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

The Sildenafil for Improving Outcomes after Valvular Correction (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.

Murashtia 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

<table>
<thead>
<tr>
<th>Status</th>
<th>Sildenafil</th>
<th>Placebo</th>
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</thead>
<tbody>
<tr>
<td>Worsened</td>
<td>33</td>
<td>14</td>
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<tr>
<td>Unchanged</td>
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<td>32</td>
</tr>
<tr>
<td>Undetermined</td>
<td>27</td>
<td>27</td>
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</table>

Clinical Outcomes

Hazard Ratio, 2.0; 95% CI: 1.0 - 4.0
log-rank P = 0.044
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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- Funded by the Spanish Government
- Coordinated by the Spanish network Center for Cardiovascular Research (CIBERCV)

The SIOVAC Trial