Evaluation of Ventricular Pacing Suppression Algorithms in Dual Chamber Pacemaker : Results of the 'LEADER' Study

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Participating Centers of this study

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- ❑ Yeungnam University Hospital
- ❑ Pusan National University Hospital
- ❑ Seoul National University Hospital
- ❑ Kyungpook National University Hospital
- ❑ Daegu Catholic University Medical Center
- ❑ Sejong General Hospital
- ❑ Chungbuk National University Hospital
- ❑ Dongguk University Medical Center
- ❑ Wonju Severance Christian Hospital
- ❑ Korea University Medical Center

Korean Heart Rhythm Society

COI Disclosure

Name of First Author: Jongmin Hwang

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Disclosure

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Introduction

- **The detrimental effects of long-term unnecessary right ventricular pacing have been extensively described.**
- **During the last decade, these observations have led to the development of a range of proprietary ventricular pacing minimization algorithms designed to deliver RV pacing only when strictly necessary.**

  - ✓ **Managed Ventricular Pacing (MVP™) – Medtronic Inc. Minneapolis MN, USA**
  - ✓ **V_p Suppression and IRSplus with AV Hysteresis – Biotronik, Berlin, Germany**
  - ✓ **AV Search Plus and RYTHMIQ™– Boston Scientific, St Paul, MN, USA**
  - ✓ **Ventricular Intrinsic Preference (VIP®) – Abbott, Sylmar, CA, USA**

Introduction

- Generally, the algorithms are based on two different mechanisms
  - ✓ (i) Atrioventricular (AV) hysteresis (AVH)
  - ✓ (ii) AAI to DDD pacing mode conversion

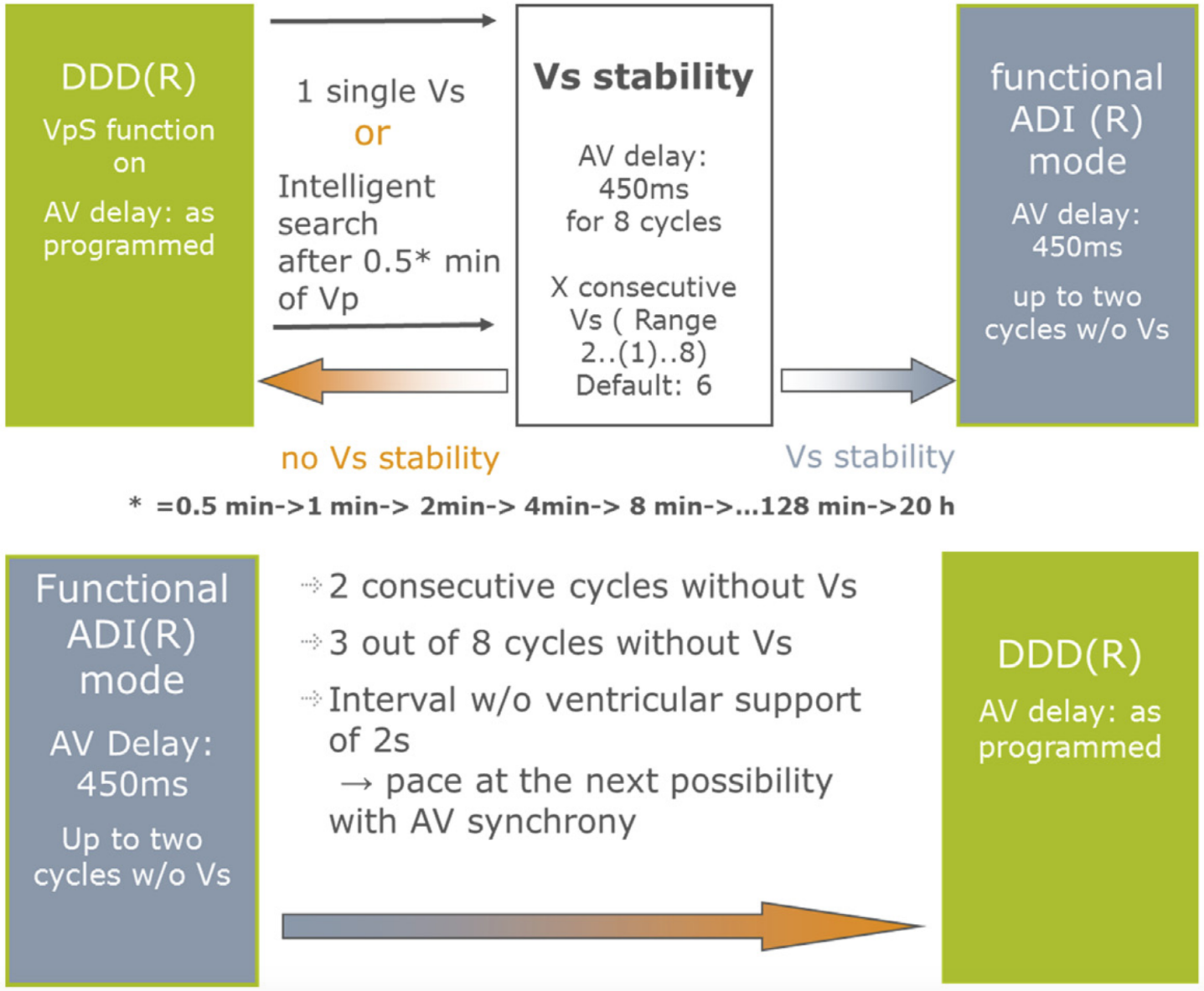
- The purpose of our study was to evaluate the efficacy and safety of two ventricular pacing suppression algorithms:
  - ✓ VP suppression (DDD to AAI mode change) algorithm (VpS)
  - ✓ Intrinsic Rhythm Support (IRS) plus algorithm (using AVH, IRSplus)

Introduction

- Especially, as there are no specific guidelines recommending the use of particular algorithms to minimize ventricular pacing, the decision on which algorithm to use is left to the physician's judgment.
- Consequently, the use of fixed AV interval has been common.

