Assessment of Residual Shunting Following Surgical or Trans Catheter Device Closure of Perimemberanous Ventricular Septal Defects in Children

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Abstract

Background: Surgical repair for the VSD has been the golden standard treatment. With the development of various device, trans catheter device closure of VSD has gradually become an alternative to conventional surgical repair, especially in patients with perimembranous defects with a promising success rate of closure. Objective: Assess the incidence of complete heart block following trans catheter device closure in comparison to surgical closure of pm ventricular septal defects in children. Methodology: This study is a retrospective study conducted on 200 pediatric patients post isolated pm VSD closure (100 post-surgical cases, 100 post catheter case). Results: Our study revealed that 4%(n=4) with CAVB and permanent pacemaker among the surgical cases in opposite to none of the catheter group.. Blood transfusion, length of hospital stay was significantly more among the surgical cases. We have no mortality in both groups. Conclusion: Our study suggests that there is no significant difference between percutaneous and surgical closure of pmVSDs in terms of early (up to 30 days) efficacy and safety in well-selected patients. Furthermore, percutaneous closure is associated with decreased hospital stay, which could potentially be cost saving.

Keyword: *Pm VSD-surgical-trans venous- device- residual- CAVB.*

INTRODUCTION

Percutaneous device closure (PDC) of peri - membranous ventricular septal defects (pmVSD) poses a significant challenge given the proximity of the defect to the aortic and tricuspid valves as well as to the conduction system (1).

Small residual defects are frequently described on intraoperative and also on postoperative trans thoracic echocardiography (TTE), but the rate of possible spontaneous closure, or the hemodynamic and clinical significance in case of a persistent residual shunt, are sparsely documented (2)

The most serious complication of this surgery is a complete atrioventricular block that has been reported in 0.7 - 3.1% of cases. A comparative study between surgical and trans catheter closure of VSD showed that the trans catheter closure is less invasive, has a shorter recovery time and requires less hospital stay time. The complication rates of both methods were comparable.

The primary aim of this study was to assess the incidence of residual shunt following trans catheter device closure in comparison to surgical closure of pm ventricular septal defects in children and follow up for two years to assess the possibility and incidence of spontaneous closure or need for redo and to

assess the incidence of early and late onset complications.

PATIENTS AND METHODS

One hundred postoperative and the same number of post catheter repair of pm ventricular septal defects in children and adolescents, were included in the study after meeting the inclusion criteria.

Study participants were recruited from: Postoperative ICUs of Children Specialized Hospital. Post catheter ICUs of Children Specialized Hospital. Some preoperative, operative, and postoperative data are collected from the patient's notes and files.

Inclusion criteria: Both sexes, weighing at least 10 kg., children and adolescents who underwent surgical or transcatheter device closure for isolated pm VSD who had any preoperative criteria indicating VSD closure including: Symptoms and signs of heart failure, failure to thrive, predominantly due to hemodynamic effects of the VSD, recurrent respiratory infections (defined as > 6 events in the preceding 12 months), cardiothoracic ratio on chest X-ray of > 0.55, left atrial-to-aortic diameter ratio on long-axis echocardiogram >1.5, left ventricular (LV) dilatation as indicated from LV end-diastolic z-score on echocardiogram, estimated pulmonary-to-systemic blood flow ratio >1.5 at cardiac catheterization, if the VSD has become smaller because of its closure by prolapsed aortic valve cusp into the defect with resultant aortic insufficiency and history of infective endocarditis related to the VSD.

Exclusion criteria: Patients with muscular ventricular septal defects or any other VSDs that are not feasible for trans catheter closure e, g Sub aortic, sub pulmonic, or doubly committed VSDs, patients with VSDs as a part of complex congenital heart disease, patients with valve diseases needing a surgical repair, patient with residual VSD postsurgical repair of pm VSD.

Children with body weight less than 10 kg and

Methodology in details: All patients are subjected to the following:

History taking, and clinical assessment (preoperative data collected from patient's notes and files) with special emphasis on: Personal and demographic data including; full name, age, sex and residence, growth and development history, the frequency of chest infection and frequency of preoperative and postoperative hospital admission and the severity of the heart failure according to NYHA classification.

