A cost-effectiveness analysis comparing two PFO occluder devices using a Markov model simulation over a 5-year time horizon from a match-adjusted indirect treatment comparison

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INTRODUCTION

Closure of a patent foramen ovale (PFO) has been associated with a reduced risk of recurrent stroke in selected patient populations[1]. In the U.K. National Health Service (NHS), understanding the cost-effectiveness of different PFO occluder devices is crucial for optimal healthcare resource allocation. This study focuses on comparing the cost-effectiveness of two PFO occluder devices: GORE® CARDIOFORM Septal Occluder, made of expanded polytetrafluoroethylene (ePFTE) with a nitinol wire frame, and ABBOTT® AMPLATZER® PFO Occluder, composed of a nitinol wire mesh with polyester fabric.

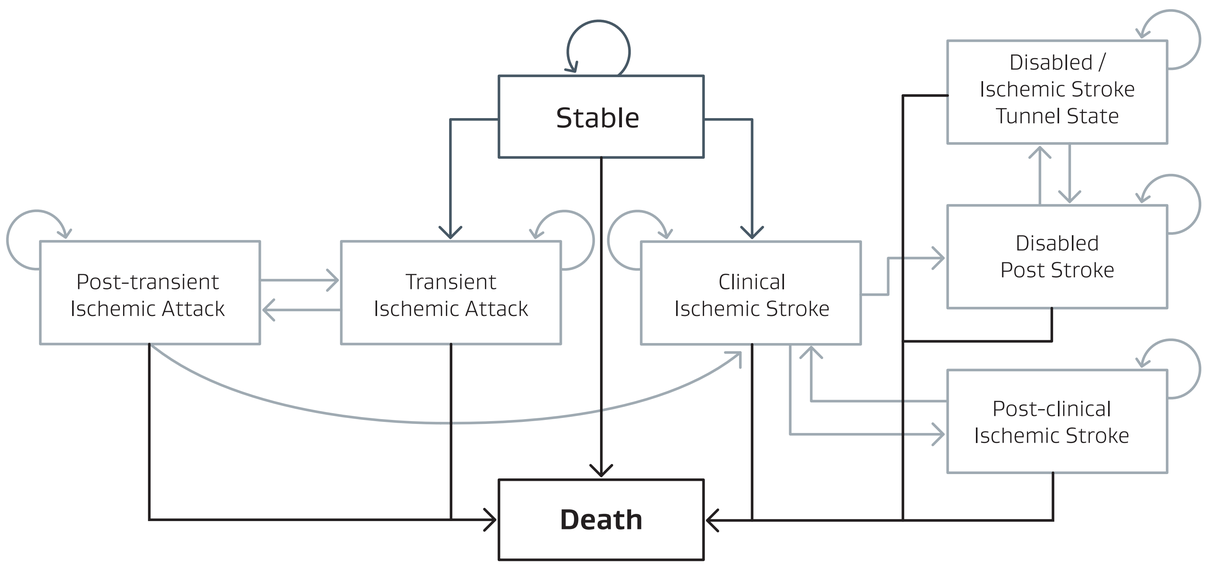
OBJECTIVE

The primary aim of this study is to evaluate and compare the cost-effectiveness of GORE® CARDIOFORM Septal Occluder and ABBOTT® AMPLATZER® PFO Occluder for PFO closure over a 5-year time horizon in the U.K. NHS perspective.

METHOD

A Markov model was developed to simulate the clinical pathways and associated costs for PFO closure using GORE® CARDIOFORM Septal Occluder and ABBOTT® AMPLATZER® PFO Occluder over a 5-year period.

- The model included 8 distinct health states (see image below).
- Transition probabilities between these health states were derived from a match-adjusted indirect treatment comparison (MAIC)[2] of randomized controlled trials (RCTs) evaluating the two devices.
- Costing data were obtained from U.K. national health care tariffs[3-5], covering hospital stays, procedures and follow-up care, and were supplemented with published literature to address data gaps, particularly for long-term follow-up costs and stroke management.

