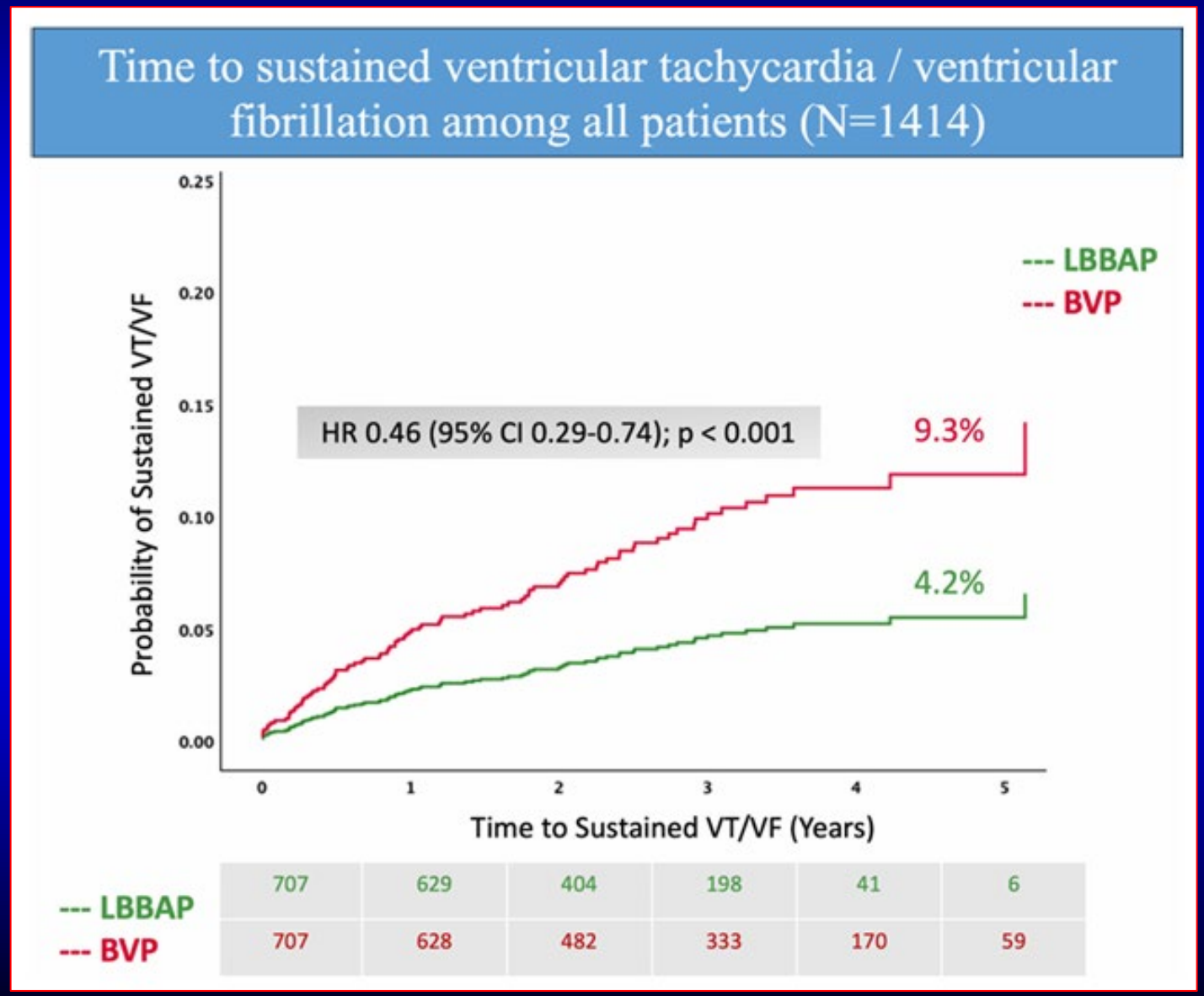
AF: LBBAP vs. BiV



I-CLASS
Propensity match

Herweg, Circulation 2024;149:379-90

VT/VF: LBBAP vs. BiV

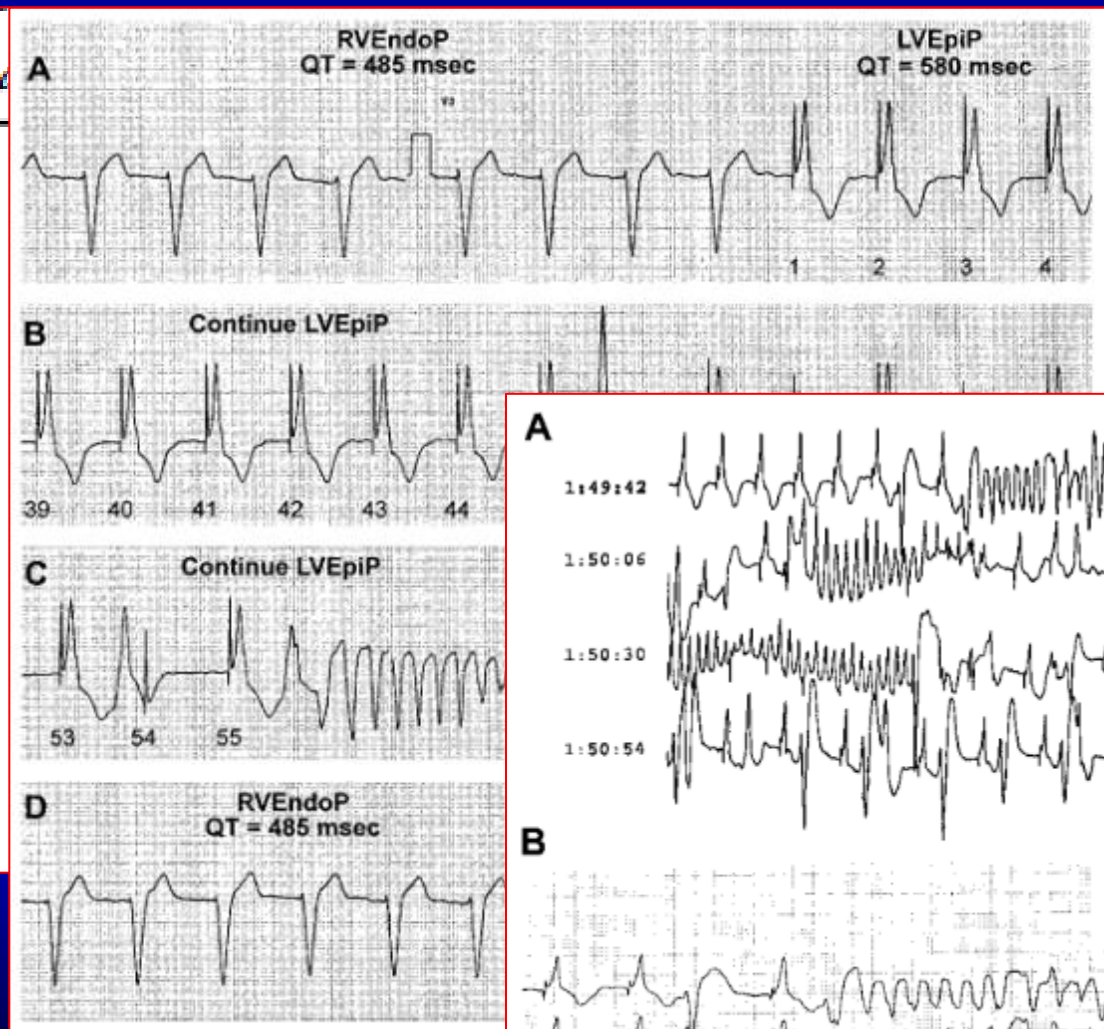


I-CLASS
Propensity match

