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RESEARCH

# Transcatheter Patent Ductus Arteriosus Closure in Premature Infants: Comparison of Echocardiogram and Angiogram Measurements

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## Abstract

Transcatheter patent ductus arteriosus (PDA) closure (TCPC) utilizing transthoracic echocardiogram (TTE) as the sole imaging guide could simplify care. This single-center study compares PDA dimensions obtained from the TTE and angiogram images of patients who underwent attempted TCPC at Stead Family Children's Hospital from 10/01/2019 to 10/31/2020. Blinded investigators measured these dimensions solely for this study and had no impact on clinical care. Also, a hypothetical Piccolo device size was chosen based on the TTE dimensions and another on the angiographic dimensions, and then the correlation was analyzed. Sixty-two patients underwent TCPC attempts. TTE tends to overestimate the PDA narrowest dimension and underestimate the PDA length and aortic end dimension. Linear regression analysis revealed a weak correlation between the length and aortic diameter ($R = 0.37$ and 0.21, respectively). A modest correlation was observed for the smallest dimension without color Doppler ($R = 0.57$) and with color Doppler, which was utilized when needed ($R = 0.6$). Bland–Altman analysis revealed a smaller mean difference between the TTE and angiogram measurements of the narrowest diameter without color Doppler (0.4 mm) and with color Doppler (used as needed) (0.4 mm). However, the mean difference is larger for the aortic end (− 1.64 mm) and the length (− 1.73 mm). TTE accurately predicted the Piccolo device size in 43 (72%) patients and overestimated the size in 17 (28%) patients to the next size. Our findings should be verified with further studies, and additional development of protocols is needed to use TTE to guide TCPC without fluoroscopy.

**Keywords** Premature infants · PDA closure · PDA dimensions

## Introduction

Patent ductus arteriosus (PDA) is commonly encountered in premature infants [1]. When medical therapy fails to close a hemodynamically significant PDA, surgical or transcatheter PDA closure (TCPC) becomes indicated [2–10]. Surgical closure was favored over TCPC for definitive PDA closure [2]. The FDA approved the first device designed for PDA closure in premature infants in 2019 [Amplatzer Piccolo Occluder (Abbott, Plymouth, MN)]. Since then, the experience with TCPC has rapidly accumulated. Many centers have adopted TCPC in premature infants as the primary definitive PDA closure option [11, 12]. Fluoroscopy and angiograms are utilized to size the PDA and guide catheter and wire manipulation. An intraoperative transthoracic echocardiogram (TTE) is employed to judge the adequacy of closure and device position. There is growing interest in performing TCPC under exclusive TTE guidance, hoping to minimize the risks involved with patient transport and exposure to radiation and contrast [12–16]. Yet studies regarding whether TTE can be reliably trusted to choose the appropriate device size are lacking.

In this study, we aim to investigate whether the PDA dimensions measured via TTE correlate with those measured angiographically.

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## Methods

This is a single-center study utilizing the TTE and angiographic images of premature infants who underwent attempted TCPC at the Stead Family Children's Hospital/University of Iowa from October 1, 2019, to October 31, 2021. The study was approved by the University of Iowa institutional review board. Patients were included when intraprocedural TTE and angiogram were performed in premature infants with hemodynamically significant PDA. Patients were excluded when TTE and angiogram images were unavailable or measurements could not be performed. Our center's TTE criteria for TCPC closure have been previously described [11]. Blinded investigators measured essential PDA dimensions, outlined below, which determine Piccolo device size for closure solely for this study and did not impact clinical decisions. Piccolo device selection was based on a sizing chart shown in Table 1. We utilized this table to predict which device size would be chosen based on TTE and compared those predictions to the device chosen based on angiogram measurements for each patient. The angiographic measurements are considered the true ductal measurements. The Piccolo device sizes placed in most patients were 2 mm long and 3 or 4 wide. For this study, the chosen hypothetical devices were based on the patient's weight and the PDA's narrowest measured dimension by each modality for each patient's dataset based on the PDA sizing chart (Table 1).

### Measuring the PDA Dimensions by TTE

All intraprocedural TTE images were obtained via either Philips iE33 or EPIQ 7 (Koninklijke Philips, Amsterdam, Netherlands). PDA dimensions were measured from the intraprocedural TTE obtained just before the start of the cardiac catheterization using the high left parasternal short-axis window, known as the "ductal view." Two-dimensional (2D) images without color Doppler were utilized to obtain the measurements when feasible. The aortic end (ampulla) (ED1) width was measured at the insertion of the PDA with the aorta. The narrowest PDA dimension (ED2) was defined as the narrowest PDA segment width, which is usually located at or close to the connection of the PDA with the main pulmonary artery (MPA). The PDA length (EL) was measured as a straight line extending from ED1 to the pulmonic end of the PDA (Fig. 1). All measurements were obtained during systole.

