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Original Article

Transcatheter Ductus Arteriosus Closure with Various Devices in the Pediatric Patient Group and Long-term Outcomes: Experience from a Single Center

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ABSTRACT

Aim: The emergence of advanced duct occluder devices has made transcatheter patent ductus arteriosus (PDA) closure the preferred treatment for pediatric patients. This study compared the effectiveness, safety, and long-term outcomes of various transcatheter PDA closure devices.

Materials and Methods: This study involved 320 patients aged 0 to 18 years who underwent transcatheter PDA closure at our hospital from 2004 to 2023. We retrospectively reviewed their records in order to assess procedure success, demographic information, clinical features, angiographic parameters, and complications. Patients were categorized by closure type: Group I for coil closure, Group II for Amplatzer Duct Occluder (ADO)-I closure, and Group III for ADO-II closure.

Results: In this study of 320 patients, 203 (63.4%) were female and 117 (36.4%) male. The average age was 56.5 months (±49.6), with a median weight of 15 kg (interquartile range 10.5-23 kg). The median diameter of the PDA at its narrowest point was 2.0 mm (interquartile range 2-3 mm). Ductal anatomy distribution was as follows: Type A (176 patients, 55%), type B (49 patients, 15.3%), type C (30 patients, 9.3%), type D (5 patients, 1.56%), type E (57 patients, 17.8%), and type F (4 patients, 1.25%). Arterial access was used in 263 patients (82.1%), and venous plus arterial access in 57 patients (17.8%). Closure techniques included the ADO-II in 107 cases (33.4%), ADO-I in 12 cases (3.75%), and coils in 201 cases (62%). The early closure rate was 97.5%, with initial shunt rates of 0.6% and 0.3% at one month. Device embolization occurred in 5 patients (1.87%). By the six-month follow-up, all PDAs had closed, resulting in an overall transaction success rate of 97.5%. The average follow-up period was 105.8±55 months.

Conclusion: Percutaneous closure of PDA in children is safe and effective, with a high success rate. Key factors include the patient's age, weight, duct dimensions, and the type and size of the PDA. ADO-I devices are ideal for larger defects, while coil or ADO-II devices are preferable for smaller ones. Proper patient selection is critical for successful outcomes.

Keywords: Children, patent ductus arteriosus, percutaneous PDA closure, PDA closure devices

Introduction

The ductus arteriosus is a blood vessel connecting the aorta and pulmonary artery during fetal development. It typically closes within 12 to 24 hours after birth. If it remains open, this condition is called "patent ductus arteriosus" (PDA) (1).

PDA occurs in about 0.03% to 0.08% of full-term infants and is more common in females (2). An open PDA can lead to serious complications such as heart failure, infective endocarditis, and pulmonary hypertension (3). Transcatheter closure of PDA began in 1967 with the Ivadon device (4). In the 1990s, coils were introduced for small

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ducts under 2.5 mm. The Amplatzer Duct Occluder (ADO), capable of closing larger PDAs up to 13 mm, was first used in 1997 and has become a standard treatment.

Various devices have since been developed for differing ductal anatomies. It is essential to select an appropriate device based on the patient's anatomy, age, and weight (5,6).

This article shares our long-term experience and compares the effectiveness and safety of different devices for transcatheter PDA closure in pediatric patients at our clinic.

Materials and Methods

This study was conducted on patients aged 0 to 18 who had transcatheter PDA closure at our hospital from 2004 to 2023. We reviewed the medical records, excluding those with other congenital heart anomalies or incomplete data. Informed consent was obtained, and this study was approved by the Medical Research Ethics Committee of Ege University (approval no.: 24-3T/74, date: 07.03.2024).

We assessed procedural success, demographic data, clinical features, angiographic parameters, and complications, categorizing patients by closure method: Group I for coil closure, Group II for ADO-I, and Group III for ADO-II.

Indications for PDA Closure

The patients in this study were chosen based on specific criteria (7,8). Closure of the PDA was primarily carried out for those with growth retardation, left atrial and ventricular enlargement, and audible murmurs. Those patients with faint murmurs but significant blood flow on echocardiograms and those without moderate to severe pulmonary hypertension were also included. Defects were assessed using transthoracic echocardiography. Those individuals with irreversible pulmonary vascular disease or high-pressure ratios were excluded.

Statistical Analysis

Statistical analyses were performed using SPSS Statistics version 26.0 (IBM Corp., 2019). Descriptive statistics included the number of units (n), percentages (%), median (M), and minimum and maximum values for categorical variables. Continuous variables were reported as mean ± standard deviation (SD) or median (range). Normally distributed data were analyzed with Student's t-test, while non-normally distributed data used the Mann-Whitney U test and the Kruskal-Wallis test. Chi-square analysis was applied to categorical data. The significance threshold was set at $p<0.05$.

