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Mid-Term Outcome of the Hybrid Method of Ventricular Septal Defect Closure in Children

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Abstract

Objective: To describe the clinical experiences and mid-term follow-up results of the hybrid method of ventricular septal defect closure in children.

Methods: This study was a combined - multidirectional cohort. Between May 2016 and December 2020, 250 patients with isolated VSD (or residual VSD after a previous repair) underwent surgery by the hybrid method at the pediatric cardiac surgery department in the National Scientific Medical Center. This study adopted a combined and multidirectional cohort approach, initially starting as a retrospective cohort and later transitioning into a prospective cohort.

Results: A total of 250 patients in this cohort underwent hybrid VSD closure, of which 233 (93.2%) patients were successful, 16 (6.4%) patients were converted to the traditional method and 1 (0.4%) death occurred. New trivial or mild tricuspid regurgitation was detected in 35 patients (15%) and aortic regurgitation in 9 patients (3.9%) by intraoperative TEE. For the remaining 10 patients with incomplete right bundle branch blocks the sinus rhythm was restored in follow-up. In addition, the left ventricular ejection fraction improved over time. One of the important points after surgery is the deformation of the chest. In 122 (91%) patients, there is no deformation; unfortunately, in 12 (9%) patients, there is deformation.

Conclusions: The hybrid method is a rapidly developing technique that has been safe and effective in a selected group of patients in recent years. The advantages of this method are minimum incision namely the size and length of the postoperative scar from 2 to 4 cm. Also, no myocardial injury, and reduces operation time, intensive care unit stay, and hospital stays.

Keywords: congenital heart disease; ventricular septal defect; hybrid method; Kazakhstan.

Introduction

Currently, the development of minimally invasive cardiac surgery is underway, with one notable approach being the hybrid method [1]. The term "hybrid method", as used in contemporary cardiology and cardiac surgery, refers to a combination of surgical and interventional techniques aimed at optimizing the therapy for congenital and acquired heart defects while reducing their limitations. The hybrid method involves minimally invasive ventricular septal defect (VSD) closure on a beating heart [2,3]. This approach offers advantages such as a shortened duration of hospitalization, reduced rehabilitation time, no X-ray exposure, and favorable cosmetic effects. However, there are drawbacks, including the potential development of arrhythmias and the risk of device dislocation after implantation [4-6].

Our study aimed to describe the clinical experiences evaluating the safety, efficacy, and mid-term follow-up results of the hybrid method of ventricular septal defect closure in children.

Methods

Patient population

Between May 2016 and December 2020, 250 patients with isolated VSD (or residual VSD after a

previous repair) aged 2 months to 18 years with a body weight of 4.7 to 100 kg, underwent surgery by the hybrid method at the pediatric cardiac surgery department in the National Scientific Medical Center. This research protocol was approved by the Ethics Committee of National Scientific Medical Center, Astana, Kazakhstan (Protocol number: 081/CR-75; Assigned number: 053/CT-63) and carried out by the principles set out in the Declaration of Helsinki 1964.

Study methods

This study adopted a combined and multidirectional cohort approach, initially starting as a retrospective cohort and later transitioning into a prospective cohort. Patient recruitment was conducted retrospectively, relying on medical documentation. For the prospective phase, a questionnaire designed for parents of children with congenital heart disease, specifically "ventricular septal defect" after surgical treatment, was created and secured with a copyright certificate. An online survey was administered to the enrolled patients.

The indications for the hybrid method:

- Patients with isolated VSD (perimembranous, muscular, inlet, outlet and residual);
- Clinical manifestations: symptoms of heart failure, recurrent respiratory infection, developmental delay, and history of bacterial endocarditis [7].

Echocardiographic Inclusion Criteria:

- Distance to the pulmonary, tricuspid, aortic (subaortic rim)valve >2 mm;
- no prolapse of the aortic valve into the defect [8];
- defect size from 4 to 12 mm;
- for perimembranous defects, the ratio of the size of the VSD and the weight of the patient was taken into account: a) ≤6 mm with a weight of 4-8 kg; b) ≤8 mm with a weight of 9–12 kg; c) ≤10 mm over 13 kg [9].

