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EDITORIAL COMMENT

Leaving (almost) nothing behind

Deixando (quase) nada para trás

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The role of percutaneous patent foramen ovale (PFO) occlusion in the secondary prevention of thromboembolic events is well established.[1–3] The European Society of Cardiology guidelines recommend the procedure in patients aged between 18 and 65 years, carefully selected by a multidisciplinary team, in whom stroke, transient ischemic attack or systemic embolism is documented and a causal relationship with the presence of a PFO is determined based on clinical, anatomical and imaging features.[4] Recent guidelines from the Society for Cardiovascular Angiography and Interventions reproduce many of these criteria, extending their indication to subgroups not included in randomized studies after individualized assessment, such as patients with thrombophilia, decompression sickness, migraine and platypnea-orthodeoxia syndrome.[5]

There is a great diversity of devices for PFO closure and part of the effort in the development of new techniques has focused on the creation of technologies without device implantation, in which the ultimate goal will be to leave no intracardiac synthetic material. The concept is appealing, given that not leaving material in the interatrial septum may conceptually have several advantages: no risk of erosion or perforation, or of device embolization or migration, less thrombogenicity, reduced risk of infection, reduced inflammatory or allergic response, and easier access for procedures by transseptal access that may prove necessary in the future. Another advantage is a theoretical decrease in the risk of atrial fibrillation (AF), which is about four times more likely to occur after PFO occlusion, varying with the series and type of device analyzed. AF usually occurs within two months of the procedure and is transient in most patients. Proposed mechanisms include patient-related factors (age, hypertension, excess weight) and/or irritation of the atrial structure by the device itself and the healing process.[6,7]

The article by Neto et al.[8] published in this issue of the *Journal* describes the first observational prospective study in Portugal in patients undergoing percutaneous PFO occlusion with a 'deviceless' suture technique (NobleStitch® EL). Some of the results presented are worth highlighting: this is the first publication on the use of the technique in Portugal, in a population with a low average age, relatively few comorbidities and a high RoPE score, reflecting appropriate referral for the technique. The absence of significant procedure-related complications and the good immediate success rate for various anatomies of the septal defect should also be noted. As the authors themselves indicate as a limitation of their work, the follow-up time is short, insufficient for assessment of medium- and long-term safety and efficacy. The procedure time, radiation exposure and use of contrast also tend to be greater than described for other types of closure devices, but the fact that general anesthesia and the use of expensive intracardiac echocardiography are not required may compensate for these drawbacks. On the other hand, the study does not enable conclusions to be drawn about the residual shunt rate, one of the potential limitations of this suturing technique. Indeed, a significant

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residual shunt rate has been reported with NobleStitch®, and there are even reports of late re-opening of the foramen.[9,10] The existence of a residual shunt can be corrected with an additional suture, a technique that was not used in the group of patients under analysis, or by implanting another type of device. The fact that there is no synthetic material implanted leads some authors and the manufacturer itself to argue for the suspension of antiplatelet or anticoagulant therapy after the procedure, which is debatable due to the lack of solid evidence for this option. The existing recommendations in this field are vague, precisely because of the lack of data.[4,5]

Regardless of these limitations, the NobleStitch® EL has promising features for PFO occlusion and even for the resolution of residual shunts resulting from the use of other types of device, for which it has been shown to be effective.[11] Publication of long-term results and comparative studies will certainly be the best way to assess its effectiveness and safety.[12]

Several other device-free techniques are under development, using bioabsorbable occlusion material and thermal and radiofrequency energy, and again evidence on the results of their use is needed.[13-15]

In the future, the wide arsenal of methods for PFO occlusion and accumulated evidence of the outcomes will ideally enable an individualized selection of the technique to be used, based on the characteristics of the patient and the anatomy of the defect.

Conflicts of interest

The author has no conflicts of interest to declare.

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