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Echocardiography Versus Angiography for Guiding Device Selection for Transcatheter Patent Ductus Arteriosus Closure Among children

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ABSTRACT
Background: The most common congenital heart abnormality in neonates is the patent ductus arteriosus (PDA). The preferred course of treatment for PDA is transcatheter device closure (TCC) in people of all ages. Adequate imaging is important to delineate the PDA. Echocardiographic and angiographic measurements of PDA both can guide device selection for transcatheter patent ductus arteriosus closure (TCPC). Currently angiographic imaging of ductus is the gold standard. Echocardiographic imaging may be good enough to substitute angiography for device selection in the Zagazig University Hospitals. **Objectives:** The aim of the current work was to investigate the efficacy of transthoracic echocardiography (TTE) in determining type & dimensions of PDA and to anticipate device size to be used during TCC.
Patients and methods: This prospective cohort study included a total of 24 patients with hemodynamically significant PDA aged 44.04 ± 44.9 months, both male and female and their weight more than 6 kg, treated at Pediatric Cardiology Unit, Department of Cardiology, Zagazig University Hospitals. Echocardiographic and angiographic examination were done.
Results: There were no statistically significant differences between either the aortic ampulla diameter, narrowest PDA diameter and detection of type of PDA measured by echocardiogram and that measured by angiography.
Conclusion: It could be concluded that using TTE-guidance can make echocardiography even simpler with fewer complications. Routine echocardiography is a useful tool for planning interventions and, in some circumstances, for directing transcatheter closure.
Keywords: PDA, angiography Echocardiography, Transcatheter closure

INTRODUCTION
In pediatrics, congenital cardiac abnormalities, one of the most common heart conditions in term infants, is patent ductus arteriosus (PDA), which accounts for 5–10% of all congenital abnormalities [(1)].

The pulmonary and systemic circulations are linked through the ductus arteriosus. The ductus arteriosus narrows and loses lumen after birth, separating the pulmonary and systemic circulations. The placenta and descending aorta receive blood from the ductus arteriosus instead of the fluid-filled lungs during the entire life of the fetus [(2)].

Failure to seal the ductus arteriosus in some neonates can result in the PDA, medium and large shunts are due to left heart volume overload and increased pulmonary blood flow, vulnerable to the development of congestive heart failure (CHF) [(3, 4)].

Cardiac imaging is useful for diagnosing, managing, and following up on surgical treatments. As echocardiography delivers quick, high-resolution physiological and anatomical data is quick, safe, noninvasive, and widely available, it is always the first-line imaging method of choice. The main drawbacks are that the image quality can suffer in children who are uncooperative or from a weak acoustic window [(5)].

The ideal method of treating patent ductus arteriosus (PDA) occlusion in patients of all ages is trans catheter device closure (TCC) [(6)].

PDA's morphology is diverse in terms of shape and size, which has methodological consequences for TCC [(7)].

As a result, many different gadgets in several PDA devices have been successfully occluded in a wide range of sizes and shapes. A thorough analysis of the PDA's shape and dimensions, including the diameter of the ductal ampulla, length, and narrowest PDA diameter at its insertion into the pulmonary artery, is necessary to ascertain the viability of device closure and choose the appropriate device type and size without obstructing flow in the aorta or left pulmonary artery[(7, 8)].

By looking at the aortic angiography images, this is accomplished at the cardiac catheterization lab. Aortic angiography does a good job of profiling the PDA architecture, albeit at the risk of radiation exposure. In some cases, particularly for big PDA, many angiograms may be necessary to accurately profile the morphology of the PDA[(8)].

The aim of the current work was to investigate the efficacy of transthoracic echocardiography (TTE) in determining type & dimensions of PDA and to anticipate device size to be used during TCC.

PATIENTS AND METHODS
This prospective cohort study included a total of 24 patients with hemodynamically significant PDA aged

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44.04 ± 44.9 months, both male and female and their weight more than 6 kg, treated at Pediatric Cardiology Unit, Department of Cardiology, Zagazig University Hospitals. This study was conducted between June 2022 till January 2023.

Exclusion criteria: Patients who weighed less than 6 kg, those with duct dependent lesions, those with insufficient images from an angiogram or echocardiogram to precisely measure PDA size, and PDA with high pulmonary vascular resistance were excluded.

All study participants underwent comprehensive medical history taking, clinical examinations that included **(**weight, Height, body surface area measurement, vital signs), general examination (low activity, dyspnea) and local examination of heart (audible murmur). The following were evaluated: GIT dysfunction (abdominal distension, eating intolerance, hepatomegaly, and jaundice), circulatory dysfunction (poor peripheral circulation, hypotension, prolonged capillary refill), and respiratory dysfunction (apnea, indications of respiratory distress). Echocardiographic examination by two different operators was done blinded to each other. Measuring the ductus in Supra sternal view and para sternal ductal view was done to measure narrowest diameter at the pulmonary end, aortic end and ductus length and determine its type if possible.

