Hospital Santos
Dumont







#### **Disclaimer**

Não há conflito de interesse nessa apresentação



**Dumont** 

#### Novas Fronteiras na Estimulação Cardíaca



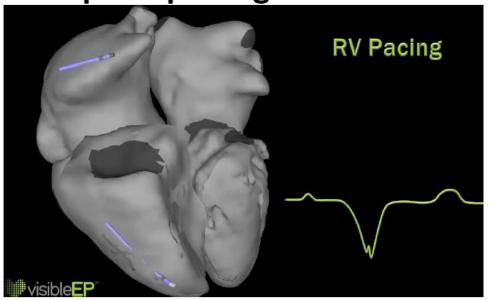


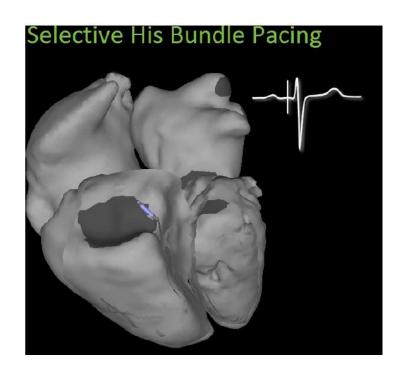
## Estimulação Hissiana - A Verdadeira Estimulação Fisiológica





**RV** apical pacing





Peter Spector University of Vermont



# Permanent His Bundle Pacing Is Associated with Reduction in Morbidity and Mortality Compared to Right Ventricular Pacing:

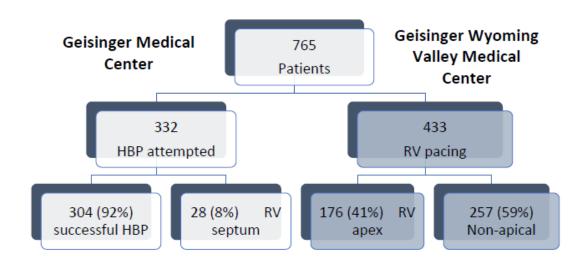
Results From Geisinger His Bundle Pacing Registry.

Abdelrahman M / Vijayaraman, P et al, JACC 2018 (Late Breaker ACC March 2018)



# Non-randomized, observational cohort study

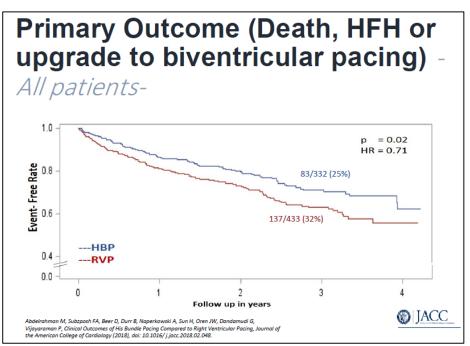
All patients undergoing new permanent pacemaker implantation for bradycardia indications

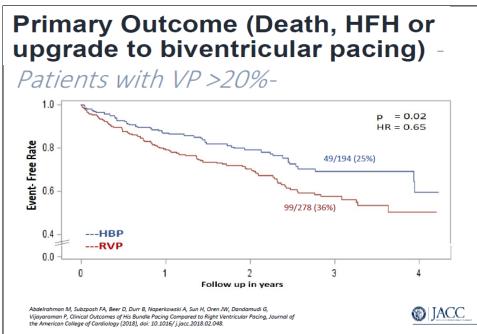


- Mean Follow-up duration 725 ±423 days
- 220 reached the primary endpoint



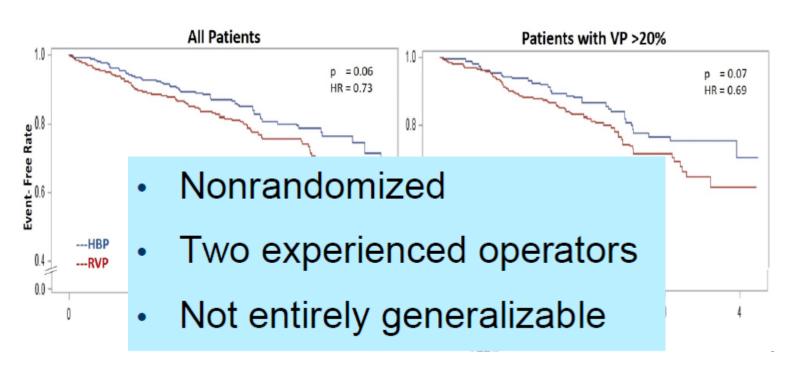








### All- Cause Mortality



Abdelrahman M / Vijayaraman, P et al, JACC 2018 (Late Breaker ACC March 2018



AV optimisation delivered with direct His bundle pacing, in patients with heart failure, long PR without left bundle branch block: randomised multi-centre clinical outcome study.

