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**Stimulation Hissienne vs stimulation de l'aire de la  
branche gauche avant ablation du noeud  
atrio-ventriculaire : une étude prospective,  
multicentrique et comparative**

Maxime Azincot

► **To cite this version:**

Maxime Azincot. Stimulation Hissienne vs stimulation de l'aire de la branche gauche avant ablation du noeud atrio-ventriculaire : une étude prospective, multicentrique et comparative. Médecine humaine et pathologie. 2023. dumas-04418713

**HAL Id: dumas-04418713**

**<https://dumas.ccsd.cnrs.fr/dumas-04418713>**

Submitted on 26 Jan 2024

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UFR DE SANTE DE ROUEN NORMANDIE

ANNEE 2023

# THÈSE POUR LE DOCTORAT EN MEDECINE

Diplôme d'État

Par

**Maxime AZINCOT**

Né le 14/02/1993 à Paris 12<sup>e</sup>

Présentée et soutenue publiquement le 10 octobre 2023

**His Bundle Pacing vs Left Bundle Branch Area Pacing in  
patients undergoing atrioventricular node ablation: a  
prospective, multicenter, comparative study.**

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## SERMENT D'HIPPOCRATE

Au moment d'être admis(e) à exercer la médecine, je promets et je jure d'être fidèle aux lois de l'honneur et de la probité'.

Mon premier souci sera de rétablir, de préserver ou de promouvoir la santé dans tous ses éléments, physiques et mentaux, individuels et sociaux. Je respecterai toutes les personnes, leur autonomie et leur volonté', sans aucune discrimination selon leur état ou leurs convictions.

J'interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité' ou leur dignité'. Même sous la contrainte, je ne ferai pas usage de mes connaissances contre les lois de l'humanité'. J'informerai les patients des décisions envisagées, de leurs raisons et de leurs conséquences. Je ne tromperai jamais leur confiance et n'exploiterai pas le pouvoir hérité des circonstances pour forcer les consciences.

Je donnerai mes soins à l'indigent et à quiconque me les demandera. Je ne me laisserai pas influencer par la soif du gain ou la recherche de la gloire.

Admis(e) dans l'intimité' des personnes, je tairai les secrets qui me seront confiés. Reçu(e) à l'intérieur des maisons, je respecterai les secrets des foyers et ma conduite ne servira pas à corrompre les mœurs. Je ferai tout pour soulager les souffrances.

Je ne prolongerai pas abusivement les agonies. Je ne provoquerai jamais la mort délibérément.

Je préserverai l'indépendance nécessaire à l'accomplissement de ma mission. Je n'entreprendrai rien qui dépasse mes compétences. Je les entretiendrai et les perfectionnerai pour assurer au mieux les services qui me seront demandés.

J'apporterai mon aide à mes confrères ainsi qu'à leurs familles dans l'adversité'. Que les hommes et mes confrères m'accordent leur estime si je suis fidèle à mes promesses ; que je sois déshonoré(e) et méprisé'(e) si j'y manque.

## REMERCIEMENTS

*Aux membres du jury :*

*A Madame le Professeur Hélène Eltchaninoff,*

Vous me faites l'honneur de présider ce jury de thèse. Je vous remercie pour votre accompagnement tout au long de mon internat. Merci pour votre bienveillance et votre écoute. C'est un honneur de pouvoir travailler dans votre service.

*A Monsieur le Professeur Frédéric Anselme,*

Je vous remercie de m'avoir fait confiance pour débiter la base de données sur la stimulation physiologique, sujet passionnant et plein de promesses qui, je le sais, tient une place majeure dans la rythmologie rouennaise. Merci pour votre aide dans la rédaction de ce travail et pour vos enseignements de rythmologie.

*A Monsieur le Docteur Arnaud Savoure,*

Merci de ta présence tout au long de mon internat que ce soit pour les bons moments ou les petites remontrances (oui je te confirme qu'à l'heure actuelle tous mes CRH sont dictés ... normalement). J'ai apprécié travailler avec toi, ton sens de l'organisation et ton efficacité sont toujours impressionnants. J'espère encore pouvoir apprendre beaucoup à tes côtés.

*A Monsieur le Docteur Corentin Chaumont,*

Je te remercie de m'avoir fait confiance et de m'avoir confié ce sujet de thèse. Merci pour ta disponibilité et ton aide tout au long de ce travail, nos échanges de messages au réveil vont me manquer. Merci pour ton enthousiasme communicatif sur la rythmologie et tes enseignements. Je te souhaite bon courage pour ton année de mobilité et j'espère te revoir bientôt.

*Au service de Cardiologie du CHU de Rouen :*

Au **Professeur Éric Durand**, merci pour ton enseignement lors des visites (c'est vrai parfois écourtées) à Laubry milieu et de tes commentaires toujours enrichissants lors de mes différentes présentations.

Au **Docteur Christophe Tron**, « Monsieur Tron », merci pour ce semestre en USIC, pour votre bienveillance, le partage de votre expérience et votre sens critique. Merci de m'avoir fait confiance y compris dans des situations difficiles.

Au **Docteur Najime Bouhzam**, merci pour vos précieux conseils et votre disponibilité durant mon semestre à l'USIC. J'ai beaucoup appris à vos côtés. Votre rigueur et votre perfectionnisme sont un véritable exemple.

Au **Docteur Bénédicte Godin**, merci pour tes conseils et ton encadrement que ce soit lors de mon passage à Laubry fond, lors des consultations de titration ou de nos gardes parfois assez compliquées.

Au **Docteur Adrian Mirolo**, merci de m'avoir fait découvrir la stimulation de branche gauche et pour ta contribution à ce travail. Merci pour ta disponibilité et pour tes conseils notamment sur les « avis ECG ».

Au **Docteur Thibaut Hemery**, merci pour ta disponibilité notamment lors des relectures d'échographie et merci de tes conseils lors de mes ponctions pleurales ou d'ascite (« pour la prochaine Maxime évite de faire des bulles de champagne », « rouge comme ça, c'est pas normal »)

Au **Docteur Nicolas Bettinger**, merci pour votre aide et vos conseils durant mon internat et plus particulièrement lors de mes premiers mois au CHU en tant qu'interne de bip.

Au **Docteur Thomas Levesque**, merci pour ta gentillesse et ta disponibilité au quotidien.

Au **Docteur Julie Burdeau**, merci pour ton encadrement et merci pour ton enseignement de l'imagerie cardiaque.

Aux Docteurs **Thibaut Verrez** et **Thomas Barbe**, merci pour cet été au labo d'écho et nos « descentes ETO en Réanimation ». Hâte de vous revoir bientôt !

Au **Docteur Charles Fauvel**, avec qui je partage deux passions, la Formule 1 et les visites professorales, merci pour ce semestre d'anthologie en USIC. Tu as eu les meilleurs dès le début, rien ne pourra surpasser le duo Abdessamie-Maxime.

Au **Docteur Raphael Al Hamoud**, dont j'avais beaucoup entendu parler et que j'ai fini par connaître lors de mon dernier semestre, merci pour ta disponibilité et pour tes explications sur les procédures de rythmologie. Hâte de travailler avec toi !

Aux **Docteurs Bastien Glinel** et **Pierre De Lamare**, merci d'avoir rendu si agréable les vacances d'échographie du mardi et du vendredi et merci de m'avoir aidé pour mes premières « ETO rythme ». Merci pour votre présence lors des différentes soutenances de thèses.

