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

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ABSTRACT

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

Methods: *Between 9/2012 tới 5/2017, a total of 36 patients with perimembranous or muscular VSD underwent an attempt of transcatheter closure at the Dept. of Interventional Cardiology, Hue Central hospital*

Results: *14 male and 26 female, mean age 17,29 ± 13.72 và 24.23 ± 12.32, respectively; including 19.44% under 6 year old; 72.22% perimembranous and 27.78% muscular VSDs, and aneurysm of 33.33%; Mean distance to AV: 5.62 ± 4.32 mm; Mean time of procedures: 57.17 ± 26.5 min; mean time of exposure15.31± 8.12 min. The mean device size 15.31± 8.12 mm; The complete closure rates by transthoracic echocardiography at 24 h, 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%. No death occurred. 1 case of hematuria, lasting 1 month; no AV block.*

Conclusions: *Transcatheter closure of ventricular septal defects is a novel, feasible and safe technique with high successful rate (97.22%). The transcather approach provides a less invasive alternative to surgical closure and may become the first choice treatment in selected patients.*

Key words: *Transcatheter closure, ventricular septal defects.*

I. INTRODUCTION

The simple VSD is the commonest congenital heart disease accouting for 25% of congenital heart disease in children. Besides, VSD also is common in other CHD as Fallot, with ASD...[3]. 70-80% of small VSD close spontaneously by late childhood; only 10-15% of large VSD close spontaneously. About 60% of defects close before age 3 and 90% before age 9. The risk factors for decreased survival for unoperated patients include: cardiomegaly on CXR, elevated PAPS (>50 mmHg) and cardiovascular symptoms. Thefore, VSD closure should be taken before these patients got elevated PAPS by surgical closure or transcatheter closure. The transcatheter VSD closure was undertaken at the first time in 1988 by Lock et al [7].

In Viet Nam, from 2003, Viet Nam National Heat Institue reported the first cases of transcatheter VSD closure [2], then other congenital hear centers such as Ho Chi Minh Children Hospital and Ho Chi Minh University Hospital [1] have undertaken the procedure routinly with impressive results.

At Hue city, thanks for the help from the Viet Nam National Heart Institue experts, we performed the fist transcatheter VSD closure in september 2012, and after that the technique has been taken

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routinly since 2013. However, because this is an advance technique, which has just applied in our hospital, so we would like to study: "Transcatheter VSD closure: the primary results at the Hue central hospital" with objective: to evaluate the feasibility and safety of the technique; short-term and middle-term results of transcatheter VSD closure at the Hue Central Hospital.

II. SUBJECTS AND METHODS

2.1. Subjects: 36 patients with memberous or muscular ventricular septal defects, hospitalized at the Interventional Cardiology department of Hue Central Hospital from 9/2012 to 05/2017.

***The inclusion criteria for device closure included** [3], [6]:*

- Patients with memberous or muscular ventricular septal defects.
- The symptomatic patients shows a Qp/Qs > 1.5:1.
- Pulmonary artery systolic pressure >50 mmHg.
- Increased left ventricular and left atrial size, or deteriorating left ventricular function in the absence of irreversible pulmonary hypertention.
- Presence of a perimembranous or outlet VSD with more than mild aortic regurgitation.
- History of recurent endocarditis.
- In children, a nonrestrictive VSD and a smaller VSD with significant symptoms failling to respond to medication.

***Exclusion criteria included**: [3],[6]*

- Weight less than 3 kg
- Distance of less than 4 mm between the VSD and the aortic, pulmonic, mitral or tricuspid valves.
- Pulmonary vascular resistance greater than 7 Woods units.
- Sepsis/ active bacterial infections.
- Contraindications to antiplatelet therapy.

2.2. Methods

The study was conducted as a prospective, nonrandomized.

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

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

• Device implantation

- The catheterization procedure was performed under general anaesthesia for children and local anaesthesia for adults.
- Access: femoral vein and femoral artery.
- Full heart catheterization
- Ventriculography to dignostic the position, size, characteristcs and number of VSDs then we can decide the devices to peform the VSD closure.
- IM or JR catheter with 260 wire, and snare to do an arteriovenus circut through the femoral vein approach.
- A delivery system (6 to 12 Fr) was advanced to the left ventricle through the arteriovenus circut. Through the delivery system, an occluder was deployed under fluoroscopic control.
- Before the release of the occluders, ventriculography and aortography was 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. A day later, cadiac echographies were done. Aspirin (5 mg/kg daily) was administered for 6 months in all patients.

Evaluation

- Sucess: the occluders in the right positions, no residual shunt or minor residual shunt.
- Faillure: the procedures could not be completed, and changed to surgical closures because of device embolization, major residual shunt..
- Complications:blood loss requiring transfusion, device embolization, new onset valvular regurgitation requiring surgical repair, AVB requiring pacemaker implantation, death.

***Data analysis**:* using Excel, SPSS

III. RESULTS

Table 3.1. 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 years old		
< 6 years old			7 (19.44%)

Male mean age was younger than female mean age significantly ($p<0.05$)

Table 3.2 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

Table 3.3. VSD diameter

VSD diameter	Echo	Catheterization	P
LV side (mm)	6.40 ± 2.27	7.42 ± 5.45	> 0.05
RV side (mm)	4.70 ± 2.94	3.73 ± 0.76	> 0.05

Table 3.4. 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 3.5. 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

36 procedures: 1 ADO II implanted; 1 Muscular VSD implanted; 34 ADO I implanted

Table 3.6. Adverse events

	In Cathlab	24h	1 month	3 month	> 6 month
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

Complete VSD closure procedures: 100%; Sucess rate : 97.22%; Follow- up (month): 11.92 ± 8.36 (3-38)

IV. DISCUSSION

4.1. Feature of clinical

In our study, the youngest patient was only one year old, and patients under 6 years old was 19.44%. This result was equivalent with other studies such as Nguyen Lan Hieu study [2] and Truong Quang Binh study[3].

