Ten years in right ventricular pacing minimization: are all algorithms equal? The VIPERS Study

Torino, 24 Ottobre 2014

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Background

- Right ventricular apical pacing results in a left ventricular electrical activation with a prolonged QRS duration due to slow myocardial conduction.

- Ventricular desynchronization may result in chronic LV remodeling, including asymmetric hypertrophy and redistribution of cardiac mass, mitral regurgitation, increased left atrial diameter, and reduced ejection fraction (EF).

- These adverse effects likely explain the increased risk of atrial fibrillation and heart failure in pacemaker therapy

- Last generation pacemakers provide sophisticated algorithms to favor the intrinsic conduction when present.

Study objective

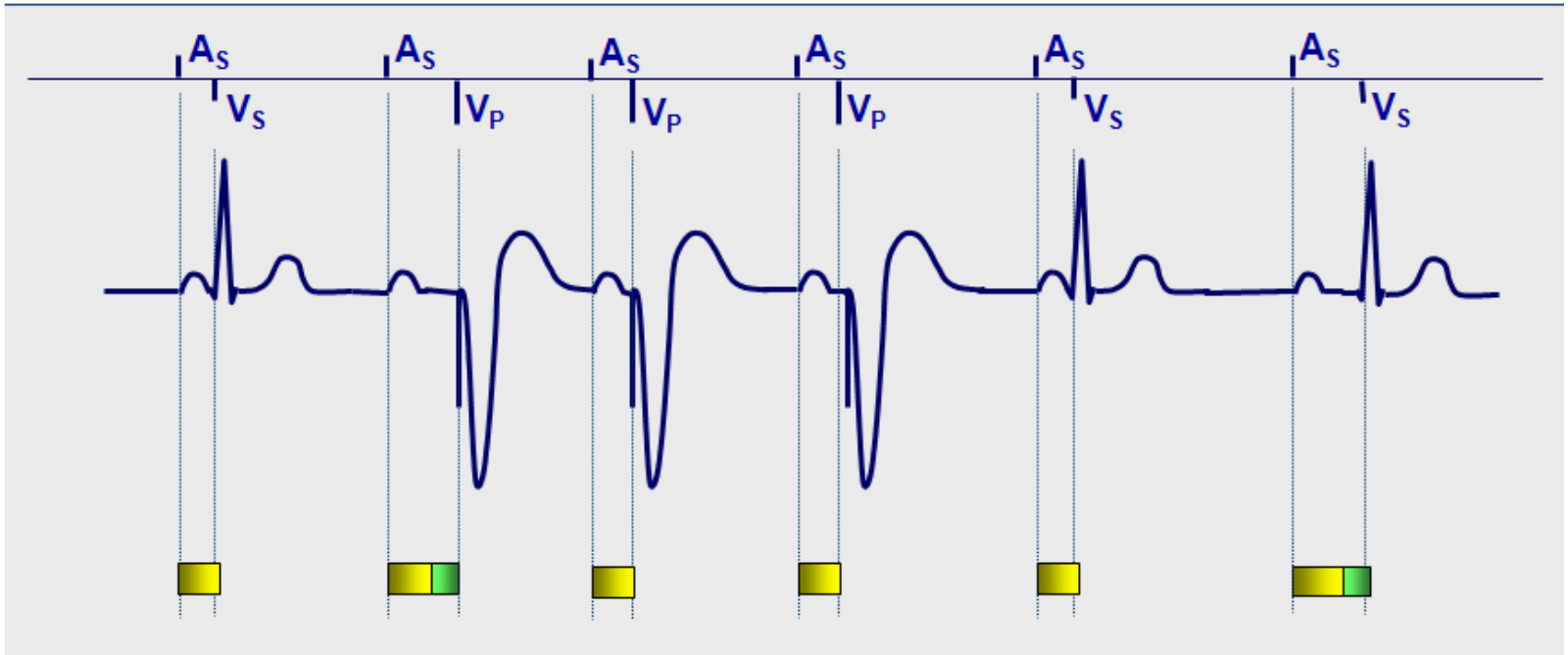
- Comparison of two algorithms for the reduction of ventricular pacing percentage: **IRS^{plus}** and **VpS**
- **Primary endpoint**
  - Right ventricular pacing percentage (Vp%)
- **Secondary endpoints**
  - Long term average AV interval (LTAV)
  - Number of AF/AT episodes
  - AF burden

IRSplus

- Intrinsic Rythm Support plus algorithm embeds:
  - AV Hysteresis
    - AV delay is increased up to 400 ms following an spontaneous ventricular event.
  - AV hysteresis Scan
    - Every 180 consecutive ventricular pacing cycles the AV delay is increased up to 400 ms. The extension is kept for 5 ventricular cycles.
  - Repetitive AV hysteresis
    - After each spontaneous ventricular event the AV delay is extended up to 400 ms. The extension is kept for 5 ventricular cycles.