Au **Docteur Marie-Christine Malergue**, merci de m'avoir fait (re)découvrir et apprécier à sa juste valeur l'échographie cardiaque et l'importance de l'hémodynamique non invasive. Merci de nous faire partager votre expérience et votre passion pour la Cardiologie. J'ai beaucoup appris à vos côtés et je vous en remercie.

A **l'ensemble de l'équipe paramédicale**, aux IDE et AS d'USIC, de Laubry, de Lenegre et du laboratoire d'échographie avec qui j'ai passé de très bons moments, merci pour votre aide et votre investissement auprès des patients et des familles. Merci aux secrétaires de Cardiologie qui ont dû me maudire plusieurs fois à cause des CRH en retard.

*Au service de Cardiologie d'Elbeuf*

Merci pour ce début d'internat avec parfois des moments difficiles en pleine pandémie de COVID. Merci au **Dr Brahim Baala**, au **Dr Amina Guetlin** et au **Dr Matthieu Godet** pour leur encadrement. Merci au **Dr Pierre Guignant** avec qui j'ai réalisé mes premières échographies cardiaques. Merci au **Dr Amandine Hatrel** et au **Dr Karl Gaudin** pour mes premières séances ECG. Grand merci à mes co-internes **Alix** et **Anne-Sophie** qui ont réussi à me supporter pendant ces 7 mois.

*Au service de Médecine interne du CHU de Rouen*

Merci pour ce semestre très enrichissant que ce soit sur les maladies vasculaires ou sur l'approche globale du patient. Merci tout particulièrement aux **Pr Ygal Benhamou**, aux **Dr Sébastien Miranda**, **Guillaume Armengol**, **Nicole Cailleux** et **Nicolas Ghirzyn** pour leur enseignements. Merci à mes co-internes (**Sarah**, **Bérangère**, **Julie**, **Nicolas**, **Teddy**, **Romain**, ...) pour leur aide et pour les soirées cet été-là (« LASILIX ! »).

*A l'équipe de chirurgie cardiaque du CHU de Rouen*

Aux chirurgiens (**Dr François Bouchart**, **Dr Vincent Le Guillou**, **Dr Chadi Aludaat**, **Dr Alexandra d'Agostino**) pour nous avoir fait confiance dans la gestion du service. Merci au **Dr Catherine Nafeh-Bizet** pour son travail et son enseignement sur les transplantés cardiaques et pour les KT biopsie. Merci au **Dr Arnaud Gay** pour ses enseignements notamment lors des visites, parfois il est vrai un peu longues. Merci au **Pr Bauer** pour ses enseignements d'échographie cardiaque et ses conseils sur l'insuffisance cardiaque avancée. Merci à la team de choc (**Loïc**, **Georges**, **Guillaume** et **Dryss**) avec qui on s'est bien marré durant ce semestre.

*A l'équipe de Réanimation d'Elbeuf*

Merci pour ce dernier semestre lors duquel j'ai encore appris beaucoup. Merci aux **Dr Jean-Baptiste Michot**, **Olivier Delastre**, **Dominique Jusserand**, **Bernard Bouffandeau**, **Christian Caillard**, **Elise Godeau** et **Tiffany Vatignez** pour leur encadrement et leur bienveillance. Merci à mes co-internes (**Camille**, **Orane**, **Margot**, **Ludivine**, **Louis** et **Antoine**) pour leur bonne humeur et l'ambiance toujours très agréable. Je tiens à leur rappeler que, officiellement, pendant ce semestre, aucune bouteille de lait ni guide n'a été perdu.



### *A mes co-internes de Cardiologie*

Grand merci à mes co-internes de promo et ces 4 années passées ensemble. A **Camillia** la chef, la seule à pouvoir encadrer cette équipe de bras cassés, à **Olivier**, le boss et son efficacité insolente, à **Emily** l'élève parfaite, à **Dryss**, la force tranquille et à **Guillaume** qui m'a accompagné depuis Paris. Sans oublier **Xavier** qui a été un peu notre grand frère à tous pendant ce premier semestre au CHU.

Aux promos du dessus, merci à **Quentin** pour nos discussions sur l'avenir, à **Romain** pour m'encourager vers la voie professorale, à **Guillaume** pour son aide et ses avis toujours pertinents, à **Théo** pour ces retours post gardes lors de son passage en USIC et son aide à l'échographie, à **Lisa** et **Juliette** pour leurs aides et à tous les autres (**Maxime**, **Thomas**, **Adrien**, **Thibaut**, ...) qui m'ont aidé à un moment donné dans mon internat.

Aux promos du dessous, à **Abdessamie** et notre duo de choc à l'USIC, merci pour ce semestre épique et content de te voir reprendre le flambeau sur la stimulation de branche gauche. A **Samia**, **Ilies**, **Charles**, **Paul** et **Jade** pour ces nombreux moments passés ensemble à l'hôpital ou en dehors. Aux plus jeunes, merci à Théo pour son aide sur la basse de données et merci à lui et aux autres (**Alix**, **Ines**, **Lucas**, **Kessel** et **Nicolas**) pour avoir supporté pendant 6 mois mes petites piques et autres commentaires. Et enfin merci et pardon d'avance à ceux de la **promo 2022** qui arrivent au CHU et qui vont devoir me supporter pendant les prochains mois.

### *A ma famille et à mes amis*

Grand merci à **mes parents** et **grands-parents** qui ont su m'accompagner tout au long de mes études prolongées et qui ont su m'encourager et me soutenir dans les moments difficiles.

Merci à ma sœur qui a réussi à me supporter pendant ses 27 dernières années.

Merci à mon ami d'enfance, **Marco** pour toutes ses années. Hâte de te revoir plus souvent.

Merci à tous mes amis de Paris qui m'ont accompagné depuis la P1 (**Kais**, **Adam**, **Gary**, **Abderramie**, **Baptiste**, **Chloé**, **Marie** et j'en oublie plein)

*Enfin, à tous les autres que je n'ai pas pu citer, merci pour tout.*



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## LISTE DES ABREVIATIONS

AF	Atrial fibrillation
AFI	Atrial flutter
AHA	American Heart Association
AT	Atrial tachycardia
AV	Atrioventricular
AVN	Atrioventricular node
AVNA	Atrioventricular nodal ablation
CAVB	Complete atrioventricular block
COPD	Chronic obstructive pulmonary disease
CRT-D	Cardiac resynchronisation therapy defibrillator
CSP	Conduction system pacing
ECG	Electrocardiogram
EP	Electrophysiology
ESC	European Society of Cardiology
HB	His bundle
HBC	His-bundle capture
HBP	His bundle branch pacing
HFH	Heart failure hospitalization
HFmrEF	Heart failure with mildly reduces ejection fraction
HFpEF	Heart failure with preserved ejection fraction
HF <sub>r</sub> EF	Heart failure with reduced ejection fraction
HRS	Heart Rhythm Society
IQR	Interquartile range

IVCD	Intraventricular conduction delay
LBB	Left bundle branch
LBBAP	Left bundle branch area pacing
LBBB	Left bundle branch block
LVEF	Left ventricular ejection fraction
NOAC	Non-vitamin K oral antagonist anticoagulant
NYHA	New York Heart Association
RBBB	Right bundle branch block
RF	Radiofrequency
RV	Right ventricle
RVP	Right ventricular pacing
RWPT V6	R-wave peak time in V6
SD	Standard derivation
SVT	Supraventricular tachycardia
TTE	Transthoracic echocardiography
VKA	Vitamin K antagonist

## **ABSTRACT**

**Background:** Pacemaker implantation combined with atrioventricular node ablation (AVNA) is a well-established strategy for non-controlled atrial arrhythmias. Over the last few years, conduction system pacing (CSP) aiming at preserving physiological left ventricular activation, has emerged as an attractive alternative to conventional right ventricular pacing. Only limited amount of data is available in the literature regarding His Bundle Pacing (HBP), or Left Bundle Branch Area Pacing (LBBAP) combined with AVNA.