Results

Between 2004 and 2023, 320 patients underwent percutaneous PDA closure at our clinic, with 203 girls (63.4%) and 117 boys (36.6%), resulting in a girl-to-boy ratio of 1.73. The mean age was 56.5 months (±49.6), and the median weight was 15 kg [interquartile range (IQR): 10.5-23 kg]. Closure methods included the ADO-II in 107 cases (33.4%), ADO-I in 12 cases (3.75%), and a coil in 201 cases (62.8%).

The median diameter of the PDA at its narrowest point was 2.0 mm (IQR 2-3 mm), with a significant difference between groups ($p<0.01$). Those patients treated with the ADO-I device had a mean PDA diameter of 4.1 mm (SD ± 2.1 mm), while those treated with the ADO-II device had a mean diameter of 2.9 mm (SD ± 0.9 mm). Overall, the mean PDA diameter was 2.2 mm (SD ± 0.6 mm).

On average, the diameter of the PDA was 1.9 mm larger for those patients using the ADO-I device compared to the coil device, while the ADO-II device showed a 0.7 mm increase. The 1.1 mm difference between ADO-I and ADO-II was not statistically significant. Ductal anatomy distribution was as follows: Type A in 176 patients (55%), type B in 49 (15.3%), type C in 30 (9.3%), type D in 5 (1.56%), type E in 57 (17.8%), and type F in 4 (1.25%). Type A ducts predominated in Groups 1 and 3, while Type B was most common in Group 2. Arterial access was used in 263 patients (82.1%), and combined venous and arterial access in 57 (17.8%). Transvenous access was more common in Group 2, while transarterial access more common in Groups 1 and 3. Closure procedures varied significantly by PDA morphology and device type ($p<0.01$), with type A ducts most frequent in Group 1 (63.2%) and Group 3 (42.1%), and type B ducts dominant in Group 2 (50%).

The PDA was successfully closed in 312 of 320 patients, achieving a 97.5% success rate. There were 8 failures (2.5%), with residual shunts in two patients on the first day. Shunt occurrence was 0.6% initially and decreased to 0.3% after one month. No residual shunts were found in the ADO-I and ADO-II device groups. By the six-month follow-up, all patients with residual shunts had their PDAs closed, leading to an overall one-year success rate of 98.1%. Device embolization occurred in 5 patients (1.87%), four of whom had been treated with coils and one with an ADO-II device.

Embolization procedures involved one coil and the ADO-II device in the main pulmonary artery, two coils in the right pulmonary artery, and one coil in the aorta. One patient required surgery to remove the embolized device and ligate the PDA, while the other four received

transcatheter treatment and later underwent PDA closure surgery due to device availability and cost issues. One patient (0.3%) experienced cardiac tamponade and needed urgent intervention. Two cases (6.2%) had post-closure leakage with duct diameters of 3 mm and 4 mm. Both were type A ducts, and all patients were monitored for residual shunts, with no complications such as hemolysis or infection reported. Long-term follow-up showed no ductus recanalization or stenosis among those with complete occlusion. The average follow-up duration was 105.8 months (SD ± 55). Success rates were high: 97.5% in Group 1, 100% in Group 2, and 99% in Group 3, with an overall rate of 97.5%. Follow-up evaluations were conducted immediately post-procedure, the following day, at six months, twelve months, and annually.

No cases of obstruction or significant gradients were found, and long-term monitoring showed no major complications such as permanent shunts, hemolysis, or infective endocarditis.

Discussion

Isolated PDA occurs in full-term infants at rates of 0.03% to 0.08% and is more common in females. In our study, 203 patients (63.4%) were female, compared to 117 males (36.4%), resulting in a female-to-male ratio of 1.73. We noted that PDA prevalence was higher among females across all device groups, consistent with the existing literature (2). Since 1938, surgical interventions have been essential in PDA treatment, with the transcatheter method gaining traction since 1967 (4). While Gianturco coils were commonly used in the 2000s, their popularity has declined due to the introduction of newer devices and the risks associated with multiple coils and embolization. As a result, the long-term outcomes of coils have been less studied (9-11). In our research, we achieved a 97.5% success rate in transcatheter PDA closure using coils, aligning with previous success rates of 89% in Germany, 90.5% by Galal (12), and 94.6% in a series involving 243 patients (11). The ADO-I device is shaped like a mushroom, while the ADO-II resembles an umbrella (13). Both devices automatically adopt their intended forms due to an innovative memory feature. The ADO-I has a larger disc on the aortic side for secure fixation, while the ADO-II features equally sized discs at both ends with a narrower waist in the middle. These devices effectively close PDA and have shown strong results. In a study of 29 patients under one year of age, 26 (89.6%) achieved successful duct closure with an ADO device. The complete closure rates were 73.1% immediately after the procedure, rising to 84.6% after 24 hours and 96.1% by the third month (14). Notably, the ADO device has a complete closure rate exceeding 98% at six months and very low complication rates (15). ADO devices have been used in our clinic since 2008. Our study achieved a 100% success rate in transcatheter PDA closure with ADO-I, with no residual shunts detected in any patients. This underscores the high success and low residue rates of ADO devices compared to coils (12-15). Our procedure success rates were 97.5% in Group I, 100% in Group II, and 99% in Group III. The ADO group consistently showed higher success rates than the coil group, with no significant difference between ADO-I and ADO-II ($p>0.05$). Small-diameter and long PDA devices may not be suitable for all patients, so device selection should depend on the PDA type and size. Most patients in our study had small PDAs, and some underwent closure before ADO devices became widely available, leading to more experience with coil closures.