- Furthermore, no studies to date have validated the effects of fixed AV interval and ventricular pacing suppression algorithms within the same patient.

Ventricular pace suppression (VpS) algorithm



- **Dual- to atrial single-chamber mode conversion (DDD(R) to ADI(R)) algorithm**
- **automatically activating when specific conduction tests have been successfully passed**
- **During DDD(R) activity, the algorithm systematically scans the AV delay up to 450 ms to determine whether there is intrinsic ventricular sensing.**
- **This search can be triggered by 2 different situations: *1) sensing of a single ventricular spontaneous event*; or *2) persistent ventricular pacing within a time interval progressively increasing after each unsuccessful search from 30 s to 20 h thereafter.***

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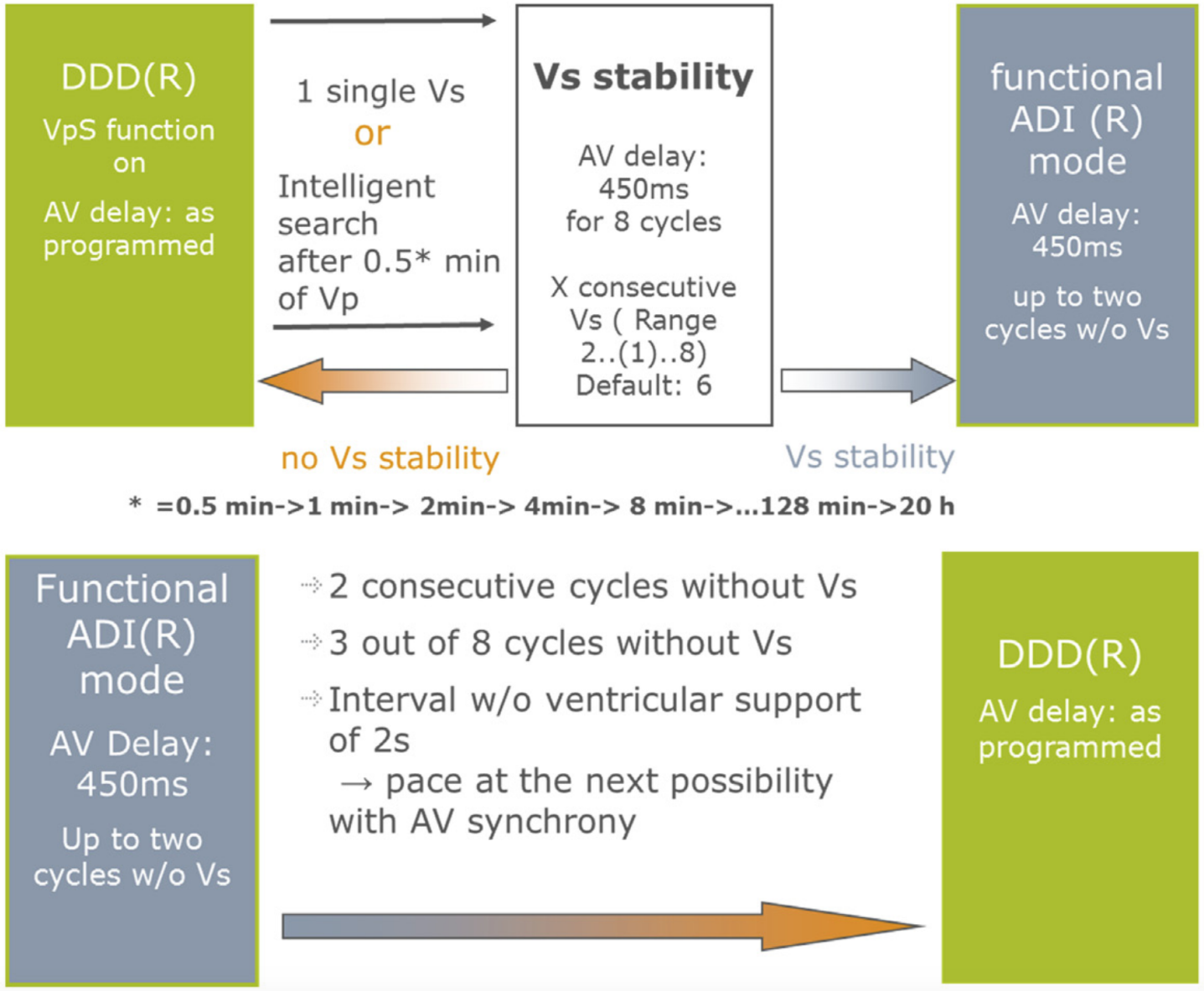
Ventricular pace suppression (VpS) algorithm



