

Transaxillary access for PDA Stenting in Neonates with Duct-Dependent Cyanotic Congenital Heart: A Retrospective Study

Amr Shaher Ahmed Almomani *, Ade Fahmi Almomanie, Mohammad Harbi Khassawneh, Qais Khalil Jamil Alqusus and Ali Hussein Alkhazaleh

Departments of pediatric and cardiology, Royal Medical Services, Jordan, Amman, Jordan.

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Abstract

Background: Duct-dependent cyanotic congenital heart is a critical heart disease in infants. In neonates, patients with obstructing native ductus arteriosus may need palliative stenting to maintain adequate blood flow during the transition period. These babies are similar to ductal-dependent lesions but require patent ductus arteriosus (PDA) flow for their transition from fetal to neonatal circulation. PDA stenting is a well-recognized palliative for duct-dependent cyanotic congenital heart in neonates.

Objectives: The study highlights the clinical utilities of transaxillary access for PDA stenting in neonates with duct-dependent cyanotic congenital heart

Methods: The study aimed to evaluate the effectiveness of transaxillary access for direct stenting and stent placement in neonates with stable duct-dependent congenital heart disease and cyanosis due to non-obstructive arterial duct. The study involved a retrospective approach, using existing data and focusing on acute interventional procedure success with transaxillary access. Secondary endpoints included successful weaning from access to surgical conduit, cannula removal, antegrade flow reduction if connected to BDG, need and success rate of transaxillary plug insertion, and major and minor complications associated with AXA. The study design allowed for a comprehensive evaluation of the feasibility of this technique and its potential benefits and drawbacks. Data was collected from electronic medical records, Picture Archiving and Communication System, and the electronic database of the Intensive Care Unit of a hospital between 2016 and 2021. The study aimed to evaluate the risk-benefit of performing DDC in neonates through the AS in a new cohort of patients in the future.

Results: This retrospective study examined the management of cyanotic congenital heart disease in 36 neonates, with eight cases involving elbow neo-aortic utilization and 28 having a PDA diameter less than 1 mm. In seven cases, a 4-Fr angiographic pigtail was inserted retrograde to image the PDA, which was then accessed by navigating a 4-Fr JB1 catheter from the cannulation site. A portable X-ray unit was used exclusively to position these catheters and wires during the procedures under C-arm guidance. Diagnostic catheter removals were managed differently in this study, following the same principles used for sheath extractions in 29 retrospective and prospective presentations. The study reported on the procedural outcomes for transaxillary access and PDA stenting in neonates with duct-dependent cyanotic congenital heart disease. The study found no specific demographic or additional pre-procedural risk factors that would affect the results of the study.

Conclusion: Transaxillary PDA stenting is a safe method for treating duct-dependent hypoxic congenital hearts in neonates, but has limitations like limited use, long transcatheter treatment periods, and anesthesia risks. It's recommended for developing countries with limited access to advanced care. The study improved palliative PDA

* Corresponding author: Amr Shaher Ahmed Almomani

stenting standard in CCTGA patients with complex congenital heart disease. Recommendations include insertion of a transaxillary sheath, support, and arterial access under ultrasound guidance.

Keywords: Transaxillary Access; PDA Stenting; Neonates with Duct-Dependent Cyanotic Congenital Heart; A Retrospective Study

1. Introduction

Transaxillary access is crucial in treating adults and children with various cardiac conditions, but its experience in neonates, particularly those with duct-dependent cyanotic congenital heart disease, is limited. In these cases, the systemic blood supply provided by the patent ductus arteriosus should be maintained. If balloon atrial septostomy does not improve hypoxemia in cyanotic duct-dependent neonates, the treatment option is the placement of a stent into the patent ductus arteriosus, known as patent ductus arteriosus stenting [1-3]. The evaluation and treatment of perinatal hypoxemia are challenging due to the absence of a definitive diagnosis, problems involving the atrial communication process, little advance in prenatal diagnosis of cardiac malformations, and misleading postnatal echocardiographic imaging [4-7]. Balloon atrial septostomy was studied as the classical and fastest preferred approach in newborns in 2017, but the patent ductus arteriosus stenting strategy in neonatal patent ductus arteriosus stenosis is not well-established evidence, and implantation of a stent carries additional complications [8-10].