As the smallest PDA dimension is a key in choosing the PDA device size, dimensions were measured on a 2D image with color Doppler when the quality of the 2D image without color Doppler did not allow satisfactory quantification.

TTE dimensions were measured by two investigators (UG) and (AB) from the same clip. We aimed to exclude poor image quality as a confounding factor in weakening the interclass correlation (ICC). As such, the second investigator (AB) measured the PDA dimensions only when the quality of the images allowed the first investigator to measure all dimensions. Both investigators were blinded to each other's measurements.

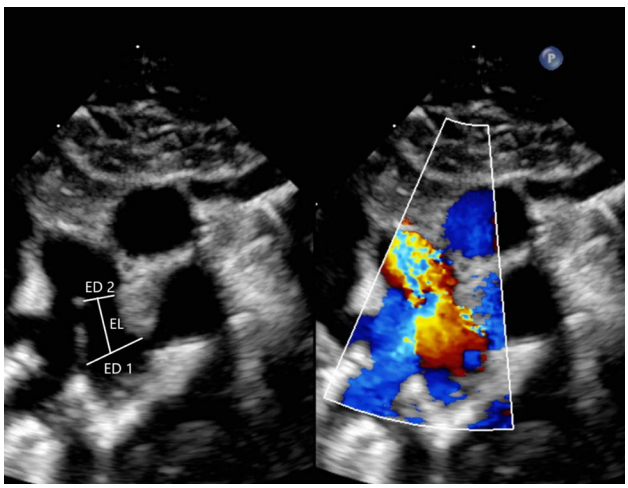


**Fig. 1** Echocardiography images with and without color Doppler demonstrate measuring the patent ductus arteriosus (PDA) dimensions PDA dimensions. ED1 echocardiography aortic end (ampulla) dimension. ED2 echocardiographic narrowest end dimension. EL Echocardiography length of the PDA

**Table 1** Sizing chart of Piccolo device selection based on the infant's weight and the narrowest PDA dimension

| Less than 1000 g | | 1000–1999 g | | 2000–3000 g | |
|---|---|---|---|---|---|
| Narrowest PDA diameter | Picolo size | Narrowest PDA diameter | Picolo size | Narrowest PDA diameter | Picolo size |
| < 3 mm | 3–2 | < 1.8 mm | 3–2 | < 2 mm | 4–2 |
| 3–3.9 mm | 4–2 | 1.8–3.2 mm | 4–2 | 2–3 mm | 5–2 |
| 4–5 mm | 5–2 | 3.3–4 mm | 5–2 | > 3 mm | None |

*PDA* Patent ductus arteriosus

## Measuring the PDA Dimension by Angiogram

All angiograms were performed using the Siemens Artis Zee Biplane fluoroscopy system (Siemens Healthcare AG, Erlangen, Germany).

Patent ductus arteriosus dimensions were measured using the lateral projection angiogram by two blinded investigators (KC and BMN), who worked separately and measured the dimensions from the same clip. They were blinded to patient identification, TTE measurements, and each other's measurements.

The measured angiographic dimensions were as follows: AD1 was defined as the aortic end dimension, AD2 as the narrowest PDA dimension (again usually at or near the insertion into the MPA), and AL was the PDA length measured as a straight line from AD1 to the pulmonic end of the PDA (Fig. 2a). All measurements were obtained in systole when the PDA was distended.

## Data Collection

Demographic data collected included procedure age, corrected age and weight, gestational age, and birth weight. The TTE data collected included PDA dimensions (ED1, ED2, and EL), aortic and LPA flow velocity, and the presence and severity of tricuspid valve regurgitation. One-hour post-procedural and last follow-up TTE data included the adequacy of device position, presence, and severity of residual shunt, aortic arch and LPA flow velocities, and severity of tricuspid valve regurgitation.

Angiogram data included PDA type and PDA dimensions (AD1, AD2, and AL).

All investigators were blinded to the measurements of the others as well as the size of the device and the TCPC outcomes.

## Outcomes

The primary outcomes were comparing the angiographic and TTE PDA dimensions and whether TTE dimensions would predict the device selection based on the angiographic dimensions using the sizing chart (Table 1).

Secondary outcomes were demographics, PDA type, procedure time, fluoroscopy time, and radiation dose.