- **To prevent continuous forward and backward mode switches, an additional test of conduction stability is performed: a switch to the ADI(R) mode is only allowed if 2 to 8 of the last 8 ventricular events (6 during the study) are sensed with a PQ interval <450 ms.**
- **Switching back to DDD(R) mode is triggered if one of the following 4 independent conditions are fulfilled:**

✓ **1) no ventricular sensed events for up to 2 s**

✓ **2) 2 consecutive cycles w/o spont. events**

✓ **3) 1 to 5 of 8 cycles (3 during the study) without spontaneous events**

✓ **4) more than 15 switches to DDD(R) per h within the last 24 h.**

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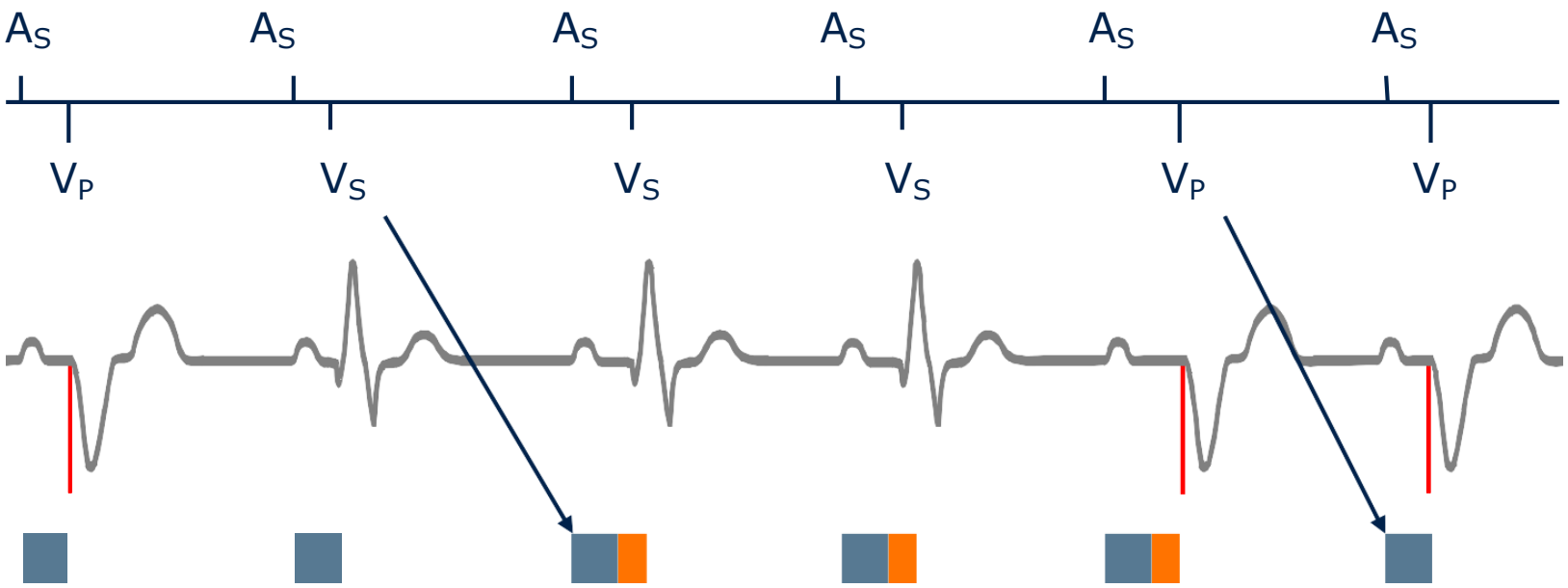
AV Hysteresis

- **Promote intrinsic ventricular activity by extending the AV delay**
- **If intrinsic AV conduction is present, AV delay maintains the hysteresis value to allow intrinsic AV conduction to occur**



AV Delay

AV Delay extension (Hysteresis)

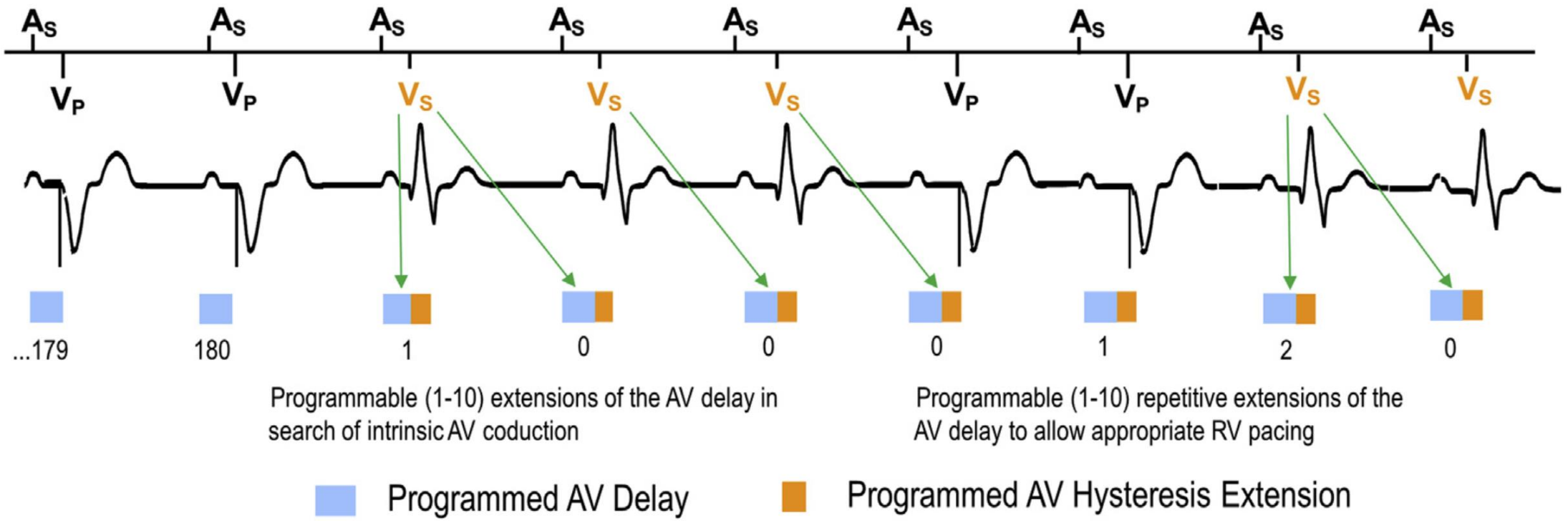
Vs leads to an AV Delay prolongation (Hysteresis)