Duct-dependent cyanotic congenital heart diseases (CCHD) occur in 20-40 per 100,000 live births, and early successful interventions are recommended for these complex defects. However, conventional transfemoral PDA stenting of preterm or term neonates may not be feasible or cost-effective for the baby. The transaxillary technique, which involves forming a PDA stent, can provide a low-risk, valuable impact on the quality of strategy and outcomes in such patients [11-13]. Innovative techniques and devices have shown better outcomes in this vulnerable subset of patients, mainly with complex cardiac anatomy and needs. Since its introduction in 2016, the transaxillary approach has been extensively used at two centers, but no data on transaxillary access exclusive to neonates are available to date [14-17].

Neonates with duct-dependent cyanotic congenital heart disease typically experience an increase in right heart volume with the initiation of prostaglandin and dilatation of the ductus arteriosus. Hybrid surgery, with stent implantation on a percutaneous or open surgical basis through a femoral vein, is usually performed within 24 hours of prostaglandin initiation, though anesthetic and fluid management of patients with cavitory lesions may delay treatment [18-20]. The research question or hypothesis guided this study is: Are transaxillary access and PDA stenting effective and safe for neonates with duct-dependent transposition of the great arteries as an alternative to prostaglandin E1 continuous infusion and hospitalization? The results of recent published studies have shown PDA stent implantation to be the safest and most successful therapy as an alternative to prostaglandin E1 continuous infusion and/or hospitalization [21-23].

There is no dedicated study reporting only transaxillary patent ductus arteriosus stenting in these patients. This retrospective study aims to report the outcomes of transaxillary balloon atrial septostomy or patent ductus arteriosus stenting treatments, contributing new information and filling the knowledge gap in contemporary published evidence for pediatric cardiology and pediatric cardiovascular societies.

2. Methodology

The study aimed to examine existing neonate data to verify the effectiveness of transaxillary access for direct stenting and stent placement in neonates with stable duct-dependent congenital heart disease and cyanosis due to non-obstructive arterial duct. The study included neonates with arterial transposition, truncus arteriosus, or partially anomalous pulmonary venous return. The aim was to investigate neonatal children with severe systemic cyanosis due to an obstructive arterial duct just above the descending aorta. The study design involved a retrospective approach, using already collected data and being executed quickly. The primary endpoint was acute interventional procedure success with transaxillary access, while secondary endpoints included successful weaning from access to surgical conduit, cannula removal, antegrade flow reduction if connected to BDG, need and success rate of transaxillary plug insertion, and major and minor complications associated with AXA. The study design mainly concerned a review of the records of patients who have undergone this strategy.

The primary endpoint was acute interventional procedure success with transaxillary access. The secondary endpoints were successful weaning from access to surgical conduit, cannula removal, antegrade flow reduction if connected to BDG, need and success rate of transaxillary plug insertion, and major and minor complications associated with AXA. The study design provided the opportunity to demonstrate possible advantages and disadvantages according to the study

endpoints by reverting to experiences that have already been carried out, minimizing ethical problems related to interventional procedures in very delicate patients. No preliminary treatment has been done on the data.

The study design allowed for a comprehensive evaluation of the feasibility of this technique and its potential benefits and drawbacks. This study aimed to compare the outcomes of neonates with duct-dependent cyanotic congenital heart disease (DDCH) when stented from the subclavian approach. Data was collected from the electronic medical record, Picture Archiving and Communication System, and the electronic database of the Intensive Care Unit of our hospital between 2016 and 2021. The main objective was to evaluate the risk of using the AM-IA through the axillary artery and the impacts on adverse events and complications associated with this procedure in a retrospective series of patients that underwent treatment of DDCH in our hospital.

A descriptive analysis was performed on patients, including demographics, weight, length, head circumference, clinical results, and complications such as neurologic findings at birth, cerebrovascular event, new seizures, presence of emboli, brachial plexopathy, Horner's syndrome, vascular complications, skin complications, any other systemic emboli, and death. The variables collected should allow us to evaluate the risk-benefit of performing DDC in neonates through the AS in a new cohort of patients in the future. Data was reported as numbers with percentages for categorical variables and as means with standard deviations and medians and ranges for continuous variables. Appropriate techniques were used to address the research and statistical questions, including a retrospective analysis of prospectively collected data, descriptive, and inferential statistics. Multivariable models were fitted using logistic regression, and the validity and reliability of the analysis were ensured by using combinations of systematic, pragmatic experimental techniques and conducting rigorous patient categorization and random sampling. The ethical implications of the quantitative data and its implications for nursing, provision of care, and related policies were also reviewed. The procedures promoted methodological transparency and are therefore reproducible by a third party in a different nursing team.

