

Who are the most appropriate heart failure patients for BAROSTIM THERAPY?

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BAROSTIM THERAPY SUMMIT

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BAROSTIM
THERAPY™

To start

MOST APPROPRIATE AT FIRST SIGHT

- Dilated cardiomyopathy
- “Narrow” QRS
- LVEDD moderately enlarged
- NYHA III
- ICD – implanted
- Age from up to 75

Is it really like this...?

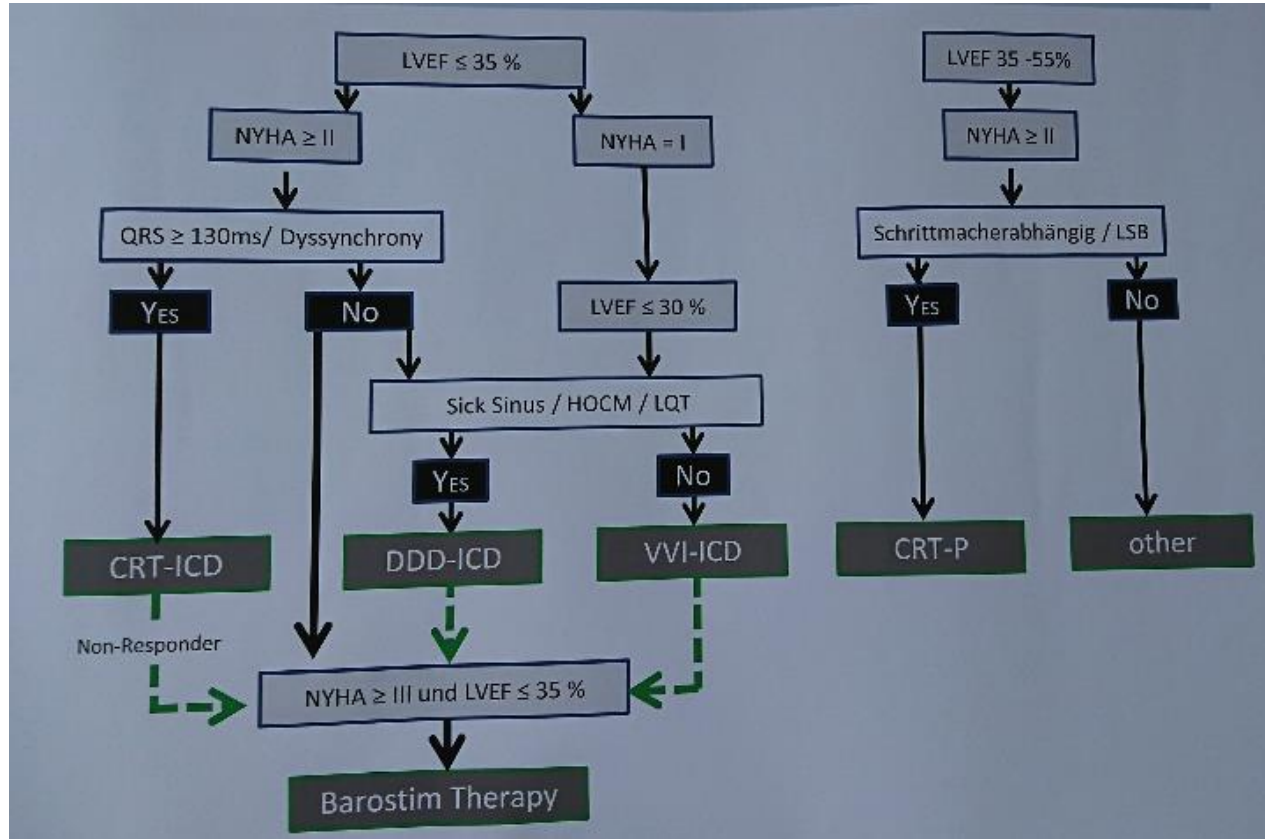
- Based on study data
- Real world and own experiences and expectations
- Possible niche indications
- Concomitant device therapy

Finally it is deemed to be most appropriate...

- “What can we do after Entresto, ICD, CRT, MitraClip... and before LVAD?”
- Is BAROSTIM THERAPY a bridge to LVAD? → Possibly!

Who could be appropriate?

