

AHA 2020 - Epanova muddies Vascepa's waters some more



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Astrazeneca's Epanova, the fish oil rival to Amarin's approved Vascepa, had been forgotten after [its massive Strength trial was terminated for futility](#). But it still has implications given that Vascepa's mechanism remains unclear. Over the weekend an American Heart Association late-breaker revealed Strength's analysis for the first time, laying bare the conundrum. MACE, the composite primary endpoint, had been recorded in 12.0% of Epanova subjects versus 12.2% for control ($p=0.84$), and there was "no correlation at all" between the levels of eicosapentaenoic acid (EPA), which Epanova increased by 269% - or of docosahexanoic acid (DHA) - and outcome, said Cleveland Clinic's Dr Michael Lincoff, Strength's principal investigator. Amarin bulls have argued that Vascepa's activity is due to it being a pure EPA, whereas Epanova additionally contains DHA, which can "mask" EPA's benefits, but Strength does not support this. Also, Strength used a neutral corn oil placebo, possibly reigniting debate around the Amarin trial, which compared Vascepa against a mineral oil that might have worsened control subjects' outcomes. There were increases in adverse events with Epanova, findings that cast "uncertainty of whether there is a net benefit or harm with any of the Omega-3 fatty acid preparations", said Dr Lincoff.

Primary Endpoint Components and All-Cause Death	Omega-3 CA (N=6539) % of patients	Corn Oil (N=6539) % of patients	HR (95% CI)	P-value
Primary composite MACE	12.0	12.2	0.99 (0.90, 1.09)	0.84
CV Death	3.5	3.2	1.09 (0.90, 1.31)	0.37
Non-fatal MI	3.3	3.5	0.97 (0.81, 1.17)	0.77
Non-fatal stroke	2.2	1.9	1.14 (0.90, 1.45)	0.28
Coronary revascularization	6.3	6.7	0.94 (0.83, 1.08)	0.41
Unstable angina hospitalization	1.3	1.6	0.84 (0.63, 1.12)	0.23
All-cause death	5.7	5.1	1.13 (0.97, 1.31)	0.11

Results: Administration of omega-2 carboxylic acid 4g daily compared with corn oil placebo did not reduce the incidence of major adverse cardiovascular events, despite a 269% increase in plasma EPA levels. There was an increased risk of atrial fibrillation with Omega- 3 CA (HR=1.69, CI 1.29-2.21).

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