AV Hysteresis

AV delay is increased up to 400 ms following an spontaneous ventricular event.



AV hysteresis scan

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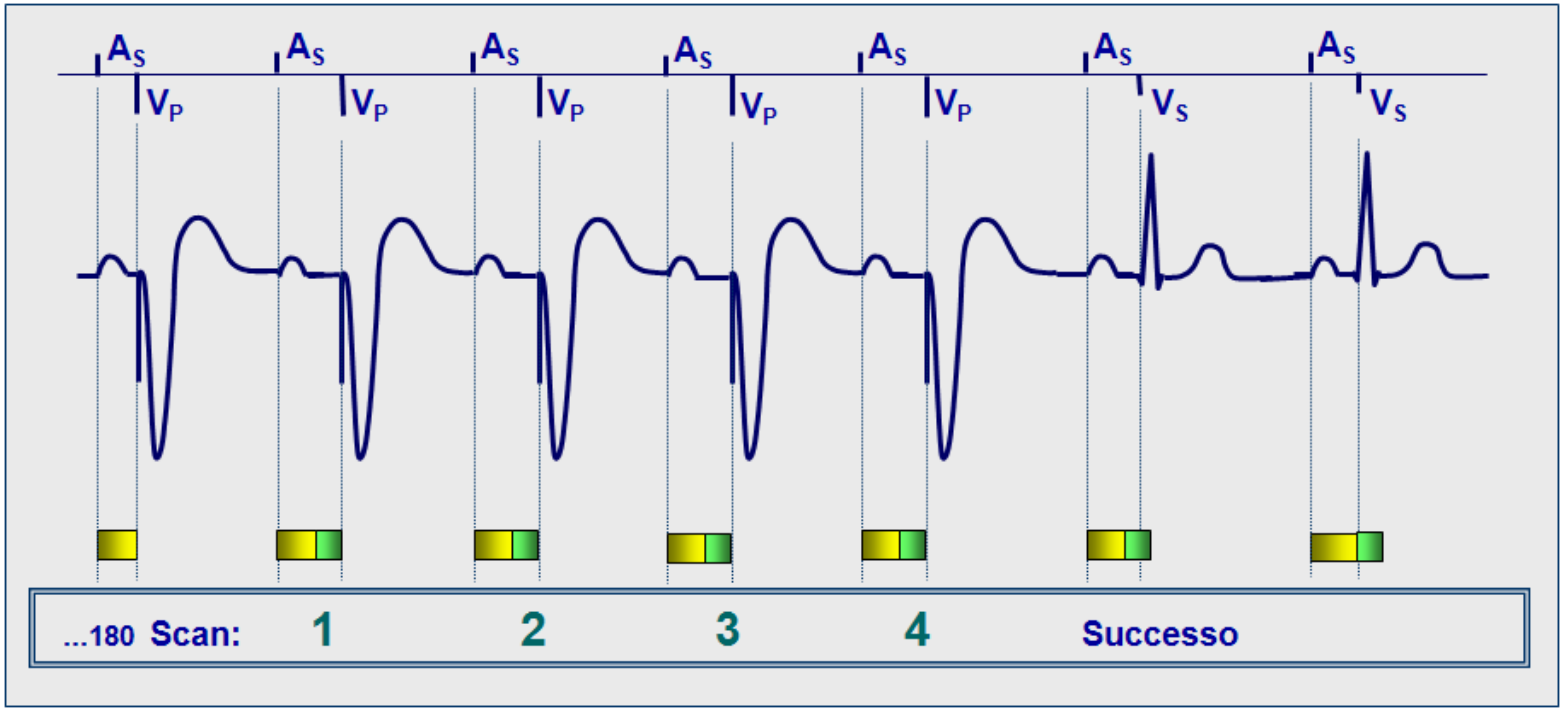
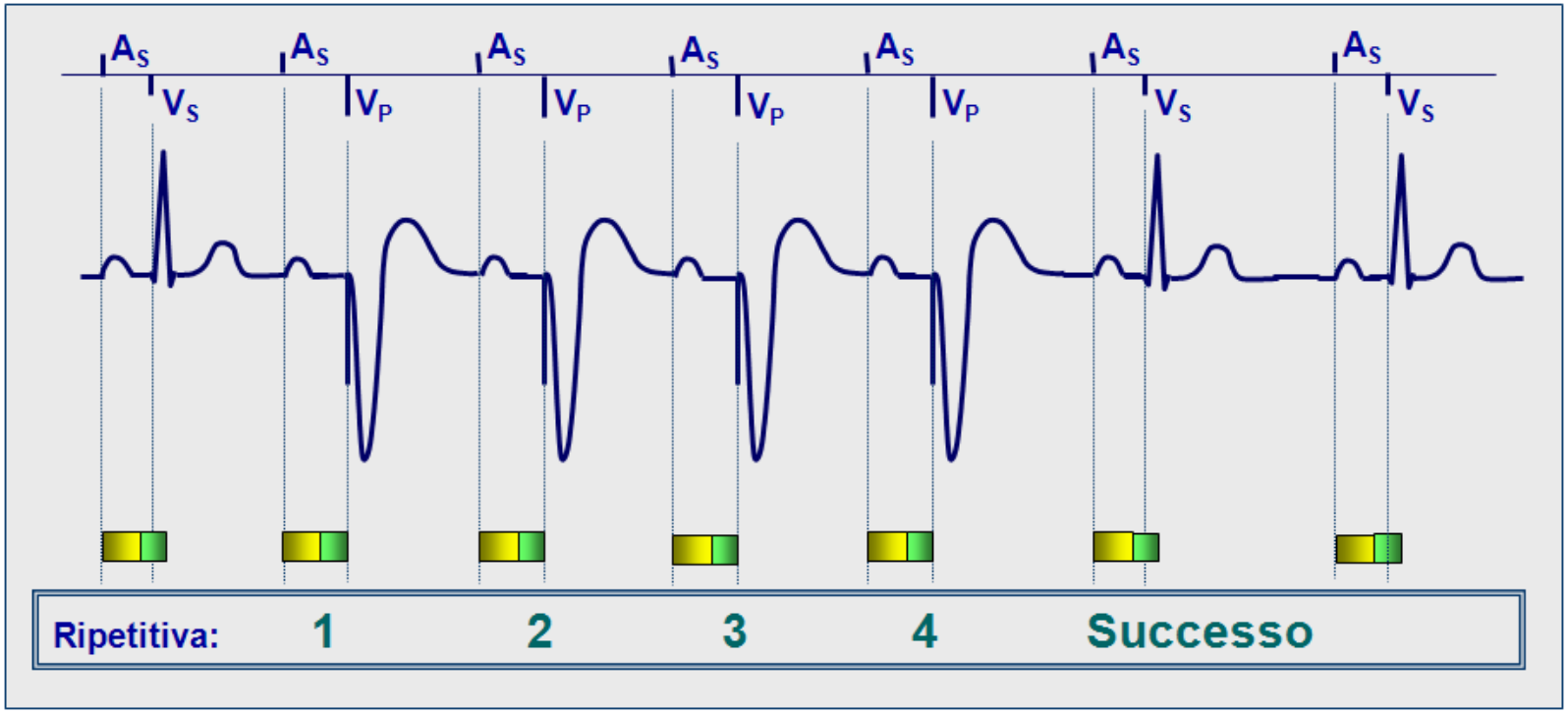
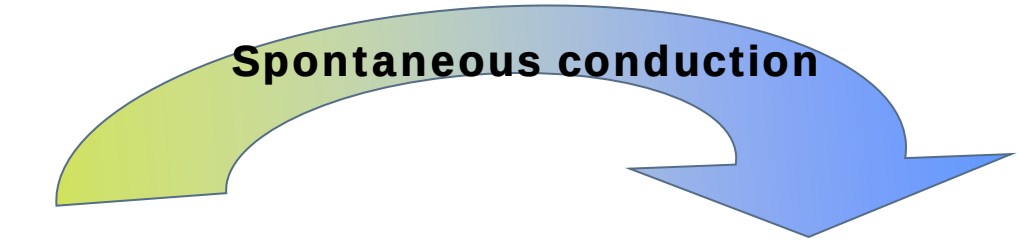