Herweg, Circulation 2024;149:379-90

Bethel

Proarrhythmie durch epikardiale Stimulation



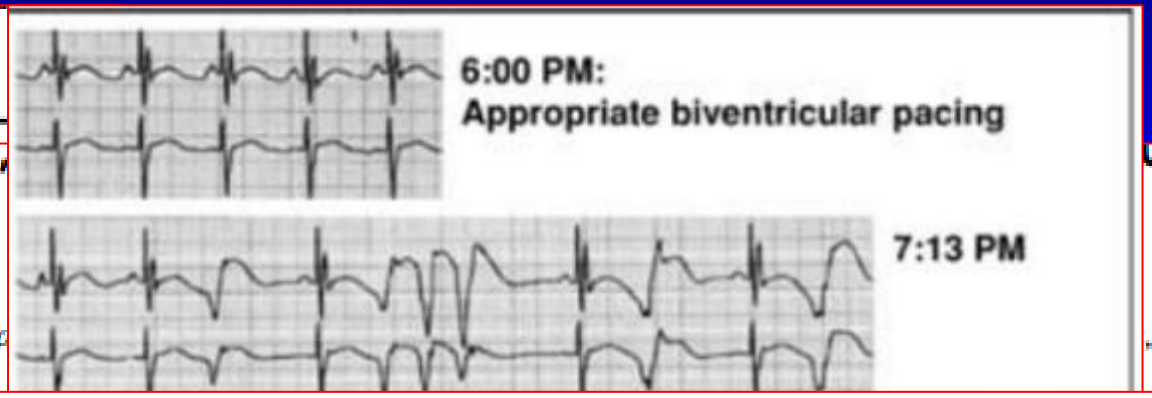
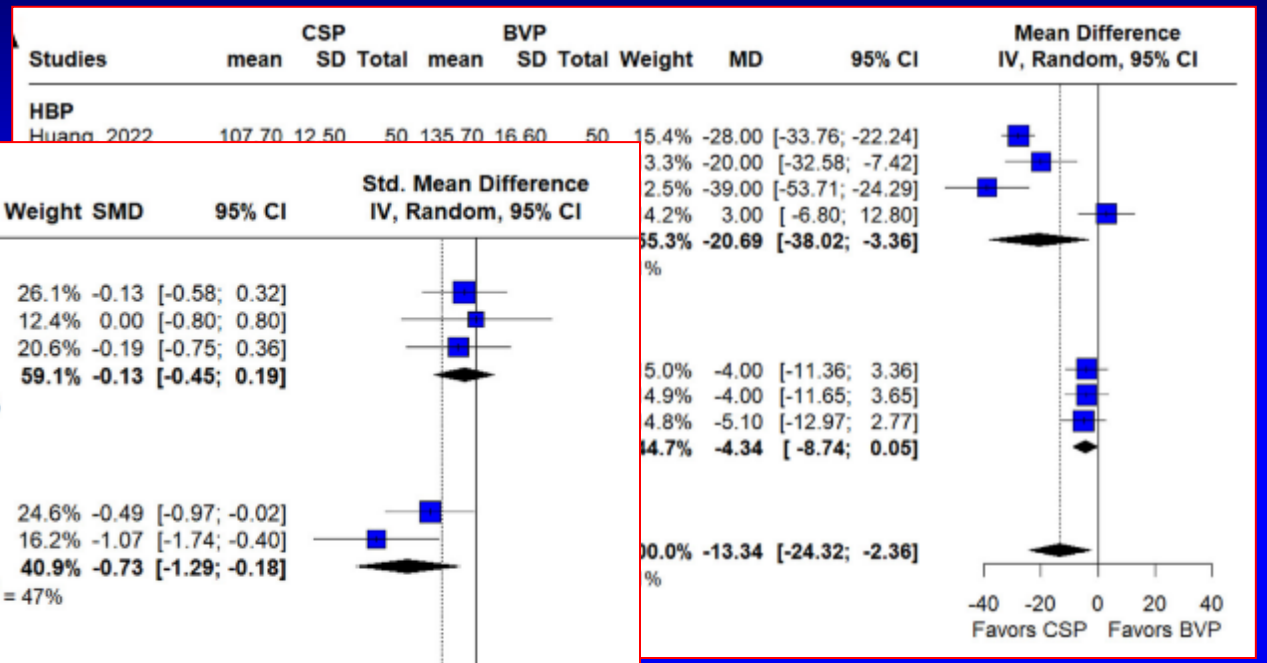
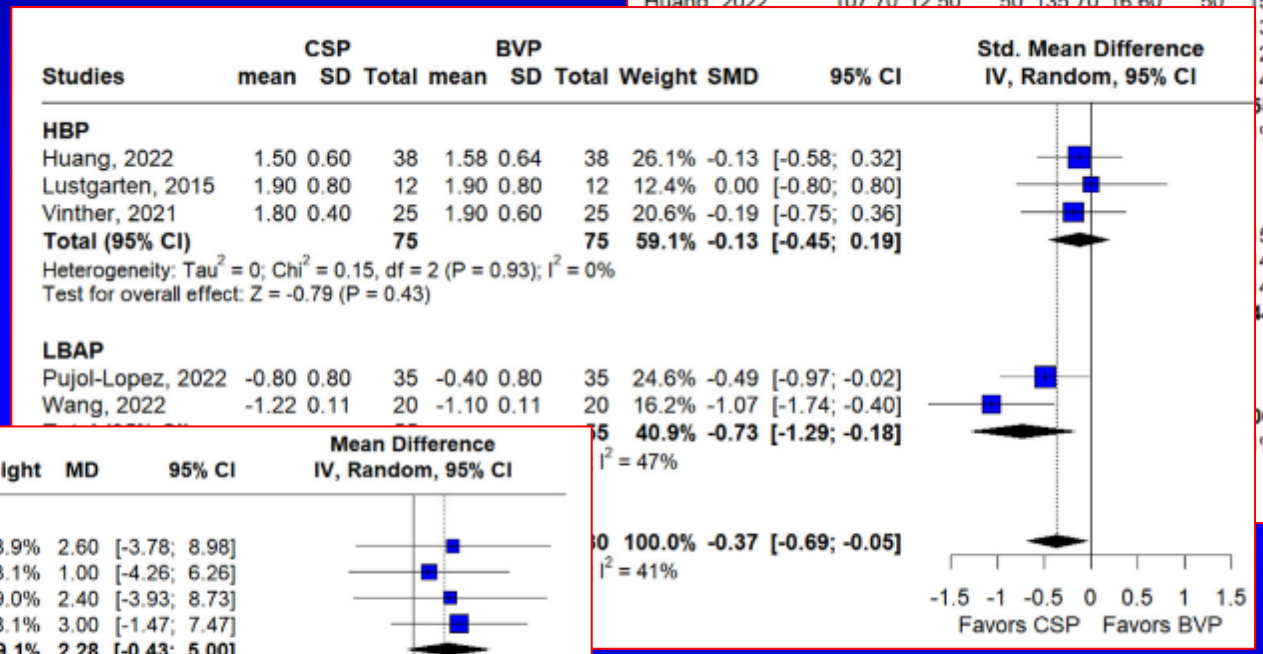