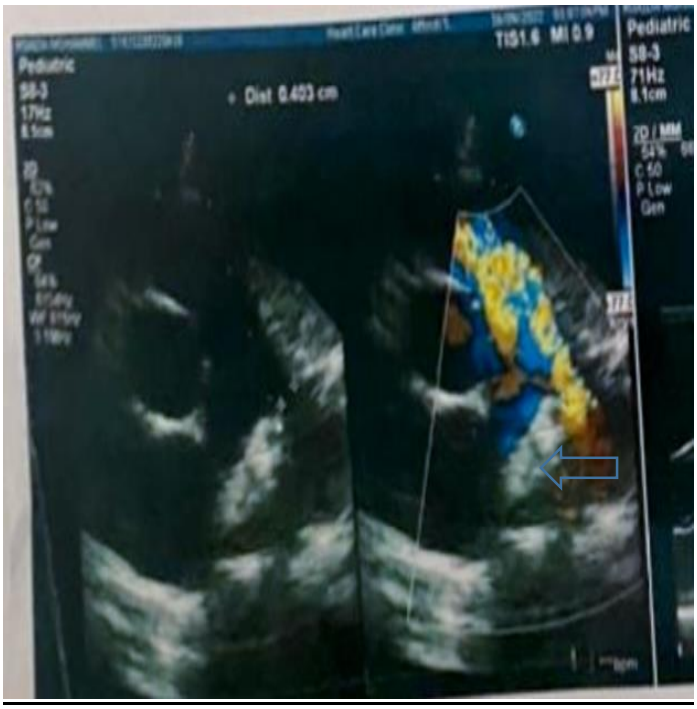

Fig (1): Narrowest PDA diameter at the pulmonary end by echocardiography.

Angiographic examination prior to the device selection and PDA Closure, angiography was done in the lateral view and right anterior oblique view to determine the ductus length, aortic and pulmonary end and type.

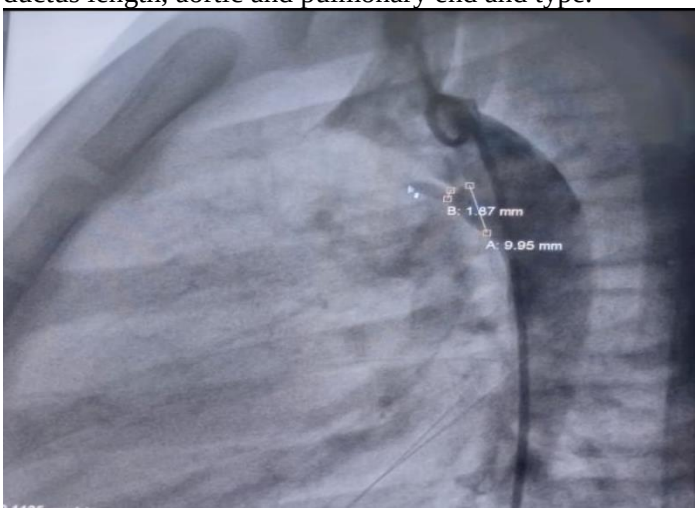

Fig (2) PDA diameter by Angio aorta and pulmonary ends.

***Ethical Consideration*:**

This study was ethically approved by Zagazig University's Research Ethics Committee (ZU- IRB #9509-2022). Written informed consent of all the participants was obtained. The study protocol conformed to the Helsinki Declaration, the ethical norm of the World Medical Association for human testing.

Statistical analysis

SPSS version 23 was used for data processing, data checking, data entry, and data analysis. The following statistical techniques were employed to analyze the outcomes: the student "t" test, one sample independent test, Bland Altman scatter plot and Chi- square test..

RESULTS

Table (1); socio-demographic characteristics and anthropometric measurements of the studied group

Variables	***The studied group*** *No= 24 (Mean ± SD) Median (Range)*
Age *(months)*	44.04 ± 44.9 19 (8-128)
Weight *(Kg)*	15.3 ± 11.6 10.5 (6-40)
Height *(Cm)*	87.9 ± 28.3 73 (60-137)
BSA *(m2)*	0.618 ± 0.33 0.45 (0.32-1.28)
Sex *Male* *Female*	7 (29.2%) 17 (70.8%)
Age group *≤ One year* *> one year*	9 (37.5%) 15 (62.5%)

Table 1 shows that the average age of the studied group was (44.04 ± 44.9) ranging from 8 to 128 months, their weight was (15.3 ± 11.6) ranging from 6 to 40 (Kg), their height was (87.9 ± 28.3) ranging from 60 to 137 (cm) and their body surface area was (0.618 ± 0.33) ranging from 0.32 to 1.28. More than half of the studied group were more than one year (62.5%) and more than two-thirds of the studied group were males (70.8%) and (29.2%) were females.