The His Optimised Pacing Evaluated for Heart Failure Trial



av optimisation delivered with



and



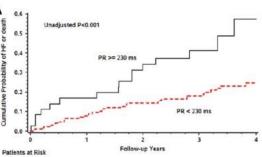
**Imperial College** London

Improve objective exercise capacity?



**MADIT** study ICD arm non LBBB

pts



Valentina Kutyifa et al. Circ Arrhythm Electrophysiol. 2014;7:645-651

Study Design

Study Type 1: Interventional (Clinical Trial)

Estimated Enrollment 6: 160 participants Allocation: Randomized Intervention Model: Crossover Assignment

Masking: Double (Participant, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: AV Optimisation Delivered With Direct His Bundle Pacing, in Patients With Heart Failure, Long PR Without Left Bundle Branch Block: Randomised Multi-centre Clinical Outcome Study,

Estimated Primary Completion Date 6: October 2019 Estimated Study Completion Date 6: October 2019

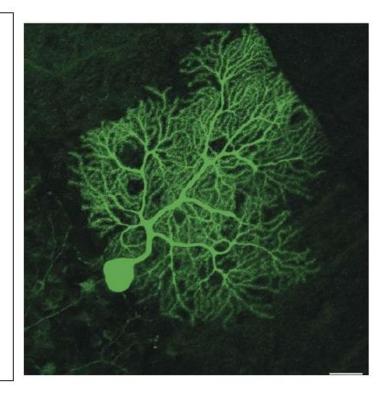




#### Concerns

#### Conduction Tissue Disease- Complex, Patchy & ? Progressive

- His Purkinje Disease
  - · Complex & undefined
  - · Not all BBB's are the same
  - Not Discrete
  - · Often progressive and patchy
- Progressive myopathies, are often times more than just electrical
  - Electro-mechanical uncoupling





# Contemporary Technical Challenges with His Bundle Pacing

- Experience counts
- Anatomic variation & its challenges:
  - Inability to record His (8-10%)
  - Inability to correct conduction disturbance with HBP (8%)
  - HBP rejected due to high threshold (up to 10-30%)
  - HBP rejected due to inability to fixate (up to 10-24%)
  - Rising thresholds a problem often seen
- Notably, there were similar & more challenges with CRT during early years





## Estimulação Hissiana - A Verdadeira Estimulação Fisiológica

HRS 2018

Sessão: All You Need to Know About His Bundle Pacing

Título: How to implant a HB lead - tricks for a

successful implant

Palestrante: Susan S.Kim (Chicago, US)

Data: 10/05/2018

Hora: **10:45h** 

Sessão: All You Need to Know About His Bundle Pacing

Título: Who is an ideal candidate for HBP?

Palestrante: Daniel L. Lustgarten (Vermont, US)

Data: 10/05/2018

Hora: 11:00h

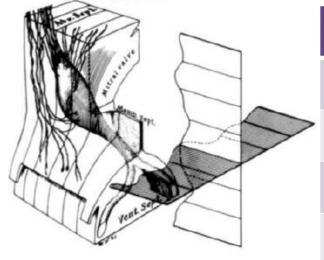




### Anatomical Configuration of the His Bundle and Bundle Branches in the Human Heart

GEORGE K. MASSING, M.D., AND THOMAS N. JAMES, M.D.

SUMMARY The relationships among the His bundle, the origin of both bundle branches, and the interventricular (IV) septum were examined histologically in 32 human hearts, and the entire bundle demonstrating multiple fiber groups which fanned out over the entire left septal surface. The LBB did not divide into two discrete divisions without multiple interconnections. The RBB formed an



P:		1976
( Irciii	arion	14/h
CIICUI	ULIVII	1010

# Pts	Membranous Septum	Interventricular Septum		
20	Partially within Inferior Aspect	Left crest of IVS		
5	( <del></del> )	Coursed to the right of the IVS		
3	Totally within Inferior Aspect			
4	Below	Coursed entirely to the left of the IVS		





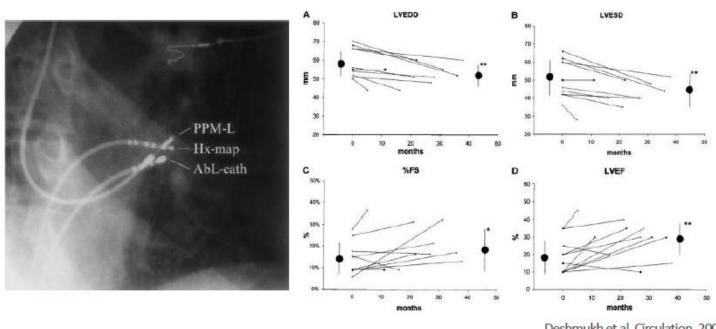


#### Permanent His-Bundle Pacing

First Clinical Description

### Permanent, Direct His-Bundle Pacing A Novel Approach to Cardiac Pacing in Patients With Normal His-Purkinje Activation

