



Comparison of Clinical Outcomes of Surgical Verses Non Surgical Techniques of Patent Ductus Arteriosus Closure - A Multicentre Trial.

KEYWORDS

Minithoracotomy, Acynotic congenital heart disease, Ligation, Device

Dr Dharmendra kumar srivastava	Dr Bhuwan chandra tiwari	Prof. Shantanu pande
associate professor, department of cardiovascular and thoracic surgery, dr rml institute of medical sciences, vibhuti khand gomtinagar Lucknow.	associate professor, department of cardiology, dr rml institute of medical sciences, vibhuti khand, gomtinagar, Lucknow.	department of cardiovascular and thoracic surgery, Sanjay Gandhi postgraduate institute of medical sciences, Lucknow.
Prof. Satayedra tewari	Prof Sushil kumar singh	Dr Anupama singh
department of cardiology, Sanjay Gandhi postgraduate institute of medical sciences, lucknow.	department of cardiovascular and thoracic surgery king George medical university, Lucknow.	plastic surgeon, department of surgery, GSVM Medical college, Kanpur.

ABSTRACT

Background- Spontaneous closure of patent ductus arteriosus (PDA) is very uncommon and anatomic existence of a PDA regardless of size is an indication for intervention.

- **Patients and methods-** In our prospective study we were used the two surgical approaches transaxillary minithoracotomy and postero- lateral thoracotomy for PDA closure and their comparisons to nonsurgical approach (percutaneous transcatheter device closure PTDC) of clinical outcomes in different aspects were done in 71 Patients between March 2012 to February 2014 in three different Tertiary hospital based institutes after ethical clearance.
- **Results-** out of 71 Patients, 26 were males and 45 were females with age in the range of 10 months to 50 years. All patients were diagnosed on transthoracic echocardiography with size of PDA in the range of 03 mm to 10 mm and left to right shunt. Transaxillary minithoracotomy was performed in 08 patients and postero lateral approach in 10 patients. All the cases of PTDC were performed in local/sedation anaesthesia with duration of procedure in range of 42-72 minutes. Cocoon duct occluder (44 cases) and Heart R occluder (08 cases) devices were used in PDA closure.
- **Conclusion-** All three techniques have excellent results without any major complications, morbidity and mortality. In the treatment of PDA with mortality rate approaching zero, we emphasise on cost effectiveness, technical expertise and decreasing morbidity of techniques of closure.

Introduction

Patent ductus arteriosus (PDA) was the first congenital heart disease to undergo surgical closure and also the first where a nonsurgical percutaneous transcatheter device closure was utilised. Therefore comparison of different modalities of PDA Closure may help to choose the procedure for specific individual cases.

4. Patients and methods- In our prospective study we were used the two surgical approaches transaxillary minithoracotomy and postero- lateral thoracotomy for PDA closure and their comparisons to nonsurgical approach (percutaneous transcatheter device closure PTDC) of clinical outcomes in terms of success rate, procedural complications, aesthetic expectations and cost analysis of surgical and non surgical techniques of PDA closure were done in 71 Patients between March 2012 to February 2014 in three different Tertiary hospital based institutes after ethical clearance.

Justifications of study – Better Education and increasing sophistication have led to a higher aesthetic expectation by the public. Clinical outcomes and cost analysis of different modalities of PDA closures widely varies in different institutes. Suitability of treatment of different age groups

Operative techniques - In the operation theatre, induction

and maintenance of general anaesthesia with single lumen endotracheal tube were done along with monitoring of pulse oximetry, ECG for heart rate, invasive arterial pressures, nasopharyngeal temperature, urine output, intermittent arterial blood gas.

The patient was placed in right lateral position. The standard posterolateral thoracotomy was done through fourth intercostals space while in transaxillary minithoracotomy, the chest cavity was entered the thoracic cavity through the third intercostals space by splitting of pectoralis major and Latissimus dorsi muscle in subaxillary area. After that PDA were identified by palpation of thrill. Pleural flap dissections, identification of recurrent laryngeal nerve, proximal and distal controls of descending thoracic aorta with umbilical tapes were taken. Ligation/ division and transfixation of the PDA was done after lowering of systolic blood pressure below 80 mm Hg and clamping of proximal and distal controls of descending thoracic aorta to avoid rupture or tear of PDA. Disappearance of thrill was noticed.

Transcatheter device closure technique - Procedure was done under sedation with local anaesthesia. Right heart catheterization and an aortogram was done to demonstrate PDA anatomy and measure the size and length of the communication taking magnification into consideration to select a device at least 2 mm larger than the duc-

tus size. After that, a catheter was advance from the right heart to the pulmonary artery through PDA and then into the descending aorta. Heparin was used. Stiff guide wire was placed with the tip of distal descending thoracic aorta. A 5-7F long sheath was then passed over the wire into the descending aorta. The appropriate-sized device was then screwed onto the delivery cable and pulled into the loader under water to prevent air entry into the device or sheath. The device was then advanced to the tip of the sheath in the descending aorta without rotation of the cable. The sheath and device were then pulled back into a position just distal to the ampulla. The position of the device was confirmed with repeated angiograms in the descending thoracic aorta and adjusted until the retention skirt was well seated in the ampulla and when good position was achieved, the sheath was retracted further and the tubular part of the device was opened within the PDA. Deploy the retention flange only in the descending aorta and pull firmly against the aortic orifice of the patent ductus arteriosus. This was observed by fluoroscopy, or it was felt as a tugging sensation in synchrony with the aortic pulsation. While applying slight tension retract the delivery sheath and deploy the cylindrical portion of the device securely in the patent ductus arteriosus. Echocardiography and fluoroscopy was used to check the implant for correct positioning.