Table (2); Complaints among the studied group;

Complaint	***The studied group No= 24 (%)***
Difficult breathing	6 (25.0%)
Cough/dyspnea	3 (12.5%)
Recurrent infection	5 (20.8%)
Patient is dysmorphic and echo done	3 (12.5%)
Delayed sitting	3 (12.5%)
Recurrent tonsillitis	2 (8.3%)
Under-weight &recurrent chest infectio	2 (8.3%)

Table 2 shows that difficult breathing was the commonest complaint (25.0%) followed by recurrent infection (20.8%) then cough/dyspnea and delayed sitting (12.5%) and lastly recurrent tonsillitis and under-weight &recurrent chest infection (8.3%) for each.

Table (3); ECHO findings among the studied group;

Variables	***The studied group No= 24*** *Mean ± SD Median (Range)*
Left ventricular end diastole	2.89± 0.73 2.55 (2.1-4.7)
Left ventricular end systole	1.75± 0.43 1.6 (1.3-2.54)
intra ventricular septum diastole *(Cm)*	0.55± 0.11 0.5 (0.36-0.8)
EF *(%)*	68.95± 6.16 68 (61-79)
FS *(%)*	39.7± 4.19 39 (32-46)

Table 3 shows that the average left ventricular end diastole of the studied group was (2.89± 0.73) ranging from 2.1 to 4.7, left ventricular end systole was (1.75± 0.4) ranging from 1.3 to 2.54, their intra ventricular septum diastole was (0.55± 0.11) ranging from 0.36 to 0.8, their EF was (68.95± 6.16) ranging from 61% to 79 % and their FS was (39.7± 4.19) ranging from 32 to 46.

Table (4); Aortic ampulla and pulmonary end diameters by ECHO among the studied group;

Variables	***The studied group No= 24*** *Mean ± SD Median (Range)*	***Test***	***P-value***
1st-time aortic ampulla diameter	8.4± 2.9 8 (4-15)	0.58^	0.56
2nd-time aortic ampulla diameter	7.95± 2.28 8 (5-14)		
The mean difference between the two measurements	0.44± 1.6	1.3^^	0.19
1st-time pulmonary end diameter	2.47 ± 0.58 2.5 (1.8-4)	0.42^	0.7
2nd-time pulmonary end diameter	2.39 ± 0.77 2 (1.8-4)		
The mean difference between the two measurements	0.08 ± 0.41	0.98^^	0.34

^= *independent t test,* ^^= *one sample t test.*

Table 4 shows that there was no statistically significant difference between the two measurements of the diameter of the aortic ampulla and narrowest PDA diameter by ECHO.

