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ORIGINAL RESEARCH

A comparative study to evaluate radiation exposure in patent ductus arteriosus device closure by conventional method and echocardiography guided method- An experience from eastern India

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ABSTRACT

Fluoroscope-guided percutaneous closure is the preferable technique in children with patent ductus arteriosus (PDA). A prospective randomized case control study was performed in children between 6 months -12 years in our institution to compare the radiation exposure and procedural time of PDA device closure by transthoracic echocardiography with the use of minimal fluoroscopy(case) to conventional method(control). Post-operative follow-up for six-month was done. Among 106 patients, 51 patients were case and 51 patients were control. There was a significant difference between the fluoroscopy time, procedural time, and amount of radiation exposure in terms of total air kerma, dose area product and dose area product/kg among the case and control group. p< 0.001 was considered significant. The result shows that PDA device closure with transthoracic echocardiography-guidance with minimal fluoroscopy as compared to the conventional method reduces radiation exposure, procedural time and complications related to arterial access.

Keywords: Patent ductus arteriosus, Echocardiography, minimal fluoroscopy

INTRODUCTION

PDA constitutes 5-10% of all congenital heart defects, with a prevalence of symptomatic PDA being 0.5/1000 live births [1]. PDA closure can be done both surgically and percutaneously. Surgical methods are more suitable for premature and newborn infants. However, these methods inevitably leave surgical scars as well as complications of anesthesia. In recent years, with decrease in procedural time for percutaneous procedures with satisfactory outcomes in older children and adults, procedures can be done under local anesthesia or conscious sedation. It has the advantage of early discharge and less anesthesia - related complications. However, during the procedure, the operators and patients are exposed to radiation [2,3]. The radiation complications faced by the children are malignancies (solid tumor, blood and lymph node), growth retardation, aplastic anemia, radiation burn mainly, while for operators commonly thyroid carcinoma, brain-tumors, infertility, chronic fatigue syndrome, alopecia mostly. In our institution we planned to compare the radiation exposure

and procedural time of PDA device closure by transthoracic echocardiography with the use of minimal fluoroscopy(case) compared to conventional method(control) in pediatric patients.

MATERIALS AND METHODS

AIMS AND OBJECTIVE

i) To compare the radiation exposure and procedural time of PDA device closure by transthoracic echocardiography with the use of minimal fluoroscopy(case) to conventional technique(control) in a tertiary care hospital**.**

ii) To compare the complications between the two groups.

METHODS

A single Center prospective randomized case control study of patients undergoing PDA device closure by transthoracic echocardiography with the use of minimal fluoroscopy as compared to conventional method of percutaneous PDA device closure was performed. Children between 6months -12years who had an indication for device closure and gave consent for the procedure were selected for the study. Six-month post-operative follow up was planned. Appropriate written informed consent in their own language was taken prior to the procedure. Total 106 patients were included in the study from July 2018 to January 2020. Randomization was done on the basis of computer-generated software. Children who underwent the procedure under echocardiographic guidance with minimal fluoroscopy use were selected as case. Out of the 55 patients selected for case arm, 4 patients in the case arm had to undergo aortogram and thus were excluded from the study. 51 patients who underwent closure following the conventional method were the control. Each group were selected with comparable age group and other characteristics. Ethical committee clearance was received from the ethical committee board of the institution prior to initiation of the study.

INCLUSION CRITERIA

Device closure was attempted in patients with hemodynamically significant PDA with class I indication. Children between 6months to 12-years who visited our outpatient department and who gave consent for the procedure were included. A detailed echocardiographic evaluation of the duct morphology was performed for all patients undergoing PDA closure as part of an institutional protocol.

DEVICE SELECTION

Device size was selected based on echocardiographic measurements or if both echocardiographic and angiographic values were available, then the larger measurement was considered. The devices used for ductal closure were Amplatzer Duct Occluders and Lifetech Duct Occluders. The devices were selected according to their availability.

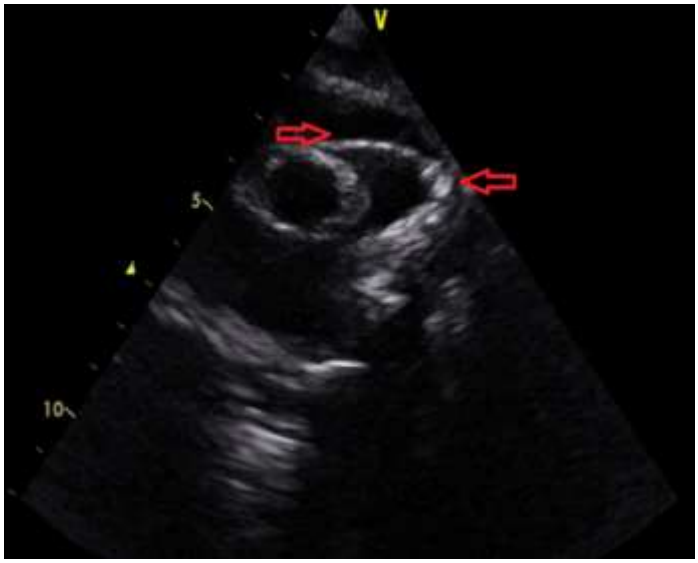
DEVICE DEPLOYMENT TECHNIQUE

ECHOCARDIOGRAPHY GUIDED PDA CLOSURE GROUP (CASE)