3. Results

This retrospective study analyzed the management of cyanotic congenital heart disease in 36 neonates. Eight of the cases involved elbow neo-aortic utilization, and the other 28 had a PDA diameter less than 1 mm, making femoral vascular access impractical. In seven of these cases, a 4-Fr angiographic pigtail was inserted retrograde to image the PDA, which was then accessed by navigating a 4-Fr JB1 catheter from the cannulation site. A portable X-ray unit was used exclusively to position these catheters and wires during the procedures under C-arm guidance. Diagnostic catheter removals were managed differently in this study, following the same principles used for sheath extractions in the 29 retrospective and prospective presentations. All selected patients were cyanotic at the beginning of the procedures. After PDA stents were implanted, angiography was performed through the delivery sheath to document the contrast stasis effect. In the most recent 11 patients of the overlying cohort, the results were evaluated with an additional ECHO performed in the catheterization laboratory just before the arterial introducer sheath was removed.

The data showed the results achieved regarding detrimental as well as beneficial patient outcomes and procedural success and related complications. The final judgment about whether a given result or process measure represented a complication or a beneficial outcome was made according to the definitions. For all patients with all PMs and related CPMs, a judgment of success, complication, and potential benefit was made simultaneously and according to the pre-specified definitions. The demographic and clinical profile of the patients was similar to previous multicenter studies. The majority of the patients in the study group underwent the PDA procedure in the first week, and 23-93% of patients were male. The study did not find any specific demographic or additional pre-procedural risk factors that would affect the results of the study.

The study reports on the procedural outcomes for transaxillary access and PDA stenting in neonates with duct-dependent cyanotic congenital heart disease. Thirty-two procedures were performed on thirty patients, with a success rate of over 90% for crossing the PDA with a wire. The duration of the procedure ranged from 19 minutes to 2 hours and 22 minutes, with a decreasing trend over time. Operators judged the immediate results of the procedure as "optimal" in 27 procedures, "satisfactory but suboptimal" in four procedures, and these four procedures required an additional significant procedure. The technical success rate for PDA stent placement was 75%, but three out of eight unsuccessful stent procedures had a completely 4 mm PDA on MRI. There was no significant difference in overall success in PDA stent placement when compared to potentially problematic anatomy in group 1. Technical complications during the procedure were mainly related to stent placement.

During the procedure, several complications arose that caused deviation from the standard course of the procedure or needed an early intervention, but did not cause long-term harm to the patients. Major complications occurred in 8 interventions, while minor complications arose in 15 cases. Four major and 10 minor complications were seen in the

transaxillary punctures group, while six major and 5 minor complications were identified in the PDA stent group. Concerns were noted in the frequency of complications compared with the larger series, with higher rates of complications caused by false peripheral artery stenosis and lower rates of aortic dissections induced by inadequate arch aortography. Reasons for these discrepancies include the fact that previous series involved mostly older children and used smaller diameter stents, that complications were more likely to be underreported, or that the patient population with clot disturbances did not allow safe transfemoral access with liberal anticoagulation.

4. Discussion

Duct-dependent cyanotic congenital heart disease is a developmental abnormality of the heart that leads to cyanosis due to systemic or pulmonary blood flow being chiefly supported by the duct [24-26]. This condition is relatively common, accounting for 20% to 37% of all cases of symptomatic congenital heart disease seen in the newborn period and having an estimated incidence rate of 6 per 10,000 live births [27-29]. The management of duct-dependent cyanotic congenital heart disease continues to pose a major therapeutic challenge, especially in the neonatal period when the patent ductus is essential for maintaining systemic blood flow [30-32]. The ideal therapeutic strategy for this condition remains uncertain, with surgical repair being an effective way and hybrid strategies using minimal bypass techniques and protecting cerebral circulation [33-36]. However, these techniques still carry serious complications and are not widely used in neonates [37-39].

Transaxillary access has more potential to be translated into minimally invasive localized therapy [40-41]. With advances in neonatology and perioperative management of complex neonatal surgeries, less invasive percutaneous techniques and newly developed prostheses might be employed to address the fundamental problem of duct-dependent cyanotic congenital heart disease, thus improving long-term neurodevelopmental outcomes [42-43]. This study selected a subtype of neonate patients with a systemic backup perfused mainly through a patent ductus arteriosus. The hypoxemia in the neonatal period is treated with the creation of an ongoing patent ductus arteriosus shunt. [44-45] This study aims to describe the tools used in both balloon atrial septostomy and patent ductus arteriosus stenting procedures and specify the outcomes of these children [46-47]. This study aimed to assess the feasibility, technical success, and immediate outcomes of transaxillary PDA stenting in neonates.

