PRAGUE-12 trial: Randomized open multicenter study

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The PRAGUE-12 trial is a randomized open multicenter study comparing cardiac surgery with MAZE versus cardiac surgery without MAZE in patients with coronary and/or valvular heart disease and with atrial fibrillation.

Surgical ablation of the left atrium to restore regular sinus rhythm is widely used in patients with atrial fibrillation (AF) undergoing cardiac surgery. The restoration of sinus rhythm might decrease the risk of heart failure, stroke and death during long-term follow up.(1) However, despite its promise, this theoretical benefit has never been clearly established - previous randomised studies have been small and performed in a selected group of patients undergoing mitral valve surgery.

Now, a multicentre study of surgical ablation (using the MAZE procedure) organised by cardiologists and cardiac surgeons at the Cardiocenter in Prague, Czech Republic, has assessed its long-term impact in patients with AF referred for cardiac surgery (for valve replacement/repair, coronary bypass or combined surgery). The study tested the hypothesis that the MAZE procedure would increase sinus rhythm prevalence one year after surgery without increasing peri-procedural complications, and possibly improve the long-term clinical outcomes (mortality, heart failure, stroke, bleeding).

Results of the study, presented here today by Professor Petr Widimsky from the Cardiocenter of Charles University, Prague, first confirmed

that the MAZE procedure performed during cardiac surgery does indeed improve the likelihood of sinus rhythm presence one year post-operatively. However, said Professor Widimsky, this effect was significant only among patients with permanent pre-operative AF. Further results also showed that the MAZE procedure had a neutral effect (neither negative nor positive) on mortality, stroke or other hard clinical end-points during one year follow up.

The primary efficacy outcome of the study was the presence of sinus rhythm (with no episode of atrial fibrillation) during 24-hour ECG monitoring one year after surgery. The primary safety outcome was the combined endpoint of death/myocardial infarction/stroke or transient ischemic attack/new onset renal failure requiring hemodialysis at 30 days.

Secondary outcomes were individual components of the primary safety outcome registered after one year, bleeding complications, heart failure, use of anticoagulation at one year, use of antiarhythmis drugs at one year, pacemaker or cardioverter implantation, and catheter ablation.

Detailed results showed that the MAZE procedure prolonged total surgical time by 20 minutes (220 min. MAZE vs. 200 min. no-MAZE). Holter ECG monitoring one year after surgery revealed sinus rhythm without any AF episodes in 60.2% of MAZE patients vs. 35.5% of the no-MAZE group (p=0.002). The combined safety endpoint (MACE) at 30 days was positive in 10.3% MAZE vs. 14.7% no-MAZE (not significant). There was no change in either the left ventricular ejection fraction or in the left atrial diameter. All-cause one year mortality was 16.2% in the MAZE group and 17.4% in the no-MAZE group (not significant). Stroke occurred in 2.7% MAZE vs. 4.3% no-MAZE (p=0.319).

There was a slight trend towards more hospitalisations for heart failure

during one year among non-MAZE patients (26.1%) than among MAZE 23.4% (p=0.680). Major bleeding occurred in 9.9% MAZE vs. 9.8% non-MAZE (p=0.654).

When patients were divided into subgroups based on AF type at randomisation, there was no difference between the MAZE and non-MAZE groups in the presence of sinus rhythm at one year among paroxysmal or persistent AF patients. There was, however, a highly significant increase in sinus rhythm restoration rate among patients with permanent AF treated by MAZE at one year (53.2% vs. 13.9%, p