Pramod Deshmukh, MD; David A. Casavant, MS; Mary Romanyshyn, CRNP; Kathleen Anderson, BSN



Deshmukh et al. Circulation. 2000





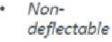




Select Secure 3830 Lead 4 French Exposed Helix Lumenless



C315 His Sheath 7F Short Sheath



 Secondary curve toward septum

Deflectable delivery cathotics

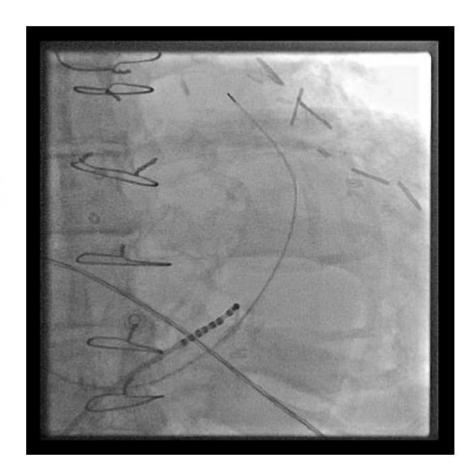
C304 Deflectable Sheath 9F Short Sheath





Sheath and Lead Positioning

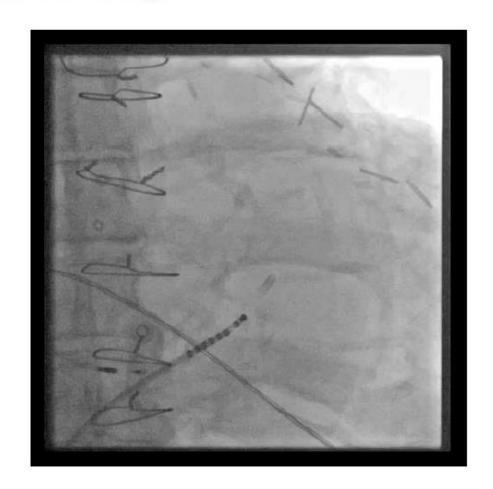
- Advance long wire to RVOT
- Advance fixed sheath over wire without dilator
- Advance sheath past the valve up to RVOT





#### Sheath and Lead Positioning

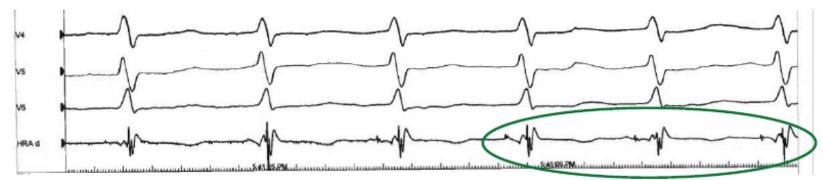
- Advance lead to distal end of sheath, just inside
  - Connect Unipolar
- Counterclock sheath (toward septum) and slowly retract
- Follow EGM

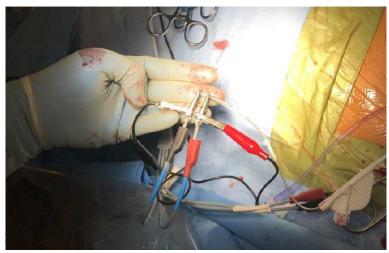


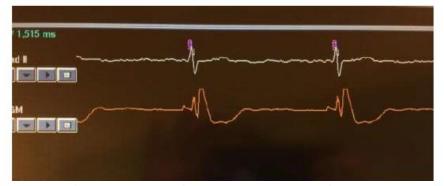




Follow EGM: On Recording System & On PSA







Recording His Lead EGM on Recording System





#### Pace to Assess Quality of Capture

#### Non-Selective Capture

- Parahisian capture (His +RV)
- Presence of a pseudo-delta wave following pacing artifact on surface QRS

