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Feasibility and Outcomes of Transcatheter Device Closure of Large Patent Ductus Arteriosus in Infants Weighing less than 5 kg and Comparison with Surgical Ductal Ligation- Experience from a Tertiary Care Hospital in India

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ABSTRACT

Objective: The study aims to assess feasibility of transcatheter device closure of patent ductus arteriosus in infants weighing less than 5 kg and retrospectively compares the result with the age and weight matched surgical duct ligation group.

Methods: Twenty infants weighing less than 5 kg underwent device closure of patent ductus arteriosus between January 2017 to May 2019. The result was compared with retrospective data from twenty other infants who under went surgical duct ligation.

Results: The patients were divided in two groups, Group A the device closure group and Group B the surgical ligation group. Within Group A, twenty infants with a mean age of 6.5 ± 2.4 months, mean weight of 4.32 ± 0.84 kg and mean ductal diameter 3.96 ± 1.38 mm underwent device closure. The mean age of patients in the surgical group was 5.6 ± 3.5 months, mean weight 3.48 ± 1.26 kg and the mean duct diameter 4.72 ± 1.94 mm. Follow up duration for group A and B was 13.4 ± 7.6 and 22.1 ± 9.2 months respectively. Device implantation was successful in all with an immediate closure rate of 95%. Rate of major complications were similar between the two groups but there were fewer minor complications in the surgical group. The duration of hospital stay (p value<0.001) and need for inotropes (p value<0.001) were significantly less in infants in group A.

Conclusion: Transcatheter device closure of large ductus in infants weighing less than 5 kg is possible with success rates comparable to surgical ligation. Appropriate patient selection and awareness of possible complications is essential.

Keywords: Patent ductus arteriosus; Transcatheter device closure; Infants; Surgical ductal ligation

INTRODUCTION

Since the first percutaneous closure of Patent Ductus Arteriosus by Porstmann in 1968, transcatheter closure of patent arterial duct has become a well established alternative to surgical ductal ligation. Transcatheter device closure or surgical ligation is indicated in hemodynamically significant ductus manifesting with refractory congestive cardiac failure or severe pulmonary artery hypertension with features of volume overloading of left atrium and left ventricle. Large hemodynamically significant

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ductus is often encountered in infants leading to recurrent, difficult to treat respiratory infections, poor feeding and hence, poor weight gain. These infants are the ones likely to benefit from an early closure of the ductus to relieve symptoms and ensure weight gain.

Earlier, literature recommended surgery for the closure of large arterial duct in symptomatic infants weighing less than 5 kg. Device manufacturers also do not recommend the use of duct occluder in patients with a body weight of ≤ 6 kg. Although, experience with device closure in infants weighing less than 6 kg is limited, there are emerging evidence in literature on challenges, feasibility and outcomes of transcatheter intervention in these small infants. Concerns regarding pulmonary and aortic encroachment by a large device, need for large delivery sheaths, risk of vascular compromise and kinking of sheath in the acute turn of the right ventricular outflow tract have been raised. Meanwhile, surgical duct ligation is also fraught with complications like wound infection, hemorrhage, recurrent la-ryngeal nerve paralysis, diaphragmatic palsy, pleural effusion, ligation of wrong structures etc. (AGA Medical Corporation). Our aim was to study feasibility, safety and outcomes of transcathether device closure of hemodynamically significant arte-rial duct in infants weighing less than 5 kg, as judged by echo having left atrium: Aorta ratio greater than 1.8 and dilated left ventricle (Z score >+ 2) and comparison with infants who under went surgical duct ligation.

MATERIALS AND METHODS

Our study included 20 infants weighing less than 5 kg, who under went elective device closure of large patent arterial duct for refractory heart failure or recurrent hospitalization due to frequent lower respiratory tract infection between January 2017 to May 2019 (Group A).

Inclusion Criteria for Group A

Infants weighing less than 5 kg with hemodynamically significant ductus as evidenced by refractory CCF, poor weight gain, recurrent hospitalizations due to LRI, dilated left heart with LA aorta ratio>1.8 and left ventricular zscore +2 for body surface area on echocardiography. Mixed lesions where the ductus was thought to be the reason for cardiac failure were also treated under this category. Examples include secundum atrial septal defect, small to moderate ventricular septal defect or a mitral regurgitation due to mitral annular dilatation and normal valve morphology.

