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His Bundle Pacing for Newly Acquired Pacing Needs in Patients Implanted with a Sub-cutaneous Implantable Cardioverter Defibrillator: A Feasibility Study based on the Automated Screening Score and Clinical Cases.

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Brief title: HBP for Newly Acquired Pacing Needs in Patients Implanted with a S-ICD.

STRUCTURED ABSTRACT

INTRODUCTION:

Management of S-ICD patients with newly acquired pacing needs remains problematic. His Bundle Pacing (HBP) allows for cardiac pacing without significant changes in the QRS morphology. We hypothesized that HBP doesn't alter S-ICD sensing and functions.

METHODS: Twenty consecutive patients were implanted with a HB pacemaker. Among them, 17 demonstrated successful His recruitment and were prospectively screened with the automated screening tool (AST). Results of screenings performed immediately after implant and during follow-up, during intrinsic rhythm and while pacing from all available pacing configurations, were compared using the AST score. Positive screening tests were defined by ≥1 positive vector.

RESULTS: Among the 17 patients successfully implanted (male: 41%; mean age: 73), 13 presented an indication of ventricular pacing and 4 of cardiac resynchronization. Absolute AST scores during both HBP (all configurations) and intrinsic rhythm were similar (p-value: ns). Due to LBBB correction, HBP resulted in higher number of

positive vectors (AST≥100). AST scores were higher during HBP when compared to RV pacing (primary vector: 272 [16; 648] vs. 4.6 [0.8; 16.2];P=0.003; secondary vector: 569 [183;1186] vs. 1.5 [0.7;8.3];P<0.0001; alternate vector: 44 [2;125] vs. 4.8 [0.9;9.3];P=0.02) and resulted in a much higher number of positive vectors. Up to 90% of the patients had a positive screening test during HBP. This passing rate was higher when compared RVP (17%; P<0.0001).

CONCLUSION: HBP restores normal intrinsic conduction and minimally modifies the surface ECG and S-EGMs. When ventricular pacing is needed, HBP might represent an ideal pacing option for patients implanted with a S-ICD.

Keywords: Subcutaneous implantable cardioverter defibrillator, S-ICD, His Bundle pacing, feasibility, pacemaker, combination of devices.

ABBREVATIONS LIST

-S-ICD: Subcutaneous Implantable Cardioverter Defibrillator

-TV: transvenous system

-S-EGMs: subcutaneous electrograms

-HB: His bundle

-HBP: His bundle pacing

-AST: automated screening tool

-HPVP: high percentage of ventricular pacing

-CRT: cardiac resynchronization therapy

-RV: right ventricular

-LVEF: left ventricular ejection fraction

-DFT: defibrillation test

-VF: ventricular fibrillation

- DC: direct current

-AV: auriculo-ventricular

-EP: electrophysiology study

-LP: leadless pacemaker

-LBBB: left bundle branch block

Introduction

In the field of cardiac defibrillation, the introduction of the Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) represents indubitably one of the most important developments over the past decade. By leaving the heart and vasculature untouched, the S- ICD significantly reduces the risk of lead related complications (1-5). However, one of the major drawbacks of the extra-thoracic positioning of the ICD remains the absence of pacing functionality. Therefore, the S-ICD should not be implanted in patients who present an indication of pacing or resynchronization therapy. Moreover, nowadays, when a patient implanted with a S-ICD develops bradycardia related pacing needs, explanting the S-ICD and re-implanting a transvenous (TV) system remains often the only therapeutic option. Despite few case-reports describing the combination of conventional endovenous, epicardial or leadless pacemakers with the

S-ICD, there is currently no clear recommendation for such pacing strategies, mainly because proper S-ICD functions rely on subcutaneous electrograms (S-EGMs) which, as precordial surface electrocardiography, might dramatically and unpredictably change during ventricular pacing. As S-EGMs after pacemaker implantation are unpredictable, pre-operative screening on the basis of the QRS amplitude and T wave is impossible and, conventional pacing implantation may jeopardize S-ICD functionality. His Bundle (HB) Pacing promotes intrinsic conduction over the conduction system of the heart and allows for cardiac pacing with only minimal or no changes of the QRS morphology. Therefore, we hypothesize that HB paced QRS vectors have higher probability of appropriate sensing than other types of pacing.