Figure 3. A, Incessant R-on-T ventricular ectopic beats and TdP were observed in a patient 3 to 4 hours after biventricular pacer implantation. Note that R-on-T extrasystoles were adequately sensed by the device. B, Typical episode of TdP during BiVP that was terminated by an ICD shock.

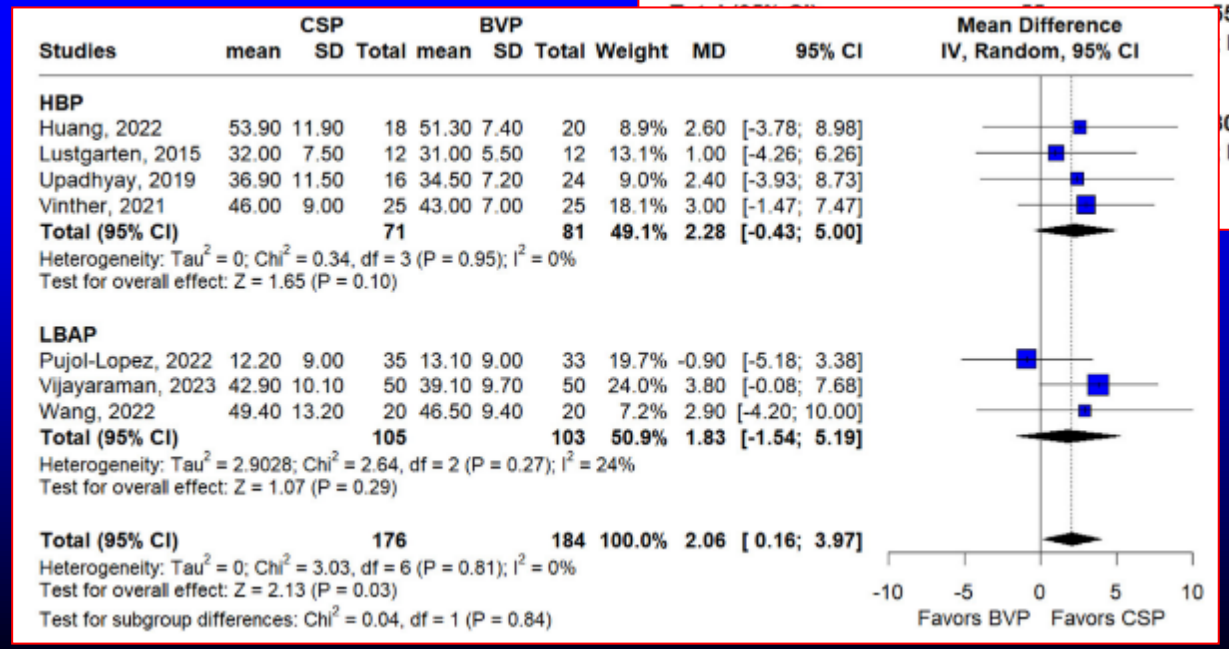
Metaanalyse BiV versus CSP



QRS



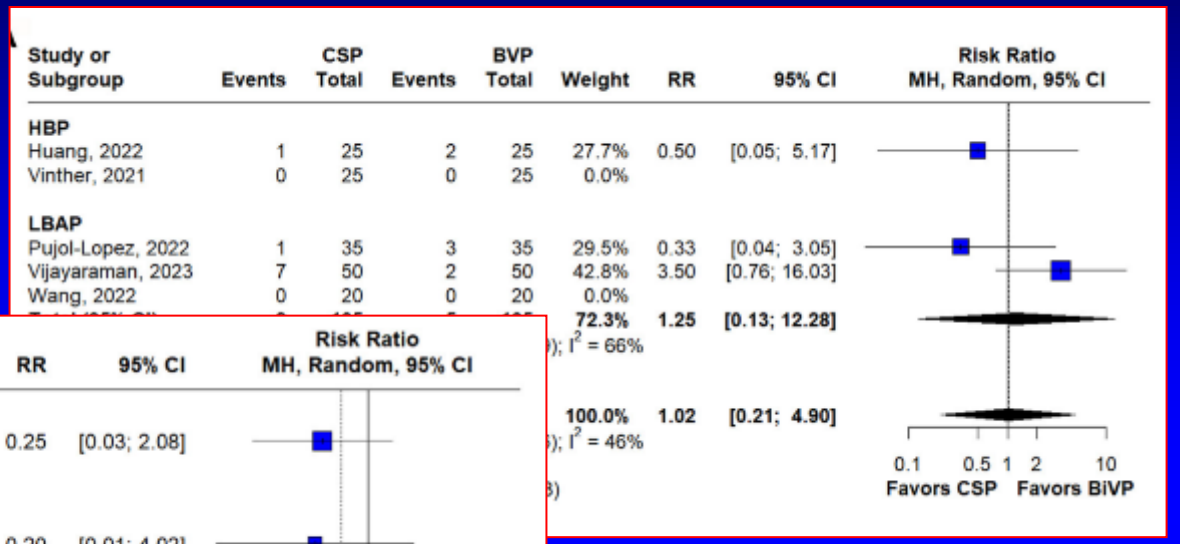
NYHA



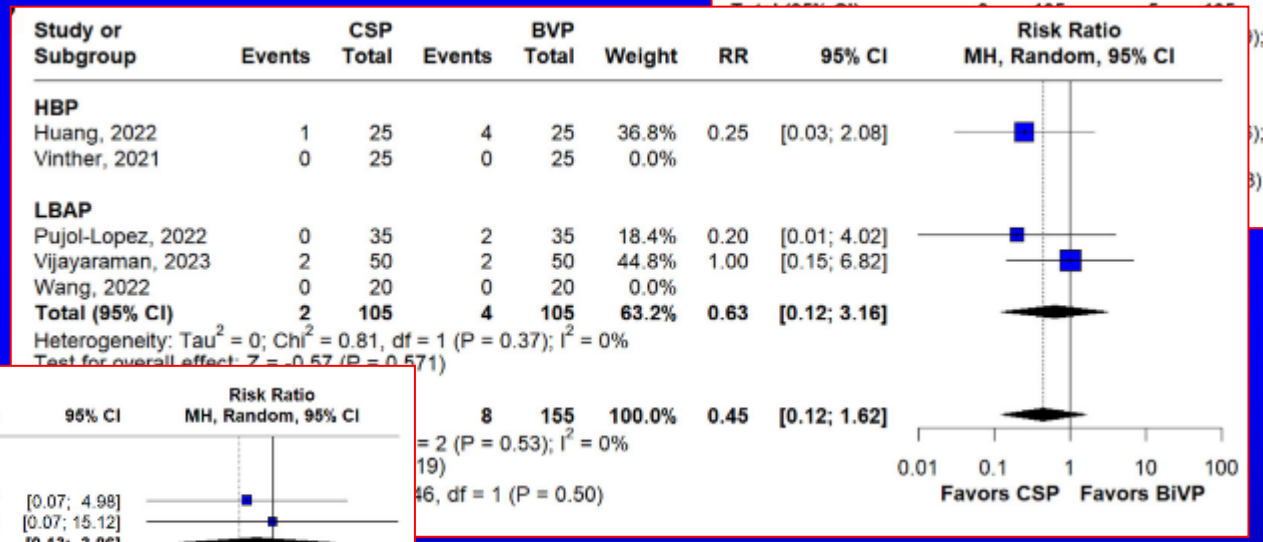
LVEF

Ferreira Felix, Heart Rhythm 2024;21:881-9

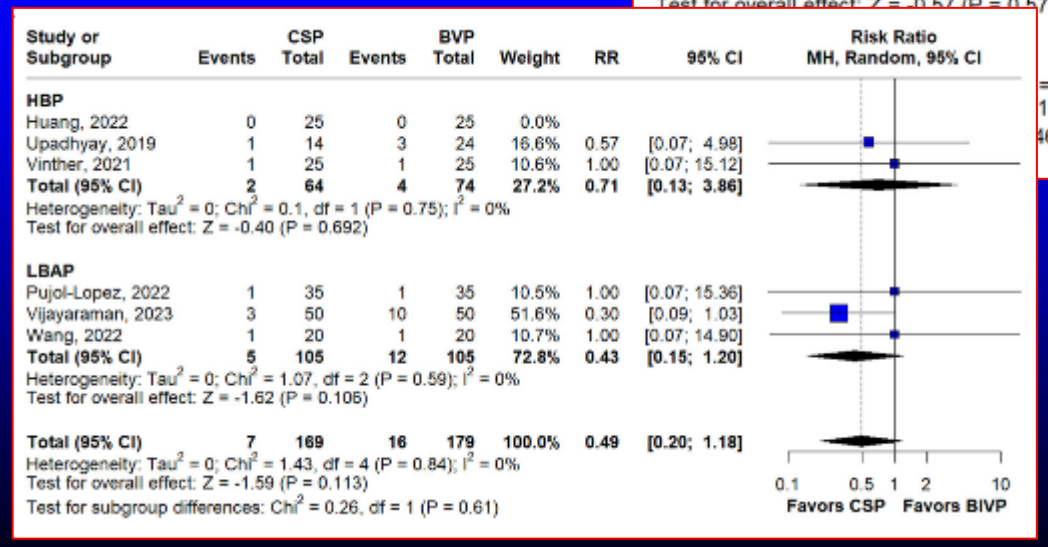
Metaanalyse BiV versus CSP



Complications



HFH



All-cause mortality

Ferreira Felix, Heart Rhythm 2024;21:881-9

Bethel

CSP: Ongoing Studies
CSP versus BiVP

Name NCT Status	Treatments	Size	Population	Primary Endpoint	Other Endpoints	Follow-up (mo)	Country
LIT-HF NCT05572957 Recruiting	His/LBBP vs GDMT	50	NICMP, LVEF≤35%, NYHA II-III, < 3 mo GDMT SR, LBBB	% with LVEF ≤35% and/or VAs	Health economics, LVEF, LVESV, LVEDV, NT-proBNP, NYHA, QoL, safety	18	China
HIS-CRT NCT05265520 Recruiting	HBP vs BVP	120	IIa, IIb indication for CRT-D, RBBB	LVEF	QRSd, LVESV, LVEDV, NT-proBNP	6	USA