## Statistical Analysis

Data were analyzed statistically using IBM SPSS Statistics ([ver. 28.0.11(14)], IBM, Armonk, NY). Categorical data were reported as counts and percentages. Continuous data were reported as either mean and standard deviation (SD) or median with interquartile range (IQR). The normality of the data was tested using Shapiro–Wilk test. Paired *t*, Pearson correlation, and Bland–Altman plot tests were utilized to compare and assess the agreement between the TTE and angiogram PDA dimensions. The interclass correlation coefficient (ICC) was utilized to assess the interobserver variability between blinded investigators. The ICC was calculated using Kappa Statistics (two-way mixed effect model). $p$ value of $< 0.05$ was chosen as a cut-off of the statistically significant results.

## A Brief TCPC Procedure Description

An abbreviated baseline TTE is performed in the cardiac catheterization lab. The following are assessed: the presence and the size of PDA (Fig. 1), flow in the LPA and the descending aorta, cardiac systolic function, and the presence and degree of tricuspid valve regurgitation.

An angiogram is obtained inside the PDA using 1 ml of contrast. Angiographic PDA dimensions are measured

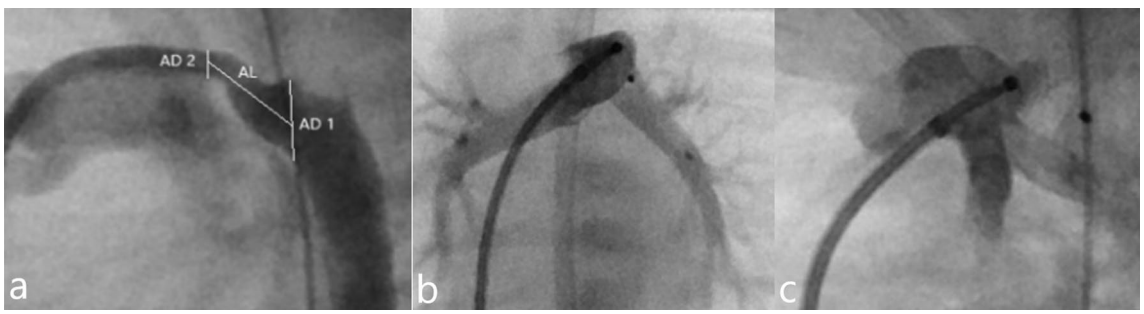


**Fig. 2** Angiogram images summarize the utility of angiogram during transcatheter patent ductus arteriosus (PDA) closure. **a** PDA demission measured by angiogram in the lateral projection. AD1 Angiogram aortic end (ampulla) dimension. AD 2 Angiogram narrowest end demission. AL angiogram length of the PDA. **b** Main pulmonary artery (MPA) angiogram in the frontal projection with 20-degree left anterior oblique and 20-degree caudal angulation and **c** in the lateral projection with 10-degree caudal angulation show no iatrogenic left pulmonary artery stenosis and the pulmonic end of the device is seated inside the PDA and not protruding into the MPA. Note, that the aortic end of the device is aligned with the nasogastric tube, which is usually aligned well with the aortic end, indicating that the device is not protruding inside the aorta

(aortic end, narrowest diameter, and length) to aid in choosing the PDA device size (Fig. 2a). The device type [Piccolo vs KA micro plug (KA Medical, Minneapolis, MN)] is chosen based on the discretion of the interventional cardiologist. The device is then deployed inside the PDA. Angiogram in the MPA (Fig. 2b and c) and TTE are performed. If the device is not entirely intraductal or obstructing the aorta or the LPA, the device is recaptured and redeployed. After confirming adequate positioning and no more than a trivial residual shunt, the device is released, and the delivery system is removed. A detailed TTE is performed after releasing the device.

## Results

### Demographics

Sixty-two patients were referred for TCPC. Two patients were excluded due to the inability to obtain an angiogram: one patient had occluded bilateral femoral veins, and the other developed inferior vena cava dissection at the beginning of the procedure. Both patients underwent uneventful surgical closure.

The median birth weight and gestational age were 687 (576–915) g and 25.1 (23.7–26.6) weeks, respectively. The median age, corrected age, and weight at the time of TCPC were 4.3 (3.4–6) weeks, 29 (28.1–30.9) weeks, and 1200 (1000–1600) g, respectively.

### Primary Outcomes (Comparison of the TTE and Angiogram Measurements)

- TTE findings

The quality of intraprocedural TTE without color allowed for satisfactory PDA measurement in 48 (80%) patients for the aortic end (ED1), 45 (75%) patients for the narrowest dimension (ED2), and 46 (77%) patients for the length (EL). Using color Dopler images, the narrowest PDA dimension was adequately measured in all patients.

The interclass correlation coefficient (ICC), evaluating the agreement between blinded investigators, revealed at best modest agreement for the narrowest (ED2) and the aortic end (ED1) dimensions with an ICC of 0.63 and 0.69, respectively. There was weak agreement for the PDA length (EL) with an ICC of 0.19.