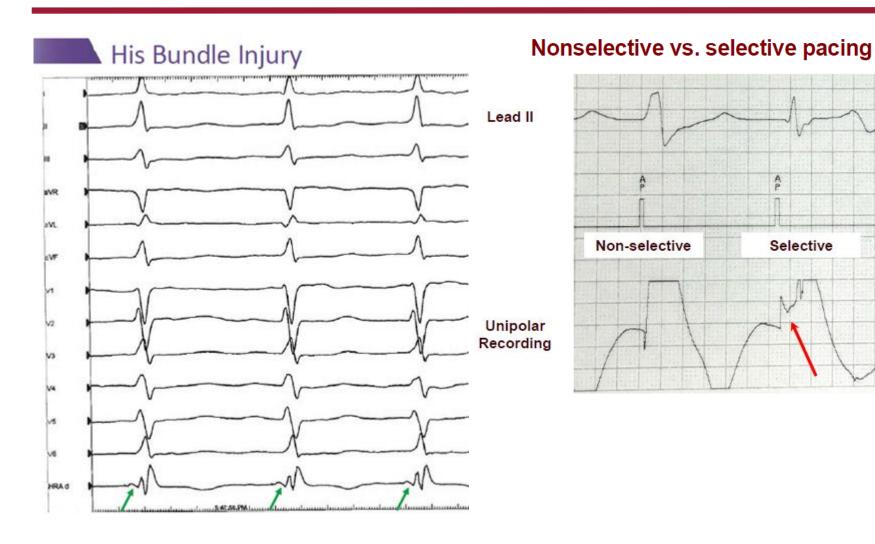
#### Selective His-Bundle Capture

- Pure His-Bundle capture
- Isoelectric period following pacing artifact on surface QRS

Non-Selective (His + RV\*\*)→ Selective (His, only\*)



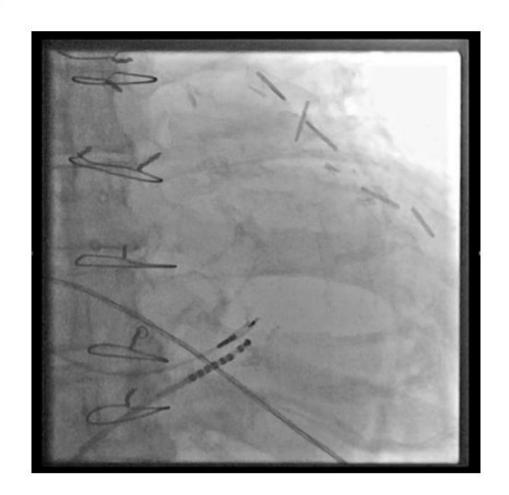








 Disconnect lead from alligator clips and turn clockwise to drive fixed screw tip into tissue

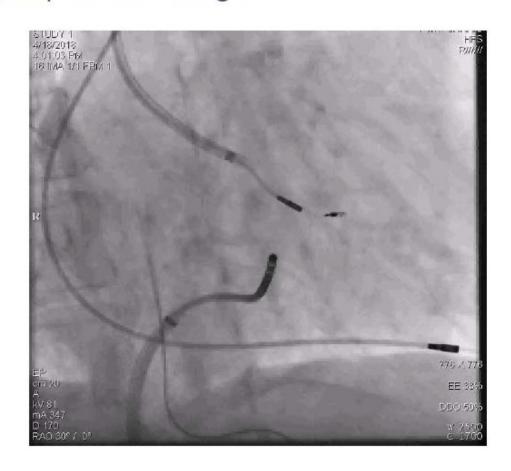






#### After Assessing Response to Pacing

- Recheck local signal and response to pacing
- Withdraw sheath allowing adequate slack; slit sheath





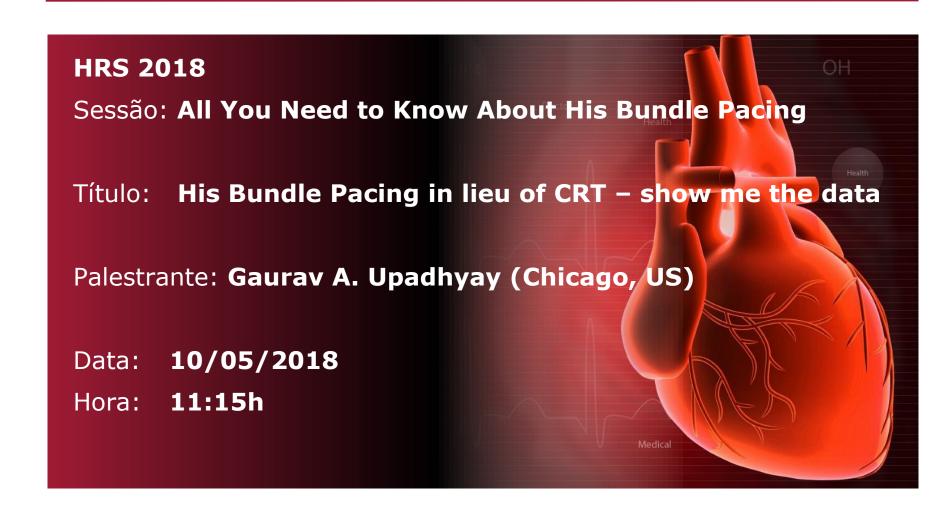
Pts at increased risk due to RV pacing: Pts with baseline cardiomyopathy Pts who require lots of V pacing



