# A Comparison of Methods to Determine Patent Foramen Ovale Size

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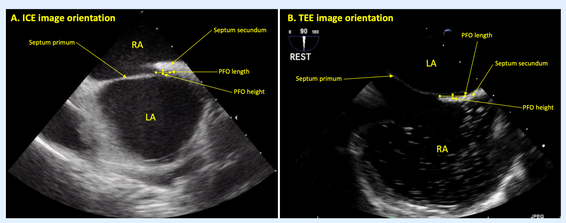
## Introduction

A patent foramen ovale (PFO) results from the incomplete fusion of the septum primum and septum secundum and is the most common congenital cardiac lesion, present in 20% of the adult population. A PFO produces a potential communication between the right and left atria. Although most patients with a PFO are asymptomatic, a variety of clinical conditions are associated with PFO, including cryptogenic stroke, migraine with aura, decompression illness, altitude illness, and platypnea-orthodeoxia syndrome. Given the multiple pathologies associated with PFO, there has been interest in determining the predictors of a symptomatic PFO, including PFO size, degree of right-to-left shunt (RLS), and presence of an atrial septum aneurysm (ASA). Several methods for measuring a PFO are available, including non-invasively with a transesophageal echocardiogram (TEE) and invasively with either an intracardiac echocardiogram (ICE) or direct balloon sizing. The PFO dimensions may influence which PFO closure device is used. However, the method chosen for PFO sizing, TEE versus ICE versus sizing balloon, is operator-dependent. Further complicating the fact that different imaging modalities exist for determining the size of a PFO is that the anatomical dimensions (length, height, and width) are often defined imprecisely and used interchangeably, yielding conflicting results for the defect size. This retrospective analysis assessed the differences in measuring the dimensions of a PFO with TEE, ICE, and sizing balloon, and it evaluated the relationship between PFO length and height to shunt grade by transcranial Doppler (TCD)

## Methods

**Patient Population:**
Of the 997 patients with a suspected PFO, 147 had adequate sizing balloon images, 67 had adequate TEE images, and 73 had adequate ICE images. Of the 147 subjects with adequate sizing balloon images, 56 had adequate TEE images and 66 had adequate ICE images for direct comparison. Of the 67 subjects with adequate TEE, 27 had adequate ICE images for direct comparison.

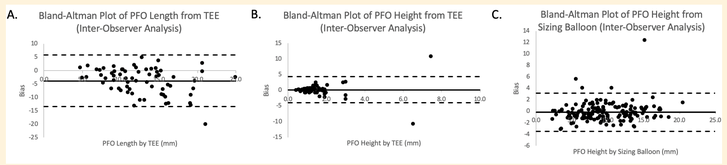
**Transesophageal echocardiography and intracardiac echocardiogram:**
Measurements were made using the caliper ruler included in the images, using the built-in ultrasound ruler for calibration. The PFO length was defined as the maximum distance of overlap between the septum primum and septum secundum. The PFO height was defined as the maximum distance between the septum primum and septum secundum.



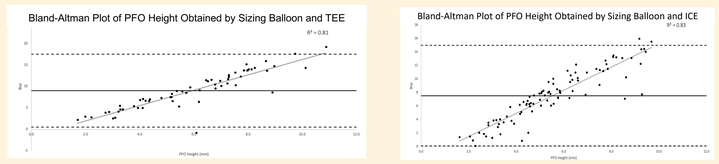

Of note, the echocardiogram definition of PFO height corresponds to the balloon waist diameter of the sizing balloon image in the left anterior oblique (LAO) projection. Routine TEE and ICE imaging do not visualize the PFO width because this requires a three-dimensional enface view of the right atrial septum. The excursion of the atrial septum into the right and left atria was measured, and the presence of an atrial septal aneurysm (ASA) was identified if the distance of septum primum excursion into either atrium was ≥10 mm or the total excursion distance was ≥15 mm.

**Sizing balloon:**
The PFO width, defined as the balloon waist diameter in the right anterior oblique (RAO) angiographic projection, was determined using a 24-mm Amplatzer sizing balloon (Abbott Vascular, Chicago, IL). The PFO height, defined as the balloon waist diameter in the LAO projection, was similarly measured. In those cases where only an LAO projection was obtained (n = 125), the PFO width was estimated to be equal to the PFO height during balloon stretching based on the observation that most PFOs are nearly circular when stretched by a balloon. The caliper ruler included in the imaging software was used to measure both the balloon waist diameter and the fixed 15-mm space between the two markers on the sizing balloon and then the resulting measurements, in units of pixels, were converted to millimeters.

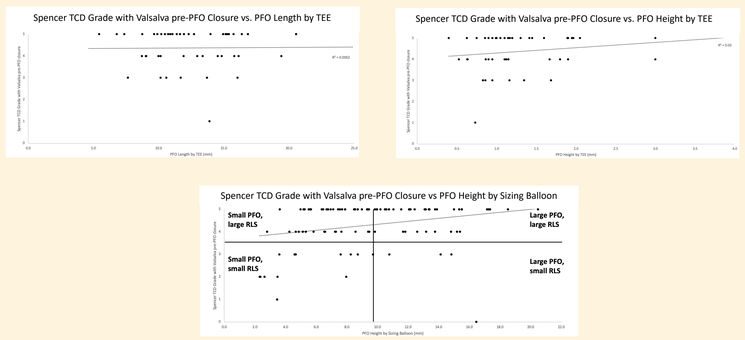
## Results




| Imaging Modality | Dimension | |
|---|---|---|
| | **Average PFO length (mm)** | |
| **TEE** (n = 47) | 12.3 ± 4.7 | p < 0.005 |
| **ICE** (n = 47) | 9.8 ± 3.7 | |
| | | |
| | **Average PFO height (mm)** | |
| **TEE** (n = 46) | 1.4 ± 0.7 | p < 0.05 |
| **ICE** (n = 46) | 1.7 ± 0.8 | |
| | | |
| **Sizing Balloon** (n = 60) | 10.5 ± 4.2 | p < 0.0005 |
| **TEE** (n = 60) | 1.4 ± 1.0 | |
| | | |
| **Sizing Balloon** (n = 92) | 9.3 ± 3.8 | p < 0.0005 |
| **ICE** (n = 92) | 1.8 ± 0.8 | |