**Objective:** The aim of this study was to compare the real-life clinical outcomes of HBP vs LBBAP in patients undergoing pacemaker implantation combined with AVNA.

**Methods:** We prospectively included all patients who underwent AVNA after successful CSP in two different hospitals between between September 2017 and May 2023. The one-year freedom from combined endpoint of first episode of heart failure hospitalization, AV node reconduction requiring a second AVNA procedure, lead revision and death from any cause was the primary outcome.

**Results:** 164 patients underwent AVNA following successful CSP (68 HBP and 96 LBBAP). The mean pacemaker implantation and AVNA procedural times were significantly shorter in the LBBAP group as compared to the HBP group ( $46 \pm 18$  min vs  $57 \pm 23$  min,  $p = 0.0015$  and  $30 \pm 12$  min vs  $46 \pm 25$  min,  $p < 0.001$ ). A complete AV block was more frequently obtained in the LBBAP group than in the HBP group (88 / 96 patients (92%) vs 54 / 68 patients (79%),  $p = 0.04$ ). The primary outcome occurred in 16 / 68 patients (24%) in the HBP group vs 9 / 96 patients (9.4%) in the LBBAP group (Hazard ratio = 2.38, 95% CI 1.08 – 5.28). The “ablate and pace” strategy was beneficial in both groups with a significant improvement in NYHA class and LVEF ( $58 \pm 10$  % vs  $46 \pm 15$  % at baseline;  $p < 0.0001$  and  $58 \pm 10$  % vs  $49 \pm 14$  % at baseline;  $p = 0.0001$ , in the HBP and LBBAP groups respectively). Secondary His Bundle Capture threshold elevation  $> 1$  V occurred in 7/63 patients (11%), one of those patients requiring a ventricular lead revision at one-year follow-up. There was no LBBAP threshold elevation  $> 1$  V.

**Conclusion:** In this multicentre, prospective and comparative study on patients undergoing CSP combined with AVNA, LBBAP was superior to HBP. A significant improvement in LVEF and NYHA functional class was observed with both techniques. Given the technical challenge of AVNA and the electrical parameters of the leads, LBBAP appeared to be the preferred technique in this setting.

**Keywords:** Atrial arrhythmia; Atrial fibrillation; Atrioventricular node ablation; Conduction system pacing; His-bundle pacing; Left bundle branch area pacing

## **Introduction**

Ventricular rate control is essential in the management of patients with permanent atrial arrhythmias to prevent from left ventricular systolic dysfunction and heart failure.<sup>1,2</sup> Pacemaker implantation combined with atrioventricular node ablation (AVNA) is a well-established strategy for non-controlled atrial arrhythmias, as an improvement of clinical outcomes and cardiac function was demonstrated with this treatment approach.<sup>3,4</sup> On the other hand, permanent right ventricular pacing (RVP) induces ventricular desynchronization in patients with narrow QRS and has been shown to increase the risk of long-term heart failure.<sup>5</sup>

Over the last few years, conduction system pacing (CSP) (i.e. His Bundle Pacing (HBP) and left bundle branch area pacing (LBBAP)) aiming at preserving physiological left ventricular activation, has emerged as an attractive alternative to conventional RVP. HBP and AVNA have previously been shown to be feasible and associated with improved LVEF and NYHA functional class.<sup>6</sup> Nevertheless, AVNA may prove difficult in those patients due to the risk of His bundle capture (HBC) threshold increase and lead dislodgement when ablating in close vicinity of the pacing lead. A suboptimal AVNA success rate has been observed following permanent HBP whereas it is usually close to 100% in other settings.<sup>7,8</sup> Despite the expected technical challenge and the significant AV nodal reconduction rate, the last ESC guidelines (2019) on supraventricular tachycardia (SVT) indicated that AVNA with subsequent HBP should be considered if SVT cannot be ablated (class I, level of evidence C).<sup>2</sup> This indication was downgraded (IIb) in the last ESC guidelines on cardiac pacing.<sup>9</sup> More recently, LBBAP has appeared as an effective alternative to HBP and has largely overtaken the latter in real world clinical practice.<sup>10</sup> Nevertheless, LBBAP as an alternative to RVP combined with AVNA was mentioned as a class IIb indication only in the last AHA/HRS guidelines on cardiac pacing and even not mentioned in the last ESC guidelines.<sup>11</sup> The evidence for conduction system pacing in AF patients undergoing AVNA is mostly limited to retrospective observational studies.

The aim of this study was to report the prospective real-life clinical outcomes of HBP compared with LBBAP in patients undergoing pacemaker implantation combined with AVNA for non-controlled atrial arrhythmia.



## **Methods**

### **Patients selection**

This was a multicenter, prospective and observational study conducted in two hospitals (Rouen University Hospital and Le Havre Hospital) between September 2017 and May 2023.

All consecutive patients who underwent pacemaker implantation with successful CSP and subsequent AVNA for non-controlled atrial arrhythmia were prospectively included in an institutional registry. Uncontrolled atrial arrhythmia was defined as: 1) failure of rhythm control strategy despite appropriate anti-arrhythmic drug therapy; 2) no indication for, patients' refusal or failure of an invasive rhythm control strategy (catheter ablation); 3) mean ventricular rate greater than 110/min despite maximal drug therapy.

The local ethics committee approved this study and all patients provided informed consent for the procedure and pacemaker data collection.<sup>12,13</sup>

### **Implant procedures**

Permanent CSP procedures were performed, according to previously described techniques, using the lumenless Select- Secure 3830 lead (Medtronic Inc., Minneapolis, USA) or Stylet-driven Solia S60 (Biotronik, SE & Co., KG, Germany) and corresponding non-deflectable preformed sheaths (C315, Medtronic or Selectra 3D-55, Biotronik).<sup>14,15</sup> HBP were defined according to standardized definitions.<sup>16</sup> LBBAP was considered successful if the paced QRS complex included a terminal R/r wave in lead V1 and if the delay from pacing spike to the peak of the R-wave in V6 (RWPT V6) was  $\leq 80$  ms (narrow baseline QRS) or  $\leq 90$  ms (baseline QRS  $> 120$  ms). Paced QRS duration was measured, using the EP recording system at a sweep speed of 100 or 200 mm/s, from the QRS onset to the final QRS component in any of the 12 ECG leads. All measures were repeated in at least three QRS complexes and were averaged.

### **AV node ablation procedure**

The AV node ablation procedure was performed under local anesthesia, typically on the following day. Right-sided AV junction ablation was first attempted with an 8-mm non-irrigated tip radiofrequency (RF) ablation catheter. The catheter was guided under fluoroscopy guidance to the His bundle area and then slightly withdrawn proximally and caudally, aiming

to precisely target the compact AV node. This technique was similar to that used with an RVP lead.

RF was delivered at 70 Watts with a target temperature of 60 °C and continued for 30 to 60 seconds after documenting complete AV block (CAVB). In case of failure with the standard approach and equipment, the decision to use of an irrigated RF ablation catheter was at the discretion of the operator. CAVB was reassessed after a waiting period of 20 minutes.

Capture threshold, impedance and R-wave amplitudes were measured at the beginning and at the end of the procedure. Acute HBC or LBBAP threshold increase during AVNA was defined as a pacing threshold elevation > 1 Volt @ 0.5 ms.