Methods

Population and study protocol

Over a 6 months period, twenty consecutive patients scheduled for implantation of a HB pacemaker were prospectively included in present study. All patients demonstrating successful His recruitment as recommended by recent published criteria (6) and with acceptable thresholds (<3.5V, pulse width 1ms) were submitted to a screening for the implantation of a S-ICD using the automated screening tool (AST, Boston scientific). Screenings were performed immediately after pacemaker implantation and during follow-up (after 3 to 6 months) while pacing from all available pacing configurations. S-EGMs during his bundle pacing with selective, non-selective, left bundle branch corrective and non-corrective capture were obtained in both unipolar and bipolar. (Figure 1) Subsequently, comparisons between each pacing modalities and intrinsic S-EGMs were analyzed in a qualitative manner (number of positive vectors) and in a quantitative manner (using the AST score). On a per patient basis, a positive screening test was defined by ≥1 positive vector. Our local

ethics committee approved the study and all patients consented to participate to the study.

Automated screening tool score

The AST score has been established to determine mathematically how compatible are the 3 available vectors (S-EGMs) with the S-ICD. It depends on the amplitude of the R-wave after filtering (3-40Hz), the R/T wave ratio and the baseline noise. The higher the score, the more compatible is the tested vector with the S-ICD and the lower is the probability of over- and under-sensing. Arbitrarily, the passing score for S-ICD screening has been set ≥100. To gather original AST scores, raw screening session were recorded and exported onto a USB key. From the saved file, AST scores are accessible in the XLM file attached to the screening session. (Figure 2)

Statistical analysis

Continuous variables are reported as median and interquartile range or mean and standard deviation. Group comparisons were performed using the Kruskal-Wallis or Mann-Whitney tests. Categorical variables are presented as counts and percentages and were compared between groups using the Fisher's exact test. A two-sided P-value of <0.05 was considered to indicate statistical significance. All analyses were performed using the SPSS statistic software (version 25.0; IBM Corp., Armonk, NY, USA).

Clinical vignettes

In addition to this series of patients, we present the clinical results and follow-up of 2 S-ICD patients who developed ventricular pacing needs, treated by the implantation of a HB pacemaker.

Results

Study population

Twenty consecutive patients were included in the study. Among them, 17 (Male: 41%; age: 73 (IQR:67-82.5) years) demonstrated successful HB recruitment according to current recommendation with acceptable thresholds. Population characteristics are presented in table 1. Thirteen patients presented an indication of ventricular pacing with an expected high percentage of ventricular pacing (HPVP group). Four patients received a "HB optimized" CRT in lieu of a traditional cardiac resynchronization (CRT group). In 14 patients, a back-up lead was placed either at the RV apex (n=8/14) or onto the high RV septum (n=6/14). Non-selective HB capture was demonstrated in 11 patients during unipolar HB pacing and in 10 patients during bipolar HB pacing. A selective HB capture was obtained with or without transition from non-selective pacing in 9 patients in both unipolar and bipolar configurations.

Results of screening tests per vector

At baseline and during intrinsic rhythm, 70% of the patients from the HPVP group and 67% from the CRT group had at least one positive vector during automated screening test. Whereas, during conventional RV pacing, only 22% of the patients from the HPVP group and none of the CRT group had at least 1 positive vector. With unipolar His bundle pacing, 88% and 100% (HPVP group) and 67% and 50% (CRT group) of the patients had ≥1 positive vector during non-selective and selective HB pacing respectively. Similarly, with bipolar HB pacing, 100% (HPVP group) and 50% (CRT group) had ≥1 positive vector during both non-selective and selective HB pacing. (Table 2) On a per vector analysis, absolute AST scores during both HB pacing (all configurations) and sinus rhythm were statistically similar (p- value for all

comparisons: ns). However, due to LBBB correction, HB pacing resulted in higher number of positive vectors (AST≥100). In contrast, AST scores were significantly higher during HB pacing when compared to RV pacing (primary vector: 272 [16;648] vs. 4.6 [0.8;16.2]; P=0.003; secondary vector: 569 [183;1186] vs. 1.5 [0.7;8.3], P<0.0001; alternate vector: 44 [2; 125] vs. 4.8 [0.9; 9.3]; P=0.02) and resulted in a much higher number of positive vectors. (Figure 3). Furthermore, positive screenings during RV pacing were similarly low with both the apical and the high septal RV positions.

