International Journal of Cardiology xxx (2017) xxx–xxx

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Patent Ductus Arteriosus closure in preterms less than 2 kg: Surgery versus transcatheter☆

Ozge Pamukcu [a,*], Aydin Tuncay [b], Nazmi Narin [a], Ali Baykan [a], Levent Korkmaz [c], Mustafa Argun [a], Abdullah Ozyurt [a], Suleyman Sunkak [a], Kazim Uzum [a]

[a] Erciyes University School of Medicine, Division of Pediatric Cardiology, Kayseri, Turkiye,
[b] Erciyes University School of Medicine, Division of Cardiovascular Surgery, Kayseri, Turkiye
[c] Erciyes University School of Medicine, Division of Neonatology, Kayseri, Turkiye

ARTICLE INFO

Article history:
Received 18 March 2017
Received in revised form 23 July 2017
Accepted 5 October 2017
Available online xxxx

Keywords:
Patent Ductus Arteriosus
Percutaneous
Surgery
Infant

ABSTRACT

Background: As new devices come into the market, percutaneous techniques improve and interventionalists become more experienced; percutaneous closure gets more common in preterms. In this study we aimed to compare efficacy and safety of Patent Ductus Arteriosus closure surgically versus transcatheter method in preterms <2 kg. Best of our knowledge this study is the first one that compares outcomes of surgery and percutaneous Patent Ductus Arteriosus closure in preterms.

Methods & results: Between the dates July 1997 to October 2014 in our center Patent Ductus Arteriosus of 26 patients <2 kg were closed percutaneously (Group A) and 31 less than 2 kg operated (Group B). Weight of patients in percutaneous Patent Ductus Arteriosus closure group was significantly more than the surgery group. Mean gestational age of the patients in Group A was 30 ± 1.8 weeks, in group B was 28.6 ± 3.5 weeks. In group A; all cases were closed successfully except 4 cases: device embolization in 2, cardiac tamponade and iatrogenic aortic coarctation were seen. Pneumomediastinum and chylothorax were the major complications of the surgery group. There was no statistically significance between complication and success rates between two groups.

Conclusion: Percutaneous Patent Ductus Arteriosus closure is the candidate for taking the place of surgery in preterms. However, it is not applied routinely; can only be done in fully equipped large centers by experienced interventionalists.

1. Introduction

Symptomatic patients who have Patent Ductus Arteriosus (PDA) should be treated as soon as possible, but the treatment method in preterm infants is a highly controversial topic. Surgical ligation is used for the definitive treatment if medical treatment fails [1,2]. However, in recent years, new devices have come onto the market, percutaneous techniques have improved and interventionalists have become more experienced, which have all led to percutaneous PDA closure gets more common in preterms.

In this study, we aimed to compare the success rate, complications in preterms weighing <2 kg whose PDA was closed surgically versus percutaneously.

To the best of our knowledge, this study is the first to compare the outcomes of surgery and percutaneous PDA closure in preterms.

2. Patients and methods

2.1. Patient population

From March 2012 to April 2016, transcatheter PDA closure was attempted in 26 patients weighing <2 kg in our center. Within this period, only 31 patients weighing <2 kg were operated on for PDA. The study was approved by the local research ethics committee.

The data of all patients were reviewed retrospectively. A comparison was made between the data from patients whose PDA were closed percutaneously (Group A) and surgically (Group B).

The main inclusion criteria for patients regarding PDA closure (transcatheter or surgical) were: 1) patients who were symptomatic, required intensive care because of the complications of prematurity; 2) patients in whom PDA was thought to be a possible contributor to the medical state of the patient by the consulting neonatologist; 3) patients whose left chambers were enlarged, 4) significant left to right shunt was detected by echocardiography; and 5) persistence of PDA after medical closure.

The main exclusion criteria were: 1) to be asymptomatic; 2) to weigh <2 kg; 3) to have bleeding diathesis; and 4) to have sepsis. The decision regarding the way of closure (whether transcatheter or surgical) was made according to the size and shape of the PDA. Large window types were usually referred to surgery. Also, the decision-making

☆ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

* Corresponding author at: Erciyes University School of Medicine, Division of Pediatric Cardiology, Kayseri 38039, Turkiye.
E-mail address: ozgepamukcu2002@yahoo.com (O. Pamukcu).

https://doi.org/10.1016/j.ijcard.2017.10.020
0167-5273/

process has changed over time. In earlier days, when we did not have enough experience in transcatheter closure and before the new devices came into the market, we used to perform surgery most often. Nowadays, as we have gained more experience and with the use of improved devices, we prefer transcatheter closure in suitable cases.