Exclusion Criteria:

- Heart arrhythmias (in particular, AV block);
- large non-restrictive VSDs;
- infective endocarditis;
- complex congenital heart disorder requiring correction using cardiopulmonary bypass;
- aortic dextraposition;
- aortic and tricuspid valve regurgitation (more than mild);
- aneurysm of the interventricular septum [7-11].

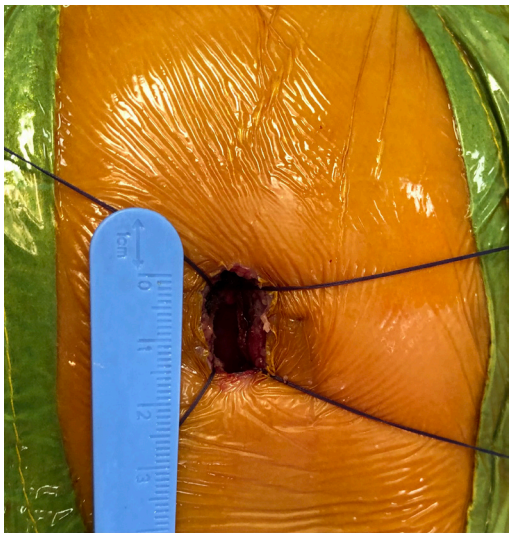

Figure 1 – Wound size with the hybrid method

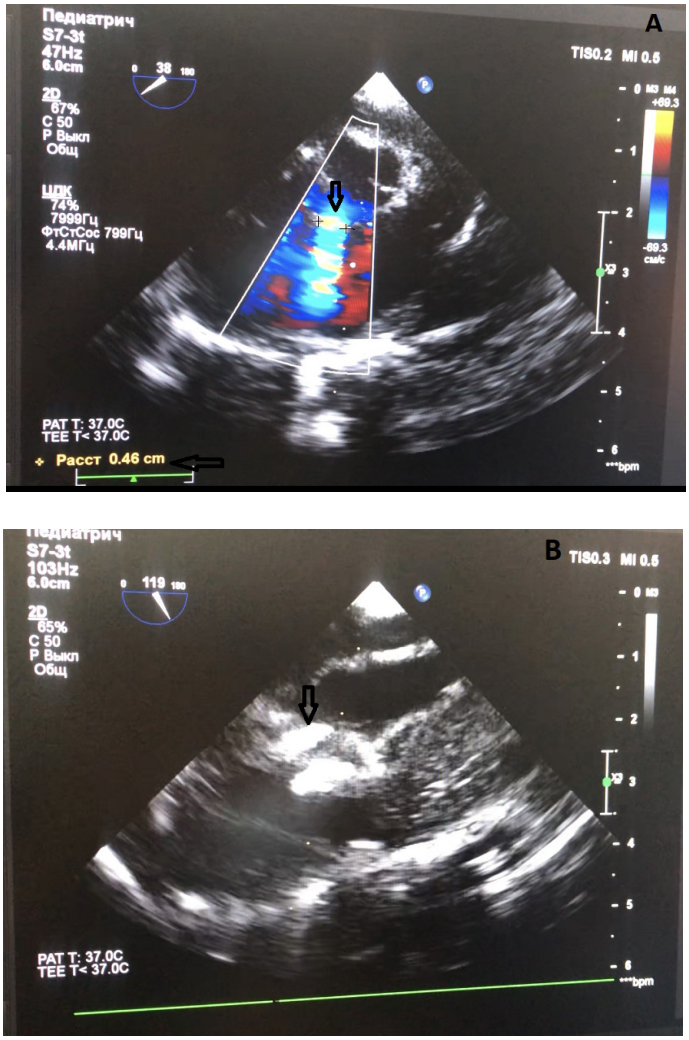

Figure 2 – A- Short-axis view of VSD from TEE and B- muscular occlude installed (long-axis view)

Surgery stages of the hybrid method

After the induction of general anesthesia, patients were positioned supine. The entire operation was guided by transesophageal echocardiography (TEE). Before the procedure, TEE meticulously assessed the location and size of VSDs (Figure 2A). Based on TEE measurements, occluders, including symmetric, asymmetric, eccentric, and muscular types, were selected.

