Patent Foramen Ovale and Stroke
To the Editor:
In his editorial on patent foramen ovale (PFO) and stroke, Lock\(^1\) claims that the frequency of PFO in a normal population is 10% to 15%. A more accurate figure for the frequency of PFO in this population can be taken from larger post-mortem studies of normal hearts, such as that done by Hagen et al,\(^2\) where a frequency of 20% to 30% is consistently found. This baseline frequency is important because, in the context of national populations, the proportion theoretically susceptible to paradoxical embolism is much higher.

Lock’s editorial on the article by Windecker et al\(^3\) glosses over the high rate of residual shunt (27%) in the latter’s study. In a similar study, Bridges et al\(^4\) reported that 18% of their 34 patients had residual shunts. The rate reported by Windecker et al\(^3\) for residual shunt represents a significant failure, particularly when patients have undergone an invasive procedure (10% of Windecker et al’s\(^3\) patients had early complications). It is not clear from the article whether these residual shunts were due to a wrong choice of device, wrong size of device used, or anatomical variations in the PFO.

Lock comments that the recurrence rate after closure of 3.4% per year for all embolic events was “reasonably low.” Previous studies have reported a combined recurrence rate for stroke and transient ischemic attack of <4% per year in patients on no treatment or antiplatelet therapy, and it may be that the benefit from transcatheter closure is negligible.\(^5\)

Despite these problems with transcatheter closure, it still seems a reasonable alternative to surgical repair, where recurrence rates have varied from 0 to 20%. However, young patients with stroke and a PFO are currently undergoing transcatheter or surgical closure, both invasive and potentially dangerous procedures, purely on the basis of the preference of their specialist physician rather than objective evidence.

Epidemiological studies on the frequency of PFO in large numbers of young persons suffering stroke with properly matched controls have not yet been performed, but they are urgently needed. We are undertaking such a study in young adults (age <40 years) surviving stroke and myocardial infarction, which is funded by the British Heart Foundation. If anyone wishes to collaborate on a case-control study on the frequency of PFO in young patients dying from these diagnoses, please contact us.

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Response
Sastry and McCollum raise thoughtful questions concerning our article\(^1\) and the accompanying editorial by Lock\(^2\) on the percutaneous closure of patent foramen ovale (PFO) in patients with presumed paradoxical embolism. The prevalence of PFO in the normal population is probably higher than the 10% to 15% quoted by Lock,\(^2\) as evidenced by an autopsy series in which a PFO was shown to persist in 20% to 34% of adults, with a declining incidence in older age groups.\(^3\)

The 27% incidence of residual shunt, as assessed during contrast transesophageal echocardiography, in our study is high. However, this rate encompasses a major proportion of trivial shunts (16% had only 1 to 5 bubbles crossing), leaving only 11% of patients with a significant leak. In addition, our series reflects an evolving technique with different devices over a 5-year period. Recent modifications in technique and device design have already resulted in lower residual shunt rates,\(^5\) which may be completely overcome in the near future. With respect to the complication rate of 10%, 2 points should be mentioned: (1) none of the complications was irreversible, and (2) changes in device selection and implantation technique at our institution have reduced the complication rate to 2% in the 50 consecutive patients undergoing percutaneous PFO closure since the submission of the article. Moreover, the complication rate of the largest surgical PFO closure series to date, which was recently published from the Mayo Clinic, was 21%.\(^7\)

We observed an actuarial risk of 2.5% for recurrent transient ischemic attacks (TIA), 0.9% for peripheral emboli, and 0% for ischemic stroke. During extended follow-up for up to 6 years, we have not observed additional recurrent events, resulting in an actuarial risk of 2% per year at this point in time. Sastry and McCollum claim that previous studies on no treatment or antiplatelet therapy had a recurrence rate of <4% per year. Careful analysis of the quoted study reveals that the majority of patients were treated with Coumadin (warfarin; 70%), and the remainder were treated with either aspirin alone or aspirin in combination with warfarin (30%). Furthermore, in this study, the recurrence rate was 1.9% for ischemic stroke, 1.9% for TIA, 1.2% for death, and 4.3% for the combined end point of death, stroke, and TIA.\(^6\) Although the absolute recurrence rate seems low, the complications of ischemic stroke and death are devastating and require prophylaxis similar to atrial fibrillation. As stated in the Discussion of our article, the therapeutic benefit of percutaneous PFO closure, as opposed to medical treatment and surgical therapy, has not been established. To address these questions, we are currently conducting an international, multicenter, randomized, prospective trial comparing the efficacy of medical treatment with percutaneous PFO closure in patients with Cryptogenic embolism (PC trial). Until results from this or
similar trials become available, the implantation of PFO occlusion devices will remain investigational and should be performed only in appropriately selected and fully informed patients.

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