There were some old patients in our study, the oldest was 59 years old. The mean age in the study was 17.29± 13.72 in male and 24.23 ± 12.32 in female ($p<0.05$). 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 [6] , the patients' mean age was 8 years old. In the both studies, the patients' mean age was younger compared to our patients' mean age ($p<0.05$). In our study, the patients were found VSDs rather late, some of them had not hospitalized after VSDs were found because of psychological fator (scare), cost or some patients didn't care to their health problem then they hospitalized rather late after that, so we could only perform the transcatheter VSD closure in late stage. This issue was rather clear in female patients.

4.2. VSD characteristics

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

In the study of Mario Carminatil, Gianfranco Butera et al [6], 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 [2] 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 which the distance from VSD to aortic valve was only 2.5 mm with aneurysm. We decided to do transcatheter closure, used a suitable device which was implanted inside the aneurysm of the VSD so the rim of the device did not affect to the aortic valve (no regurgitation) and there was no residual shunt after the VSD closure. However, it should be careful with this case because the risk of aortic valve regurgitation and heart faillure after VSD closure. So we should evaluate the position of device by ventriculography and TTE carefully before releasing the device.

In the study, there was no significantly difference about sizes of VSDs measuring by cardiac echographies and ventriculographies ($p<0.05$). However, In the left ventricles, the diameters of VSDs were a lightly bigger when measuring by ventriculographies to cardiac echographies. In the right ventricles, the results were contrary.

In Nguyen Lan Hieu study [2], the mean diameter of the VSDs on the left side was 7.05± 3.43 mm and on the right side was 4.61±2.01 mm; the mean length of VSDs was 6.61± 3.07 mm: no significant difference with the data in our study ($p>0.05$).

4.3. Technical considerations

In our study, the mean time to finish the procedures was 57.17± 26.5 (30-150) minutesand the mean time of x-ray exposures was 15.31± 8.12 min. Comparing to Mario Carminatil, Gianfranco Butera et al [6], the mean time of procedures was 120 min. (30-300 min) and the mean time of xray exposures was 33 min.(4-149 min), we could perform the trancatheter VSDclosure more rapid ($p<0.05$). However, in our study, the mean age of patients was older; the number of patients under 6 year old was only 19.44% while in Mario Carminatil, Gianfranco Butera et al study, the data was 42%. This was the main factor that affected to the mean time of procedures and x-ray expossures. In children, the procedures were performed under general anaesthesia, and it was

more difficult when doing VSD clossure in children than in aldults. Futher more, we only performed VSD closure in memberous or muscular ventricular septal defects while Mario Carminatil, Gianfranco Butera et al had undertaken VSD closure in patients with memberous, muscular, multi ventricular septal defects and residual VSDs after surgical clossures. The difficult technique fators were challenges to perform the procedures and lengthening time to finish VSD closure.

4.4. Device implantation

In our study, 94.45 % of devices were ADO I. This devices are used to perform PDA closures. According to me, this device has a disc which is in the left ventricle after implantation, and no disc in the right side so 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 number of our patients was still limited and the VSDs' characteristics were simple so we could use ADO I . In the future, we should study in large scale patients with long- term follow up to confirm this theory.

In Nguyen Lan Hieu study [2], he demanded that in VSDs with aneurysms, devices with 2 dics with lightly bigger size should be used and the devides should be positioned inside the aneurysms. If there was significantly different between the left ventricle size and right ventricle size, the size of the devices should be chosen basing on the smaller size of VSDs. In some patients, we may accept minor residual shunts rather than oversize devices that cause soon or late complete AV blocks.

In some studies, foreign authors [4],[5],[6],[8] had chosen many kinds of devices such as: Membranous Amplatzer Muscular, Amplatzer PDA, Amplatzer ASD, Amplatzer Starflex, Coil.. to perform VSD closure. They based on the size, characteristics of VSDs to chose devices.

4.5. Success and Complications

In our study, the successful rate was 97.22%. This result was equivalent to other authors: in Nguyen Lan Hieu's study(2013)[3], the successful rate was 94.76% ; Arora et al(2002) [4]: 95%; Butera et al(2007)[5]: 96%; Zuo et al (2010)[9] 97.6% .

There was a faillure in our study. A male patient with the muscular VSD, 10.17 mm in diameter was implanted with 16/14 ADO1 unsuccessfully, then 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 BBBR, then ventricular arrhythmia (stabilised with lidocain). 24 hour later, the patient 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, a lot of patients had to be pace- makers implanted. In Nguyen Lan Hieu's study, the rate of pace-maker implantation was 0.36%[3]; Arora et al(2002)[4]: 2.2%; Butera et al(2007)[5]: 5.7%; Zuo et al (2010)[9] 1%. In the study of Predescu (2008), 20 patients were performed with transcatheter VSD closure succefully (100%). All patients were followed up, and the meadian follow-up period was 23.1 month, there was 20% of them must be implanted permanent pace-makers.

V. CONCLUSIONS

Transcatheter device closure of ventricular septal defects is effective method in treating VSD patients with high success rate (96.3%).

The technique is novel, feasible and safe. Adverse events were rare and were generally manageable. The transcather approach provides a less invasive alternative to surgical closure and may become the first choice treatment in selected patients.

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