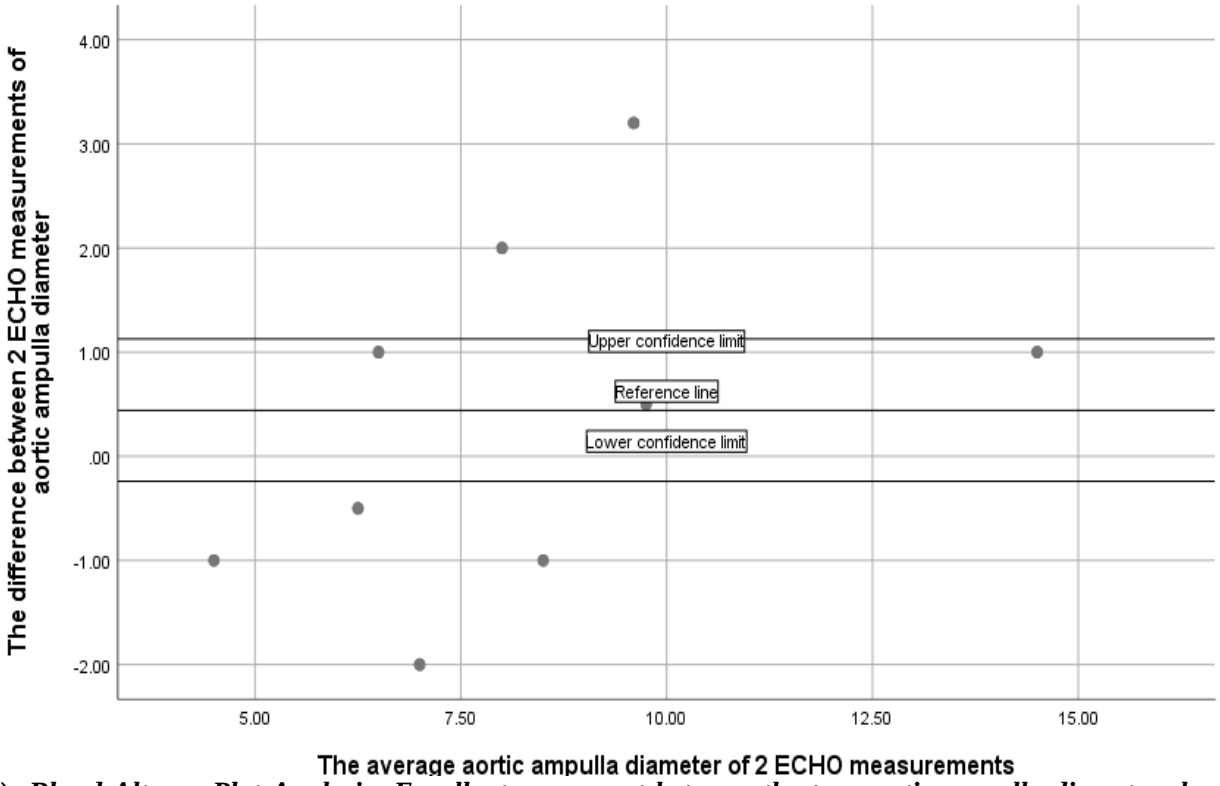

Fig (3); Bland Altman Plot Analysis; Excellent agreement between the two aortic ampulla diameters by ECHO. *The middle-dash line represents the mean difference which coincides with zero indicating no significant bias. Small dashed lines indicate the upper and lower 95% limits of agreement which is narrow.*

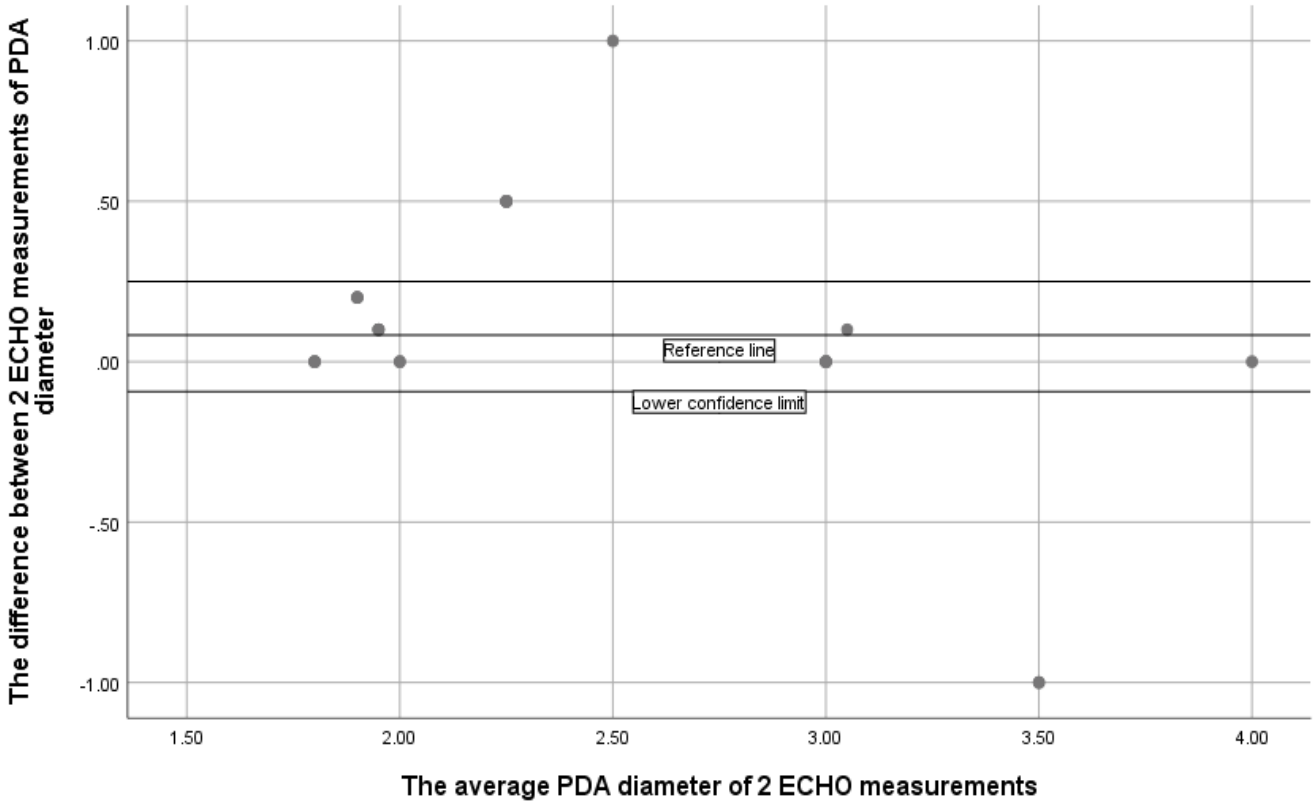

Fig (4); Bland Altman Plot Analysis; Excellent agreement between the two PDA diameters by ECHO. The middle-dash line represents the mean difference which coincides with zero indicating no significant bias. Small dashed lines indicate the upper and lower 95% limits of agreement which is narrow.

