Patient Selection for Percutaneous Closure of Patent Foramen Ovale with Transthoracic Color-Doppler Echocardiography Only. A Different Strategy

Percutaneous closure of patent foramen ovale (PFO) has been shown to reduce the rate of stroke recurrence following a cryptogenic stroke (CS). (1) Transesophageal Color-Doppler echocardiography (TEE) is recognized as the gold standard for diagnosing PFO; however, evidence suggests that transthoracic echocardiography (TTE) is a safe, non-invasive and effective method for PFO diagnosis. (2)

Our purpose was to compare the anatomical characteristics and the outcomes of percutaneous PFO closure in a group of patients diagnosed by TEE versus another group diagnosed by TTE.

A retrospective, descriptive, observational study was performed including patients undergoing percutaneous PFO closure following CS. Selected patients with CS had nuclear magnetic resonance imaging consistent with ischemic stroke, 24-hour Holter ruling out atrial fibrillation, normal Doppler ultrasound of neck vessels, lab tests ruling out procoagulant state as the cause of the ischemic event, and PFO with high risk criteria (large PFO, association with atrial septal aneurysm or septal hypermobility).

Two groups were determined, according to how PFO diagnosis was made. Group 1: patients diagnosed by TEE; Group 2: patients diagnosed by TTE who had not received TEE prior to the procedure.

Agitated saline injection test was performed in both groups. Before cannulation of the antecubital vein of the right arm, a 3-way stopcock was placed and 9 ml of saline mixed and shaken with 1 ml of previously aspirated blood was injected.

In the TTE group, the patient was placed in the left lateral decubitus position, and apical four-chamber views were used to observe right atrial filling and assess passage of bubbles into the left atrium. At least 3 injections were performed, at rest and with Valsalva maneuver.

When the diagnosis was made by TEE, mid-esophageal views ranging between 30-60 degrees were used. Patent foramen ovale diagnosis by both methods was defined as the passage of bubbles into the left atrium within 3 to 6 cardiac beats after the right atrium had been filled. (3)

All patients were monitored with TEE during percutaneous closure, under general anesthesia and mechanical ventilation.

Anatomical characteristics of PFO, such as atrial septal aneurysm (saccular deformity of the atrial septum ≥ 10 mm deep), length of the PFO tunnel, and size of the aortic edge and of the atrial septum, were compared between both groups, based on the intra-procedural TEE. The size of the implanted device was also compared. Implantation success and need for transseptal puncture, when cannulating of the PFO was not possible, were also considered.

Categorical variables were expressed as percentage, and continuous variables as median and interquartile range. Categorical variables were compared using Fisher’s exact test, and the Mann-Whitney non-parametric test for continuous variables. SPSS 17 statistical package was used for data analysis.

The study was carried out following the recommendations on clinical research and the Declaration of Helsinki. Informed consent was not requested as a review of clinical histories and echocardiographic records was performed. Privacy and confidentiality of patient data were protected. This study was approved by the Institutional Research Committee.

Between July 2017 and May 2019, 24 patients underwent percutaneous PFO closure. All the patients had CS diagnosis. Median age was 39.5 years (IQR 35.5 - 46.7 years) and 54.2% were women (13/24) (Table 1). In 12 patients, pre-procedure PFO diagnosis was made by TEE (Group 1), and in the remaining 12 patients by TTE (Group 2). The latter had not received TEE before the procedure. All patients had PFO, and 66.7% had an associated atrial septal aneurysm. Septum size was 19 mm (IQR 16-22 mm), tunnel length 7 mm (IQR 4.5-8 mm), and the aortic edge 8 mm (IQR 6-11 mm).

No anatomical differences in the atrial septum were found between the two groups at the time of percutaneous closure (Table 2) and the device was implanted in all patients without complications. Nit-Occlud® PFO (PFM Medical, Colonia, Germany) was the device used in all cases.

Our main finding has been that diagnosing PFO only by TTE with agitated saline test did not hinder the therapeutic approach, since there were no anatomical differences depending on the diagnostic method used at the time of the intervention.