Exclusion Criteria

Infants with complex cardiac defects having ductus as one of the defects, duct anatomy not suitable for device closure on echocardiography, presence of coarctation or branch pulmonary artery stenosis and parents not giving consent for the procedure.

Procedure: Patients were admitted at least 1 day prior for elective procedures. One infant (case no 3) was already on ventilator for 7 days before we took her up for device closure. A pre procedural blood sample was collected from all and checked for complete blood count, creactive protein, electrolytes, urea and creatinine. Chest roentgenogram, 12 lead electrocardiogram, and repeat echocardiogram were also obtained the day before the procedure. Written informed consent was obtained from the parents prior to the procedure.

A single dose of intravenous Cefuroxime was administered 1 hour before the procedure which was continued for 72 hours after the procedure. The patients underwent device closure in the Pediatric catheterization laboratory at Rabindranath Tagore International Institute of cardiac Sciences. The procedure was performed under conscious sedation in all but one (case no 3) who was already on ventilator. Device closure was done from the venous side as per the standard technique.

Post procedure the patients were monitored in the pediatric intensive care unit for a minimum period of 24 hours. A close watch was kept for any evidence of limb compromise and device embolization. If uncomplicated, patients were discharged from intensive care after 24 hours and discharged home the next day. All patients were followed up on the 7th day of discharge and subsequently at 1 month, 3 months, 6 months and at 1 year interval. Improvement in functional class and weight gain was noted. On follow up echocardiography, the position of the device, residual shunt if any, status of additional defects were evaluated. The presence of turbulence in the left pulmonary artery and aortic isthmus was looked for and the velocities/gradients across these struc-tures were assessed.

Comparative Data

Retrospective data from 20 infants weighing less than 5 kg who underwent surgical PDA ligation were included in Group B. These infants underwent surgery between June 2016 and December 2018. Retrospective data regarding patient and defect character-istics, additional lesions, post-operative details, complications, etc was collected from medical records. Cases with a patent ductus along with coarctation of aorta or any other lesion warranting simultaneous surgical repair were excluded.

Statistical Methods

Categorical variables are expressed as numbers and percentage and compared across the groups using Pearson's Chi square test for Independence of Attributes/Fisher's Exact test as appropriate. Continuous variables are expressed as mean, median and stan-dard deviation and compared across the groups using mann whitney U test. The statistical software SPSS version 20 has been used for the analysis. An alpha level of 5% has been taken, *i.e.* if any p value is less than 0.05 it has been considered as significant.

RESULTS

Patient Characteristics

Between January 2017 to September 2019, twenty infants un-derwent transcatheter device closure for large hemodynami-cally significant patent arterial duct (Group A). This included 14 females (70%) and 6 (30%) males. The mean age of the co-hort was 6.5 ± 2.4 months (range 3-12 months), and the mean weight was 4.32 ± 0.84 kg (range 2.6-5 kgs). The mean diame-ter of the ductus was 3.96 ± 1.38 mm (range 2.5-8 mm) **(Table 1)**. 14 cases had type A duct (70%) while 6 (30%) had type C duct by Krichenko classification. Out of 20, 9 patients (45%) had severe and 6 patients (30%) had moderate pulmonary arterial hypertension as evidenced by pulmonary artery systolic pres-sure more than 2/3rd and between ½ to 2/3rd of systemic pres-sure respectively. The duct in 5 others (25%) were judged to be restrictive with estimated pulmonary pressures less than 1/3rd of systemic

failure to thrive to justify ductal device closure **(Table 2)**. Retrospective data was collected from 20 infants who underwent surgical duct ligation between June 2016 to December 2018 (Group B). This included 11 (55%) females and 9 (45%) males. The mean age of the cohort was 5.6 ± 3.5 months (range 15 days-12 months), and the mean weight was 3.48 kg ± 1.26 kg (range 1.5-5 kgs). The mean diameter of the duct was 4.72 mm ± 1.94 mm (2-7 mm). All cases had severe pulmonary arterial hypertension.