- Non-CRT candidates
- CRT non-responders (CRT add-on)
- “Clip and stimulate”
- CHF and HF patients
- Medical non-responders / Pts. with adverse events

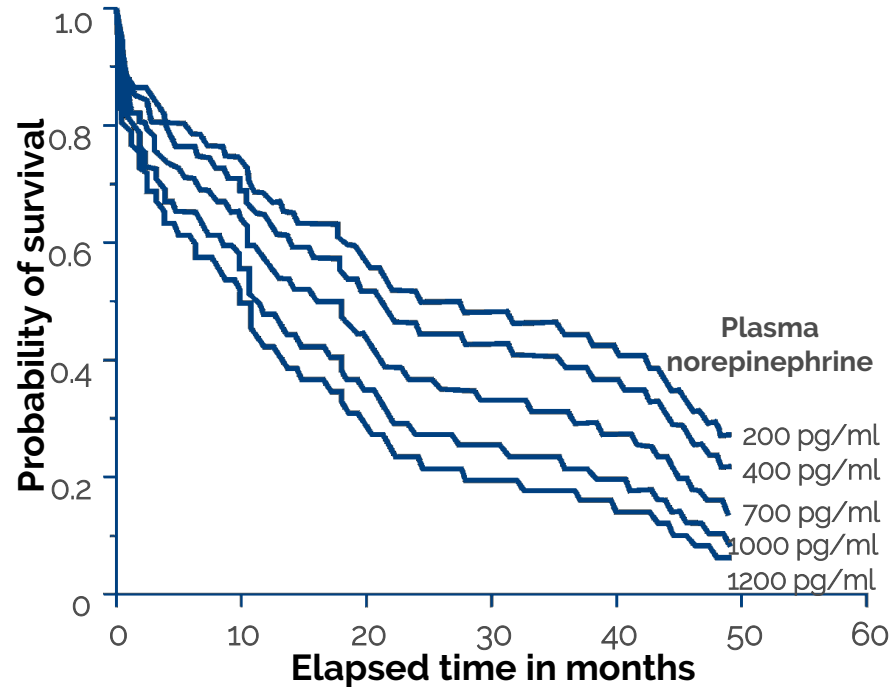


- on the ward
- ICD outpatient clinic
- heart failure outpatient clinic

Sympathetic tone and survival

AN OLD THING...

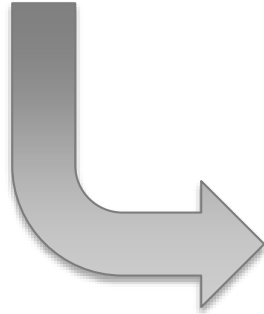
Magnitude of sympathoexcitation predicts mortality in heart failure



Cohn et al., *NEJM* 1984; 311:819.

Baroreflex Activation Therapy for the Treatment of Heart Failure With a Reduced Ejection Fraction

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Jochen Müller-Ehmsen, MD,‡‡ Jill E. Schafer, MS,§§ Michele Senni, MD,|||| Vijay Swarup, MD,¶¶
Rolf Wachter, MD,## William C. Little, MD***