Echocardiography (Detailed echocardiographic data were collected from the patient's files, and new echocardiography examination was done at the time of the study using a GE healthcare Logic V5 Ultrasound machine): Two-dimensional (2D) echocardiography(echo) for VSD assessment either securely closed or there was a residual with assessment of the residual flow through the defect, trans ventricular PG and hemodynamic significance. Flow through the VSD was characterized as none, trivial (single-color flow jet with proximal jet width <1 mm), small (single-color flow jet with a proximal jet width of 1 to 2 mm in all views in children weighing < 20 kg or 1 to 3 mm in larger children and adolescents), or greater than small (single-color flow jet with proximal jet width > 2 mm in children < 20 kg or > 3 mm in older children and adolescents; alternatively, multiple defects with small or greater than small shunting) (3) and presence of intracardiac masses or vegetations.

Electrocardiogram (ECG): Preoperative, Postoperative (immediate, 3,6,12, and 24 months post intervention)

Placement of paediatric ECG leads: In young children, the right ventricle normally extends to the right side of the sternum. To appropriately display right ventricular potentials, ECGs for children in the under

five-year age group must include an alternate lead ('V4R') on the right side of the chest, at a point analogous to the left-sided V4.

Precordial leads: V1: 4th intercostal space, right sternal border. V2: 4th intercostal space, left sternal border. V3: midway between V2 and the placement of V4 in adults (5th intercostal space, left mid-clavicular line). V4R: 5th intercostal space, right mid-clavicular line. Use this lead for V4R, must label as such on ECG. V5: anterior axillary line, same horizontal plane as V4. V6: mid-axillary line, same horizontal line as V4

Limb leads: Place on top part of arm or leg (less muscle interference) (4).

Percutaneous trans venous technique: Percutaneous device closure was performed under general anesthesia in the operating room. Patients were placed in spine position with the femoral arterial and venous accesses were obtained, and then heparin (100 IU/kg) was administered intravenously. Intraoperative TEE/TTE was used to assess the VSD position, and the circumferential margins, especially its relationship with the aortic valve and tricuspid valve.

Statistical analysis of the data: Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Qualitative data were described using number and percent. Quantitative data were described using range (minimum and maximum), mean, and standard deviation, median and inter quartile range (IQR). Significance of the obtained results was judged at the 5% level.

RESULTS

Our study was done on 100 postsurgical, 100 post catheter cases. We compared demographic data of both groups we found that the age (years) range in surgery group was 1.0 – 13.0, mean 3.55 ± 2.45, while age (years) range in catheter group was 3.0 – 16.0, mean 6.83 ± 3.03 with statistically significant difference being younger among the surgical group. In surgery group; 62.0% (n=62) of them were males and 38.0% (n=38) were females, while the catheter group; 52.0% (n=52) were males and 48.0% (n=48) were females with no statistically significant difference. The weight (kg) range in surgery group was 10.0 – 40.0, mean 15.11 ± 7.42, while the weight (kg) range in catheter group was 11.0 – 67.0, mean 24.81 ± 12.88, with a statistically significant difference being less among the surgery group (related to the younger age). 11% (n=11) of surgery cases were below the normal weight for age as assessed by the Z score of their age and sex group in comparison with only 2% (n=2) in catheter group. All cases of both groups were with normal length/height according to the Z score of their age and sex group. The range of height/length (cm) in surgery group was 65.0 – 159.0, mean 91.51 ± 19.67, while the range of height/length (cm) in catheter group was 69.0 – 160.0, mean 107.3 ± 18.50, with a statistically significant difference being less among the surgery group (related to the younger age). Illustrated in table (1);

Table (1): Comparison between Surgery Group (no =100) and Catheter Group (no. =100) as regarding demographic data

	Surgery (n = 100)		Catheter (n = 100)		P
	No.	%	No.	%	
Gender					–
Male	62	62.0	52	52.0	0.153
Female	38	38.0	48	48.0	
Age (years)					–
Min. – Max.	1.0 – 13.0		3.0 – 16.0		<0.001*
Mean ± SD.	3.55 ± 2.45		6.83 ± 3.03		
Median (IQR)	3.0 (2.0 – 5.0)		6.0 (5.0 – 8.0)		