In this group, size of the PDA was assessed mainly by echocardiography ductal view and on this basis, size of the device was chosen. Only femoral vein access was used (5 F/6 F/7F sheath). With the help of 0.032'' straight tip terumo wire and Judkin Right (JR) catheter / multipurpose catheter, PDA was crossed. The use of fluoroscopy was avoided till the wire reached the right ventricle, which was confirmed both by right sided premature ventricular complexes (PVCs) and by transthoracic echocardiography. The PDA was then crossed with minimal fluoroscopy use. Terumo wire was exchanged with 0.035''×260 cm J tip Boston Amplatz superstiff Teflon wire. JR catheter was exchanged with suitable sized delivery sheath (lifetech Steer Ease/Amplater TorVue) which crossed over Teflon wire under

transthoracic echocardiographic guidance and short duration of fluoroscopy if required. Device size (+2 to PDA size) as assessed by echocardiography was taken and then the hinging of the device across the PDA was done, by the use of minimal possible fluoroscopy and transthoracic echocardiography. After confirming the PDA device location across the defect with help of echocardiography (2D and color Doppler mode), device was deployed (Figure 1).

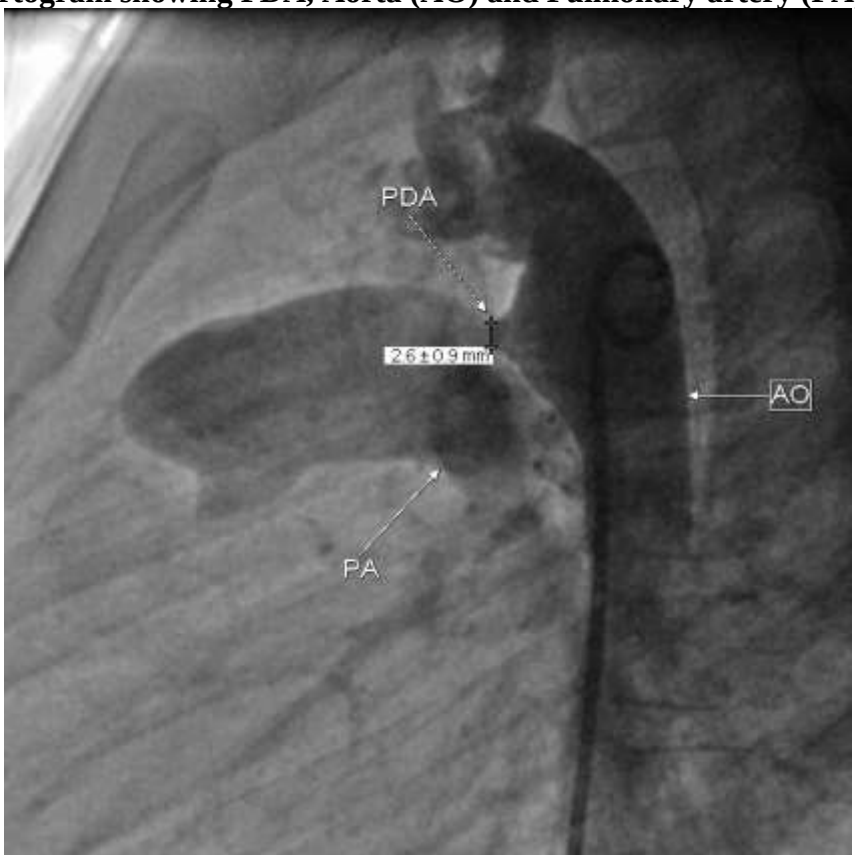
Figure 1: 2D Echo image showing delivery sheath and PDA device marked with red arrow



FLUOROSCOPY GUIDED PDA CLOSURE GROUP (CONTROL)