Vp initiates a short AV-Delay (regular AV Delay)

Courtesy from Biotronik

Intrinsic Rhythm Support (IRS) plus

- **combination of AV hysteresis and a search for intrinsic conduction**
- **When AV hysteresis is activated, the AV delay is automatically extended up to 400 ms after 1 single intrinsic ventricular event**



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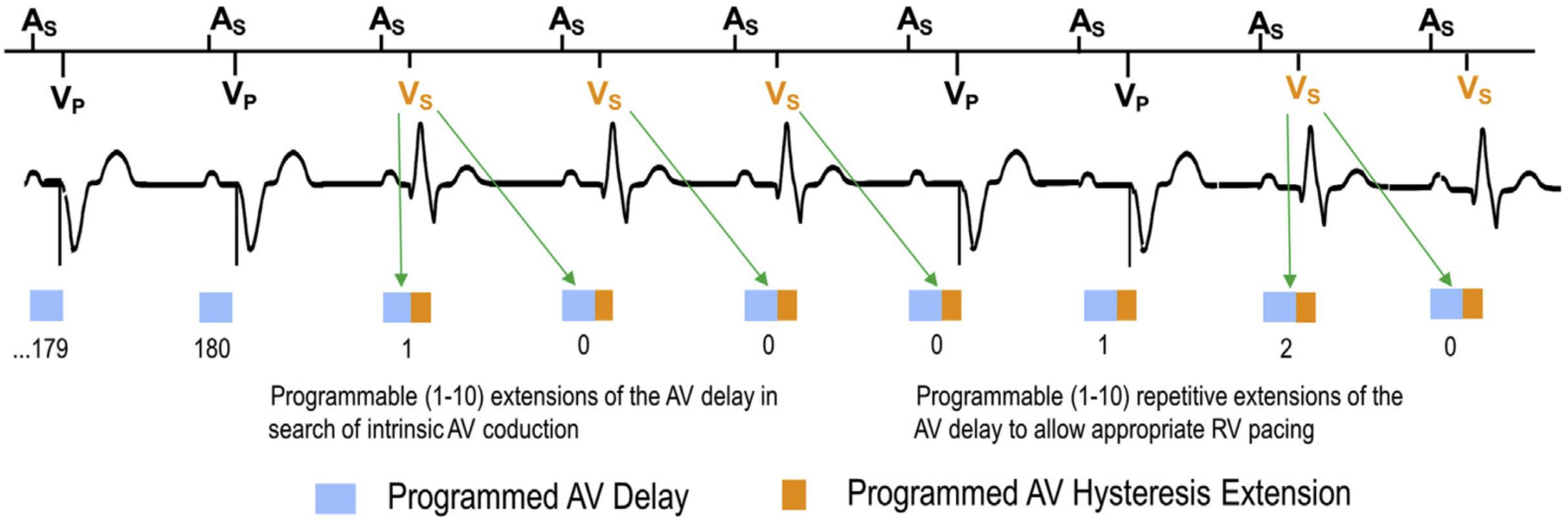
Intrinsic Rhythm Support (IRS) plus

- When intrinsic conduction is lost, the system continues applying the extended AV delay for up to 10 cycles before switching back to the nominal AV delay in order to promote restoration of conduction.
- In addition, in case of persistent ventricular pacing, up to 10 extended AV delays are applied every 180 consecutive pacing cycles to search for spontaneous ventricular activity.