HOT-CRT NCT04561778 Enrollment complete	HOT/LOT vs BVP	100	LVEF ≤35%, LBBB QRSd >120 ms or LVEF ≤50%, RVP > 40%, NYHA II-IV	LVEF, safety, success	HFH, death, VT/VF, crossover, NYHA, QRSd, LVESVi, QoL	6	USA
REINVENT-CRT NCT05652218 Not recruiting	LBBP vs BVP	20	LVEF >35%, LBBB, NYHA I- IV	MPI		6 (crossover 3 mo)	USA
HIS-alt_2 NCT04409119 Recruiting	His/LBBP vs BVP	125	LVEF ≤35%, NYHA II-IV, LBBB, or RVP > 90%	LVEF, QRS narrowing	LVEF, 6MWT, NYHA, QoL, QRSd, NT-proBNP, safety	6	Denmark
LBBAP-AFHF NCT05549544 Recruiting	LBBP vs BVP	60	Heart failure, LVEF <50%, NYHA II-IV, permanent AF, QRSd <130 ms, AVNA or slow VR with anticipated RVP ≥40%	LVEF	Implant success, safety, echo parameters, NT-proBNP, death, and HFH	6	China
CSP-SYNC NCT05155865 Recruiting	His/LBBP vs BVP	60	LVEF ≤35%, LBBB, NYHA II-III	LV volume, LVEF, NYHA, NT-ProBNP, 6MWT, QoL	Myocardial work redistribution, QRSd, arrhythmia, safety	12	Slovenia
CONSYST-CRT NCT05187611 Recruiting	His/LBBP vs BVP	130	LVEF ≤35%, LBBB, QRSd ≥130 ms or LVEF ≤35%, non-LBBB, QRSd ≥150 ms or LVEF <40%, AVB or LVEF≤35%, NYHA III-IV, AF, QRSd ≥130 ms	Composite death, cardiac transplant, HFH, LVEF	LVEF, LVESV, composite of death, cardiac transplant, HFH, QRSd, septal flash, NYHA	12	Spain
