Comparison of medical treatments in cryptogenic stroke patients with patent foramen ovale: A randomized clinical trial.

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Abstract

BACKGROUND: This randomized clinical trial compared rates of stroke or transient ischemic attack recurrence or death in patients with cryptogenic stroke and patent foramen ovale (PFO) who received medical treatment with aspirin or warfarin.

MATERIALS AND METHODS: Forty-four Iranian patients with cryptogenic stroke and patent foramen ovale participated in this randomized, single-blind trial between July 2007 and June 2010. All patients underwent transesophageal echocardiography and contrast-transcranial Doppler sonography to confirm the presence of patent foramen ovale. The patients were randomly assigned to receive aspirin or warfarin and were followed for 18 months for the recurrence of ischemic events or death. The principal investigator was blind to the group assignment. This trial is registered under number IRCT138805192323N1.

RESULTS: Five (11.4%) patients had a stroke, 2 (4.5%) had a transient ischemic attack and 2 (4.5%) died. There was no difference in the rate of ischemic events or death between the aspirin- and warfarin-treated groups (hazard ratio: 0.45; 95% CI: 0.1-1.8; P = 0.259).

CONCLUSION: There was no difference in ischemic event recurrence, death rates or side-effects between patients with cryptogenic stroke and patent foramen ovale who were treated with aspirin vs. warfarin.

KEYWORDS:

Aspirin; cryptogenic stroke; patent foramen ovale; warfarin