Weight (kg)					–
Min. – Max.	10.0 – 40.0		11.0 – 67.0		<0.001*
Mean ± SD.	15.11 ± 7.42		24.81 ± 12.88		
Median (IQR)	12.0 (10.0 – 16.50)		22.0 (16.0 – 27.0)		
Weight Z score					–
Abnormal (<-2)	11	11.0	2	2.0	0.010*
Normal	89	89.0	98	98.0	
Length or height (cm)					–
Min. – Max.	65.0 – 159.0		69.0 – 160.0		<0.001*
Mean ± SD.	91.51 ± 19.67		107.3 ± 18.50		
Median (IQR)	83.0 (78.0 – 100.0)		101.0(93.0 – 114.0)		
Length or height Z score					–
Normal	100	100.0	100	100.0	–
Abnormal (<-2)	0	0.0	0	0.0	

IQR: Inter quartile range, SD: Standard deviation

$\chi 2$: Chi square test, t: Student t-test, U: Mann Whitney test

p: p value for comparing between the two studied groups

*: Statistically significant at $p \leqslant 0.05$

At the pre intervention assessment; all cases were with normal LV function (FS%) when assessed according to Z score to their body surface area (BSA). Post catheter assessment of LV function revealed that there is no affection or impairment of the LV function at any time of follow up. 3 months follow up; surgery group revealed that 28.0%(n=28) were with still impaired LV function (FS %). 6 months follow up; 16.0%(n=16) were with still impaired LV function (FS %). 12 months follow up; detected only 6.0%(n=6) with still impaired LV function (FS %). 24 months follow up; only 4.0%(n=4) were still with impaired LV function (FS %). All were assessed according to Z score of their sex and BSA. Shown in table (2).

Table (2): Comparison between Surgery Group (no =100) and Catheter Group (no. =100) regarding LV function (FS %) assessed by Z score.

Impaired Z score for LV function (FS %)	Surgery (n = 100)		Catheter (n = 100)		P
	No.	%	No.	%	
Pre intervention	0	0.0	0	0.0	–
Post intervention					–
3 months	28	28.0	0	0.0	<0.001*
6 months	16	16.0	0	0.0	<0.001*
12 months	6	6.0	0	0.0	0.070
24 months	4	4.0	0	0.0	0.121

$\chi 2$: Chi square test

p: p value for comparing between the two studied groups

*: Statistically significant at $p \leqslant 0.05$

As regarding post intervention ICU stay; the range of ICU stay (days) in surgery group was 3.0 – 28.0 days, mean 5.85 ± 5.02 days, while the median ICU stay in catheter group was only 24 hours in all cases. There was highly statistically significant difference between Surgery group and Catheter group regarding ICU stay (days). Shown in table (3).

Table (3): Comparison between Surgery Group (no =100) and Catheter Group (no. =100) regarding ICU stay.

ICU stay (days)	Surgery (n = 100)	Catheter (n = 100)	p
Min. – Max.	3.0 – 28.0	1.0 – 1.0	<0.001*

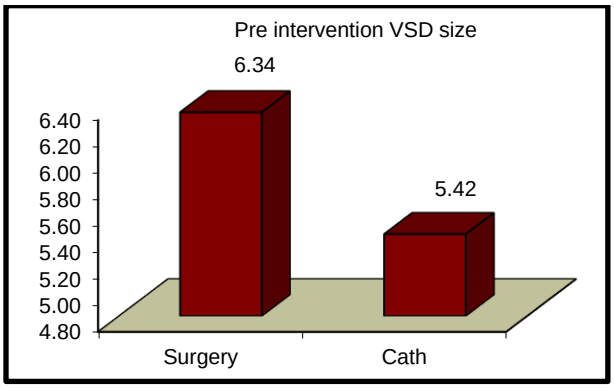
Mean ± SD.	5.85 ± 5.02	1.0 ± 0.0	
Median (IQR)	4.0 (3.0 – 6.0)	1.0 (1.0 – 1.0)	

IQR: Inter quartile range, SD: Standard deviation, U: Mann Whitney test

p: p value for comparing between the two studied groups

*: Statistically significant at p ⩽ 0.05

Figure (1): Shows the difference between (surgery and catheter cases) regarding pre intervention VSD size.



Our study showed that in the surgical group; the bypass duration ranged from 40 to 130 minutes, with mean 71.15 ± 25.16 minutes. The ischemic time (Aortic occlusion clamping time) ranged 30.0 – 110.0 minutes, with mean Ischemia duration was 53.91 ± 22.36 minutes. In the catheter cases; the fluoroscopy time (minute) ranged from 4 to 22 minutes, with mean 11.61 ± 3.74 minutes. The radiation dose (mGy) range was 6.0 – 185.0 mGy, while the mean was 59.93 ± 29.23 mGy.