Repetitive AV hysteresis

After each spontaneous ventricular event the AV delay is extended up to 400 ms.



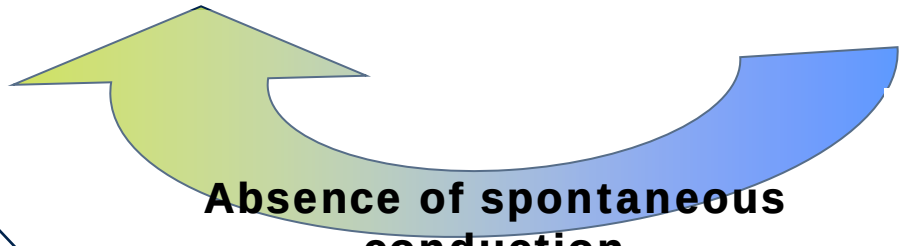
Vp Suppression



DDD(R)

ADI(R)

Atrial Tachycardia



Atrial tachycardia

Mode switch DDI(R)

Vp Suppression

Continuity Test:

- **1 single Vs**
- **Intelligent Search[1] with AV@450ms**

DDD(R)

DDD(R) -> ADI(R)

Continuity test Vs

AV Delay @ 450ms

X* / 8 consecutive Vs

ADI(R)

ADI(R) -> DDD(R)

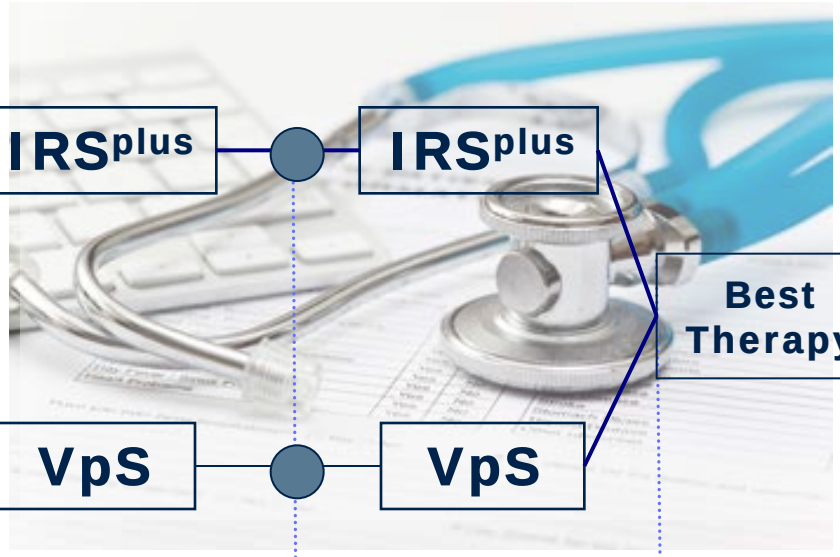
- 2 seconds without any Vs(OR)
- 2 consecutive cycles without any Vs (OR)
- X**/8 without any Vs

[1] Intelligent search: 30 sec > 1 min > 2 min > 4 min > .... > 128 min > 20 h

* Programmable [2,3,4,5,**6**,7,8]; ** Programmable [1,2,**3**,4]

ADI(R) to DDD(R): 15 switches per hour permanently switches to DDD(R) until 24:00 h of the same day

Study design



Group A*

VpS → IRSplus → IRSplus

RUN-IN mode → R → 1:1

(VpS/IRSplus) **OFF**

IRSplus → VpS → VpS → Best Therapy

Group B*

Run-in | 6 months | 6 months | 6 months

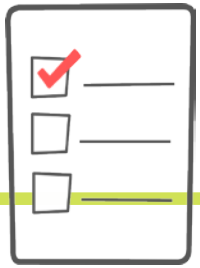
Enrollment | Randomization | Crossover | Closure visit | Last Echo visit

Study design

- 230 patients
- Patients subgroups according to their AV conduction

SAV \ PAV	< 300ms	≥ 300ms
< 200ms	Subrgroup 1	Subgroup 2
≥ 200ms	Subgroup 3	Subgroup 4

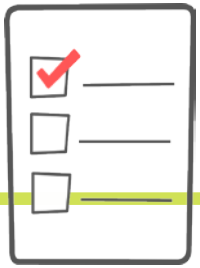
Enrollment criteria



Main inclusion criteria

- Subject with indication of dual chamber pacemaker due to Sinus Node Dysfunction;
- Subjects with a dual chamber pacemaker already implanted within six months from enrollment
- Ventricular pacing percentage ≤ 40% as demonstrated by device statistics
- RV lead in the apical position;