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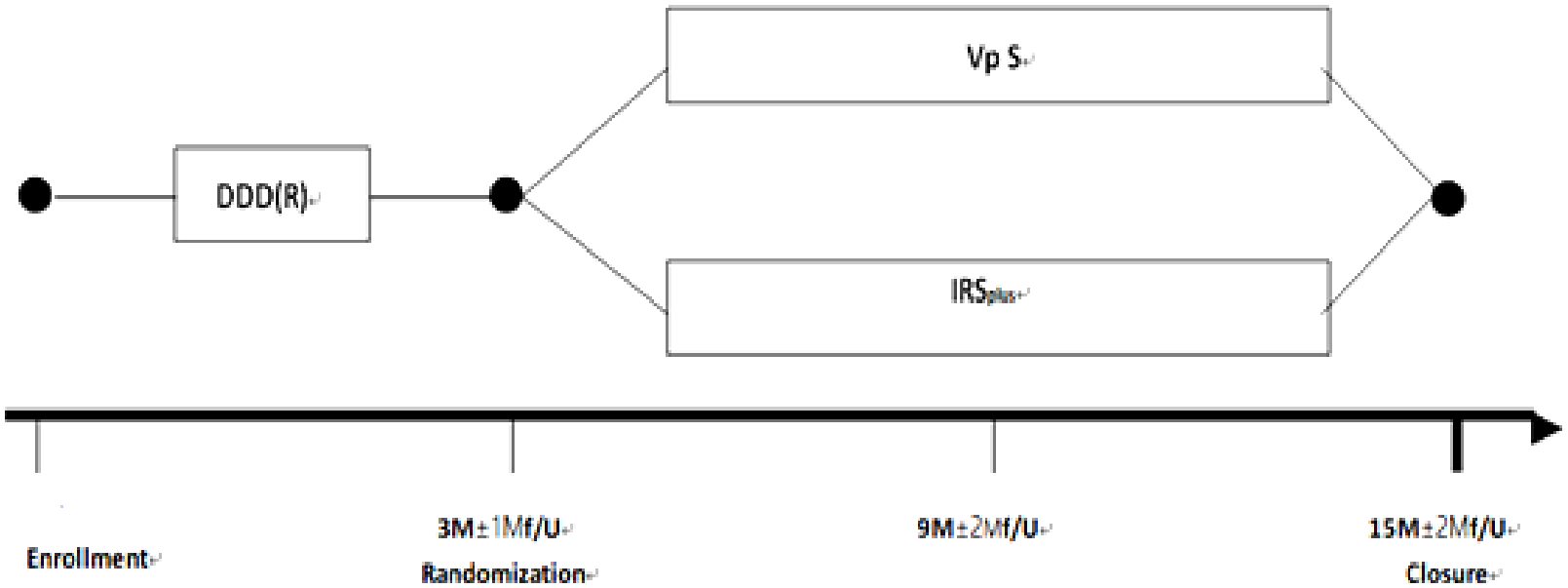
Study design

- This was a multicenter, randomized study conducted in 11 tertiary hospitals in South Korea.

- Patients with sinus node dysfunction (SND) and receiving dual-chamber permanent pacemaker implantation equipped with the VpS and IRSplus algorithms (BIOTRONIK SE & Co. KG, Berlin, Germany) were enrolled.

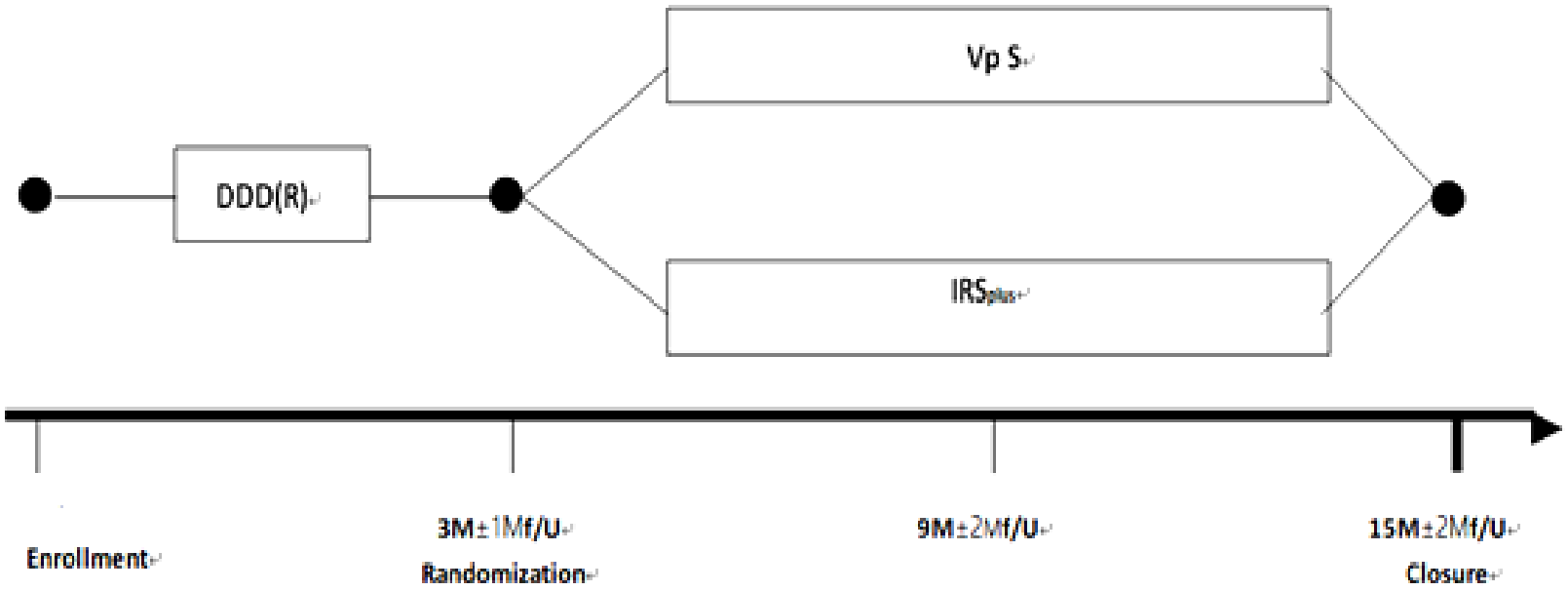
Study design

- After the implantation, patients maintained a fixed AV interval for three months.
- The AV conduction time was determined as the "atrial pacing to ventricular sensing interval" observed from the marker channel during the PPM implantation was set as the sensed AV delay. The paced AV delay was set to be the sensed AV delay+30ms.



