



# **Wearable cardioverter-defibrillator to reduce the transient risk of sudden cardiac death in coronary artery disease**

Claude Elayi, Julia Erath-Honold, Reza Jabbari, François Roubille, Johanne Silvain, Sergio Barra, Rui Providência, Mario Njeim, Kumar Narayanan, Jean-Claude Deharo, et al.

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## Wearable cardioverter-defibrillator to reduce the transient risk of sudden cardiac death in coronary artery disease

In a recent issue of *EP Europace*, Kalarus *et al.*<sup>1</sup> have published a consensus opinion titled 'Cardiac arrhythmias in the emergency settings of acute coronary syndrome and revascularization: a European Heart Rhythm Association (EHRA) consensus document'. This opinion was endorsed by the European Association of Percutaneous Cardiovascular Interventions (EAPCI) and European Acute Cardiovascular Care Association (ACCA).

However, the authors' recommendation regarding the use of the wearable cardioverter-defibrillator (WCD) post-myocardial infarction (MI) is 'non-indicated', which contradicts established guidelines. The most recent 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death (SCD) for instance gave a Class IIb recommendation for primary prevention post-MI,<sup>2</sup> similar to the 2017 American guidelines' recommendation.

It seems that Kalarus *et al.* mostly considered the non-significant primary endpoint (arrhythmic death) of the VEST trial to justify their recommendation on the use of a WCD, which is to date the only randomized controlled trial with WCD.<sup>3</sup> Even though the primary endpoint in the VEST trial did not reach statistical significance, the primary endpoint of this trial must be interpreted with caution for several reasons that include: a major lack of power (64% of patients assigned to the WCD group were not wearing the wearable cardioverter-defibrillator at the time of death, which obviously preclude any defibrillation therapy); the primary endpoint was a suboptimal, clinically adjudicated, surrogate for arrhythmic death that included many non-arrhythmic deaths not amenable to defibrillation therapy by WCD; a nominal statistically significant reduction of all-cause mortality with the WCD, a hard endpoint non-subject to misclassifications; and an on-treatment analysis that demonstrated a statistically significant reduction in SCD, non-sudden cardiac mortality and total mortality.<sup>3</sup> In addition, the evaluation of the safety and efficacy of any therapy

should take into account all available evidence, which included several other WCD studies demonstrating the WCD's efficacy to reduce SCD in real life.<sup>4</sup> These data, albeit limited by their non-randomized nature, have the major advantage of not being subject to the clinical equipoise of the VEST trial, and probably accounted for a much higher wear time of the WCD than in the VEST trial (22–23 h a day compared to <15 h daily in VEST).<sup>5</sup> Proper patient education seems of paramount importance to ensure optimal efficacy of the device, in addition to a close follow-up through the LifeVest Network remote monitoring (not provided in VEST). Finally, there are currently no alternatives to the WCD in reducing the transient risk of sudden arrhythmic death after MI.

In the editorial that accompanied the VEST trial,<sup>5</sup> the last sentence reads as follows: 'In the context of a particularly motivated patient who is at high risk, we would still offer the WCD'. Overall, we feel that the authors should at least be more cautious in making their recommendation of 'non-indicated' for the use of WCD post-MI.

**Conflict of interest:** Johanne Silvain reports during the past 2 years the following disclosures: Consulting Fees or Lecture Fees or Travel Support from Abbott Medical France SAS, AstraZeneca, Bayer HealthCare SAS, Boehringer Ingelheim France, CSL Behring SA, Gilead Science, Sanofi-Aventis France, Terumo France SAS, Zoll and is a Stockholder of Pharmaseeds. Eloi Marijon is consultant for Zoll and Principal Investigator of the Wearit-FR Study.

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