Enrollment criteria

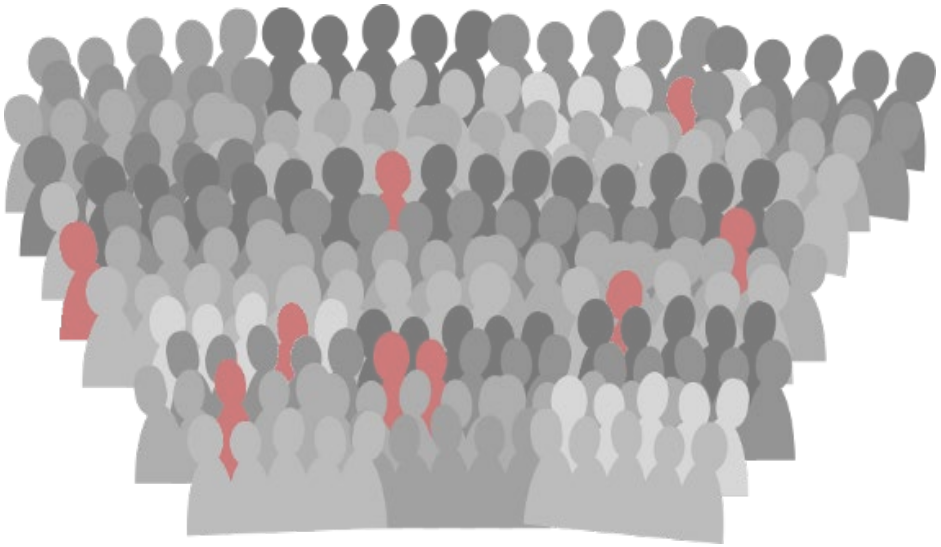


Main exclusion criteria

- Permanent or paroxysmal AV block ≥ II;
- Permanent AF/Afl;
- Device Replacement;

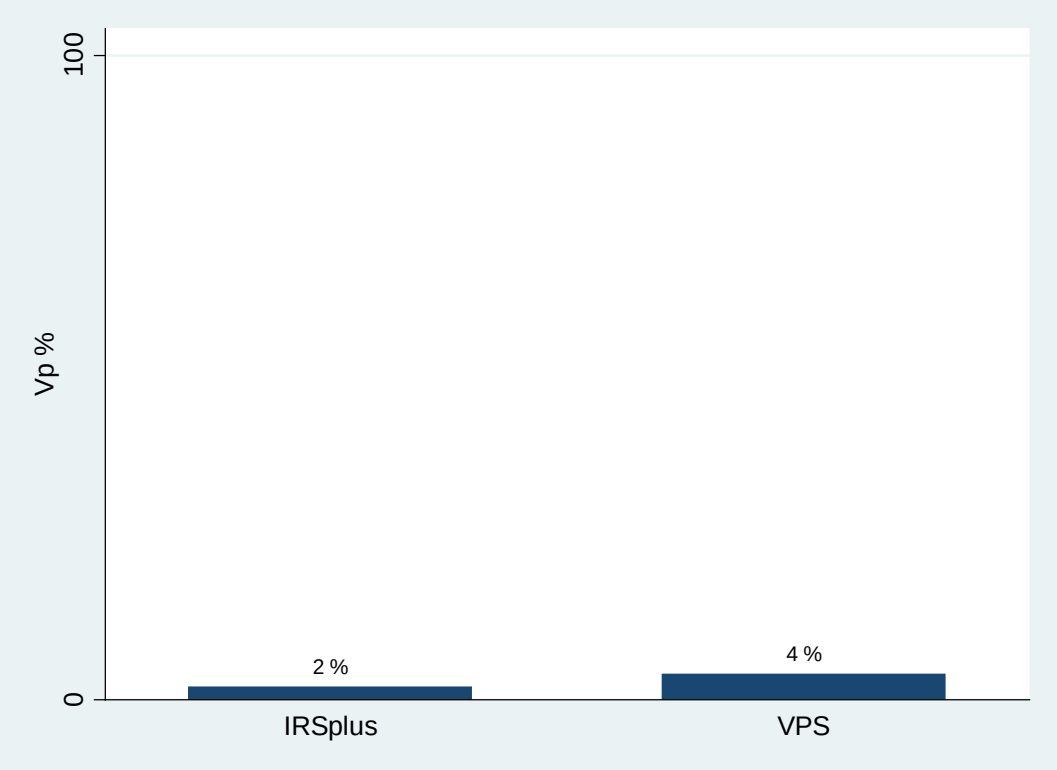
Enrolled patients

- 230 patients have been enrolled on October 3rd, 2013



Ventricular pacing after 6 months
Parallel comparison

Both algorithms achieved to keep the ventricular pacing percentage below 4%.



2 (0 - 11) %

4 (0 - 25) %

Timeline

May 2014

Data completed for parallel comparison VPs / IRSplus

December 2014

Data completed for intra-patient comparison VPs / IRS^{plus}

May 2015

Last Follow-Up