Study design

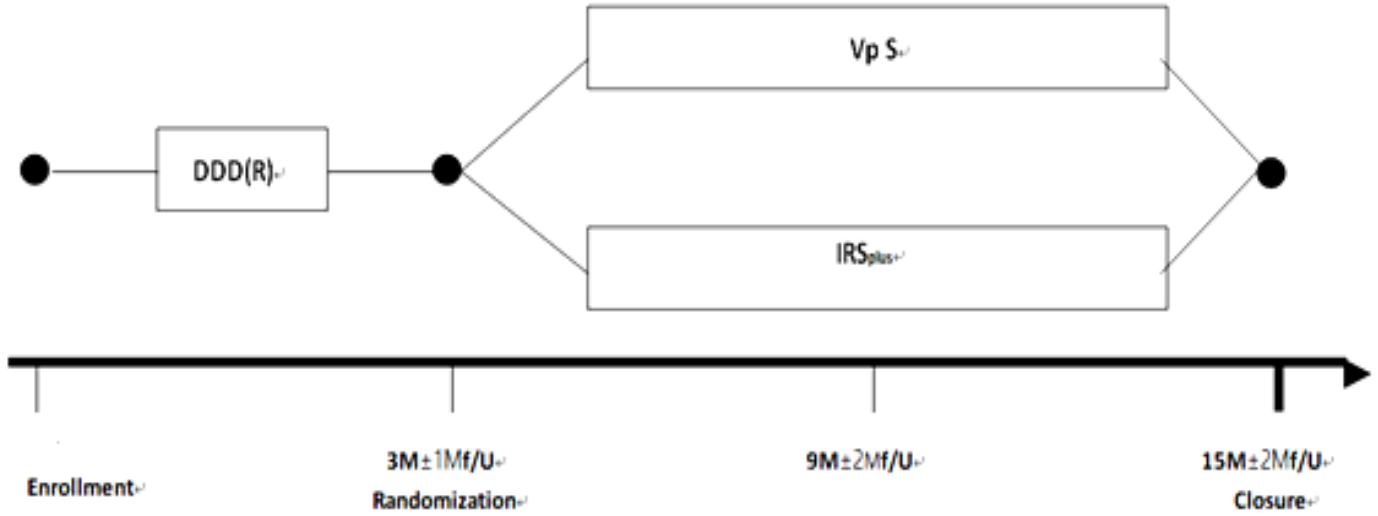
- **Subsequently, patients were randomly assigned to either the VpS or IRSplus algorithm group and were followed for 12 months with assessments every 6 months.**



Results

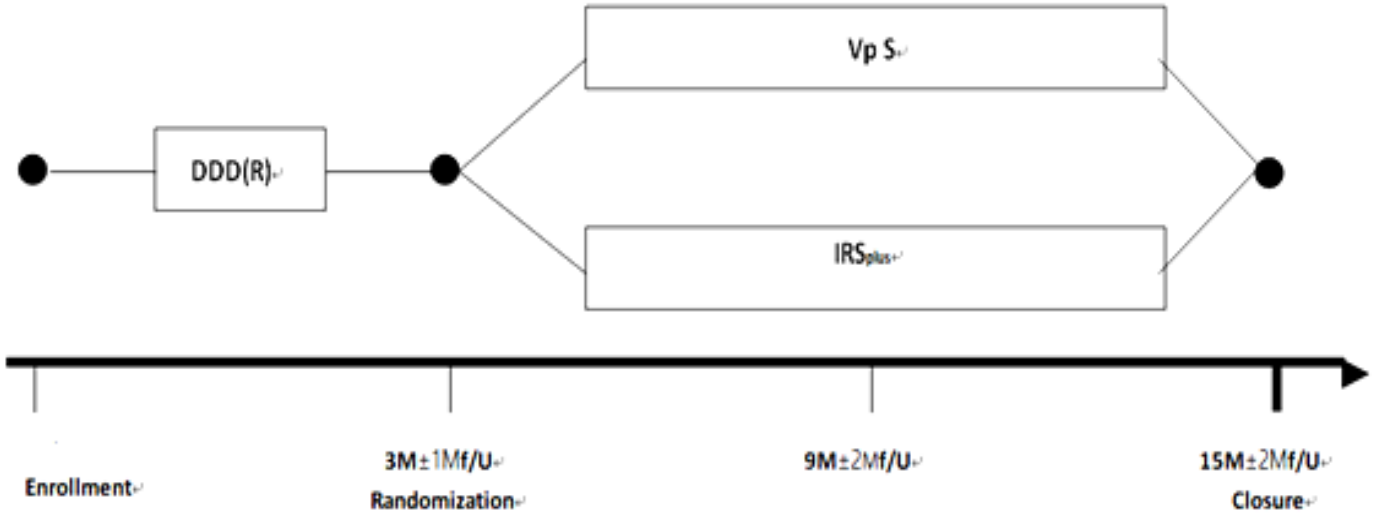
- A total of 118 patients were enrolled.
- Mean age was 69.9 ± 8.4 and 67.8% were female
- This was not different between the two groups.

