

Cost-Effectiveness of Percutaneous Closure of a Patent Foramen Ovale (PFO) Versus Antiplatelet Therapy after Stroke: A Trial and Model Based Economic Evaluation

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OBJECTIVES

The French randomized open label multi-centre superiority trial CLOSE was conducted at 32 sites in France and two sites in Germany between 2007 and 2016 (French Ministry of Health grant number P060406 - CLOSE ClinicalTrials.gov number, NCT00562289) and demonstrated that patients having experienced cryptogenic stroke and having a patent foramen ovale (PFO) with echocardiographic features representing risk of stroke benefited from PFO closure compared to antiplatelet therapy. This economic analysis determines the cost-effectiveness from the perspective of the French healthcare system of percutaneous PFO closure in combination with antiplatelet therapy (PFOC) versus antiplatelet therapy alone (APT) at a five-year horizon based on the CLOSE trial and at a ten-year horizon using a mixed methods modelling approach.

METHODS

The cost evaluation determined the average cost per patient in both groups at a five-year horizon based on the trial data (€ 2018). Patient resource consummation data was collected in the trial Case Report Forms. Unit costs were collected during the micro-costing observation, from hospital accounts records and from public databases. The comparison of efficacy between the two groups was defined as the proportion of strokes avoided.

The trial-based results were extrapolated to a ten-year horizon using a Markov cohort model comprising four health states (Figure 1). The duration of the model cycle was set at three months and was run from the beginning of year six, using the health states at the end of the follow-up period from the trial data, to the end of year ten. Total costs and incremental cost-effectiveness ratios (ICERs) were calculated. Probabilistic sensitivity analyses using bootstrapping evaluated the robustness of the cost-effectiveness results.

RESULTS

The trial efficacy results have been published elsewhere¹ but in brief a total of 473 patients aged between 16 and 60 years of age having had a recent stroke attributed to PFO, underwent randomisation and were assigned to percutaneous PFO closure plus long-term antiplatelet therapy, or to antiplatelet therapy alone. At a five-year horizon, no strokes occurred among the 238 patients in the PFO closure group and strokes occurred in 14 of the 235 patients in the control group (HR 0.03; CI95% 0 to 0.26). The total cost in both arms at the five-year horizon are shown in Table 1. The average cost of performing a PFO closure estimated using the bottom-up micro-costing method was found to be €4,987 before taking into consideration the cost of hospital stays. The ICER was estimated to be €104,069 (CI €59,359 – €213,221) per stroke avoided at five years (trial data) and €40,415 (CI €23,373 – €62,254) at ten years (extrapolated data). The results of the bootstrap analysis are shown as a scatter plot of 1,000 ICERs presented on the cost-effectiveness plane (Figure 2). The number needed to treat (NNT) in order to avoid a stroke was estimated to be 16.

CONCLUSIONS

- In this population of young patients (16 to 60 years) having had a recent cryptogenic stroke attributed to PFO with an associated atrial septal aneurysm or large interatrial shunt, the rate of stroke was lower with PFO closure plus long-term antiplatelet therapy than with antiplatelet therapy alone.
- The screening strategy must be carefully applied to select the population most at risk of stroke recurrence, and this should render the intervention cost effective in most settings.

Figure 1 Four state Markov model for the ten-year horizon

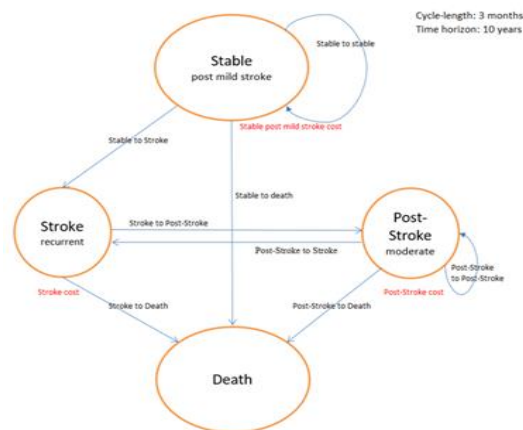


Table 1 Average five year cost based on trial data (ITT)

Cost centre	PFOC (n=238)	APT (n=235)
	€	€
Intervention costs	7 070	89
Closure device	3 766	48
Other consumables	195	2
Human resources	496	6
Operating theatre costs	529	7
Hospital stay	2 083	25
Imaging	154	57
Echography immediately prior to the intervention	130	2
IRM, scans during follow-up	24	55
Serious adverse events	251	454
Stroke	0	271
Atrial Fibrillation	137	25
Transient Ischemic Attack	86	87
Major bleeding	28	71
Other	268	944
Antiplatelet therapy	268	301
Post stroke medical care costs	0	642
Total	7 743 €	1 543 €

Figure 2 Cost-effectiveness plane showing five-year trial and ten-year extrapolated bootstrap replicates.