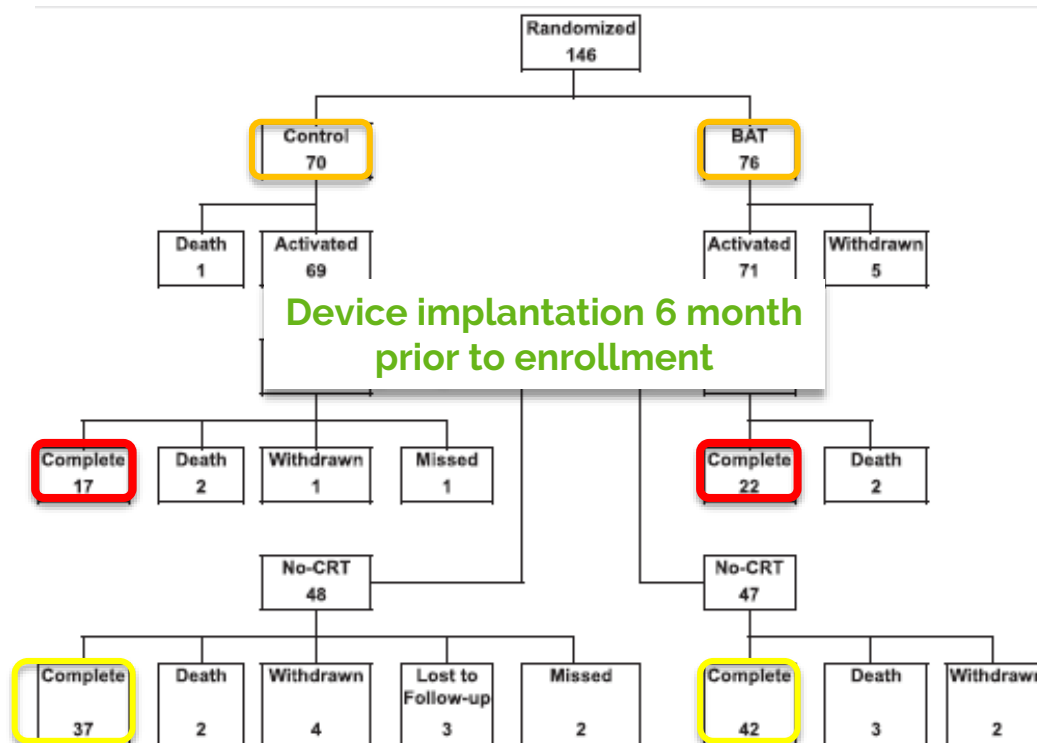


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Baroreflex activation therapy for the treatment of heart failure with a reduced ejection fraction: safety and efficacy in patients with and without cardiac resynchronization therapy

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Anique Ducharme⁵, Marcel Halbach⁶, Didier Klug⁷, Eric G. Lovett⁸,
Jochen Müller-Ehmsen⁹, Jill E. Schafer¹⁰, Michele Senni¹¹, Vijay Swarup¹²,
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Baroreflex activation therapy for the treatment of heart failure with a reduced ejection fraction: safety and efficacy in patients with and without cardiac resynchronization therapy

Variable	CRT (n = 45)	No-CRT (n = 95)	P-value
Race: Caucasian	91.1% (41/45)	83.2% (79/95)	0.30
Gender: female	8.9% (4/45)	16.8% (16/95)	0.30
NYHA: class III	100.0% (45/45)	98.9% (94/95)	1.00
Age, years	68 ± 9 (45)	63 ± 12 (95)	0.02
Body mass index, kg/m ²	29 ± 4 (45)	29 ± 5 (95)	0.40
Systolic blood pressure, mmHg	118 ± 19 (45)	117 ± 18 (95)	0.82
Diastolic blood pressure, mmHg	70 ± 10 (45)	73 ± 11 (95)	0.11
Heart rate, bpm	72 ± 10 (45)	74 ± 12 (92)	0.24
LVEF, %	24 ± 6 (44)	25 ± 7 (93)	0.72
eGFR, mL/min	55 ± 19 (34)	60 ± 20 (85)	0.18
Creatinine, mg/dL	1.4 ± 0.5 (34)	1.3 ± 0.5 (85)	0.41
NT-pro BNP ^a , pg/mL	1457 [472, 4603] (32)	1144 [534, 3529] (64)	0.84
6MHWd (m)	303 ± 84 (45)	302 ± 81 (91)	0.96
MLWHF quality of life score	44 ± 24 (45)	48 ± 21 (94)	0.33
Number of medications	4.7 ± 2.0 (44)	4.6 ± 1.7 (94)	0.79
Coronary artery disease	60.0% (27/45)	70.5% (67/95)	0.25
Atrial fibrillation on medical history	51.1% (23/45)	41.1% (39/95)	0.28

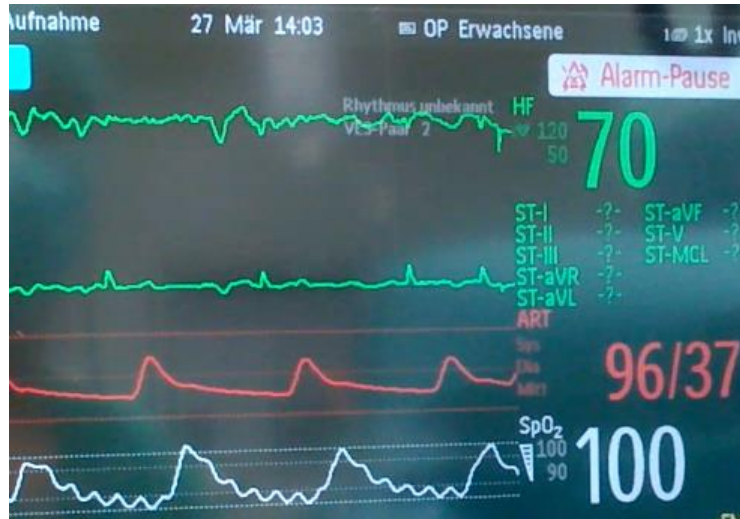
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Table 2 Differences in efficacy outcomes in BAT vs. control in CRT Patients and No-CRT patients