Results



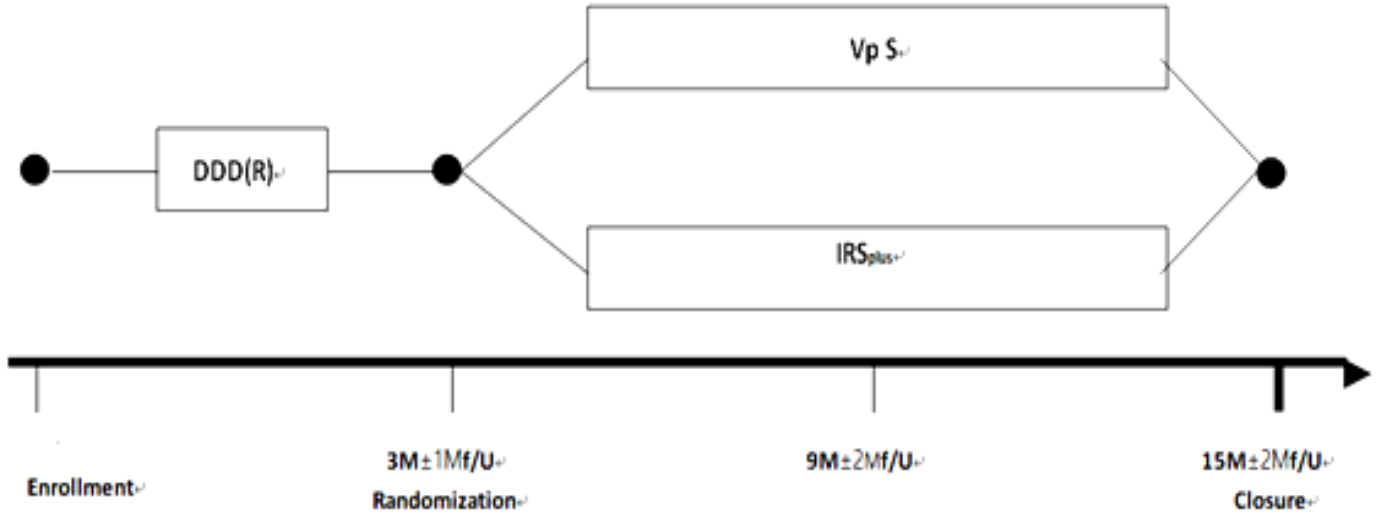
- **The baseline fixed AV interval was set as follows:**
  - ✓ **Paced AV delay: 294.7 ± 41.8 msec**
  - ✓ **Sensed AV delay: 264.4 ± 42.0 msec**
- **The patients' total RV pacing percentage (Vp%) during the 3 months with a fixed AV interval was 10.9±16.0 % on average.**

Results



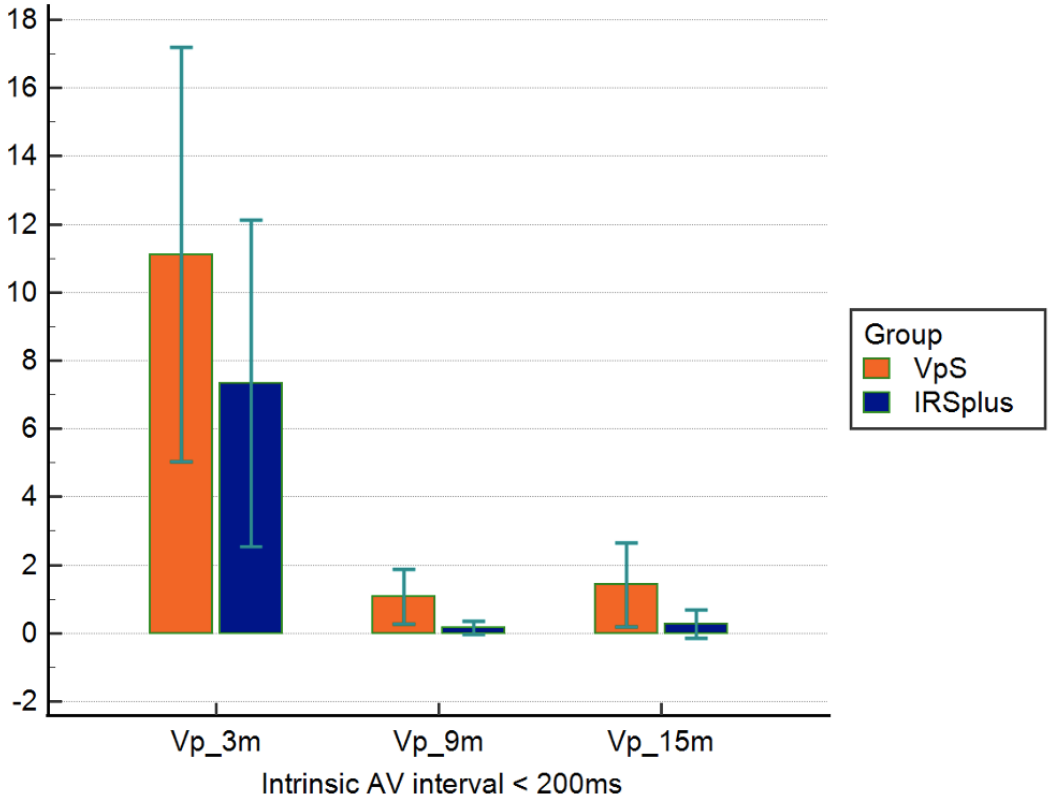
- They were randomly assigned to VpS or IRSplus algorithm groups
- Finally, 62 and 56 patients were assigned to each and completed the study and available for data analysis
- Before turn on the algorithms, Vp% in each group were as follows
  - ✓ VpS vs. IRSplus groups 14.6±18.8% and 6.8±10.9% (P<0.001)