Table-1 Patient Profile

S.No.	parameter	Value
1	Age (in range)--	10month-to-50years
2	sex --Male	26
	--Female	45
3	PDA type --Asymptomatic	13
	--Symptomatic	58
4	Echocardiography finding-	
	-Pulmonary Hypertension(mild)	04
	-Calcified PDA	00
	-Net left-to right shunting	71
	-Net right-to left-shunting	00
	-Size of PDA (range in mm)	03 to 10
	-Length of PDA(range in mm)	06 to 12
	-Shape of PDA-conical	36
	-tubular	17
	-elongated	05
-Broad and short	13	
5	Size determination method:	
	-Angiogram	53
	-TTE	71
	-TOE	03

6	Surgical procedure Details-		
	i. Posterolateral thoracotomy-		10
	A. Division and Ligation		04
	B. Double Ligation and transfixation		06
7	NonSurgicalprocedureDetails-		
	(1) Type of Device used		44
	i. cocoonDuctOccluder		08
	ii. Heart-ROccluder		
	(2) Device diameter used(in mm)-		
	Atpulmonaryartery	Atdescendingaorta	
	A.	4 6	16
	B.	6 8	19
	C.	8 10	12
	D.	10 12	04
	E.	12 14	01

Table -2 Comparison of Techniques

s. No	parameter	Surgical Techniques	Non Surgical Techniques
1	Total number of cases	18	53
2	Anesthesia--		
	-General	18	53
	-Local/Sedation		
3	Duration of Procedure(range in minutes)	60 -95	40-72
4	Procedure Evaluation-		
	-Successful	17	52
	-Insufficient	00	00
	-Procedure postponed	01	01
5	Residual shunt-		
	-Complete Closure(no thrill)	17	46
	- Minor (<1mm)	00	06
6	ICU Stay of Patients(in days)	1 to3	1 to2
7	Aesthetic value of procedure(acceptable)	08	52
8	Success rate (100%)	17	52
9	Complications(major)	nil	nil
10	Decision of Procedure		
	-Shape of PDA		
	-conical	03	33
	-tubular	01	15
	-elongated	01	04
	-broad and short	12	01
	Age groups-		
	-Paediatric age group.	14	42
	-Adults	04	11
	11	Cost (range in rupees)	10000-35000

5. Results - Out of 71 Patients, 26 was males and 45were females with age in the range of 10 months to 50 years (table 1.). All patients were diagnosed on transthoracic echocardiography with size of PDA in the range of 03 mm

to 10 mm and left to right shunt. Transaxillary minithoracotomy was performed in 08 patients and traditional postero lateral approach in 10 patients and non surgical were applied in 53 cases. There were no mortality and morbidity including superficial wound infection in 03 Patients. All the cases of non surgical technique were performed in local/sedation anaesthesia with duration of procedure in range of 42-72 minutes. Cocoon duct occluder device were commonly (44 cases) used in PDA closure. Conversion of transaxillary minithoracotomy into postero lateral approach was done in one patient because of tear of PDA. Surgery was postponed in 01 case due to associated artery aneurysm whereas nonsurgical closure of PDA was also postponed due to difficulty in device implantation in 01 case and referred for surgical closure. All patients were assessed for complete ligation of PDA clinically by disappearance of thrill and confirmed by Echocardiography/fluoroscopy. No residual patencies of PDA were found in follow-up period of six months.

Discussion-

Techniques for closure of PDA have evolved since the first report of surgical ligation by Gross and Hubbard in 1939.¹ Various surgical approaches include posterolateral thoracotomy, Transaxillary mini thoracotomy or very rarely an anterolateral thoracotomy. The first description of transaxillary minithoracotomy for PDA closure was by Denis Browne in 1952. Various surgical techniques used since then have included ligation and division, simple ligation and hemaclip application. Recently introduced therapies include percutaneous transcatheter ductal closure devices (PTDC), video assisted thoracoscopic approach (Laborde etal, 1993) or even robotic surgery (Le Bret etal 2002). Transcatheter methods, to avoid thoracotomy, were pioneered by Portsmann et al². Darbari etal³ concluded in their series of 48 patients that transaxillary thoracotomy allows safe and effective ligation of a PDA with early hospital discharge and was least expensive, highly effective along with low complication as compared to video assisted thoracoscopic surgery and transcatheter coil occlusion techniques. Qiang etal⁴ performed vertical transaxillary minithoracotomy for various congenital disorders of thoracic organs including PDA and found that approach was less invasive, simple, safe, efficient and cosmetically acceptable. Although generally associated with greater pain and morbidity than transcatheter methods, surgical ligation and surgical division are safe and effective procedures that historically have set a high standard by which transcatheter techniques have been judged. Surgical ligation or division of the PDA remains the treatment of choice for the rare very large ductus. Complete closure rates of surgical ligation (often accompanied by division of the ductus) in published reports range from 94% to 100%, with 0% to 2% mortality. Mavroudis et al⁵ concluded that recurrence rates for Percutaneous trans catheter device closure are high with yet unknown consequences of large catheter vascular access, endocarditis, or left pulmonary artery stenosis. Video- assisted thoracotomy for PDA interruption has the potential for uncontrolled exsanguinating hemorrhage. Open thoracotomy for PDA ligation and division can be performed safely and without recurrence through a muscle – sparing incision with short incision. Peirone etal⁶ reviewed the initial clinical outcomes of PDA closure using the new Nit-Occlud PDA-R device (NOPDA-R) from May 2010 to December 2010 in 20 patients (15 female) and concluded that percutaneous PDA closure using the new NOPDA-R device was feasible, safe, and effective. Longer follow-up time and a larger number of patients are required to assess long-