### **Follow up**

All patients were equipped with a remote monitoring system. Patients were prospectively followed-up onsite according to standard institutional practices at 3-month and 12-month. Pacing threshold, R-wave amplitude, and pacing impedance were measured during device interrogation. Data regarding symptoms (New York Heart Association [NYHA] dyspnea functional class, palpitations, syncope), heart failure hospitalization (HFH), pacemaker related complication were collected. Transthoracic echocardiography (TTE) was performed at baseline and at one-year follow-up. The one-year freedom from combined endpoint of first episode of heart failure hospitalization (HFH), AV node reconnection requiring a second AVNA procedure, lead revisions and death from any cause was the primary outcome.

### **Statistical analysis**

Continuous variables were expressed as mean  $\pm$  standard deviation (SD) for normally distributed data or median and interquartile range (IQR) for non-normal data. Normal distribution was assessed by a Shapiro-Wilk test. Categorical variables were expressed as counts and percentage. Comparisons were performed by Chi-squared test or Fisher's exact test for categorical variables and Student's t test or Mann-Whitney test, as appropriate, for continuous variables. Univariate Cox proportional hazard model was used to estimate survival probability for the composite primary outcome and a survival curve was plotted using a Kaplan-Meier model. Patients not experiencing the composite primary outcome were censored event

free at one-year follow-up. All tests were 2-sided, with a p-value <0.05 considered statistically significant. All analyses were performed using the R 3.6.3 software (The R Foundation for Statistical Computing, Vienna, Austria).

## **Results**

Between September 2017 and May 2023, 164 patients underwent AVNA for non-controlled atrial arrhythmia following pacemaker implantation with successful CSP. Prior to July 2020, CSP was performed using HBP exclusively (66 patients) while in the later years, LBBAP was predominantly performed (96/98 patients). Detailed clinical characteristics and medications of the study population are described in Table 1.

### **Patients baseline characteristics**

Patients in the LBBAP group were significantly older than those in the HBP group ( $75.0 \pm 10.1$  years old vs  $69.9 \pm 12.3$ ,  $p = 0.01$ ). Permanent AF was the most frequent atrial arrhythmia (81% of the overall population). The two groups were similar according to cardiovascular risk factors, medical treatments and baseline echocardiography parameters. Of interest, the mean baseline left ventricular ejection fraction (LVEF) was  $46 \pm 15\%$  in the HBP group and  $49 \pm 15\%$  in the LBBAP group ( $p = 0.12$ ). The mean baseline QRS duration was  $99 \pm 17$  ms and  $107 \pm 29$  ms in the HBP and LBBAP groups, respectively ( $p = 0.42$ ). Of note, the proportion of patients with QRS duration greater than 120 ms was higher in the LBBAP group as compared to the HBP group (25% vs 12%,  $p = 0.04$ ), mostly due to a higher rate of preexisting left bundle branch block (14/96 vs 2/68,  $p = 0.015$ ).

**Table 1: Patients baseline characteristics**

	<b>HBP (n = 68)</b> n(%) or mean $\pm$ SD	<b>LBBAP (n = 96)</b> n(%) or mean $\pm$ SD	<i>p</i>
Age (years)	$69.9 \pm 12.3$	$75.0 \pm 10.1$	0.01
Female gender	34 (50%)	58 (60%)	0.24
BMI (kg/m <sup>2</sup> )	$27.7 \pm 6.5$	$28.3 \pm 6.1$	0.53
Coronary artery disease	13 (19%)	15 (16%)	0.7

<b>Atrial arrhythmia</b>			
Permanent AF	58 (85%)	75 (78%)	0.34
Permanent left AF <sup>l</sup>	2 (3%)	5 (5%)	0.70
Paroxysmal AF*	5 (7%)	13 (13%)	0.31
Permanent left AT	3 (4%)	3 (3%)	0.69
<b>Cardiovascular Risk Factors</b>			
Hypertension	43 (63%)	62 (65%)	0.87
Diabetes Mellitus	9 (13%)	13 (14%)	1
Dyslipidemia	26 (38%)	46 (48%)	0.26
Active smoking	22 (32%)	17 (18%)	0.04
<b>Treatments</b>			
NOAC	50 (74%)	81 (84%)	0.13
VKA	18 (26%)	14 (15%)	0.09
Diuretics	41 (60%)	59 (61%)	1
Digoxin	17 (25%)	14 (15%)	0.14
Beta-blockers	60 (88%)	83 (86%)	0.92
Antiarrhythmic medications	15 (22%)	18 (19%)	0.53
<b>Transthoracic echocardiography<sup>†</sup></b>			
LVEF (%)	46 ± 15	50 ± 15	0.12
LVEF > 50%	28 (46%)	40 (52%)	1
LVEF 40 – 50%	14 (23%)	16 (21%)	0.66
LVEF < 40%	19 (31%)	20 (26%)	0.39
Right atrial area (cm <sup>2</sup> )	24 ± 7	22 ± 6	0.21

Left atrial volume (mL/m <sup>2</sup> )	57 ± 19	51 ± 17	0.29
<b>Baseline 12-lead ECG</b>			
QRS duration (ms)	99 ± 17	107 ± 29	0.42
QRS duration ≥ 120 ms	8 (12%)	24 (25%)	0.04
LBBB	2 (3%)	14 (15%)	0.015
RBBB	4 (6%)	8 (8%)	0.76
Nonspecific IVCD	2 (3%)	2 (2%)	1

*AF : Atrial fibrillation; AFL : Atrial flutter; AT : Atrial tachycardia; BMI: Body mass index; ; NOAC : non-vitamin K antagonist oral anticoagulant; VKA : Vitamin K antagonist; IVCD: Intraventricular conduction delay; LBBB: Left bundle branch block; LVEF: Left ventricular ejection fraction; RBBB. Right bundle branch block.*

*\* Paroxysmal AF with daily and highly symptomatic episodes*

*¶ Echocardiography data were not available in 7 of 68 patients in the HBP group and 20 of 96 patients in the LBBAP group.*

### **Pacemaker implant procedures**

While the proportion of dual chamber pacemakers was similar in both groups (12/68 vs 21/96,  $p = 0.71$ ), the mean pacemaker implant procedure duration, from skin incision to end of the skin suture, was significantly shorter in the LBBAP group when compared to the HBP group ( $46 \pm 18$  min vs  $57 \pm 23$  min,  $p = 0.0015$ ). There was no procedure-related acute adverse event in both groups, especially no pneumothorax, no pericardial effusion or no septal perforation.

A back-up right ventricular lead was implanted in 5/68 patients (7%) in the HBP group and none of the patient in the LBBAP group ( $p = 0.01$ ).

At implantation, the mean His bundle capture (HBC) threshold was significantly higher as compared to LBBAP threshold ( $1.25 \pm 0.6$  V at 0.4 ms vs  $0.75 \pm 0.6$  V at 0.4 ms,  $p < 0.001$ ). Mean impedance was  $727 \pm 213$  Ohms and  $480 \pm 166$  Ohms in the LBBAP and HBP groups, respectively ( $p < 0.001$ ). Mean sensed R wave amplitude was lower in the HBP group as compared to the LBBAP group ( $4.0 \pm 3.2$  vs  $11.0 \pm 5.3$  mV,  $p < 0.001$ ).

The mean paced QRS complex was wider in the LBBAP group than in the HBP group ( $116 \pm 15$  ms vs  $106 \pm 16$  ms,  $p = 0.03$ ). In patients with baseline narrow QRS, the difference between paced QRS duration and baseline QRS duration was greater following LBBAP ( $22 \pm 13$  ms vs  $12 \pm 13$  ms,  $p < 0.001$ ) whereas there was no significant difference between both groups in patients with baseline wide QRS ( $-30 \pm 13$  ms vs  $-21 \pm 19$  ms,  $p = 0.10$ ).

