

(Circulation. 2008;118:S_855.)

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Chronic Ischemic Heart Disease

Abstract 4267: PA32520 (Single-Tablet of Enteric-Coated Aspirin 325 mg + Immediate-Release Omeprazole 20 mg): Aspirin Therapy Combining Greater Thromboxane Suppression and Lower Upper Gastrointestinal Damage

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Background: Upper gastrointestinal (UGI) tolerability and safety concerns with aspirin (ASA) have prompted physicians to recommend low-dose ASA. However, low-dose ASA for secondary CV prevention may not have equivalent antiplatelet effects to high-dose ASA, as demonstrated in recent studies. High-dose ASA in combination with proton pump inhibitors may provide a reduction in UGI damage and greater thromboxane suppression.

Methods: In a randomized, single-blinded controlled trial, gastroduodenal mucosal changes using an established methodology (Lanza score) and urinary 11-dehydrothromboxane (TX)_{B2} were determined in 80 healthy subjects (mean ages 57–58 yrs) with no endoscopic evidence of gastroduodenal mucosal damage (Lanza score 0) who were treated with a daily dose of PA32520 or 81 mg enteric-coated (EC-) ASA. The primary endpoint was Lanza score 3 or 4 (>20 erosions/hemorrhages or ulcers) at Day 28. Study assessments were conducted at baseline, Day 14, and Day 28. In a separate study (n=80), the effect of PA32520 vs. 325 mg EC-ASA alone on gastroduodenal mucosal changes was studied.

Results: PA32520 was associated with a greater reduction in 11-dehydro-TXB₂ compared to EC-ASA 81 mg (–75% vs –64% mean percentage change from baseline, respectively; p=0.008) and 50%–84% less gastroduodenal mucosal damage than EC-ASA alone (Table).

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Conclusions: Treatment with EC-ASA alone is associated with a high prevalence of UGI damage that is ameliorated by PA32520 therapy. Compared to EC-ASA 81 mg, PA32520 produces superior inhibition of in vivo thromboxane generation. PA32520 may provide an important option for all patients treated with ASA.

Endpoint	Study 1			Study 2		
	PA32520 N=41	EC-ASA 81mg N=39	p-Value	PA32520 N=40	EC-ASA 325mg N=40	p-Value
Gastric and duodenal Lanza 3 or 4 Scores Day 14	4 (9.8%)	8 (20.5%)	0.22	1 (2.5%)	17 (42.5%)	<0.001
Gastric and duodenal Lanza 3 or 4 Scores Day 28*	4 (9.8%)	8 (20.5%)	0.22	3 (7.5%)	19 (47.5%)	<0.001

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