Mainstay ablation procedure for atrial fibrillation shows substantial benefit over sham procedure

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A catheter ablation procedure widely used to treat the most common heart rhythm disorder significantly reduces the burden of atrial fibrillation (AF) and results in clinically important improvements in symptoms and quality of life compared with a sham (placebo) procedure, according to late breaking research presented Sept. 2 in a Hot Line Session at this year's ESC Congress 2024.

"Despite being widely performed in clinical practice, pulmonary vein isolation ablation has never been compared with a sham procedure," said principal investigator Dr. Rick Veasey. "Our results provide conclusive evidence for the benefit of pulmonary vein isolation ablation in individuals with symptomatic atrial fibrillation, putting concerns about a substantial placebo effect to rest."

AF is the most common type of abnormal heart rhythm, affecting 2% of people worldwide. If left untreated, it can result in symptoms including palpitations and breathlessness and can lead to serious complications such as stroke or heart failure. Treatment options include drugs or ablation, which involves burning or freezing a small area of the heart to create a scar and prevent the spread of abnormal electrical impulses, often from the pulmonary veins, from causing AF.

Pulmonary vein isolation (PVI) is the cornerstone of catheter ablation for both symptomatic paroxysmal (intermittent episodes of AF) and persistent AF. During the procedure, catheters are inserted into the heart to deliver radiofrequency energy or cryoballoon ablation to destroy tissue on the veins that is causing disruptive electrical signals.

Despite numerous clinical trials advocating PVI for symptomatic AF, there are concerns that PVI has a substantial placebo effect, and there have been no trials comparing PVI with a sham procedure.

To fill this important evidence gap, the SHAM-PVI trial enrolled and randomized 126 patients with symptomatic paroxysmal or persistent AF, previously treated with at least one antiarrhythmic drug who had been referred for catheter ablation at two NHS trusts in the U.K.

The patients were randomized in a 1:1 ratio to undergo either PVI using cryoablation, during which a balloon filled with liquid nitrogen is used to freeze the heart tissue that is causing the irregular heartbeat (64

patients), or a sham procedure involving phrenic nerve pacing to simulate an ablation procedure (62 patients). Demographic and clinical characteristics were well balanced between the groups.

The main measure of interest was AF burden (% time in AF) at 6-months (excluding an initial 3-month blanking period) assessed using a tiny implantable heart monitor placed under the skin. Other outcomes included important quality of life measures reported by patients, such as physical and social functioning, AF symptoms such as palpitations and breathlessness, and time to arrhythmia events.

The researchers found that at 6 month follow-up, the average change in AF burden from the start of the trial was 60% in the ablation group and 35% in the sham intervention group.

In patients with persistent AF, there was an average reduction in AF burden of 71% in the ablation group and 45% in the sham intervention group.

In patients with intermittent AF, the average reduction in AF burden was 16% in the ablation group compared with an average increase of almost 3% in the sham intervention group.

Overall quality of life scores were found to be substantially in favor of catheter ablation at six months. Similarly, scores based on symptoms, daily activities, and treatment concern were also in favor of ablation.

In addition, measures of health-related quality of life (e.g., physical functioning, vitality, emotional well-being, social functioning) also improved much more in the ablation group than in the sham intervention group at six months.

"We expected that PVI would be more effective than a placebo

procedure in patients with symptomatic AF, and indeed, the results proved our hypothesis was correct," said lead author Dr. Rajdip Dulai. "Going forward, we would expect that patients with symptomatic AF be referred for ablation treatment without hesitation."

Provided by European Society of Cardiology

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