In this group, the size of the PDA was assessed by both echocardiography ductal view as well by aortogram done in left lateral position (Figure 2) and among the two, largest diameter was considered and the size of the device was chosen accordingly. Femoral artery and vein access were used (5Fr or 6Fr sheath was used). Aortogram was done to assess the size of PDA. With the help of 0.032'' straight tip terumo wire and JR catheter/ multipurpose (MP-1) catheter PDA was crossed under fluoroscopy guidance. Terumo wire was exchanged with 0.035''×260cm J tip Boston amplatz superstiff Teflon wire under fluoroscopic guidance. JR catheter was exchanged for the delivery sheath (lifetech Steer Ease/Amplatzer TorVue) over the Teflon wire under fluoroscopy guidance. The hinging of the suitable sized device across the PDA was done under fluoroscopy. After confirming the PDA device location across the defect by fluoroscopy and echocardiography, repeat aortogram was done in left lateral view. The device was deployed after ruling out any residual flow and turbulence in aorta or pulmonary artery. In both the groups pre-operative single dose of injection ceftriaxone at 50mg/kg/dose was given and after venous/arterial access as per requirement, unfractionated heparin was given at the dose of 50U/kg and repeated if required. In both the groups intra and post-operative heart rate, blood pressure, oxygen saturation and 12 lead ECG was monitored.

Figure 2: Aortogram showing PDA, Aorta (AO) and Pulmonary artery (PA)



DISCHARGE AND FOLLOW UP

In both the group, patients were followed for 6 months. In both the group patients were discharged within 24-48hours of post procedure with aspirin at 3-5mg/kg/day and infective endocarditis prophylaxis for 6 months. Only one patient in the control group who developed femoral hematoma was kept under observation for 7days. They were followed up with echocardiography prior to discharge, at 1 month and at 6month. The parameters assessed were puncture site condition, lower limb pulse for control, new-onset murmur, device position, evidence of any injury to any adjoining structures, hemolysis, infective endocarditis or radiation burn.

STATISTICAL ANALYSIS

Statistical analysis was done with the Statistical Package for Social sciences (SPSS, Chicago, IL, USA) program version 25. Descriptive analyses and also comparisons of baseline characteristic among both echocardiographic and fluoroscopy group were done. Categorical data were analyzed with x2 test. Continuous variables were described as mean ± standard deviation. A value of $p < 0.001$ was considered statistically significant.

RESULTS

Out of the 55 patients selected for case arm, 4 patients were excluded from the study, thus total number of patients in the case arm was 51 and equal number of patients (n= 51) was taken for the control arm. The success rate in the case arm was 92.7%. The mean age of the population in the echocardiography and in the fluoroscopic group was 3.58 ± 1.40 year and 3.56 ± 1.24 year respectively with female to male ratio being 3:1. The mean size of PDA in both groups were comparable, no stastically significant difference was noted. There was statistically significant difference in the procedural time, fluoroscopy time and radiation dose

in terms of total kerma, dose area product and dose area product/kg among the two groups, all of them were lower in the echocardiography group compared to fluoroscopy group (Table 1). The least fluoroscopy time, radiation exposure and procedural time in the echocardiography group were 43 seconds, 1mGy, 20minutes respectively.

Table 1: Demographics of patient characteristics in case and control arm:

	Echocardiography group (case)	**Fluoroscopy Group (control)**	**P value**
Number of patients	51 (48.1%)	51 (48.1%)	
Age	3.58 ±1.40 Yr.	3.56 ± 1.24 Yr.	0.9303
Male	36 (33.96 %)	43 (40.56%)	0.3961
Body weight	10.89 ± 2.66 Kg	11.22 ±2.22 Kg	0.5211
PDA size	3.46 ± 0.91 mm	3.37 ± 0.69 mm	0.6133

Table 2: Procedural characteristics:

	ECHOCARDIOGRAPHY GROUP (Case)	**FLUOROSCOPY GROUP (Control)**	**P value**
PDA size	3.46 ± 0.91 mm	3.37 ± 0.69 mm	0.6133
PDA device size	Minimum size: 4mm/6mm Maximum size: 8mm/10mm	Minimum size: 4mm/6mm Maximum size: 8mm/10mm	-
Procedural time	33.78 ± 7.93 min	59.38 ± 11.13 min	< 0.00001
Fluoroscopy time	120.49 ± 79.35 sec	287.16 ± 95.04 sec	< 0.00001
Radiation dose (total kerma)	3.05 ±2.57 mGy	9.36 ± 4.21 mGy	< 0.00001
Dose area product (DAP)	51.48±15.62 mGy	162.6±28.57 mGy	<0.00001
Dose area product/kg	5.92±6.33 mGy	15.2±4.51 mGy	<0.00001
Contrast volume	Nil	26.55±4.10 ml	-
Complication	Nil	1 case of femoral hematoma.	-
Post procedural follow- up complication	Nil	Nil	-
1)Clinical assessment	No new murmur, Access site at groin - normal	No new murmur, Access site at groin - normal	
2)Echocardiography	PDA device In situ No flow or vegetation across the device	PDA device In situ No flow or vegetation across the device	
3)Blood Parameters (CBC, Renal function test, etc.)	Within normal limits	Within normal limits	

