

Effect of Sildenafil on Clinical Outcomes in Patients with Corrected Valvular Heart Disease and Residual Pulmonary Hypertension.

The **S**ildenafil for **I**mproving **O**utcomes after **V**alvular **C**orrection (SIOVAC) Trial.

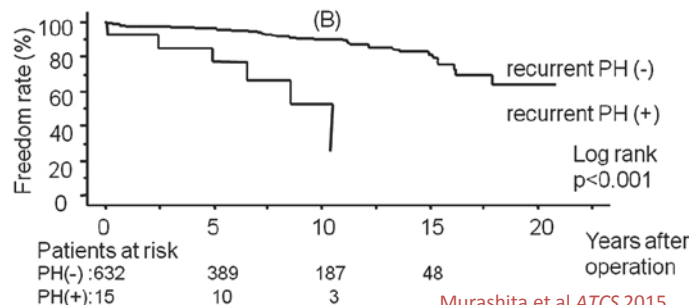
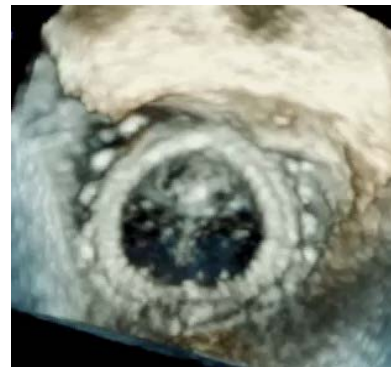
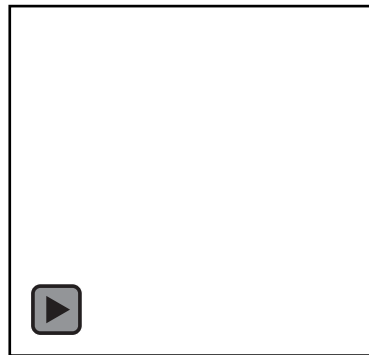
Javier Bermejo, on behalf of the SIOVAC investigators

Declaration of interest

- I have nothing to declare

Background

- ✓ Valvular disease is considered the next cardiac epidemic
- ✓ The only established treatment is repair or replacement of the valve surgically or percutaneously
- ✓ But symptoms often remain or reappear in the long-term.
- ✓ Residual pulmonary hypertension (PH) is an important risk factor for death and disability after successful correction of the valvular lesion.



Murashita et al ATCS 2015

Interest

- Sildenafil is typically used for erectile dysfunction, but has proved to be useful for treating particular types of PH.
- Chronic treatment with sildenafil has never been tested in this particular cause of PH.

Purpose

- To determine whether chronic treatment with sildenafil improves clinical outcomes in patients with successfully corrected valvular heart disease & residual PH.

- Design

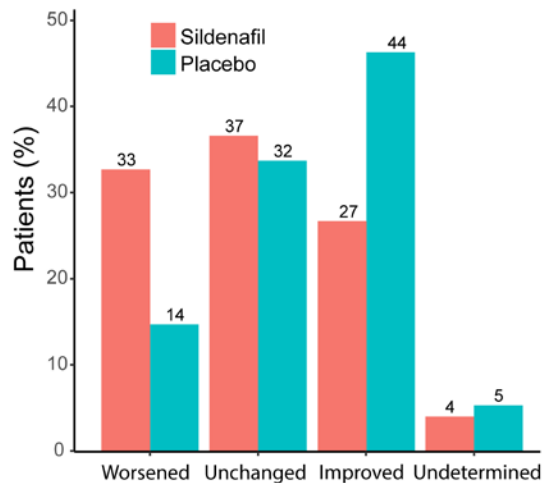
- Multicenter, double-blind, placebo-controlled, parallel-group, randomized clinical trial. 18 tertiary public hospitals in Spain.

- Methods

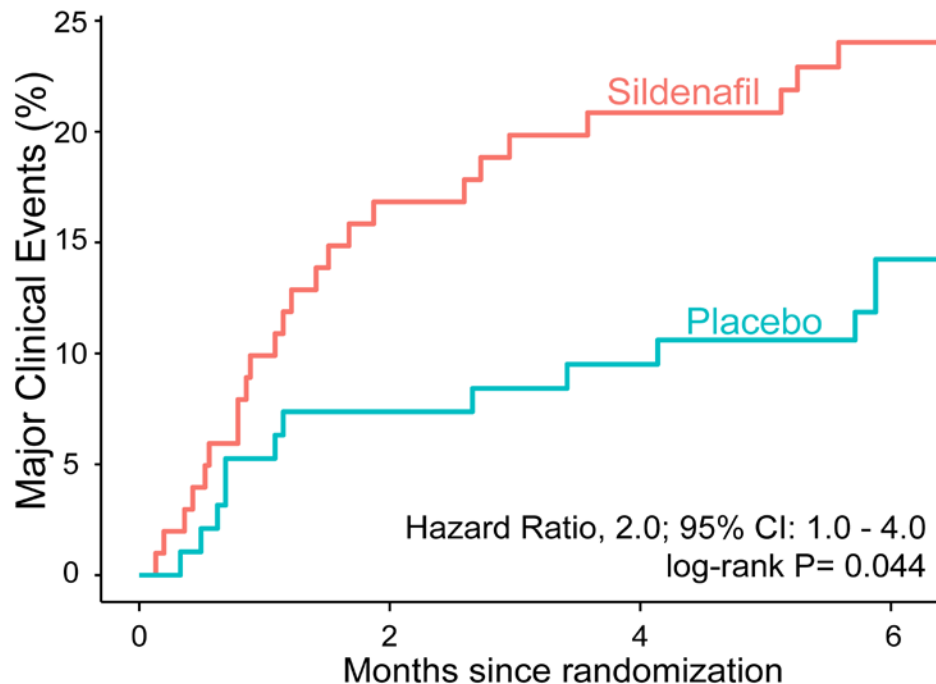
- 200 patients randomized to blindly receive either sildenafil (40 mg t.i.d.) or placebo during 6 months.
- PH confirmed by cardiac catheterization.
- Clinical, laboratory and imaging.
- Primary endpoint: The Composite Clinical Score combining different aspects of clinical outcomes.