Change from baseline	No-CRT				CRT			
	BAT (n = 47)	Control (n = 48)	Difference	P-value	BAT (n = 24)	Control (n = 21)	Difference	P-value
QoL score	-21.6 ± 3.6 ^a	3.5 ± 3.7	-25.1 ± 5.2	<0.001	-9.3 ± 4.0 ^a	-0.9 ± 6.0	-8.4 ± 7.0	0.23
NYHA class	-0.4 ± 0.1 ^a	-0.2 ± 0.1	-0.2 ± 0.1	0.09	-0.7 ± 0.1 ^a	-0.1 ± 0.1	-0.6 ± 0.2	<0.001
6MHWd, m	85.5 ± 20.5 ^a	3.6 ± 16.3	81.9 ± 26.8	0.003	16.4 ± 10.6	-3.5 ± 22.9	20.0 ± 22.4	0.38
NT-proBNP, pg/ml	-97 [-504, 93] ^b	116 [-74, 700] ^b	-318 ± 274 ^b	0.03 ^b	80 [-452, 402] ^b	433 [64, 537] ^b	-337 ± 483 ^b	0.16 ^b
LVEF, %	4.3 ± 1.2 ^a	-0.1 ± 1.7	4.4 ± 2.0	0.03	-1.2 ± 2.2	-0.1 ± 2.1	-1.2 ± 3.1	0.71
Heart failure hospitalizations, n	-0.53 ± 0.2 ^a	0.05 ± 0.3	-0.57 ± 0.4	0.08 ^b	-0.42 ± 0.3	-0.25 ± 0.3	-0.17 ± 0.5	0.78 ^b
Heart failure hospitalization, days	-8.89 ± 4.0 ^a	0.18 ± 2.2	-9.07 ± 4.7	0.09 ^b	-1.05 ± 1.2	-0.13 ± 2.5	-0.93 ± 2.6	0.78 ^b

Implant procedure

“Rate-response” in HF Patient



Start



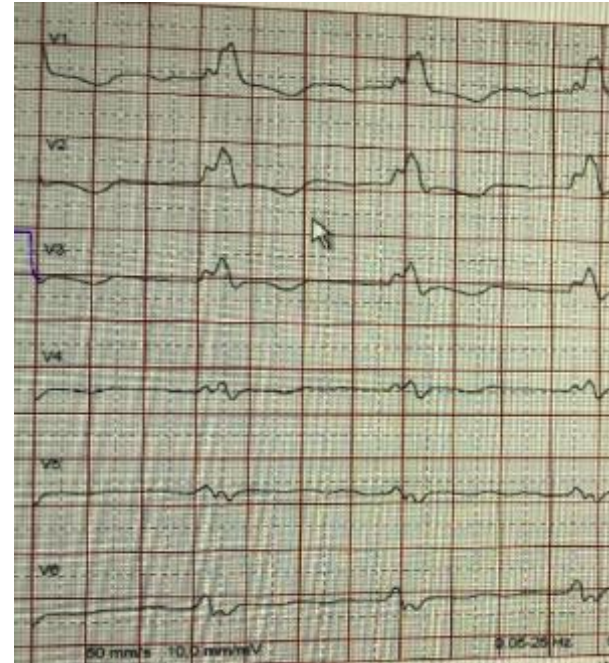
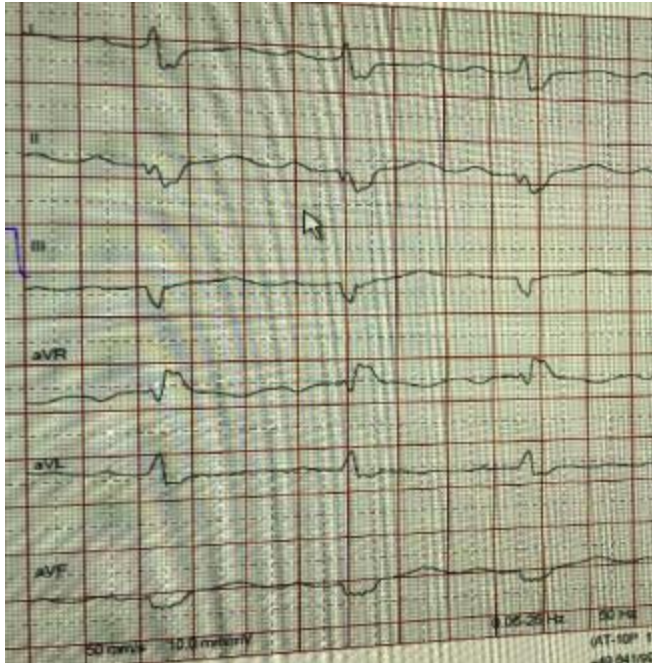
30 seconds post
BAT activation