Table (5); Concordance between echocardiographic and angiographic findings among the studied group;

Variables	***The studied group No= 24*** *Mean ± SD Median (Range)*	***Test***	***P-value***
The average aortic ampulla diameter by ECHO	8.17± 2.5 8 (4.5-14.5)	0.6^	0.5
The aortic ampulla diameter by Angio	8.58± 1.86 9 (5-13)		
The mean difference between the two measurements	0.40± 1.17	1.7^^	0.1
The average pulmonary end diameter by ECHO	2.43 ± 0.65 2.25 (1.8-4)	1.6^	0.1
Pulmonary end diameter by Angio	2.11 ± 0.41 2 (1.5-2.7)		
The mean difference between the two measurements	0.29 ± 0.77	1.86^^	0.07

^= *independent t test,* ^^= *one sample t test.*

Table 5 shows that there was no statistically significant difference between the average aortic ampulla diameter and narrowest PDA diameter by ECHO and its diameter by angiography

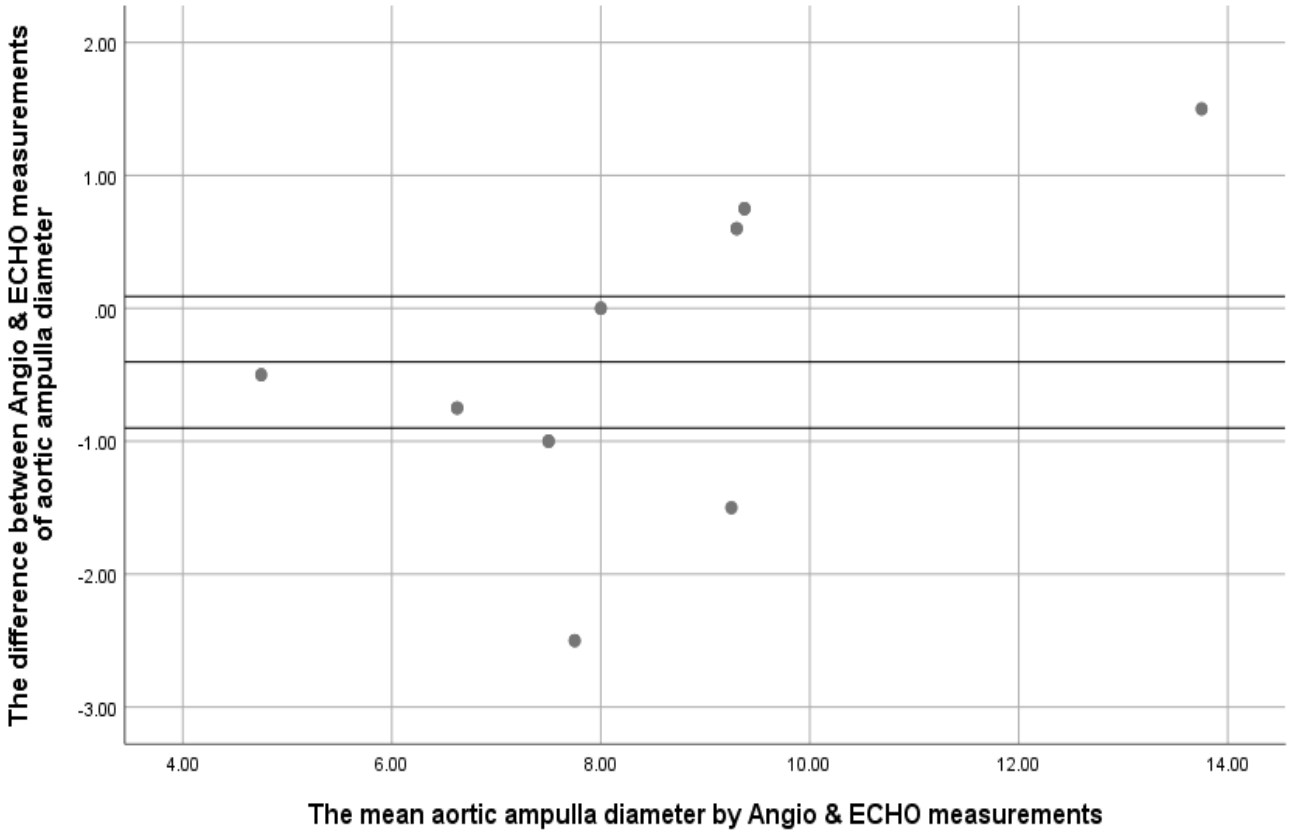

Fig (5); Bland Altman Plot Analysis; moderate agreement between the ECHO and Angiography measurement of aortic ampulla diameters by. The middle-dash line represents the mean difference which coincides with zero indicating no significant bias. Other dashed lines indicate the upper and lower 95% limits of agreement which is narrow.