# Potential Ideal Candidates: AV block requiring high % Vp Post AV node ablation CRT nonresponders



#### Estimulação Hissiana - A Verdadeira Estimulação Fisiológica





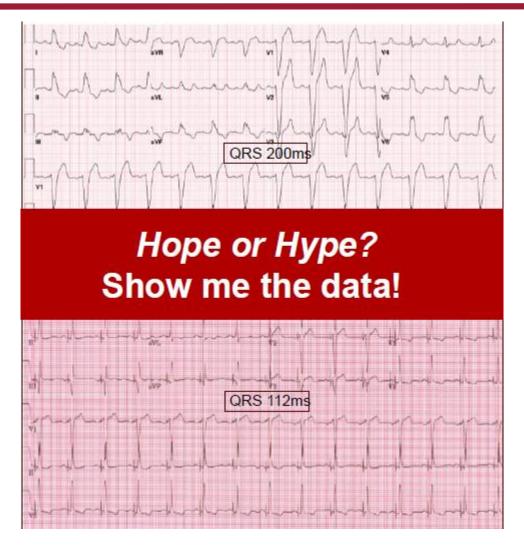
### His Bundle Pacing in Lieu of LV Lead for CRT:

Show me the data

Gaurav A. Upadhyay, MD
Assistant Professor of Medicine
Director, Heart Station

Heart Rhythm Society Scientific Sessions—Boston, MA 5/10/18







### Case Series of Permanent HBP in CRT Eligible Patients With Prior Bundle Branch Block

Author	Year	n Total / n Implanted with BBB	Indication	His bundle lead	Implant success (%)	Primary Outcome
Barba- Pichardo et al.	2013	16/9	CRT implant failure	Tendril 1488T 1788TC 1888TC	56	During mean follow-up of 31.3 ± 21.5 months, NYHA Class improved III→II and LVEF improved from 29→36% (<0.05)
Lustgarten et al.	2015	29 / 17	Cross-over study of HBP and CS lead	Select- Secure 3830	59	Patients demonstrated similar NYHA Class reduction (2.0→1.9, p<0.001) and LVEF improvement from 26→32% (p=0.043)
Su et al.	2015	25 /16	CRT implant failure	Select- Secure 3830	100	Clinical outcomes not reported. HB tip- RV coil configuration demonstrated better capture thresholds and R-wave sensing than dedicated bipolar or unipolar
Ajijola et al.	2017	21 / 16	Primary HBP	Select- Secure 3830	76	NYHA Class III→II (p<0.001) and LVEF improved from 27±10% to 41±13% (p<0.001)
Sharma et al.	2017	106 / 48	CRT implant failure and Primary HBP	Select- Secure 3830	90	Among all patients NYHA Class 2.8 $\pm$ 0.5 $\rightarrow$ 1.8 $\pm$ 0.6 ( $p$ =0.0001) and LVEF improved from 30 $\pm$ 10% to 43 $\pm$ 13% ( $p$ =0.0001).

= 106

Vijayaraman...Upadhyay et al. JACC 2018 In Press.



### LBBB correction with His pacing— <u>Theories:</u>

- Longitudinal dissociation of His bundle
  - Pre-destination of fibers
  - Localized intra/inter-Hisian disease
- Left bundle conduction delay
  - Reset/accelerate with pacing impulse
  - Source/sink mismatch overcome with current load
- Left bundle block—proximal/high
  - Leapfrog with virtual electrode





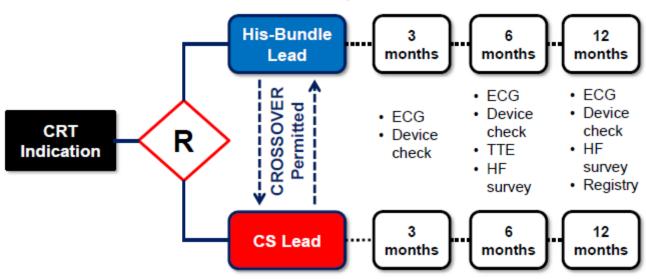
#### There is a need for RCTs

#### The HIS-SYNC PILOT

- QRS does not **↓20%** or <130
- His lead cannot be placed

#### PRIMARY ENDPOINT:

Change in ejection fraction Change in QRS width CV hospitalization/death



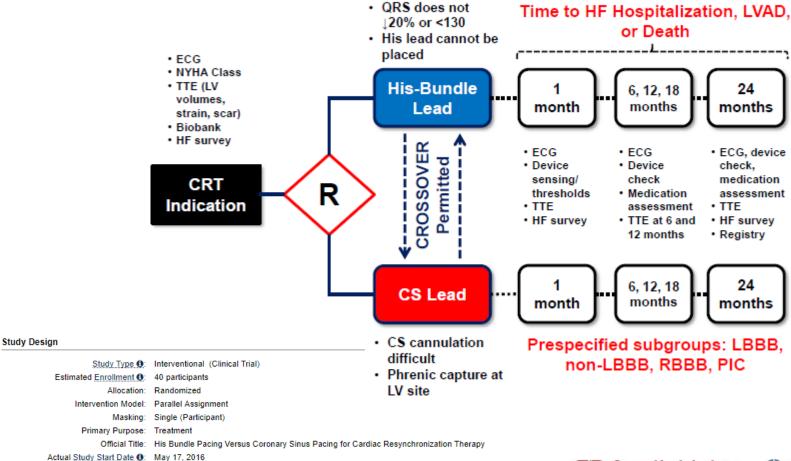
- · CS cannulation difficult
- Phrenic capture at LV site