- Angiogram findings

The quality of the obtained angiogram allowed for measuring all PDA dimensions in all patients.

The interclass correlation coefficient, gauging the agreement between blinded investigators, revealed a strong correlation for all PDA dimensions with an ICC of 0.86 for the aortic end (AD1), 0.89 for the length (AL), and 0.98 for the narrowest diameter (AD2).

- TTE and angiogram correlation

Using the paired sample *t* test, the PDA dimensions measured by TTE and angiogram were statistically different. It was noticed that the TTE tends to overestimate the smallest PDA dimension (ED2 vs. AD2) and underestimate the PDA length (EL vs. AL) and aortic end (ED1 vs. AD1) dimensions (Table 2).

Using a linear regression analysis (Pearson correlation), it was noticed that there was a modest correlation with the narrowest PDA dimension (ED2 vs. AD2) measured without color Doppler ($R = 0.57$, $P < 0.001$) as well with color Doppler when needed ($R = 0.6$, $P < 0.001$). The degree of correlation was weak for the length (EL vs. AL) ($R = 0.21$, $p = 0.017$) and aortic end diameter (ED1 vs. AD1) ($R = 0.37$, $P = 0.01$) measurements (Fig. 3).

Bland–Altman analysis revealed a smaller mean difference between the TTE and angiogram measurements of the pulmonary end (ED2 vs. AD2) without color Doppler (0.4 mm) as well as with color Doppler (when used as needed) (0.4 mm). However, the mean difference is larger for the aortic end (ED1 vs. AD1) (− 1.64 mm) and the length (EL vs. AL) (− 1.73 mm) (Fig. 4 and Table 3).

When Table 1 was used to test the ability of TTE to predict the accurate Piccolo device size, it was noticed that the TTE was able to predict the Piccolo device in 43 (72%) patients and overestimated the device to the next size in 17 (28%) patients. TTE did not underestimate the device size in any patient. Figure 5 summarizes device selections based on TTE and angiogram measurements when Table 1 is utilized.

**Table 2** Paired sample *t* test comparing the dimensions of patent ductus arteriosus measured by echocardiogram and angiogram

| Variable (*N*) | Angiogram (mm) | Echocardiography (mm) | *P* value |
|---|---|---|---|
| PDA aortic diameter (48) | 4.92 ± 0.85 | 3.20 ± 0.78 | < 0.01 |
| PDA length (46) | 8.09 ± 1.55 | 6.45 ± 1.49 | < 0.01 |
| PDA narrowest diameter without colour (45) | 1.82 ± 0.64 | 2.22 ± 0.60 | < 0.01 |
| PDA narrowest diameter with colour if needed (60) | 1.82 ± 0.63 | 2.22 ± 0.60 | < 0.01 |