Patent Ductus Arteriosus shape and diameter were assessed with aortogram. However, angiography was not done routinely in cases that surgery was planned. Therefore, in such cases, the PDA size and shape were determined by transthoracic echocardiography (TTE).

The following patient characteristics were recorded: age, weight, sex, non-cardiac medical problems, gestational week, duration of hospitalization, and complications in both groups. The duration of mechanical ventilation, procedure time, fluoroscopy duration, and radiation dosage were also recorded in the percutaneous group.

Physical examination, chest radiography, electrocardiography, and TTE were done before each procedure. All the parents were informed about the procedure and its complications, and written consent was obtained before the procedure.

2.2. Procedure

2.2.1. Percutaneous closure and catheterization

Cardiac catheterization was performed under sedation and local anesthesia. Access to a femoral artery was obtained using the Seldinger technique; in some patients, the femoral vein or umbilical vein was used. We did not have routine arterial access in all patients. In recent years, as the devices were improved and as we obtained more experience, only venous access was used. According to the age and weight of the patient, size of sheath differed. All patients were heparinized after the insertion of sheaths. The ones who had arterial sheath were heparinized 100 IU/kg, the ones who only had venous sheath were heparinized 50 IU/kg. The activated clotting time (ACT) was maintained at >250 s during the procedure with iv heparin. Therefore, when the duration of procedure gets longer we check ACT and additional heparin dosages are applied in order to keep ACT > 250 s. Following heparinization and a dose of intravenous antibiotics, angiography was performed. Hemodynamic evaluations (ratio of pulmonary to systemic blood flow (Qp/Qs) and pressure recordings) were not done in all patients because all patients were premature and we wanted to keep the procedure time to a minimum.

Angiography was performed in descending aorta using pigtail catheter (Merit Medical, South Jordan, UT), typically using Right Anterior Oblique and lateral projections to profile PDA. Aortography was performed to determine the morphology and size of ductus. In patients without arterial access, we performed aortography after passing through PDA from the pulmonary artery to aorta. According to morphology, ducti were categorized according to Kritchenko et al. [3] classification. The width of aortic, pulmonary sides and length of ductus were measured and appropriate device with appropriate size was chosen. The main types of devices used in our study for percutaneous PDA closure were Amplatzer Ductal Occluders (ADO) (St. Jude Medical, St. Paul, MN). As time progressed during the study period, technology improved new versions of ADO were produced, such as the ADO II and ADO II-Additional size (AS) was used for small ducts as well. The ADO diameter is about 1–1.5 mm larger than the diameter of the narrowest point of the duct. The PDA was closed from the pulmonary or aortic side using the Amplatzer™ TorqVue™ 90° Curve LP (St. Jude Medical, St. Paul, MN) delivery system for all ADO II AS device and Amplatzer™ TorqVue™ 180° Curve (St. Jude Medical, St. Paul, MN) delivery system for ADO 1 device. The stability of the device was assessed by gentle pulling and pushing of the delivery cable. Correct positioning of the device was confirmed by radiocontrast injection through the delivery sheath prior to device release. Angiography was repeated after the device was released to evaluate the presence of residual shunts. After implantation of device, it was checked as to whether there was a pressure gradient on pullback from the ascending aorta to the descending aorta to exclude the presence of an obstruction on aortic side. In patients without arterial access, pressure gradient on aortic side was checked by TTE.

Transthoracic Echocardiography was performed to determine whether there was an obstruction of the left pulmonary artery (LPA) and descending aorta immediately after implantation. Follow-up echocardiography was performed on the next day, then 1, 3, 6 months after implantation and yearly thereafter. At each follow-up visit, complications related to ADO implantation were noted.

2.2.2. Surgery

PDA ligation was performed in the operating room. Post-operative follow-up was done by the neonatal intensive care specialist. The ductus was identified and ligated with two strands of 2–0 silk or 3–0 Ticron (Sherwood, Davis & Geck, St. Louis, MO, USA). Hemoclips were used in two patients. A 8-10 French chest tube was inserted routinely in all cases.

2.3. Statistical analysis

SPSS for Windows 15.0 program was used for statistical analysis. Distribution of variables was determined using the Shapiro–Wilkstest. Data are expressed as a frequency or percentage for nominal variables, as the median (25th–75th quartile) for categorical variables and as the mean ± SD for continous variables. In all statistical analyses, values of $p < 0.05$ were considered to be significant.

