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Cardiac Remodeling and Tricuspid Valve Outcomes After Transcatheter Perimembranous VSD Closure in Pediatric Patients

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ABSTRACT

Background: Paediatric patients frequently experience tricuspid regurgitation as a result of a perimembranous ventricular septal defect (pmVSD), which may get better when the defect is closed. The aim of this research was to evaluate how transcatheter pmVSD closure affected children's cardiac remodelling & TR severity.
Methods: among September2023 & March2025, 55 paediatric studied cases receiving treatment at Minya University Hospital & the National Heart Institute with haemodynamically significant pmVSD & at least mildTR participated in a prospective observational study. Under the direction of fluoroscopic and echocardiographic imaging, patients underwent transcatheter closure. Transthoracic echocardiograms were used to measure the ejection fraction, left ventricular end diastolic/systolic dimensions, & TR severity at baseline, one, & six months. statistical analysis (SPSS v26) was employed.
Results: Following the surgery, there were notable decreases in the severity of TR: at 6 months, the tricuspid regurgitation jet area fell from 4.63cm² to 1.16cm², mildTR declined from 2.98cm² to 0.72cm², moderateTR decreased from 6.6cm² to 1.2cm², & severeTR reduced from 10.4cm² to 4.2cm² (all $p<0.001$). After 6months, there had been a significant improvement in left ventricular dimensions, with LVESD going from 26.8mm to 23.8mm & LVEDD going from 43.18mm to 39.4mm (both $p<0.001$). From 65.3percent to 67.1percent, LVEF rose ($p<0.001$). There were no reports of residual shunts. There were only 2 studied cases (3.6%) who had minor issues.
Conclusion: With good clinical & functional results, transcatheter closure seems to be a safe & efficient treatment for PmVSD linked to TR.

KEYWORDS: Tricuspid regurgitation; Transcatheter closure; Ventricular septal defect; Pediatric cardiology; Cardiac remodeling.

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INTRODUCTION

Nearly seventy percent of all congenital heart defects are membrane ventricular septal defects (pmVSDs), making them the most common type ***[1]***. Due to the haemodynamic burden these anomalies cause, both the right & left ventricles dilate & malfunction, which frequently leads to functional tricuspid regurgitation (TR) ***[2]***.

Although surgery has historically been the go-to treatment, transcatheter closure procedures have become a less intrusive & more well-liked substitute in recent years because of their lower perioperative risks ***[3]***.

The primary cause ofTR pathophysiology in the context of pmVSD has been anatomical distortion of the tricuspid valve caused by annular dilatation & septal displacement ***[4].*** Chronic volume overload may worsen these alterations over time and eventually result in progressive valve insufficiency. Early intervention may lessen the chance of future surgical valve replacement & prevent irreversible cardiac damage ***[5]***.

The development of technologically advanced devices, like the Amplatzer occluder, has greatly improved procedural results & reduced problems ***[6]***. Recent developments have significantly increased procedural success rates & decreased problems, like the Lifetech Konar multipurpose occlude ***[7]***. However, concerns about the longevity of valve competence after device closure persist, particularly in studied cases with severe baselineTR ***[8]***.

There is evidence that TR linked to pmVSD could improve once the defect is closed because the tricuspid valve is less stressed when the ventricles are geometrically normalized ***[9]***. Nevertheless, little is known about the long-term effects of transcatheter closure on cardiac function & TRseverity, especially in paediatric patients. By assessing the effectiveness & safety of transcatheter pmVSD closure in lowering TR & enhancing ventricular function in children, this study fills this knowledge gap.

Aim of the work

The current study set out to assess the effects of transcatheter device closure for ventricular septal defects on paediatric patients' tricuspid valve performance & cardiac remodelling.

Patients & Methods

Study Design & Participants:

fifty-five studied cases participated in this prospective research, which had been carried out at the Nation Heart Institute & Cardiology Unit of the Paediatric Department of Minya University Hospital among September2023 & March2025.

