TRANSCATHETER CLOSURE OF PERIMEMBRANOUS AND MUSCULAR VENTRICULAR SEPTAL DEFECTS: SHORT - TERM AND MID - TERM OUTCOMES

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ABSTRACT

Objective: *This study attempted to report the initial results: the safety and efficacy of transcatheter closure of ventricular septal defects (VSDs) at Hue Central Hospital with the short and medium-term follow-up.*

Methods: *From September 2012 to May 2017, a total of 36 patients with perimembranous or muscular VSD underwent an attempt of transcatheter closure at the Department of Interventional Cardiology, Hue Central Hospital.*

Results: *14 males and 26 females participated in this study, with the age of 17.29 ± 13.72 and 24.23 ± 12.32 respectively. Among these patients, 19.44% of them were under 6-year-old; 72.22% had perimembranous VSDs, 27.78% had muscular VSDs, and 33.33% had aneurysm. The distance to AV was 5.62 ± 4.32 mm. The device size was 15.31± 8.12 mm. Procedures lasted for 57.17 ± 26.5 min with 15.31± 8.12 min of exposure. The complete closure rates by transthoracic echocardiography after 24 hours, 1 month, 3 months and 6 months (transthoracic) were 94.44%; 94.44% ; 97.22% and 100%, respectively. Mean time of follow-up was 11.92 ± 8.36 (3-38) months. Success rate was 97.22% and no death occurred. There was 1 case of hematuria, lasting 1 month; no Atrioventricular (AV) block.*

Conclusions: *Transcatheter closure of VSDs is a novel, feasible and safe technique with high success rate (97.22%). The transcather approach provides a less invasive alternative than surgical closure and might become the first choice treatment in selected patients.*

Key words: *transcatheter closure, ventricular septal defects*

I. INTRODUCTION

The simple VSD, which accounts for 25% of congenital heart disease (CHD) in children, is the most common CHD. Besides, VSD is also common in other CHD as Fallot, with atrial septal defect [1]. 70-80% of small VSDs close spontaneously by late childhood; only 10-15% of large VSDs can close spontaneously. About 60% of defects close before age 3 and 90% before age 9. The risk factors for decreased survival in unoperated patients include: cardiomegaly on chest X - ray, elevated systolic pulmonary artery pressure (PAPS) (>50 mmHg) and cardiovascular symptoms. Therefore, before these patients got elevated PAPS, VSD closure should be taken by surgical or transcatheter closure. The first time that transcatheter VSD closure has been undertaken was

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in 1988 by Lock et al [2].

In Vietnam, from 2003, National Heart Institute of Vietnam reported the first case of transcatheter VSD closure [3]. Until now, other congenital heart centers such as The City Children's Hospital and Medicine University Hospital at Ho Chi Minh City [4] have undertaken this procedure routinely with impressive results.

At Hue City, thanks to the help from experts of National Heart Institute of Vietnam, we performed the first transcatheter VSD closure in September 2012, and after that the technique has been taken routinely since 2013. However, since this is an advance technique, which has just applied in our hospital, we would like to study "Transcatheter closure of perimembranous and muscular ventricular septal defects: short and medium-term outcome" with aims: the feasibility and safety of the technique according to the short and medium-term results of transcatheter VSD closure at Hue Central Hospital.

II. MATERIALS AND METHODS

2.1. Participants

The study was conducted as a prospective, non-randomized and interventional registry involving 36 patients with perimemberanous or muscular VSDs, hospitalized at the Interventional Cardiology Department of Hue Central Hospital from 9/2012 to 5/2017.

2.2. Eligibility criteria [1,5]

Patients with the following characteristics were eligible for device closure:

- Patients with perimemberanous or muscular VSDs.

- The symptomatic patients showing a Qp/Qs > 1.5:1.

- PAPS >50 mmHg.

- Increased left ventricular and left atrial size, or deteriorating left ventricular function in the absence of irreversible pulmonary hypertension.

- Presence of a perimembranous or outlet VSD with mild-to-severe aortic regurgitation.

- History of recurrent endocarditis.

- In children, a nonrestrictive VSD and a smaller VSD with significant symptoms failing to respond to pharmacotherapy.

2.3. Exclusion criteria [1,5]

- Weight less than 3 kg.

- Distance between the VSD and the aortic, pulmonic, mitral or tricuspid valves less than 4 mm.

- Pulmonary vascular resistance greater than 7 Woods units.

- Sepsis/ Active bacterial infections.

- Contraindications to antiplatelet therapy.

Before intervention, an informed written consent was obtained from all parents of participants. Physical examination, blood tests, a chest X-ray, standard 12-lead electrocardiogram (ECG), and transthoracic echocardiogram (TTE) were routinely performed in all patients.

A team including cardiologists, cardiac surgeons and interventional cardiologists decided to perform the transcatheter VSD closure or not.

2.4. Device implantation

- The catheterization procedure was performed under general anaesthesia for children and local anaesthesia for adults.

- Access: femoral vien and femoral artery.

- Full heart catheterization.