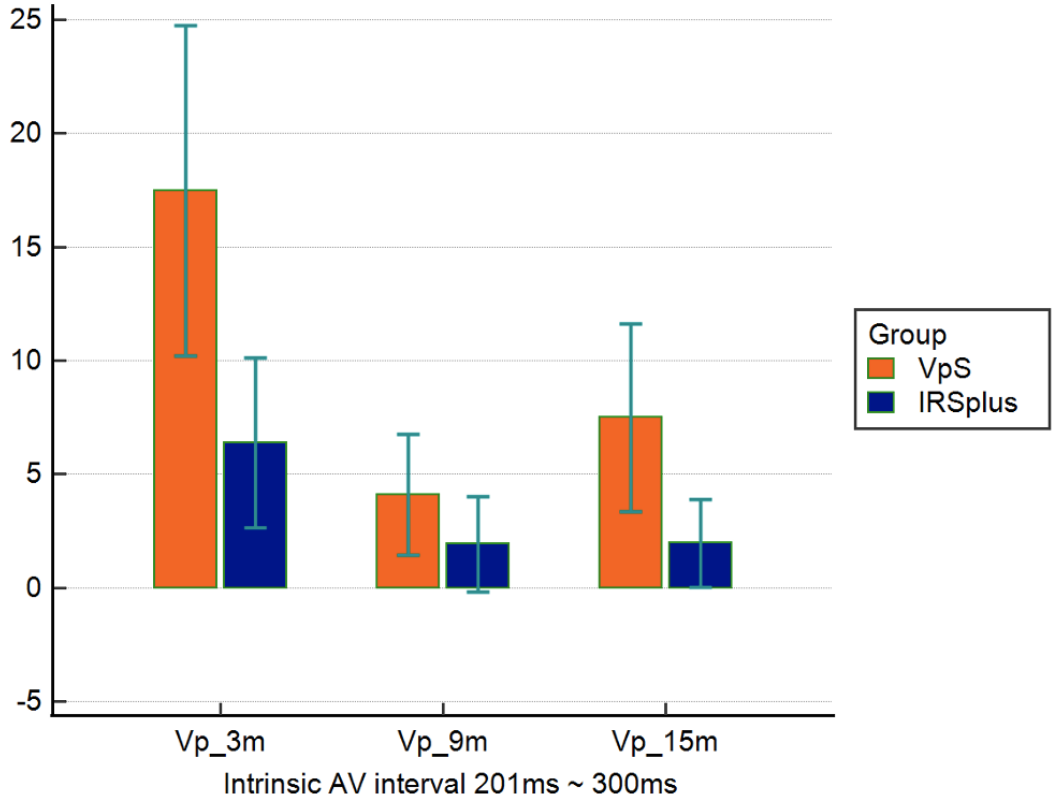
Results



- Six months later, the average Vp% was 14.6±18.8 to 2.7±6.0 (P<0.001) for the VpS groups, and 6.8±10.9 to 1.1±4.0 (P<0.001) for the IRSplus groups, respectively.
- This trend was maintained for additional 6 months (VpS group: 4.6±9.5; IRSplus group: 1.2±3.8).

Results





- **To better investigate the efficacy of the algorithms in relation to patients' intrinsic conduction, subjects were classified into 2 subgroups according to their baseline intrinsic AV interval evaluated at enrollment: intrinsic AV interval <200 ms (subgroup 1), 200 ms ~ 300 ms (subgroup 2).**

Results

- **Overt clinical AF and heart failure hospitalization did not occur during the 15 months of the follow-up period.**
- **Device recorded mode switch percent were as follows (and was neglectable) :**

AMS (%)	VpS	IRSplus
3-month	0.0 ± 0.3	0.2 ± 1.3
9-month	0.0 ± 0.4	0.7 ± 3.9
15-month	1.0 ± 6.2	1.2 ± 7.3

Conclusion

- Our results indicated that both VpS and IRSplus algorithms were highly efficient in reducing unnecessary ventricular pacing in the selected SND population.
- The IRSplus appeared particularly efficient in preventing ventricular pacing
- Despite the difference between two algorithms being statistically significant in the whole population, the cumulative number of paced ventricular beats was minimal with both algorithms and much less compared to fixed AV interval.