Among Group A, 5 infants had mild to moderate mitral regurgitation, 4 had additional muscular ventricular septal defects, while 1 had moderate to large secundum atrial septal defect. One 3 month old infant (case no 3) with 3.5 mm ductus with two muscular ventricular septal defect with severe pulmonary hypertension was on mechanical ventilation for 1 week due to severe bronchopneumonia and heart failure. Among Group B, 2 infants had additional ventricular septal defects, 2 had secundum atrial defects, while 2 had moderate mitral regurgitation.

Procedural Details

For transcatheter ductal device closure, the procedure was carried out under conscious sedation in 19 cases (95%). One infant (case no 3) who was already on mechanical ventilation prior to the procedure underwent general anaesthesia. We used a ve-nous access alone in 9 (45%) out of 20 cases, while both arterial and venous accesses were obtained in 11 (55%) cases. Decision to put in an arterial sheath was guided by weight of the patient, clarity of the echo imaging, type of the duct and individual operator's choice **(Table 2)**.

Angiograms by hand injection were obtained with the long delivery sheath if using venous access alone or arch angiogram by 4 French pigtail catheter in 90 degree left lateral and right anterior oblique (30°) views by pressure injection in patients with an arterial sheath. Diameter at the pulmonary (duct size) and aortic ends (ampulla), and ductal length were measured. The echocardiographic and angiographic ductal diameters were compared and the device size used was one to two millimetres bigger than the larger one of the two measurements. The duct was crossed from the pulmonary end and the long delivery sheath (AGA Medical Corporation, Golden Valley, MN) was introduced from the venous side over the Amplatzer super stiff guide wire (Boston Scientific, Natick, MA, USA), and was kept in the descending thoracic aorta. A French delivery system was used in most (14 out of 20.70%) cases, while French sheath was used in 6 cases (30%). There were no instances of kinking of sheath. However, one patient had severe tricuspid regurgitation due to tricuspid valve chordal entrapment at the time of passage of sheath through the valve. The most often used device was 8 mm^2 × 6 mm^2 Amplatzer Duct Occluder I (ADOI, AGA Medical Corporation, Golden Valley, MN) (12 cases, 60%). We used 10 mm^2 × 8 mm^2 Amplatzer duct occluder in 4 (20%), 5 mm^2 x 4 mm^2 in 3 (15%), and 12 × 10 Multifunctional Occluder (MFO, Lifetech, Shenzhen, China) in 1 case (5%) respectively. The multifunctional occluder device was used in an 8 month old with a 5 mm type C duct with severe pulmonary hypertension (case No 13).

The mean fluoroscopy time was 5.39 minutes (range 2.13-9.21 minutes) and mean radiation dose was 1305 $cGy.cm^2$ (range 89-6807 $cGy.cm^2$).

Post procedure

All infants tolerated the procedure well. 7 patients (35%) had loss of distal pedal pulse which responded to heparin infusion in 6 cases and heparin streptokinase in one. There was minor LPA flow acceleration (velocity ≤ 2.5 m/s) in 2 cases (case nos. 7, 13, 10%) minor arch flow acceleration (peak gradient<10 mm Hg) in one case (case no 5, 5%) respectively and both in 1 more case (case no 4, 5%) **(Table 3)**. However, there were no cases with significant left pulmonary artery or arch obstruction. Both the cases of arch flow acceleration did not increase on 6 months follow up. One infant (**Table 2**) had a left pulmonary artery gradient of 25 mm Hg at 12 months' follow up. In this patient the duct was 8 mm and a 12/10 multifunctional occluder was used. Four out of 5 patients with left pulmonary artey or arch gradient post procedure had defect weight ratio ≥ 1. None of the devices embolized or required retrieval. Immediate ductal closure rate was 95% **(Table 4)**. One patient developed severe tricuspid regurgitation due to tricuspid valve chordal entrapment during passage of the long sheath (**Table 2**). This patient is under close follow up and will be considered for tricuspid valve repair later on. One infant (**Table 2**) who underwent device closure for inability to wean from mechanical ventilation, was successfully extubated following the procedure. The duct was 4 mm in size and was closed by 8 mm^2 x 6 mm^2 Apmlatzer duct occluder. However, this patient was readmitted after 3 weeks with features of sepsis at which time echo revealed an aortic pseudoaneurysm adjacent to the duct occluder and another on the wall of the transverse aortic arch. We lost this baby as rescue surgery could not be attempted due to the poor general con-dition of the patient. The mean follow up duration after device closure was 13.4 ± 7.6 months. Among the 19 infants (95%) on follow up, there was weight gain in all and decrease in severity of mitral regurgitation in all of five infants who had it pre-procedure. Intradevice residual shunt which was present in one patient sealed off on six weeks' follow up.