*PDA* Patent ductus arteriosus

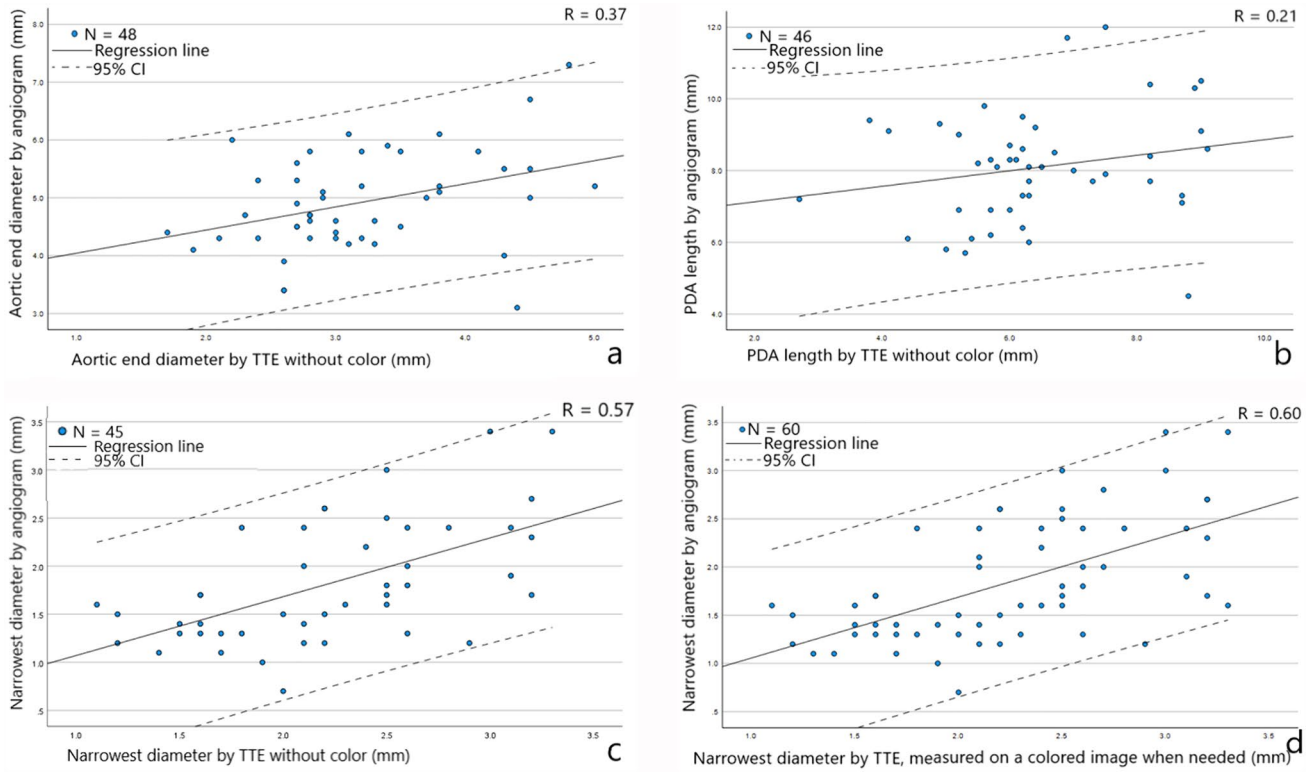


**Fig. 3** Scatterplots with regression lines show the correlation of echocardiogram and angiogram patent ductus arteriosus (PDA) measurements. **a** Correlation for the aortic end. **b** Correlation for the PDA length. **c** Correlation for the smallest PDA dimension with no color Doppler. **d** Correlation with the smallest dimension was measured without color Doppler and with color Doppler images when needed. TTE transthoracic echocardiogram. CI confidence interval. R Pearson correlation

### Secondary Outcomes

- PDA type and used devices

The type of PDA was as follows. Fetal type (hockey stick appearance) in 39 (65%), conical (type A) in 10 (16.7%), tubular (type C) in 8 (13.3%), and complex (type D) in 3 (5%).

The majority of the used devices were Piccolo devices in 58 (97%) patients. KA microplug was used in 2 patients (3%). The devices were 3/2 (width/length) mm Picclo device in 27 (45%), 4/2 mm Piccolo in 26 (43.3%), 4/4 mm Piccolo in 5 (8.3%), 5/4 mm Piccolo in 1 (1.6%), 5 mm KA micro plug in 1 (1.6%), and 3 mm KA microplug in 1 (1.6%) patients.

## Discussion

Since the Amplatzer Piccolo Occluder (Abbott, Plymouth, MN) has gained Food and Drug Administration (FDA) approval for use in premature infants weighing > 700 g, experience with transcatheter PDA device closure has been rapidly increasing [3, 17]. In many centers, including ours, TCPC was adopted as the primary method for definitive PDA closure. When compared with surgical ligation, TCPC has many advantages. It is less invasive, with high success and low complication rates [9, 11, 12, 18].

To mitigate the potential risks associated with transportation, contrast, and radiation exposure, it has been an ambition to perform the procedure solely under TTE guidance at the bedside in the NICU [12–16]. Nevertheless, the ability of the TTE to predict the angiogram PDA dimensions remains uncertain as the evidence is confined to a single-center study [12].

Contrary to Paudel and colleagues' findings which we cannot explain [12], this study did not find a strong correlation between TTE and angiogram PDA dimension measurements. Rather, the correlation was moderate for the pulmonary end measured on 2D without color Doppler images ($R = 0.57$) and on 2D with color Doppler images when needed ($R = 0.6$) (ED2 vs. AD2). In addition, the correlation was weak for the length (EL vs. AL) ($R = 0.21$) and aortic end (ED1 vs. AD1) ($R = 0.37$) measurements. The aortic end (ED1 and AD1) is not considered when choosing the device size. Furthermore, the length is not an important factor if a short device (2 mm in length) is intended to be placed [9, 19, 20]. It is worth mentioning that each Piccolo device size

