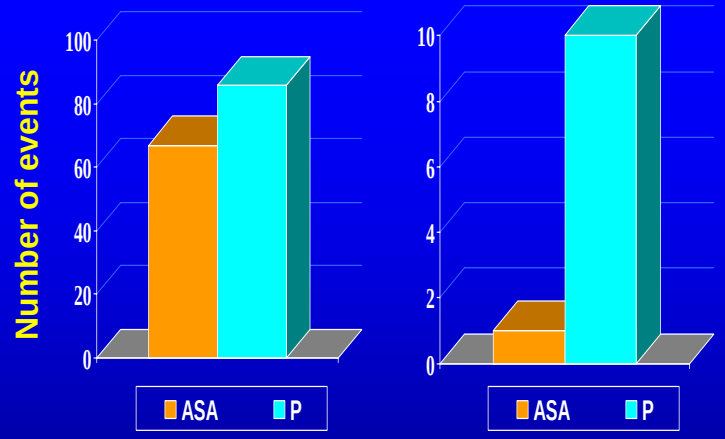
JPAD Trial

The Japanese Primary Prevention of Atherosclerosis with Aspirin for Diabetes

BACKGROUND: Diabetes is a major risk factor atherosclerotic events. The evidence of cardiovascular benefit from aspirin as primary prevention tool in patient with diabetes is lacking. **PURPOSE:** To examine the efficacy of low dose aspirin therapy for the primary prevention of CV events in type 2 diabetes. **DESIGN:** Randomized, multicenter, open-label blinded-endpoint study of 2,539 patients (age between 30 and 85 years) with type 2 diabetes to: 81 or 100 mg daily aspirin (1,262)(ASA) or placebo (n =1,277)(P). Median follow-up = 4.4 years.

Comparison of Aspirin vs. Placebo



Atherosclerotic CV event

Fatal coronary and cerebrovascular event

Primary Endpoint:

Composite fatal and nonfatal atherosclerotic CV events: MI, UA, Stroke, TIA and PVD.

Secondary Endpoint:

Individual and combination of components out the primary endpoint and all-cause mortality.

Results

Primary Outcome

ASA vs. P: HR (95% CI): 0.80 (0.58, 1.10), p =0.16.

Fatal coronary and cerebrovascular events

ASA vs. P: HR (95% CI): 0.1 (0.01 – 0.79), p = 0.0037.

Subgroup (N=1363, age > 65 years) analysis

Primary outcome (ASA vs. P): RR (95% CI) : 0.68 (0.46 – 0.998), p = 0.047.

Adverse events

Hemorrhagic stroke and severe GI bleeding: 10 (ASA) vs. 7 (P), NS.

Conclusion: Aspirin reduced the risk of atherosclerotic event in type 2 diabetic patients aged 65 yrs and older but not for the overall study patient population. Aspirin reduced the risk of coronary and cerebrovascular death.

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