

Patent Foramen Ovale and Stroke Risk: The Devil Is in the Detail

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J. Am. Coll. Cardiol. 2007;50;80; originally published online Jun 17, 2007;

doi:10.1016/j.jacc.2007.04.023

This information is current as of February 10, 2012

The online version of this article, along with updated information and services, is located on the World Wide Web at:

<http://content.onlinejacc.org/cgi/content/full/50/1/80>

JACC

JOURNAL *of the* AMERICAN COLLEGE *of* CARDIOLOGY



Table 1 Diastolic Function Groups in CHARMES and Subset: Cardiovascular Events in CHARMES Subset by Diastolic Function Group

Diastolic Function	CHARMES (n = 293)	CHARMES Subset (n = 181)	CV1	CV2
Normal	33% (n = 98)	31% (n = 56)	0%	0%
Mild dysfunction	22% (n = 65)	29% (n = 53)	7% (n = 4)	11% (n = 6)
Moderate dysfunction	37% (n = 109)	31% (n = 55)	15% (n = 8)	22% (n = 12)
Severe dysfunction	7% (n = 21)	9% (n = 17)	12% (n = 2)	18% (n = 3)

See text for explanations of end points CV1 and CV2.

relative risk for moderate to severe diastolic dysfunction versus mild dysfunction and normal function is 3.8 for CV1 and 3.9 for CV2. Mild diastolic dysfunction in this subset carries a similar prognosis as in the full study (7% vs. 6%), whereas the normal group has a nonsignificantly better prognosis (0% vs. 4%).

Thus, using a non-age-adjusted Doppler-echocardiographic classification of diastolic function, we can conclude that normal diastolic function and mild diastolic dysfunction are seen in 60% of the patients, and the relationship is graded between severity of diastolic dysfunction and outcome, with a 4-fold risk increase for moderate to severe diastolic dysfunction compared to normal diastolic function and mild diastolic dysfunction and 2-fold when comparing moderate and severe to mild dysfunction. The recalculations do not suggest a different picture from the previous primary analysis.

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doi:10.1016/j.jacc.2007.04.024

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The risk of stroke due to a patent foramen ovale (PFO) is real. Case reports document venous thrombi slipping through a foramen ovale to the left atrium and causing a stroke (1). The absolute

risk for ischemic strokes in the presence of a PFO is unknown. The report of Di Tullio et al. (2) in a recent issue of the *Journal* may not shed more light on this question, because some “minor” details could end up seriously biasing their results.

As the investigators point out in their discussion, the prevalence of a PFO in the general population is close to one-quarter (3). The prevalence of a PFO in the current study is 15%. The most likely reason for this low PFO prevalence is underdiagnosis of interatrial shunts by transthoracic echocardiography (4). Otherwise, the researchers have to argue for a lower PFO prevalence in citizens from northern Manhattan compared to other cities of the U.S. Missing 4 of 10 PFOs would lower the hazard ratio (HR) for stroke in the PFO group compared to the non-PFO group, because these nondiagnosed shunts may increase the risk for stroke in the latter group. The results of the Cox regression models as presented would underestimate the actual hazard. In addition to the problem of underdiagnosis, a question arises regarding the patients studied. The mean age of patients participating in this project was 68 to 69 years. The association of a PFO and stroke has been demonstrated for patients <55 years (5) and is probably weaker in the elderly with competing conventional cardiovascular risk factors as hypertension, diabetes, and dyslipidemia.

Last but not least, Di Tullio et al. (2) should provide not only the HR for a stroke in the setting of a PFO, but also the corresponding HRs for other cardiovascular risk factors they corrected for.

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doi:10.1016/j.jacc.2007.04.023

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