Inclusion criteria:

- Children of both sexes up to the age of sixteen.
- ECHO criteria
  - ✓ Anatomically appropriate for transcatheter closure, haemodynamically significant isolated perimembranous VSD requires a rim greater than 2mm from the aortic valve.
  - ✓ The occurrence of a left-to-right shunt.
  - ✓ The average pulmonary artery pressure is less than 40mmHg.
  - ✓ At least mildTR.

Exclusion criteria:

- Body weight < 6kg
- Pulmonary vascular resistance index > 7WU/m2 ,
- The extension of PMVSD to the inlet
- The development of new lesions that need to be operated on.
- Gerbode deficiency that mimics severe TR in certain ways.

Procedural Details:

Under either local or general anaesthesia, transcatheter closure was carried out. Devices were chosen according to the anatomy & size of defects. Heparin (100IU/kg) had been given intravenously after the femoral vein & artery were opened. The VSD was profiled & its position & size evaluated using angiography in the left ventricle at a 60°/30° left anterior oblique projection/cranial. The device being utilised and the size & location of the problem determine the procedure to be used. Device deployment was guided by transesophageal echocardiograms & real-time fluoroscopy to guarantee ideal location & reduce problems. Procedural success had been described as complete defect closure without residual shunting or significant TR progression.

Echocardiographic Protocol:

Both before & after the procedure, thorough transthoracic echocardiograms (TTE) were conducted. The left atrial maximal anteroposterior diameter, left ventricular ejection percent, & left ventricular end-systolic & end-diastolic diameters had been determined using the M-Mode technique and the modified Simpson's biplane algorithm.

Using color-Doppler flow mapping from an apical 4-chamber view, the spatial distribution of the central regurgitant jet inside the right atrium was used to determine the severity of TR. Every midprecordial & apical site that was available was searched for the TR jet in each patient until a flow signal with the highest spectrum representation of high velocities had been captured. The angle among the ultrasonic beam & the flow direction can be presumed to be negligible after a signal with a relatively dense high-velocity spectral representation has been acquired ***[10]***. The American Society of Echocardiography's approved method was used to grade the tricuspid regurgitation severity: one for mild, two for moderate, & three for severe ***[11]***. The vena contracta breadth, colour jet area TRJA (cm3), & the ratio of the maximal regurgitant area to right atrial area (%) were among these suggestions.

Outcome Measures:

- <u>Primary</u>: Modification of TRJA and TR grading (mild, moderate, and severe).
- <u>Secondary</u>: Variation in LVEF and LV dimensions (LVEDD, LVESD) at1 & 6months.
- <u>Safety</u>: Procedural problems, such as valve damage, arrhythmias, and device embolisation.

Statistical analysis of the data

- Data had been analyzed using SPSS version 26.00. A p-value < 0.05was considered statistically significant.
- To ascertain whether the data had a normal distribution, the Shapiro Walk test was employed. The qualitative data had been illustrated using relative percentages and frequencies. The quantitative data was expressed using the range and mean ± SD (standard deviation).
- For parametric variables, the difference among quantitative variables in 2groups was calculated using the independent t test.
- <u>One way ANOVA</u> test had been used to calculate difference among quantitative variables in > two groups for parametric variables.
- Repeated action to determine the difference between more than 2 linked variables, ANOVA was utilized.
- A pair of samples to determine the difference between 2related variables, the t test had been employed.

- Every statistical comparison was significant and two-tailed. A difference had been considered significant if the P-value is < 0.05, highly significant if it is < 0.001, & non-significant if it is > 0.05.
- For sample sizes, 95% confidence intervals were computed.

Ethics:
Before being included, parents & carers of the patients under study had been informed of the aim & nature of the research. Prior to enrolment, informed consent was acquired, granting participants the option to opt out of our study without resorting to dishonest tactics. Additionally, the Paediatrics Department Council & the Faculty of Medicine Minia-University's ethical committee authorised this study (No. 985/11/2023). Written informed consent had been got from all participants' guardians in accordance with the Declaration of Helsinki.