A 2- to 4-cm inferior median sternotomy and a pericardiotomy were executed (Figure 1). Following the exposure of the right ventricular free wall, the puncture site was identified under continuous TEE control. A purse-string suture was placed around the chosen location, and a trocar was used for puncture.

A 0.035-inch guide wire was introduced into the right ventricle (RV) and passed through the defect into the left ventricle (LV) using the trocar. After trocar removal, the delivery sheath was introduced along the guide wire to the LV. Subsequently, the occluder was deployed through the loading sheath under TEE guidance (Figure 2B).

Following the removal of the inner sheath of the delivery sheath and the guide wire, TEE was employed to assess for residual shunt and valve dysfunction, particularly focusing on the aortic valve. If TEE evaluation revealed indications such as atrioventricular block, residual shunt exceeding 2 mm, or new aortic or tricuspid regurgitation, patients were converted to traditional on-pump treatment.

Description of Device and Delivery System

The occluder employed in this study was the CeraTM Occluder from LifeTech Scientific Co., China (12). It is a self-expandable, double-disc device crafted from nitinol wire mesh. The two discs are interconnected by a short cylindrical waist tailored to match the size of the ventricular septal defect (VSD). Both the discs and the waist feature polytetrafluoroethylene (PTFE) membranes securely sewn to the device using nylon threads [12] (Figures 3A and B).

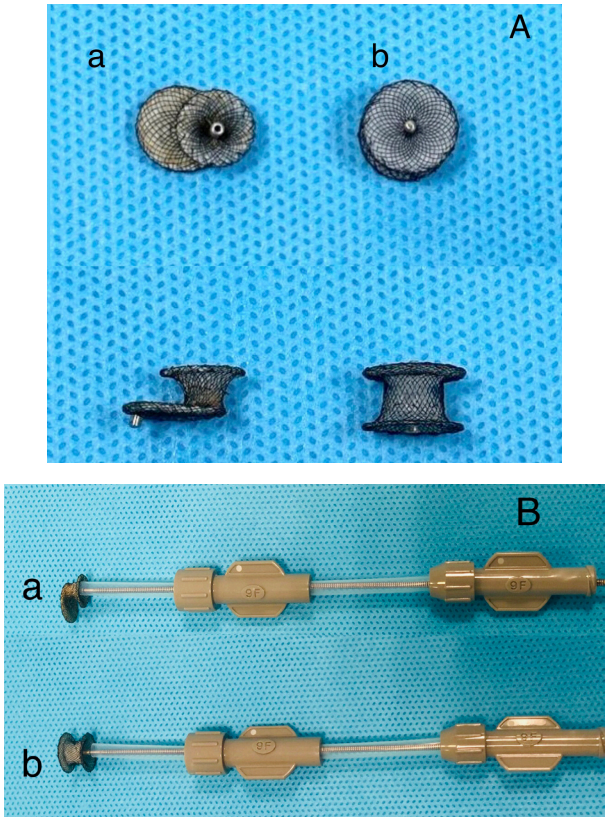

Figure 3 – Types of occluders: A – muscular(symmetric) and B – eccentric(asymmetric)

Physicians selected the occluder size based on anatomical conditions, considering factors such as the VSD's position, diameter, and the thickness of the interventricular septum.

To advance the VSD occluder to the correct position, it was used in combination with the delivery system (Figure 4).