Safety and Effectiveness of Left Bundle Branch Pacing in Patients With Cardiac Dysfunction and AV Block NCT05553626 Not recruiting	LBBP vs BVP	160	LVEF <50%, NYHA I-III, second or third AVB, or RVP >40%	LVEF	LVESV, implant success, death and HFH, safety, QRSd, TR	12	China
LeCaRT NCT05365568 Recruiting	LBBP vs BVP	170	CRT indication, NYHA II-IV, LBBB QRSd >130 ms or non-LBBB QRSd, >150 ms, or wide paced QRSd	Composite death, HFH, implant failure, CIED re-intervention	Procedure time, fluoroscopy time, QRSd, 6MWT, LVESV, ICD therapies	12	Belgium
LEFT-BUNDLE-CRT NCT05434962 Recruiting	LBBP vs BVP	176	I or IIa indication for CRT, LBBB	CRT response	LVEF, clinical outcome, 6MWT, QoL, HFH, death, cardiac transplantation, VAs, safety	12	Spain
PhysioSync-HF NCT05572736 Not recruiting	His/LBBP vs BVP	304	LVEF ≤35%, LBBB, QRSd ≥130 ms	Composite death, HFH, LVEF	Cost-effectiveness, QoL, NYHA, 6MWT NT-proBNP, LVEF QRSd, CV death and HFH, LVAT	12	Brazil
Left vs Left NCT05650658 Not recruiting	His/LBBP vs BVP	2,136	LVEF <50%, QRSd >130 ms or anticipated RVP >40% or upgrade to CRT because of RVP >40%	Composite death and HFH	QoL, death, HFH, and LVESVi >15%, CV death, NYHA, 6MWT, NT-proBNP, AF, ICD therapies, echo parameters	66	USA, Canada

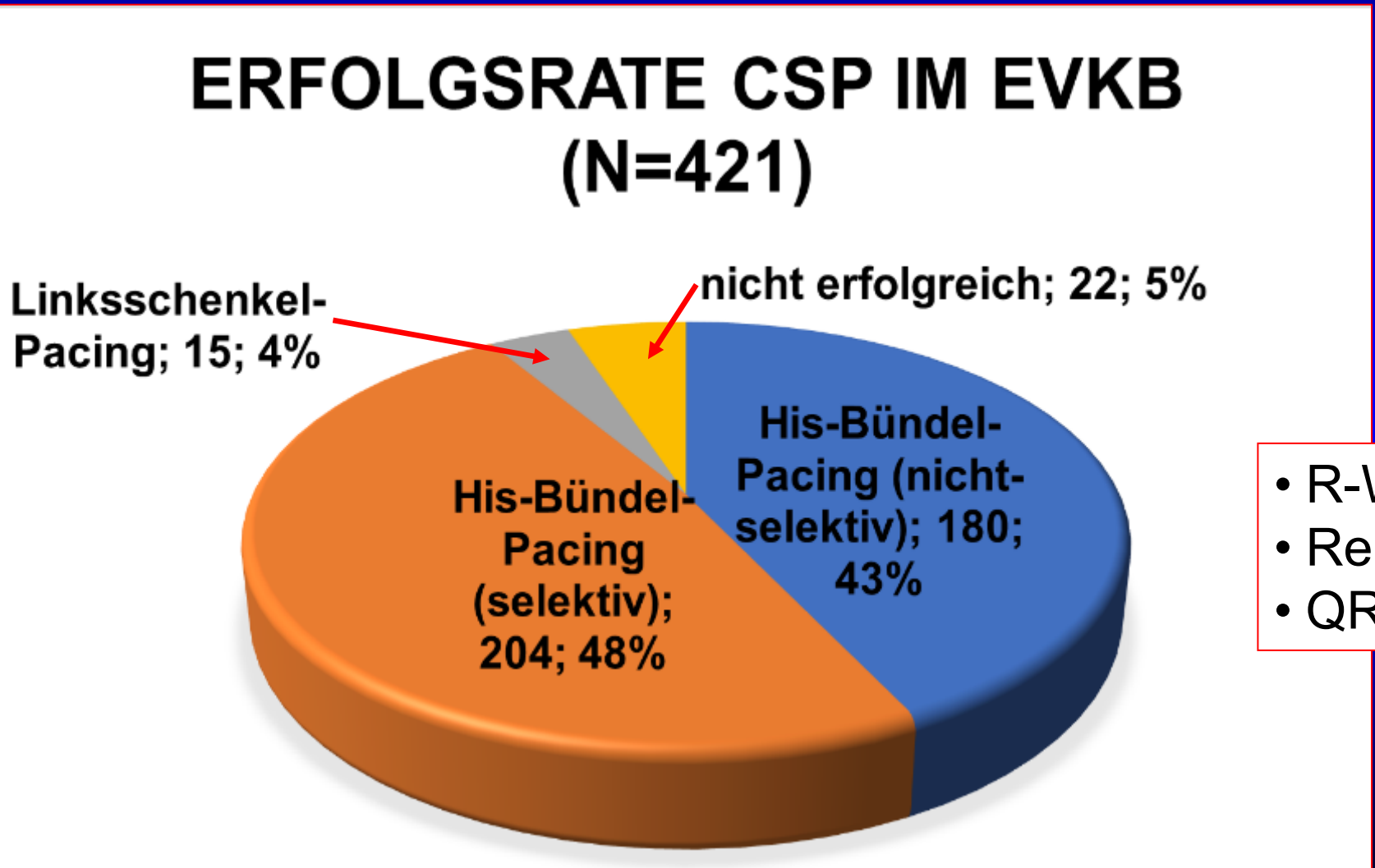
Vijayaraman, JACC Clin Electrophysiol 2023;9:2358-87