RESULTS

Patients:
Transcatheter intervention for VSD was successful in treating all fifty-five studied cases with at least mild TR. Of the studied cases, twenty-four were female & thirty-one were male. Table 1 summarises the clinical, surgical, & post-operative features of the patients under study.

(Table1): Features of the cases as clinical, operative & post-operative data.

	Descriptive statistics (N=55)
VSD size detected by TTE (mm)	
Mean ±SD	4.93±1.2
Range	2.8-7.5
Degree of TR before intervention*	
Mild	36 (65.5%)
Moderate	14 (25.5%)
Severe	5 (9%)
Device type	
ADO I	38 (69.1%)
ADO II	9 (16.4%)
Konar	8 (14.5%)
Device size (mm)	
Mean ±SD	7.39±1.02
Range	4.6-10.12
Procedure time (min)	
Mean ±SD	69.4±24.5
Range	34-120
Hospital stays (Hour)	
Mean ±SD	1.54±0.63
Range	1-4
Complication	
No	53 (96.4%)
Yes	2 (3.6%)

SD=standard deviation, VSD=Ventricular septal defect, TR=tricuspid regurgitation ADO = Amplatzer duct occluder, TTE = transthoracic echocardiography
*According to American Society of Echocardiography

According to the clinical data, the most of cases (65.5percent) had mild tricuspid resurge, 25.5percent had moderateTR, & only 9percent had severe TR. The average end-diastolic VSD size, as determined by color-Doppler TTE prior to surgery, was 4.93±1.2 mm, with a range of 2.8 to 7.5mm. In terms of the operating statistics, the majority (69.1%) had an ADO I device, the mean procedure time was69.4 minutes, and the range was 34 to 120minutes. The mean device size was7.39±1.02. After surgery, the average length of stay was 1.54±0.63 days, with a range of one to four days. Only two instances (3.6%) suffered complications, including 1 AR & another heart block, & a pacemaker had been implanted.

TR Reduction & Cardiac Remodeling:
Table 2 lists the echocardiographic characteristics that had been assessed prior to, as well as immediately following percutaneous VSD closure. The follow-up period was six months. A significant increase in tricuspid valve competence was indicated by the TRJA, a quantitative indicator of TR severity, which dropped from 4.63cm² to 1.16cm² with a mean percentage of decline of 76.1percent±15 ($p<0.001$). After one month, the mean TRJA dropped considerably from the preintervention value. All grades showed a significant decrease in TR severity at 6 months after closure: mild TR fell from 2.9percent to 0.72percent, moderate TR between 6.6percent & 1.2percent, & severe TR between 10.9percent & 4.2percent ($p<0.001$ for all). Fig. 1 displays the findings.

There was clear evidence of left ventricular remodeling: LVEDD dropped from 43.18mm to 39.4mm & LVESD dropped from 26.8mm to 23.8mm (both $p<0.001$), indicating less ventricular dilatation after defect closure. LVEF showed increased systolic function, rising from 65.3% to 67.1% (p<0.001). Subgroup analysis showed that all TR grades had improved consistently.

Table 3 summarizes the relationship among parameters & TR severity, whereas Table 4 lists the relationship among parameters' percentage improvement & TR severity.

Table (2): Comparing the parameters of the examined cases prior to VSD closure, one month after closure, & six months after closure.

	A Pre-intervention	B After one month	C After six months	Percentage change after six months percent	*P*value A & B	A & C	B & C
LAMD	24.30±2.50	22.40±2.30	21.70±2.20	10.26±3.60	<0.001	<0.001	= 0.01
LVEDD	43.18±3.40	40.90±3.20	39.40±3.20	8.60±2.50	<0.001	<0.001	<0.001
LVESD	26.80±1.90	24.60±1.80	23.80±1.90	7.76±3.60	<0.001	<0.001	<0.001
LVEF	65.30±3.60	66.40±3.20	67.10±3.04	2.90±3.20	0.001	<0.001	=0.002
TRJA	4.63±2.70	1.49±1.70	1.16±1.49	76.1±15.07	<0.001	<0.001	<0.001
Mild	2.98±1.06	0.98±0.76	0.72±0.54	75.20±12.70	<0.001	<0.001	<0.001
Moderate	6.60±1.09	1.66±1.50	1.20±1.10	83.10±12.50	<0.001	<0.001	<0.001
Severe	10.90±0.51	4.70±3.50	4.20±3.20	62.60±26.70	<0.001	<0.001	0.007