Comparison with the surgical group

Mean ages of both the groups were comparable, but the difference in their mean weights was statistically significant (P=0.045). Also the mean defect: Weight ratio was 0.93 for the device closure group and 1.45 for the surgical ligation group which was statistically significant (P<0.001). The mean duration of hospital stay for device closure was about 3.4 days (3-10 days), significantly shorter than that for surgical ligation which was 7.2 days (P =< 0.001). Also the need for inotrope use was significantly less in the device closure group (P val-ue<0.001) **(Table 5)**. In the surgical ligation group, two infants had recurrent laryngeal nerve palsy while one had diaphragmatic palsy due to injury to the phrenic nerve manifested by loss of cry, feeding difficulty and need for prolonged ventilation with persistent left lower lobar opacity on chest X-ray respectively. These cases were managed conservatively. Another baby required intercostal drain for a chylous pleural effusion. There was one death (5%) due to sepsis in the post-operative period. All the 19 patients who were discharged from hospital remained well on follow up. The mean follow up duration in this group was 22.1 ± 9.2 months.

Table 1: Baseline characteristics, defect/weight ratios in both groups.

Sl.No	Patient characteristic	Group A (PDA device closure)	Group B (PDA surgical ligation)	P value
1	Mean age (months)	6.5 ± 2.4	5.6 ± 3.5	0.327
2	Mean weight (kgs)	4.32 ± 0.84	3.48 ± 1.26	0.045
3	Defect/ weight ratio	0.93 ± 0.31	1.45 ± 0.63	0.001

Table 2: Details of infants in group a who underwent transcatheter pda device closure.

Sl. No	Gender	Age (months)	Weight (kgs)	PDA Size (mm)	PDA type	PAH status	Sheath size	Device size	Lifetech cera
1	F	5	4	5	A	Severe	6F	10*8	-
2	M	4	4.1	5	A	Severe	6F	8*6	ADO I
3	M	3	2.6	3.6	C	Severe	6F	8*6	ADO I
4	F	5	2.75	2.8	A	Severe	6F	5*4	ADO I
5	F	6	4.3	5	C	MOD	7F	10*8	ADO I
6	M	6	5	4	A	Severe	6F	8*6	ADO I
7	F	10	4	2.3	A	NO	6F	5*4	ADO I
8	F	4	5	3	A	MOD	7F	8*6	ADO I
9	F	4	5	3.1	A	NO	6F	8*6	ADO I
10	F	6	3.8	4	C	MOD	7F	8*6	ADO I
11	M	10	5	5	C	Severe	6F	8*6	ADO I
12	F	7	5	6	C	Severe	7F	10*8	ADO I
13	F	8	4.8	8	C	Severe	7f	12*10	MFO
14	F	4	3.5	3.5	A	MOD	7F	8*6	ADO I
15	M	6	4.8	4	A	MOD	6F	8*6	ADO I
16	M	7	6	3.5	A	MOD	6F	8*6	ADO I
17	F	10	3.7	3	A	NO	6F	8*6	ADO I
18	F	7	4	3	A	Severe	6F	10*8	Lifetech cera
19	F	12	5	2.5	A	NO	6F	5*4	ADO I
20	M	7	4	3	A	NO	6F	8*6	ADO I

Table 3: Complications in PDA device closure and surgical pda ligation groups.

Complication	PDA device closure (n=20)	PDA surgical ligation (n=20)	P value
Minor complication	Pulse loss (7)	Diaphragmatic palsy (1)	-
	Responded to heparin (6)	Feeding difficulty (RLN Palsy) (2)	-
	Responded to streptokinase (1)	-	-
	Minor LPA flow acceleration (velocity ≤ 2.5 m/s) (2)	-	-
	Minor arch flow acceleration (gradient<10mmHg) (1)	-	-
	Minor LPA flow acceleration (velocity<2.5 m/s) +	-	-
	Minor arch flow acceleration (gradient < 10mmHg) (1)	-	-
Total	11	3	<0.05
Major Complication	Severe TR due to tricuspid valve chordae rupture (1)	Chylous pleural effusion (1)	
	Persistent infection- aneurysm formation- death (1)	Sepsis leading to Death (1)	
Total	2	2	-

Table 4: Defect: Weight ratio and complications in pda device closure patients.