term performance. El-Said etal⁷ collected outcome data on transcatheter PDA closure at 8 centers prospectively using a multicenter registry (Congenital Cardiac Catheterization Project on Outcome Registry) between February 2007 and June 2010 in 496 PDA closures using a device in 338 (68%) or coils in 158 (32%) and concluded that PDA closure in the present era has a very low rate of complications, although these are higher in younger children. Technical intervention-related events were more common in coil procedures compared with device procedures. For PDAs ≤ 2.5 mm in diameter, institutional differences in preference for device versus coil exist. Forbes etal.⁸ reviewed retrospectively of 42 symptomatic patients weighing less than 8 kg were taken to the cardiac catheterization laboratory for attempted transcatheter occlusion of their PDA between January 1995 and May 2003 and concluded that infants less than 8 kg with an length/diameter ratio > 3.0 can safely and successfully undergo transcatheter occlusion of their PDA using transcatheter coils. Nyawawa etal.⁹ studied retrospectively 52 patients with clinical diagnosis of PDA underwent open surgical closure and concluded that open surgery for PDA closure remains the procedure of choice for facility and technically deprived countries. in comparison to above studies we found that ,the transaxillary minithoracotomy approach for PDA ligation is better option in term of clinical outcome, safety, efficacy, acceptable cosmesis ,less operative time and cost effective in comparison to posterolateral approach and percutaneous trans catheter device closure but needed more learning curve for procedure. Postero lateral approach is gold standard method for division and ligation of PDA, other cardiac defects, complications arising in other approach like transaxillary minithoracotomy and percutaneous trans catheter device closure. Percutaneous trans catheter device closure is safe, efficacious, painless, scarless and allows the patients to resume normal life within 3 days and now treatment of choice unless it is accompanied by other cardiac defects, premature newborn, very large broad and short PDA's causing heart failure are closed by surgery. All three techniques have excellent results, reported success rate nearly 100%, without any major complications, morbidity and mortality. Each of different modalities of PDA closure has their own significance therefore comparison may help to choose the procedure of PDA closure for specific individual cases. Funding -From intramural project of our institute.

Conflicts of interest statement- none

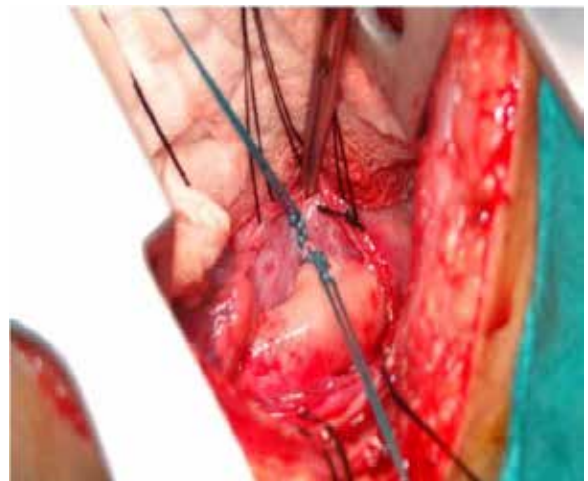


Figure-1



Figure-2

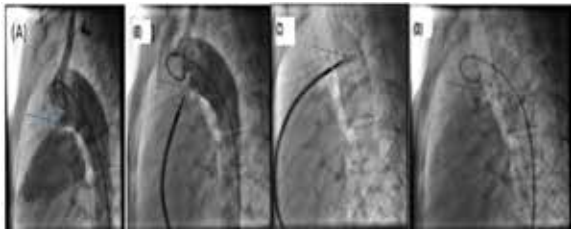


Figure-3

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- Figure legends-
- figure-1 showing ligation of PDA through posterolateral approach
- Figure-2 showing transaxillary minithoracotomy incision and intercostal drainage tube
- Figure-3 showing steps of percutaneous Trans- catheter device closure (A- aortogram showing the anatomy of PDA, B- right heart catheterization, C- PTCD device implantation, D- Implanted device)