LAMD=Left Atrium Maximum Dimension, LVEDD=Left Ventricular End Diastolic Dimension, LVEDD=Left Ventricular End Systolic Dimension, LVEF=Left Ventricular Ejection Fraction, TRJA=Tricuspid Regurgitation Jet Area

(Table3): Relation among different parameters & TR severity

	TR severity Mild TR (n=36)	Moderate TR (n=14)	Severe TR (n=5)	*P*value
LAMD before	24.8±2.2	23±2.9	23.6±2.3	**0.04***
LAMD after 1 month	22.9±2.04#	21.2±2.7#	21.8±1.9#	**0.04***
LAMD after 6months	22.3±1.9#	20.5±2.5#	21.4±2.4#	**0.03***
Pvalue	**<0.001***	**<0.001***	**0.01***	
LVEDD before	43.9±3.09	41.2±2.9	43±5.5	**0.038***
LVEDD after 1month	41.7±3.01#	39.1±2.8#	40.4±4.8#	**0.035***
LVEDD after 6months	40.2±3#	37.6±2.9#	39±4.1#	**0.033***
Pvalue	**<0.001***	**<0.001***	**0.008***	
LVESD before	26.1±2.01	25±2.05	26±1.4	**0.25**
LVESD after 1month	24.9±1.8#	23.9±1.8#	25±1.4#	**0.20**
LVESD after 6months	24.5±1.8#	22.7±1.8#	23.8±0.83#	**0.03***
Pvalue	**<0.001***	**<0.001***	**0.008***	
LVEF before	65.1±2.7	65±5.1	67.8±4.4	**0.28**
LVEF after 1month	66.1±2.9#	66.7±3.4#	68.4±4.2	**0.32**
LVEF after 6 months	66.7±2.7#	67.3±3.2#	69.4±4.5	**0.19**
P value	**<0.001***	**0.004***	**0.10**	

TR=tricuspid regurgitation, LAMD=Left Atrium Maximum Dimension, LVEDD=Left Ventricular End Diastolic Dimension, LVEDD=Left Ventricular End Systolic Dimension, LVEF=Left Ventricular Ejection Fraction, * significant at p value <0.05, _ # significant difference with baseline.

The difference among mild, moderate, & severe TR cases' LAMD & LVEDD before & after follow-up had been statistically significant (pvalue <0.05). Severe TR cases did not significantly differ from mild TR cases, but the mean had been higher for mild TR cases than for severe TR cases.

Regarding LVESD at 6months, there has been a significant difference among mild, moderate, & severe TR cases (p value <0.05), with the mean for mild TR cases being much greater than that of moderate instances. However, among individuals with mild, moderate, & severe TR, the difference between LVESD & LVEF before and after VSD closure had not been statistically significant (p value >0.05).

