Progress starts with *ONE PATIENT*

Health Economics Article Series

Projected clinical and economic benefits of improved patent foramen ovale testing among cryptogenic stroke patients in the United States[1]

John J. Volpi,[a] Scott E. Kasner,[b] Tjeerd Looman,[c] Giorgia Tiozzo,[c,d] Timon Louwsma,[c,d] Ryan J. Imhoff,[e] and Erik J. Landaas[e]

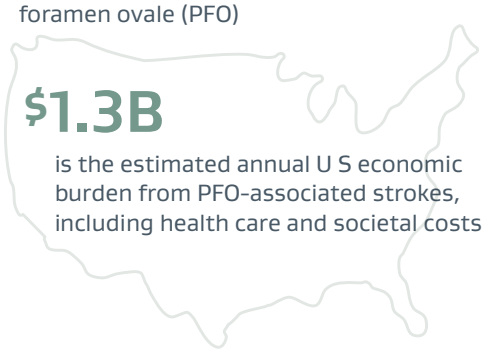
An in-depth analysis of stroke data reveals the significant patient- and budget-related impacts around the treatment of cryptogenic stroke (which occurs without a clear underlying cause), including screening, diagnosis, and device selection.

Current challenge

Unmet need/economic burden

25% to **40%**

of ischemic strokes are cryptogenic, with many potentially linked to undiagnosed patent foramen ovale (PFO)



$1.3B

is the estimated annual U S economic burden from PFO-associated strokes, including health care and societal costs

Low rates of testing

54%

Only 54% of eligible cryptogenic stroke patients currently receive PFO diagnostic testing

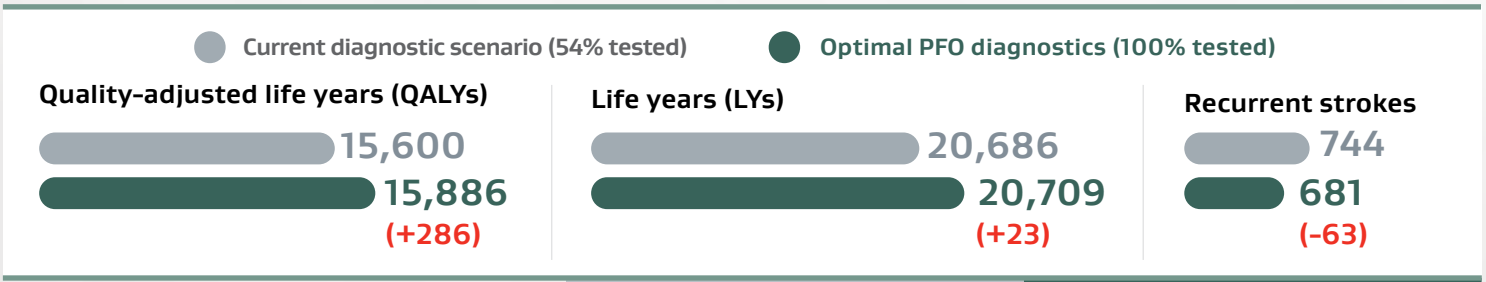
- Limited access to specialized testing
- Patient aversion to invasive procedures
- Clinical and financial benefit uncertainty
- Underuse of diagnostic practices

a. The Houston Methodist Institute for Academic Medicine, Houston, Texas.
b. Department of Neurology, University of Pennsylvania, Philadelphia, Pennsylvania.
c. Asc Academics BV, Groningen, Netherlands.
d. Department of Health Sciences, University Medical Centre Groningen, Groningen, Netherlands.
e. W. L. Gore & Associates, Newark, Delaware.

Increasing guideline-driven diagnostic testing for PFO could reduce costs and improve outcomes

Cost-effectiveness analysis model

Estimated health and economic impact of increasing PFO guideline-based diagnostic testing adherence from 54% to 100% in a simulated cohort of 1,000 patients with a history of cryptogenic stroke (over a lifetime horizon)



	Current diagnostic scenario (54% tested)	Optimal PFO diagnostics (100% tested)
Total costs	$51,219,680	$49,286,081 (-$1,933,599)
Incremental cost-effectiveness ratio (ICER)—cost per QALY	NA	Economically dominant (-$6,770)
ICER—cost per LY	NA	Economically dominant (-$83,321)
Incremental net monetary benefit	NA	$23,355,954

Conclusions

Increasing PFO diagnostic testing from 54% to 100% among cryptogenic stroke patients is **projected to prevent approximately 63 recurrent strokes and save 23 LYs per 1,000 patients.**

Enhanced PFO testing in the model yielded an estimated $1.9 million in savings and 286 QALYs gained, making it a dominant strategy—**improved outcomes at lower costs.**

The model showed screening approximately 4 patients identified 1 PFO for closure and 7 screenings prevented 1 recurrent stroke, **demonstrating strong clinical efficiency.**

By changing the way we look at PFO screening, diagnosis, and treatment, we have the opportunity to reduce PFO-associated stroke costs and potentially improve patient outcomes.

Discover the potential impact of PFO diagnosis and treatment. Access the full publication.

NA, not applicable.

This analysis is intended to provide health care decision-makers with exploratory information on potential economic and health outcomes. It is not a substitute for clinical judgment and does not establish comparative clinical superiority or cost-effectiveness in all settings. Refer to the full publication for complete details on methodology and limitations. Institutions should consult their formulary or payer representatives for guidance on local applicability.

Reference
1. Volpi JJ, Kasner SE, Looman T, et al. Projected clinical and economic benefits of improved patent foramen ovale testing among cryptogenic stroke patients in the United States. *J Med Econ*. 2025;28(1):1137-1150. doi:10.1080/13696998.2025.2535236

Consult Instructions for Use
eifu.goremedical.com

Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. Rx_{Only}

INDICATIONS FOR USE IN THE US: The GORE® CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of the following defects of the atrial septum: ostium secundum atrial septal defects (ASDs); patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke.

CONTRAINDICATIONS: The GORE® CARDIOFORM Septal Occluder is contraindicated for use in patients: unable to take antiplatelet or anticoagulant medications such as aspirin, heparin or warfarin; with anatomy where the GORE® CARDIOFORM Septal Occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins; with active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement; with known intracardiac thrombi.

Products listed may not be available in all markets.

W. L. Gore & Associates, Inc.
goremedical.com

Asia Pacific +65 67332882 **Australia/New Zealand** 1800 680 424 **Europe** 00800 6334 4673
United States Flagstaff, AZ 86004 800 437 8181 928 779 2771