Implantable devices for the closure of patent foramen ovale (PFO) in adults. Rapid HTA report

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Record Status
This is a bibliographic record of a published health technology assessment from a member of INAHTA. No evaluation of the quality of this assessment has been made for the HTA database.

Citation

Authors' conclusions
Percutaneous closure of patent foramen ovale (PFO) is one of the treatment options for patients with PFO suffering from transient ischemic attacks (TIA), cryptogenic stroke or persistent migraine. At time of writing, none of the several CE marked PFO closure devices have been approved by the US Food and Drug Administration (FDA). Currently there are 12 different PFO closure devices available on the Italian market and it has been estimated, that in 2012, 2,541 PFO procedures were performed. The price for a single PFO closure device ranged from € 5,535 to € 6,868 (excluding VAT), resulting in an estimated impact on the Servizio Sanitario Nazionale (SSN) budget of € 15 millions in 2012. We performed a systematic review and a meta-analysis of clinical studies in which patients with PFO suffering from TIAs, cryptogenic stroke or persistent migraine underwent insertion of percutaneous devices for the closure of PFO were compared to patients treated by usual care. We included 6 primary studies: 5 controlled clinical trials (CCT), and 1 randomised controlled trial (RCT). In the 5 CCTs we found that percutaneous closure of PFO was better than medical treatment in reducing stroke, TIA or the combination of both even if in the presence of significant heterogeneity. Poor methodological study quality and heterogeneity undermines our confidence in the results of this review. We attempted to stratify by device type the overall pooling of study data but it resulted in loss of power and further fragmentation of the evidence base. The safety profile of the technology appears to be of concern, in that 4.7% of device- or procedure-related serious adverse events were observed in the only RCT included. We recommend that large multicentre, sufficiently powered, and properly randomised trials be carried out in Europe with particular attention to patient selection and risk/benefit ratio.

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