Randomized trial of old and new antihypertensive drugs in elderly patients: cardiovascular mortality, and morbidity, the Swedish Trial in Old Patients with Hypertension-2 study (STOP-2 Trial)

STOP-2 Study Group. Lancet 1999;354:1751-6 (Nov 20)

Study Type: POEM
Purpose: Does reducing BP in the elderly with ACE or CCB reduce cardiovascular morbidity/mortality like conventional drugs (diuretics, beta-blockers or both)?

Study Duration: 5 year follow-up, n = 6628 (only 14 patients excluded, NNSFSC = 1)

Patients: ~67% female, ~33% male, mean age 76 yrs, BMI ~ 27, baseline sitting BP ~194/98, baseline standing BP ~ 187/101

History: ~3% MI , ~8% angina, ~9% smokers, ~2% CHF, ~4% stroke, ~5% atrial fib, ~5% other CV disease, ~11% diabetic

Trial Design: multicenter in Sweden (312 centers), randomized, prospective, open, intention-to-treat

Drugs:
- Conventional = atenolol 50 mg, metoprolol 100 mg, pindolol 5 mg, HCTZ 25 mg + amiloride
- ACE group = enalapril 10 mg or lisinopril 10 mg daily (could add a HCTZ 12.5-25 mg daily)
- CCB group = felodipine 2.5 mg or isradipine 2.5 mg daily (could add beta-blocker )

Inclusion: age 70-84, BP > 180 systolic, > 105 diastolic or both, see STOP-1

Exclusion: none noted

1. Are the results valid?
- randomized? yes
- double-blinded? no
- placebo-controlled? no
- placebo run in ? no
- patient accountability? yes
- were groups similar? yes

2. What were the results?

<table>
<thead>
<tr>
<th>Primary endpoints</th>
<th>Conventional</th>
<th>ACEI</th>
<th>CCB</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular mortality</td>
<td>none</td>
<td>none</td>
<td>none</td>
<td>NS</td>
</tr>
<tr>
<td>All MI</td>
<td>favored</td>
<td>favored</td>
<td>NS (p = 0.018 ACE vs CCB)</td>
<td></td>
</tr>
<tr>
<td>All stroke</td>
<td>favored</td>
<td>favored</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>All major CV events</td>
<td>none</td>
<td>favored</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Total mortality</td>
<td>none</td>
<td>none</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Frequency of diabetes</td>
<td>favored</td>
<td>favored</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Frequency of atrial fibr</td>
<td>favored</td>
<td></td>
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<td></td>
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<tr>
<td>Frequency of CHF</td>
<td></td>
<td></td>
<td>.025</td>
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</tbody>
</table>

Adverse Events
- Conventional group caused more shortness of breath (12%), cold hands and feet (9%)
- ACEI group caused more cough (30%)
- CCB caused more ankle edema (26%) and headache (10%)
- All groups increased dizziness ~28%

3. Will the results help me?
- BP reduction from mean supine of 198/98 to 158/81 in all groups no matter the drug after 54 months
- ACE inhibitors were favored most but not significant, except for CHF
- there was similar efficacy of CCB as diuretics and beta-blockers for prevention of CV events
- frequency of MI and CHF favored ACEI over CCB
- there is concern for falls in all groups
- From editorial: 46% were taking more than one agent, only 66% were still taking the ones allocated in the study, therefore is it the drug or the reduction in pressure?