

Premature adoption after publication of NICE guidance: a case study on Percutaneous Closure of Patent Foramen Ovale

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Introduction

- Patent Foramen Ovale is postulated to increase the risk of stroke/transient ischaemic attack(TIA).
- Percutaneous Closure of Patent Foramen Ovale (PCPFO) is a new procedure that might prevent the recurrence of stroke/TIA.
- In 2005, despite lack of randomised controlled trial (RCT) evidence, NICE guidance recommended that PCPFO could be used in the secondary prevention of stroke/TIA with audit of clinical outcomes.
- Three RCTs (CLOSURE 1, RESPECT and PC-Trial) published since 2010 have provided equivocal evidence in favour of PCPFO and a further NICE recommendation in 2013 that PCPFO was suitable for 'normal' NHS use.

Objective

To evaluate the impact of NICE guidance and subsequent trial evidence on the adoption of PCPFO

Methods & Materials

Retrospective time series study from 1 April 2006 to 31 March 2012

All PCPFO cases were identified using the relevant Office of Population Census and Surveys(OPCS) procedure code(K16.5) using the Hospital Episode Statistics (HES) database in England.

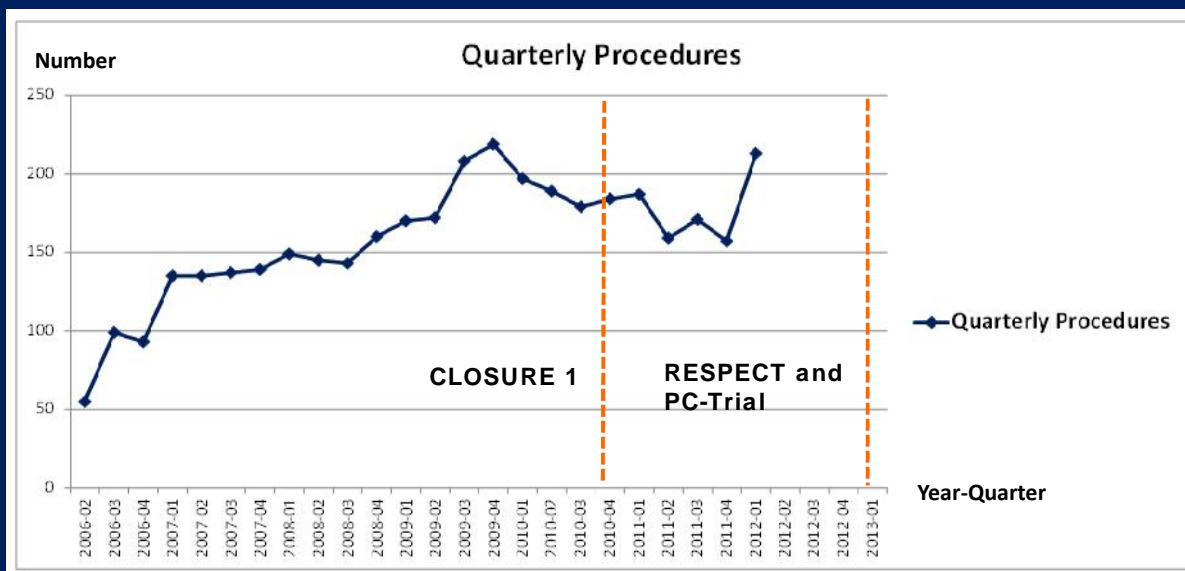
Patients aged <18 years old and > 60 years old were excluded as they were more likely to have PCPFO due to indications other than secondary prevention of stroke/TIA.

A total of 3801 cases were identified

Results

- Between April 2006 and March 2010, 2,356 PCPFO procedures were performed, with an Annual Percentage Change (APC) of 36.13%.

- The procedure rate peaked before the presentation of equivocal results from the first RCT-CLOSURE 1, and the APC declined in 2010/11 and 2011/12 (APC = -6.03%).



Conclusion

- PCPFO was rapidly adopted after the publication of NICE guidance despite the absence of RCT evidence of efficacy.
- Several thousand patients in England had the procedure before the meta-analysis of the three RCTs demonstrated a marginal benefit of PCPFO on stroke and mortality.
- Only 71 RCT patients were recruited in England.
- NICE recommendations led to premature adoption of PCPFO and failed to encourage the generation of RCT evidence.

Acknowledgements

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