Abstract 33 Table 2 Base-case analysis using Markov model

Strategy	Mean total cost	Mean total QALYs	Incremental cost	Incremental QALY	ICER
Ablation	£10,483 (€11,741)	2.801	£5,657 (€6,336)	0.039	£144,150 (€161,448)

34 EFFICACY OF PULMONARY VEIN ISOLATION IN PREVENTING ATRIAL FIBRILLATION: META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS WITH AN INVASIVE CONTROL PROCEDURE

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Introduction Pulmonary vein isolation (PVI) is a commonly used element in treatment of atrial fibrillation (AF) but has never been tested in an intentionally placebo (sham) controlled trial. Nevertheless there have been several randomized controlled trials (RCTs) in which both arms receive an ablation procedure but the only difference between treatment arms is inclusion or omission of PVI. As long as both doctor and patient have reason to believe that the procedures in both arms are effective, such RCTs could be an effective proxy for placebo controlled trials.

Methods Medline and Cochrane databases were searched for RCTs comparing catheter ablation including PVI with left atrial ablation excluding PVI. The primary efficacy endpoint was freedom from AF/atrial tachycardia at 6 months. A random-effects meta-analysis was performed using the restricted maximum likelihood (REML) estimator.

Results Overall, seven studies (909 patients) met inclusion criteria. Across the 7 trials, mean age was 57.3, 70.2% of participants were male. In four trials (352 patients) the non-PVI ablation procedure was performed in both arms, while PVI was performed in only one arm. The non-PVI ablation procedures were complex fractionated atrial electrogram ablation (2 studies), ganglionated plexi ablation (1 study) and focal impulse and rotor modulation (1 study). In these, AF recurrence was significantly lower when PVI was included (RR 0.48, 95% CI 0.26-0.90, I2 64.4%)In an analysis of all 7 studies, AF recurrence was significantly lower in ablation with an ablation strategy including PVI compared to one without PVI (Figure 1, RR 0.67, 95% CI 0.53-0.85, p = 0.001, I2 0%). Neither type of AF (persistent vs. paroxysmal, p=0.43) nor type of non-PVI ablation (p=0.35) were significant moderators of the effect size. A sensitivity analysis omitting each study in turn showed similar results to the primary analysis. In particular exclusion of the retracted OASIS trial showed results similar to the primary analysis.

Conclusion PVI significantly reduces AF recurrence against a procedural control. A true placebo controlled trial of PVI versus placebo PVI (and no other procedure) might show an even larger efficacy because there would be no background efficacy in the control arm. It remains unknown how these convincing reductions in electrically documented AF would relate to symptom regression, since the correspondence between arrhythmia and symptoms is imperfect. A placebo (sham) controlled RCT would be the ideal method of testing this.

Conflict of Interest None

Abstract 34 Figure 1