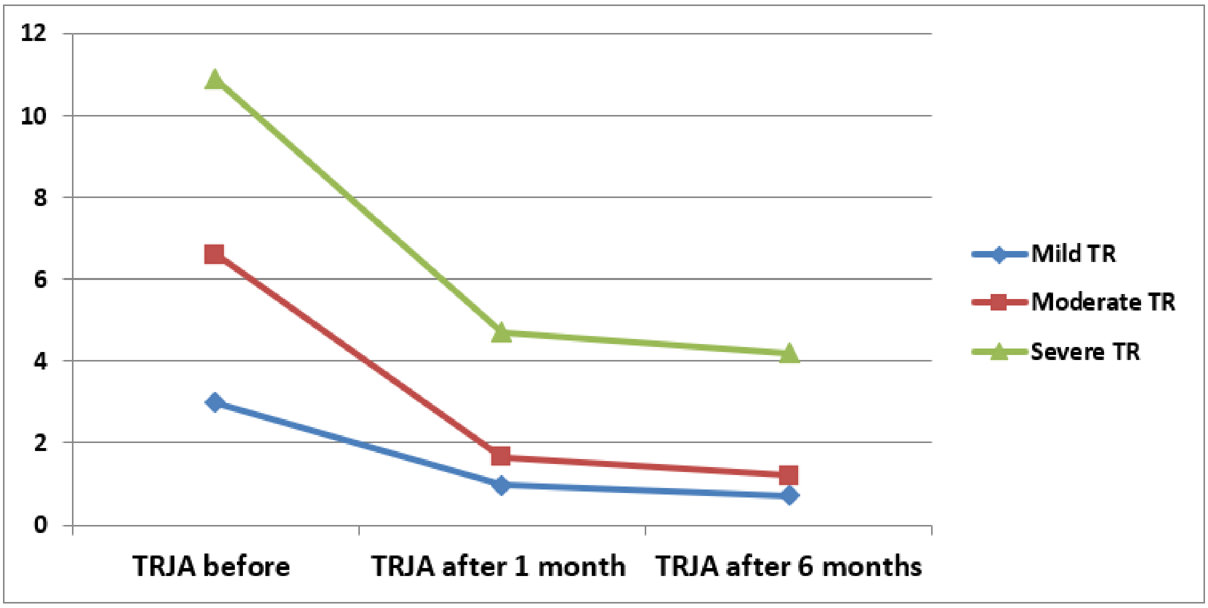
(Table4): Relation among percentage of improvement of parameters & TR severity

Percentage of change	TR severity before Mild TR	Moderate TR	Severe TR	*P* value
LAMD	10.10±3.70	10.70±4.0	9.40±2.20	0.760

LVEDD	8.50±2.40	8.60±3.050	9.10±2.00	0.890
LVESD	7.080±3.20	9.20±4.50	8.30±2.90	0.140
LVEF	2.50±2.60	3.90±4.60	2.30±2.40	0.410
TRJA	75.20±12.70	83.10±12.50	62.60±26.70	0.020*

*TR=tricuspid regurgitation, LAMD=Left Atrium Maximum Dimension, LVEDD=Left Ventricular End Diastolic Dimension, LVEDD=Left Ventricular End Systolic Dimension, LVEF=Left Ventricular Ejection Fraction, TRJA=Tricuspid Regurgitation Jet Area_** significant at p value <0.05

There has been a significant difference (pvalue <0.05) in the proportion of improvement in TRJA between subjects with mild, moderate, & severe TR. Moderate TR cases had a substantially greater mean percentage of improvement (83.1±12.5) than mild TR cases (75.2±12.7), & both had been significantly > severe TR cases (62.6±26.7). However, in terms of LAMD, LVEDD, LVESD, & LVEF, there is no discernible difference (p value >0.05).



(Fig1) line chart represents change in TRJA amid patients regarding TR severity

DISCUSSION

Mechanistic Insights:

Although there are still hazards associated with the catheter-based method for VSD, including the possibility of complete atrioventricular block, residual shunt, & interference with the tricuspid & aortic valves, it is demonstrated to be an effective alternative to surgical closure with promising outcomes ***[12]***. In some early accounts, TR complicated by VSD was noted. To the best of our knowledge, however, very few research has examined the fate of TR brought on by VSD or the results of ventricular function following VSD closure. The purpose of this research had been to look into how different levels of TR affected children's ventricular metrics.

Limited information about the mechanisms of TR in studied cases with perimembranous VSD can be found in historical literature. Aneurysm development was mentioned in earlier papers in 1978, but they could not explain how it led to TR ***[13]***. According to certain research, tricuspid valve function could be hampered by the septal leaflet's role in aneurysm formation ***[14]***.

According to pathological results, tricuspid valve adhesion can cause spontaneous closure of VSDs, frequently resulting in septal aneurysms. This procedure has the potential to cause tricuspid apparatus distortion & valvular insufficiency ***[15]***.