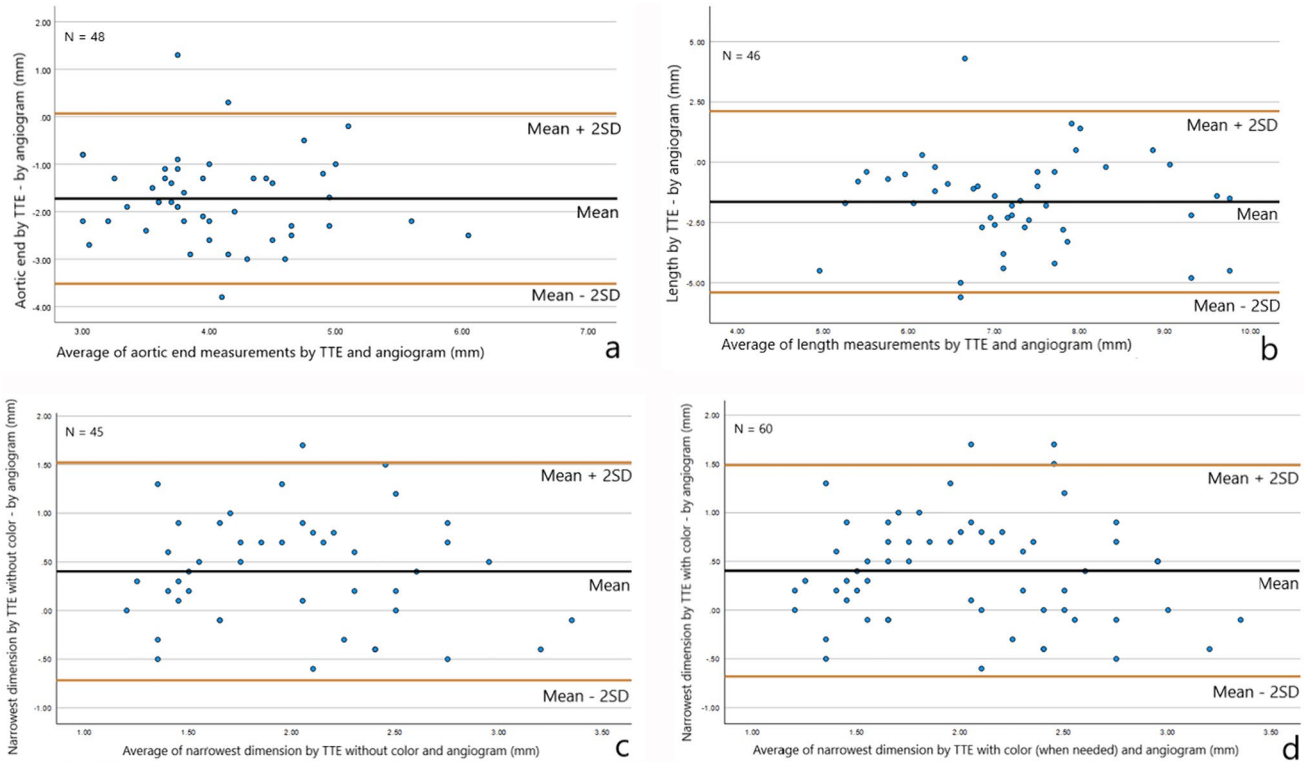


**Fig. 4** Bland–Altman plots show the correlation between the echocardiogram and angiogram patent ductus arteriosus (PDA) measurements. **a** Correlation for the aortic end. **b** Correlation for the PDA length. **c** correlation for the smallest PDA dimension with no color Doppler. **d** Correlation with the smallest dimension was measured without color Doppler and with color Doppler images when needed. TTE transthoracic echocardiogram. SD standard deviation

**Table 3** Bland–Altman test and Pearson correlation test results comparing the dimensions of patent ductus arteriosus when measured by echocardiogram and angiogram

| Variable (*N*) | Mean difference (SD) (TTE-angiogram), mm | 95% limit of agreement (−2, +2) SD | Correlation coefficient (*R*) | *P* value |
|---|---|---|---|---|
| PDA aortic diameter (48) | − 1.64 (1.92) | (− 5.40, + 2.12) | 0.21 | 0.017 |
| PDA length (46) | − 1.73 (0.91) | (− 3.52, + 0.07) | 0.37 | 0.01 |
| PDA narrowest diameter without colour (45) | 0.40 (0.57) | (− 0.72, + 1.52) | 0.57 | < 0.001 |
| PDA narrowest diameter with colour if needed (60) | (0.55) | (− 0.68, + 1.49) | 0.60 | < 0.001 |

*PDA* Patent ductus arteriosus. *SD* standard deviation. *TTE* transthoracic echocardiogram

(width) is available in 3 different lengths (2 mm, 4 mm, and 6 mm) [17]. It is widely accepted that using long Picclo devices, i.e., 4 and 6 mm, should be restricted to cases where the length of the PDA allows for full intraductal placement of the device [16, 19]. In contrast, the short, i.e., 2 mm in length piccolo device can be utilized in short as well as long PDAs as well [12, 19]. The authors prefer to use mainly 2 mm long piccolo devices regardless of the PDA length. We believe that the short devices are easier to place entirely intraductal, minimizing the risk of iatrogenic aortic and/or LPA obstruction [9, 19, 20]. Therefore, the narrowest PDA diameter is pivotal in choosing the device size for a given weight. Although a short device could theoretically increase the risk of embolization, this was not observed in this study, nor in studies where only short devices were used [9, 20].