### **AVNA procedure**

AVNA procedure duration was significantly shorter in the LBBAP group as compared to the HBP group ( $30 \pm 12$  min vs  $46 \pm 25$  min,  $p < 0.001$ ) (Table 2). The median number of RF applications was significantly higher in the HBP group than in the LBBAP group (3.5 applications, IQR 1.25 – 5.75 vs 1 application, IQR 1 – 2,  $p < 0.001$ ).

Of importance, a complete AV block was more frequently obtained in the LBBAP group than in the HBP group (88 / 96 patients (92%) vs 54 / 68 patients (79%),  $p = 0.04$ ). Ventricular escape rhythm was observed in 89% of patients with complete AV block, with no difference between HBP and LBBAP groups ( $p = 0.75$ ). Significant modulation of the AV node conduction (mean heart rate  $< 60$  bpm) was obtained in 9/68 patients and 6/96 patients in the HBP and LBBAP groups, respectively ( $p = 0.20$ ).

AVNA failure was observed in 5 patients (7%) in the HBP group and 2 patients (2%) in the LBBAP group. In the HBP group, 3/5 patients underwent a second right-sided AVNA procedure using an irrigated tip ablation catheter with success. The two last patients died from severe chronic diseases (COPD and cardiorenal syndrome, respectively) before a second ablation procedure could be performed. In the LBBAP group, 1/2 patients underwent a second successful right-sided AVNA procedure using an irrigated tip ablation catheter, whereas a left-sided approach was necessary in the second patient.

No lead dislodgement occurred during the AVNA procedures in any of the two groups. Acute transient HBC threshold increase  $> 1$  V was only observed in the HBP group (10 / 68, 14% vs 0 / 96, 0%,  $p < 0.001$ ). Of note, the HBC threshold returned to baseline value in most of the patients at day one (8/10).

**Table 2 : Procedures characteristics**

	<b>HBP (n = 68)</b> <i>n(%) or mean ± SD or median (IQR)</i>	<b>LBBAP (n = 96)</b> <i>n(%) or mean ± SD or median (IQR)</i>	<i>p</i>
<b>Pacemaker implant procedure</b>			
Procedure duration (min)	57 ± 23	46 ± 18	0.0015
Fluoroscopy duration (min)	2.2 (0.5 – 6.2)	2.9 (1.1 – 6.4)	0.54
Back-up RV lead	5 (7%)	0 (0%)	0.01
Paced QRS duration (ms)	106 ± 16	116 ± 15	0.03
Paced QRS duration – baseline QRS duration (ms) in patients with baseline wide QRS	-21 ± 19	-30 ± 13	0.10
Paced QRS duration - baseline QRS duration (ms) in patients with baseline narrow QRS	10 ± 13	22 ± 13	< 0.001
Selective HBP	49 (72%)	-	-
Non-selective HBP	19 (28%)	-	-
RWPT V6 (ms)	-	71 ± 12	-
LBB potential recording	-	44 (46%)	-
HBC or LBBAP threshold (unipolar, V @ 0.5 ms)	1.25 ± 0.6	0.75 ± 0.6	< 0.001
Impedance (Ohms)	480 ± 166	727 ± 213	< 0.001
R wave amplitude (mV)	4.0 ± 3.2	11.0 ± 5.3	< 0.001
<b>AV node ablation procedure</b>			
Procedure duration (min)	46 ± 25	30 ± 12	< 0.001
Fluoroscopy duration (sec)	132 (45 – 189)	50 (36 – 108)	0.017
Number of RF applications	3.5 (1.25 – 5.75)	1 (1 – 2)	< 0.001

RF application duration (sec)	120 (62 – 227)	90 (60 – 126)	0.18
Complete AV block	54 (79%)	88 (92%)	0.04
Significant AV node modulation (mean heart rate < 60 bpm)	9 (13%)	6 (6%)	0.20
AV node ablation failure	5 (7%)	2 (2%)	0.21
Ventricular escape rhythm	49 / 54 (91%)	77 / 88 (88%)	0.75
Acute HBC or LBBAP threshold increase > 1V during AVNA procedure	10 (15%)	0	< 0.001
Acute HBC or LBBAP threshold increase > 1 V at day one after the procedure	2 (3%)	0	0.17

*RV : Right ventricle; HBC : His bundle capture; RF : Radiofrequency; AV : atrioventricular; RWPT V6 : R-wave peak time in V6*

### **Primary outcome**

The primary outcome (one-year freedom from combined endpoint of first episode of HFH, AV node reconduction requiring a second AVNA procedure, lead revisions and death from any cause) occurred in 16 / 68 patients (24%) in the HBP group vs 9 / 96 patients (9.4%) in the LBBAP group (Hazard ratio = 2.38, 95% confidence interval 1.08 – 5.28, p = 0.032).

This difference was mainly driven by symptomatic AV node reconduction leading to a second AVNA procedure (6 vs 0 patients in the HBP and LBBAP groups, respectively).

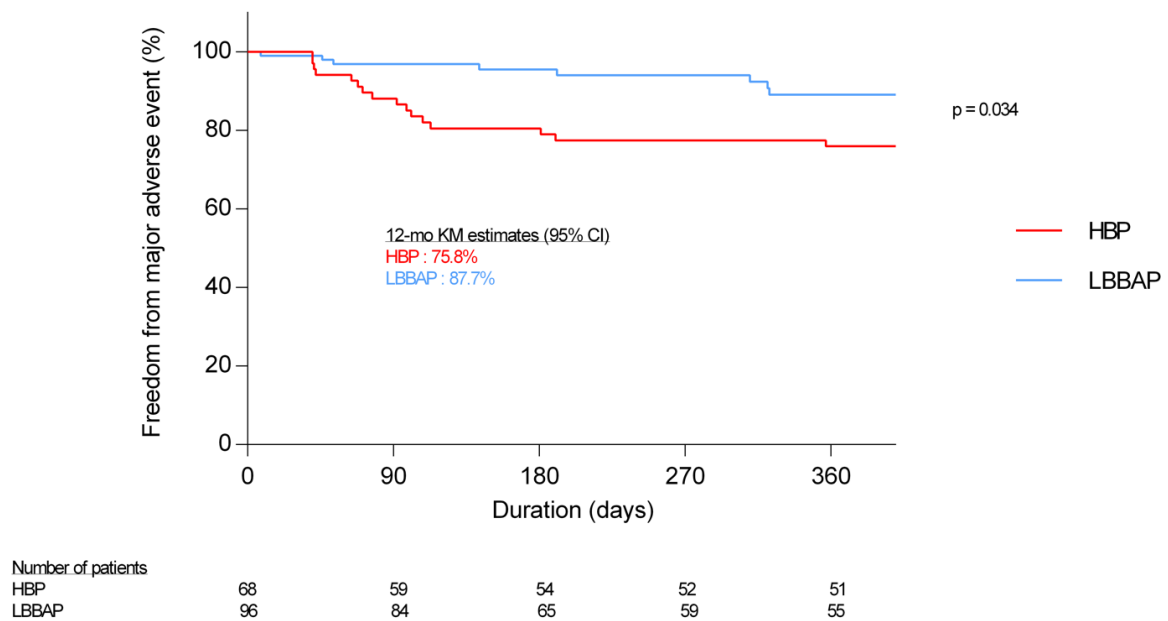
One LBBAP lead dislodgement occurred at one-month; a conventional lead was repositioned at the RV septum. Of note, this patient had undergone a shoulder manipulation early after implantation which could have explained the lead displacement. Among the HBP group,



ventricular lead revision was requested in one patient at one-year follow-up due to a progressive HBC threshold elevation reaching  $> 5V @ 1 \text{ ms}$ .