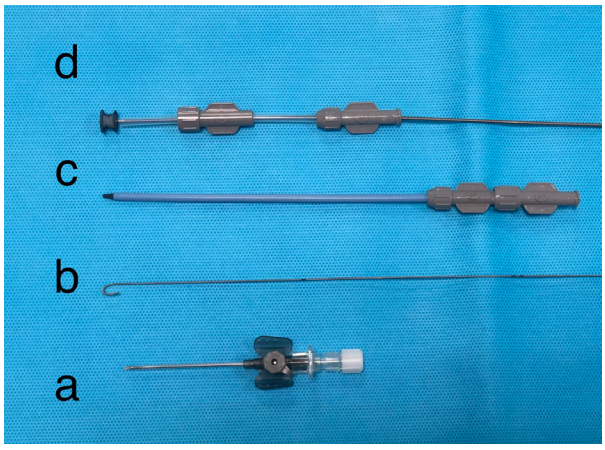

Figure 4 – Delivery system: a – trocar, b –guidewire, c – delivery sheath and dilator, d – loading sheath with a muscular occluder

Follow-up

Based on the results of a retrospective analysis, we estimate:

Efficiency: total hospital stay, preoperative and postoperative hospitalization, duration of stay in intensive care, time of mechanical ventilation, duration of operation, amount of intraoperative blood loss, number of residual shunts, number of atrioventricular blocks, insufficiency of the aortic, tricuspid valves, ejection fraction up to and postoperative period.

Safety: hospital mortality, the success rate of VSD closure, conversion rate, and reason for conversion.

Based on the results of the prospective analysis:

Long-term results: long-term safety assessment from 36 months to 84 months. To assess safety, a questionnaire was created for parents of children with congenital heart disease "ventricular septal defect" after surgical treatment. A copyright certificate has been received. An online survey was conducted among patients included in the study. Next, the patients underwent cardiac echocardiography at their place of residence, followed by remote consultation.

Results

Intraoperative and Early Postoperative Period

A total of 250 patients in this cohort underwent hybrid VSD closure, of which 233 (93.2%) patients were successful, 16 (6.4%) patients were converted to the traditional method and 1 (0.4%) death occurred. The 2 types of occluders were used: the membranous occluders were implanted in 200 patients (80%) and the muscular were implanted in the remaining patients (Figure 5). Hospital mortality was 0.4% of patients (1\234). According to the conclusion of pathological autopsies cause of death was a pulmonary hypertensive crisis.

In 16 patients who were converted to open surgery, 8 symmetric, 5 eccentric, and 3 muscular occluders were used.

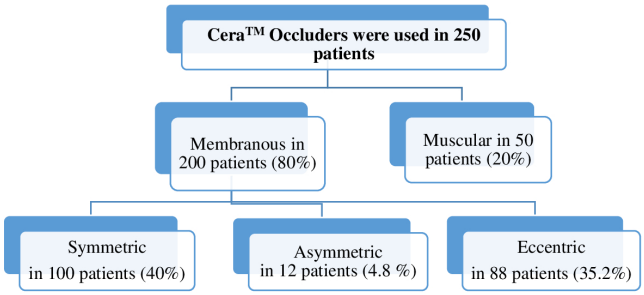

Figure 5 – Types of occluders were used for closure VSD in 250 patients (CeraTM Occluders, LifeTech Scientific Co., China)

New trivial or mild tricuspid regurgitation was detected in 35 patients (15%) and aortic regurgitation in 9 patients (3.9%) by intraoperative TEE. The absence of more than a mild degree of regurgitation and the lack of worsening with pre-existing tricuspid and aortic regurgitations before surgery in patients. Echocardiography upon discharge from the hospital showed that 16 (6.84%) patients were found with residual shunts (<2mm).

In 20 patients (8.6%) were detected the incomplete right bundle branch block while in hospital. After a short course of corticosteroid therapy (3-5 days) the sinus rhythm was restored in 10 patients. The remaining 10 patients were discharged with recommendations for observation by a pediatric cardiologist and arrhythmologist at the place of residence. Also, complete atrioventricular block (AVB) was found in 3 patients during the postoperative period: after 2 weeks (1 patient) and 5 months (2 patients) after discharge. These patients were implanted

with permanent pacemakers and under the supervision of a cardiologist and arrhythmologist at their place of residence. The average intraoperative blood loss was 27 ml. Pericardial drainage was removed on the first day after surgery in all patients, and none of the patients had repeated pericardial drainage.