Patient, U.B. *1955

- Ischemic Cardiomyopathy, STEMI (post) 1990
- CABG 2010, PTCA LAD (Scaffold) 2014
- Paroxysmal atrial fibrillation

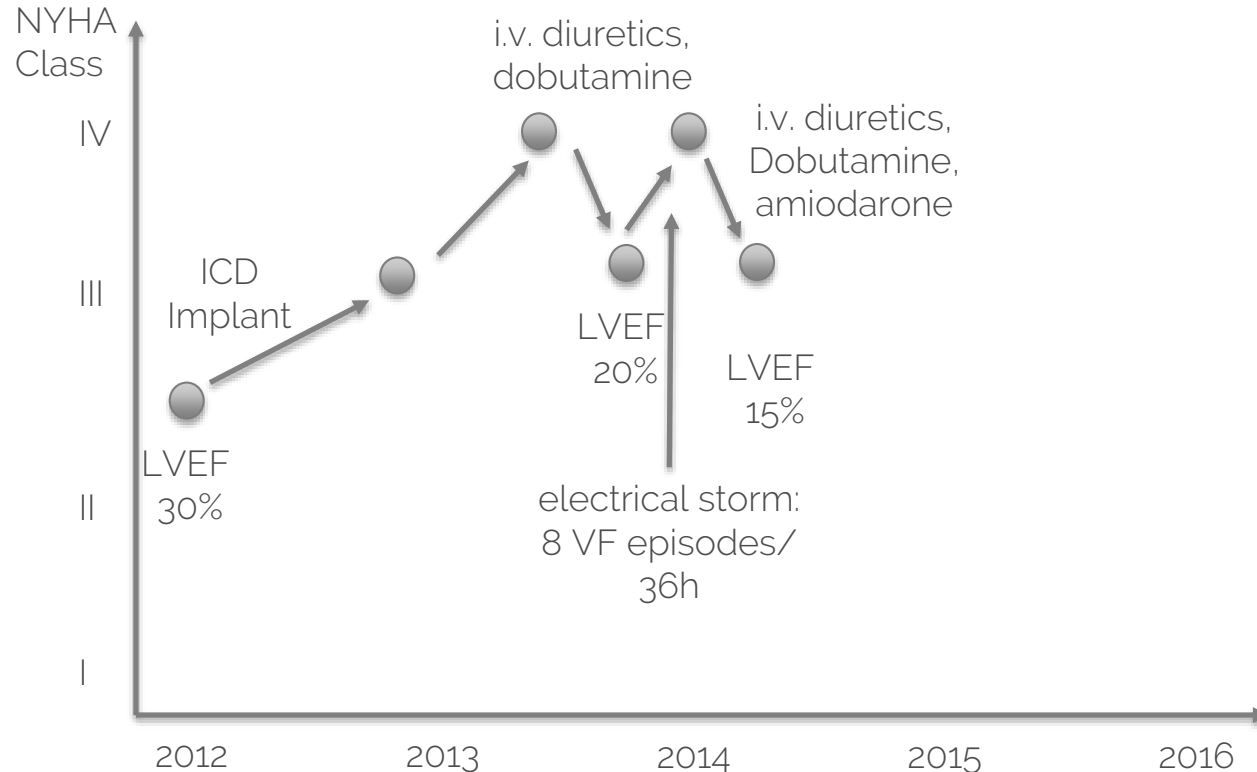
Medication 2012:	Carvedilol 12,5mg	1-0-1
	Candesartan 8mg	1-0-0
	Spirolactone 50mg	0-0-1
	HCT 25mg	1-1-0
	Clopidogrel 75mg	1-0-0
	Ivabradin 5mg	1-0-1
	Phenprocoumon	

Patient, U.B. *1955



SR, PQ 230ms (AVB I°), QRS 180ms RBBB; -> „no“ CRT

Patient, U.B. *1955



Patient, U.B. *1955

09/2014:

- Second decompensation despite intensive medication
- Electrical storm
- 14 days intensive care unit -> NYHA III