Traditionally, a 2D TTE image without color is used to measure the PDA dimensions [12]. However, due to the poor acoustic window in some patients, the PDA dimensions could not be adequately measured in all patients without utilizing color Doppler. The poor acoustic windows in some premature infants could be attributed to hyperinflated lungs and chest vibration, as most of our patients undergo the procedure on high-frequency jet ventilation [11]. Measuring the narrowest PDA dimension using colored images allowed assessing this dimension in all patients without decreasing the correlation strength with angiogram measurement

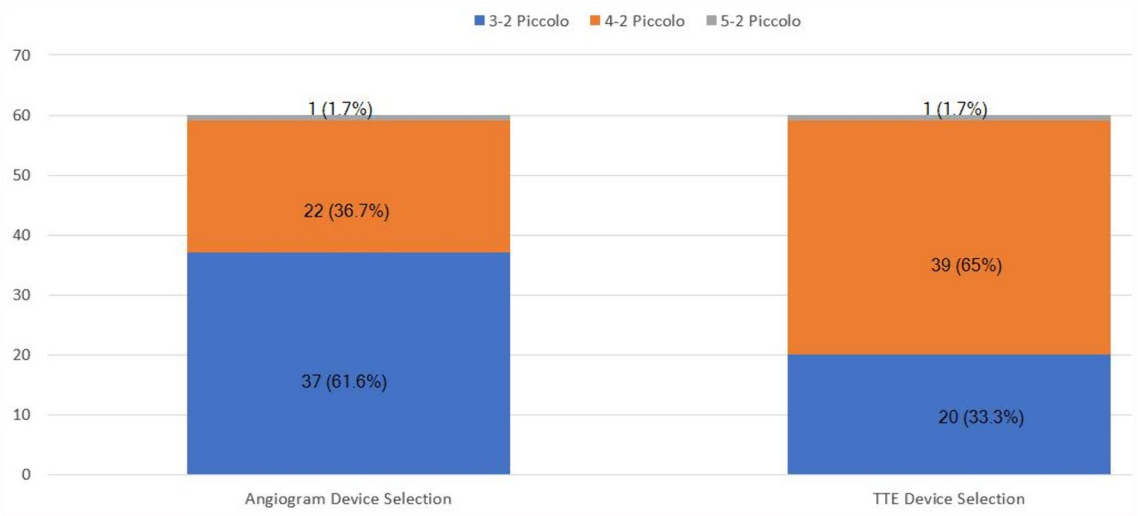


**Fig. 5** Summary of device selections based on TTE and angiogram measurements when Table 1 is utilized

($R = 0.60$). The authors speculate that the TTE ICC correlations are not strong, at least partially due to two factors. First, despite measuring the PDA dimensions is performed during systole, it is difficult to measure at the exact timing within systole. Therefore, although the investigators measured the dimensions from the same clip, the measurements at the same point in the systole could not be guaranteed. Second, as the absolute values of the PDA dimensions are small in premature infants, even a minor measurement error could result in statistically significant different numbers.

The results of this study suggest that the TTE tends to overestimate the narrowest PDA dimension (ED2 vs. AD2) and underestimate the PDA length (EL vs. AL) and aortic end (ED1 vs.AD1) measurements (Tables 2 and 3). Although the TTE tends to overestimate the narrowest dimension, this is likely clinically insignificant as the TTE could predict the accurate size in most patients [43 (72%) patients] and overestimated the device's size in the remainder of the patients (17 patients = 28%). TTE did not underestimate the size of the narrowest segment of any patient. Theoretically, this oversizing will not compromise the device's stability but could increase the risk of LPA and aortic obstruction. TTE is useful to assess LPA and aortic flows after positioning but before release. This allows for device position adjustment if needed.