Conduction System Pacing für alle?

- Bei erwarteter ventrikulärem Stimulationsbedarf >20%: BiV, HBP oder LBBP (LVEF <50%: Klasse IIa-, LVEF >50% IIb-Empfehlung)
- Schmaler QRS oder RSB: HBP (hohe Implantationsexpertise), LBBP (geringere Implantationsexpertise)
- LSB, bifaszikulärer Block: LBBP
- BiV: falls LBBP/HBP nicht möglich, breiter QRS trotz LBBP

Vielen Dank für die Aufmerksamkeit!

His-Bündel-Pacing: Erfahrung in Bethel

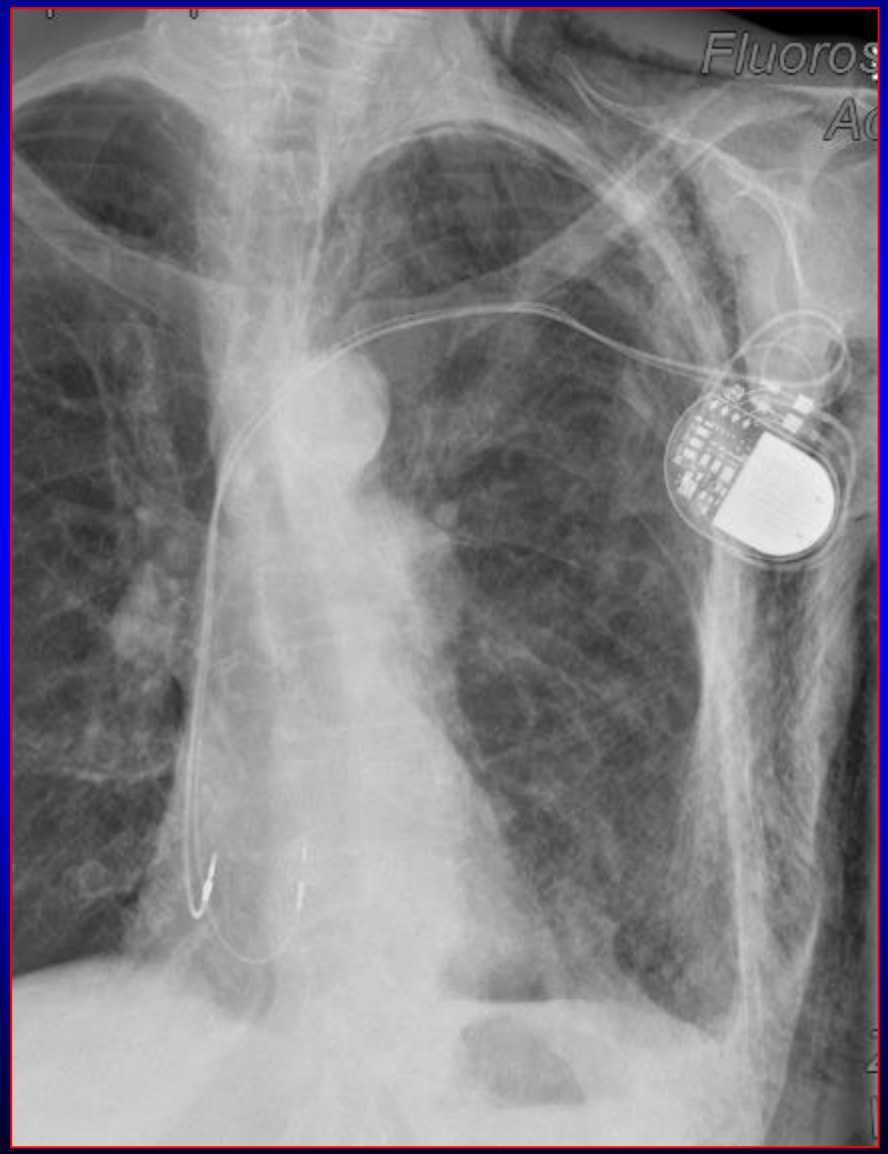


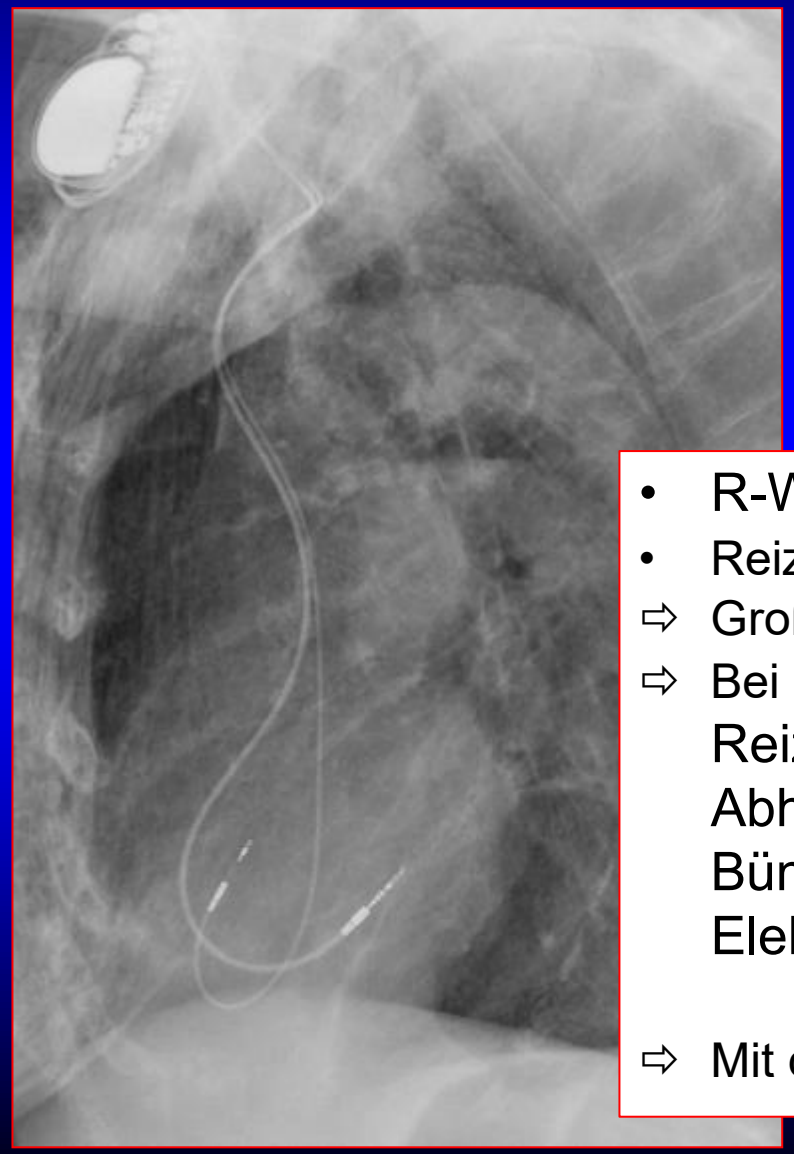
- Implantationsdauer: 92±43 (median: 86) min
- Fluoroskopie-Dauer: 10±8 (median 8) min
- His-Bündel-Verletzungs-strom: 61%