- Ventriculography to diagnose the position, size, characteristics and number of VSDs, then the devices to peform the VSD closure could be decided.

- IM or JR catheter with 260 wire, and snare to do an arteriovenous circuit through the femoral vein approach.

- A delivery system (6 to 12 Fr) was advanced to the left ventricle through the arteriovenous circuit. Through the delivery system, an occluder was deployed under fluoroscopic control.

- Before the release of the occluders, ventriculography and aortography were performed again to

verify complete occlusion of the VSD and to identify any new-onset aortic valve regurgitation.

- After the procedure, patients were transferred to the cardiac wards. One day later, cardiac echographies were done. Aspirin (5 mg/kg daily) was administered for 6 months in all patients.

2.5. Evaluation

- Sucess: the occluders were in the right positions, no residual shunt or minor residual shunt occurred.

- Failure: the procedures could not be completed, and changed to surgical closures because of device embolization or major residual shunt.

- Complications: blood loss requiring transfusion, device embolization, new onset valvular regurgitation requiring surgical repair, atrioventricular block requiring pacemaker implantation or death.

2.6. Data analysis: using Excel, SPSS.

III. RESULTS

A total of 36 patients with perimembranous or muscular VSDs were analyzed. Mean age significantly differed between men and women ($p<0.05$) (Table 1). Table 2 showed the cardiac catheterization and ventriculography. Table 3 presented the procedural data. Among 36 procedures: 1 ADO II implanted; 1 Muscular VSD implanted and 34 ADO I implanted (Table 4). Regarding adverse events (Table 5): Complete VSD closure procedures: 100%; Sucess rate: 97.22%;

Follow-up (months): 11.92 ± 8.36 (3-38).

Table 1: Patients

Patient	Male	Female	Total
n	14 (38.89%)	22 (61.11%)	36 (100%)
Mean age	17.29± 13.72	24.23± 12.32	21.50± 16.27
Youngest	1 year-old		
Oldest	59 year-old		
< 6 year old			7 (19.44%)

Table 2: Cardiac catherization and ventriculography

VSD characteristics		
Position	Perimembranous	26 (72.22%)
	Muscular	10 (27.78%)
Aneurysm		12 (33.33%)
Distance to AV (mm)	5.62 ± 4.32 (2.5- 26)	
PAPs (mmHg)	28.61 ± 2.19	
Gradient (LV/RV) mmHg	81.63 ± 8.35	
EF (%)	63.74 ± 3.36	
VSD diameter	Echo	catheterization
LV side (mm)	6.40 ± 2.27	7.42 ± 5.45
RV side (mm)	4.70 ± 2.94	3.73 ± 0.76

Table 3: Procedural data

	Mean	Minimum	Maximum
Time of procedure (min.)	57.17 ± 26.5	30	150
Time of exposure (min.)	15.31 ± 8.12	6.5	31.8
Contrast (ml)	114.22 ± 40.53	60	200

Table 4: Devides used

Devices	Mean	Minimum	Maximum
Size of Amplatzer (mm)	7.30 ± 0.52	6	16
Size of Deli (F)	9.79 ± 3.62	6	12

Table 5: Adverse events

	In Cathlab	24h	1 month	3 months	> 6 months
Death	0	0	0	0	0
Residual shunting	3	2	2	1	0
Hematuria	0	1	1	0	0
arrhythmia	1	1	0	0	0
AR/TR	0	0	0	0	0
Cardiac dysfunction	0	0	1	0	0

IV. DISCUSSION

In our study, the youngest patient was only 1-year-old, and under 6-year-old patients was 19.44%. This result was equivalent with other studies such as the study of Nguyen Lan Hieu [3] and Truong Quang Binh.

There were some old patients in our study, the oldest was 59 year-old. The mean age in the study was 17.29 ± 13.72 in males and 24.23 ± 12.32 in females ($p<0.05$). In Nguyen Lan Hieu's study, the patients' mean age was 12.75 ± 11.09 and in the study of Mario Carminatil, Gianfranco Butera et al [5], the patients' mean age was 8-year-old. The patients' mean age in both studies was younger compared to our participants ($p<0.05$). In our study, the patients were identified as having VSD rather late, since some of them didn't care to their health problem. Others, especially female patients, had not hospitalized after founding VSDs because of psychological fator (scare) or high medical treatment cost. Therefore, we had to perform the transcatheter VSD closure in late stage.

4.1. VSD characteristics

In our study, most of VSDs were perimembranous (72.22%), while only 27.78% of VSDs were muscular ($p<0.05$).

In the study of Mario Carminatil, Gianfranco Butera et al [5], there were 58.14% perimembranous VSDs, 27.67% muscular VSDs, 3.72% multi VSDs and 10.47% residual VSDs after surgical closures. Meanwhile, Nguyen Lan Hieu [3] chose 100% perimembranous VSDs for transcatheter VSD clossure in his study.