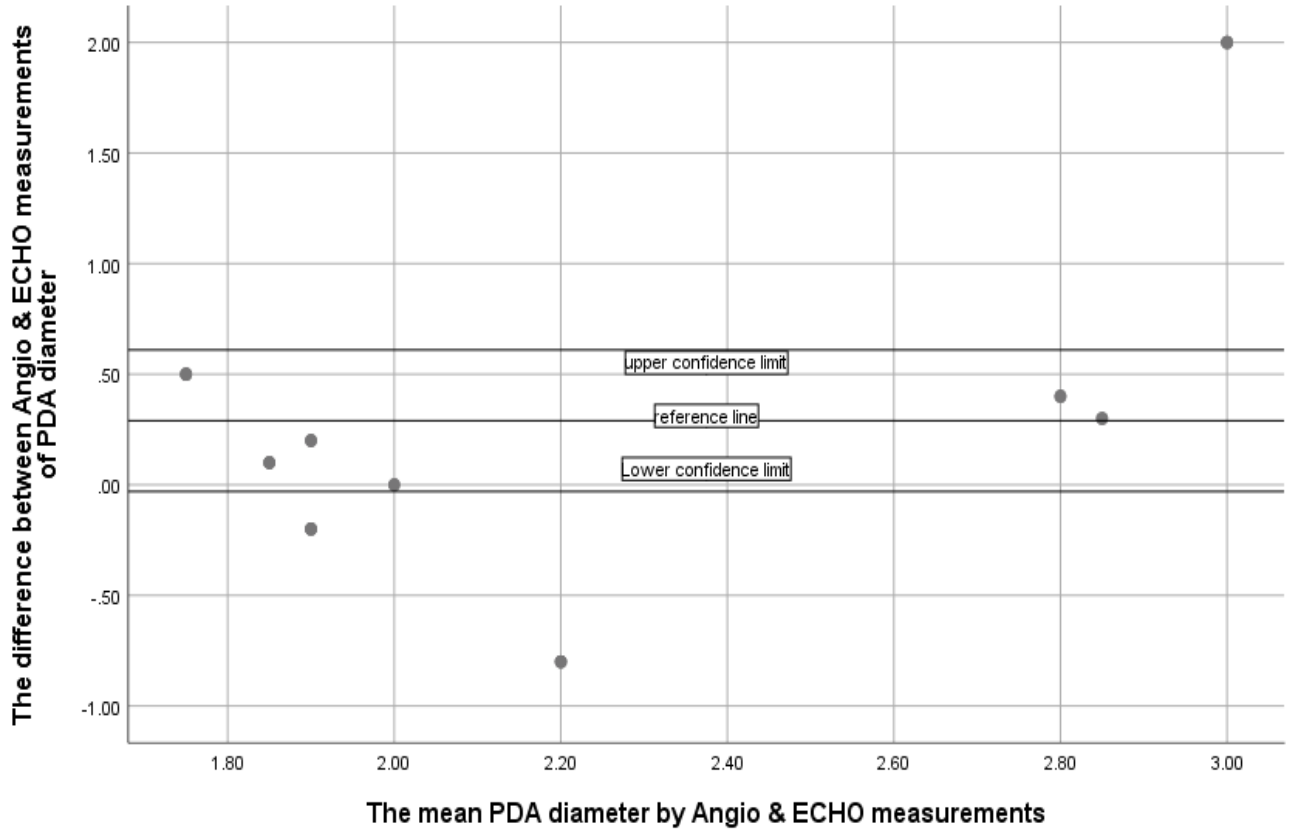

Fig (6); Bland Altman Plot Analysis; moderate agreement between the ECHO and Angiography measurement of PDA diameters by. *The middle-dash line represents the mean difference which coincides with zero indicating no significant bias. Other dashed lines indicate the upper and lower 95% limits of agreement which is narrow.*

Table (6); Comparing the type of the pulmonary end between ECHO and Angio among the studied group;

Type of pulmonary end	*The studied group No= 24 (%)*	*test*	*P-value*
1st time by ECHO		2.5	0.09
Conal Tubular	24 (100.0%)		
	0 (0.0%)		
2nd time by ECHO			
Conal Tubular	24 (100.0%)		
	0 (0.0%)		
Type by Angio			
Conal Tubular	21 (87.5%)		
	3 (12.5%)		

Chi-square test.

Table 6 shows that there was no statistically significant difference between ECHO and angiography regarding the detection of type of PDA.

Table (7); The type and size of the device of Angio;

Variables	*The studied group No= 24 (%)*
Size of device	
*OCC 6*4*	6 (25.0%)
*ADO 6*4*	13 (54.2%)
*ADO 6*8*	5 (20.8%)
Type of device	
Amplatzer Duct Occlude OCC	18 (75.0%) 6 (25.0%)

Table 7 shows that three-fourths of the studied group used Amplatzer Duct Occlude (75.0%), ADO size 6*4 was among (54.2%) while ADO size 6*8 was among (20.8%) and only one-fourth used OCC size 6*4 (25.0%).