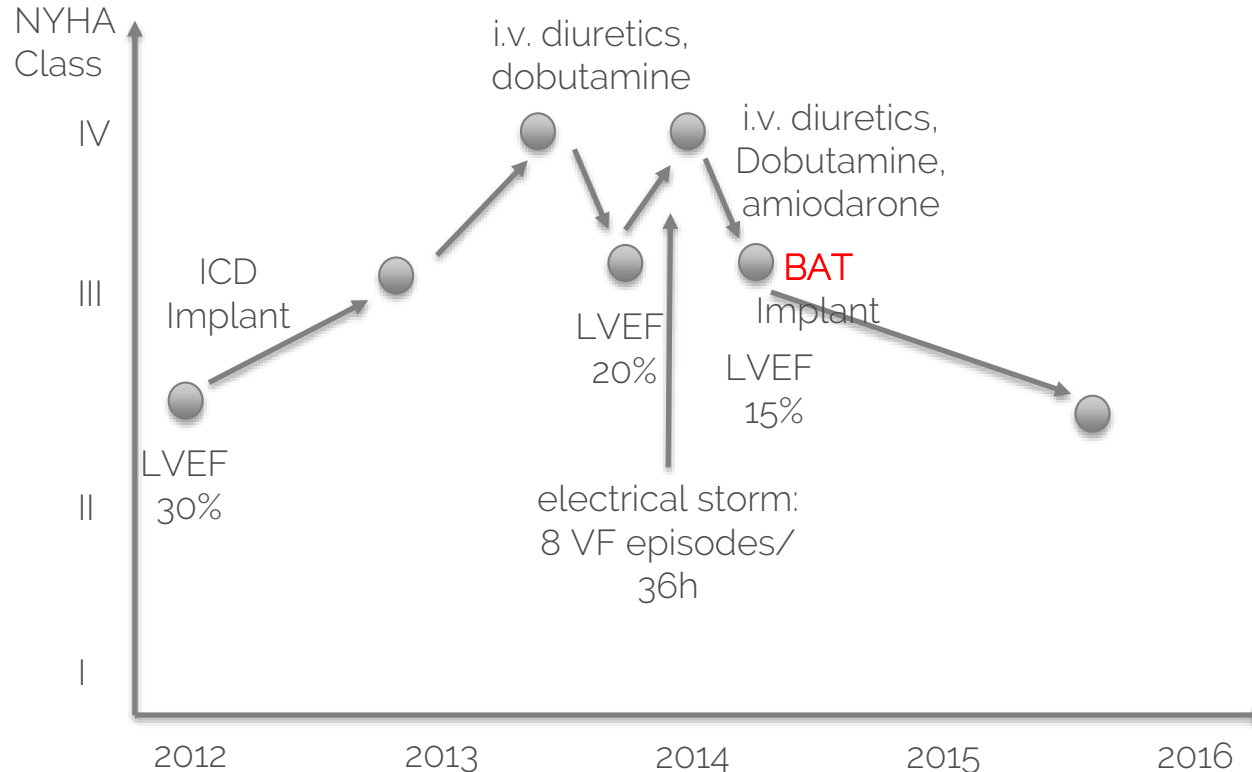


BAT eligible



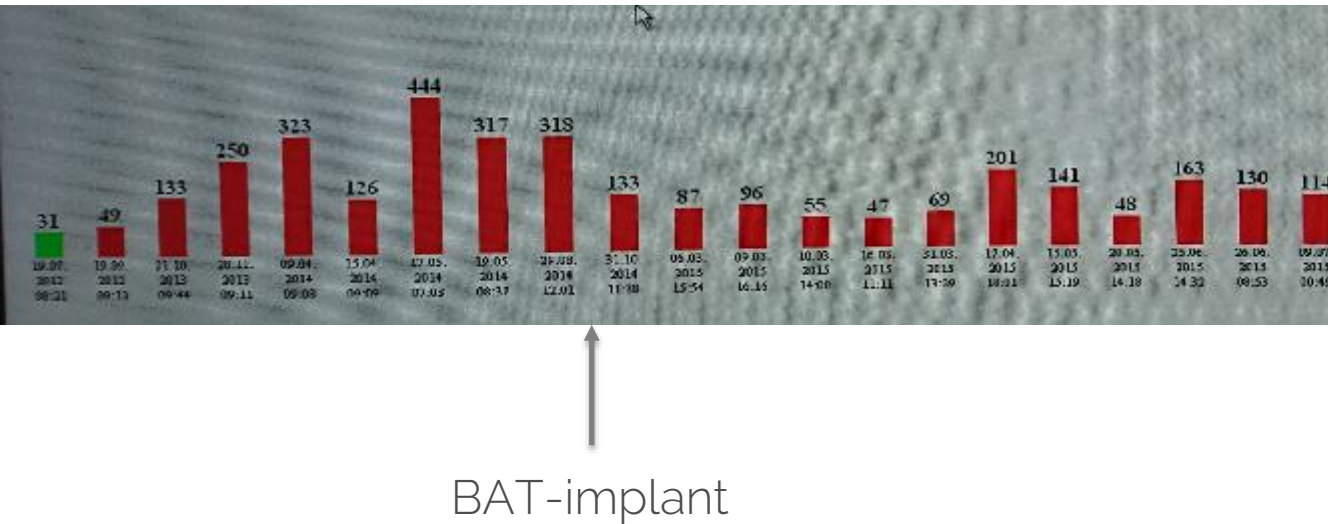
Already to worse:
LVAD implantation

Patient, U.B. *1955

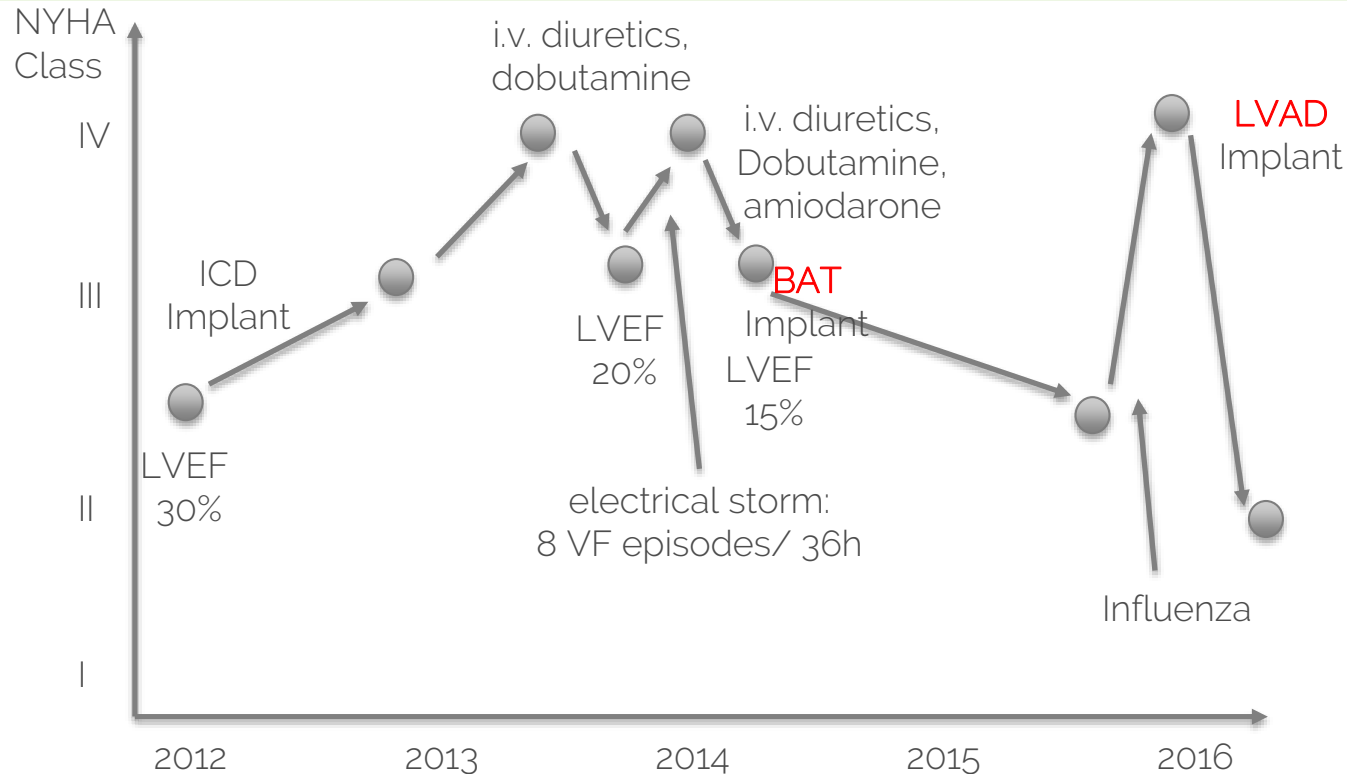


Patient, U.B. *1955

BNP-levels

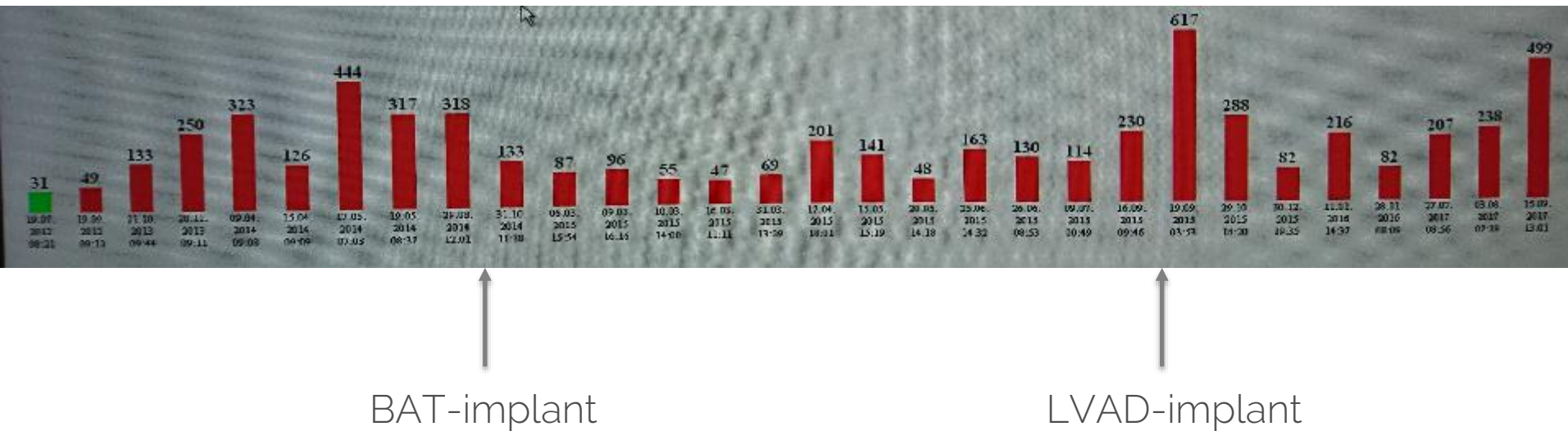