The total operative time was 84 (31 min.; 160 max.) minutes, and the time for occluder implantation ranged from 10 to 80 minutes. All patients were extubated from 6 to 10 hours after the operation and the average stay in the Intensive care unit was 1.03 days.

The average stays (days): before operation-3.12, after the operation -6.76, and total hospital stay with first step rehabilitation -9.88 days.

Cases of Conversation to the Traditional Method with the heart-lung machine in 16 Patients

Nine patients (3.6%) had residual shunts <2mm. Regardless of the complete release of disks of the occluder, the residual shunt remained. The cause of interventricular shunts were multiple defects and membranous aneurysms, which were found during open surgery. Inadequate assessment resulted from a difference between preoperative TEE data and intraoperative data.

Severe arrhythmia appeared in two patients (0.8%) upon deployment of the disks at the defect, the cessation of arrhythmia was after removing the occluder. There were several attempts, however, the arrhythmia returned, which led to the decision to open surgery. The resolution of arrhythmia upon releasing the aortic clamp is an interesting observation, although the reason behind the heart's reaction remains unknown.

New aortic regurgitation in 2 patients (0.8%) and new tricuspid regurgitation in 1 patient (0.4%) occurred. Any new regurgitation, regardless of severity, indicates that the occluder is hurting the function of the aortic and tricuspid valves, considering data TEE, patients were converted to traditional surgical closure.

Two patients (0.8%) were dislocation occluder. The causes of dislocation were underestimation of the anatomical features of the defect (difference between preoperative TEE findings and intraoperative findings), and incorrect positioning of the occluder into the defect and this arose at the stage of mastering this method.

Table 1 Before and after surgery and follow-up data of patients

	Hybrid method (n=233)	Follow-up from 36 to 72 months (n=134)
Sex (male), n	106	61
Size of device used, range (mm)	4-14	4-14
Defect diameter (mm)		
Up to 5 mm, n (%)	127 (54.5)	70 (52.2)
From 5 to 10 mm, n (%)	103 (44.2)	63 (47,05)
Over 10 mm, n (%)	3 (1.3)	1 (0.75)
Left ventricular ejection fraction (%) (before surgery) (min; max)	65.5 (59; 78)	-
Left ventricular ejection fraction (%) (after surgery) (min; max)	60.7 (55;68)	62 (55; 78)
New trivial or mild tricuspid regurgitation, n (%)	35 (15%)	12 (9%)
New trivial or mild aortic regurgitation, n (%)	9 (3.9%)	3 (2.2%)
Incomplete right bundle branch block, n (%)	10 (4.3%)	0
Permanent pacemakers	3 (1.3%)	3 (2.2%)
Residual shunts	16 (6.84%)	2 (1.5%)

Table 2 Questionnaire for parents of children with congenital heart disease "ventricular septal defect" after surgical treatment