Table (4): Distribution of the studied cases according to intervention

Intervention	
Surgery (n = 100)	
Bypass duration (minute)	
Min. – Max.	40.0 – 130.0
Mean ± SD.	71.15 ± 25.16
Median (IQR)	60.0 (50.0 – 85.0)
Ischemia time (minute)	
(Aortic occlusion clamping time) (min)	
Min. – Max.	30.0 – 110.0
Mean ± SD.	53.91 ± 22.36
Median (IQR)	45.0 (37.50 – 65.0)
Cath (n = 100)	
Fluoroscopy time (minute)	
Min. – Max.	4.0 – 22.0

Mean ± SD.	11.61 ± 3.74
Median (IQR)	11.0 (9.0 – 15.0)
Radiation dose (mGy)	
Min. – Max.	6.0 – 185.0
Mean ± SD.	59.93 ± 29.23
Median (IQR)	60.0 (44.50 – 63.0)

IQR: Inter quartile range SD: Standard deviation

In our study we found 15.0% (n=15) of postoperative cases were with abnormal junctional rhythm, while 12.0% of post catheter cases had a junctional rhythm. All junctional rhythm cases in both groups spontaneously returned back to sinus rhythm before discharge. 4.0% of surgical cases complicated with a permanent CAVB, and all needed a permanent postoperative trans venous pacemaker insertion. This could be explained by the small body weight in those patients, relatively large defect, and not all cases were operated by senior surgery staff.

None of the post catheter group were complicated with CAVB.

There was no statistically significant difference between surgery group and catheter group regarding post intervention rhythm, heart block and permanent pace maker insertion. Shown in table (10).

Table (5): Comparison between Surgery Group (no. =100) and Catheter Group (no. =100) regarding post intervention rhythm.

Post intervention Rhythm	Surgery (n = 100)		Catheter (n = 100)		P
	No.	%	No.	%	
Sinus	81	81.0	88	88.0	1.000
Junctional	15	15.0	12	12.0	
Heart block	**4**	**4.0**	**0**	**0.0**	
Need for pacemaker	**4**	**100.0**	**0**	**0.0**	0.121

p: p value for comparing between the two studied groups

DISCUSSION

Isolated ventricular septal defect (VSD) is the most commonly recognized form of cardiac malformation and constitutes over 20% of all congenital cardiac disease. Eighty per cent of these defects are peri membranous involving the membranous septum and the adjacent area of muscular septum. Although conventional surgery for peri membranous VSDs (PMVSDs) is a widely accepted procedure with minimal operative mortality, while it is associated with morbidity, postoperative patient discomfort, and a thoracotomy scar (5).

While percutaneous device closure (PDC) is a first-line therapy for isolated muscular ventricular septal defects (pm VSD), surgery is still the preferred approach for peri-membranous ventricular septal defects (pm VSD) (6).

Transcatheter VSD closure avoids extracorporeal circulatory support of surgical approach and has the benefit of faster recovery, but both methods carry a potential risk of atrio ventricular block (AVB). This occurs at an average rate of 5 % in most series but may be as high as 22 %. AVB may develop intraoperatively or postoperatively; with transcatheter closure it is more unpredictable and may occur late, months or even years after device implantation (7).

Therefore, as an alternative approach to surgery, transcatheter closure of pm VSDs has been attempted using a variety of occluding devices. However, these devices were not

specifically designed for this purpose and none has gained wide acceptance (6).

Large delivery sheaths, inability to recapture and reposition, structural failure, dislodgement and embolization of the device, interference with the aortic valve resulting in aortic insufficiency, and a high rate of residual shunting are the major limitations of the percutaneous device closure of pm VSD. So, surgery is still the preferred approach for peri-membranous ventricular septal defects (pm VSD), which is safely feasible for much lower body weights, and much larger defects. Major intraprocedure complications of trans venous pm VSD, usually needs urgent surgical intervention (6).

In regarding the demographic data, there was no statistically significant difference between surgery group and catheter group regarding gender, but there was a statistically significant difference between surgery group and catheter group regarding age (years), weight (kg), and length/height (cm) (assessed by Z score for their age). All are higher in the catheter group.