During the follow-up, 4 / 68 (6%) and 5 / 96 patients (5%) died in the HBP and LBBAP groups, respectively. Refractory heart failure was the cause of death in 5 / 9 patients. Other patients died from acute pulmonary embolism (1), brain tumor (1), digestive cancer (1) and COPD (1). There was no sudden cardiac death during the follow-up.

**Figure 1: Freedom from combined endpoint (first episode of HFH, AV node reconnection requiring a second AVNA procedure, lead revision and death from any cause) according to the CSP technique (HBP vs LBBAP)**

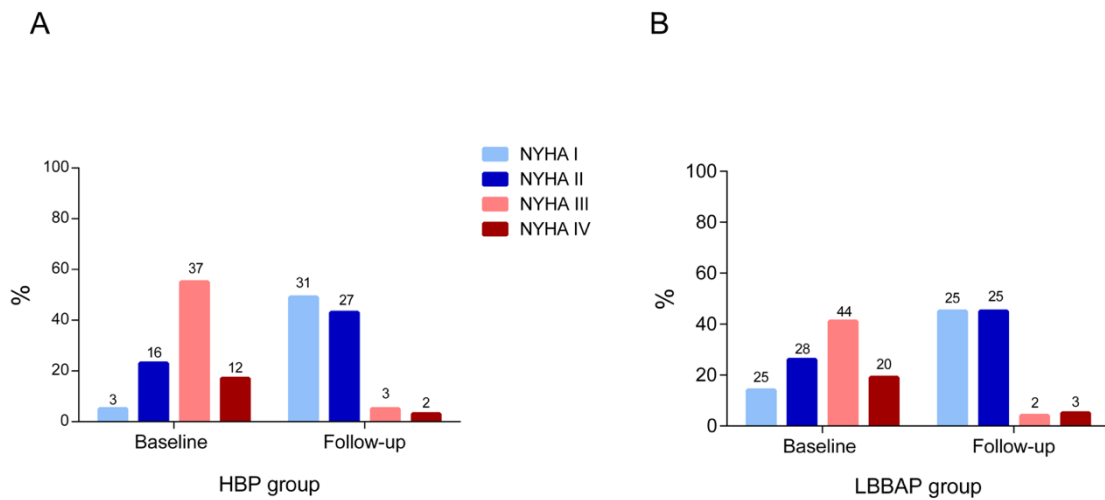


### Clinical benefit of CSP followed by AVNA

At one-year follow-up, NYHA class significantly improved in HBP group ( $1.6 \pm 0.6$  vs  $2.9 \pm 0.5$  at baseline,  $p < 0.001$ ) and LBBAP group ( $1.5 \pm 0.8$  vs  $2.7 \pm 0.9$  at baseline,  $p < 0.001$ ). Improvement in NYHA class is shown in Figure 2. Regarding heart failure hospitalizations (HFH), a positive impact of the “ablate and pace” strategy was observed in both groups. The

annualized incidence of HFH significantly decreased in both groups following the procedures (41.2 / 100 patient - year at baseline vs 9.0 / 100 patient - year in the HBP group,  $p < 0.0001$  and 43.8 / 100 patient - year at baseline vs 8.1 / 100 patient - year in the LBBAP group,  $p < 0.0001$ ).

**Figure 2: Patients' NYHA class at baseline and at one-year follow-up**



*Panel A : HBP group*

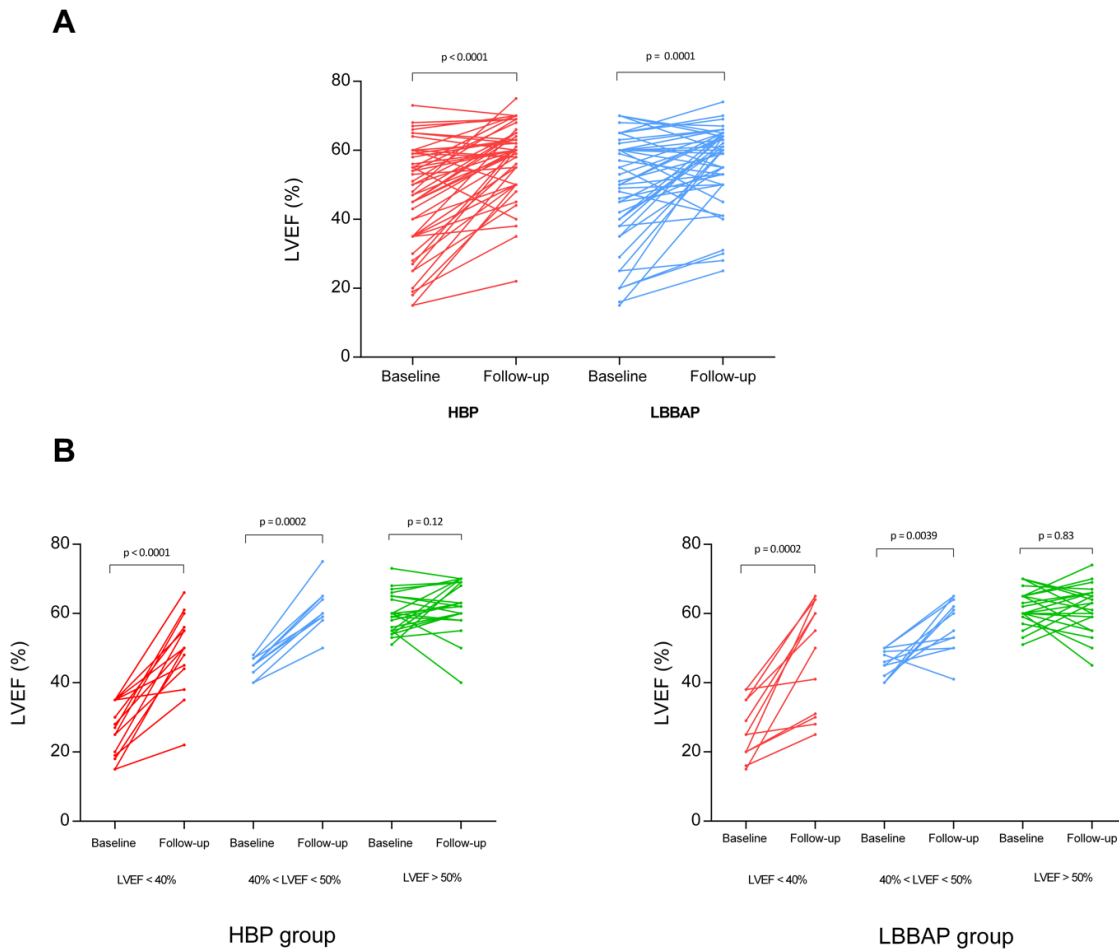
*Panel B : LBBAP group*

### Echocardiography data

In the overall population, 115 patients underwent both baseline and one-year follow-up echocardiography (60 / 68 and 55 / 96 in the HBP and LBBAP group, respectively). A significant improvement was observed in LVEF at one-year following the “ablate and pace” strategy in both HBP group ( $58 \pm 10\%$  vs  $46 \pm 15\%$  at baseline;  $p < 0.0001$ ) and LBBAP group ( $58 \pm 10\%$  vs  $49 \pm 14\%$  at baseline;  $p = 0.0001$ ) (Figure 2). Of note, the improvement in LVEF at one-year follow-up did not differ between both groups ( $+12 \pm 11\%$  vs  $+9 \pm 12\%$  in the HBP and LBBAP groups, respectively;  $p = 0.12$ ).