Results of screening tests per patient

On a per patient basis, up to 90% of the patients had a positive screening test during HB pacing. (Figure 4) This passing rate was significantly higher when compared RV pacing (17%; P<0.0001). In the CRT group, HBP resulted in a complete correction of the LBBB in 2 patients and in a partial LBBB correction in the two others. Only the 2 patients displaying a complete correction of their LBBB were positively screened for the S-ICD. After a mean follow-up period of 4±3 months, 95% of the patients demonstrated stable thresholds and similar AST scores. Leads were stable and none of the patients needed back-up RV pacing.

Clinical follow-up and defibrillation testing.

In addition to the 20 patients included in the present study, 2 S-ICD patients were implanted with a HB pacemaker after development of ventricular pacing needs. The first patient (a 66 years old man, post-infarct ischemic cardiomyopathy - LVEF: 15%) was implanted with a S-ICD in primary prevention. Despite normal PR interval at baseline, he developed 13 months after S-ICD implantation, intermittent episodes of symptomatic high degree AV block. During HB pacemaker implantation (Figure 5),

HV interval was measured at 57ms and "concealed" selective HB capture was obtained with a threshold of 0.75V / 1ms in bipolar configuration. Results of the automated vector select algorithm (Primary vector) remained similar during pacing and during intrinsic sinus rhythm. Also, AST scores obtained during the various pacing configurations (intrinsic, unipolar, bipolar with selective and non-selective HB capture) with both the automated screening tool (through the programmer) and with the auto-vector select (though the S-ICD) were similar and highly correlated. At 3 months follow-up, the ventricular pacing rate was 16%, selective HB recruitment threshold decreased at 0.5V / 1ms and S-ICD interrogation demonstrated normal functions with no inappropriate therapies, no prolongation of the intelligent detection and no auto-deactivation of the SMART-PASS algorithm. A defibrillation test (DFT) was therefore performed to confirm appropriate functioning of both devices during ventricular fibrillation (VF). The DFT was performed with the HB pacemaker programmed in bipolar configuration with the following parameters (AAI-DDD 55/min, ventricular (HB) pacing out-put: 3.0V at 1ms, ventricular (HB) sensing 0.6mV). VF induction was performed as described elsewhere (7) using a brief application of a 50Hz DC current commanded via the S-ICD programmer. During VF, and despite a relatively good R-wave sensing during intrinsic rhythm (2.1mv), continuous HB pacing was observed due to severe undersensing of the arrhythmia by the pacemaker. However, this continuous pacing did not interfere with proper detection of the VF by the S-ICD, which correctly identified the VF and successfully terminated the arrhythmia with a 65J shock after 15 seconds. Immediately post shock, HB pacing temporarily continued at sensor driven rate due to appropriate detection of concomitant atrial fibrillation during VF and commutation to DDI mode.

The second patient, a 78 years old woman, was implanted in secondary prevention (idiopathic VF) with a S-ICD. Despite a normal EP study done as a part of the clinical work-up after her resuscitation, she developed a complete, permanent AV block after 4 years of follow-up. During pacemaker implantation, non-selective HB capture was obtained in bipolar configuration with a threshold of 1.5v / 1ms. Unfortunately, as this patient refused the deep sedation protocol, no DFT was performed. At 1-year follow-up, the automated selected vector remained identical (Alternate vector) without any delivered therapy.

Discussion

Development of pacing needs in S-ICD recipients.

In theory, patients with an indication of pacemaker or CRT should not receive a S-ICD. If absent at the time of implantation, the likelihood of developing such a need appears low, especially in younger patients. Nevertheless, the evaluation of this risk is important before making the decision to implant a S-ICD. This is illustrated in the pooled S-ICD study (8), where, despite a careful selection process, 3 patients (0.3%) were explanted of their S-ICD within the first year for new pacing indications requiring a TV device. Having pacing options for treating the rare patients implanted with a S-ICD who develop bradycardia related pacing indications remains thus important.