Main Results

Clinical Status



Clinical Outcomes



Conclusions

- ✓ Treatment with oral sildenafil 40 mg thrice a day in patients with residual PH after successful correction of VHD is associated to unfavorable clinical outcomes as compared to placebo.
- ✓ Off-label indication of sildenafil in patients with LHD-PH due to valvular disease should be discouraged.

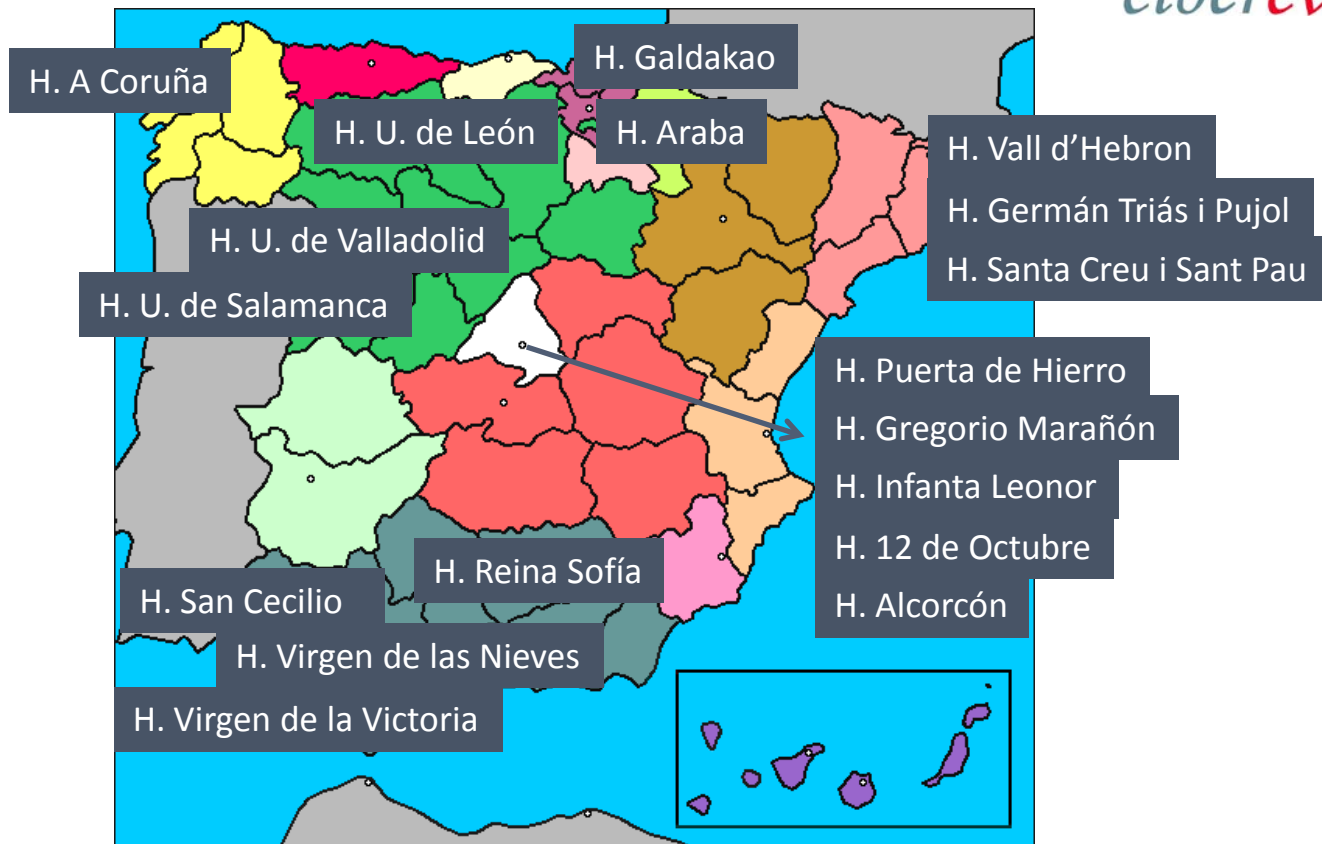
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- Javier Bermejo
- Raquel Yotti
- Francisco Fernández-Avilés

Adjudication and DSMB:

- José A. García-Robles
- Joaquín Alonso
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- Funded by the Spanish Government
- Coordinated by the Spanish network Center for Cardiovascular Research (CIBERCV)



The SIOVAC Trial