RACE II 2010

NCT00392613

1 Treatments

Studied treatment  lenient rate control (target resting HR <110 bpm)

Control treatment  strict rate control (target resting HR <80 bpm, and <110 bpm with moderate exercise)

HR control was achieved with the use of beta-blockers (45%), non-dihydropyridine calcium-channel blockers (6%) or digoxin (7.2%), or a combination of these

Concomittant treatments  -

Age (yr)    68y

Female (%)  35.4%

Rate-control targets achieved  97.7% / 67%

Resting heart-rate target achieved  97.7% / 75.2%

Exercise heart-rate target achieved  - / 72.6%

2 Patients

Patients  patients with permanent atrial fibrillation

Inclusion criteria  permanent atrial fibrillation for up to 12 months, age of 80 years or younger, mean resting heart rate above 80 beats per minute, and current use of oral anticoagulation therapy (or aspirin, if no risk factors for thromboembolic complications were present)

Exclusion criteria  -

heart failure  34.8% (NYHA 2 3)

Use of cement  -

Duration of permanent atrial fibrillation  3 mo (median)

Duration of any atrial fibrillation  18 mo (median)

CHADS2 score 3-6  13.4%

CHADS2 score 2  25.9%

CHADS2 score 0-1  60.7%
Heart rate at rest  96 bpm

Left ventricular ejection fraction  52%

3 Methods
Blinding  open
Design  Parallel groups
Centers  33
Geographical area  the Netherlands
Sizes  311/303

4 Results

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>T1</th>
<th>T0</th>
<th>d</th>
<th>95% CI</th>
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<tbody>
<tr>
<td>death by cardiac arrhythmia</td>
<td>3/311</td>
<td>4/303</td>
<td>0.73</td>
<td>[0.16; 3.29]</td>
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<tr>
<td>combined endpoint</td>
<td>38/311</td>
<td>43/303</td>
<td>0.86</td>
<td>[0.54; 1.38]</td>
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<td>major bleedings</td>
<td>15/311</td>
<td>10/303</td>
<td>1.46</td>
<td>[0.65; 3.31]</td>
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<tr>
<td>CV death</td>
<td>9/311</td>
<td>11/303</td>
<td>0.80</td>
<td>[0.33; 1.95]</td>
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<tr>
<td>stroke/TIA</td>
<td>4/311</td>
<td>11/303</td>
<td>0.35</td>
<td>[0.11; 1.13]</td>
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<tr>
<td>Peripheral embolism</td>
<td>1/311</td>
<td>0/303</td>
<td>2.92</td>
<td>[0.12; 72.03]</td>
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<td>Atrial fibrillation follow-up</td>
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<td>-/303</td>
<td>NA</td>
<td>-</td>
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<tr>
<td>hospitalisations (excluding those for cardioversion)</td>
<td>-/311</td>
<td>-/303</td>
<td>NA</td>
<td>-</td>
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<tr>
<td>death</td>
<td>-/311</td>
<td>-/303</td>
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5 References