In our study, the mean distance from VSDs to aortic valves was 5.62 ± 4.32 mm. There was a patient, who were identified as having VSD

with aneurysm, having only 2.5 mm-distance between VSD and aortic valve. We decided to do transcatheter closure, using a suitable device which was implanted inside the aneurysm of the VSD so that the rim of the device did not affect to the aortic valve (no regurgitation). There was no residual shunt after the VSD closure. However, this case should be precisely treated because of the risk of aortic valve regurgitation and heart faillure after VSD closure. So the position of device should be carefully evaluated by ventriculography and TTE before releasing the device.

In this study, there was no significantly difference in sizes of VSDs measuring by cardiac echographies and ventriculographies ($p<0.05$). However, in left ventricles, the diameters of VSDs were slightly bigger when measuring by ventriculographies than cardiac echographies. The results were contrary in right ventricles.

In Nguyen Lan Hieu's study, the mean diameter of the VSDs on the left and right side was 7.05± 3.43 mm and 4.61±2.01 mm respectively; the mean length of VSDs was 6.61± 3.07 mm. These data had no significant difference with the ones in our study ($p>0.05$) [3].

4.2. Technical consideration

In our study, the mean time to finish the procedures was 57.17± 26.5 (30-150) min and the mean time of x-ray exposures was 15.31± 8.12 min. In the study of Mario Carminatil, Gianfranco Butera et al [5], the average time of procedures was 120 min (30-300 min) and the average time of x-ray exposures was 33 min (4-149 min). Comparing these two study, it was shown that we could perform the transcatheter VSD closure more rapidly ($p<0.05$). However, the average age of our participants was older; under-6-year-old patients occupied only 19.44% while in the study of Mario Carminatil, Gianfranco Butera et al, the data was 42%. This was the main factor affecting to the mean time of procedures and x-ray exposures. In children, the procedures were performed under general anaesthesia, and it was more difficult when doing VSD closure in children than in aldults. Futhermore, we only performed VSD closure in perimembranous or muscular VSDs while Mario Carminatil, Gianfranco Butera et al had undertaken VSD closure in patients with perimembranous, muscular, multi VSDs and residual VSDs after surgical clossures. The difficult technique factors were also objections to perform the procedures and lengthening time to finish VSD closure.

4.3. Device implantation

In our study, 94.45% of devices were ADO I. This device is used to perform PDA closures. According to my opinion, this device has a disc in the left ventricle and no disc in the right side after implantation, so that there is no compression to ventricle wall as the two discs device. This advantage may help to reduce the risk of complete AV block after implantation. There was no complete AV block in our study. However, the reasons why we could use ADO I were the limited number of our patients and simple VSDs' characteristics. In the future, we should study in large scale patients with long - term follow up to confirm this theory.

In Nguyen Lan Hieu's study, he recommended that in VSDs with aneurysm, devices with 2 discs with slightly bigger size should be used and the devides should be positioned inside the aneurysm. If there was significantly difference between the left and right ventricle size, the devices' size should be chosen basing on the smaller diameter of VSDs. In some patients, we may accept minor residual shunts rather than oversize devices that would ultimately cause complete AV block. [3]

In several studies, based on the size and characteristics of VSDs, some foreign authors [5-8] had chosen many kinds of devices such as: Membranous Amplatzer Muscular, Amplatzer PDA, Amplatzer ASD, Amplatzer Starflex, Coil, etc to perform VSD closure.

4.4. Success and Complications

In our study, the successful rate was 97.22%. This result was equivalent to other authors: in the study of Nguyen Lan Hieu (2013) [3], the success rate was 94.76% ; Arora et al(2002) [6]: 95%; Butera et al(2007) [7]: 96%; Zuo et al (2010) [9] 97.6%.

There was a failure in our study. A male patient with the 10.17 mm-diameter muscular VSD was unsuccessfully implanted with 16/14 ADO1, after that we used the muscular VSD 16 to perform the VSD closure. In ventriculography, we found a residual shunt. After dicussion, we decided to release the device. However, a day later, the patient got a new Right bundle branch block (RBBB), then ventricular arrhythmia (stabilised with lidocain). 24 hours later, he got hematuria and lasting within 1 month. On cardiac echography, we found the flow of residual shunt became much stronger and the function of the heart went down. So the patient was sent to open heart operation.

In our study, there was no death or complete AV block. Meanwhile, in other studies, complete AV block was a concerning issue, since a lot of patients had to have pace-makers implanted. In Nguyen Lan Hieu's study, the rate of pace-maker implantation was 0.36% [3]; Arora et al(2002) [6]: 2.2%; Butera et al(2007) [7]: 5.7%; Zuo et al (2010) [9] 1%. In the study of Predescu (2008), 20 patients were performed with transcatheter VSD closure successfully (100%). All patients were followed up, and the average follow-up period was 23.1 month, with the result that there was 20% of them must be implanted permanent pace-makers.

V. CONCLUSIONS

Transcatheter device closure is an effective method in treating VSDs with high success rate (96.3%). This is a novel, feasible and safe technique, while adverse events were rare and generally manageable. The transcatheter approach provides a less invasive alternative than surgical closure and might become the first choice treatment in selected patients.

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