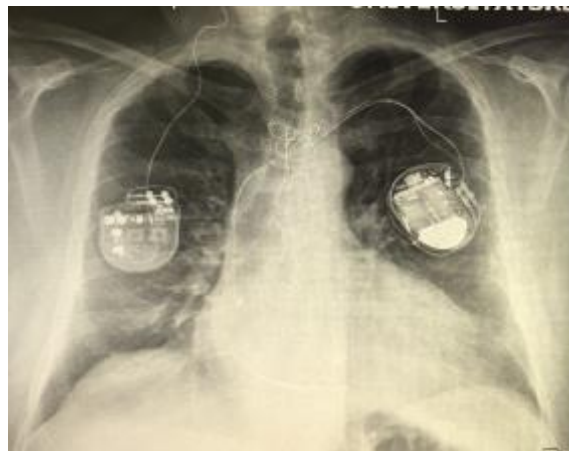
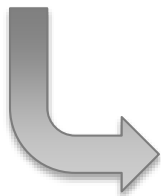
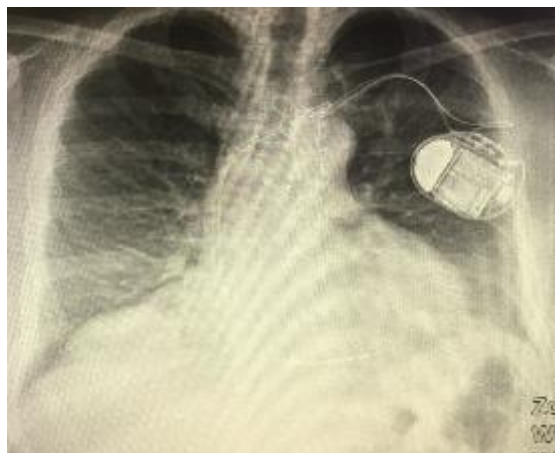
Patient, U.B. *1955



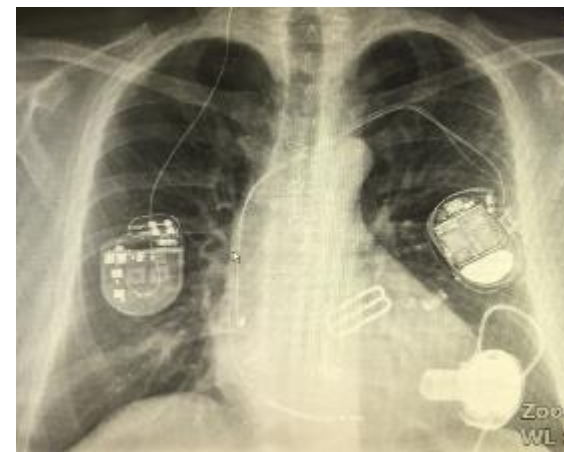
Patient, U.B. *1955

BNP-levels





„Bridge to LVAD“



WHO COULD BE APPROPRIATE?

- Non-CRT candidates
- CRT non-responders (add-on to CRT)
- “Clip and stimulate”
- CHF and AF patients
- Medical non-responders / Patients with adverse events
- Patients with HFpEF

Thank you.



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THERAPY™