Questions	Age (year) (n=134)		
	<6 year (n=30)	6–12 years (n=65)	>12 year (n=39)
Does your child go to or did you go to kindergarten? (n)			
• Yes	20	25	-
• No	5	-	
• Haven't gone yet	5	-	
• Not suitable age		40	
Does your child go or did you go to school?			
• Yes	-	45	30
• No		0	0
• Haven't gone yet		0	0
• Not suitable for age		20	9
Exercise tolerance:			
• Weak	0	2	1
• Regular	30	61	33
• Sports	0	2	5
Visiting sports sections:			
• Yes	0	25	29
• No	20	25	7
• Haven't gone yet	10	15	3
Did you as a parent and/or your child receive psychological help if they needed it?			
• Yes	5	10	8
• No	25	55	31
Does your child have any difficulties communicating with healthy peers?			
• Yes	3	2	0
• No	27	63	39
Has your child been granted disability and for how long?			
• Yes			
- 1 year	5	10	5
- 2 years		3	3
- 3 years	0	2	1
• No	20	30	20
• Removed from disability	5	20	10
Did you develop chest deformity after heart surgery?			
• Yes	5	5	2
• No	25	60	37
• Deformation of the chest was present from birth	0	0	0
Indicate whether the child had a heart rhythm disturbance in the postoperative period (dizziness, loss of consciousness, interruptions in heart function).			
• Yes	2	3	4
• No	28	62	35
Was it necessary to implant a pacemaker (pacemaker)?			
• Yes	3	0	0
• No	27	65	39
How often did the child suffer from colds in the postoperative period about the preoperative period?			
• more often	5	3	1
• rarely	20	60	37
• also	5	2	1
During what period did your child take antiplatelet therapy (ThromboASS, Aspirin Cardio, Thrombopol, Acetylsalicylic acid)?			
• did not take	2	4	3
• 1 month	4	8	7
• 6 month	19	43	28
• 1 year	5	10	1
Were there any complaints while taking antiplatelet therapy, such as nosebleeds, stool problems, or stomach pain?			
• Yes	3	6	3
• No	27	59	36

Follow-ups

Of the 234 patients who underwent surgery, 100 patients were lost to follow-up, leaving 134 (57%) patients. This is primarily due to the lack of a unified basis for the management and monitoring of patients with congenital heart defects. In the postoperative period, patients are recommended to undergo echocardiography 4 times (1, 3, 6, and 12 months) within 1 year in our hospital, and then according to the treatment protocol, further observation at the place of residence. To analyze mid-term results, a retrospective analysis was carried out based on the patient's medical history and echocardiography data (which were carried out within 1 year in the postoperative period) (Table 1). Next, for a prospective analysis, all patients were called by doctors, and all echocardiography data that were performed at their place of residence was sent to us by mail. Later, an online survey was conducted (Table 2), with a subsequent recommendation to undergo echocardiography at the place of residence. After completion, all patients were consulted online and recommendations.

For the remaining 10 patients with incomplete right bundle branch blocks the sinus rhythm was restored in follow-up (p=0,000). In addition, the left ventricular ejection fraction improved over time (p=0.465) (Table 1).

According to the results of the examination, exercise tolerance in children after surgery was good: 124/134 (92.5%), and in 7 (5.2%) patients it was athletic; only in 3 (2.3%) patients it was weak. One of the important points after surgery is the deformation of the chest. In 122 (91%) patients, there is no deformation; unfortunately, in 12 (9%) patients, there is deformation. In addition, 129 patients did not have difficulties communicating with healthy peers; this is one of the big advantages of the minimal incision, which is not visible in the jugular notch. 10 patients had complaints while taking antiplatelet therapy, in the form of nosebleeds, black stools, and stomach pain; therefore, the dose of antiplatelet therapy was adjusted, and in 124 patients, these symptoms were not observed.

Discussion

Nowadays, it is fascinating to note the dynamic evolution in surgical techniques, especially with the increasing popularity of minimally invasive procedures. It's essential to weigh the pros and cons of each method to determine the most suitable approach for each patient, considering factors such as age, overall health, and the specific characteristics of the VSD. Advances in medical technology and techniques may continue to shape the landscape of VSD correction methods.

Traditional Open Surgery:

- Open surgery with the heart-lung machine has been a long-standing and effective approach.
- Despite its effectiveness, it may be associated with larger incisions and potential cosmetic concerns.
- The use of the heart-lung machine in this procedure is associated with various complications [13,14].

Transcatheter Closure:

- This is a minimally invasive approach where catheters are guided through blood vessels to the site of the defect.
- X-ray control is used to guide the closure device to the precise location of the VSD.
- There is a noted high risk of vascular damage, particularly in early-age patients.
- Transcatheter closure is associated with shorter recovery times and reduced postoperative pain compared to open surgery [15-17].