Case no	Defect: Weight ratio	Complication
4	1.01	Minor LPA flow acceleration (velocity<2.5 m/s) + Minor arch flow acceleration (gradient<10 mmHg)
7	0.6	Minor LPA flow acceleration (velocity<2.5 m/s)
13	1.6	Minor LPA flow acceleration (velocity-2.5 m/s) (persistent)
5	1.1	Minor arch flow acceleration (gradient<10 mmHg)
3	1.38	Aneurysm

Table 5: Comparison of duration hospital stay and duration of inotropy among both groups.

Sl No	Parameter	Group A (PDA device closure)	Group B (PDA surgical ligation)	P value
1.	Mean duration of hospital stay (days)	3.4	7.2	<0.001
2.	Duration of inotropy	No of cases (percentage)		
	Nil	9 (45)	0 (0)	
3	24-48 hrs	11 (55)	2 (10)	<0.001
4	48 to 72 hrs	0 (0)	17 (85)	
5	More than 72 hrs	0 (0)	1 (5)	

DISCUSSION

Transcatheter device closure is a well-accepted treatment for patent Ductus Arteriosus. Infants with a patent arterial duct often present with refractory heart failure, failure to thrive and recurrent lower respiratory tract infection. Although effective, the severity of complications in infants undergoing PDA device closure made many recommend surgery as the first line of treatment in young infants. As of now, device manufacturers do not recommend the use of duct occluder in patients with a body weight of ≤ 6 kg albeit there are studies that show safety in infants with lesser weights. Concerns include fear of pulmo-nary artery and/or aortic encroachment by a large device, need for large delivery sheaths and kinking of sheath in the acute turn of right ventricular outflow tract. Based on emerging literature on safety and feasibility of transcatheter device closure of ductus in infants weighing <6 kgs, our policy has shifted towards device closure as the first line of treatment in carefully selected patients. Among the 20 infants who underwent device closure, the procedure was successful in 100% cases. Shaad et al. reported a similar procedural success rate among 16 cases between 20 days to 16 months of age. It is reported successful device placement in 98.4% cases in a larger cohort (60/61 cases) reported two procedural failures in their series on 28 cases, due to sheath kink and 10-8 mm device pulling through A 8 mm duct, respectively. In 45% cases, only venous access was used. However in cases with large ductus or type C ductus, we used both arterial and venous access for ease of assessment of the device positioning, especially towards the earlier part of the study when our experience was limited. In our series, 70% were type A ductus, rest being type C. This was similar to the series, where 75% of the cases that underwent device closure were type A. However the type of duct was unrelated to complications in this study. Experience with device closure in dutus other than type A is limited in this weight category. In our series, the most frequently used device for both types of duct morphology was Amplatzer Duct Occluder I (AGA Medical Corporation, Golden Valley, MN) (90 %). Use of Amplatzer Duct Occluder II, Amplatzer Duct Occluder II-additional size, angled occluder, vascular plug have all been described in literature. We used Duct Occluder I in almost all the patients without compromising either the arch or the left pulmonary artery. Various literatures have shown long tubular ductus (Type C) can successfully be closed by vascular plug, however due to lack of availability of vascular plug in our setup which might be more suitable for type C made us select Duct Occluder I in those cases with good short term (closure) and long term (no obstruction to nearby structures) outcomes. However, the size of the device needs to be carefully selected to prevent device embolization or compromise of adjacent structures. There were no instances of device embolization in our series. Although encroachment into arch or left pulmonary artery is a common concern, we did not en-counter significant obstruction to either of these structures due to careful device sizing. In one case (case no 13, 5%), the left pulmonary artery showed a gradient of 25 mmHg immediately after release of the device. This remained stable on six months' review and she remains under close follow up. Reported no gra-dients across aortic arch or left pulmonary artery in their series of 28 cases aged 2 to 18 months with successful device closure of patent arterial duct. Mild left pulmonary artery obstruction in 1.6% cases. Studies have also shown reduction of aortic and pulmonary artery gradients with somatic growth. We did have minor limb complications in 35% (7/20) cases, however the pulse loss responded well to heparin infusion (unfractionated heparin 100 unit/kg bolus followed by 20