Lastly, transesophageal echocardiographic conclusions of tricuspid valve abnormalities related to spontaneous closure of perimembranous VSD in adults were reported by Winslow et al. They came to the conclusion that their patients' at least mild tricuspid insufficiency was caused by tricuspid valve deformity combined with VSD closure, although they did not specify the precise mechanism or cause of TR ***[16]***.

Ventricular septal displacement & annular dilatation, which affect tricuspid valve coaptation, are the causes of functional TR in pmVSD. In order to lessen the strain on the tricuspid valve, transcatheter closure reduces septal dyskinesia & restores normal ventricular morphology ***[17]***.

10.9 percent of the cases (55/504) with congenital perimembranous VSD in the present research showed apparent TR (at least mild), even though the most of TR had been greatly decreased following transcatheter VSD closure. This remarkable improvement in TR lends credence to the idea that TR in cases with pmVSD has been mostly functional, reversible, & possibly related to defects.

We concur with the mechanisms for tricuspid regurgitation in perimembranous ventricular septal defects that Abdelnabi & Almaghraby have postulated. The anterior tricuspid leaflet is displaced by high-velocity flow via the VSD in the 1st mechanism. This alters normal valve dynamics by rerouting blood flow towards the right atrium. The Venturi effect of the left-to-right shunt has been responsible for the 2nd process, which is related to the creation of septal leaflet aneurysms. This aneurysm impairs tricuspid valve coaptation during systole even though it may partially obstruct the VSD. Because the valve cannot properly seal throughout ventricular contraction, the consequent partial leaflet closure causes regurgitation ***[18].***

In addition to tricuspid valve replacement or repair, surgical closure was required for severe TR linked to PMVSD. Transcatheter closure is preferred as a main intervention in current clinical trends, though, which may avoid the necessity for valve surgery ***[19]***. Indeed, our findings showed that most studied cases, including those with moderate to severe regurgitation, had total or nearly complete remission of TR.

Clinical Implications:
The mean procedure time for the operative data was 69.4 minutes, with a range of 34 to 120 minutes. We attributed this to system lag rather than the interventionists' skill level. Just 2 studied cases (3.6%) experienced difficulties; one had a cardiac block and a pacemaker was implanted, while the other patient's aortic regurgitation (AR) significantly increased. As opposed to Xu et al. ***[20]*** & Shah et al. ***[21]*** Both had comparable complication rates of 10.4% & 8.5%.

After transcatheter closure, tricuspid regurgitation severity significantly improved in all categories, according to transthoracic echocardiography. Four (80%) & one (20%) of the five studied cases with pre-existing severe TR improved to mild TR & moderate TR, respectively. Eight (57.1%) of the 14 studied cases with moderate TR resolved to trivial/absent TR, 1 (7.1%) remained with moderate TR, & five (35.7%) dropped to mild TR. Of the 36 studied cases in the mild TR group, 29 (80.6%) resolved to trivial or absent TR, while four (11.1%) did not change.

With the majority of studied cases experiencing at least one grade improvement & only a small percentage displaying persistent regurgitation, our results demonstrate the effectiveness of transcatheter closure in lowering the severity of TR.

Regarding the proportion of improvement in TRJA, there has been a significant difference among instances with mild, moderate, & severe TR ($p < 0.05$). In comparison to severe TR, both groups showed noticeably more improvement, with moderate TR cases having the highest mean percentage decrease and mild TR following closely behind. This outcome concurred with ***[20]*** which discovered that severe instances of TR show less recovery than mild or moderate occurrences.

Others have recently documented a progressive increase in tricuspid insufficiency, a notable decrease in the size of the VSD, & a correlation with the development of aneurysms***[22]***. Our results support the link among the severity of TR & interventricular septal aneurysmal remodelling. TR aetiology in this environment, however, could be mechanistically independent of defect size, as no statistically significant connection had been seen among TR severity & baseline VSD dimensions ($p > 0.05$).