- R-Welle 4,5±3,5 mV
- Reizschwelle 1,1±0,6 V/1,0 ms
- QRS 110±28 ms ⇨ 88±18 ms

Erfolgsrate EvKB 2024 (n=110) 99,1%

His-Bündel-Stimulation



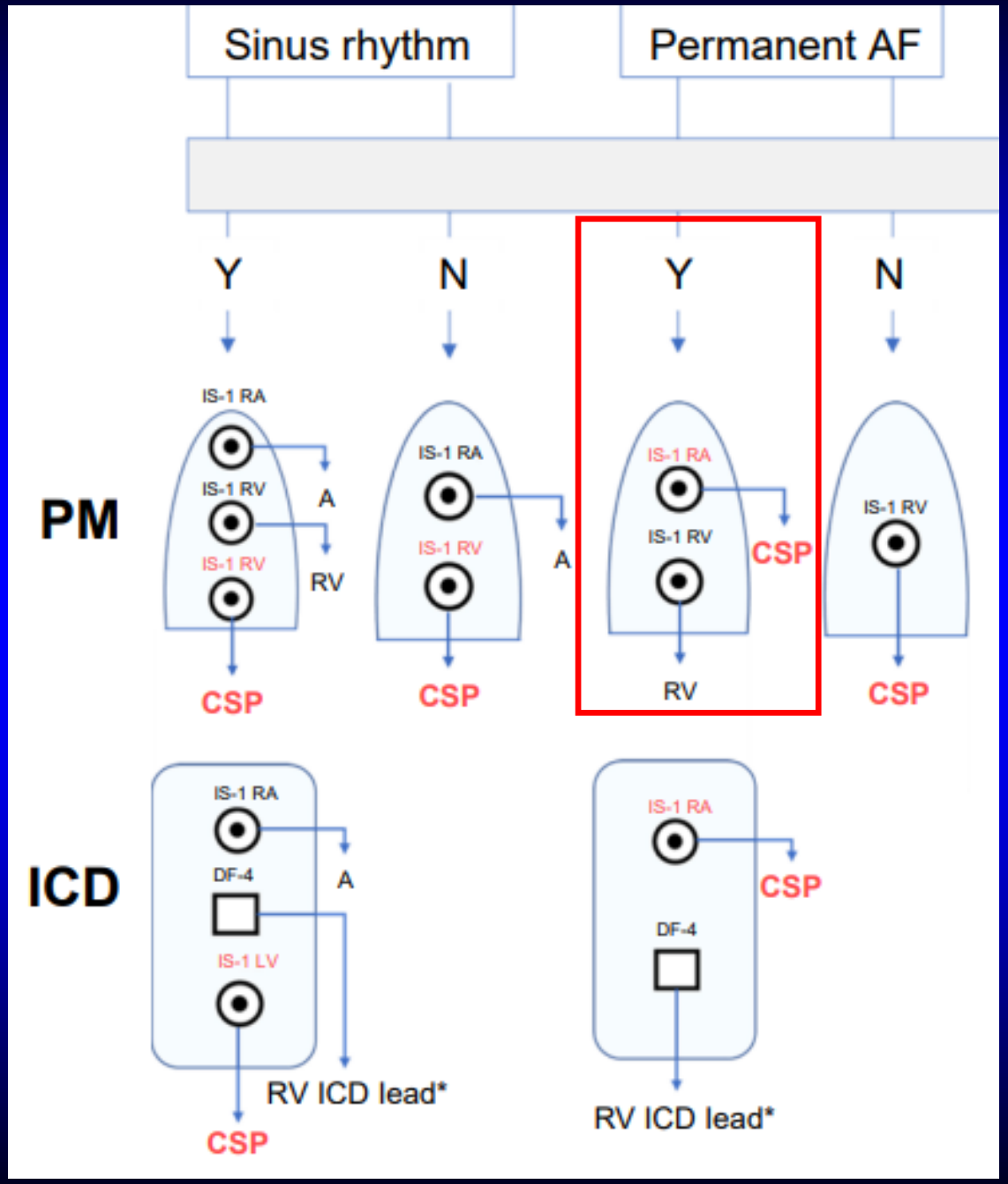


- R-Welle ≥ 1.8 mV
- Reizschwelle ≤ 1.8 V/1,0 ms

⇨ Große Batterie

⇨ Bei schlechtem Sensing, hoher Reizschwelle, Schrittmacher-Abhängigkeit oder geplanter His-Bündel-Ablation: RV-Back-up-Elektrode

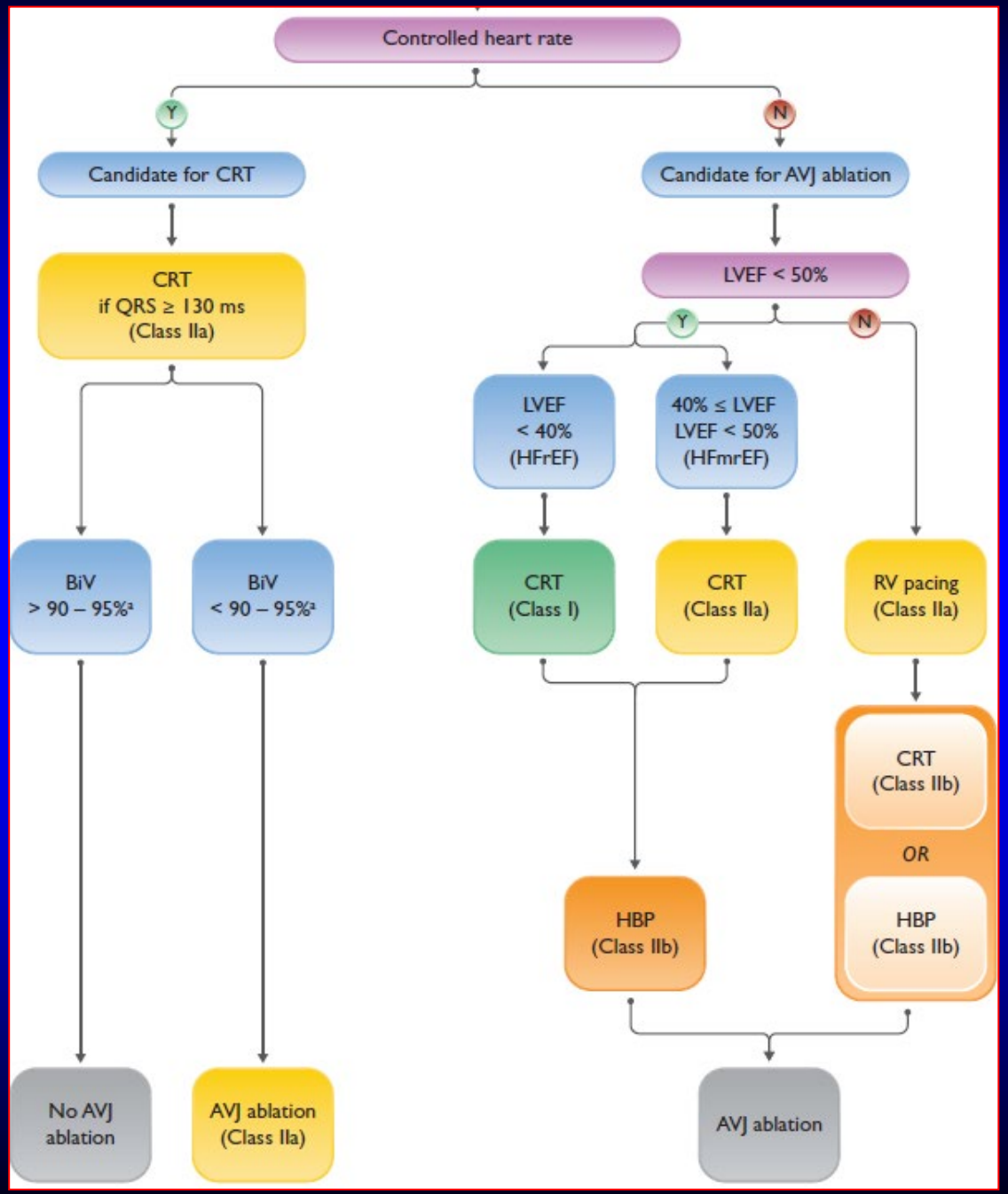
⇨ Mit dem Radiologen sprechen!!!



Konnektion an das Aggregat

- ⇨ VVIR und kleine R-Welle: Programmierung auf “AAIR“ möglich
- ⇨ AAIR bei permanentem Vorhofflimmern und komplettem AV-Block?
- ⇨ Bitte bei einem Patienten mit permanentem Vorhofflimmern, DDD-Schrittmacher + His-Bündel-Stimulation nicht auf VVI(R) programmieren!

Burri, Europace 2023;25:1208-36



AF & AV Node Ablation

2) In patients with symptomatic AF and an uncontrolled heart rate who are candidates for AVJ ablation (irrespective of QRS duration):		
2A) CRT is recommended in patients with HFrEF.[196,197,306,308]	I	B
2B) CRT rather than standard RV pacing should be considered in patients with HFmrEF.	IIa	C
2C) RV pacing should be considered in patients with HFpEF.[188,196,323]	IIa	B
2D) CRT may be considered in patients with HFpEF.	IIb	C

Glikson, Eur Heart J 2021;42:3427-520

Bethel

Permanentes Vorhofflimmern: Ablate & Pace (His)