Hospital Budget Impact of Switching to an Alternative Aspirin Formulation with Improved GI Safety for Treatment of Acute Cardiovascular Events

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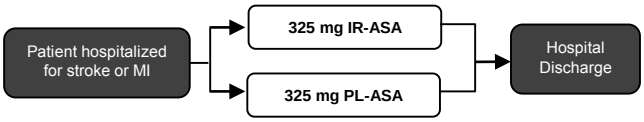
Background and Objective

- Every year about 1.6 million patients will experience either a myocardial infarction (MI) or a stroke in the United States [1]
- Aspirin is a central part of acute MI and stroke treatment protocols and immediate-release aspirin (IR-ASA) is most often used to achieve fast and predictable platelet inhibition
- Aspirin use in the acute setting has a significant risk for gastrointestinal toxicity and upper gastrointestinal bleeding (UGIB) that is not reduced by the use of enteric-coated aspirin (EC-ASA) [2]
- Accordingly, there is a clear unmet need for a novel aspirin formulation that delivers fast and predictable antiplatelet efficacy with reduced risk of GI toxicity and UGIB
- Vazalore™ (PLx Pharma, Sparta, NJ) is a novel, pharmaceutical lipid-aspirin complex formulation (PL-ASA) administered in liquid-filled capsules that has been clinically shown to significantly reduce the risk for stomach ulcers by 70% compared with IR-ASA [3]
- We sought to explore the annual hospital budget impact of utilizing the new PL-ASA with a decreased risk of UGIB, as compared to IR-ASA

Methods

- One-year budget impact model for 500-bed hospital was utilized to quantify the drug costs for aspirin and in-hospital costs for UGIB according to use of IR-ASA or use of PL-ASA, which has a lower risk of UGIB, but higher acquisition cost
- Parameters used in the model were sourced from the Nationwide Inpatient Sample and published literature
- Model uncertainty regarding UGIB rate for PL-ASA was analyzed using a one-way univariate sensitivity analysis
- The relative risk reduction for UGIB of PL-ASA compared with IR-ASA was maxed out at 70% according to the results from a published clinical study with PL-ASA wherein PL-ASA showed 70% reduction in risk for ulcer formation compared to IR-ASA [3]

Figure 1. Model overview

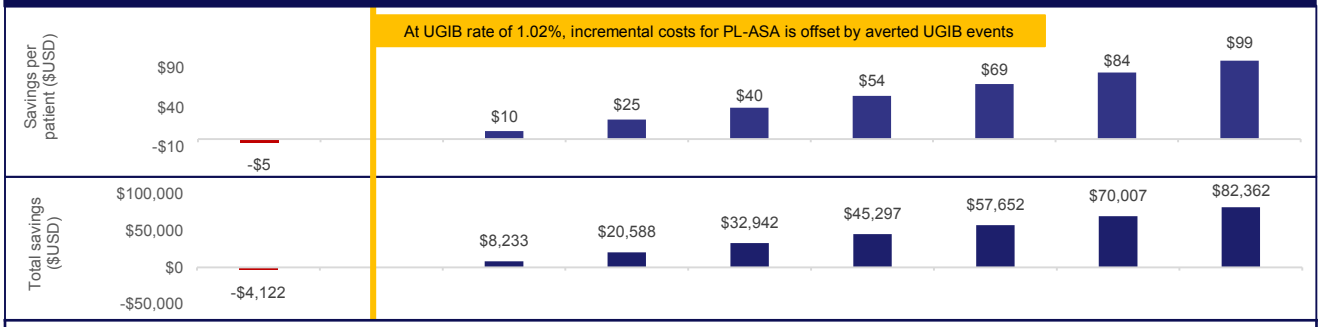


- We propose that 325 mg PL-ASA will cost more but will lower UGIB rates by 0-70%, compared to 325 mg IR-ASA

Table 1. Model parameters

PARAMETER	INPUT	REFERENCE
PATIENT COHORT (N) Annual admissions: MI + Stroke (500-bed hospital)	833	[1,4]
LENGTH OF STAY PER PATIENT (DAYS)	5	[5]
TOTAL ASPIRIN COST PER PATIENT		
325 mg IR-ASA ($0.01/pill x 1 pill daily x 5 days)	$0.05	Assumption
325 mg PL-ASA ($1.00/pill x 1 pill daily x 5 days)	$5.00	Assumption
UGIB RATE		
325 mg IR-ASA	1.05%	[5]
325 mg PL-ASA	0.32% -1.05%	[3]
COST PER UGIB EVENT	$14,120	[5]

Results and Conclusion



Range of absolute UGIB rates with PL-ASA and corresponding relative risk reduction (RRR) compared to IR-ASA

Absolute rate	1.05%	**1.02%**	0.95%	0.84%	0.74%	0.63%	0.53%	0.42%	0.32%
% RRR	0%	**3.34%**	10%	20%	30%	40%	50%	60%	70%

- Aspirin is critical in the acute treatment of myocardial infarction and stroke, but aspirin therapy is also associated with an increased risk of UGIB, a serious and costly complication
- Our model demonstrates that in a 500-bed hospital, the switch to PL-ASA would result in cost savings even if only 1 UGIB case was averted per year
- PL-ASA has potential to be an economically dominant therapy that improves clinical outcomes and reduces the overall costs

Reference [1] Benjamin EJ, Muntner P, Bittencourt MS. Heart disease and stroke statistics-2019 update: A report from the American Heart Association. Circulation. 2019;139(10):e56-28. **[2] De Abajo FJ. Association between aspirin and upper gastrointestinal complications: systematic review of epidemiologic studies. British journal of clinical pharmacology. 2001 Nov 1;52(5):563-71.** [3] Cryer B, Bhatt DL, Lanza FL, Dong JF, Lichtenberger LM, Marathi UK. Low-dose aspirin-induced ulceration is attenuated by aspirin–phosphatidylcholine: a randomized clinical trial. The American journal of gastroenterology. 2011 Feb;106(2):272. **[4] American Hospital Association. Fast Facts on US Hospitals. https://www.aha.org/system/files/2018-02/2018-aha-hospital-fast-facts.pdf. Published 2013. Accessed October 2, 2018.** [5] Rumalla K, Mittal MK. Gastrointestinal bleeding in acute ischemic stroke: a population-based analysis of hospitalizations in the United States. Journal of Stroke and Cerebrovascular Diseases. 2016 Jul 1;25(7):1728-35.