3. Results

In the percutaneous group: 10 (38.5%) of 26 patients were female and 16 (61.5%) were male. In the surgery group, 11 (35.5%) of the patients were male and 20 (64.5%) were female. The mean patient age was 27.6 ± 17.9 days in Group A and 31.3 ± 13 days in Group B. The median weight of the patients in Group A was 1455 g (967–1770 g), in Group B was 1254 g (920–1755 g) (Tables 1 and 2).

The mean PDA diameter in the percutaneous group was 2 ± 0.62 mm and 2.9 ± 0.49 mm in the surgery group (Table 1).

There were no associated heart defects in the percutaneous group; however, 9.6% of patients (n:3) in Group B had additional heart problems like a ventricular septal defect (VSD), atrial septal defect (ASD), or bicuspid aortic valve (BAV). These additional heart defects did not require surgery: VSD was muscular and hemodynamically stable, ASD was 7 mm in size, and there was no aortic insufficiency in patient with BAV. Patients who had other cardiac surgical procedures were excluded from the study.

In the percutaneous group, the morphology of PDA was assessed angiographically; 11 of them were Type A and 15 of them were Type C. The types of devices used were: ADO I in 1 patient and ADO II - AS in 25 patients. In the surgery group, we did not perform morphological classification since we did not perform angiography in these cases routinely. The vascular routes used were: umbilical vein in 2 patients, femoral vein in 16, both femoral vein and artery in 8 patients. We performed closure from a femoral venous access in 24 patients, and in 2 patients from umbilical vein. We did not use arterial site for closure as this was usually used for control angiograms. We did not obtain femoral arterial access in 18 patients, which may explain why we did not face with clinical vascular complications. The size of sheaths that we used for venous sites was 4 F in 14, 5 F in 8, 6 F in 1, and 3 F in 3 patients. For arterial sites, 5 patients had 4 F, 1 had 5 F, and 2 had a 3 F sized sheath.

The mean procedure time was: 39.3 ± 10.9 min, the mean scopy duration was 15.19 ± 6.46 min, and the mean radiation dosage was 267 ± 17 8 cGy/cm^2 (Table 3). The mean amount of contrast used in the percutaneous group was 1.96 ± 0.915 ml.

There was no statistically significance between two groups in terms of age, defect size. Only weight of patients in percutaneous Patent Ductus Arteriosus closure group was significantly more than the surgery group ($p = 0.004$). The mean gestational age of patients in the percutaneous group was 28.3 ± 2.8 weeks and in the surgery group was 28.8 ± 3.46 weeks (Table 4).

In the percutaneous group; all PDA were closed successfully in the percutaneous group except 4 cases. Major complications are categorized into 3 groups: ***a) device embolizations***: two had large PDA 4 mm and 3 mm in width. In the patient with 3 mm PDA, 4 × 2 mm ADO II - AS device had been used. Then the device embolized to LPA. 24 h after implantation. The embolized device was captured with a snare catheter and withdrawn. Then, 4 × 4 mm ADO II - AS device was delivered percutaneously. We had no other problems in 12-months follow-up interval. In another patient, 4 mm PDA was closed with 6 × 6 mm ADO II - AS device; however, it embolized to the pulmonary artery. Therefore, the patient was referred to surgery and PDA ligation was done. ***b) cardiac tamponade***: during device implantation, TTE was performed. In one patient, we recognized a pericardial effusion before the delivery of the device. As it was increasing, there was a risk of cardiac tamponade and we called the surgeons for evaluation. The surgeons determined that there was a right atrial perforation. They fixed it and PDA ligation was done. ***c) iatrogenic aortic coarctation***: the discs of the ADOII-AS are not large, so risk of aorta and pulmonary artery closure are small; still, iatrogenic aortic coarctation occurred in one patient. The device was removed surgically and the PDA was ligated.

No major complications like procedure - related death, clinical vascular complications, hemolysis, thromboembolism, or infective endocarditis were reported during the study period. There were minor complications such as device-related left pulmonary stenosis in 2

Please cite this article as: O. Pamukcu, et al., Patent Ductus Arteriosus closure in preterms less than 2kg: Surgery versus transcatheter, Int J Cardiol (2017), https://doi.org/10.1016/j.ijcard.2017.10.020