Hybrid (Transventricular) Approach:

- The hybrid approach combines elements of both traditional open surgery and transcatheter techniques.
- It involves a combination of surgical and catheter-based interventions, often performed in collaboration between cardiac surgeons and interventional cardiologists.
- This method aims to leverage the benefits of both approaches while minimizing the drawbacks [18-20].

This study included a group of patients with VSD of various localizations. Most of the patients had perimembranous defects and used 3 types of membranous occluders: symmetric occluders in 100 patients, eccentric in 88, and asymmetric in 12 patients (Figure 3).

Based on the results of a survey and echocardiography of the heart, the hybrid technique appeared safe and efficacious during a 36- to 84-month follow-up period (Tables 1 and 2). The residual shunts were in 16 patients and now only 2 patients. New trivial or mild tricuspid and aortic regurgitation was 35(15%),9(3.9%), and now 12(9%),3(2.2%) (Tables 1). After the operation, the majority of children went to kindergarten, and school, played sports, and had no health problems related to the heart.

Considering all this data the hybrid method:

- Less trauma to tissues, which reduces pain, immune suppression, inflammation, and swelling
- Less risk of infection, bleeding, and bruising, as there are no large incisions or damage to blood vessels
- Shorter duration of surgery and anesthesia, which reduces the risk of complications associated with anesthesia and pain relief
- Shorter length of hospital stay and rehabilitation, which reduces treatment costs and improves the patient's quality of life
- Better cosmetic results as there are no large scars or deformities [21-28]

The hybrid method is not a panacea, but only one of the tools in the hands of an experienced and qualified surgeon who strives for the best result for his patient.

Limitations

We acknowledge that this study is limited by its multidirectional cohort and single-center design. We would like to distribute a significant report about the experience of our medical center, the National Scientific Medical Center, located in Astana, the Republic of Kazakhstan. The hybrid method appears to be safe in the mid-term follow-up, but its long-term safety —particularly regarding the late complication of complete AVB and heart function — is unknown. More experience and long-term follow-up are necessary to assess the true safety and effectiveness of this treatment as an alternative to traditional surgery and transcatheter intervention. This is a novel approach to treating VSD that is becoming better with time. Moreover, this is not a summary derived from a lab but rather from experience. The experience gained from using three-dimensional echocardiography should help refine this method.

Conclusions

The hybrid method is a rapidly developing technique that has been safe and effective in a selected group of patients in recent years. The advantages of this method are minimum

incision namely the size and length of the postoperative scar from 2 to 4 cm. Moreover, no myocardial injury, and reduces operation time, intensive care unit stay, and hospital stays. Although, like other methods, it also has disadvantages, such as the development of arrhythmia and, dislocation of the occluder after implantation. Further use of the hybrid method and the accumulation of experience will clarify the indications for the use of this technique and the incidence of late complications, such as complete AV block. The presence of the latter implies long-term, perhaps even lifelong, follow-up of patients who have undergone this operation.

Author Contributions: Conceptualization, A.A and N.B.; methodology, A.A., N.B., M.Sh. and K.S.; validation, A.A and N.B.; formal analysis, A.A., N.B., M.Sh.; investigation, A.A and N.B.; resources, A.A and N.B.; data curation, M.Sh. and K.S.; writing – original draft preparation, A.A and N.B.; writing – review and editing, N.B., M.Sh. and K.S.; visualization, A.A., N.B., M.Sh. and K.S.; supervision, M.Sh. and K.S.; project administration, M.Sh. and K.S.; funding acquisition, M.Sh. and K.S. All authors have read and agreed to the published version of the manuscript.

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Ethical Statement: This research protocol was approved by the Ethics Committee of National Scientific Medical Center, Astana, Kazakhstan (Protocol number: 081/CR-75; Assigned number: 053/CT-63) and carried out by the principles set out in the Declaration of Helsinki 1964.

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