The percentage of change in LVEDD after 6months & VSD size before closure have a mildly negative significant correlation ($r = -0.25$, $p = 0.02$) when other correlations with VSD size are taken into account. This suggests that smaller defects could have disproportionate haemodynamic effects on ventricular geometry. On the other hand, the relative improvement in left ventricular ejection fraction after closure showed a weak positive connection with baseline VSD size ($r = 0.26$, $p = 0.01$), which may indicate improved ventricular unloading & contractile efficiency when bigger shunts were closed.

Comparison with Surgical Outcomes:
Our results support previous research showing a decrease in tricuspid regurgitation after ventricular septal defect closure. But although earlier studies have mostly concentrated on surgical cohorts ***[23]***, this research uses a minimally invasive technique to achieve a ninety one percent overall decrease in TR severity (with 67.2percent resolution to trivial/absent TR), establishing transcatheter closure as a clinically similar option.

Transcatheter procedures enable faster functional recovery (median return to normal activity: 5days vs. 21days) & shorter hospital stays (2.10 ± 1.3days vs. 7.80 ± 2.5days for surgery), even though the transcatheter cohort demonstrated comparable TR improvement to surgical norms (ninety to ninety five percent). ***[24]*** with a markedly lower rate of perioperative morbidity (3.6 percent vs to 12.4 percent for surgical controls) ***[23]***. These outcomes imply that percutaneous procedures could have two advantages: improved procedural safety, especially in paediatric populations, & haemodynamic correction comparable to surgery.

LIMITATIONS & FUTURE DIRECTIONS:

- 1st, this study's small sample size, especially the subgroup of 5 studied cases with severe TR, is a major drawback that could restrict the findings' applicability to larger populations. Even though most results were statistically significant, these outcomes need to be confirmed in larger, multicenter cohorts, particularly for severe TR.
- Second, the short follow-up period following VSD closure is a significant study restriction that makes it impossible to evaluate the long-term trajectory of TR persistence or possible late-onset valvular sequelae. Chronic remodelling processes such progressive tricuspid annular dilatation or iatrogenic valve damage from device erosion may not be sufficiently captured by the median follow-up of 6months. Additionally, it is unclear if TR improvement will last past this point, especially in studied cases with borderline pulmonary vascular resistance or baseline severe TR. To describe the temporal dynamics of TR resolution, find predictors of late recurrence, & produce enough reference data for evidence-based therapeutic decision-making, large-scale longitudinal multicenter trials with monitoring periods of at least five years are necessary.
- Additionally, Prospective comparative trials that directly compare transcatheter & surgical cohorts have been crucial to improving clinical decision-making. To clarify the relative effectiveness (e.g., TR decrease rates, ventricular remodelling) & safety profiles of the 2 strategies, such studies should use standardised outcomes. In paediatric populations, special focus must be given to long-term results, like case-reported quality of life metrics and the intrusive load of open-heart surgery against transcatheter methods. The establishment of risk-stratified treatment algorithms depends on this evidence.

CONCLUSION

In paediatric studied cases, transcatheter pmVSD closure successfully lowers functional TR & enhances heart function while maintaining a good safety record. Although larger studies have been required to validate long-term effects, these results support its use as a 1st-line treatment for some individuals.

Conflict of Interest:
The authors declare that they have no conflict of interest.

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Authors' contributions

- **Marwa Ibrahem Abdelrazic:** Conception & design of the research, data collection, & initial drafting of the manuscript.
- **Abdel-Azeem M. El-Mazary:** Supervision of the study, validation of methodology, & critical revision of the manuscript for intellectual content.
- **Moustafa Mohamad Abdelraheem:** Echocardiographic assessment supervision, data interpretation, and contribution to result analysis.
- **Ahmed Meawad Elemam:** Procedural supervision of transcatheter interventions and clinical review of the manuscript.
- **Hossam Mohamed Elhuseiny Abdelkarem:** Study design, statistical analysis, overall project coordination, and final manuscript review as corresponding author.

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