Review of currently available pacing options in S-ICD patients

There are a few case reports that examine the possible interaction between pacemaker and S- ICD systems. First, several authors have described the addition of an S-ICD in patients equipped with an epicardial pacemaker connected to either bipolar (9, 10) or unipolar (11) leads. A few publications also reported on the co-implantation of an S-ICD with a TV pacemaker (12, 13). All these reports demonstrated excellent function

of both devices and no inappropriate shocks at short-term follow-up. Still, a strict programming of the pacemaker and S-ICD was used to avoid potential oversensing of pacing artifacts, device cross talks and ultimately inappropriate shocks. For instance, the atrioventricular delay was programmed shorter than the ventricular refractory period of the S-ICD, the upper-rate limit was set lower than half of the first therapy zone, minimal thresholds and safety margins are encouraged, auto-threshold amplitudes were proscribed, auto-switch of polarity was deactivated, and manual vector selection was performed according to screenings during both pacing and intrinsic conduction. Remote monitoring of these patients is also suggested. Data on the feasibility and safety of combining a S-ICD and a leadless pacemaker (LP) are limited. Mondesert et al.(14) reported the successful combined implantation of an S-ICD with the Medtronic Micra TPS LP. Both devices demonstrated normal function at baseline and after a commended S-ICD shock. Tjong et al.(15) demonstrated the feasibility of implanting the Abbott Nanostim LP in combination with an S-ICD both in sheep models and in one human case. All these limited case-series and case-reports demonstrate that a S-ICD can potentially be used in combination with a regular trans-venous, epicardial or leadless pacemaker to provide concomitant ventricular pacing and ICD functions. However, given unexpected changes of the QRS and T- wave morphologies while pacing, as well as repolarization changes during native conduction resumption due to T-wave memory, conventional cardiac pacing may jeopardize the correct functioning of the S-ICD and expose the patient to an increased risk of inappropriate therapy or inhibition (16). Moreover, due to unexpected behavior occurring during VF, electromagnetic interference, or after auto-deactivation of the SMART-PASS, it is difficult to recommend coupling conventional pacing with the S-ICD at a larger scale without more formal safety assessment. Importantly, a leadless

cardiac pacemaker that can be used as an add-on to the existing S-ICD, which has both VVI and ATP functionality, is currently in development. However, up to date, it has never been implanted in human and has not yet received approval from regulatory authorities.

Optimal pacing option in S-ICD patients requiring ventricular pacing

The DAVID trial demonstrated that indiscriminate RV pacing could be harmful in patients with standard ICD indications (17). The incriminated mechanism being a combination of induced dyssynchrony and subsequent systolic dysfunction, followed by clinical heart failure and arrhythmias. Additionally, back-up pacing programming has been associated with Pro- arrhythmic effect in 3% of ICD recipients and considered responsible for up to 54% of all appropriate shocks (18). Accordingly, HB pacing might represent an ideal pacing option not only because we demonstrated in the present study that it allows for cardiac pacing with only minimal change of the S-EGMs, but also because by using the native conduction system, it doesn't desynchronize the heart and therefore attenuate potential negative impact of RV pacing. Furthermore, for the same reasons, no sudden changes in the repolarization due to resumption of the intrinsic conduction and memory effect are to be feared with selective HB pacing. This is however not true for non-selective capture (where change in repolarization might theoretically occur if the amount of myocardial fusion is important) and in CRT candidates with a partial or complete LBBB correction during HB pacing. Nevertheless, having the same regular stable morphology during both intrinsic and the paced rhythm guarantees a maximum safety while sensing with the S-ICD. If HB pacing is performed in a patient with an indication of physiological pacing (19), our results demonstrate better AST scores and more compatibility when compared to biventricular pacing. This suggests that HB pacing may also solve

inappropriate therapies related to intermittent LBBB associated with QRS double counting, T-wave oversensing or memory T- waves.

Insights from clinical cases

Importantly, we demonstrate the theoretical risk of undersensing of VF by the HB pacemaker to be real. In such scenario, continuous ventricular pacing during VF might delay or even inhibit S-ICD sensing and appropriate defibrillation. This is particularly true with unipolar pacing configuration as the pacing artifact is much larger. In our series of patient, careful review of the tracings obtained by the S-ICD and/or the programmer while pacing in unipolar configuration never revealed inappropriate sensing of the pulse stimulus by the S-ICD or cross talks between both devices. Still, we strongly recommend not using the unipolar configuration and turn the automated switch of polarity to monitor. Also, devices should always have ventricular sensing (ADI, DDI, DDD modes) when concomitant SICD is used.