In patients with baseline normal LVEF  $> 50\%$ , the LVEF remained stable at one-year follow-up in the HBP group ( $60 \pm 6\%$  at baseline vs  $62 \pm 7\%$  at one-year,  $p = 0.12$ ) and LBBAP group ( $62 \pm 6\%$  at baseline vs  $62 \pm 7\%$  at one-year,  $p = 0.83$ ). As shown in Figure 3, the improvement in LVEF was greater in patients with mildly reduced LVEF between 40% and 50% and even more important in patients with reduced LVEF  $< 40\%$ .

**Figure 3: Patients' LVEF at baseline and one-year follow-up after HBP / LBBAP and AVNA**



*Panel A: Echocardiography data pre- and post- AVNA in the HBP and LBBAP groups*

*Panel B: LVEF pre- and post-AVNA according to baseline LVEF. Note a preservation of LVEF in patients with normal baseline LVEF and a significant improvement in LVEF in others, both in the LBP and HBP groups.*

*Baseline and one-year follow-up echocardiography data were available in 60 / 68 patients and 55 / 96 patients in the HBP and LBBAP group, respectively.*

### **CSP leads follow-up**

At one-year follow-up, the mean HBP threshold ( $1.35 \pm 0.68$  V vs  $1.25 \pm 0.6$  V at baseline,  $p = 0.66$ ) and LBBAP threshold ( $0.61 \pm 0.14$  V vs  $0.75 \pm 0.6$  V at baseline,  $p = 0.12$ ) remained stables. The mean impedance in unipolar mode significantly decreased in both HBP group ( $333 \pm 79$  Ohms vs  $480 \pm 166$  at baseline,  $p < 0.0001$ ) and LBBAP group ( $437 \pm 100$  vs  $727 \pm 213$

at baseline,  $p < 0.0001$ ). Secondary HBC threshold elevation  $> 1$  V occurred in 7 / 63 patients (11%). As previously described, one of those patients required a ventricular lead revision at one-year follow-up. There was no LBBAP threshold elevation  $> 1$ V. Due to lack of LBBB correction by HBP and symptomatic heart failure with LVEF  $< 30\%$ , one patient underwent an upgrade to CRT-D. His Bundle Capture and LBBAP were confirmed on ECG analysis at one-year follow-up in all patients. There was no device infection, no pocket hematoma requiring revision and no late lead dislodgement.

In most patients with HBP leads, the procedure was performed at the early phase of the current study (2017 – 2020). Therefore, we could provide with long-term leads follow-up (greater than one year – median follow-up of 3.0 years, IQR 1.7 – 3.5) in 54 patients. HBP lead revision and early battery replacement was required in 3/54 patients (6%) (at two-year follow-up in two patients and 3-year follow-up in one patient) due to high pacing thresholds.

**Table 3: CSP leads follow-up**

Type of CSP	Baseline		One-year		Last follow-up*	
	HBP (n = 68)	LBBAP (n = 96)	HBP (n = 63)	LBBAP (n = 55)	HBP (n = 54)	LBBAP (n = 31)
Threshold (V at 0,4 ms)	1.25 ± 0.6	0.75 ± 0.6	1.35 ± 0.68	0.61 ± 0.14	1.46 ± 1.04	0.63 ± 0.14
R-Wave amplitude (mV)	4.0 ± 3.2	11.0 ± 5.3	3.5 ± 2.3	13.3 ± 6.3	3.1 ± 2.0	12.8 ± 7.1
Impedance (Ohms)	480 ± 166	727 ± 213	333 ± 79	437 ± 100	335 ± 78	463 ± 104

*CSP : Conduction system pacing*

*\*Last follow-up referred to patients followed-up for more than one year (median follow-up of 3.0 years, IQR 1.7 – 3.5 in the HBP group and 1.6 years, IQR 1.3 – 1.8 in the LBBAP group)*

## **Discussion**

This is the first multicenter, prospective and comparative study of consecutive patients who underwent either HBP or LBBAP combined with AVNA. The main findings were as follows. (1) LBBAP was significantly superior to HBP regarding the primary outcome (one-year freedom from combined endpoint of HFH, AV node reconnection requiring a second AVNA procedure, lead revisions and death from any cause). (2) LBBAP resulted in similar clinical benefits and LVEF improvement as compared to HBP. (3) AVNA in the presence of LBBAP lead was associated with higher success rate, shorter procedural and fluoroscopy durations and fewer thresholds elevation when compared to HBP. (4) HBP was associated with higher rates of symptomatic AV node reconnection and rates of redo AVNA procedures. (5) A significant rate of late lead-related complications was observed in the HBP group.

### **Clinical benefit of CSP combined with AVNA**

A significant improvement in NYHA functional class and a reduction of HFH rate was observed in both groups at one-year follow-up. Whatever the CSP technique used, left ventricular ejection fraction significantly improved to the same extent in patients with baseline LVEF < 50% and did not decrease in patients with baseline LVEF > 50% despite a 100% ventricular pacing burden. Our study is the first to demonstrate a similar and significant reduction in the annualized incidence rate of HFH following the “ablate and pace” strategy using either HBP or LBBAP. All patients included in this study were prospectively followed-up which provided robust evidences of the clinical benefit. Theoretically, HBP should result in more physiological activation of the ventricles as compared to LBBAP, the latter being associated with a delayed activation of the right ventricle.<sup>17,18</sup> However, our data suggested that this difference in activation patterns has no impact on clinical efficacy. We observed that we included much fewer patients with baseline LBBB in HBP group (3%) as compared to the LBBAP group (15%) which likely reflected a higher feasibility of restoration of physiological conduction with the more recent CSP technique.

Although LBBAP does not figure in the current guidelines (ESC 2021) in the “ablate and pace” strategy, this technique appears to be of particular interest as it preserves (or restore) intrinsic left ventricular synchrony, a physiological advantage that even conventional CRT does not

provide.<sup>19</sup> In the last ESC guidelines on cardiac pacing, there was no indication for CSP as an alternative to biventricular (HFrEF and HFmrEF) or RV pacing (HFpEF) in patients undergoing AVNA for non-controlled atrial arrhythmia.<sup>9</sup> Our real-life prospective data could therefore contribute to clarify the place of HBP and LBBAP in this indication.

### **Acute procedural outcomes**

LBBAP was associated with shorter implant procedures than HBP. Due to the proximity of the ablation site from the lead, AVNA appeared challenging in the HBP group, resulting in more RF applications and longer procedure durations as compared to LBBAP group. The rate of complete AV block was significantly lower in the HBP group as compared to the LBBAP group (79% vs 92%,  $p = 0.04$ ). This rate was also lower than that of reported in other studies on HBP and AVNA.<sup>20</sup> It is important to underline that other studies did not specify whether a complete AV block or only a significant modulation of the AVN conduction was obtained. Although not reaching statistical significance, AVNA failure was more frequently observed in the HBP group than in the LBBAP group (7% vs 2%).