Although TEE with agitated saline solution is the test of choice to diagnose PFO, it is not free from adverse reactions. The frequency of reported complica-

### Table 1. Population characteristics.

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<th>39.5 years (35.5-46.7 years)</th>
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<tbody>
<tr>
<td>Hypertension</td>
<td>12.5%</td>
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<tr>
<td>Hypercholesterolemia</td>
<td>8.3%</td>
</tr>
<tr>
<td>Smoking</td>
<td>4.2%</td>
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<tr>
<td>Large patent foramen ovale (more than 20 bubbles)</td>
<td>75%</td>
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<tr>
<td>Atrial septal aneurysm</td>
<td>66.7%</td>
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<tr>
<td>RoPE Score</td>
<td>8 points (7-9 points)</td>
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RoPE: Risk of Paradoxical Embolism
tions is about 2.15%. (4) Compared with TEE, sensitivity and specificity of TTE using second harmonic imaging is greater than 90% for the diagnosis of PFO. (2) It may even be more sensitive than TEE in certain circumstances, such as in heavily sedated patients unable to undergo a proper Valsalva maneuver or in patients who cannot tolerate esophageal intubation for a long time. (5)

Its extensive availability and low cost should also be pointed out. In patients with CS, a possible etiological cause is the presence of aortic plaques, which could be very difficult to visualize with TTE, especially when located in the descending thoracic aorta. However, plaques should be searched mainly in patients >50 years of age since their prevalence in younger patients is very low. (6)

When planning the percutaneous closure of atrial septal defects, the use of TEE is recommended to assess the feasibility of such approach. This includes interatrial shunting, the need to determine the size of the defect, the proper edges for implantation, and to rule out associated lesions. (3) However, the anatomical variability is less remarkable in PFO.

The anatomical features compared in our study are those that mainly influence the choice of device size at the time of implantation (e.g., the need to cover the atrial septal aneurysm (ASA), or the size of the device not larger than the size of the septum due to risk of erosion) or the septum approach (through the PFO tunnel or by transseptal puncture in very long tunnels).

Our study had a limited number of patients and was carried out in a single center; however, we believe that this strategy can be employed, since TTE with agitated saline solution is a low-complexity diagnostic test, which is performed in most echocardiography laboratories with positive cost/benefit ratio and no negative influence at the time of percutaneous closure device implantation.

Conflicts of interest
None declared.
(See authors’ conflicts of interest forms on the website/Supplementary material).

Ethical approval
Not applicable.

Table 2. Anatomical features of the septum, size of implanted devices, and implantation strategy.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Group 1 (TEE)</th>
<th>Group 2 (TTE)</th>
<th>P value</th>
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<tr>
<td>ASA (%)</td>
<td>55</td>
<td>77</td>
<td>0.40</td>
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<tr>
<td>Tunnel size (mm)</td>
<td>7</td>
<td>7</td>
<td>0.55</td>
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<tr>
<td>Aortic edge (mm)</td>
<td>8.5</td>
<td>7.5</td>
<td>0.49</td>
</tr>
<tr>
<td>Septum size (mm)</td>
<td>19</td>
<td>17</td>
<td>0.55</td>
</tr>
<tr>
<td>Device size (mm)</td>
<td>30</td>
<td>30</td>
<td>0.23</td>
</tr>
<tr>
<td>Transseptal puncture (%)</td>
<td>0</td>
<td>8</td>
<td>0.99</td>
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ASA: Atrial septal aneurysm

REFERENCES

Routine Blood Salvage with Cell Saver During Elective Cardiac Surgery

In cardiac surgery, different approaches have been developed to reduce allogeneic transfusions. Operative recovery of blood with cell saver is one of these approaches, despite its routine use is still questioned. (1-4)

The purpose of this study was to confirm whether the routine use of cell saver during elective cardiac surgery can improve hematocrit and hemoglobin levels at discharge, and also reduce blood product consumption.

An intervention study with a quasi-experimental design was conducted on a series of adult patients who underwent cardiac surgery in a community hospital in 2017 and 2018. Patients undergoing any type of elective cardiac surgery with cardiopulmonary bypass