Table (8); Complications among the studied group;

Complications	*The studied group No= 24 (%)*
Anemia & bleeding	3 (12.5%)
No	21 (87.5%)
Bleeding	0 (0.0%)
thrombus	0 (0.0%)
arrythmia	0 (0.0%)
heart perforation	0 (0.0%)
cardiac tamponate	0 (0.0%)

Table 8 shows that most of the studied group didn't have complications (87.5%) and only three cases had bleeding and anemia.

DISCUSSION

PDA (patent ductus arteriosus) still creates significant burden. Infants born preterm frequently have PDA, which is the most common cardiovascular condition among them. The prevalence of PDA and the baby's gestational age are oppositely correlated. More than 50% of newborns delivered at or before 26 weeks of gestation have an open ductus, according to recent studies more than two months after birth. According to data on term infants, PDAs account for 5% to 10% of all congenital heart disease and are present in about 1 in 2000 births. According to study of a long-term cohort, the prevalence of "silent" PDA cases—those identified through heart imaging without any clinical symptoms—approaches 1 in 20 births [9].

In our study, the average age of studied cases was (44.04 ± 44.9) ranging from 8 to 128 months. Almost half of the cohort had more than one year (62.5%).

In their study to evaluate regular 2D echocardiography's accuracy in predicting PDA device choice in children, **Galal *et al.* [10],** found average age was 2.6 ± 2.5 years (range 0.2–14 years).

In our study, the average weight was (15.3 ± 11.6) ranging from 6 to 40 (Kg).

Galal *et al.* [10], found that the study population's average weight was 11.2 ± 7.8 kg (range: 1.5-57 kg). **Paudel *et al.* [11],** stated that the average birth weight was 660 g (470-1000 g). At the time of PDA closure, the average weight was 900 g (600-1460g). **Ye *et al.* [12],** found that the mean weight ± SD among case group were (17.32 ±3.6), and the mean weight ± SD among control group were (16.68 ±2.9). **Chen *et al.* [13],** found that the median weight 50.57 kg (range 7.52- 71.20 kg).

In our study, difficult breathing was the commonest complaint (25.0%) followed by recurrent infection (20.8%) then cough/dyspnea and delayed sitting (12.5%) for each and lastly recurrent tonsillitis and under-weight & recurrent chest infection (8.3%) for each.

Ye *et al.* [12], found that in addition to respiratory infections and developmental delays, exercise-related palpitations, shortness of breath, and fatigue may occur.

In our study, the average LVIDd of the studied group was (2.89± 0.73) ranging from 2.1 to 4.7, LVIDs was (1.75± 0.4) ranging from 1.3 to 2.54, their LVSD was (0.55± 0.11) ranging from 0.36 to 0.8, their EF was (68.95± 6.16) ranging from 61% to 79 % and their FS was (39.7± 4.19) ranging from 32 to 46.

Ye *et al.* [12], found that echocardiographic parameters of LV (mm) before PDA closure was (32.28 ± 9.34), and after PDA closure was (25.47 ± 7.34) and LVEF (%), before PDA closure was (55.24 ± 5.46) and after PDA closure was (59.25 ± 7.18).

In our study, the two readings of Echo, the diameter of the aortic ampulla varied amongst them by a factor that was statistically significant by ECHO; 8.4± 2.9 mm versus 7.95± 2.28 mm (P-value=0.7). Analysis of the Bland-Altman plot showed a mean bias of 0.44 between the two measurements of the aortic ampulla diameter Having a 95% confidence interval and a standard deviation of 1.6 of -0.24 and 1.12.

Galal *et al.* [10], stated that for the research population, the smallest diameter of the PDA as determined by TTE was 2.53 ± 1.02, Aortic Ampulla Diameter was 10.2 ± 3.1 and PDA Length was 10.5 ± 3.1.

Paudel *et al.* [11], found that PDA diameter at PA end was 3.1 (0.72) mm, PDA diameter at aortic end was 4.5 (0.68) mm. Length of PDA by conventional technique (Echocardiography 1) was 8.2 (1.73) mm, length of PDA by alternate technique (Echocardiography 2) was 11.0 (1.83) mm.

Ye *et al.* [12], found that 20 PDAs cases had an aortic side diameter and were funnel-shaped of 8.5 ± 2.7 mm and a pulmonic diameter was 4.2 ± 0.6 mm. In the 12 tube-type cases, the inner diameter of the PDA was 4.2 ± 1.2 mm, and the length was 5.5 ± 0.8 mm.

Chen *et al.* [13], reported that two-dimensional echocardiography (2DE) alone was unable to see PDA in 65 individuals (21.8 %) and, as a result, was unable to determine the size of the duct in these individuals, in contrast to two-dimensional color-coded flow imaging in echocardiography (2DE–CDFI) could identify PDA in every patient, making it possible determine the size of the duct for every patient. Despite the 233 patients' 2DE-detectable PDA (78.2 %), In similar patients' matched measurements, the narrowest duct width determined by 2DE (MDW) was still much lower than the minimal shunting width determined by 2DE-CDFI (5.14 and 2.18 mm vs. 5.75 and 1.99 mm; p 0.001).