Of note, the rate of narrow QRS escape rhythm was 89% of patients with complete AV block, with no difference between both groups. Escape rhythm during the waiting period was observed in only 54% of the patients in *Pillail et al.* study, and this important safety information was not reported in *Cai et al.* study.<sup>21</sup>

Our cautious approach also led to only a small number of patients with AVNA induced persistent pacing threshold increase in the HBP group (2 / 68; 3%) which contrasted with a rate of 14.5% in *Pillail et al.* study. In the two previous studies on CSP and AVNA, the overall rate of patients with back-up / additional ventricular lead was much higher than in the present study (76% and 30% vs 7%). RF applications close to the His Bundle lead under cover of the presence of a RV back-up could explain the higher rate of complete AV block in those studies but also explained the higher rate of pacing threshold increase and lower rate of narrow escape rhythm reported by *Pillail et al.* In addition, implanting an additional RV lead is well recognized as associated with a higher risk of infection and complex pacemaker programming.<sup>22</sup> Consequently, there is no optimal approach (RV back-up lead or not) in this setting. Those issues related to the AVNA are well addressed by the LBBAP technique due to the remote positioning of the lead from the ablation site.

### **AVN reconnection rate**

Whereas not observed in the LBBAP group, symptomatic atrioventricular node (AVN) reconnection leading to a second AVNA procedure was observed in 6 / 66 patients (9%) in the HBP group. This mainly accounted for the difference between groups regarding the primary outcome. This information was otherwise not available in other studies investigating CSP and AVNA despite major implications in terms of morbidity, rehospitalizations and related healthcare costs.

### **CSP lead electrical parameters**

As LBBAP provides better pacing thresholds and higher impedances, the expected battery longevity is higher as compared to HBP. The ventricular capture management can be programmed almost always in case of LBBAP improving the battery longevity and enabling reliable remote monitoring contrary to HBP.

In line with the literature, an increase in pacing threshold was observed at one-year follow-up in 11% of the patients in the HBP group.<sup>23</sup> On the other hand, this phenomenon was not observed in the LBBAP group. In addition, long-term lead follow-up available only in the HBP group highlighted the need for HBP lead revision and early battery replacement in 6% of the patients at 3 years.

### **Limitations**

This was a non-randomized study. Patients in the LBBAP group were significantly older as compared to patients in the HBP group. Given the very positive results of the “ablate and pace” strategy using CSP and the reduced concern about pacing induced cardiomyopathy, physicians could have been more likely to propose this definitive approach in recent years, even in older patients. Despite the higher age which could have adversely affected the LBBAP group, the rate of events remained lower than in the HBP group.

Due to the later emergence of the LBBAP technique, the median follow-up duration was shorter in the LBBAP group than in the HBP group. However, the primary outcome was assessed at one-year follow-up. In addition, there were no acute or chronic lead-related complication,

excepted one lead dislodgement, in the LBBAP group whereas patients from the HBP group had already experienced threshold elevations during the 12-month follow-up period.

### **HBP or LBBAP combined with AVNA: which is the best approach?**

This study did not challenge the pathophysiological basis of permanent HBP vs LBBAP in patients undergoing an "ablate and pace" strategy for non-controlled atrial arrhythmias, but it did question the best technical approach. LBBAP seems to be the best CSP approach in the "ablate and pace" strategy as it (1) facilitates the subsequent AVNA procedure with higher safety and success rate; (2) ensures a much lower rate of symptomatic AVN reconnection requiring a second ablation procedure; (3) provides better electrical parameters limiting lead revisions and early battery replacements; without compromising the clinical benefit of this therapeutic approach.

### **Conclusion**

In this multicenter, prospective and comparative study on patients undergoing CSP combined with AVNA for non-controlled atrial arrhythmia, LBBAP was superior to HBP. A significant improvement in LVEF and NYHA functional class was observed with both techniques, along with a reduction in the incidence of HFH. Given the technical challenge of AVNA and the electrical parameters of the leads, LBBAP appears to be the preferred technique in this setting. Our real-life data could contribute to clarify the place of HBP and LBBAP in this indication. Randomized controlled studies are now required to compare LBBAP vs biventricular pacing in patients requiring an "ablate and pace" strategy.



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## **RESUME**

**Contexte** : L'implantation d'un stimulateur cardiaque associée à l'ablation du nœud atrio-ventriculaire est une stratégie thérapeutique efficace en cas d'arythmie atriale non contrôlée. Au cours des dernières années, les techniques de stimulation permanente du système de conduction, visant à préserver une activation électrique du ventricule gauche physiologique, ont émergé comme des alternatives prometteuses à la stimulation ventriculaire droite conventionnelle.

**Objectif** : L'objectif de notre étude était de comparer la stimulation de l'aire de la branche gauche (LBBAP) et la stimulation Hisienne (HBP), chez les patients ayant bénéficié de l'implantation d'un stimulateur cardiaque associée à une ablation du nœud atrio-ventriculaire pour une arythmie atriale non contrôlée.

**Méthodes** : Entre Septembre 2017 et Mai 2023, nous avons inclus de façon prospective l'ensemble des patients ayant bénéficié de l'implantation d'un stimulateur cardiaque avec succès de stimulation du système de conduction, suivie d'une ablation du nœud atrio-ventriculaire. Le critère de jugement principal était un critère combiné comprenant à un an de suivi : hospitalisations pour insuffisance cardiaque, reconductions atrio-ventriculaires nécessitant une seconde procédure d'ablation du nœud atrio-ventriculaire, réinterventions pour dysfonction de sonde et mortalité toute cause.

**Résultats** : 164 patients ont bénéficié d'une ablation du nœud atrio-ventriculaire après succès de stimulation du système de conduction (68 HBP et 96 LBBAP). Les durées moyennes de procédure d'implantation du stimulateur cardiaque et d'ablation du nœud atrio-ventriculaire étaient significativement plus courtes dans le groupe LBBAP en comparaison au groupe HBP ( $46 \pm 18$  min vs  $57 \pm 23$  min,  $p = 0.0015$  et  $30 \pm 12$  min vs  $46 \pm 25$  min,  $p < 0.001$ ). Un bloc atrio-ventriculaire complet était plus fréquemment obtenu avec la LBBAP et comparaison à la HBP (88 / 96 patients (92%) vs 54 / 68 patients (79%),  $p = 0.04$ ). Le critère de jugement principal composite à 1 an survenait chez 16 / 68 patients (24%) dans le groupe HBP contre 9 / 96 patients (9.4%) dans le groupe LBBAP (Hazard ratio = 2.38, intervalle de confiance à 95% 1.08 – 5.28). La stratégie combinée de stimulation du système de conduction associée à l'ablation du nœud atrio-ventriculaire a été bénéfique dans les 2 groupes avec une amélioration significative de la classe NYHA et de la FEVG ( $58 \pm 10$  % vs  $46 \pm 15$  %;  $p < 0.0001$  et  $58 \pm 10$  % vs  $49 \pm 14$  %;  $p = 0.0001$ , dans les groupes HBP and LBBAP respectivement). Une élévation secondaire du seuil de capture Hisienne  $> 1$  V est survenue chez 7/63 patients (11%). Un changement de sonde a été nécessaire chez un de ces patients à 1 an. Aucune élévation de seuil  $> 1$  V n'a été observée dans le groupe LBBAP.

**Conclusion** : Dans cette étude multicentrique, prospective et comparative, la stimulation de l'aire de la branche gauche était supérieure à la stimulation Hisienne chez les patients nécessitant l'implantation d'un stimulateur cardiaque suivie d'une ablation du nœud atrioventriculaire. Une amélioration significative de la FEVG et de la classe fonctionnelle NYHA était observée avec les deux techniques. Compte tenu de la difficulté de l'ablation du nœud atrioventriculaire en présence d'une sonde Hisienne et des paramètres électriques, la stimulation de l'aire de la branche gauche semble être la technique de choix dans cette indication.

**Mots clés** : Arythmie atriale ; Fibrillation atriale ; Ablation du nœud atrio-ventriculaire ; Stimulation du système de conduction ; Stimulation Hisienne ; Stimulation de l'aire de la branche gauche.