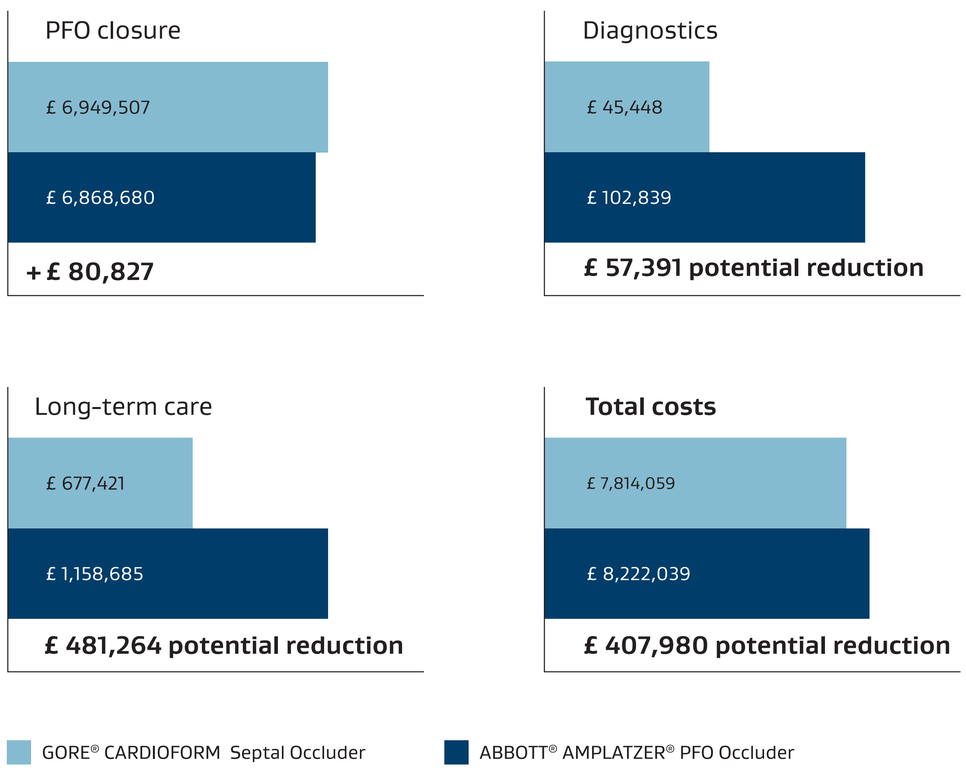


RESULTS*

Specification	GORE® CARDIOFORM Septal Occluder	ABBOTT® AMPLATZER® PFO Occluder	CARDIOFORM Device vs. AMPLATZER Device
Total QALYs	**4068.63**	**4043.98**	**24.66**
Total LYs	**4647.03**	**4646.54**	**0.49**
Total number of strokes	**23.97**	**51.83**	**-27.86**
Total number of days in hospital	**163.59**	**353.72**	**-190.13**

* Results based on a health economic simulation of 1,000 patients.

Cost Category*



* Results based on a health economic simulation of 1,000 patients.

CONCLUSIONS

- The cost-effectiveness analysis showed that the GORE® CARDIOFORM Septal Occluder was a dominant strategy compared to ABBOTT® AMPLATZER® PFO Occluder, as it was both cost-saving and more effective in terms of Quality-Adjusted Life Years (QALYs) gained.
- GORE® CARDIOFORM Septal Occluder was also highly cost-effective across the national U.K. willingness-to-pay threshold of £20,000/QALY, making it an attractive option for clinicians and policymakers within the NHS.
- These findings underscore the importance of incorporating both clinical and economic considerations in the decision-making process for PFO closure treatments, guiding to a more efficient allocation of health care resources.

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