Estimated Primary Completion Date 6: June 2019
Estimated Study Completion Date 6: June 2021

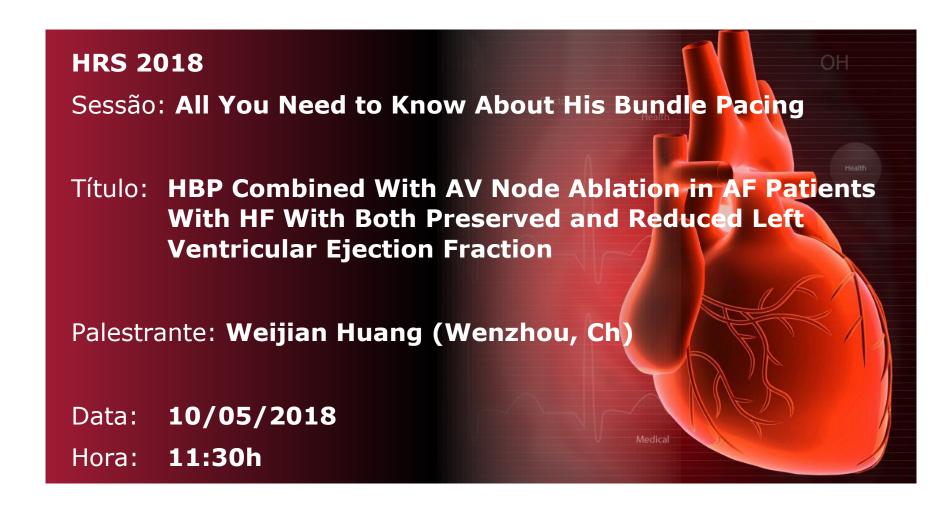
#### HIS-SYNC II Design (n=987)







#### Estimulação Hissiana - A Verdadeira Estimulação Fisiológica





'Ablate and Pace' therapy, CRT is superior to RV apical pacing in reducing the clinical manifestations of HF

Left Ventricular-Based Cardiac Stimulation Post AV Nodal Ablation Evaluation (The PAVE Study)

J Cardiovasc Electrophysiol, Vol. 16,pp. 1160-1165, November 2005

Biv pacing improves cardiac function and prevents further left atrial remodeling in patients with symptomatic AF after AVNA (AVAIL CLS/CRT)

Am Heart J 2010;159:264-70

CRT in patients undergoing AVNA for permanent AF: a randomized trial

European Heart Journal (2011) 32, 2420-2429





Benefits of Permanent His Bundle Pacing Combined With Atrioventricular Node Ablation in Atrial Fibrillation Patients With Heart Failure With Both Preserved and Reduced Left Ventricular Ejection Fraction Jam Heart Assoc. 2017;6:e005309. DOI: 10.1161/JAHA.116.005309.

Weijian Huang, MD; Lan Su, MD; Shengjie Wu, MD; Lei Xu, MD; Fangyi Xiao, MD; Xiaohong Zhou, MD; Kenneth A. Ellenbogen, MD

#### HBP post AVNA in HF patients with AF and narrow QRS Patients for His-pacing attempts and later AVN ablation :N=52 Consecutive 52 patients enrolled between Aug 2012 and Aug 2015 A single-center prospective registry study Failure of acute His bundle pacing: N=2(3.8%) Patients with long-lasting persistent or permanent AF, Achievement of acute His even though their heart rate well controlled with bundle pacing: N=50(96.2%) pharmacological treatment No permanent His bundle pacing: N=8(15.4%) Direct His bundle pacing: Para-Hisan pacing: Symptomatic HF and/or hemodynamic Test or N=38(73.1%) N=4(7.7%) (2) Echo: low EF<40% Total permanent His bundle Patients were at least18 years old and not pregnant pacing: N=42(80.8%) Schematic summary of study and patient flow. Department of Cardiology, The First Affiliated Hospital of Wenzhou Medical University, Wenzhou, China



Table 2. Comparison of the Echocardiographic Measurements at the Specific Time Points of HBP