The discrepancy between TTE and catheterization measurements could be attributed to catheter-induced ductal spasm. The TTE's overestimation of the narrowest PDA dimension could be related to the timing of TTE performance before any catheter-induced vasospasm. Furthermore, angiograms could underestimate this dimension due to the potential of catheter-induced ductal spasms. It is noteworthy that in one patient, severe ductal spasm was noticed on angiogram after the PDA was crossed uneventfully (Fig. 6). Moreover, it was observed that in 13 patients, the smallest diameter of the PDA according to the angiogram was less than 1.33 mm (which is the size of the 4-Fr AG catheter). At the same time, the TTE showed the narrowest diameter was at least 1.5 mm. In older children, the PDA is susceptible to spasm if crossed in an antegrade fashion. Therefore, a baseline aortic angiogram is obtained at the beginning of the procedure to measure the true (not spasmed) PDA dimensions. Additionally, after deploying the device, residual flow across the PDA and the device's position are assessed by repeating

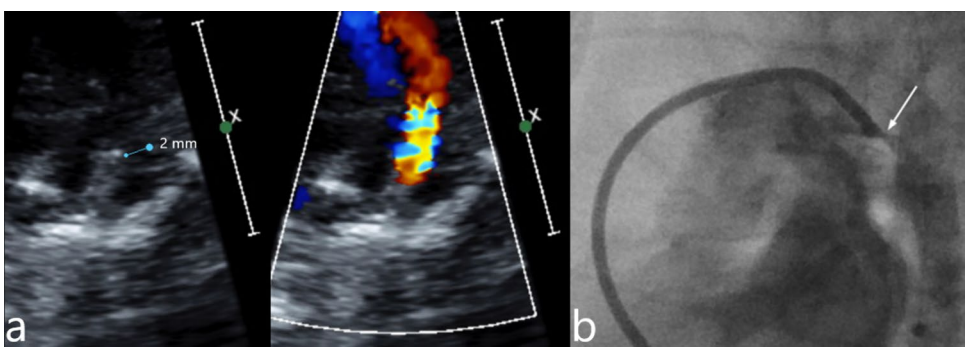


**Fig. 6** Intraprocedural Echocardiogram (**a**) and angiogram (**b**) demonstrate the occurrence of catheter-induced ductal spasm. The echocardiogram reveals that the narrowest patent ductus arteriosus (PDA) dimension measured 2 mm. The angiogram shows the narrowest PDA dimension is extremely small (spasm)

aortic angiogram through the arterial access [21]. However, in premature infants, it is widely accepted to perform the TCPC via a single venous sheath and avoid obtaining arterial access due to the high incidence of access-related complications [1, 3, 4, 8, 19, 22, 23]. Hence, the PDA is crossed from the pulmonic end (prograde fashion) before obtaining the angiogram. This could induce ductal spasm, which may result in underestimating the true PDA dimension and lead to a smaller device selection. The incidence of catheter-induced ductal spasms is unknown, especially in small premature infants. Nevertheless, older children who were born prematurely are specifically at risk of ductal spasms during TCPC [24]. When the authors suspect ductal spasm, they rely on the TTE smallest dimension to choose the device.

We speculate that TTE can be relied on to choose the Piccolo device and assess the adequacy of positioning without needing an angiogram. One of its strengths was that the narrowest PDA dimension could be measured in all patients without under-sizing device selection. Also, TTE was able to assess the arch and LPA flow in all patients. However, whether the TTE can guide catheter manipulation and device deployment is yet to be answered. The procedure might still be done at the bedside using a portable fluoroscopy machine without needing an angiogram with the help of TTE.

## Limitations

This is a single-center study with a limited cadre of patients. Larger multicenter studies might help confirm our findings across a wider population of patients. TTE requires an experienced operator to optimize each acoustic window to measure the PDA dimensions, especially when the windows are poor due to lung hyperinflation and chest wall vibration. This might be reflected in the weak to modest ICC statistics between the blinded investigators. This wider variability in measurements could require more than one clinician to take measurements during these procedures.

Catheter-induced ductal spasm could not be ruled out as a possible cause for the discrepancy in measuring the smallest PDA dimension between TTE and angiography. This question could be answered by conducting studies measuring TTE PDA dimensions before and after obtaining the angiogram. Moreover, this study was not designed to investigate whether TTE can be exclusively utilized to guide TCPC in premature infants.

## Conclusion

PDA dimensions measured by TTE do not match those obtained by angiogram. Although the difference was statistically significant, the device selection was either matched or slightly oversized compared to the one chosen based on the angiogram. The safety of relying solely on TTE to choose the device has yet to be studied.

**Author Contribution** Bassel Mohammad Nijres measured the PDA dimensions, analyzed the data, created the figures and tables, and wrote the main manuscript. Mohammad Khallaf collected the data. Kaitlin Carr, Umang Gupta, and Adrianne Rahde Bischoff measured the PDA dimensions. Jimmy Windsor, Osamah Aldoss, and Patrick J McNamara critically revised the manuscripts. All authors reviewed the final version.

**Data Availability** No datasets were generated or analysed during the current study.

## Declarations

**Conflict of interests** The authors declare no competing interests.

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