In accordance to our study, Yang et al., (8) reported in his study that average age at closure was 5.8 ± 2.4 years and 5.5 ± 2.6 years in surgery and catheter groups respectively, and body surface area was 0.5 ± 0.2 m2 and 0.7 ± 0.2 m2 in surgery and catheter group respectively.

This is the same mean age of Pawelec-Wojtalik et al. (9) studied population. This is because percutaneous closure is usually done in patients with moderate-sized VSDs with normal pulmonary artery pressure and evidence of left ventricular overload which may possibly have developed over time.

This difference between the age and the weight of the two groups is related to the indications of VSD closure and different center's strategy in choosing the most suitable VSD closure method, in addition to acess problem limitations in the interventional closure (10).

As regarding the intervention duration we found that the fluoroscopy time (minute) ranged from 4 to 22 minutes, with mean 11.61 ± 3.74 minutes. The radiation dose (mGy) range was 6.0 – 185.0 mGy, while the mean was 59.93 ± 29.23 mGy.

As regarding the surgery group in our study; the bypass duration ranged from 40 to 130 minutes, with mean 71.15 ± 25.16 minutes. The ischemic time (Aortic occlusion clamping time) ranged 30.0 – 110.0 minutes, with mean Ischemia duration was 53.91 ± 22.36 minutes. This was relatively longer than what is reported by Kumari et al. (2019), who reported that the mean bypassing time was 56.6 ± 13.5, mean aortic occlusion clamping time was 39.1 ± 12.3. This could be explained by the fact that not all surgical cases were operated by Senior Staff of Surgeons.

This was compatible with our results as all post catheter cases were discharged from ICU safely after only 1 day, but the mean time of postoperative ICU stay (days) 5.85 ± 5.02 days. As regarding the blood transfusion; our results were also compatible to the published results, as we found that blood transfusion was significantly low among the catheter group.

Two-dimensional (2D) echocardiography (echo) assessment of post intervention cardiac functions is limited as most of the studies depend mainly on tissue Doppler assessment.

(Banpurkar et al., 2021) studied patients with large perimembranous ventricular septal defects (pm-VSDs) undergo surgical repair during infancy. they assessed LV function in postoperative pm-VSD closure patients on two-dimensional (2D) echocardiography (echo) immediate and after 1 year of surgery using biplane Simspon's method, fractional shortening (FS), and ejection fraction (EF). This was a single-institution observational study. At the immediate postoperative

assessment there were 52% of cases with left ventricular dysfunction; mean values of FS, and LVEF were 22.4 ± 6.2%, 43.7% ± 5.2%, respectively. After 1 year of surgery; all except one patient had normal ventricular function. Patients with ventricular dysfunction had LV ejection fraction (LVEF) of 47%, and FS −20.5%. The mean values of FS, and LVEF were 32.0 ± 5.28%, and 62.2% ± 4.2%, respectively, in pm-VSD closure patients.

This was in parallel with our cases of post-surgical VSD closure, were 3 months post-operative assessment we have 34%(n=34) of cases still with RV dysfunction, and 14%(n=14) at 6 months follow up, but only 8%(n=8) at 1-year post intervention assessment with improved RV systolic function in 92% of cases. Our post catheter group was with normal RV function all through the period of follow up.

As regarding the outcome including early late post intervention morbidities and mortality; there was no significant difference between both groups of our study.

Jiang et al. (17) reported that the incidence of post catheter device closure in their study was 0.3% (2 cases). One died from postprocedure cAVB, whereas another 3 ‐ year ‐ old girl developed diffuse subarachnoid hemorrhage an hour after transcatheter closure with 7 ‐ mm symmetric occluder and died 11 days later. It was speculated that the cause of death might be possible congenital cerebral vascular malformation, which could have caused intracranial hemorrhage when the patient was emerging from anesthesia.

CONCLUSION

Interventional VSD closure is becoming more important with growing experience and improving devices, and appears to be safe and effective for the majority of patients. Our study suggests that there is no significant difference between percutaneous and surgical closure of pmVSDs in terms of early (up to 30 days) efficacy and safety in well-selected patients. Furthermore, percutaneous closure is associated with decreased hospital stay, which could potentially be cost saving. These findings need to be confirmed in large multi-center trials and long-term results also need to be assessed. Increasing technical expertise as well as continued improvement in the device designs could further enhance the safety profile of percutaneous closure.

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