Limitations

This study has several limitations worth noting. First, only 2 patients were co-implanted with both devices. However, as acknowledged in the discussion section, the likelihood of ventricular pacing in patients receiving an S-ICDs is exceedingly rare (around 0.3%). Given the rarity of the situation, conducting a large-scale study might just not be feasible. Secondly, none of these 2 patients co-implanted with an S-ICD and a HB pacemaker received a therapy for a spontaneous clinical event. Therefore, we feel that longer follow-up and larger number of patients is required before recommending more firmly our approach. Third, our study population consisted of patients with an indication of ventricular pacing which might only partially represent those requiring an S-ICD in general. Also, permanent HB pacing can lead to different degrees of fusion with septal pacing, which can vary depending on output programmed. Although the passing rate of selective and non-selective HB pacing were highly correlated in the present study (Kappa coefficient:0.75; P=.001), the potential effect of various degree of fusion on the AST score was not evaluated. Moreover, we recognize that implanting a HBP in S-ICD patient results in 2 separate unique devices, both with a relatively limited longevity when compared with one TV-ICD system. Subjecting these patients to repeated generator changes might increase

overall morbidity. Finally, BSCI is in process of development of a leadless pacemaker for such patients, which in addition to pacing can also provide ATP therapy in near future. We acknowledge that this latest therapeutic option might represent the ultimate solution for these patients.

Conclusion

His bundle pacing restores normal intrinsic conduction during pacing and minimally modifies the surface ECG and S-EGMs. Therefore, when ventricular pacing is needed, HB pacing might represent an ideal pacing option for patients already implanted with a sub-cutaneous ICD.

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FIGURE LEGEND

Figure 1: Results of screening session. Surface-screening ECGs directly extracted from the programmer during intrinsic rhythm, non-selective and selective unipolar and bipolar HB pacing. In all pacing configurations, all 3 vectors demonstrate a positive screening test. Due to active filtering, no pacing artifact is discernible even during unipolar pacing configurations.

Figure 2: Example of AST score. For all tested pacing configurations and all vectors, the AST score was retrieved from the XLM file attached to the recorded session. This example shows AST score calculation for the secondary vector (Same patient as in figure 1). All HB pacing configurations demonstrate positive (≥100) AST scores. (NQRS: intrinsic rhythm; BS: bipolar selective His bundle pacing; BNS: bipolar non-selective His bundle pacing; UNS: unipolar non-selective His bundle pacing; US: unipolar selective His bundle pacing)

Figure 3: Per vector comparisons of AST scores during various pacing configurations. For each pacing configuration, horizontal boxplots of AST scores for all 3 vectors are represented. No pass or pass refers to a negative/positive-screening test according to the AST score (< or ≥100 respectively). **(**HBP: His bundle pacing; NS: non-selective capture; S: selective capture; RVP: right ventricular pacing; I: primary vector; II: secondary vector; III: alternate vector)

Figure 4: AST positive vectors presented at global and individual levels. First row: For each pacing configuration and vector, the percentage of positive screening test is presented for the entire population. Second and third row: For each pacing configuration, the average number of positive vectors and the percentage of positive screening test (≥1 or ≥2 positive vector) are presented at individual level.

Figure 5: Combined S-ICD and HB pacemaker in a patient. Antero-posterior and lateral fluoroscopic projection illustrating co-implantation of a His bundle pacemaker and a S-ICD.

Figure 1.

