PFO CLOSURE META-ANALYSIS

"Meta-analysis comparing patent foramen ovale (PFO) closure versus medical therapy to prevent recurrent cryptogenic stroke" as published in the American Journal of Cardiology

Meta-analysis of five randomized controlled trials (RCTs) found PFO closure plus medical management significantly reduces the risk of recurrent stroke compared to medical management alone.¹

<table>
<thead>
<tr>
<th>Stroke events</th>
<th>Closure (N = 1829)</th>
<th>Medical (N = 1611)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>37 (2%)</td>
<td>72 (4.5%)</td>
</tr>
</tbody>
</table>

(\(p = .03\))

<table>
<thead>
<tr>
<th>Major bleeding</th>
<th>Closure (N = 1760)</th>
<th>Medical (N = 1523)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No increased risk of major bleeding with PFO closure¹</td>
<td>24 (1.4%)</td>
<td>19 (1.2%)</td>
</tr>
</tbody>
</table>

(\(p = .93\))

<table>
<thead>
<tr>
<th>Atrial fibrillation (AF)</th>
<th>Closure (N = 1784)</th>
<th>Medical (N = 1607)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased risk of AF with PFO closure¹</td>
<td>76 (4.3%)*</td>
<td>12 (.7%)*</td>
</tr>
</tbody>
</table>

71% (54 / 76) of AF events were considered transient¹

58% Relative recurrent stroke risk reduction with PFO closure plus medical therapy versus medical therapy alone¹

* Newly detected AF.
3,440 Patients
- Cryptogenic stroke† and PFO‡
- Mean age range: 43–50
- Mean follow-up: 4.1 years

1,829 PFO closure group
- Devices varied
- Medical therapy regimen: Varied per study — Antiplatelet, anticoagulation or both

1,611 Medical therapy group
- Medical therapy regimen: Varied per study — Antiplatelet, anticoagulation or both

† Variable rates of cardiovascular risk factors.
‡ Variable rates of high-risk PFO features.


INDICATIONS FOR USE IN AUSTRALIA, CANADA AND EUROPE:
The GORE® CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of atrial septal defects (ASDs), such as ostium secundum and patent foramen ovale. CONTRAINDICATIONS: The GORE® CARDIOFORM Septal Occluder is contraindicated for use in patients: unable to take anti-platelet or anticoagulant medications such as aspirin, heparin, or warfarin; with anatomy where the GORE® CARDIOFORM Septal Occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins; with active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement; with known intracardiac thrombi. Refer to Instructions for Use at goremedical.com for a complete description of all warnings, precautions and adverse events.

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