PFO height significantly correlated with bias in a linear and positive direction (r = 0.85 for sizing balloon versus TEE and r = 0.93 for sizing balloon versus ICE).

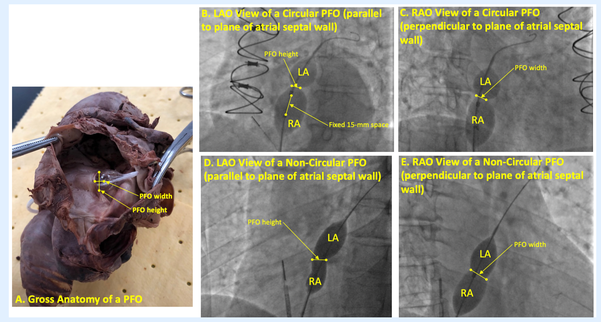



PFO height by sizing balloon correlated the most, but still poorly, with Spencer TCD grade (r = 0.27).

| Imaging Modality | | Average PFO length (mm) | | Average PFO height (mm) | | Average Spencer TCD Grade with Valsalva pre-PFO Closure | |
|---|---|---|---|---|---|---|---|
| **TEE** (n = 67) | **ASA+** (n = 11) | 12.4 ± 4.5 | p = NS | 2.2 ± 3.1 | p = NS | 4.1 (n = 7) | p = NS |
| | **ASA-** (n = 56) | 12.5 ± 5.2 | | 1.3 ± 0.7 | | 4.4 (n = 39) | |
| | | | | | | | |
| **ICE** (n = 73) | **ASA+** (n = 10) | 8.28 ± 3.61 | p = NS | 2.1 ± 1.1 | p = NS | 3.7 (n = 7) | p = NS |
| | **ASA-** (n = 63) | 9.44 ± 4.33 | | 1.74 ± 1.24 | | 4.0 (n = 42) | |

The average PFO length, PFO height, and Spencer TCD grade with Valsalva pre-PFO closure did not differ significantly between the ASA and non-ASA cohorts by TEE or ICE.

## Methods




**Transcranial Doppler:**
An agitated saline bubble study was conducted at rest and with Valsalva prior to PFO closure to evaluate the degree of RLS. The Spencer Logarithmic Scale criteria was used to classify PFO shunt grade: no bubbles (grade 0), 1–10 bubbles (grade 1), 11–30 bubbles (grade 2), 31–100 bubbles (grade 3), 101–300 bubbles (grade 4), and ≥ 300 bubbles (grade 5).

**Statistical Analysis:**
Two individuals independently completed measurements for the available images and then inter-observer Bland–Altman analyses were performed to assess the reproducibility of the PFO dimensions between observers. Outliers, defined as values that fell outside the limits of agreement (average of the difference between the two measurements ±1.96 × standard deviation), were adjudicated by a third individual, and the average of the three values was taken to be the final value. PFO length by TEE and ICE and PFO height by TEE, ICE, and sizing balloon were compared using paired Student's t-test, and $p < .05$ was considered statistically significant. The relationship between PFO length by TEE and ICE and height by TEE, ICE, and sizing balloon and Spencer TCD grade with Valsalva pre-PFO closure was analyzed using a linear regression model and then the Pearson correlation coefficient, r, was calculated.

## Conclusions

This study shows that PFO measurements obtained from ultrasound images, whether non-invasively with TEE or during a right heart catheterization with ICE, do not correspond with the measurements of the anatomic opening of a PFO tunnel with a sizing balloon. Ultrasound measurements by TEE and ICE underestimate the anatomic size of a PFO. Additionally, PFO length, height, and width, whether measured non-invasively or invasively, do not correlate with Spencer TCD grade, implying that the degree of RLS is only partially affected by PFO size. Other forces that affect right-to-left flow across a PFO include anatomic factors, such as the presence of a Eustachian valve and/or a Chiari network, and functional factors that influence right atrial pressure, such as the phase of respiration and physiologic maneuvers that increase venous return (e.g., Valsalva maneuver). These observations suggest that PFO anatomic size should not be used as a criterion when deciding whether to close a PFO.

**Limitations:** The main limitations of this study are the retrospective design, the assumption that most PFOs are nearly circular, a small sample size of ASA patients, lack of ≥1 imaging type for all patients being assessed, and measuring PFO without Valsalva maneuver. Investigators stratify a PFO as high-risk if it is associated with an ASA because it is assumed that the presence of an ASA increases the anatomic size or functional degree of RLS and therefore the risk of recurrent embolic events. The current study did not find a significant difference in PFO length, PFO height, or Spencer TCD grade between those with or without an ASA by TEE or ICE. Given the small sample size of ASA patients (11 by TEE and 10 by ICE), it is difficult to reach any reliable conclusions.

## Disclosures

The presenter and authors have no disclosures