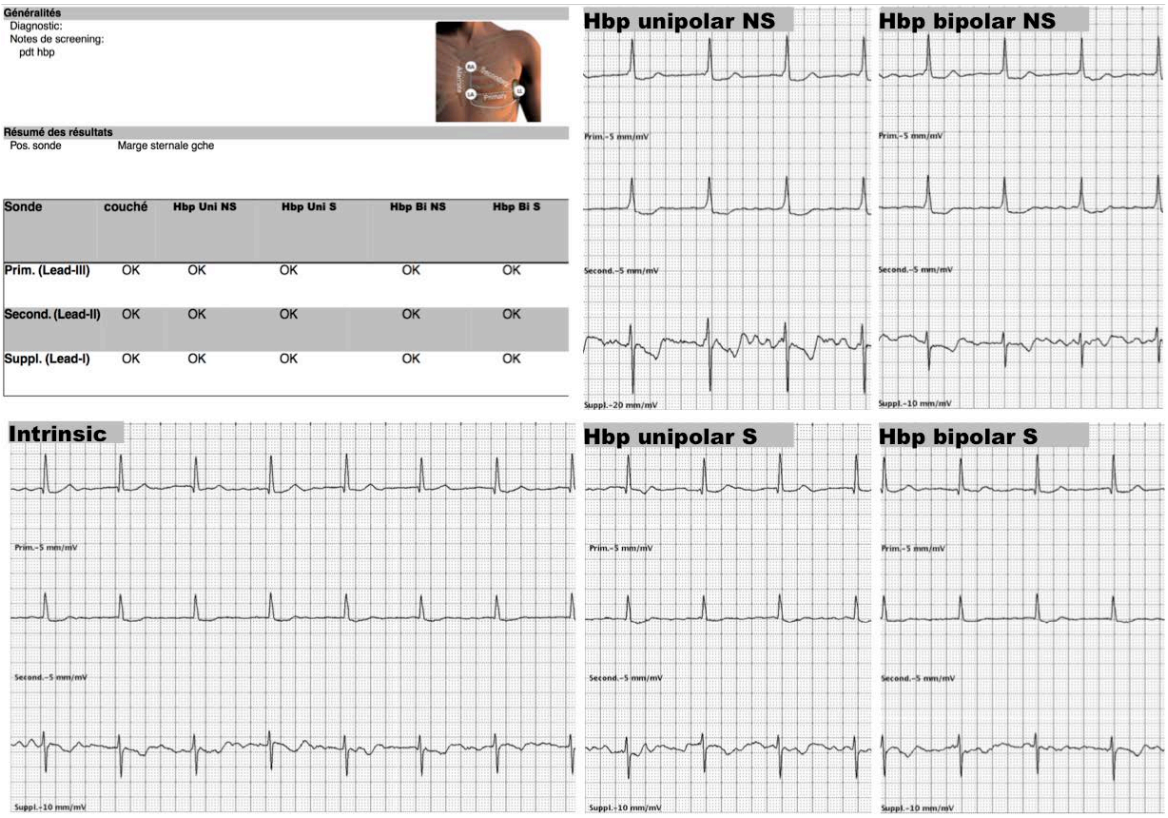

Figure 2.