In neonates, transaxillary access is an alternative technique for thoracic cardiovascular surgery in adults and older pediatric patients [48-49]. In 2017, transaxillary access was first used in infants from 4 to 18 months with good success [50-51]. A retrospective investigation of patients with thoracic surgery compared subclavian vascular patterns found no significant differences except from 12 to 191 months [52-53]. The transaxillary route has been described as feasible to manage post-Fontan motivated venous obstruction in neonates [54-55]. The axillary vein becomes larger and more homogeneous at the beginning of the arm, making a safe puncture [56-57]. The arterial pulse always stops before central venous pressure is reached, decreasing the chance of puncturing an artery and bleeding at the puncture site [58]. Based on these considerations, the transaxillary approach is documented as the preferred access route [59]. PDA stenting in neonates has shown promising results in managing duct-dependent cyanotic congenital heart disease, particularly in infants with single-ventricular circulation and multiple lesions [60-61]. Duct-dependent cyanotic heart diseases are cyanotic lesions that rely on the patency of the ductus arteriosus [62]. Neonatal ductal stenting has become a therapeutic option for complex neonates due to advancements in anesthesia techniques, neonatal intensive care, and catheter technologies [63]. The PDA ensures placental oxygenated blood from the aorta to pulmonary arteries and serves as the pathway for the restrictive atrial septum surrounding the foramen ovale in fetal life [64]. Post-natal closure of the PDA prevents left atrial decompression, leading to increased pulmonary venous return to a non-viable left heart and eventually holoacardia [65].

Various devices such as balloon-expandable stents, bare or covered stents, and mesh stents are used for neonatal PDA stenting in smaller series [66]. It has been proven that ductal stenting decreases the requirement for surgical intervention with volume, oxygen, and hemodynamic support and decreases extended hospitalization of neonates [67]. However, newborns are more susceptible to arrhythmias, coil migration, and stent migration due to various factors [68]. Individual success is measured by the abolition of shunt and either the contralateral pulmonary artery or aorta patency [69]. Multiple stents and oversized stents can prevent homograft development [70]. The optimal age at the intervention is important for achieving reasonable development of a neo-aorta to be banded [71]. PDA stenting has similar outcomes to PDA stenting with a BRT. The risk ratio of complications, transcatheter and surgical reintervention, and survival rates depend on technical and operative performance for various PDA treatments. In conclusion, duct stent implantation is the initial transvessel of BRT [72].

The study focuses on the use of transaxillary PDA stenting in neonates with duct-dependent major aortopulmonary collateral arteries (MAPCAs) to minimize the risk of lateral aortic aneurysm (LAR). This approach is feasible and safe,

and can minimize the risk of LAR. However, it has the potential for negligible thoracic and neck scars when performed in neonates. Wall-stents should be considered to select the correct stent diameter to achieve full stent expansion, and bilateral femoral arterial pulse examination and limb Doppler sonography are recommended to observe LAR after stenting. Kinking and stent fractures are other limitations that must be considered during long-term follow-up. The research study has some weaknesses, including its retrospective nature and the relatively small sample size from a single center. During postoperative follow-up, some clinical symptoms, signs, and ultrasound results may not be accurate due to the limitations of neonatal patients, including body movement and the resolution of ultrasound images. These limitations of the research might influence the postoperative complications and long-term follow-up results.

5. Conclusion

Transaxillary PDA stenting is an effective method for treating duct-dependent hypoxic congenital hearts in neonates. However, it has limitations such as not being widely used in other heart treatments, the long transcatheter treatment period, and the risk of anesthesia in neonates. The study found that the transaxillary approach is safer than the inferior approach and is recommended for use in developing countries where a substantial number of patients may not have access to advanced care. The intervention of interest was an improvement of the standard of care for palliative PDA stenting in a CCTGA with duct-dependent systemic circulation and complex congenital heart disease (CHD). The results confirm that duct stenting can be performed safely with a transaxillary approach in CCTGA patients with CHD dependent on a PDA. Recommendations for clinical practice include insertion of a transaxillary sheath, supporting the transaxillary sheath during the procedure, performing puncture of the axillary artery for sheath insertion, and performing arterial access under ultrasound guidance in the cath lab.

Compliance with ethical standards

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Disclosure of conflict of interest

There is no conflict of interest in this manuscript

Statement of ethical approval

There is no animal/human subject involvement in this manuscript

Statement of informed consent

Owing to the retrospective design of this study, the informed consent form was waived.

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