unit/kg/hour with a target Activated Partial Thromboplastin Time (APTT) of twice normal till return of pulse) in all but one (case No 4), who needed thrombolysis by Streptokinase (2000 IU/kg bolus followed by 1000 IU/kg/hour for 24 hours) used heparin and streptokinase (1000 IU/kg) successfully in femoral artery thromboses seen in 6.6% cases. Development of aortic pseudoaneurysm, on the background of recurrent blood stream infections in one infant (case no 3) who underwent device closure for refractory heart failure highlights the importance of careful case selection and the imminent risk of vascular complication in the setting of uncontrolled sepsis. Ductal pseudoaneurysm is rare but has been reported in both children and adults after both device closure and surgical ligation. In our series, among the two groups with comparable age, the procedure was successful in 100 % cases in both the groups with 1 mortality (5%) in each within 30 days of the procedure, neither being directly procedure related. The difference in the mean weights between the two groups (4.32 kg ± 0.84 kg versus 3.48 kg ± 1.26 kg) was statistically significant (P=0.045). Also the mean defect: Weight ratio was 0.93 for the device closure group and 1.45 for the surgical ligation group which was statistically significant (P<0.001). The significant difference in the mean defect: weight ratio was due to our study criteria directing infants with defect: Weight ratio>1 preferably for surgical ligation in a study on transcatheter ductal closure in infants stated that a ductal diameter greater than 3.7 mm, type C (tubular shape) and duct/patient weight ratio greater than 0.91 were significantly associated with an unsuccessful procedure and/or major complications. More studies are needed to assess feasibility of ductal device closure in infants with larger defect: Weight ratio. With comparable procedural success rates, the mean duration of hospital stay was significantly shorter (3.8 days) for the device closure group compared to the surgical ligation group (7.2 days) with the difference reaching statistical significance (p value<0.001). A similar longer hospital stay of 4+/- 2 days for surgical patients compared to those that underwent device closure. Also, the duration of inotropy post procedure was significantly shorter in the device closure group (p value<0.001), with 45% cases not requiring inotropy post procedure **(Table 3)**. This is explained by the fact that the surgical group dealt with larger duct and left ventricular sizes and consequent higher degree of left ventricular dysfunction after ligation. Studies have shown larger duct size and bigger left ventricular dimensions to be a predictor for left ventricular systolic dysfunction in the post-operative period in surgical duct ligation. There were major complications in 2 patients (10%) in both the groups. In group A there was one baby with severe tricuspid regurgitation post procedure due to chordal rupture and one baby with infective pseudoaneurysm. Risk of tricuspid valve injury is well known, and avoiding wire catheter mismatch is key to preventing the same. There were fewer minor complications in the surgical group (3/20, 15%) compared to the device closure group (11/20, 55%) (p<0.05). However the minor complications in the device closure group were self limiting. Avoidance of arterial access is essential to prevent arterial compromise, in this weight category although this takes away the angiographic advantage for device placement. Analysis of retrospective data for the surgical ductal ligationgroup, lack of availability of various devices and short follow up duration were the main limitations of our study.

CONCLUSION

Transcatheter device closure of hemodynamically significant arterial duct in infants weighing less than 5 kg is a feasible option with success rates comparable to surgical ligation. Device closure in this weight category is fraught with the risks of access site complications as well as compromise of adjacent vascular structures. Careful patient selection and echocardiographic sizing of the duct plays a major role in procedural success and avoidance of complications. The choice of device is guided by the shape and size of the duct and care should be taken to avoid oversizing. Arterial access in this weight category should be avoided as much as possible to avoid post procedure limb compromise. Patient with duct/weight ratio above 1 are at higher risk of complications due to obstruction of either left pulmonary artery or aorta and would be better candidates for surgical referral.

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CONFLICTS OF INTEREST

None.

ETHICAL STANDARDS

The authors assert that all procedures contributing to this work comply with the ethical standards of the Indian Council of Med-ical Research (ICMR), Code of Ethics 2017 and with the Helsinki Declaration of 1975, as revised in 2008, and has been approved by the institutional ethics committee of Rabindranath Tagore Institution of Cardiac Sciences.

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