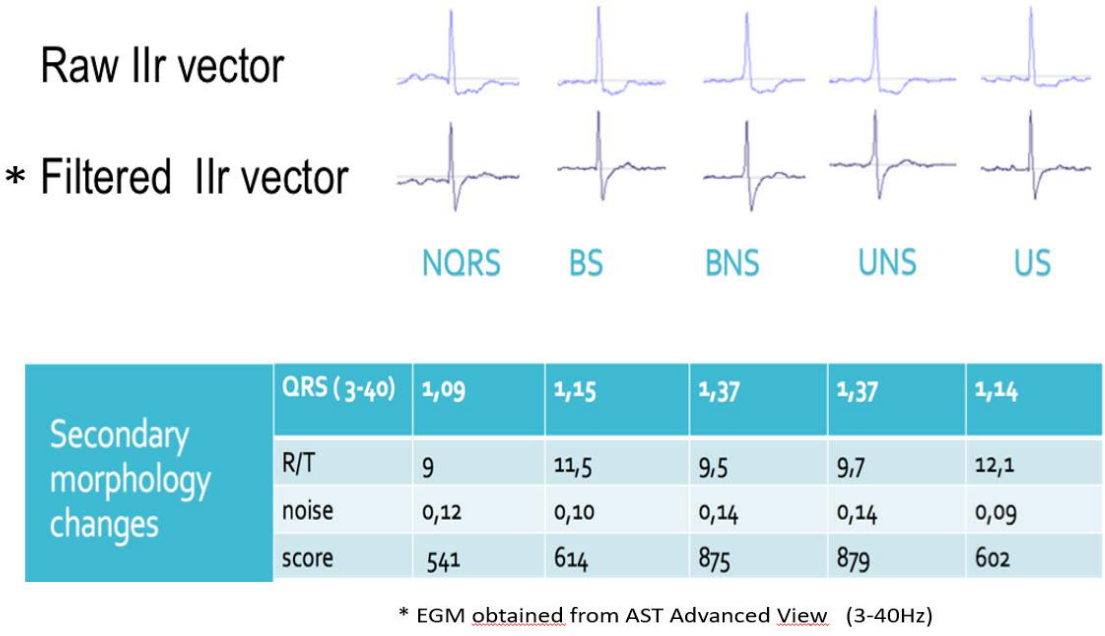

Figure 3.

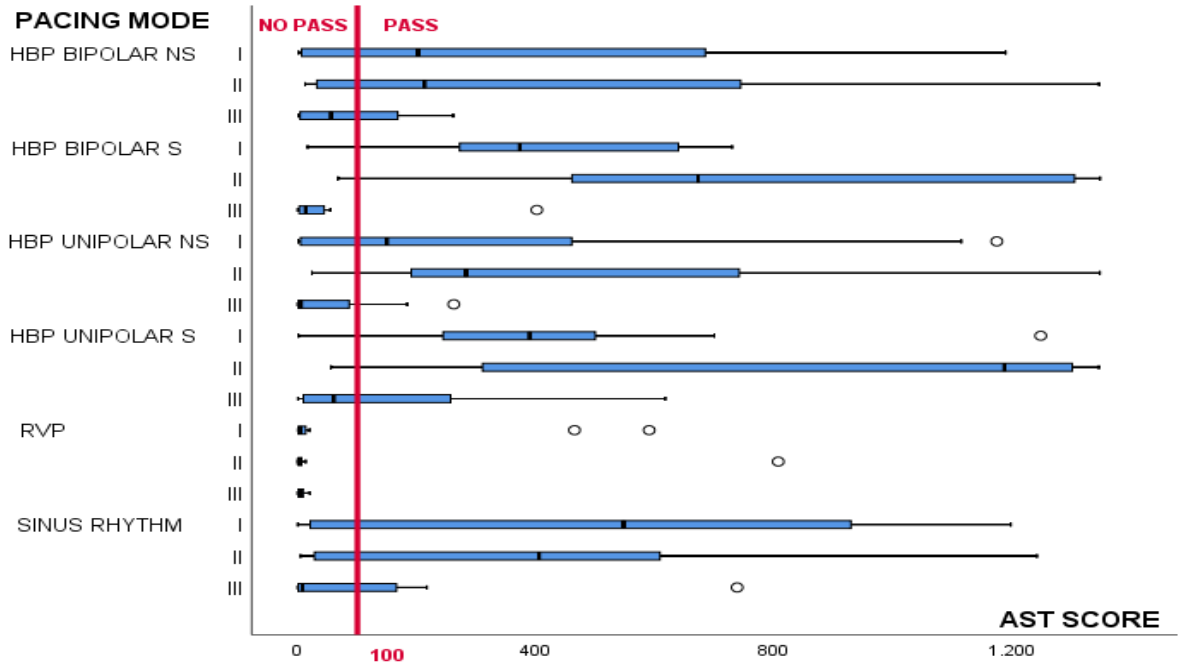

Figure 4.

		AST POSITIVE VECTORS (%)	AST POSITIVE VECTORS PER PATIENT	POSITIVE SCREENING TEST (%) (Positive vectors) ≥1	≥2
HIS BIPOLAR NS	I	60 (N=6/10)			
	II	70 (N=7/10)	1.7	90 (N=9/10)	70 (N=7/10)
	III	40 (N=4/10)			
HIS BIPOLAR S	I	78 (N=7/9)			
	II	89 (N=8/9)	1.8	89 (N=8/9)	78 (N=7/9)
	III	11 (N=1/9)			
HIS UNIPOLAR NS	I	55 (N=6/11)			
	II	82 (N=9/11)	1.6	82 (N=9/11)	73 (N=8/11)
	III	27 (N=3/11)			
HIS UNIPOLAR S	I	78 (N=7/9)			
	II	89 (N=8/9)	2	89 (N=8/9)	78 (N=7/9)
	III	33 (N=3/9)			
RVP	I	17 (N=2/12)			
	II	8 (N=1/12)	0.25	17 (N=2/12)	8 (N=1/12)
	III	0			
SINUS RHYTHM	I	62 (N=8/13)			
	II	69(N=9/13)	1.7	69(N=9/13)	62 (N=8/13)
	III	38 (N=5/13)			

Figure 5.

