Abstract

Introduction: Percutaneous transcatheter closure reduced the risk of recurrent stroke compared with medical therapy alone among young patients with cryptogenic stroke complicated with a patent foramen ovale (PFO) revealed by RCTs. Some cost-effectiveness analyses existing outside Japan have shown that PFO closure is cost-effective, but no specific Japanese studies have been found. Our objective was to assess the cost-effectiveness of PFO closure for risk reduction of recurrent stroke compared to medical therapy alone in Japan from a healthcare payer perspective.

Methods: A decision tree and Markov model were developed using recurrent stroke rates and a 5.9-year time horizon retrieved from the RESPECT study. Utility and costs were obtained from published studies and assumptions. ICER was evaluated and one-way sensitivity analyses were conducted and varied key assumptions were made to assess robustness.

Result: ICER of PFO closure compared with medical therapy was estimated to be ¥3,318,152 per QALY gained. One-way sensitivity analysis showed that the stable state utility score difference between PFO closure and medical therapy had the largest impact on ICER. PFO closure reached cost-effectiveness as the superior condition of PFO stable state utility of over 0.051 compared with medical therapy.

Conclusion: From a healthcare payer perspective, PFO closure is cost-effective compared with medical therapy in patients of 60 years or younger who had cryptogenic stroke probably attributable to PFO in Japan.

Keywords: PFO closure, cryptogenic stroke, cost-effectiveness study, stroke of undetermined source, AMPLATZER PFO Occluder