Device embolization is a significant concern, with rates varying from 0% to 6% (16-18). Coil closures have a higher risk of embolization (about 4%) compared to ADO devices (less than 1%) (16-18). In our study, embolization was noted in four coil closure patients and one patient with an ADO-II device, requiring surgical intervention to remove the embolized devices. Our clinic's transition to ADO devices post-2008 and the cost-effectiveness of the closure procedure influenced the decision for surgery. Device embolization during the release of ADO-I usually occurs in the pulmonary artery but can extend to systemic circulation. A study of 209 patients found three cases of embolization, while our study reported none with ADO-I (6). However, caution is advised when using ADO-I in young children under 5 kg, as it may cause obstruction in the pulmonary artery or aorta (14). The ADO-II device is designed for safe use in infants and offers anterior and posterior placement options (19,20). In our study, ADO-II was successfully used in 107 patients (33.4%) with a 99% success rate for transcatheter PDA closure. Overall, the coil embolization rate was only 1.9%, with none in Group II and just one case (0.93%) in Group III. After percutaneous closure of a PDA, there is a risk that closure devices may protrude into the aorta or cause stenosis in the left pulmonary artery, potentially related to the retention disc or the use of larger coils (19-21). In our study, echocardiographic Doppler evaluations before discharge showed no stenosis in any patients. In a study of 62 patients with a median age of 1.2 years who underwent transcatheter PDA closure with ADO-II, the residual shunt rate was 5% immediately post-procedure, dropping to 0% at one year and in long-term follow-ups (22). Our findings showed a 1% residual shunt rate in the coil group the day

after closure, while no residual shunt was detected in the ADO-I and ADO-II groups. By the one-year follow-up, all patients with residual shunts in the coil group had closed spontaneously.

Study Limitations

Our literature review highlights the limited use of the ADO-I device for PDA closure, with only 12 patients in our study receiving this treatment. The most common ductal structure among these patients was Type B, which is more challenging to close via transcatheter methods. We propose that ADO-I devices may be the preferred choice for Type B ductus closures. While studies are limited, Faella and Hijazi (23) suggested that ADO devices could be effective for cases of window-type ductus. However, we recommend multicenter studies with larger patient cohorts to confirm our findings. A key limitation of this study was the preference for coils and ADO-II devices for occluding PDA up to 3 mm in diameter, resulting in varying duct sizes among the participants. The small sample size and reliance on retrospective data collection further restrict our findings, particularly due to the limited number of patients with ADO-I devices, which affected statistical comparisons. Larger, multicenter studies with prospective data collection would provide stronger evidence for using these devices in pediatric patients.

Conclusion

Recent advancements have improved the closure of PDA via transcatheter procedures, achieving high success rates. Patient selection is critical, requiring careful consideration of age, weight, duct dimensions, and device size. Although the use of coils has decreased, they remain suitable for smaller duct diameters. ADO-I devices work best for large PDAs, while ADO-II devices are recommended for small to medium PDAs with shorter ducts. ADO-I devices are also ideal for Type B ducts.

Ethics

Ethics Committee Approval: This study was approved by the Medical Research Ethics Committee of Ege University (approval no.: 24-3T/74, date: 07.03.2024).

Informed Consent: Informed consent was obtained.

Footnotes

Authorship Contributions

Surgical and Medical Practices: Ş.Ş.Ö., E.D., F.E., M.B.B., G.K.K., M.Y., Concept: Ş.Ş.Ö., F.E., B.B.A., Z.Ü.T., Design: Ş.Ş.Ö., E.D., F.E., M.B.B., G.K.K., M.Y., B.B.A., B.K.B., Z.Ü.T., R.E.L., Data Collection or Processing: Ş.Ş.Ö., F.E., M.B.B., G.K.K., M.Y., B.K.B., Z.Ü.T., R.E.L., Analysis or Interpretation: Ş.Ş.Ö., E.D., G.K.K., M.Y., B.K.B., Z.Ü.T., R.E.L., Literature Search: Ş.Ş.Ö., B.B.A., B.K.B., Z.Ü.T., R.E.L., Writing: Ş.Ş.Ö., F.E.

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