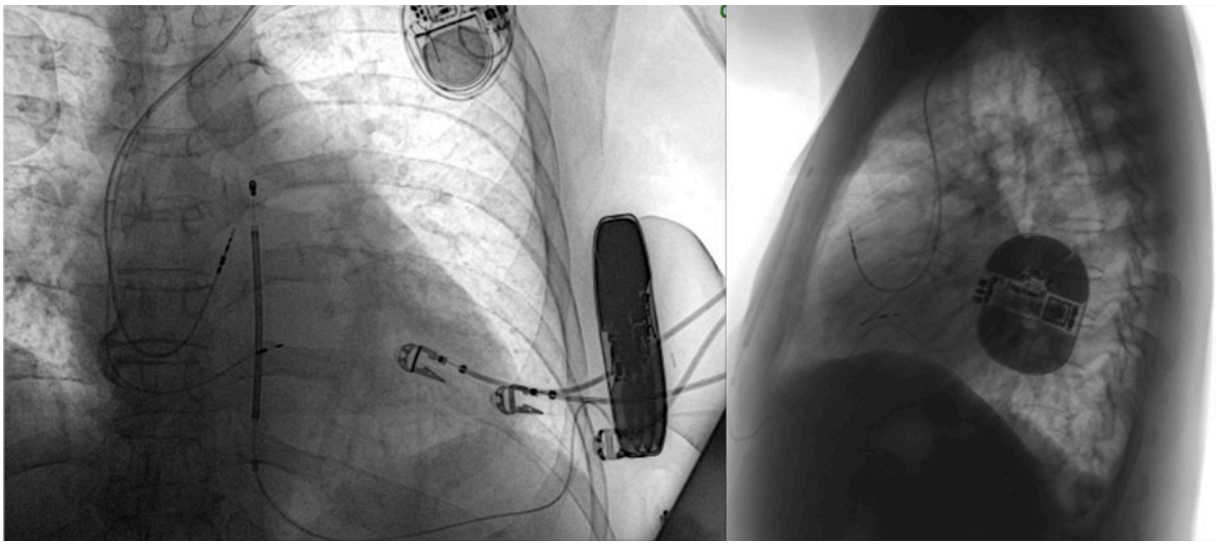

Table 1. Population characteristics

	All patients (N=17)	HPVP (N=13)	CRT (N=4)	P value*
Age (Y)	73 (16)	78 (17)	70 (12)	0.5
Male (%)	41	38	50	1
NYHA (%)				0.45
I-II	88	92	75	
III-IV	12	8	25	
LEVF (%)	52 (26)	55(14)	31(8)	0.005
QRS duration at baseline (ms)	125 ± 29	118± 28	150±20	0.4

Paced QRS duration (ms)	107± 22	105± 23	113±23	0.4
QRS characteristics (%)				0.2
LBBB	53	39	100	
AVB	12	15	/	
AF	18	23		
SR	18	23		

Values are median (IQR), mean±SD or percentage (%). LEVF: left ventricular ejection fraction; HPVP: high percentage of ventricular pacing; CRT: cardiac resynchronization therapy; LBBB: left bundle branch block; AVB: auriculo-ventricular block; AF: atrial fibrillation; SR: sinus rhythm; *P<0.05 (Mann-Whitney or Fisher's exact tests)

Table 2. Automated screening tool (AST) positive vectors comparison between HPVP and CRT indications relative to pacing modes

		AST positive vectors (≥1)					
		SR	**RVP**	**HBP unipolar**		**HBP bipolar**	
Pacing indications				**NS S**		**NS S**	
	HPVP	70%	22%	88%	100%	100%	100%

	CRT	67%	/	67%	50%	50%	50%

SR: sinus rhythm; RVP: right ventricular pacing; HBP: His Bundle Pacing; NS: non selective capture; S: selective capture; HPVP: high percentage of ventricular pacing; CRT: cardiac resynchronization therapy