DISCUSSION

The first transcatheter closure of PDA was reported by Porstmann et al in 1971[4]. Percutaneous closure of PDA is now a well-established and effective procedure for which various devices is being used. Percutaneous closure of PDA is considered as a safe method for duct occlusion but some complications such as device embolization, hemolysis, infection, and significant narrowing of the left pulmonary artery or the descending aorta have been reported in the past. Device embolization has been identified as one of the most significant complications of interventional PDA occlusion [5]. The routine practice involves arterial access for aortogram before, during, and after deployment of the device. The reason for using arterial access is that it allows initial aortography to be performed without crossing the duct, supposedly minimizing the risk of ductal spasm and consequent underestimation of the size of the duct. It also permits subsequent aortography to confirm a good position of the device prior to release and to exclude iatrogenic coarctation. Arterial access in children is reported to have a high rate of complications ranging between 3.7 and 16%, with a significant proportion of complications requiring intervention. Complications such as arterial disruption, or acute occlusion, may be limb- threatening [6,7]. The radiation related complications are well known, thus by decreasing the duration of exposure is beneficial for both patient and operator [8]. In our study both the groups were compared in terms of procedural time, fluoroscopy time, radiation dose and any possible complications. It is wise to use minimal fluoroscopy with echocardiography guidance rather not to use it, as safety of the child is our first priority. Prior studies were done to show the benefit of only venous and echocardiography guided PDA device closure but none has compared the two strategies and all were retrospective studies. Ours is a prospective case control study with the results corroborating with the prior studies and thus emphasizing the safety and efficacy of the echocardiography guided transcutaneous device closure of patent ductus arteriosus. There was statistically significant difference($p<0.001$) in the procedural time, fluoroscopy time and radiation dose among the two groups, all of them were lower in the echocardiography group compared to fluoroscopy group. The fluoroscopy time in the echocardiography guided group decreased as fluoroscopy was not used until right ventricle was reached. Echocardiography along with minimal fluoroscopy if required was used to assist in crossing the right ventricular outflow tract and the duct as safety of the child is more important. The device position was confirmed and released under echocardiography guidance, thus avoiding fluoroscopy in all these steps. All the required images were fluoroscopy saved instead of sine save thus further decreasing the radiation exposure. There was no use of dye. The procedure relied on echocardiographically measured duct size, shape and length. The procedure time also significantly decreased as time was saved from arterial access and aortography step. In a study by Zhang et al [9] solely echocardiography was used to close PDA by transcatheter method, but we have used minimal fluoroscopy for patient safety and to avoid prolonged procedure time. For assessment of radiation exposure median kerma, DAP and DAP/kg are more relevant than fluoroscopy time and so in our study we included all these parameters [10]. The radiation dose was within the safe limit for the echocardiography group as denoted by the study by Sunil J Ghelani et al [10]. The lowest radiation doses were noted in PDA closure and pulmonary valvuloplasty, among the various transcatheter procedures. In our study median kerma , DAP and DAP/kg was used to compare the radiation exposure in the two groups as fluoroscopy time doesn't correlate well with radiation exposure .[10] Single incidence of femoral hematoma occurred in fluoroscopy group which was managed conservatively. No complication during procedure or in follow up was noted in the echocardiography guided group.

CONCLUSION

In both the group the patient characteristics, size of the defect and device used was comparable. No major complication was noted neither during the procedure nor on follow up in both group of patients. In the fluoroscopy group a single case of groin hematoma occurred, which was managed conservatively. Fluoroscopy time, procedural time and amount of radiation exposure in echocardiography guided group was significantly less than the control group. The amount of contrast used in echocardiography group was nil. As no arterial access was used, so all the possible arterial access related complications can be easily prevented. Above results shows that it is safe and feasible to perform PDA device closure with transthoracic echocardiography-guided percutaneous PDA occlusion as compared to conventional method.

KEY MESSAGE

Percutaneous PDA device closure can be safely and effectively performed through venous access under echocardiographic guidance with minimal fluoroscopy exposure.

LIMITATION

Single center study. Small sample size. Sub-categorization on the basis of age was not done. As the study was done in a government institution where all the procedure were cost free, so can´t able to comment upon cost benefit related to the procedure.

SOURCE OF FUNDING

Nil

FUTURE IMPLICATION OF THE STUDY

To ensure a larger study and to incorporate echocardiography guided procedure with minimal radiation use in the guideline. To ascertain the radiation dosage for the procedure and correlate with long term complications.

DISCLOSURES

Nothing to disclose

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