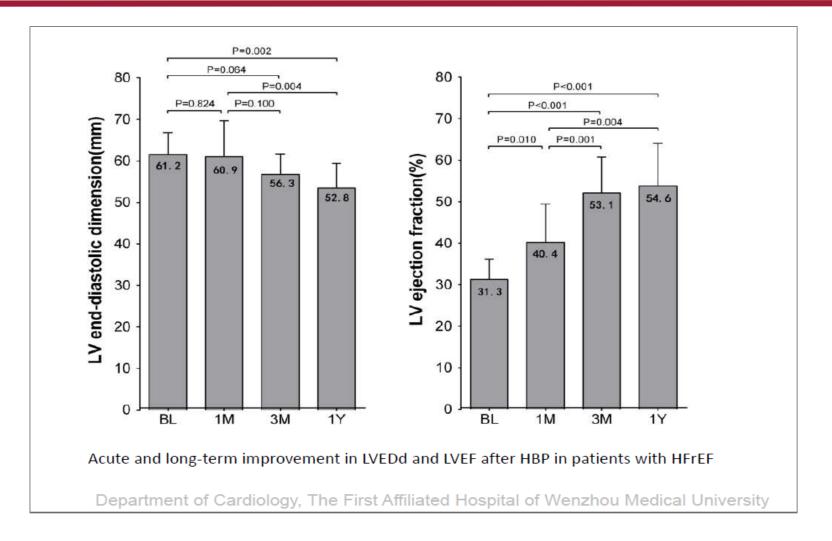
	LVEDd (mm)	P Value	LVEF (%)	P Value
All patients (N	<del>-42)</del>	808	150	100
Baseline	55.8±8.1	Ref.	44.9±14.6	Ref.
3 months	52.7±5.3	0.031	56.5±8.7	<0.001
1 year	50.6±5.4	<0.001	59.7±9.8	<0.001
Last FU	51.0±5.1	<0.001 60.0±8.1		<0.001
HFpEF patients	(N=22)			
Baseline	Baseline 51.5±5.4		56.6±9.9	Ref.
3 months	nonths 50.2±4.4		60.1±8.0	0.231
1 year	1 year 49.0±4.4		63.2±8.2	0.010
Last FU	Last FU 49.6±3.9		62.6±6.9	0.019
HFrEF patients	(N=20)			
Baseline 60.6±8.0		Ref.	32.2±4.8	Ref.
3 months 54.5±5.3		0.005	53.9±8.4	<0.001
1 year	1 year 52.3±6.0		55.7±10.2	<0.001
Last FU	52.6±5.9	<0.001	57.2±8.7	<0.001

Table 3. Comparison of the Number of Patients Receiving Medications Before and 1 Year After HBP

	Baseline	After HBP	P Value
All patients (N=42)			
Diuretics	38 (90.5)	23 (54.8)	<0.001
β-Blockers	40 (95.2)	32 (76.2)	0.011
ACE inhibitors	36 (85.7)	38 (90.5)	0.480
Digoxin	20 (47.6)	2 (4.8)	<0.001
HFpEF patients (N=2	22)		
Diuretics	18 (81.8)	9 (40.9)	0.003
β-Blockers	21 (95.5)	14 (63.6)	0.020
ACE inhibitors	20 (90.9)	19 (86.4)	0.564
Digoxin	7 (31.8)	1 (4.5)	0.034
HFrEF patients (N=2	0)		
Diuretics	20 (100.0)	14 (70.0)	0.014
β-Blockers	19 (95.0)	18 (90.0)	0.317
ACE inhibitors	16 (80.0)	19 (95.0)	0.180
Digoxin	13 (65.0)	1 (5.0)	< 0.001

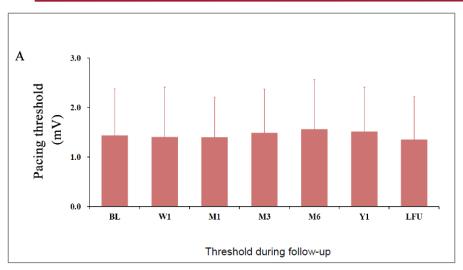
Department of Cardiology, The First Affiliated Hospital of Wenzhou Medical University