There was no statistically significant difference between the two ECHO measurements for the smallest PDA diameter; 2.47 0.58 mm versus 2.39 0.77 mm (P-value=0.7). The Bland-Altman plot analysis revealed a mean bias of 0.08 between the two PDA measurements,

with a standard deviation of 0.41 and wide 95% confidence intervals on agreements between -0.09 and 0.25.

The aortic ampulla's diameter was statistically different between TTE and angiography; 10.2± 3.1mmvs 9.6 ± 2.9 mm, p =0.047. Analysis of the Bland-Altman plots between TTE and angiography showed a mean bias of 0.57 Having a 95% confidence interval and a standard deviation of 3.2 of 7.0 and −5.8. The PDA length was somewhat overestimated by The difference between echocardiography and angiography was statistically significant (10.5 3.1 mm vs. 9.7 2.9 mm; p = 0.01). An study of Bland-Altman plots showed that TTE and angiography had biases of 0.85 and 0.85, respectively, with a standard deviation of 3.8 and wide 95% margins of agreement of 8.5 and 6.8.

Galal *et al.* [10], found that for the study population, the PDA's narrowest diameter as evaluated by TTE and angiography was equivalent; 2.53 ± 1.02 mm vs 2.53 ± 1.22 mm; p = 0.99. There was no evident bias between TTE and angiography, according to the Blande Altman plot analysis 0.9 and narrow 95% limits of agreement of 1.8 and 1.8.

Paudel *et al.* [11], stated that the angiographic measurement and On TTE, the PDA's pulmonary end diameter was accurately determined (3.1 6 0.72 mm vs 3.2 6 0.94 mm; P = .14). There was good connection between the angiographic measurements and the TTE assessment of the PDA diameter at the aortic end (4.5 6 0.68 mm vs 4.4 6 0.85 mm; P = .26). Even though the PDA's length and the angiographic length were both calculated using the traditional TTE method (EL1) although they largely agreed, the mean findings revealed that they diverged significantly (8.2 6 1.73 mm vs 10.8 6 2.15 mm; P < .001). However, a different TTE method was used to determine the PDA length (EL2) that more closely matched the length obtained by angiography (11.0 6 1.83 mm vs 10.8 6 2.15 mm; P = .40) with better correlation.

In our investigation, the average aortic ampulla diameter by ECHO and its diameter by Angiography did not differ in a statistically significant way (8.17± 2.5 mm versus 8.58± 1.86 mm (P-value=0.5). A Bland-Altman plot analysis utilizing the standard deviation of the aortic ampulla's diameter revealed a mean bias of 0.4 and broad 95% margins of agreement of -0.09 and 0.09 between the two readings of 1.17. ECHO and Angiography did not reveal any statistically significant differences in the narrowest PDA diameter (2.43 0.65 mm versus 2.11 0.41 mm) (P-value = 0.1). Between the two measurements of the PDA, there was a mean bias of 0.29, with a standard deviation of 0.77 and wide 95% margins of agreement of -0.03 and 0.61.

In our study, no statistically significant distinction existed between ECHO and Angiography regarding the detection of type of PDA.

Galal *et al.* [10], reported that statistically significant differences were seen comparing the results of the two imaging modalities to determine the PDA type ($\chi 2 = 87.9$, $p < 0.01$), Despite this, the PDA's shape was typically recognized in an appropriate manner [108 patients (82%)].

In our study, three-fourths of the studied group used Amplatzer Duct Occlude (75.0%), ADO size 6*4 was among (54.2%) while ADO size 6*8 was among (20.8%) and only one-fourth used OCC size 6*4 (25.0%).

Galal *et al.* [10], found that most of the time, TTE was able to anticipate the size and Angiography (n = 115) was used to determine the device type (Amplatzer or coil), but there was no statistically significant difference between the two modalities in terms of device selection ($\chi 2 = 1.23$, $p = 0.54$).

In our study, most of the participants in the study had no issues (87.5%) and only three cases had bleeding and anemia.

Paudel *et al.* [11], stated that unintentional stenosis of the left pulmonary artery (LPA) or the aorta is one of the side effects of transcatheter patent ductus arteriosus closure (TCPC) By implanting the gadget entirely within the PDA, these issues can be eliminated. For precise intraductal positioning of the device, transthoracic echocardiography guidance is essential. Before being released, the device must be adjusted if necessary and validated once more by transthoracic echocardiography (TTE). It is required to do continuous-wave Doppler over the aortic arch and branch PA to look for any obstruction (peak velocity > 2 m/sec). A delayed upstroke with continued diastolic flow in the pulse-wave Doppler of the descending thoracic aorta and the LPA may provide additional proof of any proximal obstruction.

CONCLUSION

Echocardiography is a feasible option for assessing duct size, shape, and choice of guide device. The results of the study indicate that using TTE-guidance can make the procedure even simpler with fewer complications.

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