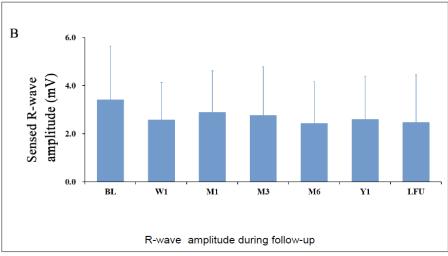


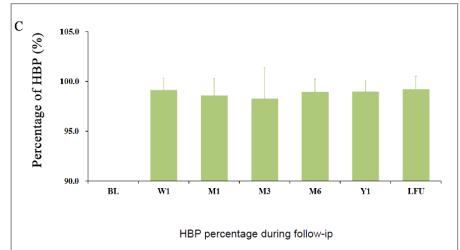














#### Studies: A-V node ablation+HBP in AF patients

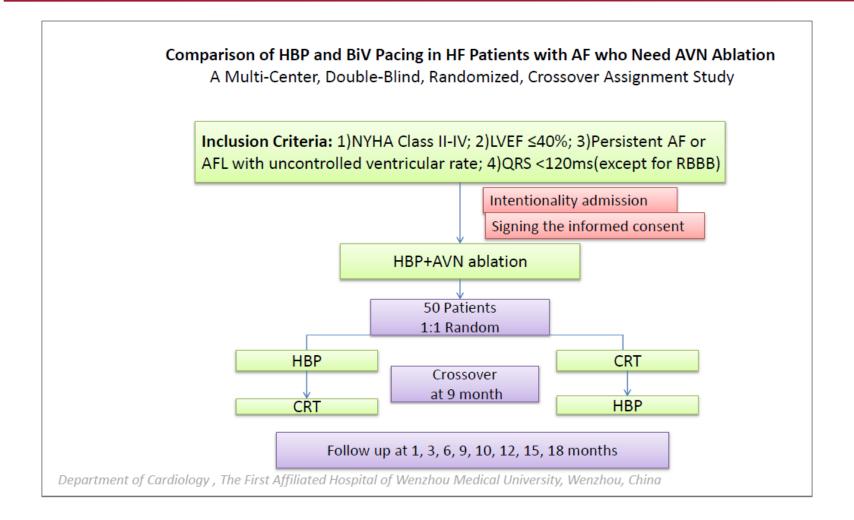
Consistent results of small sample trials

HBP was safe and effective in improvement of cardiac function

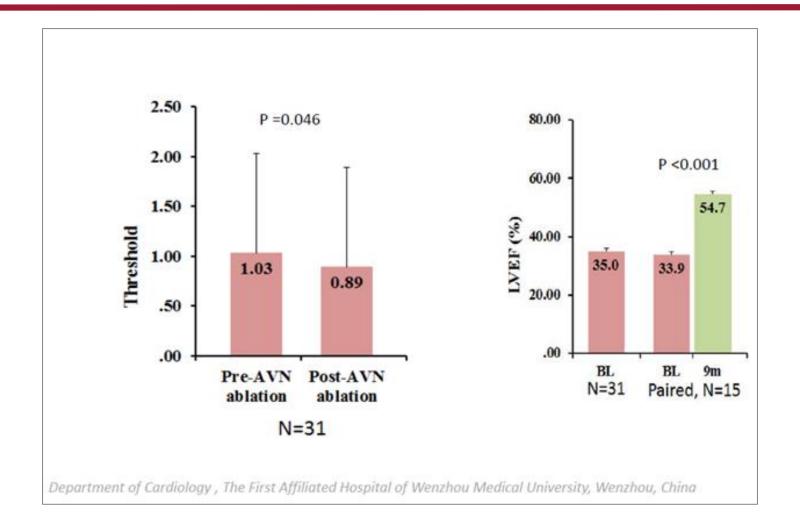
Time (year)	Magezine	No. of patients	trial contents	author	Result in favor o HBP
2000	Circulation	12	AV-node ablation+HBP Feasibility & effectiveness	Pramod Deshmukh	+
2001	Rev Esp Cardiol	12	AV-node ablation+ HBPvs.RVAP	Pablo Moriña Vázquez	+
2004	Proc West Pharmacol		AV-node ablation+ HBP vs. Amiodarone	Kirkutis A	+
2004	PACE	39	AV-node ablation+ HBPvs.RVAP	PRAMOD. M	+
2006	JACC	16	AV-node ablation+ HBPvs.RVAP	Eraldo Occhetta	+
2011	HRS Abstract	11	AV-node ablation+HBP Safety & ffectiveness	Pierre Znojkiewicz	+
2017	JAHA	42	AV-node ablation +HBP	Weijian Huang	+

Department of Cardiology , The First Affiliated Hospital of Wenzhou Medical University, Wenzhou, China













#### Conclusão

- O marcapassamento permanente do feixe de His é factível, elegante e fisiológico.
- Se mostrou terapia alternativa e eficaz nos casos de falência no implante do eletrodo de VE via seio coronário e naqueles pacientes não respondedores a TRC.
- Pode ser opção primária de estimulação em populações selecionadas.
- Para os pacientes submetidos a ablação da junção atrioventricular para controle de frequência e tratamento da insuficiência cardíaca, o marcapassamento do feixe de His melhora a fração de ejeção e a classe functional especialmente naqueles com fração de ejeção reduzida.



#### Conclusão

#### No entanto,

- Sem resultados de estudos clínicos grandes randomizados.
- Pouca experiência da maioria dos centros experiência conta: inabilidade de registro de His, inabilidade de correção do distúrbio de condução, obtenção de altos limiares e limiares crescentes, inabilidade de fixação.
- Qual a largura de QRS é recomendada?
- Resultados de longo prazo em doenças progressivas.
- Desenvolvimento da tecnologia com mais opções de ferramentas para entrega, registros e implante do sistema.





